

Manual of Patent Practice (MoPP)



Manual of Patent Practice

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Glossary of terms and abbreviations used in this Manual

(see also definitions in Section 130: Interpretation)

1949 Act The Patents Act 1949 (c.87). The authority under which patents were granted

prior to the 1977 Act.

1977 Act The Patents Act 1977 (c.37). The authority under which patents are presently

granted and enforced in the UK.

a. Article. Part of a treaty or convention (eg EPC, PCT), which will usually be

specified.

All England Reports. A series of law reports.

BL number Decisions of the Intellectual Property Office and Patents Court are indexed

according to "BL numbers" in the format "BL O/nnn/yy" and "BL C/nnn/yy" respectively. BL refers to the British Library Science Technology and Business section, which houses the UK national patent library. This was previously called the Science Reference and Information Service, and BL numbers used to be

called "SRIS numbers" for this reason.

CDP Act The Copyright, Designs and Patents Act 1988 (c.48)

CIPA The Chartered Institute of Patent Attorneys.

CMLR Common Market Law Reports.

COPS An Intellectual Property Office computer system.

CPC Community Patent Convention. A convention to establish a unitary patent

covering the entire EC, which has never come into force.

CPR Civil Procedure Rules. A procedural code for the courts, with the overriding

objective of enabling the court to deal with cases justly.

EPC European Patent Convention. A convention allowing the grant of patents

covering one or more countries within the convention by the European Patent Office. A single application may lead to grant of a patent in each country designated, but once granted the patents are treated in the same way as a set

of national applications.

EPC [1973] The European Patent Convention of 1973 which was the European Patent

Convention which was in force prior to 13 December 2007.

EPO European Patent Office. An intergovernmental organisation (not part of the EU)

set up to administer the EPC and grant European Patents.

EPOQUE A portal for online database searching provided by the EPO.

EPOR European Patent Office Reports. A series of law reports published by Sweet

and Maxwell covering cases heard by the European Patent Office Boards of

Appeal.

European Patent Bulletin A journal published by the European Patent Office giving information relating to

European patents and applications.

EWCA Civ Neutral citation assigned to judgments of the Civil Division of the Court of

Appeal.

EWHC number (Pat) Neutral citation assigned to judgments of the Patents Court.

Ex parte hearing A hearing on an issue solely between an applicant and the comptroller. Also

sometimes referred to as a "without-notice" hearing.

January 2019

FSR Fleet Street Reports. A series of law reports relating to intellectual property

decisions published by Sweet and Maxwell.

G nn/yy A decision of the EPO Enlarged Board of Appeal.

Intellectual Property

Office

An operating name of the Patent Office.

Inter partes hearing A hearing by the comptroller of an issue between two parties. Also sometimes

referred to as a "with-notice" hearing.

Ipsum The Intellectual Property Office's online patent information and document

inspection service

J nn/yy A decision of the EPO Legal Board of Appeal.

OJEPO Official Journal of the European Patent Office. A journal giving official

information from the European Patent Office.

OJ(P) Official Journal (Patents). The original name for the Patents Journal (later

called the Patents and Designs Journal (PDJ)).

PA Private applicant - an individual or small business applying for a patent

personally rather than through the services of a patent agent.

PA 1977 The Patents Act 1977.

Paris Convention The Paris Convention for the Protection of Industrial Property. An agreement

concluded in 1883 and updated several times since, providing for national treatment, right of priority and common rules between states for patents and

other forms of intellectual property.

PCT Patent Cooperation Treaty. A system to aid filing in many different states by

initially filing a single "international" application, which after search, publication

and optionally examination may be converted into a series of national

applications.

PDAX An Intellectual Property Office computer system.

PDJ Patents and Designs Journal. Now published separately as the Designs

Journal and the Patents Journal: a journal published by the Intellectual Property Office giving notices and information concerning UK patents and applications.

PLT Patent Law Treaty. A treaty agreed in 2000 to harmonise the formal

requirements for filing patent applications.

PROSE An Intellectual Property Office computer system.

r. Rule. Part of the Patents Rules 2007 unless otherwise specified.

RPC Reports of Patent, Design and Trade Mark Cases - a series of law reports

relating to intellectual property cases, published on behalf of the Intellectual

Property Office, currently by Oxford University Press.

RSC Rules of the Supreme Court. Now substantially replaced by the Civil Procedure

Rules (CPR).

s. Section. Part of the Patents Act 1977 unless otherwise specified.

SHB Secretariat Hearing Box. A system for numbering records of Office hearings.

Now discontinued and replaced by BL number.

SPC Supplementary Protection Certificate. Additional protection taking effect after

the expiry of a patent for medicinal or plant protection products to compensate the patentee for loss of effective protection due to the time taken to gain

regulatory approval.

SRIS number See BL number.

TRIPS Agreement The Agreement on Trade Related Aspects of Intellectual Property Rights,

originating from the Uruguay Round of trade negotiations setting up the WTO and completed in 1994. The TRIPS Agreement requires WTO Members to provide minimum standards of protection for a wide range of intellectual

property rights.

T nn/yy A decision of the EPO Technical Board of Appeal.

UK Intellectual Property

Office

A former operating name of the Patent Office, now known as the Intellectual

Property Office.

V nn/yy A decision of the EPO Opposition Division.

WIPO World Intellectual Property Organisation. An intergovernmental organization

with headquarters in Geneva, Switzerland, responsible for the promotion of the protection of intellectual property throughout the world through cooperation among States, and for the administration of various multilateral treaties dealing

with the legal and administrative aspects of intellectual property.

WTO World Trade Organisation. An international organisation created by the

Uruguay Round of trade negotiations completed in 1994, dealing with rules of

trade between nations.

WLR Weekly Law Reports.

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Notes

- 1. For EPO decisions, see separate list below.
- 2. "SHB" indicates a Secretariat Hearing Box number (old Office numbering system).
- 3. The Reports of Patent, Design and Trade Mark Cases (RPCs) have been published since 1884. For those published between 1884 and 1955, the first number of the RPC citation refers to the Volume number, where Volume 1 was published in 1884, Volume 2 in 1885 etc. From 1956 onwards, the year is provided instead.
- 4. In 2001, Sweet & Maxwell (then publishers of the RPCs on behalf of the Office) changed the way in which cases are cited. For citations up until the end of 2000, the final number of the citation refers to the page number in that year's volume. From the beginning of 2001, the final number refers to case number in that year's volume. This numbering system applies to the RPCs and to Sweet & Maxwell reports cited from the beginning of 2001, including FSRs and EPORs.

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Allen and Hanburys Ltd's Patent 1266058 ("labetalol")	BL O/137/85	46.62
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INTRODUCTION

s.123(2A)

The long title of the Patents Act 1977 is:

An Act to establish a new law of patents applicable to future patents and applications for patents; to amend the law of patents applicable to existing patents and applications for patents; to give effect to certain international conventions on patents; and for connected purposes.

0.01 This Act effected major changes in UK patent law and substantial harmonisation of that law with corresponding provisions of the European Patent Convention (EPC), the Community Patent Convention (CPC) and the Patent Co-operation Treaty (PCT), to provide a patent system intended to be better suited to the needs of modern industry, sufficiently flexible to accommodate future changes in technology and adapted to operate in an international context.

0.02 The Act is in three parts concerned respectively with (1) domestic law, (2) provisions to put into effect UK treaty obligations in relation to the EPC, PCT and CPC and (3) miscellaneous and general matters including the setting up of the Patents Court and other legal provisions, administrative procedures, and interpretation. There follow six schedules dealing respectively with the application of the 1949 Act to existing patents and applications; the application of the 1977 Act to existing patents and applications; repeals of provisions of the 1949 Act; certain transitional provisions relating to matters in being before the 1977 Act came into effect; amendments to other statutes consequential upon the introduction of this Act; and a list of enactments repealed. Various amendments have been made to the 1977 Act by subsequent legislation, most notably the Copyright, Designs and Patents Act 1988 (hereinafter the CDP Act) and the Patents Act 2004. The effects of these Acts and other legislation on particular sections of the 1977 Act are referred to in the chapters relating to those sections. Certain provisions of the CDP Act itself affecting patents are discussed in this Manual after the commentary on the 1977 Act.

s.123 O.03 The Secretary of State is authorised by the 1977 Act to "make such rules as he thinks expedient for regulating the business of the Patent Office" in the administration of the Act. The Patents Rules 1978, made under this provision, came into operation concurrently with the major provisions of the Act on 1 June 1978. They have subsequently been superseded by the Patents Rules 1982, the Patents Rules 1990, the Patents Rules 1995, and most recently the Patents Rules 2007, which have effect from 17 December 2007. In this Manual any reference to the Rules should be construed as referring to the Patents Rules 2007, unless there is specific indication to the contrary.

There are six schedules to the 2007 Rules. Schedule 1 made under r.13(1) makes provision regarding patents and patent applications for inventions which involve the use of or concern biological material. Schedule 2 made under r.14 sets out formal and other requirements for all documents (including drawings) contained in a patent application. Schedule 3 is made under r.73 and sets out the different classes of proceedings before the comptroller to which part 7 of the Patents Rules 2007 applies and the rules which apply to any proceedings heard before the comptroller. Schedule 4 makes provisions for the extension of time limits under r.108. Schedule 5 sets out transitional provisions which are brought into effect by r.120(1), and Schedule 6 lists the instruments which are revoked under r.120(2). The texts of the various forms required in connection with activities under the Patents Act 1977 is specified in directions made under s.123(2A). Replicas of these forms (or a form acceptable to the comptroller and containing the information required by the form specified in any such direction) must be used whenever required. The fees required to accompany the forms under the 1977 Act are prescribed by a separate statutory instrument, the Patents (Fees) Rules, see 123.15.

PRECEDENT EFFECT OF PREVIOUS LAW

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As stated in the long title, the Act established a new law. For example, the Patents Court, in *Unilever Ltd's Application*, [1983] RPC 219, rejected a submission that wording used in the Act should be interpreted in a manner which would involve least change in the concept of patentability as between the old and new statutes. Falconer J observed that "One of the striking changes in the 1977 Act was to include for the first time in our patent law a statutory definition of what constituted a patentable invention" and, referring to the principle that where the wording of a statute is susceptible of more than one interpretation there is a presumption against any change in the existing law, stated: "It seems to me that there is no basis for the operation of that principle because Parliament made it abundantly clear in the long title to the Act that the old law of patents is being swept away". However, the influence of a limited number of earlier precedents, which have not been rendered nugatory by the 1977 Act and subsequent case law, does continue to apply.

0.06 [deleted]

INTERNATIONAL AGREEMENTS

0.07 The phrase in the long title: "to give effect to certain international conventions on patents" is a reference to Part II of the Act which provides for the effect in the UK of the EPC, CPC and PCT (the CPC not being in operation).

s.130(7) s.91(1) In addition to the specific provisions in Part II, there is a general intention that the patent laws of member states of the European Union (EU) should be harmonised. To this end the Act specifies certain sections which are stated to be "so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty have in the territories to which those conventions apply". Moreover judicial notice must be taken of these conventions and of decisions and expressions of opinion given under them by the appropriate bodies, see 91.02.

In *Merrell Dow Pharmaceuticals Inc. v H.N. Norton & Co Ltd* [1996] RPC 76, the House of Lords held that, in construing a section of the Patents Act 1977 said by section 130(7) to have, as nearly as practicable, the same effects as the corresponding provisions of the European Patent Convention, the United Kingdom courts must have regard to the decisions of the EPO. Lord Hoffmann said (at page 82): "These decisions are not strictly binding upon the courts in the United Kingdom but they are of great persuasive authority; first, because they are decisions of expert courts (the Boards of Appeal and Enlarged Board of Appeal of the EPO) involved daily in the administration of the EPC and secondly, because it would be highly undesirable for the provisions of the EPC to be construed differently in the EPO from the way they are interpreted in the national courts of a Contracting State". Furthermore, the Supreme Court in *Human Genome Sciences v Eli Lilly* [2011] UKSC 51, [2012] RPC 6 held that, although decisions of the EPO Boards of Appeal are not binding upon UK courts, where the Board has adopted a consistent approach to an issue in a number of decisions, it would require very unusual facts to justify a national court not following that approach.

O.10 In the judgment given by Jacob LJ in *Actavis UK Ltd v Merck* [2008] EWCA Civ 444, it was held that the Court of Appeal can (but is not bound to) depart from its own precedent if it is satisfied that the EPO Boards of Appeal have formed a settled view of European Patent law which is inconsistent with the Court of Appeal earlier decision. Generally the Court of Appeal will follow the settled view of the EPO (see para 107 of the decision). This approach was approved of in principle in *R. v Secretary of State for Work and Pensions* [2008] UKHL 63, although it was made clear that conflicting EPO authority would not provide justification for the Court of Appeal to disregard a precedent of the House of Lords.

0.11 Given the reference in section 130(7) to the effects that the convention provisions have in "the territories to which those conventions apply", it is necessary, in

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construing and applying the sections stipulated, to have regard not only to decisions of the Boards of Appeal of the EPO but also to decisions given in other countries relating to the relevant provisions of the three treaties.

0.12 Regard may be had not only to decisions given under these international agreements, but also to the wording of the conventions themselves. This applies particularly in relation to the sections of the Act mentioned in s.130(7), see 130.30-33.

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PART I: NEW DOMESTIC LAW

PATENTABILITY

Section 1: Patentable inventions

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SECTION 1(5)

1.01 The Patents Act 1977 sets out for the first time to codify what is meant by a patentable invention. Previous legislation up to and including the 1949 Act had merely repeated the stipulation, originally set out in the Statute of Monopolies of 1623, that a patent

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may be granted only for a manner of new manufacture.

1.02 [Deleted]

Section 1(1)

A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say -

- (a) the invention is new:
- (b) it involves an inventive step;
- it is capable of industrial application; (c)
- (d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below;

and references in this Act to a patentable invention shall be construed accordingly.

- A patent may only be granted if the invention meets the above conditions. The fact that an invention meets the requirements of s.1(1) does not however mean that a patent must be granted, since there are other requirements, as set out in later sections, which must also be complied with.
- s.125(1)1.04 "Invention" in this context means that which is specified in a claim. Although the term has a meaning in ordinary speech, in Biogen Inc v Medeva plc [1997] RPC 1 Lord Hoffmann declined to attempt to define the term more closely, saying that judges "would be well advised to put on one side their intuitive sense of what constitutes an invention until they have considered the questions of novelty, inventiveness and so forth". It is possible for a specification to contain claims which relate to patentable inventions as well as claims which define inventions which are not patentable or matters which are not inventions. In such a case amendment is necessary, since a patent should be granted only when each claim defines a patentable invention. A claim will generally be held to be bad if anything falling within its scope is not patentable.
 - The term "a patentable invention" is defined by setting out four 1.05 conditions, all of which must be satisfied in order for an invention to qualify for the grant of a patent. Since they are expressed as positive requirements the onus is upon an applicant to demonstrate compliance when faced with a reasonable challenge. The manner in which each of the conditions (a), (b) and (c) is to be assessed is set forth in ss.2, 3 & 4 respectively. The fourth condition involves certain things which, for purposes of the Act, are not to be regarded as inventions (see 1.07 to 1.40.4) and certain inventions for which a patent will not be granted (see 1.41-1.46).
- s.130(7)-The tests set out in s.1(1) and further elaborated in s.1(2)-(4) and ss.2-4 s.91 are so framed as to have, as nearly as practicable, the same effects in the UK as the corresponding provisions of the EPC; these are Articles 52-57. (More particularly, EPC aa.52(1) to (3) and 53 correspond to s.1(1) to (4)). Hence, although not binding on the Office, decisions on patentability given by EPO Boards of Appeal are of persuasive value in interpreting ss.1-4 (see 0.07-09, 1.09 and 130.30-33).

Section 1(2)

It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of -

(a) a discovery, scientific theory or mathematical method;

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- (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever:
- (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
- (d) the presentation of information;

but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.

EXCLUDED SUBJECT MATTER

- 1.07 Section 1(2) of the Act defines certain categories of "things which are not to be regarded as inventions", as Jacob LJ puts it in paragraph 12 of <u>Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 [2006] EWCA Civ 1371</u>, [2007] RPC 7 (Aerotel/Macrossan). The normal meaning of "invention" is therefore qualified by the removal of these categories. Jacob LJ also considered that there is no overarching principle behind the inclusion of these particular categories, and no guidance on whether they are to be construed broadly or restrictively. In particular, he noted that, as the exclusions are not expressed as exceptions, the general principle that exceptions should be interpreted restrictively does not apply to them.
- 1.08 The current practice in dealing with excluded matter under s. 1(2) is derived from the judgment of the Court of Appeal in *Aerotel/Macrossan* (see 1.09.1, 1.18, 1.20, 1.33-1.33.1, 1.34.1). This judgment considered all previous authorities on the matter, and having been endorsed in numerous subsequent decisions is to be treated as a definitive statement of how the law on patentable subject matter is to be applied in the UK.

Relationship with the EPC and decisions of the EPO

- 1.09 As discussed above (see 1.06) decisions of the EPO Boards of Appeal are of persuasive value; furthermore where the EPO Boards of Appeal have formed a settled view of European patent law, this will generally be followed by the UK courts (see 0.08 and 130.30-31).
- 1.09.1 However in <u>Aerotel/Macrossan</u>, the Court of Appeal analysed EPO Boards of Appeal decisions on the question of excluded matter and concluded that practice was <u>not</u> yet sufficiently settled to enable the Court to depart from precedent UK case-law (see 1.11). This was reiterated in <u>Symbian Ltd's Application [2009] RPC 1</u> (Symbian) (see paragraph 46) and *HTC v Apple* (see 1.09.2), and it remains the case until the UK courts conclude otherwise.
- 1.09.2 In an attempt to address whether case-law concerning excluded matter is settled, and derive uniformity of application of European patent law, the President of the EPO referred four questions on the patentability of computer programs to the Enlarged Board of Appeal in October 2008 (G3/08). However, the Board concluded that the referral was inadmissible because the decisions referred to were not considered to be "divergent", and declined to answer the questions beyond determining their admissibility. This led to the Court of Appeal reaffirming its view that practice was not yet settled in <a href="https://example.com/https://example.
- 1.09.3 As the Office is bound by the judgments in Aerotel/Macrossan and $HTC \ V$ Apple, it cannot choose to depart from the Aerotel/Macrossan test in order to adopt EPO practice even if that practice becomes settled such a departure can only be made by the

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courts. This is emphasised in *Dell Products LP's Application* (BL O/321/10), amongst others.

1.09.4 A number of older decisions of the EPO Boards of Appeal – such as *Vicom Systems Inc* T0208/84 [1987], *IBM/Data processing network* T0006/83 [1990] and *IBM/Computer-related invention* T0115/85 [1990] – were used to inform the *Aerotel* test, as well as other later guidance such as the *AT&T* signposts (see 1.37). It has been stated, in paragraph 11 of *Symbian*, that "as a matter of broad principle, it seems to us that the approaches in [...] the great majority of cases in this jurisdiction and in the EPO, are, on a fair analysis, capable of reconciliation". And in *HTC v Apple*, Kitchen LJ, at paragraph 41, stated that "...in terms of result [...] it seems to me that whichever route is followed, one ought to end up at the same destination". The result of EPO Boards of Appeal decisions on cases with similar facts may therefore be persuasive, even though the approach taken by the EPO should not itself be followed (see 130.31).

General Principles

Balance of probabilities

1.10 The Court of Appeal, in paragraph 5 of Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 [2007] RPC 7 (Aerotel/Macrossan), made it clear that assessing excluded matter involves a question of law which should be decided during prosecution of the patent application. The position is therefore assessed fully by patent examiners before grant, and objections are not to be dropped simply because the applicant asserts that the invention relates to non-excluded subject matter. The question of excluded matter is decided on the balance of probabilities, taking into account all of the evidence available. However, as it is a question of law, it is not something on which applicants are entitled to the benefit of the doubt, in the way they would be in relation to questions of pure fact (such as the date of a particular disclosure, or the scope of the common general knowledge).

Using past decisions

- 1.11 The Office is bound to follow the decisions of the UK courts, per the English common law doctrine of binding precedent, which states that courts and tribunals must abide by the decisions of higher courts. Therefore, the Office must follow the interpretation of the Act and the practice set out in such judgments, and apply the legal principles arrived at by the judges in those cases.
- However, examiners must exercise caution in relying on the specific facts of any court judgment as support for an objection, as each case must be judged on its merits, and the facts of the individual case are certain to be different. As Pumfrey J stated in paragraph 186 of Research In Motion UK Ltd. v Inpro Licensing SARL [2006] EWHC 70 (Pat), "The test is a case-by-case test, and little or no benefit is to be gained by drawing analogies with other cases decided on different facts in relation to different inventions." Although the test being referenced was not the Aerotel test, the principle remains the same. Birss J, in paragraph 17 of Lantana v Comptroller-General of Patents [2013] EWHC 2673 (Pat), noted that "[s]imply because it is possible to construct a generalised category which includes both the claimed invention [...] and a previous decision in which a claim was held to be patentable, does not help. It shows that such things can be patentable in some cases but does not show that the invention in this case is patentable."
- 1.12.1 The Office is not bound to follow the practice of the EPO Boards of Appeal for the reasons detailed above (see 1.09.1).
- 1.12.2.2 Hearing decisions issued by the Office are non-binding, but can be persuasive in establishing an argument.

Substance over form

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- 1.13 When determining if an invention falls foul of the exclusions, it is critical that the examiner consider the substance of the invention rather than the form of claim provided, by looking beyond the strict literal wording of the claims. For example, when a claim is directed to a computer program, the examiner must look at what the computer program will do when run, as established in paragraph 49 of <u>Astron Clinica Ltd & Ors v The Comptroller General of Patents, Designs and Trade Marks [2008] EWHC 85, RPC 14.</u>
- 1.14 If the substance of an invention falls within one of the excluded categories, however, then no form of claim will circumvent an objection. If a claim is directed to a computer, but the substance of the invention is a business method running on that computer, it will still be excluded. In paragraph 44 of *Aerotel/Macrossan*, Jacob LJ noted that "If an inventor claims a computer when programmed with his new program, it will not assist him if he alleges wrongly that he has invented the computer itself, even if he specifies all the detailed elements of a computer in his claim."
- 1.15 It is not the nature of a single embodiment of an invention which is important when determining whether it is excluded, but the nature of the central idea or invention which is embodied in the claims. To determine this, the invention claimed should be assessed and construed as a whole to see whether it comprises an advance that lies in a non-excluded field. However, as Floyd J observed in paragraph 23 of <u>Kapur v Comptroller-General of Patents [2008] EWHC 649 (Pat)</u>, if there are embodiments of a claim that fall within excluded subject matter, the fact that the claim is wide enough to encompass embodiments that are not excluded under s. 1(2) will not be sufficient to save it. The exclusion "will still bite to the extent that excluded subject matter is claimed".
- 1.15.1 In his judgment in <u>Astron Clinica Ltd & Ors v The Comptroller General of Patents, Designs and Trade Marks [2008]</u>, <u>RPC 14</u>, Kitchin J. held (at paragraph 51) that in a case where claims to a method performed by running a suitably programmed computer or to a computer programmed to carry out the method are allowable, then, in principle, a claim to the program itself should also be allowable. However, he added that the program claim must be drawn to reflect the features of the invention which would ensure the patentability of the method which the program is intended to carry out when it is run. Thus, following the conclusions of *Astron Clinica*, claims to a computer program or a program on a carrier are allowable where corresponding method and apparatus claims (or notional such claims if none exist) are/would be allowable on application of the *Aerotel/Macrossan* test. (A claim to a computer program stored on a carrier such as a compact disc is sometimes referred to in the US as a Beauregard claim.) However, merely including claims to a program or a program on a carrier will not make an otherwise excluded invention patentable. As Fox LJ said in *Merrill Lynch's Application* [1989] RPC 561 (page 569):

"it cannot be permissible to patent an item excluded by section 1(2) under the guise of an article which contains that item - that is to say, in the case of a computer program, the patenting of a conventional computer containing that program. Something further is necessary."

In <u>Macrossan's Patent Application</u> [2006] EWHC 705 (Ch), Mann J (at paragraph 42) rejected submissions by the applicant that adding a product step onto an otherwise excluded claim was enough to render it patentable. This was upheld by the Court of Appeal in Aerotel/Macrossan. Similarly, in <u>Bloomberg LLP and Cappellini's Applications</u> [2007] EWHC 476 (Pat), Pumfrey J stated (at paragraph 9) that "[a] claim to a programmed computer as a matter of substance is just a claim to the program on a kind of carrier. A program on a kind of carrier, which, if run, performs a business method adds nothing to the art that does not lie in excluded subject matter".

Claims to a computer program for generating a system or for producing a product (for example claims of the form: 'a computer program comprising computer-readable code for generating a system as claimed in X' or 'storage medium having encoded thereon code for making a system as claimed in Y' or 'machine readable medium having software thereon to produce the item of claim Z on a 3D printer') will not normally be allowable unless, following the guidance of <u>Astron Clinica</u>, the computer program would cause an otherwise patentable

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process to be performed when run.

Interaction between the exclusions

1.16 The contribution made by an invention does not need to fall solely within a single excluded category for the invention to be excluded. As stated in paragraph 34 of Raytheon Company v Comptroller General of Patents, Designs and Trade Marks [2007] EWHC 1230 (Pat), where a contribution falls wholly within two or more exclusions, the invention would still be excluded. In paragraph 27 of Symbian Ltd's Application [2009] RPC 1, the Court of Appeal remarked obiter that one effect of the computer program exclusion is to prevent other excluded material becoming patentable merely by use of a computer in its implementation (although see 1.31 for the interaction with the mental act exclusion). Thus, for example, a business method implemented on a conventional computer system or network would be excluded as both a method for doing business and a computer program as such. Birss J expressed a similar view in paragraphs 32-36 of Halliburton Energy Services Inc's Applications [2012] RPC 129.

Not an exhaustive list

- 1.17 The phrase "among other things" suggests that the list of excluded fields is not a complete list of exclusions; however, to date, the courts have only given one example of matter which would also be excluded. In Ltd v Pike Signals Ltd and Faronwise Ltd [1993] RPC 107, Aldous J observed that a method of controlling traffic as such was not patentable, regardless of whether it also fell within the business method exclusion; claims to apparatus for controlling traffic flows were allowed on the basis that the particular apparatus involved a contribution in a technical (i.e. non-excluded) field. The hearing officer in Kostuj's Application (BL O/028/12) concluded that a method of developing a golf swing without a club was caught within the scope of the "among other things" phrasing, even if it did not fall squarely within the other exclusions.
- 1.17.1 Therefore, the exclusion may also apply to other matters which are essentially abstract or intellectual, but which do not fall clearly into one of the categories specifically listed. It is possible, although untested in the Courts, that such other matters would fall foul of the fourth step of the *Aerotel* test (see 1.23) as not being technical in nature.

Relationship of excluded matter to novelty and inventive step

1.17.2 In Lantana v Comptroller-General of Patents [2014] EWCA Civ 1463, the Court of Appeal reiterated that the requirements of s.1(1) and s.1(2) are separate, and that claims to novel and inventive subject matter may still be excluded. In paragraph 19 of the judgment Arden LJ held: "I see no mandate in section 1 of the PA 77 for holding that it is sufficient that there is an inventive step. It is deliberate legislative policy to exclude certain matters from patentability even if they would otherwise be patentable". This was reaffirmed in paragraph 70 by Kitchin LJ, who stated that "[t]here is no inconsistency between an acceptance that an invention [...] is new and inventive and a finding that the contribution it makes falls solely within excluded subject matter". The judge continued by remarking that "the former requires [...] an assessment of whether it forms part of the state of the art or is merely an obvious step away from it", while exclusion relates to assessing whether the contribution falls solely within excluded categories.

THE AEROTEL/MACROSSAN TEST

1.18 The Aerotel/Macrossan test (often referred to as the 'Aerotel test') is set out in paragraph 40 of the judgment in Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 [2007] RPC 7 (Aerotel/Macrossan). It provides a framework for the examiner to assess, and decide upon, the issue of excluded matter. As stated in 1.08, Aerotel/Macrossan is considered to be the definitive statement of how the law relating to excluded matter is to be applied. The Aerotel test is therefore the principal tool to be used when dealing with excluded matter

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cases, and encompasses all previous tests within it.

The test comprises four steps, which are as follows:

- (1) Properly construe the claim;
- (2) identify the actual contribution;
- (3) ask whether it falls solely within the excluded subject matter;
- (4) check whether the actual or alleged contribution is actually technical in nature.
- 1.18.1 It was stated by Jacob LJ in paragraph 47 of *Aerotel/Macrossan* that the test is a re-formulation of, and is consistent with, the previous "technical effect approach with rider" test established in *Merrill Lynch's Application* [1989] RPC 561 and followed by *Gale's Application* [1991] RPC 305 and *Fujitsu's Application* [1997] RPC 608. The Court considered it, in paragraph 48, to be "a structured and more helpful way of re-formulating the statutory test." Therefore, as Kitchin LJ notes in paragraph 44 of *HTC v Apple* [2013] EWCA Civ 451, the structured approach of the *Aerotel* test is followed in order to address whether the invention makes a technical contribution to the art, with the rider that novel or inventive purely excluded matter does not count as a "technical contribution".

Step 1 - construing the claim

1.19 As the court stated in *Aerotel/Macrossan*, the examiner must first "decide what the monopoly is before going on to the question of whether it is excluded". There are no special considerations with regard to claim construction; the normal principles apply (see 14.111-14.120, 125).

Step 2 - identifying the contribution

1.20 Jacob LJ outlined the considerations to be applied when identifying the contribution made by the claims in paragraph 43 of *Aerotel/Macrossan* – the critical factors for the examiner to consider are emphasised:

"The second step – identify the contribution - is said to be more problematical. How do you assess the contribution? Mr Birss submits the test is workable – it is an exercise in judgment probably involving the problem said to be solved, how the invention works, what its advantages are. What has the inventor really added to human knowledge perhaps best sums up the exercise. The formulation involves looking at substance not form – which is surely what the legislator intended."

Paragraph 44 states that, at application stage, the contribution may be taken to be that alleged by the inventor, although this cannot be conclusive; as Jacob LJ states, "[i]n the end the test must be what contribution has actually been made, not what the inventor says he has made". Additional guidance regarding the interpretation of this paragraph was provided in <u>IGT/Acres Gaming Inc</u>, <u>Re [2008] EWHC 568 (Pat)</u> paragraphs 23-24, which states that the examiner is not bound to accept what the applicant says, and is entitled to determine whether the alleged contribution is known or obvious, typically by performing a search.

1.20.1 Therefore, knowledge of the prior art will play a role in assessing the contribution; as Lewison J noted in paragraph 8 of <u>AT&T Knowledge Ventures/Cvon Innovations v Comptroller General of Patents [2009] EWHC 343 (Pat)</u>, the examiner should have "some notion of the state of the art". This does not necessarily mean however that the contribution is defined by what is new and inventive in the claim (see 1.21). That proper consideration of the prior art can make a difference to the outcome is best illustrated by <u>Aerotel Ltd v Wavecrest Group Enterprises Ltd & Ors [2008] EWHC 1180 (Pat)</u>. This case involved the same patent as <u>Aerotel/Macrossan</u>; however, Wavecrest was able to show that the contribution argued in the earlier case was known, by providing evidence that the 'special exchange' which formed the essential part of the new arrangement of hardware (see

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- 1.34.1) was actually within the common general knowledge. The Patents Court therefore reassessed the contribution and found that it related to how the special exchange was used and programmed, so that it fell solely within the business method and computer program exclusions.
- 1.20.2 When assessing the contribution, examiners should not consider prior art falling in the section 2(3) field.
- 1.20.3 However, a formal search is not required for the examiner to be able to assess the nature of the contribution. Peter Prescott QC (sitting as a Deputy Judge) in CFPH LLC [2005] EWHC 1589 (Pat) paragraph 96 stated that examiners are "entitled to make use of their specialist knowledge" to identify the contribution and are not bound to rely on prior art searches. Pumfrey J stated in Shopalotto.com Ltd's Application [2006] RPC 7 paragraph 12 that certain features may be "so notorious that a formal search is neither necessary nor desirable", and that examiners are "entitled to use common sense and experience" to make that determination. These views were consolidated in WMS Gaming Ltd's Application (BL O/260/13), which concluded in paragraph 60 that examiners are able to use their own judgement to determine whether to perform a search, and may accordingly use the provisions of section 17(5)(b) if appropriate (see 17.94-17.101).

What has been added to human knowledge

- As Jacob LJ stated in <u>Aerotel/Macrossan</u>, this is the summation of what the contribution is, and all of the other factors (see 1.21.2-1.21.4) weigh in to making this determination. The starting point for that assessment is the claims. It may be helpful to consider what makes the invention novel (see 1.20.1); however, it is then necessary to place that in its proper context and ensure that the effects of the invention are taken into account. It is not correct to eliminate everything in the claim that is known to arrive at that which is unknown, and then to conclude that the unknown part must be the contribution; i.e., as the Court of Appeal in Genentech [1989] RPC 205 put it, it is not the case that "an invention is unpatentable if the inventiveness was contributed only by matters excluded under section 1(2)". This approach - which is sometimes referred to as "Falconer reasoning", from its originator; or, less formally, "salami-slicing" - was expressly rejected by the Court of Appeal in that decision. In Lantana v Comptroller-General of Patents [2014] EWCA Civ 1463 paragraph 64, Kitchin LJ set out the importance of considering the proper context of an invention when assessing the contribution, accepting "[a] submission that it is the claim as a whole which must be considered when assessing the contribution which the invention has made, and that it is not permissible simply to cut the claim into pieces and then consider those pieces separately and without regard to the way they interact with each other". However, at paragraph 65, Kitchin LJ qualified this by observing: "[n]evertheless, I also have no doubt that, approached in this way, it is the actual contribution to the art which the invention has made which must be considered."
- 1.21.1 The courts have consistently found that, where claims recite standard hardware, such conventional apparatus does not form part of the contribution. This is often the case in computer program inventions an application relating to a computer program cannot be saved simply by claiming conventional computer hardware programmed in a particular way. Jacob LJ remarked on this in paragraph 44 of *Aerotel/Macrossan*, and specifically rejected the use of standard hardware when determining the contribution of the Macrossan application in paragraph 73.
- 1.21.2 What constitutes a technical contribution can change over time. Therefore the view that, once a technical contribution is made, that same contribution will always be technical may not apply. In paragraph 16 of <u>Lantana v Comptroller-General of Patents [2013] EWHC 2673 (Pat)</u>, Birss J addressed this point, noting that "[t]he fact that in the *IBM* case [T6/83] the method of communication between programs and files [...] was held patentable in 1988 does not mean that any method of communicating between programs and files [...] necessarily involves a technical contribution today". This was endorsed by Arden LJ in paragraph 43 of the Court of Appeal judgment <u>Lantana v Comptroller-General of Patents [2014] EWCA Civ 1463.</u>

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"Substance not form"

1.21.3 This is the application of the general principle (see 1.13-1.15.1) – the examiner must look beyond the literal wording of the claims to identify the contribution, and consider the central idea embodied in the claims. Recasting the claim in a different way, e.g. by claiming apparatus instead of method steps, will not usually alter the contribution.

Additional factors

- 1.21.4 Considering the additional factors that Jacob LJ in *Aerotel/Macrossan* thought relevant to identifying the contribution:
 - The problem said to be solved: an invention usually solves a problem; the problem and its solution are almost always relevant to the assessment of the contribution; an explicit statement may be included in the description, but not always it may simply be derived from the nature of the invention.
 - How the invention works may be simply the definition of the features of the invention in the claims, but it is often more useful to consider in terms of what the invention does as a matter of practical reality.
 - Finally, the advantages of the invention are normally closely linked to the problem being addressed, in the sense that the advantage is often that the problem is resolved.

All of these factors may assist in identifying the contribution, rather than defining it themselves.

Step 3 - assessing against the exclusions

The assessment carried out at step 3 is a critical part of the *Aerotel* test. How that assessment is made, and whether a particular contribution falls within one of the exclusions, will depend on the individual exclusion, and so is covered in greater detail under the specific categories in 1.25-1.40.4. In general, examiners should bear in mind that the third step does not require determining whether the contribution falls solely within the excluded subject matter categories as they are listed in section 1(2), but rather whether it falls solely within excluded subject matter <u>as such</u>. The "as such" qualification therefore narrows what is excluded – inventions may appear to fall solely with the excluded categories, but are not excluded as such. This is particularly true in the case of computer programs and discoveries, and this was recognised in <u>Merrill Lynch's Application [1989] RPC 561</u>.

Step 4 – is the contribution technical?

- 1.23 The fourth step was included in the test on the basis that it was required, in light of the earlier decision of the Court of Appeal in *Merrill Lynch*. In *Merrill Lynch* (page 569, lines 2-10), the necessity of making this assessment was characterised as follows:
 - "...it cannot be permissible to patent an item excluded by section 1(2) under the guise of an article which contains that item that is to say, in the case of a computer program, the patenting of a conventional computer containing that program. Something further is necessary. The nature of that addition is, I think, to be found in the *Vicom* case where it is stated: "Decisive is what technical contribution the invention makes to the known art". There must, I think, be some technical advance on the prior art in the form of a new result (e.g. a substantial increase in processing speed as in *Vicom*)."
- 1.23.1 The Patents Court, in paragraph 10 of <u>Oneida Indian Nation's Application</u> [2007] EWHC 954 (Pat), stated that if the invention has been found to be excluded at step 3, then there is no need to apply step 4, as any contribution would have been one of purely excluded matter, and, having regard to the rider as described in 1.18.1, would not count as a

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technical contribution.

Interaction between steps 3 and 4

1.24 Whilst the steps will often be considered separately, the examiner may already have addressed the question posed in step 4 in answering step 3, as determining whether the contribution falls solely within excluded matter may require assessing whether there is a relevant technical contribution, particularly with regard to the computer program exclusion. The Court of Appeal in Symbian Ltd v Comptroller General of Patents [2009] RPC 1 ruled that the question of whether the invention makes a technical contribution has to be addressed when considering the computer program exclusion, although whether that takes place at step 3 or 4 is not critical.

[When applying the Aerotel/Macrossan test in an examination report, examiners may find it useful to use PROSE clause RC4.]

APPLYING THE AEROTEL/MACROSSAN TEST TO SPECIFIC EXCLUSIONS

- 1.25 In all cases of excluded matter, the test in <u>Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 [2007] RPC 7</u> (Aerotel/Macrossan) is the starting point, no matter which exclusion is being relied upon. However, when applying the test, the individual exclusions have specific principles which derive from case law both before and after Aerotel/Macrossan. These can inform how the examiner assesses one or more of the steps of the test; however, they should always bear in mind that the case should be judged on its own merits (see 1.12).
- 1.25.1 That a contribution may fall within the scope of more than one exclusion and remain excluded (see 1.16) should also be kept in mind. Objections may be raised covering multiple exclusions, and examiners are encouraged to raise all relevant exclusions, so that the applicant is not surprised by an additional objection at a later stage.

Section (a) - Discoveries, scientific theories and mathematical methods

1.26 When considering the patentability of biotechnological inventions with regard to these particular exclusions, section 76A(1) should also be consulted (for discoveries in particular, see 76A.06).

Discoveries & scientific theories

1.27 The established view on when this exception applies was summarised by Peter Prescott QC (sitting as a Deputy Judge) in paragraph 34 of CFPH LLC [2005] EWHC 1589 (Pat):

"It is well settled law that, although you cannot patent a discovery, you can patent a useful artefact or process that you were able to devise once you had made your discovery. This is so even where it was perfectly obvious how to devise that artefact or process, once you had made the discovery [... The law] objects only when you try to monopolise your discovery for all purposes i.e. divorced from your new artefact or process. For that would enable you to stifle the creation of further artefacts or processes which you yourself were not able to think of."

This line of reasoning, stemming from, amongst others, the decision in *Hickton's Patent Syndicate v Patents & Machine Improvements Co Ltd* (1909) 26 RPC 339, was used by Lewison J in <u>Tate & Lyle Technology v Roquette Frères [2009] EWHC 1312 (Pat)</u>, where a claim, whose contribution was found to be the explanation of the underlying workings of a previously known method of manufacturing a sugar substitute, was refused as a discovery as such (see also 2.14.1).

1.27.1 In <u>Genentech Inc's Patent [1989] RPC 147</u>, the Court of Appeal held that the discovery of an amino acid sequence for the substance tPA led to a valid claim when

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incorporated into a conventional manufacturing process for the manufacture of tPA. Similarly, in <u>Kirin-Amgen v Hoechst Marion Roussel [2005] RPC 9</u>, the House of Lords held that a DNA sequence of a gene was not an invention on its own, but if it were necessary to isolate and extract it, then a process developed for this purpose and the material when obtained by this process could both be patentable (see also 76A.05).

1.28 This principle also applies to scientific theories – practical applications which rely on the theory may be patentable; the theory itself would not be. For example, in the two related cases of *Blacklight Power*, <u>BL O/076/08</u> saw an application for modelling atoms based on a new theory of electron states refused (in part) as relating to a scientific theory, whereas in <u>BL O/114/08</u>, an application for a practical application of that theory (a plasma reactor and a laser utilising the effects derived from the theory) was not considered to be excluded (although it was refused for lack of industrial applicability).

Mathematical methods

- 1.29 In *Vicom Systems Inc* T0208/84 [1987], the EPO Board of Appeal defined a mathematical method as one which "is carried out on numbers and provides a result in numerical form". A mathematical method was therefore merely an abstract concept prescribing how to operate on the numbers, and a claim directed solely to the mathematical method was excluded from patentability as a result of its abstract nature.
- 1.29.1 However, if the invention provides a technical contribution, it may be considered patentable even though the underlying idea may reside in a mathematical method; a claim to a method of enhancing digital images by software processing that implemented a mathematical method was considered to provide such a contribution in *Vicom* and allowed. Furthermore, where the contribution relates to the practical application of the mathematical function, it would not be considered a mathematical method as such. That said, it may still be excluded under another category, as was the case in *Gale's Application* [1991] RPC 305, which related to a program implementing the calculation of square roots on a computer. The Court of Appeal refused the application as a computer program as such, but not as a mathematical method.
- 1.29.2 The presence of real data taken from a physical entity in a claim relating to a mathematical method, for example a method of modelling, simulation or prediction of a real world system, does not necessarily imply that a corresponding invention will avoid exclusion. WesternGeco Ltd's Application (BL O/135/07), a method for processing real-world geophysical data by mere abstract manipulation of the data was held by the hearing officer to be a mathematical method as such; however, it was felt that the application of this processed data to determine parameters relating to physical properties of the Earth's interior, so that an improved seismic image could be produced, did not fall wholly within the exclusion as a result of the decision in Vicom.
- 1.29.3 Such inventions might therefore avoid exclusion if they contribute to non-excluded fields. For example, whilst a claim directed to monitoring and identifying the position of people and packages in a transportation network was refused as a mathematical method (as well as a computer program and method for doing business) in Innovation Sciences Pty Limited (BL O/315/12); in Waters Investments Limited's Application (BL O/146/07), a contribution comprising a method of analyzing samples by an analytical technique which uses chromatography and spectrometry followed by a sequence of data analysis techniques (i.e. a mathematical method) to give particular results, although including some steps that could be said to fall within excluded matter, was found to lie in the technical field of sample analysis using chromatography and spectrometric techniques, and so was not excluded.

Section (b) - aesthetic creations

1.30 If an article is distinguished from the prior art solely by its design, ornamentation or colour, then it will be excluded if this has a purely aesthetic function, but if the distinction has a practical effect then this could save it from the exclusion. For example,

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if a serving tray were characterised solely by having a particular embossed pattern on its surface, then it would fall within the exclusion, but if it were found that this particular pattern had non-slip attributes unexpectedly superior to those normally associated with embossment, this could provide a patentable feature.

- 1.30.1 Evidence may be necessary where the advantage conferred by the apparently aesthetic distinction is not clear from the disclosure. In *I.T.S. Rubber Ltd's Application* [1979] RPC 318, decided under the 1949 Act, a claim to a squash ball characterised by its blue colour was allowed because evidence showed that it had surprisingly enhanced visibility during play.
- 1.30.2 The means of obtaining a purely aesthetic effect may be patentable if it is characterised by non-excluded features, such as the structure of an article or the steps in a process. For example, a fabric may be provided with an attractive appearance by means of a layered structure not previously used for this purpose, in which case a fabric incorporating such a structure might be patentable.

Section (c) - mental act, playing a game, business methods, and computer programs

Mental act

- 1.31 The decision in <u>Halliburton Energy Services Inc's Applications [2012]</u> RPC 129 confirmed (in paragraphs 57 and 63) that the mental act exclusion is to be interpreted narrowly it only covers acts that are carried out by "purely mental means", and does not extend to those which are merely capable of being performed mentally. HHJ Birss QC (sitting as a Judge of the High Court) considered that the aim of the exclusion was to prevent patents being granted which could be infringed "by thought alone".
- 1.31.1 In the same judgment (in paragraph 43), HHJ Birss specifically outlined that, with this interpretation, a claim carried out on a computer could not be excluded as a mental act this was adopted in the Practice Notice Patents Act 1977: Patentability of Mental Acts. Therefore, if a computer, or any other hardware, is involved in the invention, it will not be excluded as a mental act. However, the claim could still fall within the computer program exclusion.
- 1.31.2 Following the *Halliburton* decision, examples such as a method of learning a language, of playing chess, or teaching reading may still be excluded as methods for performing a mental act, provided they fall within the narrow interpretation. Pure design methods may also still fall within this exclusion; for example, in *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] RPC 2, the Patents Court held that a method for creating a design of rock drilling bit amounted to a mental act. This decision was expressly endorsed in the later *Halliburton* case (in paragraph 49), where the Court held that the claims in the earlier case were not limited solely to a computer implementation, and were therefore directed to "the purely intellectual content of the design process". As a result, the claims encompassed both excluded and non-excluded embodiments (see 1.15). In contrast, the claims in the later case were restricted to a computer implementation of the design method, and therefore fell outside the narrow interpretation of the mental act exclusion.
- 1.31.3 In *Halliburton v Smith*, Pumfrey J indicated (at paragraphs 215-218) that a claim could avoid the mental act exclusion if it was "tethered" to a step of manufacturing the designed product, even if it was not solely limited to a computer implementation. The method in the specification had a "potential technical effect", but as the claims were so broad as to encompass activities outside that method, they needed to be restricted to the technical field in which the method operated to eliminate those activities from the scope of the claim. Approaching this from the perspective of the later *Halliburton* case, this is another example of a non-mental limitation which, if present in a claim, would mean that the exclusion will not apply.

Games

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- 1.32 The patentability of schemes, rules or methods for playing a game was considered by the Patents Court in <u>Shopalotto.com Ltd's Application [2006] RPC 7</u>, where the application related to a computer lottery game played over the internet. The Court held that the patentability of games should be assessed using the general approach for excluded matter, putting it in line with the other exclusions. Following *Aerotel/Macrossan*, this means that the patentability of games should be assessed using the *Aerotel* test. Patentability of games was also considered in <u>IGT v The Comptroller-General of Patents [2007] EWHC 1341 (Ch)</u> which concerned four applications relating to gaming apparatus, specifically casino-based systems using slot-machines. In each case, Warren J held that the claims as construed related to known apparatus upon which a game was played. The contribution in each case therefore lay in the rules or methods used to play the game, and fell solely within the excluded category. See also 1.16 and 1.25.1 for discussion of the interaction between the different exclusions.
- 1.32.1 In relation to non-computer based games, apparatus which involves a combination of standard game items, such as a board, playing pieces, a random outcome generator (e.g. dice), chance cards and the like, which are united by the nature of the game played will usually be excluded, since the actual contribution lies in the game that the apparatus is used to play. One example is <u>Anderson's Application (BL O/112/12)</u>, in which the Hearing Officer held that the contribution lay in a scheme, rule or method for playing a game, and that amending to include the use of known apparatus through which the game could be played did not change the contribution in substance. The application was therefore refused.

Business methods

- 1.33 The Court of Appeal in *Aerotel/Macrossan* expressly rejected the interpretation placed upon this exclusion by Mann J in *Macrossan's Patent Application* [2006] EWHC 705 that a method of doing business should be a way of conducting an entire business, rather than a tool to facilitate business transactions or procedural steps having administrative or financial character and instead took a wider view of what constitutes a business method. It found that there was no reason to limit the exclusion in the way Mann J had, and confirmed this by looking at the French and German versions of EPC Article 52(2), which are not limited to methods of conducting entire businesses. (The French refers to "economic activities" while the German refers to "business activities".)
- 1.33.1 Therefore, the exclusion is to be interpreted as encompassing such tools or steps, and not merely abstract matters or completed transactions. As the Court in *Aerotel/Macrossan* noted: "whether as an abstract or generalised activity or as a very specific activity, if it is a method of doing business as such it is excluded" (paragraph 68). Double entry bookkeeping was cited in the judgment as an example of a concept that did not involve conducting an entire business or a completed transaction, but nevertheless was clearly a method of doing business.
- The expression "doing business" is also not restricted to financial or 1.33.2 commercial activities, but embraces administrative, organisational and managerial activities. In Aerotel/Macrossan, it was noted that the idea of having three document trays - "in", "out" and "too difficult" - was a way of conducting business and no more. In Melia's Application (BL O/153/92), the Hearing Officer refused a scheme under which prisoners could exchange all or part of a prison sentence for corporal punishment as a business method - the business in question being that of administering punishment. In Cummins-Allison Corp's Application (BL O/361/12), the Hearing Officer refused a method of conducting blind balancing on documents associated with a deposit transaction, in which the deposit was displayed only if the received and calculated amounts match, as an administrative process falling solely within the exclusion. Wills' Application (BL O/089/99), relating to the provision of cards to be held by a school and the parents or grandparents of a child so as to provide an immediate source of accurate, up-to-date information in the event that the child goes missing, and John Lahiri Khan's Appn (BL 0/356/06), a method of effecting introductions between people wearing a designated device, such as a ring, were both refused under this exclusion. In Hewlett-Packard Development Company's Application (BL O/441/12), a method for

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calculating and modifying the characteristics of an item, such as a magazine, before it is printed – to produce a printed item with an optimised postage weight – was considered to be no more than a method of managing postal changes, and therefore a business method.

1.34 The business method exclusion is generic, as discussed at page 569 of <u>Merrill Lynch's Application [1989] RPC 561</u>. Therefore, the fact that an application may provide a better way of conducting business is not relevant. In <u>Halliburton Energy Services Inc's Applications [2012] RPC 129</u>, HHJ Birss QC at paragraph 35 noted that the use of a computer to implement a better business method did not confer patentability:

"The business method cases can be tricky to analyse by just asking whether the invention has a technical effect or makes a technical contribution. The reason is that computers are self evidently technical in nature. Thus when a business method is implemented on a computer, the patentee has a rich vein of arguments to deploy in seeking to contend that his invention gives rise to a technical effect or makes a technical contribution. For example the computer is said to be a faster, more efficient computerized book keeper than before and surely, says the patentee, that is a technical effect or technical advance. And so it is, in a way, but the law has resolutely sought to hold the line at excluding such things from patents."

1.34.1 The Aerotel patent was found to be valid by the Court of Appeal in Aerotel/Macrossan, as it related to a "new arrangement of hardware" due to an extra piece of equipment in the form of a 'special exchange' (although, see 1.20.1). It was therefore not considered to be a business method, because the system as a whole was new (as it contained a new piece of hardware). The contribution therefore was not limited to using an exisiting system to carry out the business of selling phone calls. However, this should be contrasted with the system of Merrill Lynch, which was only new due to the method of doing business that it produced. Therefore, when assessing whether a particular invention relates to a new system or arrangement of hardware, it should be asked whether the system is new in itself or whether the system is only new due to the business method it performs.

Computer programs

- 1.35 Where a claim involves the use of a computer program, it does not naturally follow that the claim must be excluded. Instead, the contribution of a claim to a computer program must be assessed by reference to the process the program will cause a computer to perform, because the assessment is based on the substance of the invention, as stated in Trade Marks [2008] RPC 14 (see 1.13). In Halliburton Energy Services Inc's Applications [2012] RPC 129, HHJ Birss QC emphasised that "[a] computer programmed to perform a task which makes a contribution to the art which is technical in nature is a patentable invention and may be claimed as such." Therefore, a computer program that provides a technical contribution will not fall under the exclusion, as it is more than a computer program as such. Although an invention involving a computer is undoubtedly "technical", the mere presence of conventional computing hardware does not of itself mean the invention makes a technical contribution (and so avoids the computer program exclusion) as such hardware will typically not form part of the contribution (see 1.21.1).
- 1.36 Following the development of the *Aerotel* test, <u>Symbian Ltd's Application</u> [2009] RPC 1 more closely examined the question of "technical contribution" as it related to computer programs (see 1.24). In examining the case law, the Court of Appeal concluded that creating a precise test for determining whether a computer program was excluded was difficult, and to suggest that such a clear rule existed was perhaps dangerous when considering the pace of technological development. It emphasised the need to determine each case by reference to its particular facts (see 1.12).
- 1.36.1 The court held that the contribution made by the invention in *Symbian* was not a computer program as such because "it has the knock-on effect of the computer working better as a matter of practical reality". Paragraphs 54-56 emphasised the need to look at the practical reality of what the program achieved, and to ask whether there was

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something more than just a "better program". An invention which either solves a technical problem external to the computer or solves one within the computer was not considered to fall under the computer program exclusion. The particular invention involved improving the operation of a computer by solving a problem arising from the way the computer was programmed (in that case, a tendency to crash due to conflicting library program calls). The court considered that this could be regarded as solving a technical problem within the computer, if it leads to a more reliable computer. Thus, a program that results in a computer running faster or more reliably may be considered to provide a technical contribution, even if the invention addresses a problem in the programming of the computer. The court concluded that such a technical contribution rendered the claim in this case patentable.

"Since each case must be determined by reference to its particular facts and features (*Symbian* at [52]) we need to begin by asking: what does the computer program in this case actually contribute?"

In this instance, he concluded that the program made it easier to write programs for applications to be run on the device that contains it, and that writing software in this instance did not fall within the scope of the exclusion, although the ultimate product (i.e. the software itself) may still do so.

The AT&T signposts

- Although the *Aerotel* test may involve the examiner checking "whether the actual or alleged contribution is actually technical in nature" and *Symbian* actively requires the question "does the invention make a technical contribution" to be asked when considering the computer program exclusion the judgment in *Aerotel/Macrossan* does not provide much guidance on how this is to be carried out in practice. However, in paragraph 40 of *AT&T Knowledge Ventures/Cvon Innovations v Comptroller General of Patents* [2009] EWHC 343 (Pat) (*AT&T/CVON*), Lewison J (as he then was) set out five signposts that he considered to be helpful when considering whether a computer program makes a relevant technical contribution. In *HTC v Apple* [2013] EWCA Civ 451, Lewison LJ reconsidered the signposts he had suggested in *AT&T/CVON* and, in light of the decision in *Gemstar-TV Guide International Inc v Virgin Media Ltd* [2010] RPC 10 (see 1.37.1 and 1.40.4), felt that the fourth signpost had been expressed too restrictively.
- 1.37.1 Drawing on the cases identified in *Symbian* as key to understanding the computer program exclusion, the signposts are a distillation of the reasoning and rationale of this previous case law. (The decisions that each signpost derives from can be found in brackets following each signpost).

The signposts are:-

- i. whether the claimed technical effect has a technical effect on a process which is carried on outside the computer (from *Vicom*)
- ii. whether the claimed technical effect operates at the level of the architecture of the computer; that is to say whether the effect is produced irrespective of the data being processed or the applications being run (from *IBM T* 0006/83, *IBM T* 0115/85, *Merrill Lynch*, *Symbian*)
- iii. whether the claimed technical effect results in the computer being made to operate in a new way (from *Gale*)

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- iv. whether the program makes the computer a better computer in the sense of running more efficiently and effectively as a computer (from *Vicom, Symbian;* as reworded in *HTC v Apple*)
- v. whether the perceived problem is overcome by the claimed invention as opposed to merely being circumvented (from *Hitachi* T 0258/03 note that the problem in question must be a technical problem)
- 1.37.2 It should be clear that the signposts are merely guidelines; although they provide a useful aid for the examiner in assessing the technical character of a claimed invention, they were not intended to provide a definitive test (as Lewison LJ's *obiter* remarks in paragraph 149 of *HTC v Apple* make clear). Several judgments have emphasised this point John Baldwin QC (sitting as a Deputy Judge) in *Really Virtual Co Ltd v UK Intellectual Property Office* [2012] EWHC 1086 (Ch) noted that the signposts, although useful, are no more than signposts and that there will be some cases in which they are more helpful than in others. Kitchin LJ made similar remarks in paragraph 51 of *HTC v Apple* their usefulness does not mean they will be determinative in every case. However, if the claimed invention fails all of the signposts, it will likely be a good indicator that it may be nothing more than a computer program as such.

[If referring to the AT&T signposts in an examination report, examiners may find it useful to use PROSE clause RC4A.]

Interpretation of the signposts

- 1.38 How these signposts are to be interpreted is often the subject of discussion in excluded matter cases, and hearing decisions and judgments have considered the underlying meaning of all of the signposts at one point or another. The hearing officer in *Commonwealth Scientific and Industrial Research Organisation's Application* (BL O/367/11) took the opportunity to consider each signpost in turn (although the fifth signpost was not addressed in the hearing, and so was only considered briefly) and explained her view on how each was to be interpreted in paragraphs 31-42.
- 1.38.1 To meet the first signpost, the process carried out by the program must be, or must operate on, something external to the computer on which the program is being run. As Lewison J put it in his summarisation of *Vicom* in paragraph 20 of *AT&T/CVON*, if the process would be patentable if it were not operated by means of a computer program, the fact that it is operated by means of a computer program does not render it excluded. An often-used, if limited, example is that of a computer-controlled car braking system the braking system is external to the computer, and the programming has an effect on that system. This does not mean that any effect taking place outside a single computing device meets the signpost systems operating as a network can be considered as 'the computer' for the purposes of this signpost, as emphasised by Birss J in paragraph 30 of *Lantana v Comptroller-General of Patents* [2013] EWHC 2673 (Pat). The hearing officer in paragraph 41 of *Hewlett-Packard's Application* (BL O/319/11) considered that reducing the amount of data exchanged in a network between a memory tag and its reader had no technical effect on the communication process between them, even if the process was considered to be outside the two, as no actual change was made to the process itself.
- 1.38.2 The second signpost asks whether running the program changes how the computer runs internally. In practice, this means in the sense of the operation of the processor, the cache memory, or other internal components of the computer. The "architecture" can be thought of as the combination of these components, which operate in the same way regardless of the application being run. If the effect being produced would provide a benefit to any software program which runs on the system, it is likely to meet this signpost. If the effect being produced is specific to a particular data set, type of data, or benefits only particular applications, it is likely it will fail to meet this signpost. The hearing officer in *Intuit Inc's Application* (BL O/347/10) considered that an application programming interface operating between layers of an application model did not meet the signpost, as it did not provide internal control of the architectural components or operate at a sufficiently

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high level of generality within the computer.

- 1.38.3 The third signpost emphasises that the effect must be more than just the running of a program or application on a general purpose computer the computer itself must operate differently than it did before as a result of the program being run.
- 1.38.4 The fourth signpost was reframed in *HTC v Apple*, and is approached in a similar way to the third the computer must operate more efficiently and effectively as a result of running the program. Again, this must be the computer as a whole, rather than the individual program. In several cases, such as *Q Software Global Ltd's Application* (BL O/120/11) and *JDA Software Group Inc's Application* (BL O/386/12), it was argued that the program required less processing power to run, or operated faster, and the system was therefore more efficient. This was not considered to meet the signpost, as the system itself remained unchanged the computer processed the data in the same way as it did before, the program merely made more efficient use of the hardware.
- The fifth signpost looks at the technical character of an alleged invention by means of the problem addressed. When the problem is a technical one, the alleged invention can be considered to have a technical nature leading to it falling outside the exclusion if (but not only if) it solves the problem. In Lantana Ltd v The Comptroller-General of Patents, Designs and Trade Marks [2013] EWHC 2673 (Pat), Birss J stated that "[i]t makes sense to think of something which is a solution to a technical problem as itself having technical character because it takes that character from the technical nature of the problem to be solved. But if a thing is not solving the technical problem but only circumventing it, then that thing cannot be said to have taken any technical character from the problem." Circumventing a technical problem does not automatically imply that an alleged invention is excluded, but indicates that one cannot rely on the addressed problem to deduce its technical character. At paragraph 51 of the subsequent Court of Appeal decision, Lantana v Comptroller-General of Patents [2014] EWCA Civ 1463, Arden LJ noted that "[c]ircumvention may be the result of truly original linear thinking and may lead to patentability in an appropriate case". This does not happen when circumvention consists of conventional means, as reaffirmed by Kitchin LJ at paragraphs 68 and 70 of the same judgment: "[o]verall, the invention avoids the problem...but it does so by using a conventional technique [... i]n other words it does not solve those problems but circumvents them". Similarly, if the problem to be solved is not a technical problem, the solution cannot take technical character from the problem, although it may have some other technical effect. Other examples where circumvention also lacks technical character are given in Direct TV Pty's Application (BL O/150/11, paragraphs 32-33) and Apple Inc's Application (BL O/244/13, paragraphs 38-39), amongst others, where it was argued that the problem of bandwidth limitations in transmitting data across a network was solved by the invention. In each case, this was achieved by reducing the amount of data transmitted. The Hearing Officers considered that to circumvent the problem, as there was no change to the way in which the data was transmitted, merely the volume.

Assessing "technical effect" using the AT&T signposts

- 1.39 Determining whether a computer program provides a technical effect such that it does not fall within the exclusion usually (but not always; see 1.37.2) involves assessing the contribution against the *AT&T* signposts (in the form stated in *HTC v Apple*). Decisions since AT&T have often used the signposts when answering step 3 of the *Aerotel* test.
- 1.39.1 In <u>Protecting Kids the World Over (PKTWO) Ltd's Patent Application</u> [2012] RPC 13, the invention was found to solve a technical problem lying outside the computer, namely how to improve the generation of an alarm in response to inappropriate communication, and therefore was not excluded from patentability.
- 1.39.2 In <u>HTC v Apple [2013] EWCA Civ 451</u>, a method of handling the recognition of single- and multi-touch events in devices programmed to do so had the advantage that application programmers could more easily write software to accommodate

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such recognition. Although considering that the contribution fell outside the scope of the exclusion in any event (see 1.36.2), Lewison LJ went on (in paragraph 154) to assess the contribution against the *AT&T* signposts, and found that it met all but the third signpost, which pointed to the program providing a technical effect in itself. Kitchin LJ similarly found, in paragraph 57, that the recognition handling operated at the architectural level, and caused the devices to operate in a new way. The application was found to fall outside excluded matter.

Section (d) - Presentation of information

- 1.40 Any manner, means or method of expressing information which is characterised solely by the content of the information is excluded, regardless of how it is represented. The fact that physical apparatus may be involved in the presentation will not usually be enough to avoid the exclusion. In <u>Townsend's Application [2004] EWHC 482 (Pat)</u>, Laddie J held that the exclusion encompassed both the provision of information and its expression. In <u>Autonomy Corp Ltd v Comptroller General of Patents, Trade Marks & Designs [2008] EWHC 146 (Pat)</u>, the court held that choosing where and how to display information was still the presentation of information, as it is part of the decision as to how to present the information.
- 1.40.1 If the invention relates to the technical means by which the information is presented, rather than the presentation itself, then it may not fall within the exclusion, as per <u>BBC/Colour television signal</u> [1990] EPOR 599 (T 0163/85), where the EPO Technical Board of Appeal held that a colour television signal, characterised by the technical features of the television system in which the signal occurs, was not excluded under presentation of information. However, the Board distinguished this from a television system which was defined solely by the information (e.g. moving pictures) being transmitted using a standard television signal, which they felt may fall within the exclusion.
- 1.40.2 In other words, if there is a technical effect or a contribution in a non-excluded field, the invention will not lie solely within excluded matter. In *Townsend*, an application for an invention relating to an advent calendar with an additional indicator (such as a word, picture, colour etc.) on each door was refused by the Hearing Officer in <u>BL O/266/03</u> (and, on appeal, the Patents Court) as relating to the presentation of information which served no technical purpose and included no technical advance. *TDK Electronics Co Ltd's Application* (<u>BL O/097/83</u>) held that a claim to a tape cassette of conventional construction, but with differentially coloured poles, was excluded because it encompassed a cassette where the poles were coloured subsequent to assembly, and thus did not serve any function in its assembly or use. A gaming machine in which logos or brand or product names were substituted for the conventional symbols normally depicted on the reels of a fruit machine was also found to fall within the exclusion in *Ebrahim Shahin's Application* (BL O/149/95).
- 1.40.3 A claim to a conventional package containing a known product, characterised solely by the instructions on the package, will not generally be allowed, since the contribution relates solely to the presentation of information. Several cases along these lines were rejected under the 1949 Act, including *Dow Corning Corporation (Bennett's) Application* [1974] RPC 235, and *Ciba-Geigy AG (Durr's) Application* [1977] RPC 83.
- 1.40.4 <u>Gemstar–TV Guide International Inc v Virgin Media Limited [2010] RPC</u>
 10 considered the question of computerised methods for presenting information. The case related to three EP(UK) patents covering various aspects of Electronic Program Guides (EPGs). In his judgment, Mann J emphasised that the exclusion was not solely confined to the content of information, and that, in order for the exclusion not to apply, there must be some technical effect beyond the information being presented. The court also stated that if the contribution is defined only in terms of the information to be presented, then that is a presentation of information the presence of a display does not change this. In particular, a better (or new) user interface was not considered to be a relevant technical effect the rearrangement of information was nothing more than the presentation of information; simply having something different displayed was not sufficient to overcome the exclusion. Two of

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the three patents were found to be excluded as they lacked the required technical effect; the third presented a physical effect, namely the movement of data between hard disks, such that there was more than merely the presentation of information

Section 1(3)

A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

Section 1(4)

For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.

Exploitation contrary to public policy or morality

Sections 1(3) and 1(4) were amended by the Patents Regulations 1 41 2000 (SI 2000 No.2037) so that the wording would more closely reflect the wording of article 27(2) of the TRIPS agreement. Section 1(3)(a) had previously stated that a patent would not be granted for an invention whose "publication or exploitation" would "be generally expected to encourage offensive, immoral or antisocial behaviour". In practical terms, the effect of s.1(3) remains the same, which is to prevent the grant of patent rights for inventions which the general public would regard as abhorrent or from which the public need protection. It provides a reasonably objective test which has to be applied to each invention and its particular set of facts and circumstances. Clearly what is to be regarded as contrary to public policy or morality will vary according to changes in social attitudes and on no account ought examiners to allow their own personal and individual beliefs to colour their judgment on this matter. The decision of Aldous J in the case of Masterman's Design [1991] RPC 89 under a similar provision of the Registered Designs Act 1949 deals with issues broadly corresponding with those which may arise under s.1(3). The Patents Act 1977 (Isle of Man) Order 2003 (SI 2003 No. 1249) amended sections 1(3) and 1(4) for the Isle of Man.

[Only in the clearest cases should examiners invoke this subsection and then only following consultation with their Deputy Director. Any genuine doubt should be exercised in favour of the applicant with an appropriate minute being created.]

1.42 Unlike under the previous s.1(3)(a), the exclusion from patentability is not activated if mere publication of the invention, as distinct from its exploitation, would be contrary to morality. If, however, the specification includes matter the publication or exploitation of which would generally be expected to encourage offensive, immoral or antisocial behaviour, then (irrespective of whether the invention itself is open to objection under s.1(3)) the situation can be dealt with by excision of the offending matter under s.16(2) - see 16.34-16.37.

a.53(a) EPC The corresponding provision of the EPC (see 1.06) refers to "inventions the publication or exploitation of which would be contrary to 'ordre public' or morality". In the Harvard "oncomouse" case T 315/03 ([2006] 1 OJEPO 15, [2005] EPOR 31) (see also 76A.02.1 and 76A.05), the Board of Appeal endorsed the definitions of "ordre public" and morality provided in Plant Genetic Systems T 356/93 [1995] 8 OJEPO 393 and held that the assessment of these concepts should be made as of the filing or priority date of the application. The concept of "ordre public" was accepted as covering the protection of public security and the physical integrity of individuals as part of society, and encompassed the protection of the environment. In relation to morality, the Board in T 356/93 held that the culture inherent in European society and civilisation should be the basis for determining what behaviour is right and acceptable, and what behaviour is wrong. However, the Board in oncomouse added that in making an assessment of morality, no single definition of morality

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based on e.g. economic or religious principles represents an accepted standard in European culture, and opinion poll evidence was of little value. For animal manipulation cases, the Board of Appeal in T 315/03 endorsed the guidance provided in its earlier consideration of the Harvard "oncomouse" application (case T 19/90 [1990] 12 OJEPO 476). This case held that the possible detrimental effects and risks had to be weighed and balanced against the merits and advantages aimed at. In particular, the basic interest of mankind to remedy disease had to be set against the protection of the environment of uncontrolled dissemination of unwanted genes and the avoidance of suffering to animals, including the possibility of using non-animal alternatives. In balancing these factors, the Board in T 315/03 allowed claims covering transgenic "mice", refusing broader claims encompassing rodents (see 76A.02.1).

- 1.44 For biotechnology inventions, in addition to the general exclusion of s.1(3), Schedule A2 of the Patents Act specifies that certain categories of invention are not patentable inventions; these are discussed in 76A.02-76A.06 and the Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office.
- 1.45 Section 1(4) is a rider to section 1(3) to make it clear that an act or action prohibited by a law is not to be considered as necessarily the same thing as contrary to public policy or morality. (One reason for this is that a product which could not lawfully be used in the UK may be manufactured lawfully in the UK for export to countries where its use is not illegal). However the existence of a law or regulation may be a material fact to be taken into consideration in determining whether to refuse an application under s.1(3). The nature and probable uses of the invention will need to be considered as well as the exact terms of the prohibition. Thus if the prohibition is directed unconditionally to the very act which the inventor proposes very careful deliberation must be given as to whether to invoke s.1(3). In such cases a useful test is to consider why the prohibition exists. For example it is considered that the Landmines Act 1998 (implementing the Ottawa Convention) and the Cluster Munitions (Prohibitions) Act 2010 (implementing the Convention on Cluster Munitions) were passed because the public in the UK generally now consider the development, manufacture and use of anti-personnel mines and cluster munitions to be immoral. In addition, UK is a signatory to other weapons conventions which prohibit categories of weapon, including the Chemical Weapons Convention and the Biological and Toxin Weapons Conventions; these have been implemented in UK law by the Chemical Weapons Act 1996 and the Biological Weapons Act 1974 respectively. Again, the signing of the conventions and the passage of the legislation indicate that the general feeling of the public in the UK is that the production and use of these weapons is immoral. However, it should be noted that both these Acts recognise that agents capable of use as a chemical or biological weapon may have legitimate purposes. In cases in which an invention can be exploited legally albeit in accordance with stringent regulations, it would be very difficult to argue that s.1(3) applies and the application for a patent refused.

[Any concerns about patent applications which may relate to weapons which are considered contrary to public policy or morality should be raised with Security Section]

Plant and animal varieties, and "essentially biological processes"

1.46 Prior to the Patents Regulations 2000, s.1(3)(b) set out that a patent would not be granted for "any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process". These exclusions remain in place, and are now found, along with others which relate to biotechnological inventions, in Schedule A2 to the Act, introduced by the Patents Regulations 2000 and made under section 76A of the Act, which was also introduced by those Regulations (see 76A.01-06 and the Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office).

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Section 1(5)

The Secretary of State may by order vary the provisions of subsection (2) above for the purpose of maintaining them in conformity with developments in science and technology; and no such order shall be made unless a draft of the order has been laid before, and approved by resolution of, each House of Parliament.

1.47 The white paper "Patent Law Reform" (Cmnd 6000) noted that the patent system "must evolve in response to changing conditions". This was done under previous legislation by continually re-interpreting the centuries-old definition of invention as "any manner of new manufacture". The present Act controls what is to be regarded as an invention for which a patent monopoly may be granted by means of the definitions set out in the foregoing subsections. The present subsection gives the necessary measure of flexibility to this control, whilst reserving to Parliament the authority to approve it. This would be at the instigation of the Secretary of State, who would normally take such action following the established consultative processes.

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Section 2: Novelty

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SECTION 2(6) (Repealed)

s.130(7) 2.01 Section 2 is so framed as to have, as nearly as practicable the same effect in the UK as the corresponding provisions of the EPC, ie Articles 54 and 55, PCT and CPC. Rule 5 is relevant to this section.

Section 2(1)

An invention shall be taken to be new if it does not form part of the state of the art.

2.02 An invention defined in a claim lacks novelty if the specified combination of features has already been anticipated in a previous disclosure. In <u>SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent [2006] RPC 10</u>, the House of Lords held there were two requirements for anticipation: prior disclosure (see 2.03 to 2.09) and enablement (see 2.10). These are distinct concepts, each of which has to be satisfied and each of which has its own rules.

Prior Disclosure

2.03 Prior disclosure is the first requirement to be satisfied for matter to anticipate an invention. To constitute a prior disclosure of an invention, the matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in infringement of the patent. This infringement test is detailed by the Court of Appeal in General Tire & Rubber Company v Firestone Tyre & Rubber Company Limited, [1972] RPC 457, at pages 485-6:-

"If the prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after

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the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty, that is to say, it will have been anticipated. The prior inventor, however, and the patentee may have approached the same device from different starting points and may for this reason, or it may be for other reasons, have so described their devices that it cannot be immediately discerned from a reading of the language which they have respectively used that they have discovered in truth the same device; but if carrying out the directions contained in the prior inventor's publication will inevitably result in something being made or done which, if the patentee's patent were valid, would constitute an infringement of the patentee's claim, this circumstance demonstrates that the patentee's claim has in fact been anticipated".

Actavis UK Ltd & Ors v Eli Lilly & Company [2017] UKSC 48 held that a product with a feature which is different from, but equivalent to, a claimed feature may nevertheless infringe, even though it falls outside the meaning of the claim's wording (see 125.17.3-125.18.5). The statement in General Tire that a document infringing after grant would be an anticipation before grant is not thought to apply in such cases - but clarification from the courts on this point is awaited. Note that in <a href="Generics (U.K.) Limited and others v Yeda Research and Development Company Ltd and others [2017] EWHC 2629 (Pat), Arnold J said that the doctrine of equivalents set out in Actavis v Eli Lilly does not apply to novelty.

- 2.03.1 The Court of Appeal applied this test in <u>Glaverbel SA v British Coal Corporation [1995] RPC 255</u> where it was also held that it is not necessary for the prior art to be equal in practical utility or to disclose the same invention in all respects as the patent in suit. The Patents Court considered the requirement for the prior art "inevitably" to result in a novelty-destroying disclosure in <u>Kirin-Amgen Inc. v Roche Diagnostics GmbH [2002] RPC 1</u>. It was held that "the law of patents is ultimately concerned with practicality", and so a prior art experiment which, when performed, reliably produced a particular result "more than 99 percent of the occasions on which it is conducted" would be regarded for the purposes of disclosure as "inevitably" leading to the result in question. In <u>Dr Reddy's Laboratories (UK) Ltd v Eli Lilly and Co Ltd [2008] EWHC 2345 (Pat), [2009] FSR 5</u>, the Patents Court held that where the skilled person would have recognised that there were errors in a prior disclosure, the question to be considered was whether there was a clear and unambiguous disclosure of the invention, <u>not</u> whether the skilled person would have concluded that the document probably disclosed the invention. See also 2.07-2.07.3.
- 2.04 It follows that a claim which defines an invention by reference to parameters, for example of a process or a product, is anticipated by a disclosure which when put into practice would necessarily fall within the scope of the claim, even if the disclosure does not refer to these particular parameters. (See also 14.121, 17.41).
- 2.04.1 In T 303/86 (CPC Int) [1993] EPOR 241 the Technical Board of Appeal of the EPO considered anticipation arising from two cook-book recipes of a process for making flavour concentrates from vegetable or animal substances by extraction with fat solvents under pressure in the presence of water. The claim specified certain parameters for the ratio between the vapour pressure of the water in the meat or vegetables and the vapour pressure of the free water. The Board said:

"It is sufficient to destroy the novelty of the claimed process that this process and the known process are identical with respect to the starting material and reaction conditions since processes identical in these features must inevitably yield identical products."

Furthermore, it did not matter that the cook did not realise that he was not only frying a chicken, but also making a "flavour concentrate" in the surplus oil. It was enough, as the Board said, that "some flavour of the fried chicken is extracted into the oil during the frying process even if this is not the desired result of that process."

2.04.2 In <u>Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] RPC</u> <u>76</u> Lord Hoffmann held that section 2(2) does not confine the state of the art about products

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to knowledge of their chemical composition. It is the invention which must be new and which must therefore not be part of the state of the art. It is therefore part of the state of the art if the information which has been disclosed enables the public to know the product under a description sufficient to work the invention. Thus, in Merrell Dow, which centred on a claim to an acid metabolite formed in the liver after administration of terfenadine (itself the subject of an earlier patent), the acid metabolite was held to be anticipated not by prior use (see 2.29) but because it was the inevitable result of carrying out the directions in the earlier terfenadine patent.

- A claim is bad for want of novelty if information about anything falling within its scope has already been disclosed. Thus for example if a claim specifies alternatives, or defines the invention by reference to a range of values (eg of composition, temperature etc), then the invention is not new if one of these alternatives, or if a single example falling within this range, is already known. Thus a specific example is sufficient to destroy the novelty of a claim to the same thing defined generically; for example a disclosure of a metal coil spring anticipates a claim to resilient means. In some (particularly chemical) cases it may be possible to overcome an objection of lack of novelty by means of a disclaimer (see 14.126).
- 2.06 On the other hand, a generic disclosure does not impugn the novelty of a more specific claim, so that an earlier reference to a metal coil spring cannot be used to attack the novelty of a claim specifying such a spring made of copper. In some cases however the disclosure of a comparatively small and restricted field of possible alternatives might properly be held to be a disclosure of each and every member; for example, "fluid" may be taken to disclose both liquid and gas, if the context warrants it, and a reference to an electric motor may be regarded as disclosing the use of both series- and shunt-wound types. In *Norton Healthcare Ltd v Beecham Group Plc* (BL C/62/95) Jacob J held that a prior suggestion of a combination of sodium or potassium clavulanate with amoxycillin or ampicillin trihydrate (four possible combinations only) was a disclosure of each of the combinations. (But see 2.18-2.20).
- 2.06.1 In <u>Union Carbide Corp. v BP Chemicals Ltd [1998] RPC 1</u> Jacob J held that "the information given by a direction not to do X because it will have adverse consequences is not equivalent to a direction to do X because it has beneficial consequences or does not have the supposed adverse consequences" and so novelty will not be impugned by an earlier disclosure which in effect gives clear directions not to do that which is claimed in a later application. He commented that "invention can lie in finding out that that which those in the art thought ought not be done, ought to be done."
- 2.06.2 In the situation where a prior art document discloses a range which overlaps with a range claimed in the application in suit, the EPO's Technical Board of Appeal held that the prior art would be novelty destroying if the skilled person reading the prior art would "seriously contemplate" applying the teaching of the prior art in the area of the overlap (see T 26/85 and T 666/89). However, in Jushi Group Co. Ltd v OCV Intellectual Capital LLC [2018] EWCA Civ 1416, Floyd LJ held that the conventional approach as set out in SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent [2006] RPC 10 and Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd [2010] RPC 9 (see 2.19 below) should still be followed. The judge goes on to say that "...there may be circumstances where a prior disclosure of a numerical range...may carry with it an implicit disclosure that the skilled person may choose any value within the range. Whether that is so will depend of the disclosure of the document understood with the benefit of the common general knowledge. It is wrong, however, to elevate that possible conclusion into a rule of law, so that every numerical range must be so understood, whatever the context".
- 2.07 While it is generally necessary, for a finding of lack of novelty, for all the features of the claim under consideration to have been explicitly disclosed, the teaching implicit in a document may also be taken into account. If a person skilled in the art would conclude that an earlier invention would, as a matter of normal practice, necessarily be performed in a way which would fall within the scope of the claim under consideration, then the matter defined by the claim is not new. For example the disclosure of a control

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arrangement for the cooling system of an internal combustion engine might not refer to the presence of a radiator or other heat exchanger in the system, but it is common knowledge that there would necessarily be one and so its presence is implied. Floyd J confirmed in H.Lundbeck A/S v Norpharma SpA [2011] EWHC 907 (Pat), [2011] RPC 23 that prior disclosure includes implicit disclosures. On the other hand, he held that matter may be contained in a prior art document but so submerged in it as to not form a disclosure (i.e. if special knowledge is required for the matter to be understood, such that it would not be understood by a skilled person utilising their common general knowledge).

2.07.1 On the other hand, while it may be a common practice for there to be a radiator mounted in front of the engine, this is not necessarily the case and cannot be inferred; if the claim under consideration specifies a radiator so located and the cited document is silent on this point, the question is one of obviousness rather than lack of novelty. The *General Tire* judgment cited in paragraph 2.03 continues:

"If, on the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least as likely to be carried out in a way which would not do so, the patentee's claim will not have been anticipated, although it may fail on the ground of obviousness. To anticipate the patentee's claim the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented ... A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee".

2.07.2 In discussing this judgment in <u>SmithKline Beecham Plc's (Paroxetine Methanesulfonate)</u> Patent [2006] RPC 10, Lord Hoffmann added:

"But the infringement must not merely be a possible or even likely consequence of performing the invention disclosed by the prior disclosure; it must be necessarily entailed. If there is more than one possible consequence, one cannot say that performing the disclosed invention will infringe. The flag has not been planted on the patented invention, although a person performing the invention disclosed by the prior art may carry it there by accident or (if he is aware of the patented invention) by design. Indeed it may be obvious to do so."

Therefore, a disclosure which is capable of being carried out in a manner which falls within the claim, but is also capable of being carried out in a different manner, does not anticipate - although it may form the basis of an obviousness attack.

2.07.3 In this case, Lord Hoffmann summarised the disclosure requirement as follows: "anticipation requires prior disclosure of subject-matter which, when performed, must necessarily infringe the patented invention".

A prior disclosure must be construed as it would have been understood by the skilled person at the date of the disclosure and not in light of the subsequent patent (held by the House of Lords in <u>SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent [2006] RPC 10</u>). A prior disclosure should be read in light of the common general knowledge of the skilled person at the date of the disclosure. (This compares with the situation when determining obviousness, where the common general knowledge should be determined at the priority date of the invention (see paragraph 3.11)). See <u>Teva UK Limited & Anor v AstraZeneca AB [2014] EWHC 2873</u> (Pat).

2.08.1 Care should be taken when relying on dimensions derived from drawings. It was held by the EPO Board of Appeal in Decision T204/83 (OJEPO 10/85) that although features shown solely in a drawing form part of the state of the art when a skilled person could derive a technical teaching from them without further description, it is not generally possible to derive a technical teaching by measuring dimensions in a diagrammatic representation; and that dimensions under these circumstances do not therefore form part of the state of the art. In the particular case in suit, claims to a venturi of

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particular dimensional ratio were found to be novel in the face of a prior document which diagrammatically illustrated a corresponding ratio but without specific identification of the ratio in the description.

- 2.08.2 The Office practice in relation to anticipation by a document disclosing a chemical compound is to assume that the disclosure of the chemical compound is an enabling disclosure of that compound, ie a disclosure which is clear enough and complete enough for it to be performed by a person skilled in the art and thereby citable. The applicants against whose application it is cited can challenge that assumption by argument and/or evidence. If they do, the Office will decide, on the balance of probabilities, whether the disclosure is enabling or not.
- 2.08.3 The House of Lords in <u>Generics (UK) Limited and others v H Lundbeck A/S [2009] RPC 13</u> confirmed that the disclosure of a racemate does not amount to disclosure of each of its enantiomers. For further details please see <u>Examination Guidelines for Patent Applications Relating to Chemical Inventions.</u>
- In order to demonstrate lack of novelty the anticipatory disclosure must be entirely comprised within a single document. If more than one document is cited, each must stand on its own. The cumulative effect of the disclosures cannot be taken into consideration (Ammonia's Application, 49 RPC 409), nor may lack of novelty be established by forming a mosaic of elements taken from several documents (*British Ore Concentration Syndicate Ltd v Mineral Separation Ltd*, 26 RPC 124 at page 147; *Lowndes' Patent*, 45 RPC 48 at page 57); this may be done only when arguing obviousness. However if a cited document refers to a disclosure in another document in such a way as to indicate that this disclosure is intended to be included in that of the cited document, then the two may be read together as though they were a single document.

Enablement

(see also 14.62 to 14.105 and 72.03)

- 2.10 Enablement is the second requirement for anticipation as held in *SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent* [2006] RPC 10. The ordinary skilled person must be able to perform the invention which satisfies the requirement of disclosure. In this case, the House of Lords held that the test for enablement of a prior disclosure for the purpose of anticipation is the same as the test of enablement of the patent itself for the purpose of sufficiency (see 14.62 to 14.87). There may however be differences in the application of this test to the facts; for example, because in the case of sufficiency the skilled person is attempting to perform a claimed invention and has that goal in mind, whereas in the case of prior art the subject-matter may have disclosed the invention but not identified it as such.
- 2.10.1 In <u>SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent</u> [2006] RPC 10, Lord Hoffmann emphasised that the two requirements of disclosure and enablement should be kept distinct. In particular, the role of the person skilled in the art is different. In the case of disclosure, the skilled person is taken to be trying to understand what the author meant. Their common general knowledge forms the background in construing the disclosure, with the patent being construed on similar principles. Once this performed, to determine whether or not the disclosure would infringe, the person skilled in the art has no further part to play. On the other hand, for enablement, the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work, and the question is not what the skilled person would think the disclosure meant, but rather whether they would be able to work the disclosed invention.
- 2.10.2 The House of Lords also discussed the need for "enabling disclosure" in <u>Asahi Kasei Kogyo KK [1991] RPC 485</u>, where it was held the requirement for an enabling disclosure applied equally with regard to a disclosure forming part of the state of the art

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under s.2(3) as to s.2(2). Otherwise, it would be illogical for a disclosure which was inadequate for the purposes of s.2(2) to be adequate for those of s.2(3) merely because of a difference in dates bringing it into one field rather than the other. Lord Oliver of Aylmerton said that since s.14(3) requires that the specification discloses the invention in a way which will enable it to be performed by a person skilled in the art (ie it must contain an "enabling disclosure") it follows that a description in an earlier application which contains no enabling disclosure will not "support" the invention so as to enable it, as an invention, to claim priority from the date of that application under s.5(2)(a) (although the description will be entitled to a priority as "matter contained" in the application in suit under s.5(2)(b)). He could not construe s.2(3) as deeming to be part of the state of the art anything more than that matter which is entitled to priority under s.5. However, in considering whether to cite a document in the s.2(3) field, the examiner does not normally have ready access to the priority document and should assume that the disclosure of the potentially citable document is supported by the priority document and thus entitled to the priority claimed. The applicants against whom it is cited can challenge whether such support is present and whether it is enabling.

CONSTRUCTION OF CLAIMS

(See also 14.111-14.120 and 125)

- 2.11 In general a document will destroy the novelty of a later claim only if it discloses each and every feature specified in that claim. If the claim contains equivalent or additional features, then the question normally becomes one of obviousness. However since the protection conferred may go beyond the literal wording of the claim (see 14.114-14.115), it will on occasion be possible to argue that an earlier disclosure, while not falling within the precise literal words of the claim, nonetheless shows that the invention is not new, since any differences are confined to unessential features.
- A claim to an apparatus for a particular purpose (eg for carrying out the process of another claim) is normally construed as a claim to apparatus suitable for that purpose. The words do not restrict the claim to the apparatus when used in that way (*L'Air Liquide Societe's Application*, 49 RPC 428). Apparatus which otherwise possessed all of the features specified in the claims, but which would be unsuitable for the stated purpose, or which would require modification to enable it to be so used, should not normally be considered anticipating the claim. For example, if a claim refers to "A hook for a crane" this implies particular dimensions and strength in the hook. Therefore a fish-hook could never anticipate the claim, but a hook having the necessary dimensions and strength and possessing all the other features specified in the claim would deprive the claim of novelty whether it was stated to be for use in a crane or not.
- 2.12.1 In <u>Rovi Solutions Corporation & Anor v Virgin Media Ltd & Ors [2014] EWHC 1559 (Pat)</u> the computing hardware without relevant software was <u>not</u> considered "suitable for" the functions in question since a bare computer would not be able to achieve them (the functions in this instance related to displaying future or current TV programming information).
- 2.12.2 In Qualcomm Inc v Nokia Corp [2008] EWHC 329 (Pat) Floyd J considered the expression "suitable for" in the context of apparatus which might or might not require physical modification to make it "suitable for" the purposes of the patent. He gave the following example: whether connected to the mains or not an apparatus for toasting bread infringes a claim to such an apparatus. Supplying power to a toaster does not change the apparatus: it simply puts into use the apparatus which is there already. Modifications to the apparatus are not however contemplated by the phrase "suitable for". The question in each case is whether the apparatus, as it stands, is suitable for use in a particular way. If the apparatus has to undergo physical modification before it can be used, then it is not suitable for that particular use.
- 2.12.3 In <u>FH Brundle v Perry [2014] EWHC 475 (IPEC)</u> the judge considered the

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meaning of the phrase "adapted to" in the claims, and held that:

"I accept that as a matter of ordinary English usage, 'adapted' carries a connotation of adaption or modification in design to achieve the purpose stated in the feature. However in my view... these [features] are to be construed such that they contain no subjective element. To my mind it is irrelevant where the designer started and what adaptations were made in the design process. Because these features must be assessed objectively, it seems to me that 'adapted to' and 'adapted in use to' mean the same thing as 'suitable for'"

In light of this it is unlikely that amendment of a claim to include the term "adapted to" would be sufficient to overcome a novelty objection to an earlier version of the claim which used the term "suitable for". However, the judge cautioned:

"I do not say that in the context of other claims it will never be possible to discern a difference between 'suitable for' on the one hand and 'adapted to' or 'adapted in use to', or 'constructed to' for that matter, on the other. But I think in this claim the first three mean the same thing."

- 2.12.3.1 In <u>Schenck Rotec GmbH v Universal Balancing Limited [2012] EWHC 1920</u> the judge considered the meaning of a claim to a device which was "constructed to receive" a plurality of balancing weights. The judge rejected the suggestion that the phrase "constructed to receive" referred to the intention of the device designer (or anyone else), because he found there was **nothing in the specification** that would lead the skilled person to that conclusion. Instead he found, in the circumstances, that a skilled person would understand that the device was "constructed in such a way that it is capable of receiving" a plurality of balancing weights. That is, he found there had to be some physical construction of the device which achieves the claimed objective.
- 2.12.4 A claim is not limited to an apparatus per se if the design of the apparatus is essentially tied to its functionality with some other bit of apparatus. In <u>BSH Industries Ltd's Patents [1995] RPC 183</u> Aldous J did not accept that a claim for "An isolating matching device to enable a heating element of a motor vehicle electrically heatable window to be used as a receiving aerial," was limited to the device and did not include the heating element in the vehicle window. Noting that each type of heating element is likely to have a different impedance, he reasoned that it is not possible to ascertain whether any device takes the invention without considering it in association with a particular heating element in a particular window.
- 2.13 It is often necessary to look beyond the words of a claim and to consider what it seeks to monopolise and decide whether the wording used imparts a technical, as opposed to merely verbal, distinction. For example, the claim referred to in 2.12 would not be saved by directing it to "a crane-hook", since this is in practice no different in scope from "a hook for a crane". However in Hickman v Andrews, [1983] RPC 147 at pages 183-7, it was alleged that a claim to a workbench was anticipated by a bookbinder's press. The Court of Appeal found that the press had all the features which had been used to characterise the claimed workbench, which would therefore be anticipated if, as had been argued, the press could serve as a workbench. The Court however, having described a workbench as "a surface of sufficient area to enable one to carry out manual work upon it, said surface being supported at a convenient height, and sufficiently rigidly, having regard to the nature of the relevant work", concluded that the alleged anticipating press "is not a workbench. It is in our view far too small to be regarded as such, but on the contrary it is a vice to be used on a workbench".
- s.4A(3)

 2.14

 Likewise a claim to a material or composition for a particular purpose is regarded as a claim to the material or composition per se (*Adhesive Dry Mounting Co Ltd v Trapp and Co*, 27 RPC 341; *G.E.C's Application*, 60 RPC at page 3). A known product which is per se the same as the material or composition defined in the claim, but which is in

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a form which would render it unsuitable for the stated use, would not deprive the claim of novelty, but if the known product is in a form in which it is in fact suitable for the stated use, though it has never been described for that use, it would deprive the claim of novelty. In I. G. Farbenindustrie A.G.'s Patents, 47 RPC at page 322, it was stated that "no man can have a patent merely for ascertaining the properties of a known substance". There is however an exception to this general principle where the claim is to a known substance or composition for use in a surgical, therapeutic or diagnostic method (see 4A.17). In contrast to the above general principle, the Enlarged Board of Appeal of the EPO has held in Decisions G 2/88 and G 6/88 (both in OJEPO 4/90) that a claim to the use of a known compound for a particular purpose, which is based on a technical effect which is described in the patent, should be interpreted as including that technical effect as a functional technical feature, and is accordingly not open to an objection of lack of novelty provided that such technical feature has not previously been made available to the public. In G 2/88 (Mobil), the new technical effect was the discovery that the claimed compound previously used in lubricant compositions to inhibit rust had friction reducing properties. A claim to the use of that compound in a composition for reducing friction was held to be novel even though such friction reduction had inherently occurred in its previous use. Similarly, in G 6/88 (Bayer), use of certain compounds as a fungicide was held to be novel even though the method of use was identical to a known use of the compound as a plant growth regulator. On the other hand, in Robertet SA/Deodorant compositions [2000] OJEPO 1 (T 892/94) it was held that a claim to the use of a known substance for a known purpose could not derive novelty from the discovery of a previously unrecognised technical effect underlying that use. However, these EPO decisions should not be followed and the existing practice of the Office should continue pending clarification or guidance from the courts.

2.14.1 The Office's existing practice is supported by the decision of the Patents Court in <u>Tate & Lyle Technology v Roquette Frères [2010] FSR 1</u> (upheld at appeal; <u>Tate & Lyle Technology v Roquette Frères [2010] EWCA Civ 1049</u>). Although the case does not refer to G 2/88 *Mobil*, it appears to take a different approach from the Enlarged Board to use claims based on an unrecognised technical effect. The only claim in question here was to "the use of maltotriitol to modify or control the form of maltitol crystals". This was based on a previously unsuspected effect of an impurity (maltotriitol) on the crystallisation of the sweetener maltitol. This was held to lack novelty over a number of prior art documents which disclosed crystallisation of maltitol in the presence of maltotriitol at levels at which it would control crystal formation:

"The industry has been using maltotriitol to control or determine crystal habit without knowing it. What is left of the patent as granted is no more than a discovery as such."

Nevertheless, a claim to an apparatus or material "when used in" a particular process is construed as a claim confined to the use of the apparatus or material in such a process, and its novelty is therefore destroyed only by a disclosure referring to such (If the apparatus or material per se is known to be old, this fact should be acknowledged in the specification, in order to ensure that the nature of the invention is presented in its proper perspective). In considering so-called 'product-by-process' claims, Lord Hoffmann in Kirin-Amgen Inc v Hoechst Marion Roussel Ltd [2005] RPC 9 held that it was important that the United Kingdom should apply the same law as the EPO when deciding what counted as new for the purposes of the European Patent Convention. A claim to a product obtained by a process e.g. "Product X obtained by process Y" should therefore be construed as a claim to the product as such, irrespective of whether the term "obtained", "obtainable", "directly obtained" or an equivalent wording is used (see EPO Decision T 150/82 International Flavors and Fragrances Inc. [1984] 7 OJEPO 309). A "product-byprocess" claim is therefore not rendered novel merely by the fact it is produced by means of a new process. Furthermore, the House of Lords held that the protection conferred by a process claim should extend to products directly obtained by the process in accordance with EPC Article 64(2). "Product- by- process" claims can be difficult to identify, and may also give rise to a clarity objection (see 14.120.1).

2.16 Similarly a claim such as "the use of substance X as an insecticide" is regarded as equivalent to a "process" claim of the form "a process of killing insects using

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substance X" and is not interpreted as directed to the substance X recognisable (eg by further additives) as intended for use of an insecticide.

2.17 A claim for a method of using a known apparatus may be regarded as novel provided that the method of use is new. Parker J stated in *Flour Oxidizing Co Ltd v Carr and Co Ltd*, 25 RPC 428 at page 457, "But when the question is solely a question of prior publication, it is not, in my opinion, enough to prove that an apparatus described in an earlier specification could have been used to produce this or that result. It must also be shown that the specification contains clear and unmistakable directions so to use it".

SELECTION INVENTIONS

(See also 3.88 to 3.93)

A prior disclosure in general terms embracing a number of alternatives may amount to no more than a mere suggestion that any of the members, including any specifically exemplified, might be used, and may therefore be regarded as not anticipating a claim to a specific one of the members. An invention so claimed is generally referred to as a "selection" invention and should be evaluated as set out in 3.89. In <u>Union Carbide Corp v BP Chemicals Ltd [1998] RPC 1</u>, it was held that a prior disclosure of a range should normally be regarded as disclosing each and every part of that range. However, there might be room for an invention along the lines of a selection invention if there was something special about a later-claimed part of the range. For situations in which the application in suit specifies a range which overlaps with a range disclosed in prior art, see 2.06.2.

2.19 An invention is not anticipated by a document which merely points the way which might lead to it (*Du Pont de Nemours &c (Witsiepe's) Application*, [1982] FSR 303 – NB this case was decided under the 1949 Patents Act – cf also the words of the judgment quoted in 2.07.1).

The Court of Appeal in <u>Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd [2010] RPC 9</u> decisively rejected the argument that the mere disclosure of a generic formula or class of compounds discloses every possible compound falling within that class. A particular member of a class of substances is therefore not necessarily taken to be disclosed if the prior document disclosing the broad class merely indicates the inclusion of that particular member, whether by name, formula or starting materials, without any clear indication that the substance has actually been prepared, eg by describing its manufacture or particular properties.

In <u>Rhône-Poulenc/Ester Production</u> [1999] EPOR 443 (T427/86) a process wherein a specific pair of compounds were reacted in the presence of a catalyst to form a product was held to be novel over prior art which disclosed the use of reagents and catalyst selected from a list including those specified in the patent in suit. The particular examples in the prior art did not suggest the specified combination, which resulted in a reaction speed significantly greater than could be obtained by following the examples.

In the *Du Pont* case, a document describing a copolymer with a glycol of general formula HO(CH2)nOH, where n is between 2 and 10, was held not to anticipate a claim to the copolymer where the glycol formula was HO(CH2)4OH, since all the specific examples disclosed in the earlier document used ethylene glycol (n=2). In addition the claimed copolymer was found to have a rapid hardening rate, making it especially effective in injection moulding and high speed extrusion, a fact not previously known or contemplated in the earlier document, which was concerned with textile fibres having a good affinity for dyes. The earlier document thus merely indicated that the use of one preferred glycol would produce a compound with particular properties, suggesting at the same time that use of any one of the other eight glycols would produce the same result. Although the document stated that the C3, C4, C6 and C10 glycols were examples which would be used, there was no statement that any of these others had in fact been used, or that the product resulting therefrom had been found to have any particular advantages. It was therefore open to the applicant to select one of them and discover that the product had valuable properties in a

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different field. However had the combination been specifically disclosed in the earlier document, a discovery that it had some advantage or useful quality not previously recognised would not make it patentable (see also 2.14).

2.20 The size of the class from which a member or members have been chosen is not relevant to the question of novelty of a selection invention, although it may be relevant to the question of obviousness (Du Pont de Nemours & Co (Witsiepe's) Application, [1982] FSR 303 at page 310), (see also 2.06).

Section 2(2)

The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

- 2.21 The state of the art comprises everything made available to the public before the priority date, wherever in the world this may be, and in whatever manner or language the disclosure takes place (see also 3.37.1 for discussion of s.2(2) in relation to inventive step). There is no limit on the age of the disclosure. Matter may be disregarded only in the circumstances specified in s.2(4) (see 2.37-2.41).
- s.125(2)It should be borne in mind, when deciding whether or not matter forms part of the state of the art in respect of an invention, that it is the priority date of the invention which is relevant, and not the declared priority date of the application, which may be earlier. Moreover different claims, or different alternatives specified in a single claim, may have different priority dates. (For the practice to be followed during search and substantive examination, see 17.74 and 18.14-18.16).
 - 2.22.1 The date of a disclosure should be determined when viewed from the time zone of the office at which the priority document was filed (Unwired Planet International Ltd v Huawei Technologies Co Ltd & Ors [2015] EWHC 3366, upheld by the Court of Appeal in Unwired Planet International Ltd v Huawei Technologies Co Ltd & Ors [2017] EWCA Civ 266). This is of significance for disclosures which occurred on (or very close to) the priority date. For example, a disclosure which (in accordance with local time) has occurred before the priority date may actually have occurred on the priority date, once considered in the time zone of the office where the priority document was filed.
 - 2.23 In practice the bulk of the matter which needs to be considered consists of documents, such as patent specifications, textbooks or technical journals which have been published in the conventional sense of that term, for example by being on sale or available in libraries.
- s.130(1)Publication does not however depend on the degree of dissemination; s.118(1)communication to a single member of the public without inhibiting fetter is enough to amount to making available to the public (Bristol-Myers Co's Application, [1969] RPC 146). There is no need even to show that a member of the public has actually seen the document. Any document is regarded as having been published, and thus forms part of the state of the art, if it can be inspected as of right by the public, whether on payment of a fee or not; this includes for example the contents of the "open" part of the file of a UK patent application once the application has been published under s.16. And in Monsanto (Brignac's) Application, [1971] RPC 153, it was held that a company had published a document by supplying it to its salesmen, since it had been given to them with no restriction on disclosure; indeed it had been put into their hands with the intention that they should make the information available to the public.
 - 2.24.1 In T 1553/06 (Public availability of documents on the World Wide Web/PHILIPS) the EPO Board of Appeal considered whether a document stored on the

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World Wide Web but only accessible via a specific URL could be considered a disclosure which had been made available to public. The Board of Appeal set out the following test: if, before the filing or priority date of the patent or patent application, a document stored on the World Wide Web and accessible via a specific URL,

- i) could be found with the help of a public web search engine by using one or more keywords all related to the essence of the content of that document and
- ii) remained accessible at that URL for a period of time long enough for a member of the public, i.e. someone under no obligation to keep the content of the document secret, to have direct and unambiguous access to the document, then the document was made available to the public in the sense of Article 54(2) EPC.

However the Board held that failure to meet this test does not automatically mean that the document was not made available to the public, as the URL itself may have been made available. In exceptional circumstances the URL may be so straightforward or predictable that it could readily be guessed and would therefore be considered to publically disclose documents at that location. EPO Board of Appeal decisions are not binding upon the UK courts but are of great persuasive value. It therefore remains to be seen what approach the UK courts will take in light of this decision of the Board, given the longstanding approach to the interpretation of the phrase "made available to the public" as described in 2.24.

- 2.24.2 The EPO Board of Appeal in T 0002/09 (Public availability of an e-mail transmitted via the Internet/PHILIPS) considered whether sending an email over the internet could act as a public disclosure even if the recipient treated the contents of the email as confidential. Having considered whether and in what circumstances an email may be intercepted the Board concluded that the act of transmitting the email via the internet did not in itself make the email available to the public in the sense of Article 54(2) EPC.
- A date of publication which appears on or in connection with a document is presumed to be the date on which publication actually took place, and any allegation to the contrary must be established by evidence. In *Microsonics Corporation's Applications*, [1984] RPC 29, a cited US patent was granted before, but published after, the date of filing the application in suit. A notice in the US Official Gazette stated that the delay in printing did not affect the availability to the public of the files, which could be inspected from the date of grant. The applicant however alleged that there was a possibility that the files had not in fact been available to the public. It was held that, in view of the notice in the Gazette, the onus was on the applicant to rebut, on the balance of probabilities, the presumption that the file had been available, and that the evidence adduced (affidavits consisting largely of reports of conversations with staff of the US Patent Office) was mostly hearsay, but even if admissible was not enough to rebut this presumption.
- A document published too late to form part of the state of the art may reproduce or summarise disclosure which is alleged to have taken place before the priority date of the invention. For example the document may be a report of a lecture or a public exhibition. In such a case it should be assumed that the account given is correct both as to subject-matter and as to the date on which disclosure is reported to have taken place, unless reasonable ground for doubting either of these is put forward by the applicant, or there is other good reason for doubting them. Likewise any description of prior disclosure given in the specification in suit should be assumed, at least in the first instance, to be accurate (see 18.67).

PRIOR USE

(For the practice at substantive examination, see 18.24).

2.27 The only matter which becomes part of the state of the art as the result of the use of an invention is that which is thereby made available to the public. Prior secret use does not therefore invalidate a patent, although the user may have some protection against action for infringement [see s.64]. In Lux Traffic Controls Ltd v Pike Signals Ltd and

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Faronwise Ltd, [1993] RPC 107 Aldous J recognised that what was made available to the public often differed according to whether the public had an article in their possession to handle, measure and test or whether they could merely look at it. Depending on the circumstances a skilled person might be able to determine how an article was constructed and operated or nothing material might be disclosed. If an article or a material is unconditionally supplied to a member of the public, possibly as the result of just a single sale (T482/89 OJEPO 11/92), this is regarded as also making available any information which could be obtained by dismantling or analysing the article or material, even to destruction (G1/92 OJEPO 5/93). Novelty is destroyed by prior use of a product if analysis of the product using available techniques shows the skilled person that it falls within the scope of the claims; beyond that, it is not necessary for complete analysis to be possible (T952/92 OJEPO 11/1995). In Milliken Denmark AS v Walk Off Mats Ltd and Anr [1996] FSR 292 Jacob J held that the hiring of mats to customers who were free to inspect them amounted to anticipatory prior use even though the mats relied on perforations not visible to the naked eye for their function. While there was no reason to suppose that any customer should have conducted tests which would have revealed the perforations, a skilled person called on to investigate the mats would nonetheless have discovered them. The knowledge of the perforations would enable the skilled person to perform the invention. It was irrelevant that they would not know of its virtues. Moreover, if the process by which the article or material has been made can be deduced with certainty from such examination, that would also form part of the state of the art. Similarly, if for example a machine is displayed or operated where it can be seen by a member of the public, such as at an exhibition, on the highway, or in a part of a factory to which persons not bound to secrecy are admitted, then all information which a person skilled in the art might be able to glean is regarded as having been disclosed (see T84/83 1979-85 EPOR 796).

2.27.1 On the other hand, use of a battery in cars on the highway by employees who were well aware that the design was confidential did not amount to disclosure of the battery (*J Lucas (Batteries) Ltd v Gaedor Ltd*, [1978] RPC 297). The Patents Court in *Folding Attic Stairs Ltd v Loft Stairs Co. Ltd.* [2009] FSR 24 and the Hearing Officer in *Loadhog Ltd. v Polymer Logistics BV BL O/195/10* both considered whether a single instance of a viewing of a prototype (in a non-public location) by a small and defined group of visitors without any duty of confidentiality was novelty-destroying (for discussion of breaches in confidentiality see 2.38). In both cases it was decided on the balance of evidence that it was highly improbable that the visitors would or could have ascertained the features of the claimed invention. This was distinguished (in *Folding Attic Stairs Ltd v Loft Stairs Co. Ltd.*) from the display of an item in a public place, where anyone could have inspected it, which would lead to a presumption of disclosure regardless of whether there was any evidence of anyone actually inspecting the item.

2.28 In considering prior use in <u>Quantel Ltd v Spaceward Microsystems Ltd</u> [1990] RPC 83, Falconer J pointed out that the requirements under the 1977 Act are different from those of the 1949 Act as represented by the decision in Wheatley's Application [1985] RPC 91 in that "it now requires the prior use, to constitute anticipation, to have made available to the public an enabling disclosure of the invention". Even if the tests which could have been carried out on a product would have had an ambiguous result, in <u>PCME Ltd v Goyen Controls Co UK Ltd [1999] FSR 801</u> Laddie J held that the conclusion that "it is probably A but may be B" was a disclosure and even if it were not sufficiently precise to support anticipation it may well render a patent claim obvious.

2.29 In <u>Merrell Dow Pharmaceuticals Inc v N H Norton & Co Ltd [1996] RPC 76</u> (see also 2.04.2), where lack of novelty arose because a claim for an acid metabolite sought to monopolise the product as metabolised in the liver, Lord Hoffmann held that making matter available to the public requires the communication of information since an invention is a piece of information. He went on to hold that the use of a product makes an invention part of the state of the art only so far as that use makes available the necessary information. Thus acts, which are done without knowledge of the relevant facts but nevertheless would amount to infringement after the grant of the patent, will not count as anticipations before. In Merrell Dow the fact that volunteers in clinical trials had taken terfenadine and therefore had made the acid metabolite in their livers, was held not to

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constitute anticipation by use. The volunteers had been given terfenadine capsules for the sole purpose of swallowing them; they took them without knowing their composition and produced within themselves a substance, which was not then readily capable of being identified and was only later known to be the acid metabolite. This construction of s.2(2) is supported by *PLG Research Ltd v Ardon International Ltd* [1993] FSR 197, 225 in which Aldous J said:

"Under the 1977 Act, patents may be granted for an invention covering a product that has been put on the market provided the product does not provide an enabling disclosure of the invention claimed. In most cases, prior sale of the product will make available information as to its contents and its method of manufacture, but it is possible to imagine circumstances where that will not happen. In such cases a subsequent patent may be obtained and the only safeguard given to the public is section 64 of the Act."

Merrell Dow was distinguished in *Evans Medical Ltd's Patent* [1998] RPC 517 where a prior art vaccine had been made available to the public such that it would have been possible to analyse it to determine its contents. Actual prior identification of the process or product claimed was not in itself necessary to find a lack of novelty - merely instructions which, if followed, would inevitably result in the use of the claimed process or product (see also 2.07). This was confirmed in *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] RPC 2 where the Patents Court held that a dumb anticipation (i.e. one not explicitly stating the invention) would be effective if it conveyed sufficient information to enable it to be dumbly reproduced.

2.29.1 In cases of alleged prior use, the required standard of proof is the balance of probabilities. Within this standard, the Patents County Court in Kavanagh Balloons Pty Ltd v Cameron Balloons Ltd [2004] RPC 5 held that a flexible degree of probability should be applied to evidence relating to prior use. The cogency of the evidence had to match the occasion and be proportionate to the subject matter. Because of the nature of the monopoly itself and question of public interest, no stricter standard should be applied. It was held that it was not necessary for an opponent to prove their case "up to the hilt" as had been required by the EPO Technical Board of Appeal in Sekisui/shrinkable sheet [1998] OJEPO 161 (T 472/92). The hearing officer in Colley's Application [1999] RPC 97 also distinguished from Sekisui by not requiring proof "up to the hilt", but followed this decision and Demmeler Maschinenbau GmbH & Co KG (T 908/95) in holding that mere assertion of prior use was insufficient: place, time and detail were essential. In Memcor Australia Pty Ltd v Norit Membraan Technologie BV [2003] FSR 43, it was held that when the patentee is aware of the prior disclosure (e.g. if the alleged prior disclosure was by themselves) the patentee is expected to provide proportionally logical answers, positive and negative, to contradict the evidence that the opponent was able to establish with the disadvantage of having been privy to none of it.

Section 2(3)

The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say -

- (a) that matter was contained in the application for that other patent both as filed and as published; and
- (b) the priority date of that matter is earlier than that of the invention.

2.30 The only kind of document whose contents can form part of the state of the art by virtue of this subsection is an application for a patent, that is, either an application which is made under the Act or one which is treated as such. The field for s.2(3) therefore

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consists only of the following:-

- applications made under the Act and which have been published under (a) s.16;
- s.128(2)(b) patent specifications published under the 1949 Act;
- s.78(2), (3)applications for European patents (UK) which have been published by the (c) European Patent Office under a.93 EPC (see also (e) below).
- ss.89(1) international applications for patents (UK) which have been published by and 89B(2) WIPO under a.21 PCT and which have entered the national phase (that is, the national fee (if any) has been paid and, if the application is in a foreign language, an s.89(A)(3)(English translation has been filed at the Office; see 89A.06.1 and 89B.04); a)
- international applications for European patents (UK) which have been s.79(1)(e) published by WIPO under a.21 PCT and which have entered the regional phase s.79(2)(that is, the national fee has been paid and, if the application is in a language other than English, German or French, a translation into one of those languages has been filed at the European Patent Office).

[COPS can be used to determine whether an international application has entered the national phase. The European Patent Register can similarly be used to determine whether an international application has entered the regional phase (see 18.20).]

- Only the matter contained in the specification (that is, the description, s.14(7)drawings and claims) of an application of the kind referred to in 2.30 can form part of the state of the art by virtue of s.2(3). The abstract contained in such an application does not form part of the state of the art under this subsection, nor does a priority document filed in respect of such an application (although both of these, when published in any way including being made available to public inspection under s.118(1), can form part of the state of the art under s.2(2)).
- Subject-matter enters the s.2(3) field when the application containing it 2.32 has been published (and, in the case of an international application, it has also entered the (5A) national or regional phase - see 2.30). Once this has occurred, the status of the matter is not affected by the subsequent fate of the application; the matter remains part of the state of the art even if the application is subsequently withdrawn or otherwise terminated. However, if the application is withdrawn prior to publication, but too late to prevent publication (see 14.205, 16.02) then it is not regarded as forming part of the state of the art under s.2(3) (following the Patents Court decision in Woolard's Application [2002] RPC 39). A European application which is terminated without being published will not be treated as an application for a patent under the Act, and will thus not enter the s.2(3) field. However, once an application for a European patent (UK) has been published, it remains part of the state of the art by virtue of s.2(3) even if the application is later refused or withdrawn, as provided for by s.78(5A). Under the EPC all European patent applications filed on or after 13 December 2007 designate all Contracting States (including the UK) automatically at the date of filing. Every European patent application will therefore become a European patent (UK) application. Section 78(5A) further provides that removal of the UK designation before publication of the European patent (UK) application does not prevent the matter contained in the European patent (UK) application becoming part of the state of the art by virtue of section 2(3). Every European patent application which was filed after 13 December 2007 will therefore enter the state of the art by virtue of section 2(3) once it is published. For European patent applications filed prior to 13 December 2007, removal of the UK designation before publication will continue to prevent the matter contained in those applications from forming part of the state of the art by virtue of section 2(3).
 - 2.33 Only matter which was present both in the application as filed and as published forms part of the state of the art under s.2(3). If for example the published

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s.78(5),

application contains claims added subsequent to filing, then their subject-matter does not form part of the state of the art under s.2(3). (It is of course in the state of the art under s.2(2), even if the matter is subsequently deleted from the application during substantive examination).

- 2.34 It should be remembered that it is the priority dates of the matter in the earlier application and of the invention in suit which need to be compared, and not the declared priority dates of the respective applications. Moreover a claim to priority is not established until the requirements of r.6 have been complied with (see 5.04 to 5.13); in particular, even if the application has already been published, a claimed priority date which has subsequently been lost (for example through failure to file a translation in time) must be disregarded when deciding whether the application forms part of the state of the art under s.2(3). (For the practice to be followed at search and examination, see 17.74 and 18.14-18.16). With regard to the need for enabling disclosure, see 2.10.2.
- s.3 2.35 In order to decide whether or not an invention is new, matter which is in the state of the art under s.2(3) is considered in exactly the same way as matter in the s.2(2) field (see 2.02-2.20). This was confirmed by the Court of Appeal in SmithKline Beecham plc's Patent [2003] RPC 6. Matter which is in the state of the art under s.2(3) cannot however be used to argue obviousness (but see the remarks in 2.07-2.08 on implicit disclosure, and in 2.11 on purposive construction of claims).
- s.73(1) 2.36 The comptroller may on their own initiative revoke a patent which has been granted for an invention which, having regard to matter in the s.2(3) field, is not new (see 73.02-73.04).

Section 2(4)

For the purposes of this section the disclosure of matter constituting an invention shall be disregarded in the case of a patent or an application for a patent if occurring later than the beginning of the period of six months immediately preceding the date of filing the application for the patent and either -

- (a) the disclosure was due to, or made in consequence of, the matter having been obtained unlawfully or in breach of confidence by any person -
 - (i) from the inventor or from any other person to whom the matter was made available in confidence by the inventor or who obtained it from the inventor because he or the inventor believed that he was entitled to obtain it; or
 - (ii) from any other person to whom the matter was made available in confidence by any person mentioned in sub-paragraph (i) above or in this sub-paragraph or who obtained it from any person so mentioned because he or the person from whom he obtained it believed that he was entitled to obtain it;
- (b) the disclosure was made in breach of confidence by any person who obtained the matter in confidence from the inventor or from any other person to whom it was made available, or who obtained it, from the inventor; or
- (c) the disclosure was due to, or made in consequence of the inventor displaying the invention at an international exhibition and the applicant states, on filing the application, that the invention has been so displayed and also, within the prescribed period, files written evidence in support of the statement complying with any prescribed conditions.

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Section 2(5)

In this section references to the inventor include references to any proprietor of the invention for the time being.

2.37 If an applicant wishes an earlier disclosure to be regarded as not forming part of the state of the art, the onus is on them to make out a sufficient prima facie case (on the basis of an affidavit or other evidence if necessary) that one of the conditions specified in s.2(4) is satisfied. Moreover the disclosure can be disregarded only if it occurred after a date six months before the filing date (not the priority date) of the application; thus for example, while the protection of this subsection would apply to an application made within six months of display at an international exhibition, it would not apply to a subsequent application claiming priority from that application and filed more than six months after the display. For the purpose of s.2(3), s.2(4) provides for the disregarding of disclosure in patent applications published not only during the six months before the filing date but also on or after the filing date (but of earlier priority than the application in suit).

UNLAWFUL OBTAINING: BREACH OF CONFIDENCE

2.38 An allegation that an earlier disclosure was made as a result of unlawful obtaining or breach of confidence must be fully particularised, and the examiner should disregard the disclosure only if they are convinced by the applicant's submissions that, on the balance of probabilities, s.2(4) applies. It may be necessary to ask the applicant to clarify or substantiate their allegation, for example by filing evidence or a statutory declaration. If the applicant is either unable or unwilling to substantiate their allegation, they should be informed that the objection based on the earlier disclosure is still outstanding and a hearing should be offered. Any person desiring an actual determination of their entitlement may make a reference under section 8 or 37. An obligation of confidence may exist where there is no formal contract between the parties. Guidance as to what constitutes a breach of confidence was set out by Megarry J in Coco v A N Clark (Engineers) Ltd [1969] RPC 41 and was followed by the Hearing officer in Threeway Pressings Ltd's Application [2012] RPC 129 BL O/124/12. For a breach of confidence to have taken place the information must be of a confidential nature, the information must have been imparted in circumstances importing an obligation of confidence and there must be an unauthorised use or disclosure of information relating to the invention to the detriment of the inventor.

Any communication on this subject will be open to public inspection. If the applicant requests under r.53 that the communication be treated as confidential, they should be informed that such treatment would not be justified, having regard to the interests of third parties and that, unless the allegation is withdrawn within one month the communication will be placed on the open file; a hearing may be offered on this point.

INTERNATIONAL EXHIBITIONS

(For procedure, see 17.84, 18.23)

If an applicant wishes disclosure by, or in consequence of, display of the invention at an international exhibition to be regarded as not forming part of the state of the art they must, at the time of filing the application, inform the comptroller in writing of the display. They must also, within four months of the date of filing the application, file a certificate issued by the authority responsible for the international exhibition and a statement, duly authenticated by that authority, identifying the invention as being the invention displayed at the exhibition. The certificate must also state the opening date of the exhibition or if later, the date on which the invention was first displayed. For the requirements in the case of an international application for a patent (UK), see 89A.12.

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s.118(1)

r.5

r.67

s.130(1) s.130(2) r.5(6) Only an exhibition which falls within the terms of the 1928 Convention on International Exhibitions (as modified by the 1951 Protocol) is regarded as an international exhibition. Such an exhibition has to satisfy stringent conditions; for example, it must run for at least three weeks, and invitations to participate must be issued at government level through diplomatic channels. A statement published in the Patents Journal that an exhibition constitutes an international exhibition within the meaning of the Convention is conclusive evidence of that fact. Regularly held events and trade fairs organised by particular industries are unlikely to qualify.

[A list of exhibitions which have been designated as international exhibitions is available from the Bureau International des Exhibitions (www.bie-paris.org or telephone 0033 1 45 00 38 63). Upcoming qualifying international exhibitions are also published in the Official Journal of the EPO. See also 17.84.]

[Section 2(6) Repealed]

[Subsection 2(6) was concerned with the patentability of substances or compositions for use in methods of treatment or diagnosis. This is now provided for in section 4A(3)]

[2.42 - 2.52 moved to 4A.16 - 4A.26]

[2.53 - 2.56 moved to 4A.30 - 4A.33]

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Section 3: Inventive step

Note: This section of the Manual is presented as three sub-sections: General approach & legal background, Examining for inventive step, and Assessing obviousness. The third sub-section provides some of the more prominent methods for answering the final question in the Windsurfing/Pozzoli approach – ie "is it obvious?"

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s.130(7)

- 3.01 This section is concerned with the second of the tests for patentability set out in s.1(1). It is intended to have, as nearly as practicable, the same effect as the corresponding provisions of the EPC, PCT and CPC, ie Article 56 of the EPC.
- 3.02 The question of whether or not an invention is obvious is a matter which is normally decided on the technical facts of the particular case rather than on any general legal principles, but insofar as any such principles can be derived from decisions given under previous legislation they will generally continue to be relevant.

Section 3

An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above).

GENERAL APPROACH AND LEGAL BACKGROUND

3.03 What constitutes an inventive step may depend on the nature of the invention. The matter was considered by Lord Hoffmann in *Biogen Inc v Medeva plc* [1997] RPC 1 (at page 34) as follows:

"Whenever anything inventive is done for the first time it is the result of the addition of a new idea to the existing stock of knowledge. Sometimes, it is the idea of using established techniques to do something which no one had previously thought of doing. In that case the inventive idea will be doing the new thing. Sometimes it is finding a way of doing something which people had wanted to do but could not think how. The inventive idea would be the way of achieving the goal. In yet other cases, many people may have a general idea of how they might achieve a goal but not know how to solve a particular problem which stands in their way. If someone devises a way of solving the problem, his inventive step will be that solution, but not the goal itself or the general method of achieving it."

Obviousness must be decided on an objective test

EPC aa.52& 56

- The test for obviousness should, as far as is possible, be an objective one. The question is whether the invention would have been obvious to a skilled person in the art, and not whether it was or would have been obvious to the inventor or to some other particular worker. It is immaterial whether the invention was the result of independent work and research done without knowledge of the prior art (*Allmanna Svenska Elektriska AB v The Burntisland Shipbuilding Co Ltd*, 69 RPC 63 at page 70). Although evidence of what was in the inventor's mind may be admissible as evidence of the state of the art, it would seldom be otherwise admissible (*The Wellcome Foundation v VR Laboratories (Australia) Pty. Ltd*, [1982] RPC 343). The EPO Board of Appeal has held that the subjective achievement of the inventor is not relevant; the fact that an invention relating to steel refining came, not from the steel industry, but from an applicant who normally deals with other fields of technology is not evidence for the existence of an inventive step (Decisions T36/82, OJEPO 7/83).
- 3.05 In the judgment of the Court of Appeal in *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd*, [1985] RPC 59 (in considering whether claims relating to a sailboard were obvious) it was stated that:

"the question of whether the alleged invention was obvious has to be answered

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objectively by reference to whether, at the material time (that is, immediately prior to the priority date), the allegedly inventive step or concept would have been obvious to a skilled addressee" and that "what has to be determined is whether what is now claimed as inventive would have been obvious, not whether it would have appeared commercially worthwhile to exploit it".

- 3.06 In *Molnlycke AB v Procter & Gamble Ltd* [1994] RPC 49 the Court of Appeal recognised the usefulness of the analysis formulated in *Windsurfing* but did not consider that it assisted to ask whether the patent discloses something sufficiently inventive to deserve the grant of a monopoly. The criterion for deciding the issue of inventive step as laid down by statute was held to be a wholly objective qualitative and not quantitative test.
- 3.07 The Court of Appeal followed *Windsurfing* in *Hallen Co v Brabantia (UK) Ltd* [1991] RPC 195, observing that "obvious" in s.3 is not directed to whether an advance is "commercially obvious" and stating:

"We do not think that the hypothetical technician must also be taken as applying his mind to the commercial consequences which might follow if the step or process in question were found in practice to achieve or assist the objective which he had in view".

However the Court of Appeal has more recently appeared to retreat from this position, stating in *Dyson Appliances Ltd v Hoover Ltd* [2002] RPC 22 that:

"commercial realities cannot necessarily be divorced from the kinds of practical outcome which might occur to the skilled addressee as worthwhile"

and so it followed that a "commercial mindset will have played a part in setting the notional skilled addressee's mental horizon".

3.08 In *Petra Fischer's Application* [1997] RPC 899 it was held that a diesel cabriolet was obvious even though there may be commercial prejudice against the idea; Jacob J stated that:

"The patentee in her patent has told the skilled man nothing which he did not know before, to whit, that in the engine space of a basic production model he could put a diesel engine, if he wanted to. Whether it was worth doing that or not is another matter. Whether he thinks it will sell or not, that is another matter."

3.09 It is also unsound to fasten on the word "step" and to look at the steps which were actually taken by the inventor; this interpretation places too much weight on the choice of the particular word "step" whereas the word used in the French and German texts of the corresponding provisions of the European Patent Convention means "activity" (judgment of Court of Appeal in *Genentech Inc's Patent* [1989] RPC 147 at page 275). It is necessary to ask by what routes it would have been possible for the skilled person to proceed to the goal (ie the invention) from the starting point, considering how obstacles might be overcome or avoided on any such route, not only that followed by the inventor.

Structured approach needed when assessing obviousness

3.10 Anyone who is considering the question of whether or not an invention is obvious must beware of hindsight or *ex post facto* analysis. It can be very easy to be misled by a line of reasoning that involves working forward from the stated problem in a succession of easy steps when one knows the desired solution. In particular one must avoid looking at a prior publication under the influence of the patent or patent application in question, and one should attempt to place oneself in the shoes of the skilled person faced with the problem at hand. This is necessarily an artificial position, since the patent or patent application presents both the solution (the invention) as well as the problem (or instead of the problem, a pointer to the problem since, in some cases, one may be only able to infer this from the

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description of the invention).

The four-step Windsurfing approach

3.11 In Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd, [1985] RPC 59, the Court of Appeal held that the question of obviousness

"has to be answered, not by looking with the benefit of hindsight at what is known now and what was known at the priority date and asking whether the former flows naturally and obviously from the latter, but by hypothesizing what would have been obvious at the priority date to a person skilled in the art to which the patent in suit relates".

Thus the court formulated a four-step approach to assessing obviousness:

- (1) Identify the claimed inventive concept.
- Assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge of the art in question.
- (3) Identify what, if any, differences exist between the matter cited as being "known or used" and the alleged invention.
- (4) Decide, without any knowledge of the alleged invention, whether these differences constitute steps which would have been obvious to the skilled person or whether they require any degree of invention.

The Windsurfing/Pozzoli approach; a reformulation of the Windsurfing approach

- 3.12 In <u>Pozzoli SPA v BDMO SA [2007] EWCA Civ 588</u>, Jacob LJ restated and elaborated upon the <u>Windsurfing</u> approach. This decision of the Court of Appeal does not formally replace, supersede or supplant the <u>Windsurfing</u> approach. It is included here because it gives an insight to the Court's latest thinking on obviousness, and for its very useful discussion of the processes that should be adopted when one uses the <u>Windsurfing</u> approach. There is no suggestion that outcomes will be any different under the <u>Pozzoli</u> reformulation, it is a matter of style and clarity of approach and not substance. It follows that <u>Windsurfing</u> and <u>Pozzoli</u> taken together should now be seen as the precedent for deciding questions of obviousness.
- 3.13 At paragraph 23 of *Pozzoli*, Jacob LJ reformulated the *Windsurfing* approach as follows:
 - (1)(a) Identify the notional "person skilled in the art"
 - (1)(b) Identify the relevant common general knowledge of that person;
 - (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
 - (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
 - (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

The reasoning behind this reformulation is set out at paragraphs 15 & 16 of Pozzoli:

"First one must actually conduct the first two operations in the opposite order -

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mantle first, then concept. For it is only through the eyes of the skilled man that one properly understand what such a man would understand the patentee to have meant and thereby set about identifying the concept.

Next, that first step actually involves two steps, identification of the attributes of the notional "person skilled in the art" (the statutory term) and second identification of the common general knowledge ("cgk") of such a person."

Later, at paragraphs 21 & 22, Jacob LJ discusses the prior art and the third step in the *Windsurfing* approach:

"Identification of the concept is not the place where one takes into account the prior art. You are not at this point asking what was new. Of course the claim may identify that which was old (often by a pre-characterising clause) and what the patentee thinks is new (if there is characterising clause) but that does not matter at this point.

The third step also requires a little reformulation – *Windsurfing* was a case under the 1949 Act where the statutory words for the prior art were "known or used". The European Patent Convention uses the words "state of the art"."

3.13.1 In <u>Lalvani et al's Patent BLO/220/13</u> the hearing officer addressed the question of whether, following the decision in <u>Human Genome Sciences v Eli Lilly [2011] UKSC 51, [2012] RPC 6</u>, the Office should follow the problem-solution approach of the EPO when deciding questions of obviousness. The hearing officer decided that although decisions of the EPO Boards of Appeal are persuasive, the Office is bound to follow the reformulated *Windsurfing* approach set out by the Court of Appeal in *Pozzoli*.

What does this "4-step" approach do?

- 3.14 In *DSM NV's Patent* [2001] RPC 35, Neuberger J pointed out that the four-step *Windsurfing* approach ends up with the original issue to be resolved being embodied in the final question. Nevertheless it was held appropriate to apply this structured approach in order to ensure a reasoned, methodical and consistent analysis of obviousness,
 - "...not merely because it has been approved and applied in a number of previous cases, including in the Court of Appeal. It is also because it ensures that one does not go straight to the question of obviousness by reference to a general impression as to the evidence as a whole. By adopting the structured approach one ensures that there is a measure of discipline, reasoning and method in one's approach. Indeed, it helps to ensure that there is consistency of approach in different cases involving the issue of obviousness."
- 3.15 Thus the first three steps of the *Windsurfing/Pozzoli* approach are preliminary or preparatory steps to put one in the proper frame of mind to answer the question posed in the fourth step; and the final step of the *Windsurfing/Pozzoli* approach can be seen as a restatement of the statutory test for inventive step ie "is it obvious?"

Consequences of not using the Windsurfing/Pozzoli approach

3.16 The Court of Appeal in *Wheatley v Drillsafe Ltd* [2001] RPC 7, in overturning the decision of the Patents Court on obviousness, highlighted how a failure to use the structured Windsurfing approach to assessing obviousness had led the Patents Court to fall into the trap of using hindsight and to fail to distinguish what was known from what was common general knowledge.

Collocations

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3.17 Special consideration is needed when an invention may be to a combination or a collocation. In <u>SABAF SpA v MFI Furniture Centres Ltd [2005] RPC 10, Lord Hoffmann held that before you can ask whether the invention involves an inventive step, you first have to decide what the invention is. In particular, the first step is to decide whether you are dealing with one invention or, for the purposes of s.3, two or more inventions. If two integers interact upon each other, if there is synergy between them, they constitute a single invention having a combined effect and one applies s.3 to the idea of combining them. But if each integer performs its own proper function independently of any of the others, and the claim is a mere aggregation or juxtaposition of features, then each is, for the purposes of s.3, a separate invention. The combination of a series of known or obvious features, each playing its usual part in the final entity, will be a matter of design or mere collocation, not of invention, and objection should be raised under s.3 (for discussion of anticipatory disclosures in multiple documents see also 2.09).</u>

In this decision, Lord Hoffmann quoted with approval passages from the EPO Guidelines for Substantive Examination, providing guidance on how to determine whether two features display synergy. This guidance was re-stated and further explained in the EPO Technical Board of Appeal decision in T 1054/05:

"Two features interact synergistically if their functions are interrelated and lead to an additional effect that goes beyond the sum of the effects of each feature taken in isolation. It is not enough that the features solve the same technical problem or that their effects are of the same kind and add up to an increased but otherwise unchanged effect."

The individual steps of the Windsurfing/Pozzoli approach

- 3.18 What follows are some discussions of some of the steps within the *Windsurfing/Pozzoli* approach, and some of the factors that will influence one's thinking when using the *Windsurfing/Pozzoli* approach.
- 3.19 One may also wish to consider the discussions of these steps available in guides such as "Terrell on the Law of Patents" 16th (2016) Edition and the "CIPA Guide to the Patents Acts" (8th Edition). The locations of the relevant discussions in these guides are summarized in the table below.

Topic	Terrell	CIPA Guide
person skilled in the art	8.01, 12.73	3.07
common general knowledge	8.56, 12.54	3.11
identifying the inventive concept	12.74	3.18
identification of differences	12.80	3.25
difference involves an inventive step?	12.81	3.26

The skilled person

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- 3.20 The "person skilled in the art" is not a highly skilled expert or a Nobel prize winner, nor is he some form of lowest common denominator. Instead he is best seen as someone who is good at their job, a fully-competent worker. To a large degree the capacities of the skilled person will be determined by the nature of the common general knowledge identified as being "relevant". An important consequence of imparting to this person the relevant common general knowledge is that he will generally not be aware of individual patent specifications, scientific papers, or the like see the extract from *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* at 3.32 below.
- 3.21 He should be taken to be a person who has the skill to make routine workshop developments but not to exercise inventive ingenuity or think laterally as set out, for example, by Laddie J in *Pfizer Ltd's Patent* [2001] FSR 16 at paragraphs 62 and 63, and by the Court of Appeal in *Technip France SA's Patent* [2004] RPC 46, per Jacob LJ at paragraphs 6 to 10, who held that the person skilled in the art, if real, would be very boring a nerd.
- 3.22 His level of skill will, however, depend on the scope of the subject matter of the patent in question (see, for example, *Dyson Appliances Ltd v Hoover Ltd* [2001] RPC 26, upheld by the Court of Appeal [2002] RPC 22; see also 14.75).
- 3.23 He is assumed to be at least sufficiently interested to address his mind to the subject and to consider the practical application of the information which he is deemed to have (see *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd* [1985] RPC 59). While recognising this, the Court of Appeal in *PLG Research Ltd and anr. v Ardon International Ltd and others* [1995] RPC 287 held that knowing a piece of prior art is one thing but appreciating its significance to the solution to the problem in hand was another. Whitford J had similarly warned in *Sandoz Ltd (Frei's Application)* [1976] RPC 449 against too ready an assumption that the significance of existing published material in relation to the problem dealt with would necessarily be apparent to the hypothetical skilled person.
- 3.24 The skilled person should not be expected to try all combinations unless he has a problem in mind and particular combinations might assist him in solving it; he is not to be expected to take steps or try processes which he would not regard as worthwhile as a possible means of achieving or assisting in practice the objective which he has in view (see the judgment of the Court of Appeal in *Hallen Co v Brabantia (UK) Ltd* [1991] RPC 195, see also 3.07).
- 3.25 Although obviousness generally is assessed on the basis of technical rather than commercial considerations the Court of Appeal in *Dyson v Hoover* (see 3.07) appeared to indicate a softening of that approach, holding that commercial realities cannot always be divorced from the kinds of practical outcome which might appear worthwhile to the skilled addressee and that commercial considerations will play a part in the mindset of the skilled person.

The skilled person seeks expert advice, and can be considered a team

- 3.26 With a prospective solution in mind, the skilled person might need to seek advice from an expert in another field. In *Tetra Molectric Ltd v Japan Imports Ltd* ([1976] RPC 547) the Court of Appeal held that a claim to a smoker's lighter using piezoelectric ignition was obvious. Since the possibility of using piezoelectricity in a lighter would have occurred to the industry, a skilled lighter manufacturer, himself not an expert in piezoelectricity, could reasonably be expected to seek advice from those who were. If such experts had been consulted, they would have advised that the suggestion was definitely worth trying, and they could have solved such problems as arose. The person skilled in the art may, in such circumstances, be regarded as combining his own common general knowledge with expert advice from the other field.
- 3.27 Alternatively the hypothetical skilled person acting under expert advice can be

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seen as a team composed of skilled persons from each of the relevant fields, see *Genentech Inc's Patent* [1989] RPC 147 at pages 278 & 280 or *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] RPC 2 at paras 39 & 40. Where the skilled person is represented by a team of individuals each practicing their particular art, it makes no difference whether they work together as a single unit or as sub-contractors. The standard for skills is the same. In the example of the piezoelectric lighter above the team might be composed of a skilled person from the field of piezoelectricity and a skilled person from the field of lighter manufacture. (See also 3.44 & 3.83).

- 3.28 However, it cannot be assumed for the purpose of assessing inventive step that the "person skilled in the art" necessarily comprises a team made up of experts with all the different skills needed to perform the invention. In *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] RPC 33, the Court of Appeal considered the inventiveness of a method for oil exploration which utilised an electromagnetic surveying technique known as CSEM to determine whether a potential undersea reservoir actually contained oil or gas. CSEM was a known technique, but this application of it had not been contemplated. Jacob LJ held that the correct approach was to ask whether the exploration geophysicist would realise that there was a solvable problem and that CSEM might realistically be the solution. The problem also needed to be approached from the other side; would the CSEM expert be aware of the exploration geophysicist's problem and appreciate that CSEM was a potential solution?
 - "...if it would not be obvious to either of the notional persons or teams alone and not obvious to either sort of team to bring in the other, then the invention cannot fairly be said to be obvious."
- 3.28.1 Jacob LJ held that in such a case, the "person skilled in the art" for the assessment of inventiveness under s.3 (Art. 56 EPC) was not necessarily the same person or team as that used to assess sufficiency (see 14.75) or the scope of the claims. For the latter two purposes, this "person" would be a person or team with all the skills necessary to perform the invention in this case, an exploration geophysicist and a CSEM expert. This was not necessarily the case for inventiveness, if there was no reason for this team to be assembled without the benefit of hindsight.
- The question of whether a team with disparate skills would be assembled was also at issue in Mutoh Industry Ltd's Application ([1984] RPC 35). In this case, the hearing officer held that a drawing board employing magnetic bearings was obvious, since it was reasonable for the drawing-board man concerned with the problem of reducing friction to consult a bearings expert. The Patents Court however allowed an appeal, finding that users of the known device were not struggling to overcome a problem which inhibited their activities, nor were manufacturers failing to put the known device on the market because it was not sufficiently friction-free; there was therefore no reason for the manufacturer or user to look for outside assistance. In ABT Hardware Ltd's Application (BL O/36/87), the hearing officer distinguished the circumstances from those in Mutoh and held the invention to be obvious. It was concerned with the use in a letterplate of a known type of magnet comprising an elastomer loaded with ferrite powder to hold a flap in sealing engagement with a frame over an opening in the frame. There were specific problems associated with prior magnetic letterplates which could arguably have led the applicants to seek specialist advice, and the general availability and widespread use of the magnets in question might also reasonably be expected to have led the applicants naturally to consider their adoption in letterplates, with or without consultation of specialists.

Common general knowledge

3.29 One cannot overstate the importance of the notion of common general knowledge. It is central to everything that is required of the hypothetical skilled person, for example in reading and understanding the patent for the purposes of purposive construction, or in understanding and reacting to the cited prior art. Common general knowledge can, perhaps, be summarized as a part of the mental equipment or mental toolkit needed so as to be

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competent in the art concerned. It is what makes the skilled person skilled.

3.30 The courts have attempted to define the common general knowledge many times over the years. In *Raychem Corp's Patents* [1998] RPC 31 Laddie J explained common general knowledge as follows:

"The common general knowledge is the technical background of the notional man in the art against which the prior art must be considered. This is not limited to material he has memorized and has at the front of his mind. It includes all that material in the field he is working in which he knows exists, which he would refer to as a matter of course if he cannot remember it and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work or to help understand the pleaded prior art. This does not mean that everything on the shelf which is capable of being referred to without difficulty is common general knowledge nor does it mean that every word in a common text book is either. In the case of standard textbooks, it is likely that all or most of the main text will be common general knowledge. In many cases common general knowledge will include or be reflected in readily available trade literature which a man in the art would be expected to have at his elbow and regard as basic reliable information."

- 3.30.0 In <u>Teva UK Limited & Anor v AstraZeneca AB [2014] EWHC 2873 (Pat)</u> Sales J said that guidance on what constitutes common general knowledge (CGK) needs to be kept up to date in the age of the internet and digital databases of journal articles. He stated that searches of databases are part and parcel of the routine sharing of information in the scientific community and are an ordinary research technique, and further added that:
 - "...if there is sufficient basis ... in the background CGK relating to a particular issue to make it obvious to the ... skilled person that there is likely to be not merely a speculative possibility that there may be relevant published material bearing directly on that issue which would be identified by such a search, the relevant CGK will include material that would readily be identified by such a search."
- 3.30.1 A set of industry standards may be considered to be part of the common general knowledge, even if they are of such length and complexity that no skilled worker could possibly be expected to know even a fraction of the information contained therein, providing the skilled person would know where to find the information relevant to the task in hand (*Nokia v Ipcom* [2010] EWHC 3482; upheld at appeal [2011] EWCA Civ 6).
- 3.30.2 Unconventional knowledge can still be part of the common general knowledge. In *Apimed Medical Honey Ltd v Brightwake Ltd* [2011] EWPCC 2, [2011] RPC 16, the patent concerned surgical dressings for wounds comprising honey and a gelling agent. The court held that, at the priority date, there may have only been a few people working within the wound care field who would have seen a clinical future in treating wounds with honey, but that fact did not eliminate the idea from being a part of the common general knowledge.
- 3.30.3 In Generics (UK) Ltd (t/a Mylan) v Warner-Lambert Company LLC [2015] EWHC 2548 Arnold J held that matter being relied on as common general knowledge must be common general knowledge in the UK. He explained:

"The reason for this is that, whether one is concerned with the validity of a European Patent (UK), or a UK patent, one is concerned with a right in respect of the UK. It is true that the prior art may have been published anywhere in the world, but I do not think that alters the need for the skilled team to consider that art as if they were located in the UK. I do not think it matters that a fact was common general knowledge in (say) China, if it was not common general knowledge here. The position may be different if all the persons skilled in a particular art in the UK are acquainted with the position in China".

3.31 A much older definition comes from Fletcher-Moulton LJ in *British Ore Concentrate Syndicate Ltd v Minerals Separation Ltd* (1909) 26 RPC 124 (the reference to "public

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general knowledge" should be read as common general knowledge):

"[The court] has to arrive as closely as it can at the mental attitude of a well-instructed representative of the class to whom the Specification is addressed, and no more. In other words, in the performance of this part of its task it has to ask itself what ought fairly to be considered to be the state of knowledge in the trade or profession at the date of the patent with respect to the matters in question, and if any facts or documents are such that in ordinary probability they would not be known to competent members of such trade or profession they ought not to be taken, either for or against the public on the one hand, or the inventor on the other, as forming part of public general knowledge."

3.32 A much longer passage from the speech by Sachs LJ in *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457 is of particular interest because it sets out the relationship of patent specifications to the common general knowledge ("it is clear that individual patent specifications and their contents do not normally form part of the relevant common general knowledge"). It also sets out the relationship of scientific journals and papers to the common general knowledge ("it is not sufficient to prove common general knowledge that a particular disclosure is made in an article, or series of articles, in a scientific journal"). This passage is taken from pages 482-483 of the *General Tire* judgment:

"The common general knowledge imputed to such an addressee must, of course, be carefully distinguished from what in patent law is regarded as public knowledge. This distinction is well explained in *Halsbury's Laws of England*, Vol. 29, para. 63. As regards patent specifications it is the somewhat artificial (see per Lord Reid in the *Technograph* case [1971] FSR 188 at 193) concept of patent law that each and every specification, of the last 50 years, however unlikely to be looked at and in whatever language written, is part of the relevant public knowledge if it is resting anywhere in the shelves of the Patent Office. On the other hand, common general knowledge is a different concept derived from a commonsense approach to the practical question of what would in fact be known to an appropriately skilled addressee—the sort of man, good at his job, that could be found in real life.

The two classes of documents which call for consideration in relation to common general knowledge in the instant case were individual patent specifications and 'widely read publications'.

As to the former, it is clear that individual patent specifications and their contents do not normally form part of the relevant common general knowledge, though there may be specifications which are so well known amongst those versed in the art that upon evidence of that state of affairs they form part of such knowledge, and also there may occasionally be particular industries (such as that of colour photography) in which the evidence may show that all specifications form part of the relevant knowledge.

As regards scientific papers generally, it was said by Luxmoore J. in British Acoustic Films (53 RPC 221 at 250):

In my judgment it is not sufficient to prove common general knowledge that a particular disclosure is made in an article, or series of articles, in a scientific journal, no matter how wide the circulation of that journal may be, in the absence of any evidence that the disclosure is accepted generally by those who are engaged in the art to which the disclosure relates. A piece of particular knowledge as disclosed in a scientific paper does not become common general knowledge merely because it is widely read, and still less because it is widely circulated. Such a piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art; in other words, when it becomes part of their common stock of knowledge relating to the art.'

And a little later, distinguishing between what has been written and what has been

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used, he said:

'It is certainly difficult to appreciate how the use of something which has in fact never been used in a particular art can ever be held to be common general knowledge in the art.'

Those passages have often been quoted, and there has not been cited to us any case in which they have been criticised. We accept them as correctly stating in general the law on this point, though reserving for further consideration whether the words 'accepted without question' may not be putting the position rather high: for the purposes of this case we are disposed, without wishing to put forward any full definition, to substitute the words 'generally regarded as a good basis for further action'."

3.33 Over time the growth of proprietary and specialist knowledge, that is knowledge known only within certain organisations or companies or known only to a few experts, makes it increasingly difficult to distinguish the common general knowledge from the state of the art. Although a feature, item or concept may be well-known to a few, it is not part of the common general knowledge unless it can be shown to be known to and accepted by the large majority of those skilled in the art. In *Beloit v Valmet (No.2)* [1997] RPC 489 Aldous L.J. put it as follows:

"It has never been easy to differentiate between common general knowledge and that which is known by some. It has become particularly difficult with the modern ability to circulate and retrieve information. Employees of some companies, with the use of libraries and patent departments, will become aware of information soon after it is published in a whole variety of documents; whereas others, without such advantages, may never do so until that information is accepted generally and put into practice. The notional skilled addressee is the ordinary man who may not have the advantages that some employees of large companies may have. The information in a patent specification is addressed to such a man and must contain sufficient details for him to understand and apply the invention. It will only lack an inventive step if it is obvious to such a man.

It follows that evidence that a fact is known or even well-known to a witness does not establish that that fact forms part of the common general knowledge. Neither does it follow that it will form part of the common general knowledge if it is recorded in a document."

3.33.1 The Hearing Officer in *Maxluck Biotechnology's Application* BL O/130/10 highlighted (citing *Ratiopharm GmbH v Napp Pharmaceutical Holdings* [2009] RPC 11) the dangers of selectivity in deciding what is common general knowledge in the field:

"However, when deciding what is common general knowledge, one cannot just take those parts of it that support (or rebut) the objection that is being made. To do so opens oneself up to an accusation of ex post facto selection. The notional skilled person comes armed with all the common general knowledge and cannot pick and choose selectively with the benefit of hindsight. Some aspects of the common general knowledge may lead the skilled person from the prior art towards the inventive concept; but equally other aspects of common general knowledge may lead him away from the inventive concept."

3.33.2 The Patents Court in *KCI Licensing Inc & Ors v Smith & Nephew Plc & Ors* [2010] EWHC 1487 identified a further class of information, which, although not part of the common general knowledge, may nevertheless be taken into account in determining obviousness. In a passage endorsed by the Court of Appeal ([2010] EWCA Civ 1260), Arnold J observed that:

"...even if information is neither disclosed by a specific item of prior art nor common general knowledge, it may nevertheless be taken into account as part of a case of obviousness if it is proved that the skilled person faced with the problem to which the patent is addressed would acquire that information as a matter of

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routine. For example, if the problem is how to formulate a particular pharmaceutical substance for administration to patients, then it may be shown that the skilled formulator would as a matter of routine start by ascertaining certain physical and chemical properties of that substance (e.g. its aqueous solubility) from the literature or by routine testing. If so, it is legitimate to take that information into account when assessing the obviousness of a particular formulation. But that is because it is obvious for the skilled person to obtain the information, not because it is common general knowledge."

Identifying the inventive concept

- 3.34 Applying Windsurfing International v Tabur Marine and Molnlycke v Procter & Gamble Jacob J observed in Unilever PLC v Chefaro Proprietaries Ltd [1994] RPC 567 at page 580 that it is the inventive concept of the claim in question which must be considered, not some generalised concept to be derived from the specification as a whole. Different claims can, and generally will, have different inventive concepts. The first stage in identifying the inventive concept of a claim is likely to involve a purposive construction of the claim (see 125.14) what does it mean to the skilled person? However merely doing that can be too wooden because one does not distinguish between portions which matter and portions which, although limiting the ambit of the claim, do not. It is the essence of the claim that should be identified when considering the inventive concept. Finding that essence will involve constructing something akin to a précis, stripping out unnecessary verbiage from the purposively construed claim.
- 3.34.1 In <u>Generics (UK) Limited and others v H Lundbeck A/S [2009]</u> UKHL 12, [2009] RPC 13, Lord Walker explained that there is a difference between the "inventive concept" of a claimed invention and its "technical contribution to the art". He stated at paragraph 30:

"Inventive concept" is concerned with the identification of the core (or kernel, or essence) of the invention—the idea or principle, of more or less general application (see *Kirin-Amgen* [2005] RPC 169 paras 112-113) which entitles the inventor's achievement to be called inventive. The invention's technical contribution to the art is concerned with the evaluation of its inventive concept—how far forward has it carried the state of the art? The inventive concept and the technical contribution may command equal respect but that will not always be the case.

This case related to a straightforward product claim. The House of Lords held that the novel and non-obvious product claimed formed the technical contribution to the art, whilst the process of how it had been made formed the inventive concept (see also Examination Guidelines for Patent Applications Relating to Chemical Inventions).

- 3.34.2 Although the inventive concept can in certain respects be broader than the claim (because immaterial features of the claim may be ignored), it cannot be narrower than the claim. In <u>Datacard Corp. v Eagle Technologies Ltd. [2011] EWHC 244 (Pat), [2011] RPC 17</u>, Arnold J held that the inventive concept cannot be defined in terms which apply only to a narrow sub-group of embodiments with certain technical advantages, and which do not apply to the rest of the claim. If the patentee has chosen to claim the invention broadly, the inventive concept must be of at least equivalent breadth.
- 3.35 In <u>Raychem Corp.'s Patents [1998] RPC 31</u> (upheld on appeal [1999] RPC 497) the practice of drafting claims in an unnecessarily complicated way was criticised. It was pointed out that a properly drafted claim will state the inventive concept concisely, but it was held that where the claims were prolix and opaque the court should break free of the language and concern itself with what they really meant.

The state of the art

3.36 The state of the art for the purposes of deciding whether an invention is obvious is defined by s.2(2); that is, it includes everything which has been made available to the public,

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anywhere in the world, before the priority date of the invention (see further 2.21-2.29). Matter which forms part of the state of the art by virtue of s.2(3) is specifically excluded from consideration.

3.37 [moved to 3.75.1]

Consideration of the prior art: age of documents and other criteria

3.37.1 Any disclosure falling within the s.2(2) field may be used as the starting-point for an inventive step objection. The objection cannot be overcome by an argument that the skilled person would simply not have discovered a document in the course of his work, if that document has been made public anywhere in the world, in any language, at any time before the priority date. (However, as discussed at 3.40-3.42, this does not necessarily apply when considering whether the skilled person would have considered a **further** document together with the first document, as then the likelihood of the skilled person considering the two documents together must be assessed.) For example, in *Wake Forest University Health Sciences & Ors v Smith & Nephew Plc & Anor* [2009] EWCA Civ 848, the prior art in question was a Russian language research paper ("Bagautdinov") which had been shown to have been made available in four libraries in the former Soviet Union. Jacob LJ noted that it was highly unlikely that the inventor or anyone involved in the litigation knew of its existence at the priority date of the claimed invention. However, he observed (emphasis added) that "Mr Alexander [the patentee's representative] accepts, **as he must**, that the skilled person will have read Bagautdinov and have done so carefully but with no imagination". This general principle was set out by Laddie J in *Pfizer Ltd's Patent* [2001] FSR 16:

"A real worker in the field may never look at a piece of prior art for example he may never look at the contents of a particular public library or he may be put off because it is in a language he does not know. But the notional addressee is taken to have done so. This is a reflection of part of the policy underlying the law of obviousness. Anything which is obvious over what is available to the public cannot subsequently be the subject of valid patent protection even if, in practice, few would have bothered looking through the prior art or would have found the particular items relied on."

- 3.37.2 However, this does not mean that all prior art will be accorded equal weight or significance; any piece of prior art must be viewed through the eyes of the skilled person at the priority date, and the common general knowledge in the field may cause him to disregard it. For example, in *Actavis v Merck* [2008] RPC 26, the Court of Appeal considered whether the use of a drug to treat alopecia was obvious over a prior art document which disclosed the use of the same drug, to treat the same condition, at a different dosage. It was held that, at the time the document was published, the claimed invention would have been obvious from this disclosure. However, by the priority date, the accepted wisdom in the field would suggest that this drug would be ineffective at any dosage. Jacob LJ therefore highlighted the importance of assessing inventiveness at the priority date, and not before or after:
 - "...one might assume that when an invention becomes obvious it must remain so thereafter. But such an assumption would be wrong: obviousness must be determined as of a particular date. There is at least one other well-known example showing how an invention which might be held obvious on one date, would not be so held at a later date. That is where there has been commercial success following a long-felt want. Time can indeed change one's perspective. The perspective the court must bring to bear is that of the skilled man at the priority date and not any earlier time."
- 3.38 An old specification which teaches specifically the solution of the problem which an invention seeks to overcome so that the skilled person should readily appreciate its significance can form a good basis for an obviousness objection (*Jamesigns* (*Leeds*) *Limited's Application* [1983] RPC 68). A further example of a circumstance in which a lack of inventive step objection based on an old document could be sustained is a case where the

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modification of the older invention could not have been effected before recent technological advances had been made, such as the development of a new material. Documents which have resulted in practical application or which are acknowledged as well known are also likely to have greater force.

3.39 Be wary of uncritical ageism in relation to the prior art. In *Brugger and others v Medic-Aid Ltd* ([1996] RPC 635) Laddie J held (at 653 and 655) that:

"The fact that a document is old does not, per se, mean that it cannot be a basis for an obviousness attack. On the contrary, if a development of established and ageing art is or would be obvious to the skilled worker employed by a hungry new employer, it cannot be the subject of valid patent protection even if those who have been in the trade for some time, through complacency or for other reasons, have not taken that step. Each pleaded piece of prior art must therefore be assessed as if it was being considered afresh at the priority date. It is not to be excluded from this exercise merely because it is old. There is no rule of commerce that every new product or process must be developed and put on the market or published in literature as soon as it becomes obvious."

and

"It is only when the answer to the question "why was this not developed earlier" is "a likely and reasonable explanation is that people looking for a way round an existing problem did not see this as the answer" that the age of the prior art should play a part in meeting an obviousness attack. If it is likely that in the real world no one was looking for an answer the fact that none was found says nothing about whether the answer proposed in the patent under attack was obvious."

3.39.1 In *Merck Sharp & Dohme Corp v Teva UK Ltd* [2011] EWCA Civ 382 the argument was made that a document published only six days before the priority date was not relevant for inventiveness, as it would not have been possible to perform the steps leading from the prior art to the claimed invention in the period between the publication of the prior art and the priority date. This argument was decisively rejected by the Court of Appeal; all that needs to be decided is whether the claimed invention is obvious over the prior art, not whether there would in fact be time to arrive at the invention by the priority date.

See also 3.78-3.79, 3.80-3.81.2 and 3.97-3.101.

Combining documents, "mosaicing"

3.40 While it is not possible to combine the disclosure of a given document with other matter to demonstrate lack of novelty (see 2.09), it is permitted to combine any of the prior art (whether published documents, instances of prior use or common knowledge) in order to argue that an inventive step is lacking. However, although a single disclosure, however remote, of the whole invention will destroy novelty, in order to establish that a combination of teachings from the prior art shows an invention to be obvious, it must be likely that the skilled person would have considered those teachings together. Laddie J in *Pfizer Ltd's Patent* [2001] FSR 16 at paragraph 66 stated:

"When any piece of prior art is considered for the purposes of an obviousness attack, the question asked is "what would the skilled addressee think and do on the basis of the disclosure?" He will consider the disclosure in the light of the common general knowledge and it may be that in some cases he will also think it obvious to supplement the disclosure by consulting other readily accessible publicly available information. This will be particularly likely where the pleaded prior art encourages him to do so because it expressly cross-refers to other material. However, I do not think it is limited to cases where there is an express cross-reference. For example if a piece of prior art directs the skilled worker to use a member of a class of ingredients for a particular purpose and it would be obvious to him where and how to find details of members of that class, then he will do so and that act of pulling in

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other information is itself an obvious consequence of the disclosure in the prior art.".

- 3.41 There is no simple rule as to whether information from different documents, or from different parts of a single document, can properly be combined as a "mosaic" to provide a case that an invention is obvious. The greater the number of documents which must be so combined to reach the invention, the more likely on the whole that there is an inventive step, but regard must be paid to the nature of the features which are combined. The combination of a series of known features, each playing its usual part in the final entity, is often simply a matter of design or mere collocation, and not of invention (see 3.17).
- 3.42 In *Dow Chemical Company (Mildner's Patent)*, [1973] RPC 804, Whitford J indicated that in order to establish obviousness from a combination of documents it is necessary to consider the extent to which you can conclude that the documents are ones which the seeker after information would come across and would consider together. Two extremes that are sometimes put forward are (a) that no two documents may be combined to make a mosaic unless at least one is well known, and (b) that all the information in any set of documents can be combined provided they are all in the same art. Neither of these extremes is acceptable as a general principle. Although the second extreme may be the more likely to reflect the true situation it should not be used as a pretext for not investigating beyond the immediate field of the invention (see 3.26-3.27).

Factors to consider before combining documents

- 3.43 In deciding whether or not it is obvious to combine the disclosure in two or more documents, the following considerations are likely to be relevant:-
 - (a) How the nature and the contents of the documents influence whether the person skilled in the art would combine them. For example where the disclosed features seem at first sight to have an inherent incompatibility or where one document has a tendency to lead from the mosaic, this would be a pointer towards the combinations being inventive (see 3.91).
 - (b) Whether the documents came from the same technical field or from neighbouring or remote technical fields (see 3.26-3.28.2 and 3.44).
 - (c) The presence of references in one document to another.
 - (d) The amount of selection required to isolate the separate disclosures from the surrounding documentary material.
 - (e) Whether the contents of one document are so well known that the skilled person would always have them in mind in reading other documents (see 3.45).
 - (f) The age of the documents (see 3.37.2-3.39.1).
- 3.44 Where the documents are from different technical fields the question is whether the problem would have prompted search in those fields. In *Dow Chemical Company (Mildner's) Patent* [1973] RPC 804, an invention residing in an electrical cable in which a plastics jacket was securely bonded to a metal shield using a specified copolymer was held to be obvious in the light of one document disclosing all the features of the cable but not mentioning the adhesive copolymer, and other documents disclosing the copolymer. Although these latter documents did not refer to cable manufacture, they did refer to the copolymer as having high moisture resistance and being suitable for bonding plastics to metal, both essential properties in adhesives for use in cables. It was therefore reasonable to expect the skilled person concerned with the problem of adhering plastics to metal in cables to have found and considered these documents. The Technical Board of Appeal of the EPO has considered it reasonable to expect a person skilled in the art, unable to fulfil a need in the relevant field, to look for suitable parallels in a neighbouring field so closely

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related that he would take developments therein into account, or in the broader general field in which the same or similar problems extensively arise and of which he must be expected to be aware (Decision T 176/84, OJEPO 2/86).

Combining documents with common general knowledge

3.45 If the invention can be produced by combining the teaching of one document with common general knowledge or with standard practice in the art, then even if the inventor has not conceived it nor the applicant presented it in such terms, there is a strong presumption that such a combination would be obvious to the skilled person. If, in his application, the applicant refers to prior art as "conventional", this may be taken to indicate that the prior art is common general knowledge (*NEC Corporation's Application* (BL O/038/00)).

EXAMINING FOR INVENTIVE STEP

A warning against overelaborating the question of obviousness

- 3.46 When considering an inventive step objection the examiner should always bear in mind this warning from Jacob LJ in *Angiotech Pharmaceuticals v Conor Medsystems Inc* [2007] EWCA Civ 5:
 - "...one can overelaborate a discussion of the concept of "obviousness" so that it becomes metaphysical or endowed with unwritten and unwarranted doctrines, subdoctrines or even sub-sub-doctrines. In the end the question is simply "was the invention obvious?""

A reminder to consider obviousness whenever a novelty objection is overcome

3.47 The examiner should always consider the obviousness of a claim when a novelty objection in respect of that claim has been overcome.

Determining obviousness

3.48 The determination as to whether an invention is obvious or not is of considerable importance both to applicants and the public, and the substantive examiner must be prepared to put considerable effort into this task. It is particularly important that the examiner correctly identifies the relevant common general knowledge that is to be imparted to the skilled person. In conferring on the substantive examiner power to consider inventive step, s.18(2) implies that the examiner is required to exercise an expertise, and that he must be recognised as qualified to do so. This view has been reinforced by Pumfrey J in *Degussa-Huls AG v The Comptroller-General of Patents* [2005] RPC 29:

"Examiners are appointed because of their general technical skills. They will, in the classes which they examine, acquire extensive knowledge and they will be able to form a clear view of the qualities which are to be expected of the person skilled in the art in that particular field."

3.49 The nature of the expertise implied depends on the matter to be determined and on the circumstances of the application. For example the substantive examiner is not in most cases in a position to deny simply from his own knowledge facts (such as whether a given technique is well-known, or whether a given reaction has specified by-products) to which evidence has been brought forward from a witness -possibly the applicant himself - who can claim relevant expert knowledge. In such circumstances the examiner is likely to have to accept the evidence from the applicant unless he can produce documentary

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evidence of contrary effect. Nevertheless, the substantive examiner must be taken to be qualified to decide, given the prior art and other relevant technical facts, whether the resulting position implies the presence or absence of an inventive step.

The Windsurfing/Pozzoli approach

- 3.50 From the discussions at the beginning of this Section it is clear that the examiner must use the *Windsurfing/Pozzoli* approach when deciding whether or not to object and, if objecting, setting out that objection. Before raising a lack of inventive step objection a substantive examiner should be clear in his own mind as to what point in the prior art he is starting from and the nature and number of steps it would take for a person skilled in the art to get from the starting point to the invention.
- 3.51 The examiner need not spend an undue amount of time in debating the precise nature of the skilled person, whether that person is a designer, a technician, a manufacturer, etc. As indicated in 3.20 the character of this person is largely set by the relevant common general knowledge imparted to them, rather than their position in any organizational chart.
- 3.51.1 In *Eli Lilly & Co. v Human Genome Sciences, Inc.* [2008] EWHC 1903 (Pat), [2008] RPC 29, which related to a patent for a polynucleotide sequence encoding a Neutrokine- α polypeptide, Kitchin J. applied the *Windsurfing/Pozzoli* test and reached the conclusion that the claimed invention was not obvious from the prior art. However, he nevertheless held that the claims lacked an inventive step on the grounds that the patent made no technical contribution to the art and did not solve a technical problem. Kitchin J. held that this should be determined by considering whether the invention lies in making the products of the claim or rather whether the invention must lie in a disclosure that the DNA products of the claim code for useful proteins and, if so, whether the specification does no more than speculate as to what those uses might be. Any deficiency in this regard cannot be remedied by evidence coming into existence after the application has been filed. However, this objection appears to be specific to certain types of biotechnology patents, wherein the inventiveness of a nucleic acid or protein lies in the identification of its function rather than in its production per se.

Consider different starting points

- 3.52 A matter which requires invention when tackled from one starting point may be commonplace when started from a different disclosure or with a different known problem in mind. The applicant may for example have presented his invention as a combination of features A, B, C, D which he admits are known in combination, with a further feature E which it would undoubtedly be inventive to add to the acknowledged combination. It may be however that a prior document discloses the combination of features A and E, and that the addition of the remaining features B, C, D is then obvious.
- 3.53 The starting point of the invention from the point of view of the applicant may be apparent from the specification. For example, the description may contain an account of the prior art and/or the problem to be solved, or the main claim may be in the two-part form, in which a preamble specifying a set of features known in combination in the prior art is followed by a characterising portion setting out the new features. The applicant is however not obliged to do this, nor does a reader of the specification have to accept the applicant's assessment of the invention.

No rules of thumb; precedents to be treated with caution

3.54 The decision to raise an objection of lack of inventive step must be made on a proper consideration of the facts of the particular case and any kind of rule of thumb approach should be avoided. Caution should be exercised in relying on precedent cases, since, more than with any other topic to be decided by the substantive examiner, attempts to

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line up a particular case with some decided case can mislead.

Raise any sound objection

- 3.55 The substantive examiner should not raise an objection when he has no good reason to suppose that there is no invention just to fish for a weakness in the applicant's position. As in any other area of examination it is thoroughly bad practice for an examiner to raise an objection which, with thought, he would see was not justified, merely to pass the burden of thinking about the matter to the applicant.
- 3.56 However, even if he thinks he can foresee how the applicant will amend or argue to overcome the objection, the examiner should raise any sound obviousness objection. The applicant may amend in any way he thinks fit; there is no guarantee that the applicant will act as the examiner has predicted.
- 3.57 A substantive examiner faced with a prima facie case of obviousness which might be capable of rebuttal by special information of a sort which is not available to the examiner, but which must be available to the applicant, should always put the objection to the applicant. An example of such information is whether the applicant's process avoids a drawback which experts in the art would expect it to have, or whether the applicant is merely prepared to tolerate the drawbacks, so that he has not made any inventive contribution. If the applicant fails to make a satisfactory answer to such an objection the examiner can safely assume that this is because the facts are against the applicant (see 3.64).

Mosaics

- 3.58 In practice the guidance above on combining or "mosaicing" documents can be difficult to satisfy (see 3.40–3.44). In particular the examiner must explain why he believes that the skilled person would make that combination of documents.
- 3.59 The examiner must always keep sight of what use he is making of the cited documents. Oftentimes the examiner is not making a true combination in the sense of using a combination of two or more documents to arrive at a solution to a particular problem. Instead the examiner will find that he is using some of those documents to illustrate the common general knowledge, acknowledged prior art or some other point as in 3.62. In these circumstances the examiner may find the combination easier to justify.

Content of the report

- In addition to citing documents the first examination report should state a prima facie case, not going into overmuch detail. This *prima facie* case does not have to explicitly mention *Windsurfing* or *Pozzoli*, but it should leave the applicant in no doubt that the *Windsurfing/Pozzoli* approach has been adopted. The aim should be to oblige the applicant to state what he considers the inventive step to be and to justify his assertion. This first report should, so far as is practicable, set out explicitly any assumptions of a technical character which have been made. Where it seems unlikely that the applicant will challenge these assumptions, support for the assumptions need not be sought unless and until the applicant challenges them (but see 3.62).
- 3.61 Subsequent reports responding to the applicant's amendments and/or arguments should be more detailed, explicitly setting out the examiner's reasoning for each of the *Windsurfing* steps.
- 3.62 When matter considered to be well-known in the art is used in formulating an obviousness objection, it need not be supported by document references unless and until it is challenged. However it is probably best that all document references that the examiner will be using are put before the applicant at the earliest opportunity. When documents are cited

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as examples illustrating common general knowledge or background art, for example, where the contention is that the invention claimed comprises an obvious modification to known apparatus and documents are cited, one showing the modification per se and one or more others exemplifying the apparatus, this should be made clear at the outset. Documents should be included in the initial citations where necessary to substantiate background art considered to fall short of well-known. It should be made clear whether documents cited are being relied on individually or in combination and/or in conjunction with common knowledge.

Reporting both novelty and inventive step objections

3.63 In putting to the applicant objections of lack of novelty and inventive step the substantive examiner should make clear which claims are attacked on each of these grounds. Where the examiner attacks the main claims but defers consideration of the inventiveness of subordinate claims he should make this clear to the applicant (see 18.43). In attacking subordinate claims, where it is not clear what response the applicant is likely to make to the objections to the main claims, it is sufficient to indicate the general nature of an objection to lack of inventive step leaving any elaboration until this is made necessary by the applicant's response.

Responding to the applicant's case

3.64 An objection should not be withdrawn merely because an argued response has been submitted - the argument must be adequate to overcome the objection. In *Degussa-Huls AG v The Comptroller-General of Patents* [2005] RPC 29, in dismissing an appeal against the Hearing Officer's finding of obviousness, Pumfrey J held that:

"when a case of prima facie obviousness or anticipation is made out ... the evidential burden shifts on to the applicant to produce evidence upon which the Examiner can properly act in saying either that there is insufficient material before him to say that the objection of obviousness is in fact made out or possibly even to say that the objection of obviousness must, on the material available to him, fail ...

- ... Where an Examiner forms a view upon what, at first sight, are sound grounds for supposing there is a strong case of obviousness, then it is up to the applicant to put convincing material in front of the Examiner upon which, as I have said, he can act contrary to what was to him the apparent position".
- 3.65 In that case, evidence that the invention had unforeseeable advantages which were unrelated to the reasons for the initial finding of obviousness did not overcome this finding. Evidence from the applicant, or from a witness provided by the applicant, to the effect that the situation does imply an inventive step (as distinct from evidence on a point of fact), must therefore be regarded solely as argument which the examiner accepts or rejects of his own judgment, supplemented of course by whatever advice he decides to seek from his colleagues.
- 3.66 A technical assertion on behalf of the applicant which is unsupported by published material should be in the form of sworn evidence unless the substantive examiner can confirm independently that it is correct. It should be clear who is making the assertion and what their status is. A statement attributed to a third party, whether identified or not, is hearsay evidence see 123.18. If the assertion runs counter to what is published, this fact should be commented on and justified. Any evidence should preferably be filed before the matter is brought to a hearing since if it is not then it is unlikely to be allowed to be filed in support of an appeal (see 101.20).

Standard of certainty, benefit of the doubt

3.67 When a prima facie objection of lack of inventive step is contested the examiner

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will determine the matter on the balance of the evidence available, the standard of certainty being the same pre-grant as post-grant, ie it is determined on the balance of probabilities.

- 3.68 An objection of obviousness should not be pursued if there is a genuine possibility that there is an inventive step. The possibility must however be real and it is far from sufficient in rebuttal of an objection that there is merely a case to be answered, or that the applicant asserts that there is doubt. The matter should be decided on the balance of the evidence available.
- 3.69 If the substantive examiner is unable to reach a conclusion on inventive step because of lack of technical knowledge which he cannot readily rectify and there seems a strong *prima facie* case that the invention is obvious, it is reasonable for the examiner to put a specific query to the applicant or to object that there is no inventive step and see what reply the applicant makes. If expert evidence would be required for him to judge whether the applicant's reply to an objection establishes that there is invention, only then must the applicant be given the benefit of the doubt. This is consistent with the test applied in *Blacklight Power Inc. v The Comptroller-General of Patents* [2009] RPC 6 (see 4.02 for a case where there was substantial doubt on a question of the scientific validity of the basis of an invention. In this case, the judge held that the examiner should consider whether the evidence provided by the applicant gives rise to a reasonable prospect that, if the issue were to be fully investigated at trial with the benefit of expert evidence, it would be resolved in the applicant's favour.

Other matters

- The question of whether a claim involves an inventive step does not normally arise if the claim lacks novelty. It would be illogical to say that there is no step but that the step is non-inventive. In particular the same prior art should not be formally cited against the same claims under s.1(1)(a) and (b) simultaneously. However, in appropriate cases an objection that an invention is not new may be followed by a "fall-back" objection that if the claim were shown to be novel then it involves no inventive step. Thus the substantive examiner should investigate whether there is invention in a claim which he has objected to as lacking novelty where the novelty objection depends, for example, on a verbal coincidence or a matter of interpretation or construction and does not strike at the basic inventive concept. When a document is relevant to a lack of novelty objection against certain claims and also to an obviousness objection against other claims at the same action, it should be cited in respect of both objections. As a general rule, and subject to the above considerations, the first report under s.18(3) should refer (by formal citation or otherwise) to all the prior art documents considered to be relevant to novelty and/or inventive step (although if the documents referred to are only examples of many, that fact should be stated without listing all of the many).
- 3.71 The substantive examiner may also object that the claim is not clear but that so far as the claim can be understood it appears that the invention is not new, and/or does not involve an inventive step. If there is no substantial novelty objection some indication of the *prima facie* case for the lack of inventive step against the assumed invention should normally be given.

[RC5 should be used.]

ASSESSING OBVIOUSNESS

3.72 The question is, does the invention make available to the person skilled in the art something that he would not reach by normal exercise of his skill? If so, the inventor has made a contribution to the art which provides the consideration justifying the grant of a patent. The contribution must be of a technical nature. This is not to say that it must be technically complex; simplicity does not count against an invention and may indeed point to

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its being non-obvious. There may be invention in appreciating commercial features, for example in realising that there is a market for a new product. The Court of Appeal has provided competing views on this, see *Hallen Co v Brabantia (UK) Ltd* [1991] RPC 195 and *Dyson Appliances Ltd v Hoover Ltd* [2002] RPC 22 at 3.07.

Deciding the fourth Windsurfing/Pozzoli step

- 3.73 Many different approaches to deciding the fourth *Windsurfing/Pozzoli* step, the substantive assessment of inventive step, have been put forward over the years. What follows are discussions of some of the more prominent suggestions. The approach taken at this stage will depend upon the particular circumstances of the case under consideration.
- 3.74 One may also wish to consider the discussions of these and other approaches available within guides such as "Terrell on the Law of Patents" 18th (2016) Edition and the "CIPA Guide to the Patents Acts" (8th Edition). The locations of the relevant discussions in these guides are summarized in the table below.

Topic	Terrell	CIPA Guide
simplicity no objection	12.150	3.26
Avoidance of hindsight	12.145	3.40
technical not commercial obviousness	12.18	3.33
obvious to try	12.126, 12.142	3.30
long-felt want; commercial success	7.77, 81	3.32, 3.33
right to work		3.26
lying in the road		3.26
"would" not "could"	12.91	3.12
if obvious, why was it not done before?		3.34
selection	12.41, 12.188	3.31
overcoming a technical prejudice	12.55-62, 12.174-179	3.17

The Haberman questions

3.75 A number of issues should be considered in determining whether a development is obvious or not. In *Haberman v Jackal* [1999] FSR 685 (at 699 to 701), Laddie J considered the following non-exhaustive list of relevant questions some of which may not be answerable before grant or without evidence:

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- (a) What was the problem which the patented development addressed?
- (b) How long had that problem existed?
- (c) How significant was the problem seen to be?
- (d) How widely known was the problem and how many were likely to be seeking a solution?
- (e) What prior art would have been likely to be known to all or most of those who would have been expected to be involved in finding a solution?
- (f) What other solutions were put forward in the period leading up to the publication of the patentee's development?
- (g) To what extent were there factors which would have held back the exploitation of the solution even if it was technically obvious?
- (h) How well had the patentee's development been received?
- (i) To what extent could it be shown that the whole or much of the commercial success was due to the technical merits of the development?
- 3.75.1 In determining whether an invention is obvious in the light of a given document combined with common general knowledge, other documents, or instances of prior use, there are two major considerations: (i) whether the skilled person could reasonably be expected to find the document in conducting a diligent search for material relevant to the problem in hand (see 3.26 & 3.44) and (ii) whether, if he had found the document, he would have given it serious consideration. So far as (ii) is concerned, relevant factors may be the age of the document (see 3.37.2-3.39.1) and whether, if it is one of a large number, there was any reason why the skilled person should have selected it (see 3.88). Passages which lead away from the applicant's invention must be taken into account as well as those that lead towards it. It is relevant in looking at a prior document to consider whether the matter of interest to the obviousness question constitutes a principal feature of the prior document or whether it is mentioned merely as a detail in the performance of an entirely different concept, without any recommendation to the reader which would encourage him to use it in different circumstances.

Right to work

3.76 Just as an invention will lack novelty if the claim to it would re-monopolise something already disclosed (the so-called "post-infringement test" - see 2.03), likewise it will be regarded as obvious if a claim to it would inhibit the rights of a skilled workman to carry out routine modifications of what is already in the public domain. Just as the notion behind anticipation is that it would be wrong to enable the patentee to prevent a man from doing what he has lawfully done before the patent was granted, that behind obviousness is that it would be wrong to prevent a man from doing something which is merely an obvious extension of what he has been doing or of what was known in the art before the priority date of the patent granted (judgment of Court of Appeal in *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd*, [1985] RPC 59 at page 77).

Lying in the road

3.77 In *Philips (Bosgra's) Application*, [1974] RPC 241 the applicants proposed to amend a claim (which had been held obvious) to a method of producing a vaccine in order to specify the use of certain emulsifying agents. The hearing officer held that the amended claim was not obvious since, although these emulsifying agents were well known, it was not certain that a notional research group would be directly led as a matter of course to try these particular agents. On appeal however, Whitford J ruled that this was not the correct

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question; although the skilled person would not necessarily be led directly to try these materials, they were obvious in the sense that they were lying in the road (ob via) for the worker to use, and it was wrong that he should be stopped by a monopoly from doing so. Moreover, just as it has been established that to impugn novelty, prior enabling disclosure is required, so a claim to a product will only be obvious if not only the idea of the product is obvious but also a way of producing the product is obvious (*Boehringer Mannheim GmbH v Genzyme Ltd* [1993] FSR 716).

Why was it not done before? (see also 3.37.2-3.39.1, 3.80-3.81.2 and 3.97-3.101)

- 3.78 The fact that no-one has followed a particular path before does not of course dispose of an obviousness objection, otherwise any invention which was new would automatically be inventive. However the reasons why this has not been done before may well be important. If the inventor has solved a long-standing problem by using in a conventional way materials or techniques which have only recently become available, then this is not inventive.
- 3.79 Nor is it inventive to respond to a change in economic circumstances; for example if a product has not been made from a particular material or by a particular process for reason of cost, and the material or process becomes cheaper or the market value of the product increases, it is not inventive to take advantage of this. And if a newly-arisen problem is solved by the use of available resources in an obvious way, then there is no inventive step (unless the inventor has been the first to identify the problem). But if the inventor has solved a long-recognised problem by means which others could have used but did not, then there may be an inventive step (*Minnesota Mining and Manufacturing Co v Rennicks (UK) Ltd* [1992] RPC 331). In *Chiron Corpn v Organon Teknika Ltd* [1994] FSR 202 a claim to a polypeptide comprising an antigenic determinant of the hepatitis C virus was found to be non-obvious because despite the attempts of numerous research groups over a 10 year period to identify the agent responsible for Non-A, Non-B Hepatitis (latterly named Hepatitis C), the patentees succeeded in a unique fashion by adopting a known technique which would not have been obvious to try in the circumstances.

Fulfilling a need (see also 3.37.2-3.39, 3.78-3.79 and 3.97-3.101)

- 3.80 Evidence that an invention fulfils a long-felt want and has been commercially successful may be taken into account in assessing obviousness (see for example *Hickman v Andrews*, [1983] RPC 147 and *PLG Research Ltd v Ardon International Ltd*, [1993] FSR 197). Aldous J held in *Optical Coating Laboratory Inc. v Pilkington P.E. Ltd.* [1995] RPC 145 at page 166 that while it is always important to consider why a possibly inventive step had not been suggested before, without evidence of a long-felt want or unsuccessful attempts to solve a particular problem, any evidence as to novelty, years of delay in developing the prior art and an advantage stemming from the invention carries no weight.
- 3.81 Moreover the commercial success of the invention may be attributable to factors achieved independently of the invention, such as the quality or price of the product, or to superior marketing. In *Haberman v Jackal* (see 3.75) the development was a small and simple change to a "trainer cup" to make it leakproof. The new product achieved large success despite small advertising budgets and "unconsidered aesthetics" in its original version. The materials for the design had long been readily available and the advantages were immediately apparent once it was thought of. In this context, the commercial success was held to demonstrate that the invention itself fulfilled a significant long-felt want and that if the development had been obvious it would have been found by others earlier. Similarly, in *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] RPC 33, the Court of Appeal considered the evidence from published material at the time of the invention and held that:

"The plain fact is that there was no real explanation of why the idea was not taken up well before the date of the Patent. The simplest explanation – indeed the only one that fits the known facts – is that the inventors hit upon something which

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others had missed."

- 3.81.1 In <u>Tetra Molectric Ltd v Japan Imports Ltd</u>, [1976] RPC 547 on the other hand, it was held that the commercial success of a cigarette lighter was due in large part to hammer mechanisms developed since the date of the invention; although claim 1 covered lighters which had enjoyed commercial success, it also covered lighters which could never do so, and no features which might ensure success were recited.
- 3.81.2 <u>In Dr Reddy's Laboratories (UK) Ltd v Eli Lilly and Co Ltd [2008] EWHC 2345 (Pat),</u> [2009] FSR 5, the Patents Court pointed out at paragraph 187 that arguments based on commercial success of products the subject of anterior patent protection are more or less doomed to failure because the existence of that patent (application) provides a clear explanation of why no third party ever launched the product. The earlier cases of <u>Cipla Ltd v Glaxo Group Ltd [2004] EWHC 477</u>, RPC 43 (at [115]) and <u>Generics (UK) Ltd v H Lundbeck A/S [2007] EWHC 1040, [2007] RPC 32 (at [251]) were referred to.</u>

Advantages of the invention

3.82 Where a variation from published matter proposed by the applicant has no advantages, or is even disadvantageous, although it can be argued that the resulting inferior procedure is not obvious in the sense that no skilled person would regard it as obvious to do something inferior, the application should nevertheless, if the variation is one whose possibility a skilled person would appreciate, be refused on the ground that there is no inventive step. Such a view was taken by the Technical Board of Appeal of the EPO in Decision T119/82, OJEPO 5/84, see particularly paragraph 16. The position is of course different if the applicant has discovered that a variation thought to be disadvantageous is in fact not so, or if from a large number of variants which would have been regarded as no more than feasible alternatives with no advantages, the applicant has selected a variant with an unexpected advantage (see also 3.88-3.93).

Obvious to try

- 3.83 In Johns-Manville Corporations Patent, [1967] RPC 479 it was held that where a skilled worker in a particular field could be expected to know of a use of material to achieve a certain result in that field, an invention which is concerned with the use of that material to achieve the same result in a part of that field which had not been previously disclosed is obvious if a person versed in the art would assess the likelihood of success sufficient to warrant a trial. In more recent cases the courts have however departed somewhat from this view (see 3.87.2). The invention was concerned with the use of particular flocculating agents in asbestos cement manufacturing. It was held that, filtration processes being common to many industries, two cited documents, although addressed primarily to the mining and paper industries respectively, were likely to be read by those concerned with the asbestos cement industry, and that such readers would have realised that here was a newly-introduced flocculating agent which it was well worth trying out in their filtration process.
- 3.84 In *Brugger and others v Medic-Aid Ltd* [1996] RPC 635 Laddie J held that if a particular route is an obvious one to try, it is not rendered any less obvious from a technical point of view merely because there are a number, and perhaps a large number, of other obvious routes as well. Similarly in *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, Jacob J held that an effect which was revealed by following the obvious course of action did not make the action non-obvious.
- 3.85 [Deleted]
- 3.86 The Court of Appeal in Saint-Gobain PAM SA v Fusion Provida Ltd and Electrosteel Castings Ltd [2005] EWCA Civ 177, [2005] IP & T 880 held that the mere possible inclusion of something within a research programme on the basis you will find out more and something might turn up is not enough to show obviousness. If it were otherwise there would be few inventions that were patentable. The cited prior art pointed to the possibility that using a Zn/Al alloy as a coating for a cast iron pipe to be buried in soil might

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be beneficial by showing results for this alloy coating for buried steel plates. It was not however possible for the skilled person to predict success, so the invention was not obvious. Jacob LJ held that "the 'obvious to try' test really only works where it is more-or-less self-evident that what is being tested ought to work".

3.87 An invention can therefore only be said to be "obvious to try" if there is a reasonable expectation of success (see also 3.99). In *Angiotech Pharmaceuticals Inc's Patent (Application for Revocation by Conor Medsystems Inc)* [2006] RPC 28, the Patents Court held that the contribution to the art made by the specification had to be assessed in order to decide whether it was sufficient to show that something was an obvious candidate for testing without any expectation of success, or whether it was necessary to show that the skilled person must have had an expectation of success sufficient to induce him to use it in practice. This decision was upheld by the Court of Appeal ([2007] RPC 20) but was later overturned in the House of Lords (*Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] RPC 28) where this distinction was rejected. Lord Hoffmann stated

"...there is in my opinion no reason as a matter of principle why, if a specification passes the threshold test of disclosing enough to make the invention plausible, the question of obviousness should be subject to a different test according to the amount of evidence which the patentee presents to justify a conclusion that his patent will work."

In this case, the patent specification disclosed that taxol could be incorporated on a stent (a tubular device which acts as scaffolding to hold a diseased artery open). The prior art disclosed a very similar stent with a large range of drugs which could be incorporated on the stent to prevent restenosis. While taxol was not specifically mentioned, a range of classes, which could include taxol, were listed as possible candidates. The lower courts considered that the specification gave no suggestion that taxol would be safe or prevent restenosis (closure of the lumen of the artery caused by proliferation of smooth muscle cells) i.e. there was no disclosure that taxol would be a better candidate than any other possible candidate. Consequently a claim to a taxol-coated stent was held by the lower courts to be invalid as it was concluded to be obvious to a skilled person that taxol should be incorporated onto a stent with a view to seeing if it prevents restenosis and is safe. The House of Lords, however, held that there was evidence provided in the specification as filed that taxol was a particularly effective anti-angiogenic agent, and the invention was based on the principle that inhibition of angiogenesis could be used to prevent restenosis. The issue to be decided was therefore whether it was obvious to use a taxol-coated stent to prevent restenosis, not whether taxol was an obvious candidate for further investigation. Lord Hoffman held that the claim was not obvious and confirmed that the notion of something being obvious to try was useful only in a case where there was a fair expectation of success. How much of an expectation would be needed would depend upon the particular facts of the case. While the House of Lords accepted that the absence of any evidence to support a speculative claim could lead to an objection of lack of support or insufficiency (quoting the decision in Prendergast's Applications), they held that this requirement should not be confused with the requirement for inventiveness.

3.87.1 The main issue to be decided in <u>Omnipharm Limited v Merial [2011] EWHC 3393 (Pat)</u> related to a claim to a "spot on" formulation for the treatment of fleas in pets, the closest prior art being a "spray on" formulation of the same active ingredient. Floyd J held that since "spot on" formulations have advantages in terms of ease of application it would be obvious to try to develop a spot on formulation; however in this particular situation the skilled team was considered to have no common general knowledge basis on which to make a prediction as to whether a "spot on" formulation would work. Therefore the skilled person would not have had sufficient expectation of success to render the invention obvious.

3.87.2 In Novartis AG v Generics (UK) Ltd (trading as Mylan) [2012] EWCA Civ 1623, it was held that it is important to have regard to "all the circumstances of the case including, where appropriate, whether it was obvious to try a particular route with a reasonable or fair expectation of success. What is a reasonable or fair expectation of success will again depend upon all the circumstances and will vary from case to case". Kitchin LJ went on to

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hold that "it may be appropriate to consider whether it is more or less self-evident that what is being tested ought to work" and "simply including something in a research project in the hope that something might turn up is unlikely to be enough. But I reject the submission that the court can only make a finding of obviousness where it is manifest that a test ought to work. That would be to impose a straightjacket upon the assessment of obviousness which is not warranted by the statutory test and would, for example, preclude a finding of obviousness in a case where the results of an entirely routine test are unpredictable". In Actavis Group PTC EHF v ICOS Corporation & Ors [2017] EWCA Civ 1671, it was held that a dosage of 5mg of tadalafil was obvious over prior art which stated 50mg of tadalafil was possible. The court held that a skilled team would try different doses of the drug, in a routine clinical trial, and would reach a dosage of 5mg. The judge noted that "there are some steps which can be characterised as so routine that the skilled person would carry them out simply because they are routine, and irrespective of any prospect of success. An example is routine dose ranging studies in the clinical testing of a known drug". The court went on to say that they have "been at pains to warn against the over-elaboration of the "obvious to try" line of cases. While there are a number of factors which, depending on the circumstances, may bear on the question it is not always necessary for all of them to be ticked off as if on a checklist". Also see Gedeon Richter v Bayer Schering [2011] EWHC 583 (Pat).

Selection

(See also 2.18-2.20)

3.88 Although there is no inventive step if it is clear from the prior art that taking that step is likely to lead to success, there may be invention if that is only one of many courses possible, and there is no reason to infer from the prior art that this one is more likely than the others to be profitable. In *Bayer AG (Baatz's) European Application* [1982] RPC 321, carbonless copying paper was characterised by microcapsules made of a particular polymer, which was already known for forming coatings on textiles, leather, wool and metal. Even if these were thought to be neighbouring fields, there was no reason to expect that improved results would be obtained by the use of this material (as the results of comparative experiments showed they were), and thus it was not obvious to select it from the enormous number possible. And in *Olin Mathieson Chemical Corporation v Biorex Laboratories Ltd*, [1970] RPC 157 at page 192, it was held not to be obvious that a useful drug would be obtained by substituting -CF₃ for -Cl in a known drug, given the large amount of prior material, leading in a number of different directions, which was before the skilled person at the date of the invention.

3.89 When faced with claims that may relate to a selection invention the *prima facie* inventive step objection should be raised using the *Windsurfing/Pozzoli* approach, unless the selection is so clear-cut as to make this unnecessary. If the applicant/agent maintains (or it is clear from the specification) that the inventiveness may lie in a selection invention, then the approach used by the Court of Appeal in *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* [2010] RPC 9 should be followed. In such cases, the question to be asked is whether the invention makes a hitherto unknown technical contribution or is merely an arbitrary selection. If it is merely an arbitrary selection then the invention is obvious. In *Generics [UK] LTD (t/a Mylan) v Yeda Research and Development co. LTD & Anor* [2013] EWCA Civ 925 the Court of Appeal considered the law regarding selection inventions, with reference to *Dr Reddy's* and the EPO Board of Appeal decision in T 939/92 AGREVO/Triazoles 6 OJEPO 309. The position following the judgment in *Generics* is as follows:

- i) Article 56 of the EPC is in part based on the underlying principle that the scope of the patent monopoly must be justified by the patentee's contribution to the art;
- ii) If the alleged contribution is a technical effect which is not common to substantially everything covered by a claim, it cannot be used for the purposes of judging obviousness;
- iii) In such circumstances the claim must either be restricted to the subject matter

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which makes the technical contribution, or a different contribution common to the whole claim must be found;

- iv) A selection from the prior art which is purely arbitrary and cannot be justified by some useful technical property is likely to be held to be obvious because it does not make a real technical advance;
- v) A technical effect which is not rendered plausible by the patent specification may not be taken into account in assessing inventive step;
- vi) Later evidence may be cited to support a technical effect made plausible by the specification;
- vii) Provided the technical effect is made plausible, no further proof of the existence of the effect is to be demanded <u>of the specification</u> before judging obviousness by reference to the technical effect put forward.

3.89.1 [Deleted]

s.118

- 3.90 The Court of Appeal in *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* disregarded the criteria set out in *IG Farbenindustrie AG's Patents* 47 RPC 289. In *Dr Reddy's* Jacob LJ stated that as these rules related to pre-1977 law they could be regarded "as part of legal history, not as part of the living law".
- 3.91 The hitherto unknown technical effect (i.e. advantage gained or disadvantage avoided) relied upon to justify a selection invention should be clearly identified or otherwise made plausible (e.g. discernible from tests provided in the application), in the specification at the time of filing (see also T 1329/04 Johns Hopkins University School of Medicine/Growth Differentiation Factor [2006] EPOR 8). Later-filed evidence may be used to provide support for the presence of such an effect or the fact that it is common to everything claimed, but unexpected bonus effects not described in the specification cannot form the basis of a valid claim to a selection invention (see *Glaxo Group Ltd's Patent* [2004] RPC 43). If there is no statement of advantage in the specification at the time of filing it may not be added later, since, as stated by Jacob J. in *Richardson-Vicks Inc.'s Patent* [1995] RPC 568 at 581, in the context of synergy, whether or not the advantage was demonstrated "by experiments conducted after the date of the patent cannot help show obviousness or non-obviousness ... and it would be quite wrong for later-acquired knowledge to be used to justify the amended claim."
- 3.91.1 The judgment in <u>Generics [UK] LTD (t/a Mylan) v Yeda Research and Development co. LTD & Anor [2013] EWCA Civ 925 also addressed the question of what happens if the technical property or effect made plausible by the specification does not exist in fact. The lower court had held that since later evidence cannot be used to support a technical effect not indicated in the specification, neither can it be used to refute such an effect. The Court of Appeal held however that in considering later evidence on this issue one is not judging the obviousness of the invention by reference to later evidence; one is simply defining by evidence what the invention is. The Judge allowed the admission of later evidence which, according to Mylan, showed that the composition as claimed did not demonstrate the relied upon technical effect. The Judge however found that the evidence provided did not prove the absence of the technical effect and rejected the appeal.</u>
- 3.92 Although the size of the class from which a member or members have been chosen is not relevant to the question of novelty of a selection invention, it may be relevant to the question of obviousness (*Du Pont de Nemours &c (Witsiepe's) Application*, [1982] FSR 303 at page 310), see 2.19 2.20.
- 3.93 The technical significance of the parameters by which the product or process is selected should be considered. Where unusual parameters are used in a claim it may be difficult to prove whether or not the prior art would have inevitably exhibited those

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parameters, but in Raychem Corp.'s Patents [1998] RPC 31 it was held (at pp.46-47) that:

"although it may not be obvious, in the common use of that word, to limit a claim by reference to some particular meaningless and arbitrary parameter, that had nothing to do with patentability. Patents are not given for skill in inventing technically meaningless parameters."

If a product or process with obviously desirable characteristics happens to fall within the limits of such claims then they cover what is obvious and will thus be invalid.

Additional advantage not inventive

- Although the discovery of an unexpected advantage may point to a step not being obvious if it was only one of many steps which could have been tried (see 3.88) or if it was one taken counter to accepted views (see 3.97), if the prior art leads directly to the step then it is not made inventive by any additional advantage obtained. In *Inventa AG's Application*, [1956] RPC 45, the use for spinning nylon of a process which had been disclosed (before the introduction of nylon) for spinning artificial filaments in general was held to be obvious, and not to be saved by an additional advantage, since no further modification of the process was required to secure this advantage. And in *Union Carbide Corporation (Hostettler's) Application*, [1972] RPC 601 at page 609, Whitford J observed (obiter) that "if in fact the step taken was an obvious step, it remains an obvious step however astonishing the result of taking it may be".
- 3.95 An added benefit, however great, will not found a valid patent if the claimed innovation is obvious for another purpose (judgment of the Court of Appeal in *Hallen Co v Brabantia (UK) Ltd* [1991] RPC 195). In *Hallen*, it was held to be obvious to coat a corkscrew of self-pulling type with PTFE to facilitate its penetration into a cork; the claimed invention was not saved by the non-obvious additional advantage of facilitating extraction of the cork from the bottle (although it might have been saved as a selection patent if the specification had contained clear assertions that the corkscrew in question turned the use of PTFE to special advantage over other corkscrews in the extraction stage, thus overcoming a problem of all previous self-pullers).
- 3.96 In general, an otherwise obvious combination is not saved from a finding of obviousness by some unexpected advantage caused by an unpredictable co-operation between the elements of the combination (see *Glaxo Group Ltd's Patent* [2004] RPC 43).

Overcoming a technical prejudice

3.97 An invention may be regarded as non-obvious if it goes against the generally accepted views and practices in the art. As the Patents Court in Dyson Appliances Ltd v Hoover Ltd [2001] RPC 26 made clear (upheld by the Court of Appeal [2002] RPC 22), the common general knowledge held by the skilled person may have both positive and negative aspects, and it is necessary to take account of both; in other words to take account of what the skilled person would consider doing and what the skilled person would be prejudiced against doing, as a result of that knowledge. If the common general knowledge was such that the skilled person did not perceive a problem with the prior art, it becomes "considerably more difficult" to establish the obviousness of taking a particular step which would bring that prior art within the scope of the claims in question. In the case in question it was held that the common general knowledge of the skilled person at the relevant time, along with a lack of a perceived problem, would mean that the skilled person would never have considered using anything other than bag technology in a vacuum cleaner. Further examples are if persons skilled in the art would regard certain materials or techniques as unsuitable for a particular purpose, then if the inventor has found that this prejudice is not well-founded, then he has made an inventive contribution to the art. A patentee who advances the art by showing that, contrary to the prevailing view, the idea will work or is practical has shown something new and inventive (see Pozzoli SPA v BDMO SA [2007] EWCA Civ 588). Likewise the omission of a step hitherto thought to be necessary may constitute an inventive

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step.

3.98 It must however be clear that the technical prejudice which the applicant claims to have overcome did in fact exist, and that it was not justified. A prejudice which is insufficiently widespread for it properly to be regarded as commonly shared should not be attributed to the notionally skilled person. In Glaxo Group's Patent [2004] RPC 43, it was held that a prejudice does not exist if some people engaged in the art laboured under a particular prejudice if a substantial number of others did not. Thus a rooted objection to the regular use of b2-antagonists in the treatment of asthma, which was the subject of an ongoing dispute amongst specialist physicians, was not ascribed to the skilled person. Another situation is where scientific opinion is out of accord with what is done in the market, as occurred in Ancare New Zealand Ltd's Patent [2003] RPC 8 for a sheep drench comprising two known agents, one active against roundworms and one active against tapeworms. Here, the patentee argued that an inventive step lay in including the tapeworm agent because there was scientific hostility against treating tapeworms in sheep. However, it was common practice for New Zealand farmers to treat their lambs for tapeworm at the priority date. The Privy Council, upholding judgments of the New Zealand High Court and Court of Appeal to revoke the patent for obviousness and not involving any inventive step over what was known or used before the priority date of the claim in New Zealand, held that:

"the fact that scientific opinion might have thought that something was perfectly useless did not mean that practising it, or having the idea of making a preparation to do it, was an inventive step. Otherwise, anyone who adopted an obvious method for doing something which was widely practised but which the best scientific opinion thought was pointless could obtain a patent".

3.99 For an invention to overcome a technical prejudice, and therefore be non-obvious. a genuine prejudice must exist which would have prevented the skilled person from taking the step that would lead to the claimed invention. In Teva UK Ltd and others v AstraZeneca AB [2012] EWHC 655, the patent claimed a sustained release formulation of a drug, quetiapine, for the treatment of schizophrenia. AstraZeneca, the patent holder, argued that there were technical considerations preventing the skilled person from considering developing a sustained release formulation of quetiapine, so called "lions in the path", and therefore the patent was inventive. They argued that the skilled team in light of the prior art would be deterred from considering a sustained release formulation because quetiapine is rapidly metabolized by the liver (see also 3.83-3.87.1). The claimants however, argued that it would be obvious to formulate quetiapine for sustained release and that the alleged prejudices against doing so were illusory, mere "paper tigers". The judge held that an immediate release once-daily formulation would not be efficacious without increasing the dose and therefore there was rationale for the skilled person to seek a sustained release formulation. The judge also held that on the evidence quetiapine is not metabolised in a way which would deter the skilled person from attempting a sustained release formulation. Accordingly AstraZeneca's patent was held to be obvious and was revoked. In Actavis UK Ltd v Novartis AG [2010] EWCA Civ 82 a claim to a sustained release formulation for the drug fluvastatin was also held to lack an inventive step since the obstacle put forward in the patent against being able to make such a formulation was illusory.

3.100 There is also no invention in merely tolerating the disadvantages which have deterred others. For example if an inexpensive plastics material is thought unsuitable for making tools because it is not durable, there is no invention in using it to make a cheap screwdriver intended only for light work and accepting that it will have only a short life.

3.101 Some of these points may be illustrated by a hypothetical example. Suppose that it has been stated for years in textbooks that a particular class of chemical reaction carried out under elevated pressure, gives poor yields, and an inventor now claims the synthesis of a particular compound by such a process. If all he has done is take advantage of the high price commanded by the product, or the cheapness of the starting materials, and has decided to accept the disadvantage of low yield, then that is not inventive; it is an obvious response to prevailing economic circumstances. On the other hand, if the inventor has discovered that good yields can be obtained by the use of still higher pressures, a fact not

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suggested in the prior art, then that would be inventive. But if higher yields would be expected at difficult-to-obtain pressures, and the inventor has merely taken advantage of new techniques making such pressures more available, then that is not inventive. Finally, if the inventor has discovered that the standard accepted views on the low yields, while being normally true for this reaction, are not in fact true for this particular compound, then there is inventive step in the choice of this process.

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Section 4: Industrial application

s.130(7)

4.01 This section relates to the third of the tests for patentability set out in s.1(1). It is so framed to have, as nearly as practicable, the same effect in the UK as the corresponding provisions of the EPC, PCT and CPC, ie Article 57 of the EPC.

Section 4(1)

An invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

"Industry" should be understood in its broad sense as including any useful and practical, as distinct from intellectual or aesthetic, activity. It does not necessarily imply the use of a machine or the manufacture of a product, and covers such things as a process for dispersing fog or a process for converting energy from one form to another. In Chiron Corp v Murex Diagnostics Ltd and other [1996] RPC 535 (page 607) the Court of Appeal held that the requirement that the invention can be made or used "in any kind of industry" so as to be "capable of industrial application" carries the connotation of trade or manufacture in its widest sense and whether or not for profit. The Court went on to hold that industry does not exist in that sense to make or use that which is useless for any known purpose. Many of the matters which are excluded as lacking industrial application would have been rejected under previous laws as not being manners of manufacture, and in fact the views of the High Court of Australia in NRDC's Application, [1961] RPC 134, give a good guide to the meaning to be attributed to industrial application; there must be a product, but this need not be an article or substance, but must be something in which a new and useful effect, be it creation or alteration, may be observed. It may for example be a building, a tract or stratum of land, an explosion or an electrical oscillation, but it must be useful in practical affairs. A method of eradicating weeds was held to give rise to a product (an improved crop) because this was an artificially created state of affairs; moreover it was one whose significance was economic.

4.03 In many cases, an invention which passes (or fails) the test for industrial application under s.4(1) will equally pass (or fail) the test for patentability under s.1(2) (see 1.07-1.40.4). This was the case in *Melia's Application* (BL O/153/92), where an application relating to a scheme for exchanging all or part of a prison sentence for corporal punishment was held to lack industrial applicability and also to be a method for doing business. In *John Lahiri Khan's Application* (BL O/356/06) a method for effecting introductions with a view to making friends was held not to be industrially applicable, even though it could be carried out by a commercial enterprise. It was also found to be excluded as a method of doing business. It should be remembered however that, even though they will frequently give the same answer, the tests for industrial application and patentability are separate and independent.

4.04 [Deleted]

4.05 Processes or articles alleged to operate in a manner which is clearly contrary to well-established physical laws, such as perpetual motion machines, are regarded as not having industrial application, as was held in *Paez's Application* (BL O/176/83), *Webb's Application* (BL O/84/88), and in *Peter Crowley v United Kingdom Intellectual Property Office* [2014]. An alternative or additional objection may be that the specification is not complete enough to allow the invention to be performed under s.14(3) (see 14.67). For example, in *Eastman Kodak Co. v American Photo Booths Inc.* (BL O/457/02), which concerned a patent for a photo-booth camera, it was held that the folded optical path as described and claimed could not give rise to the claimed narrowing of the depth of field. As a result, the hearing officer held that the invention could not work as described and claimed, and so lacked both industrial applicability and sufficiency of disclosure. See also *NEWMAN/Perpetual motion* (EPO decision T 5/86). Objecting to insufficiency may be particularly appropriate if the claims do not refer to the intended function or purpose of the invention, for example if a "flying gyroscope" is claimed merely as an article having a particular specified construction.

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Regardless of whether objection arises under s.4(1) or s.14(3), one of the procedures set out in 17.94-17.96.4 should be followed at the search stage.

- 4.05.1 In considering whether an invention operates in a manner which is clearly contrary to well-established physical laws, the examiner should consider the material before them on the balance of probabilities. If there is substantial doubt about an issue of fact which could lead to patentability, following the Patents Court judgment in Blacklight Power Inc. v The Comptroller-General of Patents [2009] RPC 6, the examiner should consider whether the evidence provided by the applicant gives rise to a reasonable prospect that the applicant's theory might turn out to be valid if it were to be fully investigated at a trial with the benefit of expert evidence. In such a case the application should be allowed to proceed. The reasonable prospect must be based on credible material before the Office. Moreover, the greater has been the opportunity for the applicant to produce such material at the application stage, the smaller scope there is for supposing that giving them the benefit of the doubt will lead to a different conclusion before the courts. It should also be noted that the test set out in Blacklight Power should be applied only where there is "substantial doubt" on an issue of fact. In the case of a claim to a perpetual motion machine, there is no substantial doubt, and as pointed out by the judge in this case, there would be no reasonable prospect that matters would turn out differently on a fuller investigation at trial.
- 4.05.2 The "reasonable prospect ... at trial" test set out in *Blacklight Power Inc. v The Comptroller-General of Patents* was applied by the hearing officer on remittal of this case from the Patents Court back to the Office (*Blacklight Power Inc.*'s *Application BL O/170/09*), and also by the hearing officer in *Robinson's Application BL O/336/08*. In both cases the claimed invention relied on a scientific theory of doubtful validity. The criteria used by the hearing officers in these cases to determine whether there was a reasonable prospect that the applicant's theory might turn out to be valid if it were to be fully investigated at a trial with the benefit of expert evidence included; consistency with existing generally accepted theories, testable predictions made by the theory together with evidence to match its predictions, and the level of acceptance of the theory by the community of scientists working in the relevant discipline.
- 4.06 Methods of testing are generally regarded as capable of industrial application if the test is applicable to the improvement or control of a product, apparatus or process which itself is capable of industrial application. It is therefore advisable to indicate the purpose of the test if this is not otherwise apparent (see 14.82). In particular, the use of animals for test purposes in industry, e.g. for testing industrial products or for monitoring water or air pollution, may be patentable.
- s.1(3)(b) 4.07 Although "industry" includes agriculture, a process used in agriculture will not be patentable if it is a method of surgery, therapy or diagnosis practised on animals (see section 4A) nor if it is an essentially biological process for the production of animals or plants (see 1.43-1.46).
 - 4.07.1 Special considerations apply to inventions in the field of biotechnology, as the industrial application (i.e. useful purpose) of a biotechnological invention, such as a gene or protein sequence, is very often not apparent from the invention itself. It is frequently also necessary to take account of the specific requirements of European Directive 98/44/EC on the legal protection of biotechnological inventions (as set out in Schedule A2 to the Patents Act 1977), which provides (amongst other things) that the industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application as filed see 76A.06. The Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office provide extensive guidance for dealing with applications in this specific area of technology.
 - 4.07.2 The question of the industrial applicability of a gene was considered by the Supreme Court in <u>Human Genome Sciences v Eli Lilly [2011] UKSC 51, [2012] RPC 6.</u> Previously, in <u>Eli Lilly & Co. v Human Genome Sciences, Inc.</u> [2008] EWHC 1903 (Pat), [2008] RPC 29 (upheld by the Court of Appeal [2010] EWCA Civ 33 [2010] RPC 14), Kitchin J applied nine principles which summarized UK and EPO case law in this area, and rejected

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the application on the grounds that it lacked industrial applicability. However the Supreme Court, having considered UK case law and European jurisprudence, concluded that the basis upon which the judge in the lower court had decided the issue was not consistent with the approach adopted by the EPO Technical Board of Appeal. Lord Neuberger summarized the Board's approach regarding the requirements of Article 57 EPC in relation to biological material in a set of fifteen points, and concluded that in light of these points the patent in suit satisfied the requirement of Article 57 i.e. was industrially applicable. The majority of the fifteen points relate specifically to the biomedical fields; however the principles set out in points 1-4 can be applied broadly when considering the industrial application of a patent. The first four points for consideration are as follows:

- i) The patent must disclose "a practical application" and "some profitable use" for the claimed substance, so that the ensuing monopoly "can be expected [to lead to] some ... commercial benefit":
- ii) A "concrete benefit", namely the invention's "use ... in industrial practice" must be "derivable directly from the description", coupled with common general knowledge;
- iii) A merely "speculative" use will not suffice, so "a vague and speculative indication of possible objectives that might or might not be achievable" will not do:
- iv) The patent and common general knowledge must enable the skilled person "to reproduce" or "exploit" the claimed invention without "undue burden", or having to carry out "a research programme";

Points 5-10 relate to situations where a patent discloses a new protein and its encoding gene, while points 11-15 relate to situations where the protein is said to be a member of a family or superfamily. For further discussion of these points see the Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office.

[Section 4(2) Repealed]

[Subsection 4(2) was concerned with the patentability of methods of treatment or diagnosis. This is now provided for in section 4A(1)]

4.08 [deleted]

[4.09 - 4.20 moved to 4A.02 - 4A.13]

4.21 [deleted]

4.22 [deleted]

[4.23 moved to 4A.14]

[Section 4(3) Repealed]

[Subsection 4(3) was concerned with the patentability of substances for use in methods of treatment or diagnosis. This is now provided for in section 4A(2)]

[4.24 moved to 4A.15]

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Section 4A: Methods of treatment or diagnosis

s.130(7) 4A.01 This section relates to exceptions to patentability and novelty. It is so framed to have, as nearly as practicable, the same effect in the UK as the corresponding provisions of the EPC, PCT and CPC, ie Articles 53(c), 54(4) and 54(5) of the EPC.

[The Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Intellectual Property Office provide further details on practice in this field.]

Section 4A(1)

A patent shall not be granted for the invention of-

- (a) a method of treatment of the human or animal body by surgery or therapy, or
- (b) a method of diagnosis practised on the human or animal body.

4A.02 The term "therapy" includes the prevention as well as the treatment or cure of disease, as held by the Patents Court in Unilever Limited (Davis') Application, [1983] RPC 219. Although some medical dictionaries cited pointed towards a narrow interpretation of the term, other works of reference, including non-specialist dictionaries, indicated a more general meaning; this was preferred in this case, following the principle that words in statutes dealing with matters relating to the general public are presumed to be used in their popular, rather than their narrowly legal or technical, sense. However, for a treatment to constitute therapy there must be a direct link between the treatment and disease state being cured, prevented or alleviated, as held by the hearing officer in Commonwealth Scientific and Industrial Research Organization's Application (BL O/248/04). A photodynamic method of controlling wool growth to reduce the incidence of blowfly strike and balanitis in sheep was therefore determined not to be a method of therapy. Furthermore, in Schering AG's Application [1971] RPC 337, it was held that a method of chemical contraception was not considered to be therapeutic. The prohibition does apply if a method of chemical contraception is associated with a therapeutic method by means of combined delivery system. This was decided by the EPO Technical Board of Appeal in The General Hospital Corporation's Application T820/92 (OJEPO 3/95) in which certain steroids were used in conjunction with a main contraceptive ingredient to alleviate health problems caused by that ingredient. The EPO Board of Appeal in another case, T74/93 (OJEPO headnote 4/95), confirmed that methods of contraception in general are not considered to be therapeutic, as pregnancy is not a disease. The Board held that the claimed method in this case lacked industrial applicability as it was a purely personal method carried out in private. In the UK methods of contraception are not considered to lack industrial application merely because they are for "private and personal use". Under s.60(5)(a) of the Patents Act 1977 the private use of such a method would not constitute an infringing act, and so a patent to such a method is allowable.

4A.03 It appears that any medical treatment of a disease, ailment, injury or disability, ie anything that is wrong with a patient and for which they would consult a doctor, as well as prophylactic treatments such as vaccination and inoculation, is to be regarded as therapy. The same considerations apply for animals as for human patients, so that for example prophylaxis and immunotherapy in animals are regarded as therapy.

4A.03.1 In *Bristol-Myers Squibb v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, Jacob J held that the exception should be construed narrowly. Its purpose is merely to keep patent law from interfering directly with what a doctor actually does to a patient, not to stop patent monopolies from controlling what the doctor administers to the patient or the implements that they use on the patient. However methods of therapy carried out on materials

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temporarily removed from the body, for example when blood is circulated through an apparatus while remaining in living communication with the body, are not patentable (cf *Calmic Engineering Co Ltd's Application*, [1973] RPC 684).

- In Ciba-Geigy AG's Application (BL O/30/85), objection was raised under now repealed section 4(2) (equivalent to s.4A(1)) to certain claims for a method of controlling parasitic helminths (worms which may develop in the animal body, for example, in the intestinal tract of animals such as sheep) by the use of a particular (novel and inventive) anthelmintic composition. The hearing officer considered that such an infestation was a disease requiring medical treatment of the animal and that such treatment, whether curative or preventative, constituted therapy practised on the animal body and consequently held that the claims in question were not allowable.
- 4A.03.3 Section 4A(1) excludes only treatment by surgery or therapy, and it follows that other methods of treatment of live human beings or animals, eg treatment of a sheep in order to promote growth, to improve the quality of mutton or to increase the yield of wool, are patentable provided that (as would probably be the case) such methods are of a technical, and not essentially biological, character. However, where an increase in meat yield or other industrial benefit is merely an inevitable consequence of improved health through therapeutic treatment, then such a method is unpatentable. On the other hand, a claim to the non-therapeutic use of antibiotics or other drugs may be acceptable if the claimed effect is not a mere consequence of improved health. Where the method set out in the claim may be patentable but could also cover non-patentable embodiments, a claim must be clearly limited (e.g. by a disclaimer) to methods which are patentable, and there must be support in the description for a non-therapeutic method. If necessary, the description should be amended to clarify that therapeutic methods do not form the invention.
- Application of substances to the body for purely cosmetic purposes is not therapy. In allowing claims to a process for improving the strength and elasticity of human hair and finger nails, the High Court of Australia observed that, while a process for the treatment of the human body as a means of curing or preventing a disease or other disorder was not patentable, "Those who apply chemical preparations to the skin to prevent sunburn in climates which enjoy sunshine and moderate air temperatures can scarcely be regarded either as, in a relevant sense, treating their bodies or as undergoing treatment. On the other hand, the application to the skin of an ointment designed and effective to remove keratoges from the skin would be an instance of medical treatment. To be treatment in the relevant sense, it seems to me that the purpose of the application to the body whether of a substance or a process must be the arrest or cure of a disease or diseased condition or the correction of some malfunction or the amelioration of some incapacity or disability" (*Joos v Commissioner of Patents*, [1973] RPC 59).
- In *Oral Health Products Inc (Halstead's) Application,* [1977] RPC 612, claims to a method of removing dental plaque and/or caries were refused, as was a claim to a method of cleaning teeth which embraced both curative and cosmetic effects. This decision has been followed under the 1977 Act in *ICI Ltd's Application No 7827383* (BL O/73/82), where a claim was refused to a method of cleaning teeth which removed both plaque and stains; it was argued that when applied to perfectly healthy teeth the method was purely cosmetic, but the hearing officer observed that practically all medical treatments which are preventative in nature (such as vaccination) must at times be applied to people who would have remained healthy anyway, but they remained medical treatments. It was held in *Lee Pharmaceuticals' Applications*, [1978] RPC 51, that since one of the results of sealing pits and fissures in teeth was to prevent the onset of dental decay, the purpose of the treatment was therapeutic rather than cosmetic.

4A.06 Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general

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physical state of an individual (e.g. a fitness test) is not considered to be diagnostic if it is not intended to identify or uncover a pathology. Section 4A(1) relates to methods of diagnosis practised on the human or animal body; diagnosis in itself is a method of performing a mental act and is excluded from patentability under section 1(2)(c). The scope of the term "diagnostic methods practised on the human or animal body" within the meaning of Article 53(c) EPC (equivalent to section 4A(1)) is discussed by the EPO Enlarged Board of Appeal decision in G 01/04 Diagnostic Methods [2006] 5 OJEPO 334, [2006] EPOR 15. Typically, the process of diagnosis involves a number of steps leading towards identification of a condition. The Enlarged Board characterised these steps as being; (i) the examination and collection of data, (ii) comparison of the data with normal values, (iii) recording any deviation from the norm, and finally (iv) attributing the deviation to a particular clinical picture. The Enlarged Board held that for a claim to fall under this prohibition, it must include both the deductive step of making the diagnosis (step iv) and the preceding steps constructive for making that diagnosis involving specific interactions of a technical nature with the human or animal body. The exclusion is therefore a narrow one, and also requires all the method steps of a technical nature to be practised on the body. However, the Board pointed out that the exclusion could not be circumvented by omitting one of the essential features of the diagnostic method as the claim would then not satisfy Article 84 EPC (equivalent to section 14(5)(a) to (c)), since this requires that all the essential features necessary for clearly and completely defining a particular invention are present in the claim. In determining whether or not a method is diagnostic, the Board held that it is irrelevant whether it is necessary for a medical or veterinary practitioner to be involved. Furthermore, a method is "practised on the human or animal body" if it involves any interaction which necessitates the presence of the patient, so will include both invasive and non-invasive methods.

- 4A.06.1 In practice, there are two key questions to be asked with any claim to a diagnostic method. Firstly, does the claimed method include both the first, measurement step and the final deductive step; i.e. does it allow the disease or condition to be identified? (The intermediate steps (ii) and (iii) may be inferred if the first and last steps are clearly included.) Second, is the examination or measurement (step (i)) practised on the body? The remaining steps (ii) to (iv) are never practised on the body, but are generally not technical in nature. If the answer to both of these questions is "yes", objection should be made under Section 4A.
- 4A.07 Methods of diagnosis performed on tissues or fluids which have been permanently removed from the body are not excluded, and so, for example, genetic or immunological tests on blood or urine samples are patentable. "Body" should be taken to mean living body, and a method practised on a dead body, for example in order to determine the cause of death, would not be excluded.
- 4A.08 Surgery is defined as the treatment of disease or injury by operation or manipulation. It is not limited to cutting the body but includes manipulation such as the setting of broken bones or relocating dislocated joints (sometimes called "closed surgery"), and also dental surgery. In general, any operation on the body which required the skill and knowledge of a surgeon would be regarded as surgery (see also 4A.10). The Enlarged Board of Appeal in G 01/07 MEDI-PHYSICS/*Treatment by surgery* [2011] 3 OJEPO 134 held that a method should be excluded if it comprises or encompasses an invasive step which constitutes a substantial physical intervention on the body, and which entails a significant health risk even when carried out by a medical professional.
- 4A.09 In *Unilever Limited (Davis') Application*, [1983] RPC 219 (see also 4A.02), Falconer J observed that any method of surgical treatment, whether curative, prophylactic or cosmetic, is not patentable. This view, which was obiter, was cited by the hearing officer in *Occidental Petroleum Corporation's Application* (BL O/35/84) in refusing to allow claims to a method of implanting an embryo transplant from a donor mammal into the uterus of a recipient mammal, since the method would necessarily have to be carried out by a surgeon or veterinary surgeon. In contrast, the EPO Technical Board of Appeal in T 383/03 GENERAL

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HOSPITAL/Hair removal method [2005] 3 OJEPO 159 held that the exclusion only applies to surgical methods which are potentially suitable for "maintaining and restoring the health, the physical integrity, and the physical well-being of a human being or animal, and to prevent diseases". This was overturned by the Enlarged Board of Appeal in G 01/07 MEDI-PHYSICS/Treatment by surgery [2011] 3 OJEPO 134, in which it was held that the purpose of the method is irrelevant – the exclusion is **not** limited to therapeutic or reconstructive surgery. Instead, surgery is defined by the nature of the method, and in particular the level of skill required and risk incurred. This is consistent with previous UK practice, and with the Office decision in *Virulite Ltd's Application* BL O/058/10. In this decision a claimed method of treating the skin with electromagnetic radiation was held not to be surgical on the grounds that it was not a significant physical intervention – the treatment did not damage cells or burn the skin – and the patent, if granted, would not interfere with the work of a medical or veterinary practitioner in their treatment of patients.

- 4A.10 It may often be helpful, in deciding whether or not a method is excluded under s.4A(1), to consider who would in practice carry out the method. The apparent purpose of s.4A(1) is to prevent a medical practitioner being inhibited by legal monopolies. Thus for example bone setting is regarded as surgery, while applying a plaster cast is not, since the former is carried out by a doctor, the latter by a technician. And in *Upjohn Co (Kirton's) Application*, [1976] RPC 324, the hearing officer observed that abortion in humans, in contradistinction to contraception, necessarily involved a registered medical practitioner. (See also 4A.11). However, this consideration is not decisive, and a method may still be considered to be therapeutic, diagnostic or even surgical even if it can be carried out by non-medical personnel. In G 01/07 MEDI-PHYSICS/*Treatment by surgery* [2011] 3 OJEPO 134 it was held that whether a method is excluded or not cannot depend on who carries it out, not least because of the changing medical roles in healthcare systems.
- 4A.11 Once it has been decided, in the way indicated in the preceding paragraphs, that a method constitutes surgery, therapy or diagnosis practised on the human or animal body, it is necessarily non-patentable. For example, methods of abortion or induction of labour are always considered to be unpatentable, irrespective of the reason for the treatment. The fact that abortion or induction of labour may be carried out for social reasons, or that these or other methods may be practised on animals for reasons of agricultural economies, does not save them from exclusion.
- 4A.11.1 Unlike section 1(2) of the Act, there is no proviso in s.4A(1) that methods are only excluded "to the extent that a patent or application for a patent relates to that thing as such". The EPO Enlarged Board of Appeal in G 01/07 MEDI-PHYSICS/*Treatment by surgery* [2011] 3 OJEPO 134 confirmed a body of earlier EPO case law by holding that any multi-step method which includes a step comprising a method of surgery or therapy is excluded from patentability.
- 4A.12 Claims objected to under section 4A(1) are often in the form "A method (or process) for treating medical or veterinary condition Y by", but other forms of claim are also objected to such as "The use of substance (or composition) X in treating medical condition Y by", "A compound (or composition) X when used in the treatment of medical condition Y by" and "The use of substance (or composition) X as a pharmaceutical". The last of these claims is interpreted as a method claim to the use of the substance in therapeutic treatment, rather than simply a claim to its use in a pharmaceutical formulation.
- 4A.13 Patents may, however, be obtained for surgical, therapeutic or diagnostic instruments or apparatus intended for use in such methods. Also the manufacture of prostheses or artificial limbs and taking measurements therefore on the human body are patentable. In addition, tests on human or animal bodies should be regarded as patentable inventions if they do not meet the criteria for "methods of diagnosis" set out in 4.06.

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4A.14 If a claim is capable of embracing both excluded and non-excluded methods. amendment is necessary to limit the claim to methods which are patentable, for example by disclaiming the excluded methods, and if necessary, by amending the description to exclude the non-patentable methods. Any disclaimers must meet the requirements set out in 14.126-14.127. The Enlarged Board of Appeal in G 01/07 MEDI-PHYSICS/Treatment by surgery [2011] 3 OJEPO 134 confirmed that an "undisclosed disclaimer" (i.e. one where neither the disclaimer nor the subject matter excluded by it is disclosed in the application as filed) to exclude methods of treatment by therapy or surgery, or methods of diagnosis practised on the human or animal body, is in principle allowable and does not necessarily constitute added matter. Any form of disclaimer is allowed which removes the objection and leaves the scope of the monopoly remaining clear. While in ICI (Richardson's) Application [1981] FSR 609 a claim which included a disclaimer employing the wording of the Act was disallowed since it left the scope of what was being claimed unclear, there is no objection in principle to any other form of disclaimer, provided always that the scope of the monopoly remaining is clear, and there is support in the description for the invention claimed. Regardless of whether the disclaimer itself is disclosed, the subject matter remaining in the claim after the introduction of the disclaimer must be disclosed in the application as filed (G 02/10 SCRIPPS/Disclaimer OJEPO 2012, 376).

Section 4A(2)

Subsection (1) above does not apply to an invention consisting of a substance or composition for use in any such method.

4A.15 This subsection is for the avoidance of doubt; the exclusions of s.4A(1) apply only to methods and not to materials to be used in such methods.

Section 4A(3)

In the case of an invention consisting of a substance or composition for use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

4A.16 Section 4A(3) has the effect that a known substance or composition may be patented for use in a method of treatment by surgery or therapy or a method of diagnosis practised on the human or animal body, provided that its use in any such method is new ("first medical use"). That is to say, if a known substance or composition not previously used in surgery, therapy or diagnosis is found to be useful in treating, say a human disease, or to obtain a specific "therapeutic" effect (eg analgesic or antibiotic), a patent for the substance or composition for use in therapy (unspecified) may be obtained, i.e. the claim need not be limited to the specific therapeutic effect; additional claims directed towards more than one specific therapeutic effect may be allowed in the same patent application, provided of course that they are supported by the description. The terms surgery, therapy and diagnosis are discussed in more detail in paragraphs 4A.02-4A.14.

s.4A(1) 4A.17 This is an exception to the general rule (see 2.14) that a claim to a substance or composition for a particular purpose is construed as a claim to the material per se, and that if the invention lies in a new method of using a known material only the new method can be claimed. (Where the new use is a method of surgery, therapy or diagnosis practised on the human or animal body a claim to the method would not be allowable). In a case where the

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main claims related to a contraceptive composition comprising compounds that were already known as pharmaceuticals, the EPO Technical Board of Appeal, in decisions T303/90 and T401/90 (not reported), was of the opinion that the composition as claimed could not be considered as novel and the added word "contraceptive" did not change the product claim into a use claim.

- 4A.18 The first medical use of a known substance can be claimed for use in a method of medical treatment the first time such a use is disclosed. Once the use of the compound in any method of medical treatment has formed part of the state of the art the same substance or composition may subsequently be patented for use in treating a different disease, whether human or animal, or in surgery or diagnosis as a second use (see 4A.26-4A.31).
- s.1(2)(d) 4A.19 In *Bayer A G (Meyer's) Application*, [1984] RPC 11, the hearing officer refused claims of the form "Commercial package containing as an active pharmaceutical agent compound X together with (or bearing) instructions ..." for treating condition Y; it was only the content of the instructions which distinguished these claims from the prior art, and this was mere presentation of information and not an invention (see 1.40.3). See also 4A.20 below.
 - A similar conclusion was reached in John Wyeth and Brother Ltd's 4A.20 Application, [1985] RPC 545. In that case it was argued on behalf of the applicant that a claim to the use of X in treating Y included procedures which are not practised on the human or animal body but which are of an industrial nature, such as the preparation of the compounds and of compositions containing them and their packaging, including the enclosure of instructions, for the new use; a decision of the German Federal Court of Justice (Bundesgerichtshof), reported at OJEPO 1/84 pages 26-41, was cited in support of this view. The hearing officer rejected a suggestion that he was obliged, because of s.130(7), to follow this decision, and observed that there appeared to be a fundamental difference of approach to the validity of claims, since the German Court seemed to take the view that because a claim includes some patentable matter it should be allowed, whereas under UK law a claim as a whole is regarded as bad if it includes something that is non-patentable. In a judgment ([1985] RPC 545 at page 556) on the Wyeth case and Schering AG's Application, the Patents Court agreed with the findings of the hearing officer in the Bayer case (see 4A.19) but followed the EPO Enlarged Board of Appeal (G 05/83 EISAl/Second medical indication, [1985] 3 OJEPO 64) in allowing Swiss-type claims of the form "the use of substance X for the manufacture of a medicament for a specified new and inventive therapeutic application"; this type of claim has now been superseded by the direct form of second medical use claim as discussed in 4A.26-4A.28.
 - 4A.21 A claim to a known substance or composition for the first use in surgical, therapeutic and/or diagnostic methods should be in a form such as "Substance or composition X" followed by the indication of the use, for instance ".... for use as a medicament", ".... for use as an antibiotic", or ".... for use in treating disease Y". There is no objection to a claim being directed to substance X for use in a medical method in the case where X is novel, whether or not the substance is also claimed per se.
 - 4A.22 EPO case law in relation to both first (T 1758/07) and second (T 1099/09) medical use claims indicates that protection for medical uses of known substances or compositions is only available for the use of a substance or composition as an active agent in medicine. The use of a known substance or composition as an inactive carrier or excipient for a therapeutic agent cannot therefore be protected by a first medical use claim. Following the same logic, the previous use of the compound purely as an inactive carrier or excipient for a therapeutic agent does not anticipate a first medical use claim, as held in T 1758/07.

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- 4A.23 Section 4A(3) is restricted to substances and compositions; apparatus cannot be so protected. Claims may be allowed however under Section 4A(3) to compositions having a surface and in the form of an article ie having a shaped form.
- 4A.24 Since cosmetic methods of treatment of the human body are not considered to be therapeutic (see 4A.04), a substance or composition for use in a non-surgical cosmetic method cannot be protected by Section 4A(3).
- 4A.25 To provide evidence of prior use of a substance or composition in therapy, actual disclosure of therapeutic use must be found. It is not sufficient for a research paper to disclose experiments which show an activity which would make the substance or composition suitable for use in therapy, or discloses in vitro testing for such a use. The section requires the use of the substance or composition in a method of therapy to form part of the state of the art. Such disclosures of experiments and tests might of course be used as a basis for an obviousness attack under section 3.

Section 4A(4)

In the case of an invention consisting of a substance or composition for a specific use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if that specific use does not form part of the state of the art.

- Before implementation in 2007 of the medical provisions of the 2000 revision of the EPC (EPC 2000 introduced into UK law by the Patents Act 2004), a second or subsequent medical use could only be protected by a claim in the "Swiss type" format of "the use of substance X for the manufacture of a medicament to treat disease Y". Section 4A(4) now enables patent protection to be obtained for a second, or subsequent, different use of a substance or composition in a method of treatment or diagnosis by a direct claim in the form "substance X for use in the treatment of disease Y". A claim of this type for a known substance or composition for use in a specific method of treatment or diagnosis is treated as new if that specific use was previously unknown. This does not extend the availability of patent protection in respect of inventions consisting of a substance or a composition for use in a method of treatment or diagnosis; it simplifies and clarifies the manner in which patent protection may be obtained for such inventions.
- Following implementation of the EPC 2000, the practice in both this Office and the EPO was to allow inventions relating to second medical uses to be claimed using either the direct second medical use claim format under Section 4A(4), or the Swiss-type format, or both, pending guidance from the UK courts and/or the EPO Boards of Appeal. In February 2010, the EPO Enlarged Board of Appeal issued its decision in G 02/08 ABBOTT RESPIRATORY/Dosage regime [2010] 10 OJEPO 456. This decided that applicants may no longer claim second medical use inventions in the Swiss format. The Enlarged Board held that Swiss-type claims were previously accepted (in G 05/83 EISAI/Second medical indication [1985] 3 OJEPO 64) as the only possible means of protecting inventions relating to second medical uses in order to fill a loophole in the provisions of the EPC 1973. The new Article 54(5) (equivalent to Section 4A(4)) fills this loophole by explicitly allowing claims to the further specific use of a known drug, and so the reason for this special, "judge-made" law no longer exists.
- 4A.27.1 Claims in the "Swiss-type" format in new or pending applications should be objected to on grounds of clarity, and must either be deleted or replaced by claims in the direct second medical use format "substance X for use in the treatment of disease Y". This change

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in practice was announced in a Practice Notice issued on 26 May 2010. The basis of the objection is that a Swiss-type claim lacks clarity because, although it is worded as defining a method of manufacturing a medicament, the invention in fact relates to the intended use of the product rather than the method of manufacture. As stated in G 02/08, there is no functional relationship between the feature conferring novelty (the intended use) and the claimed manufacturing process. Amendment of a patent application to replace a Swiss-type claim with the new form of second medical use claim is not considered to add matter, since regardless of the wording or scope of the claim, the technical disclosure (i.e., a new medical use for a substance or composition) is the same. Similarly, replacement of an unpatentable method of treatment claim with a second medical use claim protecting the same use does not add matter. This practice does not have any bearing on the validity of patents already granted and including Swiss-type claims.

A request to make a post-grant amendment to replace Swiss-type claims with the new form of second medical use claim is unlikely to succeed, particularly as the Enlarged Board in G 02/08 suggested that the new form of claim may have a broader scope than Swiss-type claims. Moreover, in an earlier Technical Board of Appeal decision (T 250/05) it was held that a postgrant amendment from a Swiss-type claim to the new form of second medical use claim would extend the scope of protection and thus would not be allowable under Art. 123(3) EPC (equivalent to s.76(3)(b)). The Boards of Appeal in T 1780/12 and T 879/12 highlighted this difference in scope and also claim category between Swiss-type claims (which, strictly, are process claims) and the new form of second medical use claims (which are "purpose-limited" product claims). For this reason, it was concluded in both these decisions that where a divisional application included the new claim form, and the granted parent claimed the same medical use in the Swiss form, this did not constitute "double-patenting". No objection should therefore be raised under s.18(5) or s.73(2) to conflict between applications including the new form of second medical use claim and granted GB or EP patents which protect the same medical use solely through Swiss-type claims. The Patents Court in Generics (UK) Ltd (t/a Mylan) v Warner-Lambert Company LLC [2015] EWHC 2548 confirmed that Swiss-type claims are process claims - this has consequences for infringement as discussed in 60.16.2 and 60.19.2.

4A.28 The protection of second medical uses by Swiss-type claims was originally allowed by the Enlarged Board of Appeal in G 05/83 EISAI/Second medical indication [1985] 3 OJEPO 64, and this was followed by the Patents Court in John Wyeth's and Schering's Applications [1985] RPC 545. The Enlarged Board in G 05/83 also decided that a claim to the use of a substance for treatment was regarded as confined to the step of treatment and was thus contrary to a.52(4) EPC [1973]. (See also 4A.20). Despite the fact that Swiss-type claims are no longer allowable, the case law that has developed from the UK courts and EPO Boards of Appeal concerning second medical use claims in the Swiss form continues to govern our practice in relation to inventions in this field. Second medical use claims which relate to the use of a substance for the same therapeutic application as the prior art, but claiming a different technical effect or mechanism of action, should be objected to for lack of novelty. In Bristol-Myers Squibb v Baker Norton Pharmaceuticals [1999] RPC 253, the Patents Court held that a new piece of information about how a treatment worked did not constitute an invention if it did not lead to a new use, which was upheld by the Court of Appeal [2001] RPC 1. In this case, the drug, method of administration and therapeutic purpose were exactly the same as given in a prior lecture; the only difference was the discovery that if the drug was infused over a shorter time period, an undesirable side-effect was less and the therapeutic effect remained. This decision was followed by the Patents Court in El-Tawil's Application [2012] EWHC 185. In this case a claim was considered to relate to a combination of newly discovered technical effects, and newly discovered advantages of a known treatment, neither of which conferred novelty. Similarly, in Actavis UK Ltd v Janssen Pharmaceutica NV [2008] EWHC 1422, [2008] FSR 35, it was held that "merely explaining the mechanism which underlies a use already described in the prior art cannot, without more, give rise to novelty".

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- 4A.28.1 The Court of Appeal in *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1 also held that second medical use claims must define a new and inventive purpose; ie the treatment of a new disease. It was held that claims which defined the new use in terms of, for example, a new dosage regime, were disguised method of treatment claims, and also lacked novelty over the use of the substance to treat the same disease at a different dosage. However, the Court of Appeal in *Actavis v Merck* [2008] RPC 26 reversed this aspect of the *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* decision and decided that a second medical use claim which defined the use in terms of a new and inventive dosage regime was valid, despite the fact that the substance in question had been used in the prior art to treat the same condition (alopecia) at a different dosage. It was emphasised that in most cases a new dosage regime would not be inventive, as investigating appropriate dosage regimes is standard practice.
- 4A.28.2 The reasons the Court of Appeal gave in Actavis v Merck [2008] RPC 26 for departing from its own precedent (in Bristol-Myers Squibb v Baker Norton Pharmaceuticals [2001] RPC 1) were threefold. Firstly it was decided that Bristol-Myers Squibb v Baker Norton Pharmaceuticals provided no clear ratio in relation to novelty, and so was not binding in this respect. Secondly, that the ratio of Bristol-Myers Squibb v Baker Norton Pharmaceuticals in respect of the method of treatment objection was on the narrow grounds that the claim at issue in that case was directed at the actions of the doctor rather than the manufacturer, and this was not the case with dosage regime claims in general. Finally, the Court of Appeal in any case felt it was able (but not bound) to depart from its own precedent on the grounds that the earlier decision was inconsistent with the "settled view" of European patent law as interpreted by EPO Board of Appeal decisions; which had allowed second medical use claims which define a new dosage regime or method of administration. The Enlarged Board of Appeal in G 02/08 ABBOTT RESPIRATORY/Dosage regime [2010] 10 OJEPO 456 confirmed earlier EPO case law in allowing second medical use claims to new and inventive dosage regimes, even where the substance or composition, and the disease to be treated, are the same as in the prior art. Second medical use claims which are distinguished from the prior art solely by the dosage regime used are therefore allowable if the claimed use is both new and inventive.
- 4A.28.3 As with first medical use claims, second medical use claims can only derive novelty from their intended use if the use is in a medical method excluded under s.4A(1), and so cannot be used to protect the new use of a known substance in, for example, a cosmetic method. Section 4A(4) is restricted to substances and compositions; apparatus cannot be so protected. In T 1099/09 it was held that second medical use claims can only be used to protect the use of a known substance or composition as an active agent. The use of a known substance or composition as an inactive carrier or excipient for a therapeutic agent cannot therefore be protected by a second medical use claim.
- AA.29 Second medical use claims to the further medical use of a substance or composition must be supported by evidence, in the application as filed, that the substance or composition is (or at least is likely to be) effective for the specified use. In *Prendergast's Applications* [2000] RPC 446, it was held that tests showing that the known substance or composition works in the proposed new circumstances are an essential part of the description if second medical use claims are to be adequately supported under s.14(5)(c). (Also see 14.152). This ensures that purely speculative second medical use claims are not allowed. However, Neuberger J emphasised that rudimentary tests would suffice and that full, detailed and rigorous testing of the drug for the proposed condition is not necessary. The requirement for some experimental support for second medical use claims was confirmed by the Patents Court decision in *El-Tawil's Application* [2012] EWHC 185, and so an objection of lack of support should be made if such evidence is lacking, or is only present for some of the claimed diseases. Nevertheless, a claim to a broader class of diseases may be justified if the applicant can show that it could reasonably be predicted from the demonstrated activity that the substance or composition will treat the diseases in question. In *Regeneron Pharmaceuticals*

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Inc v Genentech Inc [2012], EWHC 657 (Pat) (upheld at appeal [2013] EWCA Civ 93), it was held, on the facts of the case, that it was reasonable to predict that an anti-angiogenic effect demonstrated in tumours would also extend to non-cancerous diseases characterised by excessive angiogenesis (growth of new blood vessels into a tissue).

4A.29.1 The Patent's Court in <u>Hospira UK Ltd v Genentech Inc [2014] EWHC 1094</u> held that in order to establish a priority claim in the case of a second medical use invention, the earlier application must show that the claimed therapeutic effect is plausible. If this is not the case, then the earlier disclosure would not be considered enabling. Therefore, if a claimed priority application does not include any evidence beyond mere assertion of a therapeutic effect then the examiner should disregard this claimed priority date for the purpose of assessing novelty and inventive step (see 5.23.2).

4A.30 The court in American Home Products Corp. v Novartis Pharmaceuticals UK Ltd [2001] RPC 8 considered second medical use claims for the use of a known antibiotic (rapamycin) for the preparation of a medicament for inhibiting organ or tissue transplant rejection. The Court of Appeal reversed the lower court's decision and held that the claim did not cover derivatives of rapamycin - thus finding the claim not infringed by the use of a rapamycin derivative as an immunosuppressant. The court also noted that, had the claim been construed as covering derivatives, the patent would have been insufficient because there was no disclosure in the description enabling the skilled person to decide which of the many possible derivatives would have worked (see also 14.82- 14.84). Furthermore, the claim was held not to be infringed by the use of rapamycin to produce a derivative-based medicament, since this would require a wide construction of the term "medicament" in the claim (that is, to mean a medicament not restricted to one comprising rapamycin), and this would leave the claim hopelessly broad. The court also held that the claim was not infringed if rapamycin was present as an impurity in the derivative-based medicament, since there was no suggestion that at the quoted impurity levels the rapamycin had any effect.

4A.31 In Bristol-Myers Squibb Co. v Baker Norton Pharmaceuticals Inc. [2001] RPC 1, it was held that a second medical use claim directed to the manufacture of a medicament "for treating cancer" should be construed as "suitable for trying to treat cancer", since the skilled person would realise that drugs which are suitable for treatment will not always have a 100% success rate. However, drugs which are perceived as being suitable for treatment, but actually have no effect, do not fall within the scope of the claim because they are not, in fact, suitable. Where two or more substances are used together to treat a disease, then each falls within the scope of a second medical use claim for the use of that substance (Pfizer Ltd's Patent [2001] FSR 16 at paragraphs 40-43). However, the previous use of the compound purely as an inactive carrier or excipient for a therapeutic agent does not anticipate a second medical use claim, as held in T 1758/07. In Hospira UK Ltd v Genentech Inc [2014] EWHC 1094 it was further explained (at paragraph 56) that "for treatment of [disease Y]" means "suitable and intended for treatment" - this definition was considered to apply to claims both in the Swiss form and in the "product for use" form. As second medical use claims are construed as being limited to the intentional treatment of the disease, the fact that the prior art use of the substance to treat a different condition may have inherently treated or prevented the claimed disease in some patients does not constitute an anticipation if the prior art does not disclose the new therapeutic use.

In an interim decision, the Court of Appeal in <u>Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Ors [2015] EWCA Civ 556 held that "intended for" means that the manufacturer would know or could reasonably foresee that the product would be used for the claimed therapeutic method. In applying this test at the full trial (<u>Generics (UK) Ltd (t/a Mylan) v Warner-Lambert Company LLC [2015] EWHC 2548</u>) Arnold J held that this meant the manufacturer would know or could reasonably foresee that a doctor or pharmacist would intentionally prescribe or administer the manufacturer's drug for the claimed purpose. However, on appeal from this decision, the Court of Appeal (<u>Warner-Lambert Company v</u></u>

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<u>Generics (UK) Ltd (t/a Mylan) & Ors [2016] EWCA Civ 1006</u>) held that Arnold J's interpretation was too restrictive – instead, all that is required (to fall within the scope of the claim) is that the manufacturer could reasonably foresee that there would be intentional use of the drug for the claimed medical use.

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Section 5: Priority date

s.130(7)

5.01 This section is intended to have, as nearly as practicable, the same effect as the corresponding provisions of the EPC, PCT and CPC. Articles 87 and 88 and rule 53 of the EPC and Article 8 of the PCT appear to generally correspond to s.5. Relevant requirements are prescribed in rr.6 to 9. The principles of the section derive from Article 4 of the Paris Convention for the Protection of Industrial Property.

Section 5 was amended by the Regulatory Reform (Patents) Order 2004 (S.I. 2004 No. 3204) to incorporate the principles of Article 13 of the Patent Law Treaty. The amended section applies to applications made on or after 1 January 2005; for earlier applications, the provisions of section 5 prior to the Order coming into force apply. These earlier provisions are indicated in the text where they may be relevant to pending applications made before 1 January 2005.

Section 5(1)

For the purposes of this Act the priority date of an invention to which an application for a patent relates and also of any matter (whether or not the same as the invention) contained in any such application is, except as provided by the following provisions of this Act, the date of filing the application.

5.03 The priority date of all matter (whether claimed or not) in an application is, prima facie, the date of filing of the application. The onus is therefore on an applicant who wishes to claim an earlier priority date to comply with the specified conditions (see 5.04).

Section 5(2)

If in or in connection with an application for a patent (the application in suit) a declaration is made, whether by the applicant or any predecessor in title of his, complying with the relevant requirements of rules and specifying one or more earlier relevant applications for the purposes of this section made by the applicant or a predecessor in title of his and the application in suit has a date of filing during the period allowed under subsection (2A)(a) or (b) below, then-

- (a) if an invention to which the application in suit relates is supported by matter disclosed in the earlier relevant application or applications, the priority date of that invention shall instead of being the date of filing the application in suit be the date of filing the relevant application in which that matter was disclosed or, if it was disclosed in more than one relevant application, the earliest of them;
- (b) the priority date of any matter contained in the application in suit which was also disclosed in the earlier relevant application or applications shall be the date of filing the relevant application in which that matter was disclosed or, if it was disclosed in more than one relevant application, the earliest of them.

Section 5(2A)

The periods are-

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- (a) the period of twelve months immediately following the date of filing of the earlier specified relevant application, or if there is more than one, of the earliest of them: and
- (b) where the comptroller has given permission under subsection (2B) below for a late declaration to be made under subsection (2) above, the period commencing immediately after the end of the period allowed under paragraph (a) above and ending at the end of the prescribed period.

Section 5(2B)

The applicant may make a request to the comptroller for permission to make a late declaration under subsection (2) above.

Section 5(2C)

The comptroller shall grant a request made under subsection (2B) above if, and only if-

- (a) the request complies with the relevant requirements of rules; and
- (b) the comptroller is satisfied that the applicant's failure to file the application in suit within the period allowed under subsection (2A)(a) above was unintentional.
- 5.04 If the date of filing of an earlier application is to be treated as the priority date of some or all of the matter in an application in suit, the following conditions must be metr-
 - (a) a declaration must be made, and this must comply with the "relevant requirements" as set out in rr.6 and 7 (see 5.07-5.13);
 - (b) the earlier application should have a date of filing not more than twelve months earlier than that of the application in suit (see 5.18);
 - (c) an applicant can nevertheless request permission from the comptroller to make a declaration of priority in respect of an application filed within the period prescribed by r.7(1) (i.e. within two months of the expiry of 12 months from the date of filing of the earlier application) but such permission will only be granted when the request complies with r.7 and the comptroller is satisfied that failure to file the application within the 12 month period was unintentional (see 5.26.3-4);
 - (d) the earlier application must have been made by the same applicant as the application in suit or by his predecessor in title (see 5.19-19.2); and
 - (e) it must be a "relevant application" (see 5.30).

The earlier application must also be one which is not disregarded under the provisions of s.5(3) (see 5.27-5.28.5). However so long as it has a filing date, the outcome of the earlier application is not relevant, and it may serve to establish a priority date even if it is subsequently withdrawn or refused.

5.05 The priority date conferred by an earlier application cannot be earlier than the date on which it was filed, even if the authority with which it was filed has allowed it to be antedated, for example to the date on which it was shown at an exhibition (*La Soudure*

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Electrique Autogene SA's Application, 56 RPC 218).

5.06 Priority may be claimed from any number of earlier applications. So long as they are all "relevant applications" (see 5.30) there is no requirement that they should have been filed under the same national law or international agreement. However it should be remembered that the periods for complying with r.6 to 8 (see 5.08-5.12) are measured from the date of the earliest declared application (see 5.16), and that all necessary documents should be supplied within this period.

RELEVANT REQUIREMENTS

The Declaration

Where the earliest priority date to be claimed is not more than 12 months before date of filing of the application in suit

Where the earliest priority date to be claimed is not more than 12 months s.5(2A)5.07 before the date of filing of the application in suit, the declaration should be made at the r.6(1) r.6(4)time of filing. However, there are possibilities to make a declaration after filing the application (see 5.07.1). In all cases, the declaration must state the date of filing of the (or each) earlier application and the country it was filed in or in respect of. Such a declaration is made by completing the relevant part of Form 1. Errors or mistakes in declarations can be rectified by correction (see 117.19). In order for the earlier application to be uniquely identified, it is advisable to give the application number of that application at the earliest time that it is available although this information may be added later (see 5.08)

If a declaration is not made at the time of filing, it can be made (or another declaration can be added) at any time up to sixteen months after the earliest r.6(3)PR Sch. 4. priority date claimed provided that the declaration is made on a Form 3 accompanied by Part 1 the prescribed fee and a request to publish the application under section 16(1) has either not been made or any such request was withdrawn before the preparations for publication of the application had been completed. This sixteen month period cannot be extended. The provisions allowing a declaration of priority to be made later than the filing date only apply to applications filed on or after 1 January 2005.

> Where the earliest priority date to be claimed is more than 12 months before date of filing of the application in suit

- s.5(2A)(b) 5.07.2 An applicant may request permission to make a declaration of priority in s.5(2B) respect of an application filed in the two months following the expiry of the period r.7(1) specified in s.5(2A)(a) but the comptroller shall only grant such permission if:-
- s.5(2C)(a) (a) the permission is requested in accordance with rules, and
- s.5(2C)(b) the comptroller is satisfied that failure to file the application within the time (b) specified in s.5(2A)(a) was unintentional (see 5.26.4), and
- r.7(8)either there is no request for accelerated publication under section 16(1), or if a request for accelerated publication was made, it was withdrawn before the preparations for publication were completed.
- r.7 5.07.3 Except for the situation set out in 5.07.4, the request must be made on PR Sch. 4 Form 3 and must be filed before expiry of the two month period prescribed in r.7(1), which Part 1 cannot be extended. The declaration must be made at the time of filing the request and the reason why the application was not filed within the period allowed by s.5(2A)(a) must be stated. Evidence supporting that reason must also be provided. Where that evidence does not accompany the request, the Comptroller must specify a period within which the evidence must be filed. Where an international application has entered the national

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r.6(2)

phase, a request may be made under s.5(2B) within one month of the date the national phase of the application begins.

r.7(4) 5.07.4 If, however, the application in suit is a new application filed under section r.7(6) 8(3), 12(6) or 37(4) or as mentioned in section 15(9), the request may be made in writing instead of on Patents Form 3, no evidence need accompany the request, and both the new application and the request may be made after the end of the two-month period prescribed in r.7(1) but must be made on the same date.

Priority documents

Certified copies

r.8(1)-(2) 5.08 The application number of the priority application must be supplied within sixteen months (extendable in accordance with r.108(2) or (3), see 123.34-42) of the r.8(5)declared priority date. Moreover, except in the circumstances referred to in paragraph r.21 5.09, a copy of the earlier application, either certified by the authority with which it was PR Sch. 4 filed or otherwise verified to the satisfaction of the comptroller, should also be supplied within this period. Where the application claims an earlier date of filing, these conditions should be complied with within two months of the date of filing (or later in accordance with an extension under r.108(2) or (3) and (4) to (7), see 123.34-41) if the sixteen month period has already expired (but see 5.09), except if the new application is filed less than six months before the compliance date, in which case these conditions should be complied with on the filing date (extendable under r.108(2) or (3) and (4) to (6)). In the case of a divisional application the sixteen month period is automatically extended if that period has been extended in respect of the earlier application. Failure to comply with these conditions within the prescribed period cannot be rectified under s.117 (Klein Schanzlin & Becker AG's Application [1985] RPC 241, see 117.01).

- r.8(3)

 5.09

 However, if an application specified in the declaration is an application for a patent under the Act, an international application for a patent which was filed at the Office, or any other application of which a copy has been filed pursuant to a declaration of priority in respect of another application under the Act, then, under r.112 any necessary certified copy will be prepared in the Office without the applicant having to request it or pay any associated fee. If the earlier application has been withdrawn or treated as withdrawn, documents may be transferred to serve as priority documents for the application in suit (see 15A.18). In all cases, the applicant should inform the Office of the number of the file on which the earlier application is to be found.
- r.8(4) 5.10 Where the application in suit is an international application for a patent r.8(5) (UK), the requirements referred to in 5.07 and 5.08 are regarded as having been complied with to the extent that the requirements of r.4.10(a) and (b), subject to rules 26bis.1 and 26bis.2(b), and of rule 17.1 of the PCT have been fulfilled. (A copy of the priority documents is supplied to the Office by the International Bureau). Likewise if the application is one converted from a European application under s.81, these conditions are treated as having been met to the extent that r.52 and 53 of the EPC have been complied with.

Translations

Applications filed on or after 1 January 2005:

r.9 5.11 Translations of foreign-language certified copies of priority applications (or declarations that the application in suit is a complete translation into English of the priority application) will only be required where the matters disclosed in the earlier application are relevant to the determination of whether or not an invention, to which the application in suit relates, is new or involves an inventive step. Where an examiner considers that a translation is necessary, a direction will be issued to the applicant and a period for complying with the direction will be specified. The period is extendable under s.117B and r.109. Failure to comply with a direction will result in the declaration made for

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the purposes of s.5(2) being disregarded.

r.115

5.12 There is no requirement for any translation filed in response to a direction of the comptroller under r.9(1) to be verified. Where there is a genuine doubt with respect to the accuracy of a translation the comptroller may notify the applicant of the reasons for his doubts and require evidence to establish the accuracy of the translation.

Applications filed before 1 January 2005:

PR r.6(6) RRO)	 5.13	[deleted]
	5.13.1	[deleted]

. .

5.13.2 [deleted]

Loss of priority

5.14 If any of the requirements of rr.6-9 are not met in respect of an application declared for priority purposes, then the declaration is invalid in respect of that application and any rights which would have derived from it are lost. If (but only if) preparations for publication have not yet been completed, the declared priority date may be affected (see 5.16).

DECLARED PRIORITY DATE

- s.130(1)
- 5.15 "Priority date", as used in the Act, is defined in s.130(1) as "the date determined as such under section 5", and is a property ascribed to the invention(s) and other matter contained in an application but not to the application itself. Instead the term "declared priority date" of an application is defined (in r.3); this date confers no rights, but serves only as a "marker" from which various time limits are measured. It may be noted that while the contents of an application may have several priority dates (one of which may be the filing date), an application can only have one declared priority date, and may have none (in which case prescribed periods are measured from the filing date).
- r.3 In the case of an application made under the Act, "declared priority date" means the date of filing of the earliest relevant application specified in a declaration made for the purposes of s.5 where the date has not been lost or abandoned, or the declaration withdrawn, before the completion of preparations for publication. Thus for example if a certified copy of the (or the earliest) declared application is not supplied within the prescribed period (see 5.08), then not only is the priority date claimed from that application lost, but also, since the application in suit will necessarily not yet have been sent for publication, that date will cease to be the declared priority date; its place is taken by the next earliest declared application or, where there is none, the filing date, and time limits and dates, including the date when publication is due, are reckoned from this new date. On the other hand, where a translation is required and it (or a declaration that the application in suit is a complete translation into English of the priority application) is not filed within the specified period (see 5.11-5.13.1), then although this will result in the priority claim being disregarded, if (as will generally be the case) this takes place after completion of preparations for publication, the declared priority date will remain unchanged.
 - 5.17 Similarly, the declared priority date of an international application is the earliest priority date which has not been lost or abandoned under the provisions of the PCT, i.e. before entering the national phase (see 89A.04). And in the case of a converted European application it is the earliest priority date still extant when the comptroller directs under s.81 that it be treated as an application under the Act.

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PERIOD FOR CLAIMING PRIORITY

In accordance with Article 4C of the Paris Convention, priority may be claimed from an earlier application if the application in suit has a date of filing not more than twelve months later than that of the earlier application, and this is reflected, via s.5(2), in s.5(2A)(a). However if this period expires on an excluded day or on a day which is certified as one on which there was an interruption under r.110(1) (see 123.43) then the period is extended to include the first following day which is not excluded or certified. The period may also be extended under r.111 in particular cases affected by a failure or undue delay in a communication service (see 123.46-47). The period may also be extended under r.107 in particular cases where the circumstances of r.107(3) exist (see 123.06-10). In no other circumstances may the twelve months period be extended – although in limited circumstances it is possible for the date of filing of the application in suit to be outside the twelve months period; see 5.07.2 to 5.07.3, and 5.26.2 to 5.26.4.

THE APPLICANT

- 5.19 For priority to be claimed, the person making the application in suit must either be the same person who made the earlier application or must be his successor in title. Furthermore, for priority to be claimed in the circumstances where the earlier application has more than one applicant, the application in suit must be made by all of the same applicants, or their successor(s) in title. It is not sufficient if the application in suit is made by only one or some of the earlier applicants, as confirmed by the Patents Court in Edwards Lifesciences AG v Cook Biotech Inc [2009] EWHC 1304 (Pat); [2009] FSR 27.
- 5.19.1 Where the applicant of the application in suit is not the applicant of the earlier application, the applicant for the application in suit must have acquired from the earlier applicant (or applicants) the right to be granted a patent, for example by virtue of employment or by assignment. It does not matter if the original applicant retains some rights in the earlier application he may for instance have assigned the rights to some only of the matter contained in that application, or have assigned only the right to apply in certain countries so long as he has transferred to the present applicant the right to be granted a patent on the application in suit. In order for the declaration of priority to be valid at the time it is made, i.e. at the time of filing the application in suit, the transfer must already have taken place. This was also confirmed in *Edwards Lifesciences v Cook Biotech*.
- In KCI Licensing Inc & Ors v Smith & Nephew Plc & Ors [2010] EWHC 1487 (Pat); Arnold J considered whether an application having two applicants could validly claim priority from an earlier application made by only one of those applicants, where no formal assignment of priority rights had been made. He concluded that the circumstances surrounding the filing of the later application inferred that the earlier applicant had agreed by conduct to transfer part of their interest in the invention to the second applicant, and that was sufficient to make the second applicant a successor in title for the purposes of claiming priority. It follows that, where an application names a further applicant (or applicants) in addition to the applicant(s) named on a priority application, a formal assignment may not necessarily be required for the priority claim to be valid.

PRIORITY DATE OF INVENTION OR OTHER MATTER

5.20 The test for deciding whether an invention is supported and sufficiently described by matter disclosed in an earlier application is basically the same as that for deciding whether a claim of a specification is supported and sufficiently described by the description (see 14.60-14.104 and 14.142-14.156).

s.130(3) 5.21 As Article 4H of the Paris Convention makes clear, it is not necessary

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- s.125(2) that the invention be found in the claims of the earlier application. In order to determine whether there is support for an invention or other matter in the earlier application, everything claimed or disclosed (other than by way of disclaimer or acknowledgement of prior art) in the earlier application may be taken into account (see 14.171.1 for practice relating to what is included in an abstract). Support may not however be derived by combining the teaching of separate applications unless one of them contains directions to do so.
 - 5.22 The priority date of a feature or combination of features is the date of the earliest application whose disclosure supports that feature or combination and if different ways of putting an invention into practice were disclosed at different dates, they will have different priority dates, even if they are covered by a single claim.
 - 5.23 The earlier application must disclose the particular combination of features which make up the invention and also provide an enabling disclosure of that invention (Asahi Kasei Kogyo KK [1991] RPC 485). Thus, in Biogen Inc v Medeva Plc [1997] RPC 1 it was confirmed that the same test for sufficiency of disclosure applies whether directed to an earlier application for determining whether a claim is entitled to a priority date or to the description of the application or patent in suit under sections 14(3) and 14(5)(c). The Court of Appeal adopted this approach in Pharmacia Corp. v Merck & Co. Inc. [2002] RPC 41, in which it was held that the technical contribution to the art contained in the earlier application must justify the claimed monopoly in the application in suit, with the result that the earlier application contains sufficient disclosure to constitute an enabling disclosure across the entire width of the claim. In the case in question, the application in suit claimed a narrower range of compounds than that disclosed in the earlier application. The court held that the priority claim was not supported, since the earlier application did not provide an enabling disclosure concerning the technical contribution to the art made by selecting the subclass of compounds claimed in the application in suit.
 - 5.23.1 In Hospira UK Generics (UK) Ltd (t/a Mylan) v Novartis AG [2013] EWCA Civ 1663 the Court of Appeal held that claim 7 of the Novartis patent was not entitled to priority because the disclosure of the priority document was either too broad or too specific. Claim 7 contained features relating to a drug for the treatment of osteoporosis, an intravenous mode of administration, a dosage size of about 2-10 mg and a dosing interval of about once a year. Although the priority document contained a passage disclosing "2-10 mg once a year", it did not tell the reader that this dosage range would be suitable no matter what condition was being treated or mode of administration was used. The passage instead suggested that, dependent on the method of administration and condition being treated, some doses within the given range may be suitable. The priority document also contained an example (example 5) specific to intravenous administration which showed that 4 mg, once a year was effective in treating post-menopausal osteoporosis. Example 5 did not however teach anything about other doses at that dosage interval and so the other doses claimed were not supported by the disclosure in this example.
 - 5.23.2 In *Evans Medical Ltd's Patent* [1998] RPC 517, Laddie J held that what is important is what the document teaches, not how the contents got there, saying "if an inventor through clever foresight or lucky guess work describes something which works and how to do it, his disclosure is enabling". Nevertheless, in a case relating to a second medical use invention, the Patent's Court in *Hospira UK Ltd v Genentech Inc* [2014] EWHC 1094 held that the earlier application must show that the claimed therapeutic effect was plausible. If this was not the case, then the earlier disclosure could not be considered enabling (see 4A.29.1).
 - 5.23.3 In <u>Unilin Beheer BV v Berry Floor NV [2004] EWCA (Civ) 1021</u>, Jacob LJ held that the approach to determining priority is not formulaic, it is a question about technical disclosure, explicit or implicit. The question is whether there is enough in the priority document to give the skilled person the same information as is in the subject of the claim and enables them to work the invention in accordance with that claim. He goes

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on to say that a priority document should contain the information that justifies the later claim irrespective of whether it is expressed in a claim, consistory clause, statement of invention, other text or drawing or in any combination of these. In this case it was submitted that the priority document disclosed three features, A+B+C, in combination. It was therefore argued that a claim to one of those features, without the other two, cannot have priority. However, the judge rejected this argument, noting "that when features A+B+C are disclosed, a lot must turn on what they actually are. Some inventions consist of a combination of features – the invention consists in the very idea of putting them together. In other cases that is simply not so – the features are independent one from the other. Whether, given a disclosure of A+B+C, there is also a disclosure of A or B or C independently depends on substance, not a formula. The ultimate question is simply whether the skilled man can derive the subject-matter of the claim from the priority document as a whole."

- The criteria to be applied can be said to be similar to those used to decide whether a claim is anticipated by the disclosure of an earlier document (see 2.03-2.20). Thus if a priority document is silent about any essential element for which a patent is sought, the right to priority cannot generally be established. In particular, if a claim in a priority document is broad enough to cover a particular specific technical feature, it does not follow that it discloses that feature for the purpose of claiming priority. On the other hand, a feature which would necessarily be present when the teaching of the earlier application is put into practice may be treated as having been disclosed by implication (c.f. 2.07). In *Letraset Ltd v Rexel Ltd* [1974] RPC 175 at pages 195-7, a claim which included the feature that adhesion between indicia and a carrier sheet was breakable by local stretching of the sheet was held to be fairly based on a provisional specification which was silent on this feature, since it was in fact something which could be shown to happen when the material described in the provisional specification was made and used.
- 5.25 This approach is also consistent with the Opinion of the Enlarged Board of Appeal in Requirement for claiming priority of the "same invention" [2002] EPOR 17 (G 2/98), in which it was held that implicit disclosure in the earlier application may be taken into account, so that a priority claim is valid if the skilled person can derive the subject matter of the claim of the application in suit "directly and unambiguously, using common general knowledge, from the previous application as a whole". This would appear to be consistent with the earlier decision in Biogen/Human beta-interferon [1999] EPOR 451 (T207/94), in which it was held that the disclosure of the earlier application was enabling in respect of the claims of the later application, despite the fact that the disclosure would have required a non-negligible amount of work on the part of the skilled person to achieve the invention as claimed in the later application. This was acceptable since the work required by the skilled person would have been quite feasible given the existing state of the art. Nevertheless, the criteria for assessing a valid priority claim are not identical to those used when considering anticipation. As the Enlarged Board concluded in G2/98, priority can only be validly claimed where the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole. However it is also possible for a single claim to set out a number of alternative subject matters (an "OR"-claim) which may each be entitled to different priority dates – see below.
- 5.25.1 A claim in a patent application can have multiple priority dates, see 125.08. In *Novartis AG v Johnson & Johnson* [2009] EWHC (Pat) 1671, Kitchin J referred to G 2/98 and said that different priority dates can be assigned to different parts of a patent claim where those parts represent a limited number of clearly defined alternatives and those alternatives have been disclosed by different priority documents. This is known as partial priority.
- 5.25.2 In <u>Nestec SA & Ors v Dualit Ltd & Ors [2013] EWHC 923 (Pat) the claims of a patent were held to lack novelty over the disclosure of the document from which it claimed priority. In this case the claims of the patent were found not to be entitled to the claimed priority date, as they covered a whole range of different arrangements (i.e. not a limited number of clearly defined alternatives) some of which were not disclosed in the</u>

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priority document. The earlier document was published, thereby forming part of the state of the art under s. 2(3), and anticipated the claims of the patent (see 5.26, 15.22). This situation is sometimes referred to as 'poisonous priority'. It is important to note that this situation can also arise when the state of the art is not the priority document itself but a published application sharing a priority claim, for example in a divisional application (see 15.22).

5.25.3 This issue of partial and poisonous priority was considered by the EPO Enlarged Board of Appeal in G 01/15. In its decision, the EBA concluded that, where claims are generalised, they may be conceptually divided into two parts corresponding to that aspect which was disclosed in the priority application and is entitled to partial priority, and that aspect which was not disclosed and is not entitled to priority. Following this decision, the previous requirement (arising from G 02/98) that a claim must provide a "limited number of clearly defined alternative subject-matters" to be allowed partial priority, no longer applies at the EPO. Decisions of the Enlarged Board of Appeal are not binding on UK courts, although they are persuasive (see 0.09), so it remains to be seen whether the UK courts adopt this approach or continue with the approach set out in *Nestec* above. In the meantime, examiners remain bound by, and must therefore follow, the approach in *Nestec* above.

EXAMINATION OF CLAIM TO PRIORITY

Application filed within 12 months of earliest priority date claimed

Declaration made at the time of filing

r.6(1) r.24(1) r.6(4)

r.6(5)

r.23

5 26 Where the declaration of priority is made at the time of filing of the application in suit, the formalities examiner must determine during the preliminary examination whether the requirements of r.6 to 9 have been met and whether any priority date claimed is more than twelve months before the filing date of the application in suit; any other discrepancies noticed in the declaration or the priority documents should be reported at this stage (see 15A.13-15A.17). In general no comment should be made on the content of the earlier application, except that the applicant should be informed if it is so different from the application in suit that it appears likely that he has declared and/or filed the wrong earlier application. The question of whether the invention is supported by matter disclosed in the earlier application should be considered only when this is necessary in order to determine whether or not a given document forms part of the state of the art (see 18.15-18.17). Examiners should be aware that if the declaration of priority is found invalid the priority document itself, if published, may form part of the state of the art (see 5.25.2). Even if it is found that an invention is not supported by an earlier application, the "declared priority date" should remain unchanged (see 5.15).

Declaration made after time of filing

5.26.1 Where a declaration is made or added after the date of filing of the application in suit, the formalities examiner must ensure the Form 3 was filed within the sixteen month period prescribed in r.6(2)(b), that option (ii) on part 4 of the Form has been correctly indicated, and that the application has not already been published. If the applicant requested accelerated publication but the preparations for publication have not yet been completed, the publication cycle should be suspended and the applicant given the opportunity to withdraw the request to enable the priority declaration to be accepted. The criteria are otherwise as given in 5.20-25 above, and, if the declaration is validly made, the priority date must be recorded and other dates recalculated as necessary.

Application filed more than 12 months after earliest priority date claimed

r.7 5.26.2 Whenever permission to make a late declaration of priority is made on a Form 3, the formalities examiner must check:-

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- (a) that option (i) is correctly indicated on part 4 of the Form;
- (b)(i) that for domestic applications both the request and the application in suit were filed before expiry of the two-month period prescribed in r.7(1) (unless the application in suit is a new application filed under section 8(3), 12(6) or 37(4) or as mentioned in section 15(9), in which case see 5.07.4;
- (b)(ii) that for PCT applications, the application in suit was filed before expiry of the two-month period prescribed in r.7(1) and the request was filed within one month of entry into the national phase;
- (c) that the reason for failing to file the application within the period specified in s.5(2A)(a) is entered into part 5 of the Form and is supported by evidence;
- (d) that the declaration has been correctly made in part 6 of the Form.
- 5.26.3 Where a request is correctly made in compliance with rules and the comptroller is satisfied that the failure to file the application in suit within the period allowed by s.5(2A)(a) was unintentional, he shall grant the permission and treat the declaration as valid. The priority date should be recorded and other dates recalculated as necessary, but the date of filing of the application in suit will remain the date on which it was actually filed.
- 5.26.4 There is no definition in the Act or rules as to what is meant by "unintentional" as stated in section 5(2C)(b) in determining whether to allow a request for permission to make a late declaration of priority under section 5(2B). In Abaco Machines (Australasia) Pty Ltd's Application [2007] (CH/2006/APP/0827) Lewison J held that an intention to file a PCT application was not an intention to file the "application in suit", which the judge expanded by way of the meaning given to "application in suit" in section 5(2) of the Act and the definition of "application" provided by section 130(1) of the Act to read "an application for a patent under this Act". In the similar case of Sirna Therapeutics Inc's Application [2006] RPC 12, the hearing officer held that the unintentional failure by the applicant to file the application within twelve months of the earliest priority date must however relate to the application in suit in its entirety and not merely a failure to file the subject matter of the application. As in the case of Abaco this case involved a request for late declaration of priority which was refused as the application that was unintentionally not filed was a PCT application and there was no intention to file the application in suit within the twelve-month priority period. The hearing officer observed that the requirement to show an intention to file an application in time differed from the test of "continual underlying intention to proceed" as held in Heatex Group Ltd's Application [1995] RPC 546 when exercising discretion under rule 110(4) of the Patents Rules 1995, which is equivalent to rule 108(3) under the Patents Rules 2007 (see 123.37), but case law under this rule may be of relevance in analysing the evidence to establish the applicant's intentions.
- 5.26.5 Sirna Therapeutics Inc's Application [2006] RPC 12 and Anning's Application (BL O/374/06) established that the "continual underlying intention" test in Heatex is not applicable in determining the meaning of the word "unintentional" (in section 5(2B) or section 20A).
- 5.26.6 In *Matsushita Electric Industrial Co. v Comptroller General of Patents* [2008] EWHC 2071 (Pat), which concerned a request for restoration under s.28, Mann J gave some guidance on the level of evidential burden required to "satisfy" the Comptroller that the failure in section 28(3) was "unintentional". The applicant in that case chose not to file any evidence beyond a bald assertion of the statutory test that the failure to pay the renewal fee on time was unintentional. It argued that that was all the statute required to satisfy the comptroller. It was held by the Judge that a mere assertion that the failure to pay the renewal fee was unintentional is not sufficient to enable the Comptroller to determine that the requirements of s.28(3) are fulfilled. He said:

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- "...the Act requires a judgment to be formed by the Comptroller so that he can be satisfied of the relevant matters. A judgment usually has to be made on the basis of evidence... The evidence required in any particular case where satisfaction is required depends on the nature of the enquiry and the nature and purpose of the decision to be made... A significant matter requires significant proof. I repeat, the Act does not require a statement that the failure to pay fees was unintentional. It requires the Comptroller to be satisfied of that fact."
- 5.26.7 It is clear from this judgment that while there is no universal rule as to what level of evidence has to be provided to satisfy the comptroller of the unintentional lapse in section 28(3), and by implication in sections 5(2B) and 20A, some evidence is required above and beyond a bald assertion that the statutory test has been met.

Section 5(3)

Where an invention or other matter contained in the application in suit was also disclosed in two earlier relevant applications filed by the same applicant as in the case of the application in suit or a predecessor in title of his and the second of those relevant applications was specified in or in connection with the application in suit, the second of those relevant applications shall, so far as concerns that invention or matter, be disregarded unless -

- (a) it was filed in or in respect of the same country as the first; and
- (b) not later than the date of filing the second, the first (whether or not so specified) was unconditionally withdrawn, or was abandoned or refused, without -
 - (i) having been made available to the public (whether in the United Kingdom or elsewhere);
 - (ii) leaving any rights outstanding; and
 - (iii) having served to establish a priority date in relation to another application, wherever made.
- 5.27 Subsection (3) derives from Article 4C(4) of the Paris Convention and deals with the situation where two (or more) earlier applications both contain the subject matter of the application in suit. The effect of the subsection is that, in most circumstances, the priority date of the subject matter in question is established by the earliest previous application containing that matter. However, the subsection goes on to provide an exception to that position, by which a second (or subsequent) earlier application can be used to establish the priority date of that matter. This exception only applies when certain specific conditions have been met regarding the earlier applications.
- 5.28 The specific conditions which must be met in order for the application in suit to use the second (or subsequent) earlier application as the basis for a priority claim are derived directly from Article 4C(4) Paris Convention, and are as follows:
 - (a) the second application was filed in or for the same country as the first application, and
 - (b) at the date of filing of the second application, the first application had been unconditionally withdrawn, or abandoned or refused, had not been published, and did not leave "any rights outstanding", and
 - (c) at the date of filing of the second application, the first application had not been used for priority purposes for any other application.

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- 5.28.1 Article 4C(4) goes on to make clear that, once these conditions have been met, the first application cannot be used subsequently as a basis for claiming priority. The effect of meeting these conditions is therefore that the first application is entirely disregarded, and the second application can legitimately be used as a basis for claiming priority and as the starting point of the 12 month priority period (see 5.18). Withdrawing the first application and filing a second application while meeting these conditions is often referred to as "regenerating the priority date".
- An applicant who files a second application and wants to use it for priority purposes must therefore ensure that the first application has not been published or used to form the basis of a priority claim. He must also ensure that, at the time of filing the second application, the first application has been withdrawn, abandoned or refused "without leaving any rights outstanding". On an application that has been refused by a decision of the comptroller, an outstanding right may be the right to appeal that decision, or the right to request reinstatement of the application under section 20A (see 20A.02 to 20A.07). On an abandoned application (i.e. one that is treated as refused or withdrawn), the right to request reinstatement under section 20A may again be an outstanding right. On a withdrawn application, an outstanding right may be the right to request correction of an erroneous withdrawal under section 14(10) and section 117 (see 14.209 and 117.22.1).
- 5.28.3 In order to regenerate the priority date successfully, the applicant therefore needs to ensure that any such outstanding rights on the first application have explicitly been given up at or before the date of filing of the second application. For example, the applicant may make an explicit statement, on withdrawing the first application, that the withdrawal is done "without leaving any rights outstanding". Making such a statement leaves open the possibility of filing a second application later and using it as the priority application. However, the statement would also seem to rule out the possibility of later making a request to correct the withdrawal of the first application. Another example may be where the first application has been treated as withdrawn. If the applicant wishes to regenerate the priority date, he will need to make clear (at or before filing the second application) that no rights are being left outstanding on the first application. Again, such a statement would seem to rule out the possibility of later making a request to reinstate the first application.
- 5.28.4 If the conditions for regenerating the priority date have not been met, and the application in suit is filed too late to use the first application as a basis for claiming priority (see 5.18), then the application in suit will not be able to use either the first or the second application as a basis for claiming priority of the subject matter in question. The effect is that the priority date of that subject matter, contained in both the earlier applications, is the filing date of the application in suit. If either of the earlier applications has been published then that matter will also form part of the state of the art with respect to the application in suit.
- 5.28.5 Section 5(3) is only concerned with subject matter which appears in both the first and second earlier applications. Therefore, it does not rule out the possibility that the application in suit may legitimately claim priority from both the earlier applications. For example, the two earlier applications may contain different subject matter, all of which is relevant to the application in suit. Alternatively, the two earlier applications may share matter, but the second earlier application may contain further matter relevant to the application in suit, which is not present in the first application. The fact that the second application contains matter which is also present in the first application does not affect the legitimate use of the first application to establish the priority date for this matter.

Section 5(4)

The foregoing provisions of this section shall apply for determining the priority date of an

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invention for which a patent has been granted as they apply for determining the priority date of an invention to which an application for that patent relates.

The priority date of an invention in a specification is therefore determined 5.29 in the same way regardless of whether the specification forms part of an application or of a granted patent.

Section 5(5)

In this section "relevant application" means any of the following applications which has a date of filing, namely -

- an application for a patent under this Act; (a)
- (aa) an application in or for a country (other than the United Kingdom) which is a member of the World Trade Organisation for protection in respect of an invention which, in accordance with the law of that country or a treaty or international obligation to which it is a party, is equivalent to an application for a patent under this Act;
- an application in or for a convention country (specified under section 90 below) for protection in respect of an invention or an application which, in accordance with the law of a convention country or a treaty or international convention to which a convention country is a party, is equivalent to an application for a patent under this Act.
- 5.30 Priority may be claimed only from a "relevant application", which must be:
- ss.78,89
- an application for a patent under the Act, including a European or International application designating the UK,
 - an application for protection for an invention filed in a country which is a member of the World Trade Organisation (WTO), or
 - an application for protection for an invention which was filed either under (b) the laws of a convention country (see 90.02-90.03) or under the PCT or EPC (designating a country other than the UK) or some other international agreement to which a convention country is a party.
 - s.130(7)What constitutes "protection for an invention" is not specified in the Act; however s.5 is intended to have the same effect as the corresponding provisions of the EPC, and it appears likely that the term is restricted to the kinds of application referred to in Art.87(1) EPC, which allows priority to be claimed only from an application for a patent, for the registration of a utility model (e.g. German Gebrauchsmuster), for a utility certificate or for an inventor's certificate. During pre-grant proceedings in the Office no objection should be raised to a claim to priority based on a US provisional patent application (notice in Official Journal (Patents), 31 January 1996). Such a provisional application is valid in the USA as a priority document for a subsequent patent application and expires after one year. Following a change in US law in 1999, a provisional application can be converted into a full US patent application within one year of filing. UK practice as it relates to US provisional applications would have to be reviewed if doubt were to be cast upon it in any proceedings before the courts or the comptroller. An application for a registered design is not a relevant application (Agfa-Gevaert AG's Application, [1982] RPC 441).

Section 5(6) [Repealed]

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- 5.31 Section 5(6) was added by the Patents and Trade Marks (World Trade Organisation) Regulations 1999 with effect from 29 July 1999, with the aim of enabling WTO member countries to be automatically treated as convention countries. However, an Order in Council was still needed to declare such WTO member countries as convention countries.
- 5.32 Section 5(5)(aa) was inserted and section 5(6) was repealed on 1 October 2014 by the Intellectual Property Act 2014, with the effect that from 1 October 2014 an application filed in or for a country which is a member of the WTO is automatically treated as a "relevant application".

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Section 6: Disclosure of matter, etc, between earlier and later applications

Section 6(1)

It is hereby declared for the avoidance of doubt that where an application (the application in suit) is made for a patent and a declaration is made in accordance with section 5(2) above in or in connection with that application specifying an earlier relevant application, the application in suit and any patent granted in pursuance of it shall not be invalidated by reason only of relevant intervening acts.

Section 6(2)

In this section -

"relevant application" has the same meaning as in section 5 above; and

"relevant intervening acts" means acts done in relation to matter disclosed in an earlier relevant application between the dates of the earlier relevant application and the application in suit, as for example, filing another application for the invention for which the earlier relevant application was made, making information available to the public about that invention or that matter or working that invention, but disregarding any application, or the disclosure to the public of matter contained in any application, which is itself to be disregarded for the purposes of section 5(3) above.

6.01 This is an avoidance of doubt section and is based on the wording of Arts. 4A and 4B of the Paris Convention. The section confirms the provisions of ss.2, 3 and 5 that if an invention in an application in suit is entitled for priority to the filing date of an earlier application specified in a declaration of priority under s.5(2) then any disclosure or use of matter contained in that earlier application on or after the filing date of the earlier application cannot invalidate a claim to that invention.

6.02 In *Beloit Technologies Inc v Valmet Paper Machinery Inc* [1995] RPC 705 Jacob J held that s.6(1) does not carve out from the state of the art matter made available to the public in the priority interval just because that matter is in the priority document. Thus, an invention which is not entitled to the priority date of an earlier application can be invalidated by the disclosure or use, between the filing dates of the earlier application and the application in suit, of matter contained in the earlier application.

In his judgment in *Beloit Technologies* Jacob J reached the same general conclusions as the Enlarged Board of Appeal (G3/93 OJEPO 1-2/1995) which considered the implications of a document published during the priority period, the technical content of which corresponds to that of the priority document, and concluded that the published document constitutes prior art citable against the application claiming priority from the priority document to the extent that such priority is not validly claimed. This also applies if a claim to priority is invalid due to the fact that the priority document and the subsequent application do not concern the same invention because the application claims subject matter not disclosed in the priority document.

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RIGHT TO APPLY FOR AND OBTAIN A PATENT AND BE MENTIONED AS INVENTOR

Section 7: Right to apply for and obtain a patent

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Any person may make an application for a patent either alone or jointly with another.

7.01 The status of a properly-launched application (see 15.02-15.06) is not impugned if it subsequently transpires that the applicant has no right to the grant of a patent or that he only acquired the right after making the application.

7.02 The term "person" includes one or more individuals or a corporate body but not a firm, partnership or body which is unincorporate, although in such cases application may be made by individual partners jointly. In the case of a limited partnership, the application may be in the names of all personally responsible partners (see also 7.05).

7.03 The following are regarded as corporate bodies:-

British companies limited by guarantee;

Cooperative Societies (Home and Foreign);

Euratom and similar international organisations;

Foreign States;

Limited liability partnerships (LLP) in the UK;

Ministers and other Heads of Government Departments (Home and Foreign);

Trade Associations (on evidence of incorporation);

Universities.

See 32.06 with regard to the effect of re-registration as a p.l.c and conversion to LLP.

7.04 The following are examples of foreign companies regarded as corporate bodies by whom applications may be made:-

Akciova spolecnost

Aktiebolag, Aktiebolaget

Aktiengesellschaft (A.G.)

Aktieselskab, Aktieselskabet, Aktieselskapet

Arbeitsgemeinschaft

Besloten Vennootschap met beperkte aansprakelijkheid (B.V)

Eingetragene Genossenschaft

Eingetragenen Verein

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Gesellschaft mit beschrankter Haftung (G.m.b.H)

Gewerkschaft

Handelsbolag

Handelsvenootschap

Kabushika Kaisha

Kollektivgesellschaft

Kommanditbolag

Kommanditgesellschaft auf Aktien

Naamlooze Vennootschap (N.V.)

Reszveny-tarsasag

Sociedad anonima

Sociedad Limitada

Societa Anonima

Societa per Azioni (S.p.A.)

Societe Anonyme

Societe a responsibilite limitee

Societe en commandite par actions

Societe en commandite simple

Societe en nom collectif

Versicherungsverein auf Gegenseitigkeit.

An application by a German or Austrian "Kommanditgesellschaft", "offene Handelsgesellschaft" or a Swiss "Societe Commandite", may be made in the names of the responsible partners. Following a decision by the Patents Appeal Tribunal (Schwarzkopf's Application, [1965] RPC 387) an application made in the names of one of these bodies is also allowed to proceed, but such a course is at the risk of the applicants should their representations thereafter be found to be false. Consideration will be given to other foreign firms if it is affirmed by the applicant or agent, that under the laws of the foreign state in question, such firms can acquire title to land and property in their own name, such title being wholly unaffected by changes in the personnel of the members. A Scottish partnership firm may apply in its own name, the partners' names being given. Applications may also proceed in the name of a limited partnership organised under the laws of the American state of Arkansas, California, Connecticut, Delaware, Illinois, Louisiana, Michigan, Minnesota, Missouri, New York, Ohio, Pennsylvania , Tennessee, Texas or Wyoming. In Canada, limited partnerships may be incorporated either federally or provincially. In the latter case, the name of the province (e.g. Quebec, Ontario) should be given as the state or incorporation.

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Section 7(2)

A patent for an invention may be granted -

- (a) primarily to the inventor or joint inventors;
- (b) in preference to the foregoing, to any person or persons who, by virtue of any enactment or rule of law, or any foreign law or treaty or international convention, or by virtue of an enforceable term of any agreement entered into with the inventor before the making of the invention, was or were at the time of the making of the invention entitled to the whole of the property in it (other than equitable interests) in the United Kingdom;
- (c) in any event, to the successor or successors in title of any person or persons mentioned in paragraph (a) or (b) above or any person so mentioned and the successor or successors in title of another person so mentioned; and to no other person.
- The right to grant of a patent belongs primarily to the inventor, but this may be overridden by any rule of law or any legally enforceable agreement existing at the time the invention was made. The commonest way in which this proviso would cause the rights to pass from the inventor is when the invention was made in the course of employment (see s.39). The right to the patent will also pass to another person if for example the inventor or a person who has acquired the right by operation of law assigns those rights, or dies or becomes bankrupt.
- s.13(2) 7.07 Any applicant who is not an inventor must file Form 7 identifying the inventor and indicating his own right to be granted a patent see 13.08-13.16. If the period allowed for doing this has expired at the time the rights are assigned, the procedure described in 32.08-09 must be followed.
 - 7.08 If an applicant dies the application may proceed in the name of his personal representative. Likewise if an inventor dies before an application is made the personal representative may act on his behalf. If the Office becomes aware of the death of an applicant before a patent is granted but the application has not been assigned to another party by the time it is in order for grant then, if a personal representative has been appointed, the patent should be granted in the name of the personal representative. If, however, a personal representative has not been appointed by the time the application is in order for grant, the patent should be granted in the name of the deceased applicant.
 - 7.09 The term "personal representative" is interpreted in its ordinary meaning as "executor or administrator", and is restricted to a representative appointed in the UK. Probate or Letters of Administration must be produced to confirm the standing of the personal representative. A person is not regarded as a personal representative merely by being an assignee or by holding a power of attorney, nor is an Official Receiver or trustee in bankruptcy. The personal representative may be a corporate body.
 - 7.10 Where an applicant is less than eighteen years of age the application may proceed in his name. Alternatively, the application may be made by his parent or guardian.
 - 7.11 Where an applicant is of unsound mind the application should nonetheless proceed in his name. Where there is no patent agent acting the application should be signed (see 14.04.20) by the person duly appointed to administer the applicants' property.

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Section 7(3)

In this Act "inventor" in relation to an invention means the actual deviser of the invention and "joint inventor" shall be construed accordingly.

s.130(1) 7.12 This definition of "inventor" applies to all references in the 1977 Act. In Henry Brothers (Magherafelt) Ltd v The Ministry of Defence and the Northern Ireland Office [1999] RPC 442 the Court of Appeal emphasised that a two-step approach was necessary to determine inventorship. One must first identify the inventive concept and then determine who devised that concept.

Identifying the inventive concept

- 7.12.1 The need to keep in mind the inventive concept was also highlighted in Stanelco Fibre Optics Ltd's Applications [2005] RPC 15, where Christopher Floyd QC, sitting as a Deputy Judge in the Patents Court, commented "It is clear that a mechanistic, element by element approach to inventorship will not produce a fair result. If A discloses a new idea to B whose only suggestion is to paint it pink, B should not be a joint inventor of a patent for A's product painted pink. That is because the additional feature does not really create a new inventive concept at all. The feature is merely a claim limitation, adequate to overcome a bare novelty objection, but having no substantial bearing on the inventive concept. Patent agents will frequently suggest claim limitations, but doing so does not make them joint inventors. Some stripping of a claim of its verbiage, may be necessary to determine the inventive concept, and consequently the inventor." This statement was approved by the Court of Appeal in Markem Corp v Zipher Ltd [2005] RPC 31. In the case of joint inventorship, the question is therefore whether all parties are jointly responsible for devising the inventive concept.
- 7.12.2 The inventive concept may reside in more than an idea and may encompass the means of realisation of that idea (*Minnesota Mining & Manufacturing Company v Birtles, Lovatt and Evode Ltd* (BL O/237/00)). Where the invention consists of a combination of individually known elements, the inventor is the person who in substance made the combination rather than one who merely contributed to it (*Henry Brothers (Magherafelt) Ltd v The Ministry of Defence and the Northern Ireland Office* [1997] RPC 693; whilst the Court of Appeal disagreed with Jacob J on the facts of this case, it did not disagree with the principle). In *Statoil ASA v University of Southampton* (BL O/204/05), the hearing officer held that if the thrust of the disclosure is that the invention covers a broad area, it would be wrong to determine inventorship and entitlement solely by considering only a narrow subset of that area.

Determining who devised the inventive concept

7.12.3 A person is not the inventor merely because he contributed to a claim his contribution has to be the formulation of the inventive concept (University of Southampton's Applications [2005] RPC 11). In this case, Laddie J also held that devising an invention and providing an enabling disclosure were two quite different things, and pointed out that it is possible to make a good invention but to lose one's patent for failure to make an enabling disclosure. The requirement to include an enabling disclosure is concerned with teaching the public how the invention works, not with devising the invention in the first place. On the facts of this case, the Court of Appeal ([2006] RPC 21) concluded that all that was needed to get a patent was disclosure of the idea for the invention (substituting electrostatic particles for magnetic particles in an insect trap); from this idea the skilled person could readily practice the invention without disclosure of a means of enablement. However, Jacob LJ held obiter dictum that: "In the context of entitlement to a patent a mere, non-enabling idea, is probably not enough to give the patent for it to solely the deviser. Those who contribute enough information by way of necessary enablement to make the idea patentable would count as 'actual devisers', having turned what was 'airy-

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fairy' into that which is practical ... On the other hand those who contribute no more than essentially unnecessary detail cannot on any view count as 'actual devisers' as Laddie J rightly said, see his para. [45]."

- 7.12.4 Stanelco Fibre Optics Ltd's Applications [2005] RPC 15 demonstrated that more than a theoretical proposal is required to be an "actual deviser". An antecedent worker responsible for an initial prompt without which the invention might never have been made but with no idea as to whether it could actually be done or how it might be done could never be an inventor. Christopher Floyd QC (sitting as Deputy Judge) continued in this case: "But where the antecedent worker comes up with and communicates an idea consisting of all of the elements in the claim, even though it is just an idea at that stage, it seems to me that he or she will normally, at the very least, be an inventor of the claim. What US patent law calls 'reduction to practice' is not, it seems to me, a necessary component of a valid claim to any entitlement."
- 7.12.5 In Statoil ASA v University of Southampton (BL O/204/05), the hearing officer held that contributing information that cannot really be said to have an owner and that might include the knowledge of an expert may not be sufficient to justify a claim to entitlement.

Section 7(4)

Except so far as the contrary is established, a person who makes an application for a patent shall be taken to be the person who is entitled under subsection (2) above to be granted a patent and two or more persons who make such an application jointly shall be taken to be the persons so entitled.

s.72(2) s.37(4) Thus an applicant who has stated that he is the inventor or that he derives a right from the inventor (see 13.08-13.10) is presumed prima facie to be entitled to be granted a patent. The Office makes no attempt to question these assertions. If any person wishes to dispute them and to claim that the patent should be granted to them, either instead of or as well as, the present applicant they must take action under s.8 or 37 as appropriate. In *University of Southampton's Applications* [2005] RPC 11, the Patents Court held that in order to succeed in being added to an application the claimants had to prove on the balance of probabilities that they had made a relevant contribution to the inventive concept. But the requirement to remove the defendants as inventors was greater, as the claimants also had to overcome the presumption in s.7(4) and prove not only that they devised the inventive concept or concepts but that the named inventors contributed nothing of substance to any of them.

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Section 8: Determination before grant of questions about entitlement to patents etc

- 8.01 Questions about entitlement to patents may be referred to the comptroller under s.8 (patents under the 1977 Act which have not yet been granted), s.12 (patents under foreign or international law which have not yet been granted) or s.37 (granted patents under the 1977 Act). Such entitlement is a matter of property in a patent or application and is distinct from the right under s.13 to be mentioned as an "inventor" as defined in s.7(3). The comptroller is the primary jurisdiction for entitlement disputes.
- 8.02 A granted European patent (UK) is treated for the purposes of these sections as if it were a patent under the 1977 Act resulting from an application made under the 1977 Act, so that questions relating thereto may be referred under s.37. Questions arising before the grant of a European patent are however dealt with in accordance with s.82, by virtue of which s.12 is to some extent applicable.
- s.9 8.03 The procedure for a reference under s.8 is prescribed by Part 7 of the Patents Rules 2007 (see 123.05 123.05.13). Certain effects of orders or directions given under s. 8 are laid down by s.11. Where an order is made under s.8 (or s.12) that a patent application should proceed in name(s) none of whom was an original applicant, or that a new application for a patent may be made, the Office notifies all original applicants and their licensees of whom it is aware of the making of the order.
- s.25(1) 8.03.1 If a question referred to the comptroller under s.8 has not been determined by the time the patent in question is granted, the question shall, in accordance with s.9, then be treated as having been referred under s.37. For the purpose of section 8 (as with all of sections 1-24), the date of grant is the date on which the grant letter is issued informing the applicant under s.18(4) that the application complies with the requirements of the Act and Rules and that the patent is therefore granted. However, for the purpose of s.37, the effective date of grant is the date on which the notice of grant appears in the Journal and the patent is published, and so further action under s.37 on an existing reference cannot take place until after this date. If a question relating to entitlement is referred to the comptroller between the date on which the grant letter is issued and the date on which the notice of grant appears in the Journal, then no immediate action can take place under either of sections 8 or 37. Instead, the question is treated as having been referred under s.37 on the date on which the notice of grant appears in the Journal.
 - 8.04 Some guidance with regard to the determination of questions of entitlement is given by the judgments and decisions referred to below, some of which were under s.8, but others of which were under s.12 or s.37. The considerations applying to such questions under s.8, s.12 or s.37 are essentially the same, subject to the effects of the relevant foreign or international law in the case of a s.12 reference.

Section 8(1)

At any time before a patent has been granted for an invention (whether or not an application has been made for it) -

- (a) any person may refer to the comptroller the question whether he is entitled to be granted (alone or with any other persons) a patent for that invention or has or would have any right in or under any patent so granted or any application for such a patent; or
- (b) any of two or more co-proprietors of an application for a patent for that invention may so refer the question whether any right in or under the application should be transferred or granted to any other person;

and the comptroller shall determine the question and may make such order as he thinks fit to

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give effect to the determination.

s.8(7)

8.05

A question about entitlement may be referred to the comptroller under s.8 at any time before a patent has been granted for an invention, even before the making of an application. Such a reference may be made by any person claiming a right in any application or resultant patent for that invention, in accordance with subsection (1)(a), see 8.12 to 8.16, or by a co-owner of an application contending that a right therein should be transferred or granted to any other person, in accordance with subsection (1)(b), see 8.20. The comptroller normally in due course determines the question but he may instead decline to deal with it, see 8.28-8.30.

[The action officer in Tribunal Section should check at each stage of the proceedings whether or not a patent has been granted on the application. If and when a patent is granted, action should be initiated under s.9 (see 9.04).]

8.05.1 In line with the preliminary decision in *Brooks and Cope's Application* (BL O/71/93), in general the preliminary examination, search, publication under s.16 and substantive examination of a patent application should not be deferred pending the determination of a reference under s.8. Similarly, grant of the patent in general should not be deferred if the patent is in order for grant before the determination of a reference under s.8; the claimant is then treated as having made the reference under s.37 (see 9.03).

8.06 The law on entitlement was considered by the House of Lords in *Yeda Research and Development Company Limited (Appellants) v. Rhone-Poulenc Rorer International Holdings Inc and others (Respondents)* [2007] UKHL 43. Lord Hoffmann giving the leading judgement noted:

"Section 7(2), and the definition in section 7(3), are in my opinion an exhaustive code for determining who is entitled to the grant of a patent. That is made clear by the words "and to no other person." In saying that the patent may be granted "primarily" to the inventor, section 7(2) emphasises that a patent may be granted only to the inventor or someone claiming through him. The claim through an inventor may be made under one of the rules mentioned in paragraph (b), by which someone may be entitled to patent an invention which has been made by someone else (the right of an employer under section 39 is the most obvious example) or the claim may be made under paragraph (c) as successor in title to an inventor or to someone entitled under paragraph (b).

In my opinion, therefore, the first step in any dispute over entitlement must be to decide who was the inventor or inventors of the claimed invention. Only when that question has been decided can one consider whether someone else may be entitled under paragraphs (b) or (c).

The inventor is defined in section 7(3) as "the actual deviser of the invention". The word "actual" denotes a contrast with a deemed or pretended deviser of the invention; it means, as Laddie J said in *University of Southampton's Applications* [2005] RPC 11 (at page 234), the natural person who "came up with the inventive concept." It is not enough that someone contributed to the claims, because they may include non-patentable integers derived from prior art: see *Henry Brothers (Magherafelt) Ltd v Ministry of Defence* [1997] RPC 693 (at page 706); [1999] RPC 442. As Laddie J said in the University of Southampton case, the "contribution must be to the formulation of the inventive concept". Deciding upon inventorship will therefore involve assessing the evidence adduced by the parties as to the nature of the inventive concept and who contributed to it. In some cases this may be quite complex because the inventive concept is a relationship of discontinuity between the claimed invention and the prior art. Inventors themselves will often not know exactly where it lies.

The effect of section 7(4) is that a person who seeks to be added as a joint inventor bears the burden of proving that he contributed to the inventive concept underlying the claimed invention and a person who seeks to be substituted as sole inventor bears the additional burden of proving that the inventor named in the patent did not contribute to the inventive concept. But that, in my opinion, is all. The statute is the code for determining entitlement and there is nothing in the statute which says that entitlement depends upon anything other than being the inventor."

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8.07	[deleted]
8.07.1	[deleted]
8.08	[deleted]
8.08.1	[deleted]

8.08.2 Where a dispute concerns a claim under section 7(2)(b) involving a contract, then the issues often centre on implied, rather than express, terms. For example, in *Goddin and Rennie's Application* [1996] RPC 141 the claimant had shown prototype fish tank covers to the defendant in confidence. The claimant subsequently entered into a contractual agreement with the defendant for him to make improved net covers for use with an arched frame devised by the claimant. On appeal to the Court of Session it was held that the claimant was entitled to the benefit of the improved net covers. It would not have made business sense if there were an implied term of the contractual relationship between the parties that any improved design which was worked out by the defendant was the property of the defendant rather than the claimant. On the other hand the Court held that the defendant was entitled to the benefit of claimed improvements suggested by him prior to and separately from the contractual arrangement. The Court therefore ordered that the patent should be granted in the name of the claimant alone subject to the condition that he granted to the defendant an irrevocable exclusive licence with power to sub-licence under the claims for the non-contracted improvements.

Although section 74 does not allow validity to be put in issue in inventorship 8.09 or entitlement disputes, where an unanswerable case of validity was raised, the Court of Appeal in Markem Corp v Zipher Ltd [2005] RPC 31 held that the Comptroller can act upon it. Jacob LJ said: "If a patent or part of it is clearly and unarguably invalid, then we see no reason why as a matter of convenience, the Comptroller should not take it into account in exercising his wide discretion. The sooner an obviously invalid monopoly is removed, the better from the public point of view. But we emphasise that the attack on validity should be clear and unarguable. Only when there is self-evidently no bone should the dogs be prevented from fighting over it". In this case, the claimants alleged that a claim was invalid, but that this should be considered irrelevant to their entitlement claim. The court disagreed, saying that there is simply no point in the Comptroller handing rights in an invalid monopoly from one side to another, and concluded that if an inherent part of a claim to entitlement is also an assertion of or acceptance of invalidity, the entitlement claim must fail. The hearing officer in Statoil ASA v University of Southampton (BL O/204/05) held that this principle should apply to both parties, so that a defendant should not be allowed to get away with pleading invalidity as an inherent part of his defence.

8.10-8.11 [moved to 8.21]

Procedure

PR part 7

8.12 A reference under s.8(1) (or s.12(1) or 37(1)) should be made on Patents Form 2 accompanied by a copy thereof and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.13.

Reference by person other than co-owner (s.8(1)(a))

8.13	[deleted]
8.14	[deleted]
8.15	[deleted]
8.16	In proceedings under s.8(1)(a), the hearing officer may where appropriate

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grant any of the orders or reliefs set out in s.8(2) and (3), see 8.21 to 8.25.1. This is without prejudice to the general power to make orders under s.8(1), see 8.21.1.

Reference by co-owner (s.8(1)(b))

8.17	[deleted]
0.17	ideleted

8.18 [deleted]

8.19 [deleted]

s.8(4) 8.20 In proceedings under s.8(1)(b), any order made by the hearing officer under s.8(1) may contain directions to any person for transferring or granting any right in or under the patent application in question (see also 8.26 where such directions are not complied with).

Section 8(2)

Where a person refers a question relating to an invention under subsection (1)(a) above to the comptroller after an application for a patent for the invention has been filed and before a patent is granted in pursuance of the application, then, unless the application is refused or withdrawn before the reference is disposed of by the comptroller, the comptroller may, without prejudice to the generality of subsection (1) above and subject to subsection (6) below -

- (a) order that the application shall proceed in the name of that person, either solely or jointly with that of any other applicant, instead of in the name of the applicant or any specified applicant;
- (b) where the reference was made by two or more persons, order that the application shall proceed in all their names jointly;
- (c) refuse to grant a patent in pursuance of the application or order the application to be amended so as to exclude any of the matter in respect of which the question was referred:
- (d) make an order transferring or granting any licence or other right in or under the application and give directions to any person for carrying out the provisions of any such order.

Specific remedies available

- 8.21 The remedies available under s.8(1)(a), provided that the patent application in question has not been granted, refused or withdrawn, thus include orders under subsections (2)(a), (b) or (d) with regard to the name(s) in which the application or any licence or other right therein should proceed or be vested. However, where there is alleged to be a transaction, instrument or event as set out in s.8(6), no such order is made unless notice of the s.8 reference has been given to the affected parties as required by subsection (6) (such notice normally having been given by the Office). See also 8.26 if directions for putting into effect an order under subsection (2)(d) are not complied with.
- 8.21.1 Section 8(1) provides that the comptroller may make such order as he thinks fit to give effect to his determination of an entitlement question. In *Szucs' Application* (BL O/4/86) where relief under s.8(2) or (3) was not available under s.8(1), the hearing officer held that the claimants were entitled to a declaration that certain matter (a beam of particular cross-sectional form) was their property.
- 8.21.2 In Georgia Pacific Corp's Application [1984] RPC 467, the applicants claimed that their

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application should be deemed to have as its priority date one of the priority dates of an earlier application which they alleged was made in contravention of their rights. They also sought revocation of the patent resulting from the earlier application. The hearing officer held that there was no provision for an application to be accorded an earlier priority date unless it was claimed in a declaration of priority at the time of filing of the application; and that s.37 did not provide any facility whereby the application in suit could be deemed to have a more favourable priority date, whatever the outcome of the revocation action. (The same is apparently true of s.8).

Other remedies in s.8(1)(a) proceedings include refusal of the application 8.22 or an order for amendment of the application to exclude any of the disputed matter, under subsection (2)(c).

Section 8(3)

Where a question is referred to the comptroller under subsection (1)(a) above and -

- (a) the comptroller orders an application for a patent for the invention to which the question relates to be so amended;
- any such application is refused under subsection 2(c) above before the comptroller has disposed of the reference (whether the reference was made before or after the publication of the application); or
- any such application is refused under any other provision of this Act or is withdrawn before the comptroller has disposed of the reference, (whether the application is refused or withdrawn before or after its publication);

the comptroller may order that any person by whom the reference was made may within the prescribed period make a new application for a patent for the whole or part of any matter comprised in the earlier application or, as the case may be, for all or any of the matter excluded from the earlier application, subject in either case to section 76 below, and in either case that, if such a new application is made, it shall be treated as having been filed on the date of filing the earlier application.

Making of new application

Subsection (3) provides, at the discretion of the comptroller, for the making of a new application by the claimant under s.8(1)(a) when the original application is no longer proceeding or (as a result of amendment ordered under s.8(2)(c)) no longer contains the matter to which the claimant is held to be entitled, with the new application being treated as having been filed on the filing date of the original application. If no longer proceeding, the original application must have been refused under s.8(2)(c), refused under any other provision of the Act or withdrawn before the comptroller has disposed of the reference. In Stevens' Application (BL O/63/93) the hearing officer held that where a claimant was seeking an order under s.8(3)(c) allowing him to file a fresh application in respect of matter comprised in an earlier application, it was incumbent on him clearly to identify the subject matter of which he was claiming ownership. It was not sufficient for the claimant merely to state that there was subject matter somewhere in the specification to which he was entitled and which could form the basis for a fresh application. Amendment of the register as to ownership of a withdrawn application was allowed by the hearing officer in Shape and Potemkin's Applications (BL O/140/92) so that the claimant could claim priority in a new application made under s.8(3)(c).

r.20(1) The new application should be made within a period of three months calculated from the day on which the order was made under s.8(3) or, where an appeal is r.20(4) brought, from the day on which it is finally disposed of. This period may be extended or shortened at the discretion of the comptroller. r.108(1)

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r.20(3)

8.25 The new application under s.8(3), 12 or 37(4) is treated as having been filed on the date of filing of the earlier application. If matter extending beyond that disclosed in the earlier application or patent is disclosed, s.76(1) requires that such an application shall not be allowed to proceed unless it is amended so as to exclude the additional matter, and the examiner should make an objection (much as in the case of an attempted application under s.15(9), see 15.35 and 15.45).

8.25.1 In the case of new applications filed under s.8(3), 12(6) or 37(4) as the result of entitlement proceedings, the compliance period for putting the application in order is prescribed by r.30(3).

Section 8(4)

Where a person refers a question under subsection (1)(b) above relating to an application, any order under subsection (1) above may contain directions to any person for transferring or granting any right in or under the application.

Section 8(5)

If any person to whom directions have been given under subsection (2)(d) or (4) above fails to do anything necessary for carrying out any such directions within 14 days after the date of the directions, the comptroller may, on application made to him by any person in whose favour or on whose reference the directions were given, authorise him to do that thing on behalf of the person to whom the directions were given.

Directions not complied with

8.26 An application under s.8(5) for authority to do anything on behalf of a person to whom directions have been given under s.8(2)(d) or (4) is not included in Schedule 3 to the Patents Rules 2007. Patents Form 2 need not therefore be filed in order to start an application under s.8(5); the application should however set out fully the facts upon which the applicant relies and the nature of the authorisation sought. Such an application may be made by any person in whose favour or on whose reference the directions were given.

8.27 The Office sends a copy of the application to the person alleged to have failed to comply with the directions. The comptroller may give such directions as he may think fit with regard to the subsequent procedure, and may grant authorisation if he thinks fit.

Section 8(6)

Where on a reference under this section it is alleged that, by virtue of any transaction, instrument or event relating to an invention or an application for a patent, any person other than the inventor or the applicant for the patent has become entitled to be granted (whether alone or with any other persons) a patent for the invention or has or would have any right in or under any patent so granted or any application for any such patent, an order shall not be made under subsection (2)(a), (b) or (d) above on the reference unless notice of the reference is given to the applicant and any such person, except any of them who is a party to the reference.

Section 8(7)

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If it appears to the comptroller on a reference of a question under this section that the question involves matters which would more properly be determined by the court, he may decline to deal with it and, without prejudice to the court's jurisdiction to determine any such question and make a declaration, or any declaratory jurisdiction of the court in Scotland, the court shall have jurisdiction to do so.

Comptroller declines to deal with question

CPR 63.11

- 8.28 The comptroller has discretion under s.8(7) (and similarly under s.12(2) and s.37(8)) to decline to deal with a question if it appears to him that it involves matters which "would more properly be determined by the court". In such a case any person entitled to do must, within 14 days of the comptroller's decision, issue a claim form to the court to determine the question.
- 8.29 There is no corresponding provision for the comptroller to transfer s.13 inventorship proceedings to the court. However, if the comptroller declines to deal with the entitlement reference, the comptroller can order a stay in the s.13 proceedings pending decision by the court, as occurred in *BioProgress Technology Limited v Stanelco Fibre Optics Limited* (BL O/351/03).
- 8.30 The questions to be considered by the comptroller in declining to deal with entitlement cases under sections 8 and 12 of the Patents Act 1977 were considered in Luxim Corp v Ceravision Ltd [2007] EWHC 1624 (Ch), [2007] RPC 33. Whereas previous practice had been to consider declining to deal only where one or both of the parties requested it, following Luxim, it is necessary for hearing officers to consider the matter in all cases. Furthermore in some cases where both parties request it, the hearing officer may decide that it is nevertheless proper for the matter to be determined by the comptroller. The most common reason for a request is that there are parallel High Court proceedings covering much the same issues, and it would be undesirable for the both the court and the comptroller to be deciding the same issues. However, other arguments may be advanced and the hearing officer will have to decide where the balance lies. If he does decline to deal then the court can exercise all the powers given to the comptroller by section 8, which it could not do if the parties had simply gone first to the court and launched proceedings for a declaration as to entitlement.

8.31 [deleted]

[Further guidance on declining to deal is given in chapter 2 of the Patents Hearings Manual.]

Section 8(8)

No directions shall be given under this section so as to affect the mutual rights or obligations of trustees or of the personal representatives of deceased persons, or their rights or obligations as such.

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Section 9: Determination after grant of questions referred before grant

9.01 This section deals with the situation where a reference to the comptroller made under s.8 has not been disposed of when the patent application in question is in order for grant. Section 8 provides for the determination of questions of entitlement to a patent for an invention prior to the grant thereof but is not applicable once grant has occurred, when s.37 instead applies to the determination of such questions.

9.02 [deleted]

Section 9

If a question with respect to a patent or application is referred by any person to the comptroller under section 8 above, whether before or after the making of an application for the patent, and is not determined before the time when the application is first in order for a grant of a patent in pursuance of the application, that fact shall not prevent the grant of a patent, but on its grant that person shall be treated as having referred to the comptroller under section 37 below any question mentioned in that section which the comptroller thinks appropriate.

9.03 When an application is in order for grant, it proceeds to grant in the normal way notwithstanding the existence of an unresolved entitlement question under s.8.

9.04 On the grant of the patent, the Office sends a letter informing the claimant that the reference is being treated as made under s.37, and that this may affect the relief available, but should not otherwise affect the course of the proceedings. A letter in identical terms is sent to the defendants. Unless the claimant and defendant respond, it is assumed that both parties agree that the question of relief should be deferred until the substantive hearing.

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Section 10: Handling of application by joint applicants

Under this section, certain disputes between joint applicants for a patent may be resolved by the comptroller in response to a request in accordance with part 7 of the Patents Rules 2007 (see 123.05 - 123.05.13).

In addition, a joint applicant may under s.8(1)(b) refer to the comptroller the question whether any right in or under the application should be transferred or granted to any other person, see 8.05 to 8.12 and 8.20. The rights of and relating to joint applicants are laid down by s.36.

10.03 Section 10 is applicable in relation to European and foreign applications to the extent laid down by s.12(4), see 10.05.

Section 10

If any dispute arises between joint applicants for a patent whether or in what manner the application should be proceeded with, the comptroller may, on a request made by any of the parties, give such directions as he thinks fit for enabling the application to proceed in the name of one or more of the parties alone or for regulating the manner in which it shall be proceeded with, or for both those purposes, according as the case may require.

10.04 The disputes to which s.10 relates are those between joint applicants whether or in what manner the application should be proceeded with. Any of the parties may make a request to the comptroller for directions under this section.

- s.12(4)10.05 In the case of an application under the Act, the comptroller may give such directions as he thinks fit for enabling the application to proceed in the name of one or more of the parties alone and/or for regulating the manner in which it should be proceeded with. However, in the case of an application under foreign or international law (including the EPC) such directions enabling the comptroller to regulate the manner in which an application is to proceed cannot be given. In all other respects, s.10 applies to disputes between joint applicants under foreign or international law as it applies to joint applicants under the Act.
- 10.06 Any directions given under s.10, including those given under s.10 by virtue s.12(5)of s.12(4), are subject to s.11. Section 11 concerns the effects of such directions in relation to any licences or other rights in or under the application.

10.07 In N J M Pelling and R J Campbell's Application (BL O/134/87), the first of the joint applicants had paid all the costs of making patent applications in the UK and elsewhere; the second applicant refused to contribute except from any proceeds of future exploitation of the invention. The hearing officer declined to make any direction under s.8 or s.12 but, under s.10, directed the second applicant to assign his interest in the UK patent application to the first, in return for a free non-assignable, non-revocable licence excluding any right to sub-licence. With regard to the object to be achieved in such proceedings, he observed: "the correct approach is for the comptroller to seek to implement the overall purpose of the Act in the most equitable manner that he can".

10.07.1 At a preliminary hearing the hearing officer in Brooks and Cope's Application (BL O/71/93) made a direction under s.10 that substantive examination of a UK application should proceed and that the report under s.18 should be sent to both parties.

Procedure

PR part 7 A request under s.10 (or s.12(4)) by a joint applicant should be made on Patents Form 2 accompanied by a copy thereof and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at

> Page 1 of 2 **April 2008**

123.05 - 123.05.13.

10.09 [deleted]

10.10 [deleted]

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Section 11: Effect of transfer of application under s.8 or 10

11.01 Orders or directions regarding the name(s) in which a patent application should proceed may be given under s.8 (determination before grant of questions about entitlement to patents under the Act) or s.10 (disputes between joint applicants). The effects of such orders or directions on licences or other rights in or under the application are laid down by s.11. This section also gives certain rights to applicants or licensees who worked the invention, or prepared to do so, before the registration of a reference under s.8, see 11.05 to 11.07.

s.12(5)

11.02 Section 11 is also applicable in relation to orders made under s.12(1) (determination before grant of questions about entitlement to patents under foreign or international law) and orders made by a convention court with respect to corresponding questions. For the purposes of s.11, those orders are treated as if made under s.8. The directions under s.10 to which s.11 applies include those given in relation to patents under foreign or international law by virtue of s.12(4). With regard to the applicability of sections 8 to 12 in relation to European patents, see also 8.02, 10.03 and 12.09.

Section 11(1)

Where an order is made or directions are given under section 8 or 10 above that an application for a patent shall proceed in the name of one or some of the original applicants (whether or not it is also to proceed in the name of some other person), any licences or other rights in or under the application shall, subject to the provisions of the order and any directions under either of those sections, continue in force and be treated as granted by the persons in whose name the application is to proceed.

Where an original applicant is retained

11.03 This subsection applies where the effect of an order or directions under s.8 or 10 (or s.12, see 11.02) is that the name(s) in which the application proceeds include one or more of the original applicants. Licences or other rights continue in force as if granted by the person(s) in whose name the application proceeds, unless the order or directions provide otherwise.

Section 11(2)

Where an order is made or directions are given under section 8 above that an application for a patent shall proceed in the name of one or more persons none of whom was an original applicant (on the ground that the original applicant or applicants was or were not entitled to be granted the patent), any licences or other rights in or under the application shall, subject to the provisions of the order and any directions under that section and subject to subsection (3) below, lapse on the registration of that person or those persons as the applicant or applicants or, where the application has not been published, on the making of the order.

Where none of the original applicants is retained

11.04 Subsections (2) to (5) apply where the effect of an order or directions under s.8 (or s.12, see 11.02) is that the name(s) in which the application proceeds include none of the original applicants. Licences or other rights lapse on registration of the new name(s) or, where the application is unpublished, on the making of the order, unless in either case the order or directions provide otherwise (but see 11.05 to 11.10).

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Section 11(3)

If before registration of a reference under section 8 above resulting in the making of any order mentioned in subsection (2) above -

- (a) the original applicant or any of the applicants, acting in good faith, worked the invention in question in the United Kingdom or made effective and serious preparations to do so; or
- (b) a licensee of the applicant, acting in good faith, worked the invention in the United Kingdom or made effective and serious preparations to do so;

that or those original applicant or applicants or the licensee shall, on making a request within the prescribed period to the person in whose name the application is to proceed, be entitled to be granted a licence (but not an exclusive licence) to continue working or, as the case may be, to work the invention.

Section 11(3A)

If, before registration of a reference under section 8 above resulting in the making of an order under subsection (3) of that section, the condition in subsection (3)(a) or (b) above is met, the original applicant or any of the applicants or the licensee shall, on making a request within the prescribed period to the new applicant, be entitled to be granted a licence (but not an exclusive licence) to continue working or, as the case may be, to work the invention so far as it is the subject of the new application.

11.05 The making of a reference under s.8 (or s.12) is recorded in the register, see 123.05.4. If the reference results in an order under s.8 (or s.12) to the effect that none of the original applicants is retained or that a new application for a patent may be made, the Office notifies all original applicants and their licensees of whom it is aware of the making of the order.

r.90(1) r.108(1)

- 11.06 An applicant or licensee so notified may make a request under s.11(3) (or under that subsection as applied by s.12(5)) to the person in whose name the application is to proceed for a non-exclusive licence to work or continue working the invention. Similarly, following the insertion of s.11(3A) by the Patents Act 2004 with effect from 1 January 2005, an applicant or licensee notified may make a request to the person making a new application under s.8(3) for a non-exclusive licence to work or continue working the invention. Any such request should be made within two months of the date of the order under s.8 or, where s.11 is applied by s.12(5), under s.12(1), this period being extensible at the discretion of the comptroller. (For the meanings of "exclusive licence" and "non-exclusive licence", see s.130(1).)
- 11.07 The original applicant or licensee making the request is entitled to such a licence if he, acting in good faith, worked the invention in the UK or made effective and serious preparations to do so, before the registration of the reference. The period and terms of the licence should comply with s.11(4), ie, be "reasonable". Any dispute regarding such period or terms or whether he is entitled to a licence may be referred to the comptroller under s.11(5) by either party, see 11.08 to 11.10.

Section 11(4)

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A licence under subsection (3) or (3A) above shall be granted for a reasonable period and on reasonable terms.

Section 11(5)

Where an order is made as mentioned in subsection (2) or (3A) above, the person in whose name the application is to proceed or, as the case may be, who makes the new application, or any person claiming that he is entitled to be granted any such licence may refer to the comptroller the question whether the latter is so entitled and whether any such period is or terms are reasonable, and the comptroller shall determine the question and may, if he considers it appropriate, order the grant of such a licence.

- PR part 7 11.08 The dispute (see 11.07) should be referred by filing Patents Form 2 accompanied by a copy thereof and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 123.05.13. The statement should include the period or terms of the licence which the claimant is prepared to accept or grant.
- r.77 11.09 The Office sends a copy of the reference and statement to every person (not being the claimant) in whose name the application is to proceed or, as the case may be, who makes the new application, and every person claiming to be entitled to a licence. If any recipient does not agree to grant or accept a licence as specified he should file a counter-statement in the proceedings.
- s.108 11.10 When the comptroller determines the question to which the reference relates he may, if appropriate, order the grant of such a licence (see 11.06). Without prejudice to any other method of enforcement, such an order has effect as if it were a deed, executed by the proprietor of the patent and all other necessary parties, granting a licence in accordance with the order.

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Section 12: Determination of questions about entitlement to foreign and convention patents, etc

- 12.01 This is the second of the three sections (8, 12 and 37) under which questions about entitlement to patents may be referred to the comptroller. Section 12 relates to such questions in the case of patent applications under foreign or international law, ie the law of any country other than the UK or any treaty or international convention. This includes the EPC, for which subsections (3) and (6) make special provision, see 12.09 and 12.14.
- s.12(7)(a) 12.02 This section also applies in relation to applications under foreign or international law which are equivalent to applications for patents or are for protection of inventions by means other than patents.
- s.12(4) 12.03 Section 12 makes additional provision for the resolution of disputes between joint applicants, see 12.11.

Section 12(1)

At any time before a patent is granted for an invention in pursuance of an application made under the law of any country other than the United Kingdom or under any treaty or international convention (whether or not that application has been made) -

- (a) any person may refer to the comptroller the question whether he is entitled to be granted (alone or with any other persons) any such patent for that invention or has or would have any right in or under any such patent or an application for such a patent; or
- (b) any of two or more co-proprietors of an application for such a patent for that invention may so refer the question whether any right in or under the application should be transferred or granted to any other person;

and the comptroller shall determine the question so far as he is able to and may make such order as he thinks fit to give effect to the determination.

- Questions about entitlement may be referred to the comptroller under this section at any time before a patent (or other form of protection, see 12.02) for an invention is granted, even before the making of an application. Such a reference may be made by any person claiming a right in any application or resultant patent etc. for that invention, in accordance with subsection (1)(a), see 12.06, or by a co-owner of an application contending that a right therein should be transferred or granted to any other person, in accordance with subsection (1)(b). In Magill's International Application (BL O/256/00) a US patent for the invention had already been granted in pursuance of the international application. Whilst the comptroller thus had no jurisdiction as far as that patent was concerned, s.12 was interpreted as meaning that the comptroller retained jurisdiction in respect of all other live designations in the international application.
- s.12(2) The comptroller normally in due course determines the question so far as he is able to although he may instead decline to deal with it, see 12.08. The comptroller may make such order as he thinks fit to give effect to the determination. Much of the discussion with regard to the determination of questions of entitlement under s.8, see 8.06 to 8.11, is applicable mutatis mutandis to s.12 proceedings. However, the extent to which the comptroller is able to determine the question may be affected by the particular foreign or international law under which the application in question was or is to be made and the stage reached in the prosecution of the application, as well as the availability of information regarding the issues in question. The exercise of the comptroller's discretion with regard to the making of orders may be affected by similar considerations. In some cases, the

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comptroller may be able to make a determination but not to make any effective order, in view of the fact or likelihood that the foreign or international authorities in question also have jurisdiction. In Cannings' United States Application, [1992] RPC 459, where an employeeinventor had refused to execute an assignment of his rights in a US application, which had entered the national phase by the PCT route, it was determined that (a) the comptroller has powers, subject to such other provisions of the Act as are relevant, to determine the question of ownership of an invention, which is the subject of such a US application; (b) although the comptroller's powers under s.12 were inherently limited by the particular foreign or international law under which an application is made, since the inventor's employer was entitled to the invention, he was also entitled to the US application itself and to any patent granted thereon; (c) it was within the comptroller's broad powers under s.12(1) to order the employee to execute an assignment if this was necessary to give effect to the determination of entitlement and if such an assignment was required for the employer to enjoy the full benefit of any patent on the US application; and (d) the generality of s.12 in relation to the orders that may be made to give effect to the determination of entitlement permitted the comptroller to follow the approach sanctioned by s.8(5), which establishes the principle that in appropriate circumstances the comptroller has powers, at least in relation to rights in UK patent applications, effectively to bypass the unwillingness of an uncooperative party by authorising an affected party to sign, for example, a licence or assignment on his behalf.

12.05.1 In University of Southampton's Applications [2002] RPC 44, the hearing officer was mindful of the fact that where an entitlement action under s.8 has been launched, the Office will avoid taking any irrevocable action which might be detrimental to the claimant, should they subsequently be found to be entitled. He therefore held that the same approach should, as far as possible, be taken to actions under s.12 and so ordered that the defendants should identify any foreign equivalent applications to the application in dispute, thus allowing the claimants to draw national or regional offices' attention to their interest.

Procedure

12.06 The procedure with regard to a reference under s.12(1) is the same as that for a s.8(1) reference, see 8.12.

12.07 [moved to 12.06].

Section 12(2)

If it appears to the comptroller on a reference of a question under this section that the question involves matters which would more properly be determined by the court, he may decline to deal with it and, without prejudice to the court's jurisdiction to determine any such question and make a declaration, or any declaratory jurisdiction of the court in Scotland, the court shall have jurisdiction to do so.

Comptroller declines to deal with question

CPR 63.11 12.08 The comptroller may decline to deal with a question, referred under s.12, involving matters which he considers would more properly be determined by the court. This provision has the same wording as s.8(7) and the comments in 8.28 to 8.30 and chapter 2 of the Patent Hearings Manual are also relevant here. The procedure for transfer to the court, subject to rule 63.11 of Part 63 of the Civil Procedure Rules, is the same as set out in 8.28.

Section 12(3)

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Subsection (1) above, in its application to a European patent and an application for any such patent, shall have effect subject to section 82 below.

Entitlement to European patents

s.82(8)

12.09 Prior to grant, entitlement questions relating to applications for European patents may be referred under s.12 which is applicable to the extent laid down by s.82 (see the chapter on that section) in line with the EPC Protocol on Recognition. The court and the

comptroller each have jurisdiction to determine such a question (including the making of an order under s.12) if the circumstances set out in s.82(4) to (6) are met. Determinations of such questions by authorities of other states which are party to the EPC may have effect in the UK, see s.83. See also 12.14 to 12.16.1 with regard to applications for European

patents (UK) which are terminated.

12.10 Once a European patent (UK) has been granted, it is treated for the determination of questions about entitlement as if it were a patent under the Act resulting from an application under the Act, and such questions should then be referred under s.37.

Section 12(4)

Section 10 above, except so much of it as enables the comptroller to regulate the manner in which an application is to proceed, shall apply to disputes between joint applicants for any such patent as is mentioned in subsection (1) above as it applies to joint applicants for a patent under this Act.

Disputes between joint applicants

PR part 7

12.11 This subsection makes s.10 apply (except as follows) to disputes between joint applicants for patents (or other forms of protection, see 12.02) under foreign or international law as it applies to those under the Act. Any of the parties may therefore make a request to the comptroller for directions to settle a dispute such as referred to in 10.04, the procedure for such a request being that described in 10.08 and 123.05 – 123.05.13. The exception is that the comptroller cannot give directions under s.12(4) which regulate the manner in which an application is to proceed.

Section 12(5)

Section 11 above shall apply in relation to -

- (a) any orders made under subsection (1) above and any directions given under section 10 above by virtue of subsection (4) above; and
- (b) any orders made and directions given by the relevant convention court with respect to a question corresponding to any question which may be determined under subsection (1) above;

as it applies to orders made and directions given apart from this section under section 8 or 10 above.

Effect of transfer of application

s.130(1) 12.12 This subsection makes s.11 apply to orders under s.12(1) (see 12.04 and 12.05) and directions given under s.10 by virtue of s.12(4) (see 12.11) as it applies to other orders and directions under s.8 or 10. It also makes s.11 similarly apply to orders and directions given by the "relevant convention court" with respect to questions such as may be

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determined under s.12(1). That court, in relation to any proceedings under the EPC, CPC or PCT, means the court or other body which under that convention or treaty has jurisdiction over those proceedings, including (where it has such jurisdiction) any department of the EPO.

12.13 Section 11 concerns the effects of orders or directions regarding the name(s) in which an application should proceed. Its provisions and the procedures to be followed thereunder are discussed in the chapter on s.11 which is equally applicable to operation of the section by virtue of s.12(5).

Section 12(6)

In the following cases, that is to say -

- (a) where an application for a European patent (UK) is refused or withdrawn, or the designation of the United Kingdom in the application is withdrawn whether before or after publication of the application but before a question relating to the right to the patent has been referred to the comptroller under subsection (1) above or before proceedings relating to that right have begun before the relevant convention court;
- (b) where an application has been made for a European patent (UK) and on a reference under subsection (1) above or any such proceedings as are mentioned in paragraph (a) above the comptroller, the court or the relevant convention court determines by a final decision (whether before or after publication of the application) that a person other than the applicant has the right to the patent, but that person requests the European Patent Office that the application for the patent should be refused; or
- (c) where an international application for a patent (UK) is withdrawn, or the designation of the United Kingdom in the application is withdrawn, whether before or after the making of any reference under subsection (1) above or the publication of the application;

the comptroller may order that any person (other than the applicant) appearing to him to be entitled to be granted a patent under this Act may within the prescribed period make an application for such a patent for the whole or part of any matter comprised in the earlier application (subject, however, to section 76 below) and that if the application for a patent under this Act is filed, it shall be treated as having been filed on the date of filing the earlier application.

Making of new application

- Subsection (6) provides, at the discretion of the comptroller, for the making of a new application for a patent under the Act for matter comprised in an earlier application for a European patent (UK) which is no longer proceeding (in the circumstances of subsection (6)(a) or (b)) or international application for a patent (UK) which is no longer proceeding (in the circumstances of subsection (6)(c)). The comptroller may make an order allowing such a new application to be made by any person other than the original applicant who appears to him to be entitled to the grant of a patent for the matter in question. (See 12.12 for the meaning of "relevant convention court" in subsection (6)(a) and (b); and s.12(7)(b) for the meaning of "final decision" in subsection (6)(b)).
- 12.15 The period for making the new application is the same as for an application under s.8(3) see 8.24
-) 12.16 The new application is treated as having been filed on the date of filing of the earlier application. However, the application requires amendment in order to be so

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s.76(1)

treated if it discloses matter which extends beyond that disclosed in the earlier application as filed, as discussed in 8.25.

12.16.1 The r.30 compliance period for putting in order an application under s.12(6) is the same as that for an application under s.8(3) or 37(4) -see 8.25.1.

Section 12(7)

In this section -

- (a) references to a patent and an application for a patent include respectively references to protection in respect of an invention and an application which, in accordance with the law of any country other than the United Kingdom or any treaty or international convention, is equivalent to an application for a patent or for such protection; and
- (b) a decision shall be taken to be final for the purposes of this section when the time for appealing from it has expired without an appeal being brought or, where an appeal is brought, when it is finally disposed of.

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Section 13: Mention of inventor

This section deals with the right of an inventor to be mentioned in an application or a patent, the obligation on the applicant to identify the inventor(s) and the right of any person to object to a mentioned inventor. Relevant procedures are prescribed in r.10 and part 7 of the Patents Rules 2007. The inventor may also apply to waive his right to have his name and address mentioned following the procedures prescribed by r.11.

s.125(1)Since the invention to which a patent or an application relates is determined by the claims, which may differ as between application and patent, it is possible that a person may be entitled to be named as an inventor in the application but not in the patent. The meaning of "inventor" is discussed in paragraph 7.12.

Section 13(1)

The inventor or joint inventors of an invention shall have a right to be mentioned as such in any patent granted for the invention and shall also have a right to be so mentioned if possible in any published application for a patent for the invention and, if not so mentioned, a right to be so mentioned in accordance with rules in a prescribed document.

13.03 The front pages published with the specification of the application and any r.11(2) patent granted normally each contain separate lists of all the applicants and all the r.11(3) inventors even when these lists are identical. However, before the preparations for publication have been completed, anyone identified as an inventor may apply in writing to the comptroller to waive his right to have his name and address mentioned as those of the inventor, or to waive this right in respect of his address only. If the application is to r.51(3)(e) withhold both the inventor's name and address, satisfactory reasons must be given, but this is not required if the application is to withhold just the address. Where an application to withhold an inventor's details has been accepted, they will not appear in the patent application as published. The comptroller will also omit the details from the Register, and unless otherwise directed, no document bearing them shall be open to public inspection.

> 13.03.1 Where an application to waive an inventor's right to be mentioned has been accepted, the inventor can later apply to the comptroller to end the waiver. An agreement by the comptroller to end such a waiver may be subject to any conditions he may direct.

> 13.04 Under s.13(1) and r.10(2) any person who alleges that he or another person ought to have been mentioned as the or an inventor in a granted patent or a published application may apply on Form 2 to have the matter rectified. There is no time limit on when an application may be made. Form 2 should be accompanied by a copy thereof and by a statement of grounds in duplicate; this starts proceedings before the comptroller, the procedure for which is discussed at 123.05 - 123.05.13. There is no need to file an additional Form 2 and statement to deal with inventorship when it has been put in issue by a reference in entitlement proceedings under section 8 or 37.

> 13.04.1 In the case of an application for a European patent (UK) an incorrect designation of an inventor may also be rectified before the EPO under r.21 EPC. (An application under s.13(1) may be made once the grant of a patent has been mentioned in the European Patent Bulletin (see also 13.18)).

The front page of the specification will be republished together with an amendment sheet giving details of the changes indicating that the addition is only in respect of EP(UK) (see file of EP 0370590). Publication Section will send a copy of the republished specification to the applicant. A copy should also be sent to the EPO for information suggesting that they might like to associate it with the B publication (again see EP 0370590).]

r.11(1)

r.26(2)

r.44(2)

r.11(4)

r.11(5)

PR part 7

s.78(2)

r.77 13.05 Provided that they have not given written consent to the application, the comptroller will send a copy of Form 2 and the statement to the or each proprietor of, or applicant for, the patent, to each person identified as an inventor either in the application or on Form 7 (see 13.08) and to any other person whose interests the comptroller considers may be affected by the application under s.13. Copies are not of course sent to the person making the application. Any recipient of such a copy who wishes to oppose the application should file a counter-statement in the proceedings.

13.06 [deleted]

r.10(1) 13.07 If the comptroller is satisfied that a person should have been mentioned in the published application or patent an addendum or erratum to this effect should be issued. The Register should be altered but not Form 7.

Section 13(2)

Unless he has already given the Patent Office the information hereinafter mentioned, an applicant for a patent shall within the prescribed period file with the Patent Office a statement -

- (a) identifying the person or persons whom he believes to be the inventor or inventors; and
- (b) where the applicant is not the sole inventor or the applicants are not the joint inventors, indicating the derivation of his or their right to be granted the patent;

and, if he fails to do so, the application shall be taken to be withdrawn.

r.10(4)

13.08 The request for grant of a patent (Form 1) requires an indication as to whether the applicant(s) is/are the sole/joint inventor(s). If the or any applicant is not an inventor or if any inventor is not an applicant it will be necessary to file Form 7 identifying the inventor(s) and indicating how any applicant who is not an inventor derives the right to be granted a patent.

[The surname or family name of the inventor(s) should be underlined in black ink. Where this has not been done the underlining can be effected in the Office. However, caution must be exercised in the case of overseas inventor since the surname or family name may not be obvious. Guidance from the applicant/agent should be sought in such cases.]

13.09 While it is not necessary to give details of the derivation of right, sufficient information particular to the application should be given. For example it is acceptable to indicate that the applicant is the employer of the inventor, or has rights by virtue of an assignment from the inventor to the applicant, or that the applicant is the personal representative of a deceased inventor. Alternatively, at the very least an indication should be given of which of the s.7(2) categories the applicant falls under (*Nippon Piston Ring Co Ltd's Application* [1987] RPC 120). Thus, vague statements to the effect that the applicant acquires his rights "by operation of law", or "by virtue of s.7(2)" are not sufficient, nor is an incomplete chain of title, such as "by assignment from A to B", the applicant being C. However "By assignment" on its own is, in the context of Form 7, sufficient to indicate an assignment directly from the inventor to the applicant.

[Where the Formalities Examiner discovers a defective description of derivation of right, the matter must be immediately discussed with the Formalities Manager. If the Formalities Manager confirms the objection, and provided at least three weeks remain of the prescribed sixteen-month period for submitting the Form 7, the

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agent/applicant must be telephoned and advised to correct the defect within two weeks by submission either of a fresh Form 7 or of a written request for correction. (A telephone conversation report should issue in the usual way, with a copy placed on file). If, however, there is less than three weeks left of the sixteen-month period, or the agent refuses to correct the defect, or the Form 7 or written request for correction is submitted after expiry of the sixteen-month period, the Formalities Manager must refer the matter immediately to the Divisional head of admin for further action.]

- s.7(4)
- 13.10 An applicant is not required to substantiate a statement of derivation of right to the invention. In the absence of anything being established to the contrary he is assumed prima facie to be entitled to be granted a patent (see 7.13).
- r.10(3) r.21
- 13.11 The period prescribed for filing Form 7 is sixteen months from the declared priority date or, where there is none, from the filing date. This period may be extended in accordance with r.108(2) or (3) and (4) to (7), see 123.34-41, if for example all the required information has not been supplied in time. A longer time limit may however apply in the case of a divisional application (see 15.26) or other application claiming an earlier date of filing. Different periods also apply in converted European applications (see 81.11) and international applications (see 89A.12 and 89A.18); see also 13.12.
- s.81(3)(c) s.89B(1)(c)
- 13.12 In the case of a converted European application the requirements of s.13(2) are regarded as being met, and hence Form 7 is not needed, if the provisions of the EPC requiring the applicant to give the full name and address of each inventor and an indication of the derivation of title to the invention have been met. In the case of an international application which enters the UK national phase, Form 7 is not needed if a statement required by the PCT giving the name and address of each inventor has already been filed.
- 13.13 If, in a case where it is required, a properly-completed Form 7 is not filed within the prescribed period (see 13.11) the application is taken to be withdrawn, and is consequently not published. (See also 15A.12).

[For termination procedure, see 14.199 and 15.55.]

13.14 A defect in the form may be rectified by filing a fresh form, provided that the prescribed period has not expired or, if it has, an extension has been allowed (see 13.11). (If the application is one where copies of Form 7 are sent to the inventors (see 13.15), they should be sent copies of the replacement form). No evidence is needed to substantiate this alteration, but if the prescribed period and any extension has expired the only way in which the information on the form can be changed is (in an appropriate case) by submitting a written request to correct an error (see 117.22). However if any discrepancies are minor, so that the requirements of r.10(3) can be regarded as having been complied with, they can be rectified, within a period specified by the Office. An insufficient indication of the derivation of title (see 13.09) is not regarded as a minor discrepancy, and if the prescribed period has expired an extension of the period would need to be sought under r.108 to enable the required information to be supplied. The decision in *Payne's Application* [1985] RPC 193 means that s.117 cannot be invoked to overcome the mandatory requirements of s.13(2) (see 13.13).

[If the fresh form is acceptable the Formalities Examiner should endorse it as the effective form.]

- 13.14.1 In the case of an international application in its international phase, a request to record any change in the person, name or address of the inventor should be made to the International Bureau under PCT Rule 92 bis before the expiry of 30 months from the priority date.
- 13.15 There is no longer a need for more than one copy of Form 7 to be filed for multiple inventors. The comptroller will, however, send a copy to each inventor who is not

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one of the applicants.

If a copy of Form 7 is undelivered and is returned to the Office, the agent or applicant should be contacted to see if the address is correct or if a current address is available. If this is not forthcoming, the undelivered Form 7 should be placed on file.

[Where a forwarding address has been lodged with the Post Office, mail will be redirected automatically. Under no circumstances is the Post Office allowed to give details of any forwarding address. The application should be minuted accordingly whenever an undelivered Form 7 is placed on file. 1

Section 13(3)

Where a person has been mentioned as sole or joint inventor in pursuance of this section, any other person who alleges that the former ought not to have been so mentioned may at any time apply to the comptroller for a certificate to that effect, and the comptroller may issue such a certificate; and if he does so, he shall accordingly rectify any undistributed copies of the patent and of any documents prescribed for the purposes of subsection (1) above.

- PR part 7
- 13.17 Anyone may apply for a certificate to the effect that a person should not have been mentioned as inventor in a published application or a granted patent. The application is made by filing Form 2 and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 -123.05.13 and is essentially similar to that for an application under s.13(1), (see 13.04-13.05). If the person making the application satisfies the comptroller he will issue a certificate accordingly and will correct, by means of an erratum, any copies of the patent which are subsequently distributed. The formal decision incorporates any such certificate. The Register is altered accordingly, but not Form 7.
- 13.18 Where before a patent is granted, an application is made on Form 2 for a certificate that a person should not have been mentioned in a published application, the hearing officer should issue a certificate in respect of the application if appropriate and make an order that that person is not entitled to be mentioned as an inventor in any patent granted for the invention.
 - The order shall be given effect as far as the register is concerned by the head of Tribunal Section. If an erratum or addendum is required for the published application, these will be issued by the appropriate formalities group at the earliest opportunity in the pre-grant cycle. If the patent is granted, responsibility for requesting republication of the front page and production of an amendment sheet giving details of the changes rests with Tribunal Section.]
- 13.18.1 Action under s.13(3) is not immediately appropriate where, following amendment of an application before a patent is granted, it is no longer fitting for a person correctly mentioned as an inventor in the published application still to be mentioned in any granted patent. Form 2 should not be filed in such cases. Instead the relevant facts accompanied by, whenever possible, the agreement of all parties to the person not being so mentioned, should be filed in writing at the Office. If necessary, the Office will write to any party who has not already consented, giving an opportunity for comment. If the Office is satisfied that all registered applicants, named inventors and any other person whose interests it considers might be affected, agree, it will not mention the inappropriate person as an inventor in any granted patent. If the matter cannot be agreed and the patent application becomes in order, then the application should be granted and the question resolved by an action under s.13(3).
- In the case of an application for a European patent (UK) an application under s.13(3) may be made either before or after the mention of grant of a patent in the

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s.78(2)

European Patent Bulletin but if made before such mention of grant, the relief available in respect of a published application is limited to the issue of a certificate (see also 13.04.1). An incorrect designation of an inventor may also be cancelled before the EPO under r.21 EPC.

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14.01 This section prescribes the manner of making an application, its form and content, the requirements which must be fulfilled by the contents, and provides for withdrawal of the application. Specific provisions relating to some of these matters are also laid down in rr.12-16.

The Regulatory Reform (Patents) Order 2004 and Patents (Amendment) Rules 2004: Coming into Force and Transitional provisions

14.01.1 The form and contents of an application as set out in s.14(1) and the conditions governing withdrawal of applications at the request of the applicant under s.14(9) were deregulated by the Regulatory Reform (Patents) Order 2004 ("the 2004 Order") in conjunction with the Patents (Amendment) Rules 2004 ("the 2004 Rules"). The 2004 Order and the 2004 Rules incorporated the principles of Articles 5 and 6 of the Patent Law Treaty, and both statutory instruments came into force on 1 January 2005. The Patents Rules 1995 as amended have been replaced entirely from 17 December 2007 by the Patents Rules 2007.

CODE OF PRACTICE

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- 14.01.2 The Code of Practice (the first part of which can be found below) identifies best practice points for patent applicants and agents, which if followed widely will lead to savings and efficiencies in the Office, and consequently to better service and better value. Examiners and other Office officials may on occasion draw the Code to the attention of the applicant or agent, and may ask for it to be complied with before the case is processed further if that would be more efficient.
- 14.01.3 However, it is not to be expected that best practice can always be adhered to. The Office has no right to demand compliance with the Code of Practice because the Code is advisory only and has no legal force.
- 14.01.4 If an application does not comply with one of the points of the Code of Practice then this does not necessarily justify an objection under the Patents Act or Rules. For example, an application having more than one independent claim in one category would not comply with code point 1e, but this would not usually justify an objection under s.14(5)(b). When drawing attention to non-compliance with the Code of Practice, examiners should therefore make it clear whether they are also raising a formal objection under the Act or Rules.

CODE OF PRACTICE FOR APPLICANTS AND AGENTS

Drafting and filing patent applications

This part of the Code of Practice for applicants and agents relates to the drafting and filing of patent applications under the Patents Act 1977. The quality of the application that is received by the Office determines in large part the effort that has to be expended during the statutory search and examination, in putting the application in a state to be granted, and is thus a central factor for the Code. The Code does not seek to eliminate the need for search and examination, but rather to optimise drafting towards UK law and practice and to avoid formulations that are clearly problematic for the UK search and examination. When drafting specifications for filing at this Office the aim should therefore be to adhere to the Code points below.

This part of the Code also deals with presentational and procedural matters that have to be checked by the Office after the initial filing. The Office tries to keep red tape to a minimum, but some formalities are necessary for the system to work properly. There is substantial scope for efficiency savings if the best practices set out in this Code are known and followed.

POINT 1: The claims as filed: structure

The claims as filed should be structured to have:

- a. One independent claim defining all the technical features essential to the invention or inventive concept. Inessential or optional features should not be included in this claim; consequently terms such as "preferably", "for example", or "more particularly" should not be included, as the feature being introduced by such terms does not restrict the scope of the claim in any way. The independent claim should include sufficient details of interrelationship, operation or utility of the essential features to enable the scope of the claim to be determined (see 14.110.1); and
- b. Dependent claims incorporating all the features of the independent claim and characterised by additional non-essential features (see 14.134).

In addition:

c. Further independent claims are only justified where the inventive concept

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covers more than one category, e.g. apparatus, use, process, product (see 14.159 and 14.168), complementary versions within one category, e.g. plug and socket, transmitter and receiver, which work only together (see 14.161), or distinct medical uses of a substance or composition (see 14.162).

Therefore claims as filed should not, where it might have been avoided, contain:

- d. Multiple unrelated inventions that would clearly give rise to a plurality objection (see 14.157.1).
- e. Multiple independent claims in any one category, even if only one inventive concept is present (see 14.110.1 and 14.140).
- f. Claims of a total number or complexity not justified by the nature of the invention (see 14.110.1 and 14.140).
- g. Claims which are in principle unsearchable by reason of the number of alternatives embraced, or the choice of characterising parameters or desiderata (see 14.110 and 14.133).
- h. Dependent claims that are not fully limited by the terms of the preceding independent claim, e.g. dependent claims which omit, modify or substitute a feature of an independent claim (see 14.134).

If these points are not met on filing, suitable claim amendments should be filed if the search examiner requests them to enable search (see 17.94.9 and 17.108). Amendments may be required by the substantive examiner before examining such claims (see 18.43.1 and 18.39).

The above points also apply at the entry into the UK national phase of international applications under the Patent Cooperation Treaty.

POINT 2: The claims as filed: patentability

a. The claims as filed should not, where it might have been avoided, define an invention which is clearly excluded from being patentable under the Act (see 1.07 to 1.40.4).

If this point is not met on filing, suitable claim amendments should be filed if the search examiner requests them to enable search (see 17.94.9). Examiners may either require amendment before searching or examining such claims, or may issue a report that a search would serve no useful purpose (see 17.94-17.94.10 and 17.98).

POINT 3: Other aspects of the specification as filed

- a. The use of a compact style of consistory clause, which in the description defines the invention by reference to the claims, is strongly encouraged (see 14.148).
- b. Trade marks are an indication of the origin rather than the composition or content of goods, and should not be used in patent applications where a generic term can be used instead. Trade marks are only permitted in claims where it can be shown that their use is unavoidable and does not introduce ambiguity (see 14.137). Where marks that are registered are mentioned, they should be acknowledged as such (see 14.100 and 14.101). If a trade mark is not registered, its owner should be indicated (see 14.100).
- c. Passages which confuse the scope of the invention (see 14.139.1) or claims that are unspecific (e.g. those claiming "Any novel matter...") (see 14.139)

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should not be filed. Removal of such passages will be required.

- d. The specification should be clear and precise. It should not repeat matter unnecessarily, nor should it contain matter which is irrelevant to the invention for example the complete details of well-known ancillary features need not be given (see 14.74).
- e. Only the most relevant prior art should be discussed (see 14.91 and 14.92). For example, a few documents which illustrate how a problem has previously been approached could be discussed with a view to distinguishing the invention in suit from them or illustrating its advantages.
- f. If the specification has been drafted abroad then it should be adapted to comply with sections 14(3) and 14(5) of the Patents Act 1977 and the Code points before it is filed here. Action should be taken to ensure that it is written in a reasonable standard of English before it is filed.
- g. The patent specification is intended to describe the invention precisely and it is vital that the meaning of all abbreviations and words used is clear and unambiguous. Words, abbreviations or acronyms used in the specification that are new, may be considered to be jargon, or may be at risk of being ambiguous (for example because their meaning is not yet generally settled in the field in question) should not be used unless unavoidable, in which case a definition should be given in the specification.

POINT 4: The abstract

- a. The abstract and abstract title should meet the requirements of rule 15 of the Patents Rules 2007, concisely summarising the matter contained in the specification, including the technical field, distinctive technical features, and principal use of the invention (see 14.173 to 14.184).
- b. An abstract having wording that merely reproduces an independent claim will not comply with this Code and may be rejected on the ground of non-compliance with the Rules (see 14.184).

POINT 5: Forms and formalities on filing

- a. The presentation of the application (including drawings) should meet the requirements of rule 14 of the Patents Rules 2007 (see 14.26 14.57). For example, documents must be legible and capable of reproduction, and the margins should be kept clear and free from headers or footers denoting references or other matter (see 14.28). Shading is allowed in drawings so long as it does not obscure any detail in the drawings. In addition, a specification may include photographs if they are clear enough to be reproducible (see 14.41).
- b. An official form should be used where required by the Rules, and it should be completed fully and accurately (see 14.04 for the application form).
- c. Supporting documents should also be provided where appropriate; for example:
 - a fee sheet where fees are being paid a covering letter where some explanation is needed.
- d. To allow us to direct incoming items quickly to the right place all appropriate identifiers should be given:
 - Form 1 should give ADP number(s) and customer reference;

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- Forms and letters filed after Form 1 should give application number and (optionally) customer reference;
- Fee sheets should give all relevant details, such as deposit account number or credit/debit card details;
- Bank transfers should state the application or patent number, or, if not known, the reason for payment e.g. search fee.

In correspondence with applicants and their representatives, the Intellectual Property Office will use customer references if given, and will tell agents the applicant's ADP numbers (see 14.04.1 and 14.04.5).

- e. If it is critical that an application be filed within a certain time window such as the twelve months of the Paris Convention, the application should be filed with sufficient time remaining for any fatal defects to be detected and put right.
- f. The originals of faxed documents should only be filed when requested to do so by the Office (see 14.02).
- g. Electronic filing of applications is strongly encouraged; official fees are reduced for certain electronically-filed documents. See www.ipo.gov.uk/p-apply-online.

[Deleted]

Section 14(1)

Every application for a patent -

- (a) shall be made in the prescribed form and shall be filed at the Patent Office in the prescribed manner;
- (b) [repealed]

Section 14(1A)

Where an application for a patent is made, the fee prescribed for the purposes of this subsection ("the application fee") shall be paid not later than the end of the period prescribed for the purposes of section 15(10)(c) below.

s.119 CoP 14.02 The prescribed form of the application is laid down in the rules. The filing fee was abolished by the 2004 Order, which replaced it with the application fee specified in s.14(1A). An application may be filed by hand, by post, or by facsimile transmission (fax). Alternatively, an application may be submitted online via the Office website, or using the secure online filing system provided by EPO Online Services if the filer has completed the enrolment procedure for that service. The number for fax filing of applications is +44 (0)1633 817777. Applications should not be sent to any other fax number in the Office; amendments and correspondence relating to applications should not be sent to any other number unless specifically instructed otherwise in a particular case. Although the Office's designated fax filing machines are open to receive transmissions 24 hours a day, seven days a week and record the time and date of receipt automatically, the filing date accorded is the date of receipt if the Office is open for that class of documents; if not, the next working day (see also 14.29). Confirmation copies are only required if requested by the Office e.g. if there is a problem with the clarity/completeness of the faxed

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document received. Confirmatory copies should be prominently marked "In confirmation of fax". See also 22.07 for filing considerations relating to documents which might include information of relevance to national defence or security. The hours and days when filings may be made are governed by s.120. Under r.97 of the Patents Rules 1995, an application filed by post was deemed to have been filed when the letter containing it would be delivered in the ordinary course of post. However, the Patents Rules 2007 do not include a rule relating to postal deeming and therefore any document posted on or after 17 December 2007 will be accorded the date of receipt it is actually received in the Office.

[Normally if an urgent document is expected by fax, the intended recipient should instruct the sender to mark the header sheet clearly as urgent and for the attention of the recipient. The staff attending the fax machine should be alerted by telephone (ext.4570) and will then advise the recipient when the fax arrives so that it may be collected by hand. In the exceptional case that correspondence or draft amendments is requested to be sent to a fax machine other than at the number above it is the recipient's responsibility to ensure that it is properly stamped as received and sent to Index & Scan to be scanned on to the relevant dossier.]

Section 14(2)

Every application for a patent shall contain -

- (a) a request for the grant of a patent;
- (b) a specification containing a description of the invention, a claim or claims and any drawing referred to in the description or any claim; and
- (c) an abstract;

but the foregoing provision shall not prevent an application being initiated by documents complying with section 15(1) below.

14.03 While an application must eventually contain all the items referred to in s.14(1A) and this subsection, the final proviso of s.14(2) makes clear that for an application to be initiated and given a filing date it is sufficient for it to comply with the conditions of s.15(1), (see 15.02-15.06).

REQUEST FOR THE GRANT OF A PATENT

r.12(1) 14.04 The request must be made on Patents Form 1; this is designated a r.25(1) formal requirement (see 17.07).

Considering each part of the form:-

1 Reference Number

CoP

14.04.1 Although there is no obligation to provide such a reference, it is clearly in the applicant's interest to do so, since until an application number has been accorded by the Office there is no reliable way of identifying a particular application. It may also be useful should any confusion arise over the application numbers accorded to several cases filed together. If provided, the Office will use the applicant's reference number in correspondence related to the application.

14.04.2 [deleted]

14.04.3

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2 Applicant's Details

CoP r.12(2) r.12(3) 14.04.4 The applicant's name and address should be entered in Part 2 of the Form (see 15.03), but failing that the Form must contain sufficient information to enable the applicant to be contacted. Where a date of filing is accorded to an application which does not give the applicant's name and address, the applicant must be notified of the failure, and the comptroller may refuse the application if the applicant fails to file his name and address within two months of such a notification. Under r.108(1) together with r.108(5) and (7), the two-month period for filing the applicant's name and address may be extended at the comptroller's discretion in tranches of 2 months, but no extension may be granted after two months following the expiry of the period as prescribed or previously extended - see 123.36.10-12. Where Parts 2 and 4 of the Form do not, between them, contain enough information to enable the applicant to be contacted, the contact information in Part 12 may suffice.

[If contact details are provided but establishing contact is difficult, advice should be sought from Legal Section.]

- s.7(1)

 14.04.5 An application may be made by any person either alone or jointly with another. ("Person" means either an individual or a corporate body, see 7.02). If the inventor is not also an applicant he should not be named on Form 1.
 - 14.04.6 An applicant who is an individual should apply in his true name. Exceptionally, a pseudonym may be used if it is well established and is customarily used by the individual for banking and other business purposes. The name must be given in full, the surname or family name being underlined. Letters or statements denoting academic or professional qualifications may appear after the name. A statement of nationality or occupation is not required and should not be given. Once a particular established name and signature has been used subsequent business should not be effected by the same individual using a different name or signature unless the name has changed, eg due to marriage. A corporate body should be designated by its legal name. In the case of either an individual or a corporate body, a business name or trading style, eg "trading as XYZ", or a former name is not required and should not be given. If known, the automatic data processing (ADP) number of the applicant should be given for identification of the applicant; this number will supplied to an applicant's agents.
 - 14.04.7 If an application is made on behalf of a Government Department, the applicant should be stated to be the Secretary of State or Minister responsible for the department, and not the individual holding such office. Applications from police forces should be made by the relevant Police Authority.
 - 14.04.8 Each applicant must give, in full, a permanent address, which may be either a private or a business address. A c/o is not acceptable unless it can be shown that it is a permanent address for the applicant which the Office can rely on for communicating with the applicant, e.g. if, in the case of a company, it is registered with Companies House as the company's address. It is in the applicant's best interests to provide the Office with a secure and reliable address. Standard abbreviations, e.g. Rd, USA, are allowable.
 - 14.04.9 Since the United Kingdom does not accord diplomatic recognition to Taiwan the statement "Republic of China" for the country of incorporation or address of an applicant located in Taiwan cannot be accepted and should be objected to. If the applicant disagrees he should be advised that the onus is on him to ascertain from the Foreign Office what is considered to be an acceptable designation.
 - 14.04.10 Where there is not enough space on the form for the details of more than one applicant, any further names and addresses should be given on a continuation sheet and the use of a continuation sheet should be indicated in part 9 of the form.

3 Title of Invention

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r.44(1)(d)

14.04.11 This is the title entered in the register and in the list of new applications in the Journal. By virtue of s.14(1)(a) and r.12(1), a title is a formal requirement, thus if there is no title given on Form 1 the applicant should be required to provide one, or to confirm that the title, if any, on the specification is to be used on Form 1. (See also 14.49-51 and 19.24). The title should avoid disclosing the invention, since it is published in the Journal prior to publication of the application under s.16(1).

4 Address for Service Details

14.04.12 If the applicant has appointed an agent his name should be given in this part of Form 1. The agent need not be registered (see 274.03).

[If the agent's name is missing from Form 1, but it is clear from the information supplied who the agent is, the agent's details should be inserted on COPS by the Formalities Examiner, and Form 1 annotated appropriately.]

[Deleted]

CoP r.101(1) 14.04.13 An agent filing an application is assumed to be duly authorised to act for the applicant, and in general no specific evidence to this effect is required. (The comptroller has the power to require an agent to produce evidence, at any stage in proceedings, that he is authorised. This will be done only if there is some reason for doubting the authority or for requiring it to be confirmed). If however, subsequent to the filing of Form 1, the applicant wishes to change his agent or an agent is appointed for the first time, the incoming agent must file Patents Form 51. Notification on Form 51 should not be made if the (new) agent will only perform administrative tasks such as paying renewal fees or registering an assignment. If an applicant who has been represented by an agent decides to dispense with the services of the agent and represent himself as a private applicant, then he should be advised to provide written confirmation of this change. A copy of the applicant's letter will then be sent to the former agent.

[The Office is no longer prepared to retain general authorisations; if one is filed it should be returned to the agent. If a specific authorisation is filed it will, although redundant, be allowed to remain on the file.]

r.103 CDPA

s.281(5) r.104

PR Sch. 4 Parts 2 & 3 14.04.14 Every application must include an address for service, which must be in the United Kingdom, another EEA state or the Channel Islands. An address for service of a patent agent cannot be accepted in the Channel Islands unless they also have a residence or place of business in the UK, Isle of Mann or the European Economic Area (see 281.04). The address for service is treated for all purposes as the address of the person concerned with the proceedings and all communications must be addressed to the applicant at or c/o this address. Communication with the applicant can only be through this address; if an agent has been appointed and the applicant contacts the office direct he must be advised to communicate through his agent. If there is no acceptable address for service on an application and there is sufficient information to contact the applicant, he should be contacted and be directed to file an acceptable address for service within 2 months (this period can be extended using Rule 108(2) and 108(3) – see 123.36.5). If an acceptable address is not provided within this time period, or there is insufficient information to make contact with anyone to provide such an address, the application is treated as withdrawn.

[Where the address for service is not in the EEA or the Channel Islands, a request for compliance with this requirement within 2 months should be made, with a warning that failure to comply will lead to the application being withdrawn under r.104(4)(a).]

[If no address has been given at part 5, but it is clear from the information given that an agent is acting for the applicant the Agent's address will be entered on COPS by the formalities examiner, and Form 1 annotated appropriately. Likewise

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if no agent has apparently been appointed and an address given in part 3 is within the United Kingdom, another EEA state or the Channel Islands, this will be entered as the address for service on COPS.]

[Deleted]

5 Declaration of Priority

r.6(1) & (4)

14.04.15

If priority is claimed from an earlier application (see s.5), the date and country of filing of the earlier application should normally be declared at the time of filing the application in suit. The file number of the earlier application should preferably also be stated if it is available. A copy of the earlier application and any necessary translation do not however need to be filed at this stage.

6 Claiming an Earlier Application Date

s.15(9) 14.04.16 The number of the earlier application and its filing date should be given. In the case of an application under s.15(9) (a divisional application) the request for an earlier filing date must be made at the time of filing the application in suit, (see 15.18).

7 Inventorship

- s.13(2)

 14.04.17 Where all the applicants named in Part 2 of the Form 1 are also the inventors, a mark should be made in the top "Yes" box. If one or more of the applicants is not an inventor, the top "No" box should be marked instead. Where there is one or more inventor whose name is not given as an applicant in Part 2 of the Form, a mark should be placed the lower "Yes" box in part 7 of the Form. It follows that the lower "No" box in part 7 of the Form should only be marked in the case where all inventors are named applicants and all named applicants are inventors.
- s.7(3)

 14.04.18 Since "inventor" means the actual deviser of the invention a corporate body cannot claim to be an inventor. Where an applicant named in Part 2 of the Form is a corporate body and the top "Yes" has been marked in Part 7, an objection should be raised.

8 Application Fee

s.15(10)(c) r.22(2) r.22(7) 14.04.17.1 While the application fee may be paid at any time up to the expiry of the period prescribed by r.22(7), nevertheless when it is paid at the time of filing this fact should be indicated by placing a mark in the "Yes" box in part 8 of the Form 1, and where it is not paid at the time of filing it follows that the "No" box should be marked. If the application fee is paid at a later date, a surcharge will be payable.

9 Documents making up the application

14.04.19 It should be noted that the information in the check list relates to the application as filed; pages filed subsequently should not be indicated in this check list.

s.15(1)(c)(ii) s.15(10)(b) r.22 14.04.18.1 Where the application is not accompanied by a description, and a reference to an earlier application under s.15(1)(c)(ii) is relied upon for qualifying for a date of filing, the application number, country of filing and date of filing of that earlier application should be entered in Part 9 of the Form. A reference must be substantiated by the filing of a certified copy within the time specified by rule 22(3), which is four months from the date of filing, and a description must be filed within the time specified by rule 22(1), which is the same period as for the claims and abstract and is the later of twelve months from the earliest date or two months from the date of filing. Where both a description is filed and the details of an earlier application are given in Part 10 of the Form, the applicant (or his agent) should be contacted to clarify under which of the (mutually exclusive) options of s.15(1)(c) the application is made.

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[If the check list has not been completed, or if it has been completed in a manner which is not consistent with what has been filed, the formalities examiner should raise the matter with the agent or applicant.]

10 Documents accompanying the application

14.04.20 Documents or forms filed subsequently should not be indicated in this check list.

11 Request

14.04.21 The form must be signed at this part either by the or each applicant or by the agent who has filed the application. Where a signature is missing, the formalities examiner should raise an objection requiring a duly signed form to be submitted (see 15A.20).

12 Person to contact

14.04.22 If a contact name and telephone number is given any telephone enquiry about how the form has been filled in should be made to the person named.

Application of Rule 4(2)

r.4(2)

14.04.23 Where an earlier version of Form 1 is used, and where the information on that Form is sufficient for the application in question, no objection should be raised and the Form should be regarded as a Form acceptable to the comptroller and containing the information required.

[14.05-14.24 Deleted]

Amendment or correction of Form 1

r.49 14.25 If the applicant wishes to correct his or her name, then Form 20 is required. However, correction of any of the other information given on Form 1 merely requires notification in writing. (See 19.05-19.12, 32.06 and 117.17-117.21.)

FORM AND PRESENTATION OF DOCUMENTS

r.25(1) 14.26 The size and presentation of the documents (including drawings) r.25(2) making up an application are governed by r.14. The requirements of r.14(1), (2) and (3) are designated as formal requirements (except for where an application is delivered in electronic form or using electronic communications, in which case only the requirements of rule 14(1) are formal requirements); those that are not so designated are identified in paragraphs 14.54, 14.55 and 14.57. Some general provisions regarding the content of the specification are laid down in r.12(4)-(7); these are not designated formal requirements.

Size and presentation

PR Sch. 2 14.27 All documents making up an application must be on A4 matt white part 1 paper.

PR Sch. 2 14.28 For drawings, the minimum margins must be 20mm at the top and the parts 1-3 left hand side, 15mm at the right hand side and 10mm at the bottom. There must not be any frames (lines surrounding matter). For documents other than drawings the minimum margins must be 20mm at the top, right, left and bottom. The margins of all documents should be completely blank, even from case reference details; line numbers and page numbers are regarded as being part of the text rather than being in the margin.

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[It will not be necessary to object to de minimis deviations from the prescribed minima if it is certain that printing and binding of the document will not be affected.]

PR Sch. 2 14.29 The contents of all documents, including drawings, making up an part 1 para. application or replacing such documents must be suitable for reproduction.

Any document which has been filed by facsimile transmission (fax) must be legible, and the responsibility for ensuring legibility rests with the sender. If upon subsequent examination any part of a document received is unintelligible, no filing date will be accorded to that part. Appraisal of documents filed by fax occurs not upon receipt but when they are examined in the normal course of business (see 14.02).

PR Sch. 2 14.30 The description, claims and abstract must use at least 1½ line spacing parts 1-3 and the capital letters in any typeface or font used must be more than 2mm high.

[If the specification of a private applicant's case does not meet the r.14 requirements the applicant should be given the opportunity to overcome any deficiency. In the event that the applicant does not comply with an initial request and providing that there are no other outstanding requirements, the specification should be retyped in the Office with the approval of the Formalities Manager. The retyped application should be accompanied by a suitable instruction for publication. The applicant should also be advised in writing that his application has been retyped and given four weeks from the date of the letter being issued in which to object. If there is no objection, the application can be allowed to proceed to A-publication.]

14.31 [deleted]

PR 1995 14.32 The specification (including drawings) and abstract, and any r.20(2) replacement sheets, must be filed in duplicate for cases filed before 26 June 2006, but there is no need to do so for cases filed after this date. (See also 14.02 and 14.29 regarding documents filed by fax.) Carbon copies are acceptable provided that the requirements set out in Schedule 2 are met.

PR Sch. 2 14.33 The request for grant (Form 1), the description, the claims, the paras. 8 & drawings and the abstract must each begin on a new sheet. The pages of the description, claims and abstract are normally secured, eg by stapling, in the top left-hand corner; the request for grant and the drawings normally remain as separate sheets.

PR Sch. 2 14.34 The pages of the description and claims must be numbered paras. 4, 5, 12 & 14 filed later than the description. The sheets of drawings must also be numbered consecutively in a single series, and the drawings themselves must be numbered consecutively in a single series. Where a sequence listing is set out at the end of the application, it must be numbered consecutively in a separate series.

[When re-numbering of pages is required as a consequence of addition or excision of pages, this will be carried out by the formalities examiner before grant. Replacement pages therefore should not be required. Numbering with a letter suffix (eg page 2a) is not satisfactory and should be corrected (together with deletion of any explanatory note such as "page 2a follows" on a preceding page) before an application is sent for grant. The formal re-numbering will then be effected prior to B publication. No objection should be raised to the absence of line numbering.]

PR Sch. 2 14.35 For documents other than drawings, page numbers must be located at the top or bottom of the page (but not in the margin) in the centre; the numbers are regarded as part of the text rather than as being in the margin.

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[If page numbers are in the wrong place and there is a space in the right place, the amendment should be made by the formalities examiner by deleting and reentering without making an objection. Line numbering may be ignored when measuring margins.]

Alterations

PR Sch. 2 14.36 All documents, including drawings, making up an application or replacing such documents must be suitable for reproduction and must not include frames (lines surrounding matter).

14.37 Alterations may thus be allowed if they can be regarded as de minimis. Any such alterations in manuscript should be neat and printed rather than written. They must not extend into the minimum margins and they must not be so placed as to hinder the normal scanning of the page by the reader. They must also be in black ink - blue ink is not acceptable as it cannot be reproduced reliably.

[In applying the de minimis rule the overriding consideration is that the resulting document must, in all respects, be suitable for direct reproduction and that the legibility of the text must not be impaired by any alterations. Further, the number of alterations and the manner of their execution should not give the page an untidy appearance. The determination of where to draw the line must be left to good sense. As a guide it may be taken that if, say, one or two words of a claim are changed, the consequential manuscript amendment of these words whenever they occur throughout the description could be permitted. On the other hand, a manuscript amendment of several lines should not be regarded as de minimis. Manuscript insertions made by the examiner should be printed, but objections should not be raised if the applicant or agent writes rather than prints provided the writing is neat and clearly legible.]

14.38 The question as to what is the number and nature of deletions that would be considered reasonable is a matter for judgement; it should be borne in mind that the aim is to obtain a document which is reasonably free of deletions. It may be reasonable to delete the same word or part of a word throughout the specification, or to delete a few words, all or part of a sentence or a short paragraph on a single page. A single deletion comprising most of a page is not considered reasonable unless it is done in a manner leaving the deleted area blank. Nor is it considered reasonable to have many deletions on a single page, or deletions which break up the text in a manner making reading awkward. No objection is raised to otherwise reasonable deletions occurring on several pages so long as the total number remains moderate having regard to the length of the specification. While the extent of deletions may not be such as to require objection the subsequent inclusion of further deletions may not be allowable.

14.39 Whilst the overriding consideration is that the specification shall be capable of being directly reproduced, there is a further consideration that any deletions should not either by their number or the manner of their execution spoil the appearance of the finished document. Deletions should preferably be effected by erasure or obliteration -visible or "invisible". Striking-out should be clear and neat; a straight-edge should be used, except for crossing out single letters. Deletions should be made in black ink and be such as to ensure satisfactory reproduction. There must be no uncertainty as to the extent of the deletion.

Further requirements for drawings

PR Sch. 2 14.40 Drawings must not only be such as to permit direct reproduction, as laid down in paragraph 2 of Schedule 2, but the scale of the drawings and the distinctness of their graphic execution must be such that it would still be clear if it were reduced by linear reduction to two thirds of its original size. Since the drawings when reproduced may be of a different size than when filed, no scale should be specified in words and no dimensions

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should be given in the drawings. If it is considered desirable, a scale or other reference for making reference may be included, but it must be represented diagrammatically.

- PR Sch. 2 14.41 Drawings should comprise black lines, but may also include shading so long as the shading does not obscure detail within the drawings. Cross-sections should be indicated by hatching. A specification may include photographs, however as with all parts of the specification, they must be clear enough for reproduction. Colour drawings or photographs are not allowable.
- PR Sch. 2 14.42 Figures of the drawings should be numbered consecutively in a single para. 12 series, independently of the numbering of the sheets.
- PR Sch. 2 14.43 All numbers, letters and reference signs on the drawings should be simple and clear; brackets, circles or inverted commas should not be used in association with numbers and letters. The capital letters in any typeface or font used in any drawing must be more than 3mm high. The Latin, and, where customary, the Greek alphabet should be used.
 - 14.44 The drawings should not contain extensive textual matter. A few words may be allowed as aiding understanding of the drawings. In the case of electrical circuits and block schematic or flow sheet diagrams, a few short catchwords are allowable and may be desirable. If extensive text is present, such that the sheet may be considered to constitute part of the description, then objection should be raised under r.14(3) together with paragraph 19 of schedule 2, which states that a drawing must not be included in the description.
 - 14.45 The title of the invention, and the applicant's or agent's name, should not appear on the drawings.
 - 14.46 Flow sheets and diagrams are considered to be drawings.

Language

- r.14(1) r.113(1) s.15(2)(a)
- 14.47 Apart from the certified copies of priority applications required by r.8, all documents (including drawings) making up an application, or replacing such documents, must be in English or Welsh. Where the original document is not in English or Welsh this requirement can be met by the foreign-language document being accompanied by a translation into English.
- r.12(8) r.12(9)
- 14.47.1 Notwithstanding the requirement to file an application in English, an application can qualify for a date of filing if the description (or what appears to be the description) is in a foreign language, providing that the indication that a patent is sought and the identity of the applicant (or the means of contacting him) are in English. Where a date of filing is accorded to an application comprising a foreign-language description, the applicant must be notified of the failure to comply with r.14(1). The comptroller may refuse the application if the applicant fails to file a description in English or Welsh within two months of such a notification (extendable at the discretion of the comptroller under r.108(1) together with r.108(5)-(7)).

Content of the application

r.12(4) r.12(7) 14.48 The specification should state the title of the invention and should continue with the description, claim or claims and any drawing referred to in the description or any claim, in that order. Where the specification includes drawings, the description must include a list of drawings briefly describing each of them. The claims should be headed in such a way that the commencement of the claims is clearly identifiable, eg by the title "Claims". In *R v Comptroller-General of Patents, ex parte Penife International Ltd* [2004] RPC 37 which considered the requirement of Art.11(1) of the PCT to file claims with the application, it was held that a consistory clause setting out the scope of the invention was

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part of the description and was not a claim.

[There is no prescribed preamble to the claims. Although the simple title "Claims" is preferred, no objection should be raised to any title which serves the required purpose. The title "What I (or we) claim is", (as used under the 1949 Act) is allowable.]

Title

r.12(6)

14.49 The title must be short and indicate the matter to which the invention relates. If it is not in agreement with that given on Form 1, (see 14.04.10), or even if there is no title on the specification, the specification as filed should be published under s.16(1). The substantive examiner will in due course require the presence of a suitable title on the specification but it is permissible for this to differ from that on Form 1; amendment of the latter would not be necessary.

[The maximum length of a title permitted by COPS on the computerised register is 158 characters. If a title to be entered on the Register exceeds this the Office will amend the title accordingly (see also 18.42, 18.86).]

- 14.50 The title should not contain a fancy or trade name, a person's name, the word "patent" or the abbreviation "etc" whatever is intended to be covered by this later term should be indicated more explicitly, or the words "and the like" may, if appropriate and clear in context, be used.
- 14.51 The titles of specifications (and those on Form 1) are used by patent searchers and to be of assistance in this connection a title should not only adequately indicate the subject of the invention but should also avoid the use of words which might convey different meanings to persons interested in different arts.

Some requirements for the technical content

PR Sch. 2 14.52 The request for grant, the description, the claims and the abstract must not contain drawings; any drawings forming part of the specification must be on sheets which are separate from the text and numbered as a separate series.

r.13(7) PR Sch. 2 para. 5 14.53 The description, the claims and the abstract may contain chemical or mathematical formulae. If it is considered necessary an applicant may be required to file a copy of such formulae prepared in the manner prescribed for drawings (see 14.31). For applications which include a sequence listing, this listing is considered to form part of the description (rather than the drawings) and therefore may be inserted at any point in the description. These would then be subject to excess pages fees as they are part of the description. It is usual, however, for the sequence listing to be placed at the end of the description and before the claims. Alternatively, a sequence listing may be set out at the end of the application, in which case it must be numbered consecutively in a separate series to the description and claims, and rule 12(4) does not apply. In this case, the sequence listing would not be subject to excess pages fees. See 15A.04 for practice at preliminary examination stage when a sequence listing has not been filed.

[Rule 13(6) requires that, if it is reasonably possible, a sequence listing shall be delivered in electronic form or using electronic communications, even where the patent application is not delivered in electronic form or using electronic communications.]

PR Sch. 2 14.54 para. 22 contai r.25(1) set ou

r.14

14.54 The description and the abstract may contain tables. The claims may contain tables of information only if the comptroller agrees. This is one of the requirements set out in part 4 of Schedule 2 and is therefore not a formal requirement. The question as to whether tables in a claim are allowable is therefore a matter for the substantive examiner, and no objection should be raised at an earlier stage.

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PR Sch. 2 14.55 The terminology and any references used must be consistent part throughout the application for a patent. Only technical terms, signs and symbols which are r.25(1) generally accepted in the field in question may be used. The same features should be denoted by the same reference sign throughout the application. References must only be r.14 included in the drawing(s) where they are mentioned in either the description or the claims. These are not formal requirements; hence amendment to meet them should not be required at the preliminary examination stage.

PR Sch. 2 Where units of measurement used in the application are not standard para. 24-25 international units of measurement, the equivalent standard international units of measurement must be provided, and where no international standard exists, units must be used which are generally accepted in the field. Temperatures should be given in degrees Celsius (centigrade), except that as a matter of practice, degrees Kelvin are acceptable to express cryogenic or colour temperatures. There is, however, no objection to nonstandard units used in a statement of prior art by way of direct quotation.

> [Council Directive 80/181/EEC (as amended by Council Directive 89/617/EEC and Directive 1999/103/EC of the European Parliament and of the Council) prescribes the use of SI units. While applicants should be advised to use such units, there is no sanction against the use of non-SI metric-based units (eg Angstrom units), and they should not be objected to.]

14.57 The EC Units of Measurement Directive (Council Directive 80/181/EEC, r.25(1) as amended by Council Directive 89/617/EEC and Directive 1999/103/EC of the European Parliament and of the Council of 24 January 2000) requires the sole use of metric units in documents (such as patent specifications) sent out by any part of government on or after 1 October 1995. Under transitional provisions which last until 31 December 2009, nonmetric units may be used but only in conjunction with metric ones and then only as supplementary indications with metric units predominating. There is therefore an inconsistency between paragraph 24 of Schedule 2 of the Patents Rules 2007 and the Directive in that the Rules permit dual expression without limit to time and without any requirement for metric predominance. The same inconsistency exists between the Directive and PCT Rule 10.1(a). Moreover, for international applications entering the national phase it is not permissible under the PCT to impose national or regional requirements relating to the form or the content of the application different from or additional to those of the PCT itself. Pending resolution of these inconsistencies, examiners should simply ensure that the requirements of paragraph 24 of Schedule 2 are met in any specification sent for grant. No amendment should be required at the preliminary examination stage to secure compliance with that rule, since it does not define a formal requirement nor is it specified in rule 23 as being one of the rules relevant to preliminary examination. Applications which do not comply with paragraph 24 of Schedule 2 (or the Directive) are nevertheless published under s.16 as filed.

> [RC35 should be used to object to the absence of metric or Celsius units. When both non-metric and metric values are given, the examiner should not check that the conversions are accurate for consistency's sake, but objection should be raised in the case of manifest error.]

Section 14(3)

The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.

S.14(3) is intended to have, as nearly as practicable, the same effect 14.58 as the corresponding provisions of the EPC, PCT and CPC. Article 83 EPC and Article 5 PCT require the invention to be disclosed "in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art". An objection under this section of Art is

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s.130(7)

often said to relate to "sufficiency of disclosure" or "sufficiency". The pre-grant provision under s.14(3) accords directly with s.72(1)(c) which sets out the same requirement for the validity of the granted patent. Whilst the bulk of the case law discussed below relates to proceedings under s.72, the principles set out in these cases are pertinent both to s.14(3) and s.72(1)(c).

s.76(2)

14.59 It is the responsibility of the applicant to ensure that, at the time of filing the application, the disclosure is clear and complete in respect of the invention claimed in each of the claims. If it is not, then either the application must be refused or, if it is possible to do so, the claims must be restricted to that matter which has been adequately disclosed i.e. that for which there is an enabling disclosure (see 14.67 relating to enablement). Deficiencies in the disclosure cannot be rectified by adding matter subsequent to filing without falling foul of s.76(2).

SUFFICIENCY: SUMMARY OF GENERAL PRINCIPLES

14.60 In <u>Eli Lilly v Human Genome Sciences [2008] RPC 29</u> at [239] Kitchin J gave the following summary of the relevant principles, to be applied when assessing whether an application satisfies this section of the Act:

"The specification must disclose the invention clearly and completely enough for it to be performed by a person skilled in the art. The key elements of this requirement which bear on the present case are these:

- (i) the first step is to identify the invention and that is to be done by reading and construing the claims;
- (ii) in the case of a product claim that means making or otherwise obtaining the product;
- (iii) in the case of a process claim, it means working the process;
- (iv) sufficiency of the disclosure must be assessed on the basis of the specification as a whole including the description and the claims;
- (v) the disclosure is aimed at the skilled person who may use his common general knowledge to supplement the information contained in the specification;
- (vi) the specification must be sufficient to allow the invention to be performed over the whole scope of the claim;
- (vii) the specification must be sufficient to allow the invention to be so performed without undue burden."

Similar summaries have also been utilised in a number of court decisions (see e.g. Wobben v Vestas-Celtic Wind Technology Ltd [2007] EWHC 2636 (Pat).)

The purpose of the requirements imposed by s.14(3) and s.72(1)(c) is to prevent a patentee laying claim to products or processes which the teaching of the patent does not enable the skilled addressee to perform (*Zipher Ltd v Markem Systems Ltd* [2009] FSR 1). Thus, all consideration of sufficiency in essence deals with the extent to which the applicant has provided an enabling disclosure for their invention (see also 2.10 and 72.03).

14.61 Whilst there is only one provision under the Act, it is now settled law that sufficiency in terms of the disclosure being clear and complete enough for the invention to be performed by the person skilled in the art is approachable in three different ways:

- (1) Classical insufficiency
- (2) Insufficiency by ambiguity

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(3) Insufficiency by excessive claim breadth

A summary of what should be understood by each of these approaches to sufficiency is provided in *Zipher Ltd v Markem Systems Ltd* [2009] FSR 1, with the first two also being set out in *Medimmune Ltd v Novartis Pharmaceuticals UK Ltd, Medical Research Council* [2011] EWHC 1669 (Pat). These three approaches will be considered in more detail in 14.67-14.82 below, however first it is necessary to set out some general points common to all three.

Claim construction

14.62 Construction of the claims should be approached in the usual fashion (see s.125). This involves putting a purposive construction on the claims, interpreting them in the light of the description and drawings as set out in Section 125(1).

Date at which sufficiency is judged

14.63 In <u>Biogen Inc. v Medeva plc [1997] RPC 1</u> the House of Lords held that sufficiency should be decided at the date of filing of the application (rather than the date of publication as had been the case under the 1949 Act). This being the case because "[i]t would be illogical if a patent which ought to have been rejected under section 14(3) is rendered immune from revocation under section 72(1)(c) by advances in the art between the date of application and the publication of the specification."

The person skilled in the art

14.64 The concept of the skilled person is that of the uninventive, but technically competent person (or team) who is considered for the purpose of assessing inventive step (see 3.26-3.28.2). As stated by Aldous J in *Mentor Corporation v Hollister Inc.* [1991] FSR 557 (at page 561):

"The section requires that the skilled man be able to perform the invention. Such a man is the ordinary addressee of the patent. He must be assumed to be possessed of the common general knowledge in the art and the necessary skill and expertise to apply that knowledge. He is the man of average skill and intelligence, but is not expected to be able to exercise any invention. In some arts he may have a degree, in others he will be a man with practical experience only. Further, in circumstances where the art encompasses more than one technology, the notional skilled addressee will be possessed of those technologies which may mean that he will have the knowledge of more than one person."

However, although the phrase "person skilled in the art" is construed in the same way when considering sufficiency and inventive step, for the purposes of s.14(3) the skilled person is seeking to make the patent work and does so with the common general knowledge at the time the patent was filed. In contrast to the situation for inventive step purposes, the skilled worker has the patent in front of them, and thus is "trying to carry out the invention and achieve success,...not searching for a solution in ignorance of it." (see Zipher Ltd v Markem Systems Ltd [2009] FSR 1 at page 50). This can be significant in determining the nature and skills of the skilled person (or team), as they need not be the same for both inventive step and sufficiency purposes (See Schlumberger Holdings Ltd v Electromagnetic Geoservices AS [2010] RPC 33 at paragraphs 40 and 61-64, and MoPP 3.28-3.28.2).

14.65 In <u>Halliburton Energy Services Inc v Smith International (North Sea) Ltd</u> [2006] RPC 2, the Patents Court held that where a programmer formed part of the

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addressee team of a computer-based invention, it was essential to form a view of his capabilities. It was mentioned that the writing of anything other than a trivial program required substantial effort in writing and debugging even though much programming required no creative thought and a competent programmer would have substantial experience in his area of expertise.

14.66 The court in <u>Kirin-Amgen Inc. v Roche Diagnostics GmbH [2002] RPC</u> 1 concluded that, once the addressee's skill and knowledge has been assessed, it may nevertheless be appropriate to consider that the skilled person might consult someone else on a certain point when trying to implement the teaching of the patent. Since a patent is a document which is intended to be practical, rather than theoretical, in nature - and its teaching is there for the purpose of being worked - it would be unrealistic to adopt too rigid an approach to the guestion of the knowledge of the skilled addressee.

14.66.1 In *Regeneron Pharmaceuticals v Kymab Ltd* [2018] EWCA Civ 671, it was held that "the skilled person is not bound to carry out the invention precisely as described and can use the common general knowledge to perform the invention and make any obvious changes that may be necessary, provided of course that any work involved is not undue" (see 14.85-14.88 for detail on undue burden).

Classical Insufficiency

14.67 This is the name now commonly given to what was previously understood simply as 'insufficiency'. It relates to the situation where there is no enabling disclosure. In <u>Zipher Ltd v Markem Systems Ltd [2009] FSR 1</u> Floyd J offers the following useful summation of the objection:

"Classical insufficiency arises where the express teaching of the patent does not enable skilled addressee to perform the invention. This type of insufficiency requires an assessment ...of the steps to which it would be necessary for the skilled reader or team to take in following the teaching of the specification and in order to arrive within the claim. Plainly the steps should not include inventive ones. But a patent can also be found insufficient if the steps can be characterised as prolonged research, enquiry or experiment."

Degree of sufficiency required

14.67.1 In order to be sufficient the application must include at a minimum something amounting to one embodiment or example that can be put into effect. However this should not be equated with one embodiment being enough to necessarily render the application sufficient as was regarded as the situation under some previous authorities (Chiron Corp. v Organon Teknika Ltd (No.3) [1994] FSR 202 at 241, Mölnlycke AB v Procter Gamble (no.5)[1994] RPC 49). Indeed Generics (UK) Limited and others v H Lundbeck A/S [2009] RPC 13 illustrates how even when a claim defines only a single discrete product, in that case a single chemical compound, there can still be argument over whether that is sufficiently enabled. Instead the application must be sufficient to enable the whole breadth of the claim to be worked. This is discussed further under 'Insufficiency by excessive claim breadth' below (14.79-14.82). However in all situations sufficiency is a question of fact - does the patent enable the invention to be worked across the breadth of the claim? The courts have sought to provide some guidance in answering this question, but have warned "one must be on one's guard against formulations that gloss the statutory requirement as there is always a risk that they will end up being substituted for it" (Halliburton Energy Services Inc v Smith International (North Sea) [2006] RPC 2 at para.133). As noted in Kirin-Amgen Inc v Hoechst Marion Roussel [2005] RPC 9 "Whether

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the specification is sufficient or not is highly sensitive to the nature of the invention. The first step is to identify the invention and decide what it claims to enable the skilled man to do. Then one can ask whether the specification enables him to do it."

14.68 There has been much discussion regarding what should be expected of the skilled worker in establishing this enablement. However, a useful test, given in *Edison and Swan Electric Light Co v Holland* 6 RPC at page 282, consists in asking whether anything new has to be found out by a person of reasonably competent skill following the directions in the specification in order to succeed; if the answer is yes, the disclosure is not complete enough. Similarly, the classic statement of the test for insufficiency in *Valensi v British Radio Corporation* [1973] RPC 337 at 377 (CA) is useful:

"We think the effect of these cases as a whole is to show that the hypothetical addressee is not a person of exceptional skill and knowledge that he is not to be expected to exercise any invention nor any prolonged research, inquiry or experiment. He must, however, be prepared to display a reasonable degree of skill and common knowledge of the art in making trials and to correct obvious errors in the specification, if a means of correcting them can readily be found."

14.69 This negative test, the absence of prolonged research, was approved by the Court of Appeal in <u>Mentor Corporation v Hollister Inc [1993] RPC 7</u> as was the judge in the lower court's statement regarding the positive test that only the performance of "routine trials" should be required:

"When, a little later, Aldous J came to apply the law to the facts of this case, he refers to "routine trials" and "normal routine matters that the skilled man would seek to do and would be able to do". Mr. Thorley criticises the use of the word "routine". To require the performance of routine trials is, he said, to ask too much of the addressee. I do not agree. "Routine" is just the word I would have chosen myself to describe the sort of trial and error which has always been regarded as acceptable; and "routine trials" has the further advantage that it is a positive concept, which is easily understood and applied. In practice, therefore, it may provide a surer test of what is meant by "clearly enough and completely enough" in section 72(1) of the Act than the negative test proposed in Valensi, namely the absence of prolonged research, enquiry and experiment. If the trials are unusually arduous or prolonged, they would hardly be described as routine."

14.70 However, it was stressed in <u>Halliburton Energy Services Inc v Smith International (North Sea) Ltd [2006] EWCA Civ 1715</u> that not only did the setting of a gigantic project, even if merely routine, not satisfy the test, but also that no analogy should be drawn with genetic engineering and pharmaceutical inventions, where much routine work is involved in implementation, as in such cases the work that goes into bringing them to market relates to testing efficacy and safety — not in actually making the invented product.

14.70.1 In Regeneron Pharmaceuticals v Kymab Ltd [2018] EWCA Civ 671 it was held that the patentee does not have to enable each and every embodiment of a claimed invention and that "a claim may encompass inventive improvements of what is described and a specification is not insufficient merely because it does not enable the person skilled in the art to make every such invention. It is important, however, that any such improvement is still a way of working the original invention". In addition, the court held that if the claim of a patent is adequately enabled across its breadth and its scope is comparable with the technical contribution made to the art, the patent does not cease to be sufficient simply because the specification promises too much. For example, the present case related to genetically modified mice where large sequences of DNA were inserted into the mice's DNA. At the time of the earliest date, the skilled person was not able to insert large sequences. However, Regeneron argued that the skilled person would be able

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to reduce the size of the DNA sequence and insert each smaller sequence. The court agreed and held that the skilled team would have identified that inserting large sequences would be a challenge but they would also appreciate that an obvious way forward would be to reduce the size of the inserts. Therefore, even though the specification promised too much (i.e. inserting larger sequences), the court held that the skilled person would be able to overcome the challenge and so implement the claimed invention without undue effort.

Quality of product enabled

14.71 In <u>Mentor Corporation v Hollister Inc</u> [1993] RPC 7 (at page 17 lines 4-14) it was accepted that it was enough that the patent allowed a "workable prototype" to be arrived at with comparative ease (see reference to routine trials above at 14.69) and the requirement was not to produce a "successful commercial product". Similarly, the fact that a specification does not refer to a step which may well be useful for the purpose of being able to reproduce consistently reliable products of commercial quality and range does not render the disclosure incomplete provided that the directions in the specification lead to a product which has "patent utility", i.e. is suitable for and fulfils the purpose for which the specification states it is intended. For instance, a useful perfecting step in making a compound does not have to be disclosed if the imperfectly produced compound can still be used for the application's purpose. (<u>American Cyanamid v Ethicon</u> [1979] RPC 215 at page 265). Thus the applicant also does not have to disclose preferred embodiments.

In addition, the applicant is not required to disclose the best method of performing the invention which he is entitled to claim. (Rule 5.1(a)(v) of the PCT specifies that the best mode should be described, but goes on to say that where the national law of a designated state does not require description of the best mode (as in the UK) failure to describe the best mode shall have no effect in that State).

Functional claims

14.72 The criteria for adequacy of disclosure are the same whatever the form of the claim and are not stricter when the claim is of functional form, that is when it is limited by result, e.g. is of the "No-Fume" type (see 14.120), (*International Business Machines Corporations Application* [1970] RPC 542). However, where claims are defined by functional features or desirable results, the specification does need to provide enough instruction for the skilled person to be able to achieve the desired result without embarking on a research program (see 14.69, 14.82 and 14.87). In order to be sufficient, functional or mechanistic claims must also not be so ambiguous as to be unworkable (see 14.76-14.78).

Errors and omissions

14.73 An error will not cause a patent to be found invalid, whether it is found in the description or in a drawing, provided that the skilled worker would both observe it and be in a position to correct it. In *No-Fume Ltd v Frank Pitchford & Co. Ltd.* (1935) 52 RPC 231 at 243 Romer LJ stated:

"The test to be applied for the purpose of ascertaining whether a man skilled in the art can readily correct the mistake or readily supply the omissions, has been stated to be this: Can he rectify the mistakes and supply the omissions without the exercise of any inventive faculty? If he can, then the description of the specification is sufficient. If he cannot, the patent will be void for insufficiency."

14.74 It is neither necessary nor desirable that details of well-known ancillary

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features should be given, but the specification must disclose any feature essential for carrying out the invention in sufficient detail to render it obvious to the skilled person how to put the invention successfully into practice. In *Badische Anilin and Soda Fabrik v La Societe etc du Rhone* 15 RPC 359, a specification which referred merely to the use of an autoclave of unstated material, was held to be insufficient. It was necessary for success that an iron vessel be used, and yet it was shown that other autoclaves, e.g. enamelled, were frequently used in the trade.

14.75 In <u>Mayne Pharma v Debiopharm and Sanofi-Synthélabo [2006] EWHC 1123 (Pat)</u>, it was held that for a claim defining "a stable oxaliplatin solution formulation comprising oxaliplatin, an effective stabilising amount of a buffering agent ... and a pharmaceutically acceptable carrier" to be sufficient, it must be possible to design a test which can answer the question: "have I used such an amount or not?". The specification pointed, however, to the answer "you don't have to add any at all", and the invention so claimed was therefore insufficiently disclosed.

Insufficiency by ambiguity

14.76 Whilst the skilled person is taken to be trying to make the invention work, as held by Lord Hoffmann in Kirin-Amgen Inc v Hoechst Marion Roussel [2005] RPC 9, the second way in which sufficiency can arise is when the disclosure is so ambiguous as to make it impossible to know whether one had worked the invention or not. This Lord Hoffman distinguished from a simple lack of clarity in Kirin Amgen. The relevant claim required the recombinant erythropoietin (rEPO) of the invention to have a higher molecular weight compared to urinary erythropoetin (uEPO). However different uEPOs have different molecular weights, thus whether or not a product fell within the claim depended on the choice of uEPO and the specification did not tell the skilled person how to make this choice. Lord Hoffman elaborated "In the present case, however, the choice of uEPO has nothing to do with making the invention work. It is simply a criterion against which one tests whether rEPO falls within the claims...All the skilled man can do is try and guess which uEPO the patentee had in mind and if the specification does not tell him, then it is insufficient." Elsewhere in his judgement Lord Hoffman provided an artificial example of how lack of clarity can overstep the mark into insufficiency:

"If the claim says that you must use an acid, and there is nothing in the specification or context to tell you which acid, and the invention will work with some acids but not with others but finding out which ones work will need extensive experiments, then that in my opinion is not merely lack of clarity; it is insufficiency. The lack of clarity does not merely create a fuzzy boundary between that which will work and that which will not. It makes it impossible to work the invention at all until one has found out what ingredient is needed."

Similarly in <u>Sandvik Intellectual Property AB v Kennametal UK Ltd [2011] EWHC 3311 (Pat)</u> (at paragraph 164), a claim to a coating having a particular texture coefficient on a cutting tool was insufficient for ambiguity because calculating the value of the coefficient required reference to a value measured against a standard and there was no disclosure of which of the two widely used common standards was used by the patentee. In this case, this ambiguity only made a difference between infringement and non-infringement at the extremities of this one parameter, nonetheless in those circumstances it was impossible to say whether the product fell within the claim or not, because it was uncertain what the correct test was. In <u>Zipher Ltd v Markem Systems Ltd [2009] FSR 1</u> (at paragraph 374) Floyd J cautioned that "If the skilled person cannot tell whether he is working the invention or not, the specification is insufficient. It is not, however, enough to establish this type of insufficiency to show that there may be a puzzle at the edge of the claims. It will normally be necessary for the problem to permeate the whole claim".

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14.77 Functionally or mechanistically-defined uses are not considered to be inherently so ambiguous as to be insufficient by the UK courts. In the context of medical uses, *Regeneron Pharmaceuticals v Genentech* [2012] EWHC 657 the Patents Court considered whether a claimed use for the treatment of "a non-neoplastic disease or disorder characterised by undesirable excessive neovascularisation" was so ambiguous as not to be defined sufficiently for the skilled person to determine whether or not the claims are infringed. Floyd J rejected this allegation:

"There was no evidence that the skilled addressee would have any difficulty in determining whether a given disease would fall within the terms of the claim as I have construed them."

14.78 The description is presumed to be addressed to a person skilled in the art who is doing his best to understand and not to criticise; technological defects or obscurities which are unimportant and do not cast doubt on the scope of the invention are not fundamentally objectionable. Objection should not be raised merely because it is possible to describe the invention more clearly, provided there is an invention that is sufficiently described (cf. *Schwarzkopf and Ors' Application*, 31 RPC 437 at 439).

Insufficiency by excessive claim breadth

14.79 The disclosure of an invention must be sufficient to enable the invention to be performed to the full extent of the monopoly claimed. In contrast to the situation where a patent or application is classically insufficient, there may be an enabling disclosure for some portion of the invention, but not for the full breadth of the claims. It therefore follows that restricting the scope of the claims to that which is enabled can overcome the objection.

The House of Lords in Biogen Inc v Medeva plc [1997] RPC 1 held that for the purposes of s.14(3) and 72(1)(c) the disclosure must be sufficient to enable the whole width of the claimed invention to be performed, and the disclosure of a single embodiment will not always satisfy the requirement regardless of the width of the claim. Insufficiency arising from a disclosure which does not enable the invention to be performed across the entire claim width is thus sometimes referred to as "Biogen insufficiency". This principle is not confined to chemistry and biotechnology patents. In Nokia GmbH v IPCom GmbH & Co KG [2009] EWHC 3482 (Pat) the patent for synchronization of mobile radio telephones was attacked on the grounds that the whole scope of the claim was not workable. The initial synchronization required "coarse frequency synchronization at least if the accuracy of the carrier frequencies is not adequate, in which case the coarse frequency synchronization operates independently of bursts and determines whether the frequency of the determined carrier is within a tolerance band". Nokia's attack was based on the fact that the coarse frequency synchronization was not enabled while IPCom argued that if the coarse frequency synchronization did not work then it would have been possible to obtain an oscillator of sufficient accuracy to avoid the need for coarse frequency synchronisation at all. In effect two methods were claimed and IPCom's defence was, that if one didn't work. the skilled person could still perform the other. Floyd J (as he then was) rejected the argument and restated the principle set out in Biogen that the entire scope of the claim must be enabled, not just part of it. In effect both methods had to be enabled.

14.80 Pumfrey J held in <u>Minnesota Mining & Manufacturing Co's (Suspension Aerosol Formulation) Patent [1999] RPC 135</u> (at 150-151) that a specification is insufficient if it provides no teaching relating to the criteria according to which the skilled person is taken to be using the invention. What will suffice to satisfy the criterion that the disclosure must be sufficient across the whole width of the claimed invention will vary depending upon the nature of the claim. Thus, for example, when there is in truth more than one product which is claimed, the question has to be asked whether the invention of one product is the

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invention of the other. Unless it is they are different inventions and each must be sufficiently described. A similar conclusion had been reached by the Court of Appeal in that case and <u>Chiron Corp. and ors v Murex Diagnostics Ltd and ors [1996] RPC 535</u> (pages 612 and 613).

14.81 This approach is consistent with that taken by the EPO Technical Board of Appeal in EXXON/Fuel oils [1994] 9 OJEPO 653 (T409/91) and UNILEVER/Detergents [1995] 4 OJEPO 188 (T435/91) which held that an application should provide enough information to allow a person skilled in the art to carry out substantially all that which falls within the ambit of what is claimed. In T435/91 the Board considered the sufficiency of a 'functional' definition of a component in a claimed composition and found that the indefinite and abstract host of possible alternatives must all be available to the skilled person if the definition is to satisfy the requirement for sufficiency. *Novartis AG v Johnson & Johnson* [2009] EWHC (Pat) 1671 drew on the EPO case law in T 435/91, T 694/92 and (in particular) T 1743/06 when considering the sufficiency of a claim to a contact lens defined almost entirely by desirable characteristics. Kitchin J (as he then was) stated:

"...a claim to a class of products said to possess a useful activity must be based upon the identification of a common principle which permits a reasonable prediction to be made that substantially all the claimed products do indeed share that activity. Further, it is not permissible to by-pass that requirement simply by adding a functional limitation which restricts the scope of the claim to all products which do have the relevant activity, that is to say all those which 'work'. In the case of a claim limited by function, it must still be possible to perform the invention across the scope of the claim without undue effort."

This was upheld at the Court of Appeal in <u>Novartis AG v Johnson & Johnson [2010] EWCA</u> Civ 1039. Jacob LJ observed:

"Generally patents with functional claims give you guidance as to what to do if you embark on a trial and error process. The reader can learn from the errors so as to reach something that works. But not here."

The claim was therefore considered to amount to "if you try any pair of polymers, to see if they work...and find anything that does, we claim it." Moreover, it was not clear even whether the examples provided in the patent "worked" according to the parameters defined in the claim. The patent was therefore revoked on grounds of sufficiency.

14.82 In American Home Products Corp. v Novartis Pharmaceuticals UK Ltd [2001] RPC 8, the invention concerned the use of a known antibiotic (rapamycin) for the preparation of a medicament for inhibiting organ or tissue transplant rejection. The Court of Appeal reversed the lower court's decision and held that the claim only covered rapamycin, but did not cover derivatives of rapamycin, and was thus sufficient. The court then observed that, had the claim covered derivatives, the patent would have been insufficient because there was no disclosure in the description enabling the skilled person to decide which of the many possible derivatives would have worked. Although there was a strong possibility that some of the large number of derivatives would work in the same way as rapamycin itself, it was impossible to say which would so work, unless the skilled person undertook the "vast and correspondingly burdensome" research task necessary. Thus the court distinguished between a sufficient description, which requires the skilled person to use his skill to perform the invention, and an insufficient description, which requires the skilled person to go to the expense and labour of trying to ascertain which of the products encompassed by the claim actually has the required properties. Similarly, in DSM NV's Patent [2001] RPC 35 (see paragraphs 181-194), a claim was insufficient because a skilled worker seeking to implement the invention over the whole width of the claim would have been required to depart from the express teaching of the patent and experiment over a long period of time before possibly achieving the desired result.

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14.83 The approach taken in the functionally defined cases above (*Novartis, American Home Products* etc.) deals with the question of where the specification discloses a "principle of general application". In both *Novartis* and *American Home Products* (above), the insufficiency arose in part because the cases did not contain a "principle of general application" by which the limited examples could be said to enable the general terms used in the claims. In Biogen Inc. v Medeva plc [1997] RPC 1 Hoffmann LJ stated:

"Thus if the patentee has hit upon a new product which has a beneficial effect but cannot demonstrate that there is a common principle by which that effect will be shared by other products in that class, he will be entitled to a patent for that product but not for the class, even though some may subsequently turn out to have the same beneficial effect... On the other hand, if he has disclosed a beneficial property which is common to the class, he will be entitled to a patent for all products of that class (assuming them to be new) even though he has not himself made more than one or two of them."

14.84 Biogen Inc. v Medeva plc (above) was clarified by the Court of Appeal in <u>Kirin-Amgen Inc. v Transkaryotic Therapies Inc. [2003] RPC 3</u>, and at the House of Lords appeal (<u>Kirin-Amgen Inc v Hoechst Marion Roussel [2005] RPC 9</u>). Lord Hoffmann held that "a principle of general application" was simply an element of the claim stated in general terms. Such a claim was sufficiently enabled if it could be reasonably expected that the invention would work with anything falling within the general terms. For example, a requirement of "connecting means" was enabled if the invention could reasonably be expected to work with any means of connection, but it was not necessary for the patentee to have experimented with all of them.

Similarly in Regeneron Pharmaceuticals Inc v Genentech Inc [2012] EWHC 657 (Pat) (upheld at appeal Regeneron Pharmaceuticals Inc, Bayer Pharma AG v Genentec Inc [2013] EWCA Civ 93) the Patents Court considered that a second medical use claim relating to "Use of a hVEGF antagonist in the preparation of a medicament for the treatment of a non-neoplastic disease or disorder characterised by undesirable excessive neovascularisation" did relate to a "principle of general application" and as such a claim in correspondingly broad terms was acceptable (See also Examination Guidelines for Patent Applications relating to Medical Inventions in the Intellectual Property Office paragraphs 149 and 156-7). In many of these cases, the extent to which the breadth of the claim is excessive has to be assessed according to how much work the skilled person needs to carry out to make the invention work.

Undue burden

14.85 The specification does not need to disclose all the details of the operation to be carried out in order to perform the invention since an enabling disclosure is to be interpreted by the skilled person, in light of common general knowledge, who is reasonably expected to carry out tests. In *Eli Lilly & Co. v Human Genome Sciences, Inc.*[2008] EWHC 1903 (Pat) [2008] RPC 29, Kitchin J held that the specification must be sufficient to allow the invention to be performed without undue burden, having regard to the fact that the specification should explain to the skilled person how the invention can be performed. The question whether a burden is undue must be sensitive to the nature of the invention, the abilities of the skilled person and the art in which the invention has been made (at the time of filing).

14.86 It should always be remembered that the skilled person is also taken to be trying to make the invention work, as held by Lord Hoffmann in *Kirin-Amgen Inc v Hoechst Marion Roussel* [2005] RPC 9. Thus if the skilled person would quickly realise that

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one method would work and another would fail, the specification is not insufficient because the claim is expressed in terms broad enough to include both methods.

14.87 In Chiron Corp. v Organon Teknika Ltd. [1994] FSR 202 where it took the applicants themselves several years from filing an application, claiming among other things a vaccine, to successfully produce the vaccine, the vaccine claim was held to be invalid. However, in American Cyanamid v Ethicon [1979] RPC 215 at 265, in which it had been contended that a patent claiming a surgical suture made of a particular polymer was invalid for, inter alia, insufficiency in that it did not point out the need for adequately drying the polymer and freeing it from undesired monomer, it was held that the disclosure was not insufficient since these were steps which "the instructed reader desirous of achieving success could be expected, if necessary, to take". Accordingly the hypothetical addressee had to be prepared to display a reasonable degree of skill and common knowledge of the art in making trials and to correct obvious errors and omissions in the specification if a wav of correcting them could readily be found (Mentor Corporation v Hollister Inc [1993] RPC 7), although is not expected to exercise any invention or any prolonged research, inquiry or experiment. Referring to this case, Pumfrey J in Halliburton Energy Services Inc v Smith International (North Sea) Ltd [2006] RPC 2 agreed that the straightforward test for sufficiency was whether the specification required the addressee to carry out tests or developments that went beyond routine trials. Where the specification is very complex and its development would be expected to be accompanied by a great amount of work, it is always necessary to keep a balance between the interests of the public and the interests of the patentee in the sense that it is necessary to guard against imposing too high a standard of disclosure merely because the subject matter was inherently complex.

14.88 The question of an undue burden was at the heart of the sufficiency of a claim to a functionally-defined product in T 1743/06 INEOS/Silicas. In this case, the Board held that, while it was acceptable that the skilled person would need to use a reasonable amount of trial and error to select conditions which would achieve the desired result, there must be adequate instructions in the specification, or on the basis of common general knowledge, to lead the skilled person towards success, through evaluation of initial failures.

Considerations during examination and search

14.89 Care should be taken to make it readily apparent what sort of sufficiency objection is being made. Therefore a classical insufficiency objection should be raised only in the clearest cases, when the disclosure appears inadequate to support a valid claim. However where the claims are unduly broad and speculative objection may be raised under s.14(3) and/or under s.14(5) (see also 14.102-14.104). Such an objection may not be overcome by the addition of further examples or features to the specification since this is prohibited under s.76(2), however an objection to the excessive breadth of the claims under either section may be remedied by restricting the scope of the claims. If made under s.14(3) as an objection to insufficiency due to excessive claim breadth then some indication that a portion of the claim(s) is regarded as enabled should be made clear to the applicant. This is not only an issue to be considered at substantive examination, but the examiner should consider the scope of the search to be conducted in light of the enabled disclosure. If the search has been restricted because only a portion of the claims appear to be enabled then that should be made clear to the applicant either in the search letter, exam opinion or examination report as applicable.

Inventions contrary to well-established laws

14.90 If successful performance of the invention is inherently impossible because it would be contrary to well-established laws (e.g. where the alleged invention is a

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perpetual motion machine) objection may arise under s.14(3). If the claims are directed to its function and not merely its structure objection may also arise under s.4(1) - see 4.05 and also *Eastman Kodak Co. v American Photo Booths Inc.* (BL O/457/02), in which the hearing officer held that the invention could not function as described and claimed, and so lacked both industrial applicability and sufficiency of disclosure. Similarly, the Hearing Officers in *Blacklight Power Inc.'s Application* BL O/170/09, and *Robinson's Application* BL O/336/08 held that the applications in question were both insufficient and lacking in industrial applicability as the claimed inventions relied on scientific theories of doubtful validity. The hearing officers in these cases followed the test set out in the Patents Court judgment in *Blacklight Power Inc. v The Comptroller-General of Patents* [2009] RPC 6 and held that there was not a reasonable prospect that the applicant's theory might turn out to be valid if it were to be fully investigated at a trial – see 4.05.1-4.05.2. Regardless of whether objection arises under s.4(1) or s.14(3), one of the procedures set out in 17.94-17.96.4 should be followed at the search stage.

Prior art

14.91 The applicant is not obliged to describe or acknowledge the prior art, since the reader is presumed to have the general background technical knowledge appropriate to the art. There may however be instances in which the absence or inadequacy of a statement of prior art renders it difficult to understand how the invention is to be performed. Alternatively, documents found during the search or otherwise, may show that the statement of prior art is inadequate or misleading. This could be the case if an ambiguous presentation gave the impression that the prior art had solved less of the problem than was actually the case.

A specification may include fair and reasonable comment on prior inventions with a view to distinguishing the invention in suit from them or illustrating its advantages, but no statement disparaging a prior patent or describing it in an unfair or misleading manner should be included. There is however no objection to a mere statement that a prior invention is in some respects unsatisfactory.

References to other documents

An application as filed may contain a reference to another document or webpage, in which further information is to be found. For example, the application may refer to another document or webpage "the contents of which are incorporated herein by reference". The allowability of such a reference must be considered if the further information to be found in the other document is essential for there to be a clear and complete disclosure of the invention (see 14.94). On the other hand, a reference to a document containing information which is not essential for sufficiency need not be considered; such references are allowable.

14.93.1 Pumfrey J in <u>Halliburton Energy Services Inc v Smith International (North Sea) Ltd [2006] RPC 2, [2005] EWHC 1623 made it clear that cross-referencing for the purpose of supplementing a disclosure is highly undesirable, stating that applications should be complete in themselves (see paras. 61-62 and 30). Since the date at which sufficiency has to be judged is the date of filing, not the date of publication (see 14.63), Pumfrey J also held in the same case that a document referred to in the specification must have been published by the date of filing the application for a reference to be effective.</u>

14.94 If the information contained in a referenced document is necessary for a person skilled in the art to carry out the invention then the examiner should confirm that the document was published at the filing date. If not, then objection should be raised under s.14(3) informing the applicant that references to documents containing essential information and published later than the filing date, or not at all (including applications withdrawn before publication and applications unpublished at the time of filing of the

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application in suit) should be deleted. Supplementing or replacing of the reference by an indication of the contents of the documents (beyond what is already explicitly contained in the application as filed) is not allowed. Where the publication date of a reference containing essential information is unclear the applicant should be asked to verify the date. For instance, in the case of a reference to a webpage essential for a complete disclosure of the invention, a copy of the verifiably-dated webpage showing its contents prior to the date of filing must be provided. Furthermore, in the situation where it appears to the examiner that a referenced document might contain information necessary for sufficiency but the document is not readily available, the applicant should be asked to file a copy and verify its publication date.

[If the entire text of another specification is appended to the application in suit it should be removed from the copy for publication but should remain on the open part of the file so that it will subsequently be published by laying open. The following footnote should be added to the front page of the published application (see 16.29) - "A specification referred to in the application and appended to it is not included in this publication but is available for inspection in accordance with the provisions of Section 118(1) of the Patents Act 1977". At substantive examination the removal from the specification of the appended specification should be required. Relevant matter from it may be added to the description if required for sufficiency.]

14.95 Provided that the publication requirements set out above are satisfied and if requested by the applicant, the examiner should allow a reference to be replaced by the matter referred to, provided that, when the reference is to another application, the matter was present in that application as filed. Where the language of the documents referred to is other than English and the disclosure of the invention would not be clear and complete enough without the reference, such replacement (in English) should be required. Where the reference is to a document not readily available to the examiner the applicant should be asked to file a copy and/or a translation, as necessary.

14.96 There is an indication on the front page of a granted patent specification if that case relates to a "parent" or divisional application. There is no reason why applicants should not be encouraged to include cross-references in other suitable circumstances where the front page of the granted patent will not give any warning of a related application or patent, e.g. where another application of the same date by the same applicant claims matter described in the application in suit.

Trade marks

r.44

14.97 The description should be as clear and straightforward as possible, with the avoidance of unnecessary technical jargon. Since however it is addressed to persons skilled in the art to which it relates it is acceptable, and will often be desirable, for it to use technical terms which are well known in that art. Little known or specially formulated technical terms may be used provided they are adequately defined and that there is no generally recognised equivalent. Foreign terms may be used where there is no English equivalent. Terms already having an established meaning should not be used differently if this is likely to cause confusion, but in some circumstances it may be appropriate for a term to be borrowed from an analogous art.

14.98 A recognised trade description should not be used in such a way as to give rise to uncertainty or ambiguity; eg "leather" should not be used as a general term covering materials resembling leather, unless the precise meaning given to the word "leather" is defined. If a specification contains a reference to a proprietary article or specific product the composition of which is not well known, the description should state the composition of the article or the way in which it is prepared. If the applicant maintains that the information is well known in the art, or if the specification so states, and the examiner is

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unable to verify this, evidence in support of the contention may be required.

14.99 The use of proper names or similar words to refer to materials or articles is undesirable in so far as such words merely denote origin, or where they may relate to a range of different products. The product should be sufficiently identified, without reliance on the word, to enable the invention to be carried out by the skilled person. Such words which have generally accepted meanings as standard descriptive terms may however be used without further explanation; examples are Bowden cable, Belleville washer, zip fastener.

CoP

14.100 A trade mark should preferably not be used in a specification since it is an indication of origin rather than of composition or content and on that account cannot properly be used to describe an article. (For trade marks in claims, see 14.137). If a registered trade mark is used it should generally be accompanied by wording showing that it is a trade mark, since its use as a descriptive term without acknowledgement may be prejudicial to the rights of its owner (Official Ruling 1914 (A) 31 RPC Appendix i). However, a word that has been registered as a trade mark only requires acknowledgement if it is being used in the specification with reference to the goods or services for which the trade mark is registered. Acknowledgement should preferably take the form of "(RTM)" inserted after the trade mark. However, use of the symbol ® is also regarded as acceptable. The acknowledging of registered trade marks should extend to their obvious derivatives. Any word which is a trade mark should commence with a capital letter. Any statement that a term is a trade mark or a registered trade mark should not be challenged, nor should any attempt be made to determine whether such a term is being used within its registered class; the registered owner may be using the mark for goods not covered by registration and he may have common law rights to its use in this way. If a mark is known not to be registered it is good practice to indicate the name of the owner. The validity of the trade mark is not material. Community trade marks and international trade marks registered under the Madrid Protocol (and effective in the U.K.) should be acknowledged in exactly the same way as trade marks registered directly with the Office. acknowledgement of trade marks without the applicant's consent, see 19.24-19.26).

[In order to check whether a word used in a specification is a registered trade mark, the examiner should access the Trade Mark Database provided on the Office's external website. This contains details of all trade marks registered or effective in the U.K., including Community and international trade marks effective in the U.K. For advice on how to ensure that trademarks are acknowledged, see 19.24-19.26. See 14.137 if a trade mark is used in a claim.]

14.101 A number of words which are registered trade marks have come into such general use that the fact that they are trade marks tends to be overlooked. Examples of such words are 'Bakelite', 'Caterpillar', 'Filofax', 'Frisbee', 'Jacuzzi', 'JCB', 'Kodak', 'Lycra', 'Rollerblade', 'Tabloid', 'Thermos', 'Vaseline', 'Velcro', 'Walkman' and 'Yale'. Such words should be acknowledged in just the same manner as other less well-known trade marks.

Relationship of s.14(3) with s.14(5)

s.125(1) s.76(2) 14.102 Since "the invention" whose disclosure must be clear and complete is that defined in the claims, the requirement of s.14(3) may overlap with those of s.14(5), that the claims define the invention, be clear and be supported by the description, since all are concerned with the relationship between the extent of the disclosure and the scope of the claims.

14.103 When considering whether an objection should be made under s.14(3) or under s.14(5) consideration should first be given as to the extent of the enabling disclosure. If the objection to be made is clearly that the, or part of the, claim lacks an enabling disclosure then objection should be made under s.14(3). If the objection is simply one of consistency between the claims and description, or the description in some other way casts doubt on the true scope of the invention, then objection should be made under

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s.14(5)(c). Examples of this would be a reference to an embodiment or variant not falling within the scope of the claims. Many situations will fall between the two scenarios but care should always be exercised to ensure that the invention considered is that of the claims properly construed rather than simply the embodiment(s). However where the claims are unduly broad and speculative objection may be raised under s.14(3) and/or under s.14(5) (see also 14.79-14.82). Such an objection may not be overcome by the addition of further examples or features to the specification since this is prohibited under s.76(2), however an objection to the excessive breadth of the claims under either section may be remedied by restricting the scope of the claims. When considering whether an objection should be made under s.14(3) or s.14(5)(b) then consideration should first be given to whether the unclear word or phrase creates merely a "fuzzy boundary", as described by Lord Hoffman in *Kirin-Amgen Inc v Hoechst Marion Roussel* [2005] RPC 9, to the scope of the claim or whether it renders it impossible to determine what falls within and without the claim as a whole (see insufficiency by ambiguity above at 14.79-14.82).

14.104 Objection does not arise under s.14(3) merely because particular matter claimed is absent from the description, since it is the specification (which includes the claims) which is required to disclose the invention; objection should in such a case be made under s.14(5)(c), (see 14.145). However while the insertion in the description of a passage in agreement with an originally unsupported claim may overcome the objection under s.14(5)(c), objection will remain if this passage is not in itself a clear and complete enough disclosure of that particular aspect of the invention, so that the applicant has failed to discharge his duty under s.14(3) not only to disclose the invention but to do so in a manner which allows it to be performed.

[Section 14(4) Repealed

14.105 Subsections (4) and (8) of s.14 were concerned with how an invention which required for its performance the use of a micro-organism could be disclosed. This is now provided for in s.125A.

Section 14(5)

The claim or claims shall -

- (a) define the matter for which the applicant seeks protection;
- (b) be clear and concise;
- (c) be supported by the description; and
- (d) relate to one invention or to a group of inventions which are so linked as to form a single inventive concept.

Section 14(6)

Without prejudice to the generality of subsection (5)(d) above, rules may provide for treating two or more inventions as being so linked as to form a single inventive concept for the purposes of this Act.

s.130(7) 14.106 S.14(5) and (6) are specified as provisions which are so framed as to have, as nearly as practicable, the same effect as the corresponding provisions of the

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EPC, PCT and CPC; a.84 EPC and a.6 PCT use essentially the same wording as s.14(5)(a)-(c), and a.82 EPC is essentially the same as s.14(5)(d). (There is no requirement of unity of invention in the articles of the PCT, but Rule 13.1 of the Treaty is essentially equivalent to s.14(5)(d)).

14.107 The provision in the Rules referred to in s.14(6) is to be found in r.16. There is no article in the EPC or PCT equivalent to s.14(6) but Rules 44 and 13.2 of the respective treaties use wording similar to that of r.16. (See further 14.159).

DEFINING THE INVENTION: CLARITY

14.108 With the exception of r.16 there is no provision in the Rules regarding the form and content of claims. Although the EPC and PCT Rules do contain such provisions, s.130(7) is not interpreted as requiring compliance with these rules, and indeed some of the provisions of the EPC and PCT are at variance with UK practice. Rule 43(1) EPC and Rule 6.3 PCT prescribe the so-called Germanic form of claim, in which a recital of the prior art is followed by a statement of what characterises the invention. This type of claim is often described as being in "two-part form", and in the US is sometimes referred to as a Jepson claim. (The PCT Rule goes on to say that where the national law of a State does not require this form of claiming, failure to use it shall have no effect).

14.109 In contrast it is established practice in UK law that the form of the claim is a matter for the applicant, any claim which fulfils the requirements of the Act being acceptable. Although the Germanic form of claim may in many cases be the most convenient, particularly for example when the invention is an improvement in a known type of apparatus, the applicant cannot be required or urged to present his claim in this way. In *British United Shoe Machinery Co Ltd v A Fussell and Sons Ltd*, 25 RPC at page 651, it was stated that "a man must distinguish what is old from what is new by his claim; but he has not got to distinguish what is old from what is new in his claim".

CoP

14.110 The claims must be drafted in terms of the technical features of the invention and should not contain any statements relating, for example, to commercial advantages or other non-technical matters. In addition, claims should not define the invention over the prior art by unusual, non-standard or unreasonable parameters against which no comparison with the prior art can be made, unless the invention does not allow of a clear alternative definition. Statements of purpose, or reference to results or desiderata should only be used in claims if they assist in defining the invention and no better mode of definition is possible. It is not necessary that every feature should be expressed in terms of a structural limitation. Functional limitations may be included provided that a skilled person would have no difficulty in providing some means of performing this function without exercising inventive skill (see 14.48 for the relation of claims to the description).

CoP

14.110.1 The claims as a whole should aim to define and delimit the features of the invention, with the independent claims clearly establishing the essential features of the invention as well as sufficient details of interrelationship, operation or utility to establish that the invention achieves the intended objectives. The more independent claims there are, the more doubt is cast on the essential features of the invention, particularly where there is more than one independent claim in the same category, such as multiple independent claims for a product, process, apparatus, or use. The aim should therefore be to define the essential features of the invention using a single claim for each category, and to leave additional non-essential features to dependent claims. Under certain limited circumstances, this may not be appropriate, for example: where the invention relates to a number of closely-related products - such as transmitters and receivers (see 14.161), where there are different uses of a product or apparatus, or where there are closely-related alternative solutions to a particular problem. It follows that claims in a style where many independent claims in one category are included, all of varying scope and features, are

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particularly inappropriate. In addition to lacking clarity, this style of patent claim may also be considered to lack conciseness (see 14.140) and give rise to plurality of invention (see 14.157-14.168).

Construction of the claims

s.125(1) (See also 2.11-2.17, 125 and, with regard to biotechnological inventions, 76A.07-76A.09)

14.111 The requirement that the claims shall be clear applies to individual claims and also to the claims as a whole, and is of the utmost importance in view of the function of the claims in defining the monopoly sought. Each claim should be read giving the words the meaning and scope which they normally have in the relevant art. The claim should also be read with an attempt to make technical sense of it; such a reading may involve a departure from the strict literal meaning of the wording of the claim (see 14.114). The claims are to be interpreted having regard to the description and any drawings (see also 125). If, in a particular case, the description gives the words used in a claim a special meaning, by explicit definition or otherwise, this should be clear from a reading of the claim alone; where a special meaning is given to a term or phrase in a claim by a definition in the description the use of some such phrase as "as hereinbefore defined" will reduce the risk of ambiguity. A reference to prior art in the specification is a factor to be taken into account in interpreting a patent. In Ultraframe (UK) Ltd v Eurocell Building Plastics [2005] RPC 7 the Patents Court held that this would depend on the way the prior art was acknowledged. If the specification identified some particular feature of the prior patent as disclosing a problem which the inventor claimed to have overcome, it might be of considerable relevance in interpreting the width of the claim.

14.112 The prima facie meaning of words used in a claim may not be their true meaning when read in the light either of a definition found elsewhere in the specification or of technical knowledge possessed by persons skilled in the art. In these circumstances a claim may bear a meaning different from that which it would have borne had no such assisting light been available. Thus, if the draftsman has specifically indicated somewhere in the specification what he means by a particular expression, then that must be taken into account - see Kirin-Amgen Inc. v Roche Diagnostics GmbH [2002] RPC 1, in which Neuberger J also cautioned against too heavy a reliance on dictionary definitions, which are "shorn of any relevant context". The House of Lords appeal on this case, Kirin-Amgen Inc v Hoechst Marion Roussel Ltd [2005] RPC 9, confirmed that the meaning of words is what the skilled person would have understood the author to mean by using these words. Nonetheless, the starting point for interpreting words – especially non-technical words – in a claim will usually to be their ordinary definition, before considering their context and use in the specification; as held by the Court of Appeal in both Fabio Perini SPA v LPC Group plc and others [2010] EWCA Civ 525 and Occlutech GMBH and anr v AGA Medical Corp. and anr [2010] EWCA Civ 702. Further, in Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd [2010] RPC 8, the Court of Appeal held that the skilled reader is taken to suppose that the patentee knew some patent law - that his claim is for the purpose of defining the monopoly and that it should be for something new. Knowledge of that may well affect how the claim is construed. For instance, the patentee would not be expected to have claimed what he had expressly acknowledged was old.

14.113 There is no justification for departing from the unambiguous and grammatical meaning of a claim and narrowing or extending its scope by reading into it words which are not in it, or for using stray phrases in the body of a specification for the purpose of narrowing or widening the boundaries of the monopoly fixed by the plain words of a claim. For example, the Court of Appeal in *Fabio Perini SPA v LPC Group plc and others* [2010] EWCA Civ 525 rejected an argument that the word "slit" should have a narrowly-defined meaning based on the exemplification in the patent, rather than the ordinary meaning of a long, narrow opening. The patentee is under a statutory obligation to state in the claims what is the invention he desires to protect. In *Glaverbel S A v British Coal Corporation* [1995] RPC 255 the Court of Appeal held that the claims should be read

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together with the body of the specification but if a claim is expressed in clear language, ie the meaning of the claim is clear, the monopoly sought cannot be extended or cut down by reference to the rest of the specification. This approach has subsequently been endorsed in, for example, *Lubrizol Corporation v Esso Petroleum Co. Ltd* [1998] RPC 727 and *Cartonneries de Thulin SA v CTP White Knight Ltd* [2001] RPC 6.

- 14.113.1 In the UK, "consisting of" is generally interpreted to mean "consisting exclusively of" whilst "comprising" is generally interpreted to mean "including" (i.e. other integers or features may be present). The conventional interpretation of "comprising" to mean "including" was approved of by Kitchin J. in *DLP Ltd's Patent* [2007] EWHC 2669 (Pat), [2008] RPC 11. These terms are considered to be clear unless, on the facts of the particular case, there is genuine doubt as to their meaning. See also 14.123.1.
- 14.114 In view of the differences in the scope of protection which may be attached to various categories of claim (eg directed to a product, process, apparatus or use), the wording of a claim should leave no doubt as to its category.

Purposive construction; variation in non-essential features of a claim

(see also 125.13-125.14)

14.115 A patent specification should be given a purposive construction rather than a purely literal one as held by Lord Diplock in Catnic Components Ltd and another v Hill and Smith Ltd [1982] RPC 183 (see also 125). Variation in unessential features of the claimed invention may not be sufficient to take a product or process outside the protection of the claim. In Catnic, a claim to a lintel having inter alia a support member "extending vertically" was held to have been infringed by otherwise identical lintels in which the support member was 6 ° or 8° from vertical, since this produced a negligible reduction in the vertical support provided by the member. Another example of purposive construction was the interpretation of the word "opaque" by Jacob J in Minnesota Mining and Manufacturing Co. and anr. v Plastus Kreativ AB and anr. (BL C/64/95; upheld on appeal [1997] RPC 737) where he construed the term by considering the stated reason for the flap being opaque, which was to eliminate the disadvantages of the prior art. However, when considering this case in Nikken Kosakusho Works v Pioneer Trading Co. [2005] FSR 15, Mann J held that although the meaning of a word in a claim can be qualified or explained by reference to the objective intended to be realised, this has to be stated clearly enough in the specification; otherwise the skilled but unimaginative reader, through whose eyes the patent had to be read, would be confused.

14.116 [deleted]

14.116.1 For discussion of the Protocol to Article 69 of the EPC, see 125. For a discussion on <u>Actavis UK Limited and others v Eli Lilly and Company [2017] UKSC 48</u>, see 125.17.3-125.18.5 and 125.26.

Inventions defined by ranges

14.117 In Auchincloss and another v Agricultural & Veterinary Supplies Ltd. and Others [1997] RPC 649, Peter Prescott QC (sitting as a deputy judge) distinguished (at pages 663-665 and 689) a stated range from the term "descriptive word or phrase" used by Lord Diplock in Catnic and found that a departure from this range, however small, is not a variant in the Catnic sense. He stated (at page 689):-

"The aim of the *Catnic* line of cases is to ascertain the purpose of the patentee, but objectively, that is, through the eyes of the skilled reader of the document. Where the patentee has expressed himself in terms of a descriptive word or phrase there may be room for supposing that he was using language figuratively, and did not intend to restrict himself to the purely literal meaning. But where the patentee has defined an integer of his claim in terms of a range with specified numerical limits at each end, his purpose must be taken to have been to claim thus far and no

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further."

- 14.117.1 In Halliburton Energy Services Inc v Smith International (North Sea) Ltd [2006] RPC 2, Pumfrey J held that a claim which defined the axial force on each cone as being between 31 and 35 per cent of the total axial force should be construed to mean the specified number to two significant figures, so including, for example, 30.500 per cent to 35.499 per cent.
- In Smith & Nephew Plc v Convatec Technologies Inc [2015] EWCA Civ 14.117.2 607 Kitchen LJ confirmed that the approach to the interpretation of claims containing a numerical range is no different from that for any other claim. That is, the claims are construed to mean what a skilled person would have understood them to mean. The judge also considered a series of relevant cases and drew out certain points of particular relevance to claims which include a numerical range. First, the scope of any such claim must be exactly the same whether one is considering infringement or validity. Secondly, there can be no justification for using rounding or any other kind of approximation to change the disclosure of the prior art or to modify the alleged infringement. Thirdly, the meaning and scope of a numerical range in a patent claim must be ascertained in light of the common general knowledge and in the context of the specification as a whole. Fourthly, it may be the case that, in light of the common general knowledge and the teaching of the specification, the skilled person would understand that the patentee has chosen to express the numerals in the claim to a particular but limited degree of precision and so intends the claim to include all values which fall within the claimed range when stated with the same degree of precision. Fifthly, whether that is so or not will depend upon all the circumstances including the number of decimal places or significant figures to which the numerals in the claim appear to have been expressed.
- 14.117.3 The judge went on to determine that in this particular case the claimed range of "between 1% and 25%" would be understood by a skilled person to include all values greater than or equal to 0.5% and less than 25.5%. That is, the claim would include all values which would fall within the claimed range, once the values are rounded to the nearest whole number. He found that in the context of the claimed method, the purpose of expressing numbers to a particular degree of precision was to convey to the reader the range of permissible values and the accuracy with which those values need to be determined. The judge dismissed the 'significant figures' approach (which would have resulted in the claimed range including all values greater than or equal to 0.95% and less than 25.5%) in part because this would require values close to the bottom of the range to be determined with much greater accuracy than those near the top.
- 14.117.4 The above approach was reaffirmed in <u>Napp Pharmaceutical Holdings Ltd v Dr Reddy's Laboratories (UK) Ltd [2016] EWCA Civ 1053</u>. Floyd LJ agreed with the decision in Smith & Nephew Plc, that claims must be construed to mean what the skilled person would understand them to mean. All of the figures in the patent were multiples of five. Floyd LJ stated that even though this is the case, this fact says nothing about the degree of precision to which these numbers are expressed and that this does not contradict the skilled person's normal understanding that numbers written in this way would be treated as expressed to the nearest whole number. Floyd LJ also stated that the term "about" in a claim (e.g. about 10%) suggests that something wider was meant than if the word "about" was omitted and that a more generous degree of imprecision was claimed. He concluded, agreeing with the decision of the Patents Court, that "about 10%" in the claim should extend to 9-11%.
- 14.117.5 For situations in which the application in suit specifies a range which overlaps with a range disclosed in prior art, see 2.06.2.

Invention defined by reference to intended use

14.118 A claim to an apparatus or material for a particular purpose is construed as a claim to any apparatus or material having the features specified which is suitable for that purpose (see 2.12-2.14). On the other hand, a claim to something "when used in" a

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particular process is regarded as protecting only the use of the invention in this way (see 2.15), while a claim to "the use of" a material is regarded as equivalent to a claim to a method of using the material (see 2.16).

14.119 A claim merely directed to "Apparatus for carrying out the method of according to claim X", or some such wording will not normally be clear in scope. For further discussion of construction of phrases such as "for", "suitable for" and "adapted to" see 2.12-2.14.1. The claim should normally clearly specify the essential features of the apparatus unless all the integers which would constitute such apparatus are clearly implicit in the method claimed, and all such apparatus would be novel and non-obvious.

14.120 The area defined by the claims must be as precise as the invention allows. As a general rule, claims which attempt to define the invention, or a feature thereof, by a result to be achieved should not be allowed. However, they may be allowed if the invention can only be defined in such terms or cannot be defined more precisely without unduly restricting the scope of the claims and if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description and involving nothing more than trial and error. In No-Fume Ltd v Frank Pitchford Co Ltd, 52 RPC 231, a claim to an ash receptacle for smokers in which the dimensions of certain parts were such that smoke from objects thrown into the receptacle did not emanate from the receptacle was allowed on the grounds that the invention could be realised by dimensions other than those disclosed, by experiments not involving inventive ingenuity. However, claims of this kind are generally undesirable and it should be noted that the No-Fume claim was allowed solely because the invention did not admit of precise definition independently of the result achieved. Any claim which includes a subordinate clause prefaced by words such as "so that" or "the arrangement being such that" requires special consideration from this point of view. In BL O/031/17, the hearing officer considered a claim defining a seating assembly for an aircraft cabin. The claim was defined by the result that a passenger access path was produced between seats. The hearing officer found it was possible to define the invention without reference to the result to be achieved, however defining the invention in any other way would unduly restrict the scope of the monopoly sought. He also determined that the claimed result could be easily verified by a person skilled in the art. Based on these findings, and on the specific facts of the case, he concluded that the claim was clear despite being defined by result.

Product by Process claims

The House of Lords in Kirin-Amgen Inc v Hoechst Marion Roussel Ltd 14.120.1 [2005] RPC 9 held that 'product-by-process' claims (e.g. "Product X obtained by process Y") should be construed as a claim to the product as such in line with EPO practice (see Decision T 150/82 International Flavors and Fragrances Inc [1984] OJEPO 309); this is irrespective of whether the term "obtained", "obtainable", "directly obtained" or an equivalent wording is used. Claims for products defined in terms of a process of manufacture are allowable only if the products as such fulfil the requirements for patentability; a "product-by-process" claim is not rendered novel merely by the fact it is produced by means of a new process (see also 2.15). A claim for a patentable product defined by its process of manufacture is only allowable if the product cannot satisfactorily be characterised by reference to its structure or composition; if the product can be defined by other means, an objection under clarity and/or conciseness should be raised. Product by process claims can be difficult to identify so care should be taken when assessing claims. If a product claim includes any method or process steps (even if those steps are not explicitly defined as 'manufacturing' steps), the claim is a product by process claim. For example, a claim to "an apparatus comprising features A and B, where feature A is treated in an oven", is a product by process claim. In addition, a product by process claim will result if a product claim incorporates method/process steps as a result of a reference to another claim.

Chemical cases

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- 14.121 Where the invention relates to a chemical compound it may be characterised in a claim in various ways, eg by its chemical formula, or, exceptionally, by its parameters or as a product of a process. Characterisation of a chemical compound solely by its parameters should, as a general rule, be allowed only in those cases where the invention cannot be adequately defined in any other way, for example in the case of macromolecular chains. In such cases however only parameters usual in the art should be employed to characterise the compound, since use of unusual parameters may disguise lack of novelty (see 2.18-2.20 and 3.88-3.93).
- 14.122 Chemical "process" claims should define the starting material, the end product and also the means adopted for converting the one into the other (*British Celanese Ltd's Application*, 51 RPC 192). The definition of a process in the claims with reference to such "tools of the trade" as condensation, polymerisation, esterification and sulphonation, or even by the use of the term "reacting", is permissible provided the specification contains no reservations affecting the universality of the process. In *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 9, the House of Lords held that the process in accordance with EPC Article 64(2) (see also 14.120.1)
- 14.123 The extent to which the ingredients of a composition need to be specified in order adequately to define the invention depends greatly on the subject-matter concerned. Thus a claim to "a pharmaceutical composition containing compound X together with a diluent or carrier" is allowable, X being a medically active compound which characterises the composition, and the diluent or carrier being any material suitable for the purpose and being choosable by knowledge of the art or by non-inventive experiment. In the field of alloys, sufficient of the constituents should be specified such that the claim is not speculative and is adequately supported by the disclosure.
- 14.123.1 In EPO Decision T 589/89, NATIONAL RESEARCH/Polyurethane compositions ([1994] EPOR 17), the use of the word "comprising" was held to mean that further reactive ingredients may be present in the claimed composition. However, where the word "consists" is used, the proportions of the specified ingredients must total 100 per cent (EPO Decision T 711/90, unreported). This is consistent with the long-standing practice in the UK that "consisting of" is generally interpreted to mean "consisting exclusively of" whilst "comprising" is generally interpreted to mean "including" (i.e. other integers or features may be present). The EPO has interpreted the phrase "consisting essentially of" as meaning that unspecified components could be present in the claimed composition if the characteristics of the claimed composition are not materially affected by the presence of these unspecified components (EPO Decision T 472/88, GENERAL ELECTRIC/ Thermoplastic resin ([1991] EPOR 486), EPO Decision T 340/89, GENERAL FOODS/caffeine ([1992] EPOR 199), EPO Decisions T 522/91 and T 759/91(each unreported)). This settled view of the EPO is followed in the UK. This has been confirmed by Anan Kasei Co Ltd & Rhodia Operations SAS v Molycorp Chemicals & Oxides Ltd [2018] EWHC 843 (Pat). Thus a claim to a composition "consisting essentially of X, Y and Z" could be found to be anticipated if the prior art includes such a composition which also contains other components which do not appear to materially affect its characteristics (e.g. its activity or function).

Omnibus claims

r.12(6A)

14.124 Claims to the preferred embodiments of the invention which end with some such words as "substantially as described and shown (or illustrated) in the accompanying drawings" are limited to the embodiments described and depicted in the drawings. Such claims fall within the type known as "omnibus" claims which also include claims referring to examples (eg in chemical cases) or to tables. As a result of the Patents (Amendment) (No.2) Rules 2016, it is not possible to include omnibus claims in UK patent applications, unless this is the only way to define the technical features of the invention clearly and

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concisely. If in response to an objection to an omnibus claim the applicant demonstrates that the invention cannot otherwise be clearly and concisely defined using words, a mathematical or chemical formula or any other written means, the examiner should allow the omnibus claim to remain. An example might be where the invention involves some peculiar shape, illustrated in the drawings, but which cannot be clearly defined either in words or by a simple mathematical formula.

[Substantive examiners should raise an objection to any omnibus claims present in a pending patent application, using PROSE clause RC37, unless:

- (a) A notification of intention to grant has already issued; or
- (b) The examiner is already convinced that the technical features of the invention cannot otherwise be clearly and concisely defined.

Examiners should note their reasons for not raising an objection in a minute.]

14.125 An omnibus claim should not suggest that a drawing, example or table illustrates or exemplifies the invention if it does not, for example if it is present for comparison or as prior art, but there is no objection to referring to the invention "as described with respect to" such drawings, examples or tables, provided the wording of the claim and of the description makes the position clear. However the words "substantially as described" are insufficient by themselves to limit a claim to the embodiment described, and its scope will be construed to be as wide as the statement of invention. In such cases care should be taken to ensure that the invention is set forth in precise terms in the body of the specification, that ambiguity does not arise (see 14.139.1 and 14.139.2) and that the statement of invention is not broader than the main claim (see 14.146). With regard to omnibus claims of copending applications describing the same apparatus, see 18.95.

In Raleigh Cycle Co Ltd and Anr. v Miller and Co Ltd, 65 RPC 141, an omnibus claim directed to a generator "constructed, and arranged substantially as described with reference to and as illustrated in the accompanying drawings" was construed as a narrow claim, but was held, by virtue of the qualification "substantially", to have been infringed by a generator not having stepped stator windings, even though the only embodiment specifically disclosed did have such windings. In Jansen Betonwaren B.V. v Ian Robbie Christie (BL O/496/15) the Hearing Officer considered the validity of an omnibus claim to "A building block substantially as described with reference to the drawings." The claim was construed narrowly such that it required the "four main design features" disclosed in the description and all features shown in the sole figure. The claim was nevertheless determined to lack novelty on the basis of prior public use. The Hearing Officer also found an even narrower construction of claim 1 was possible. Under this construction the claim required the building block to be manufactured using "a mix of concrete sand and cement as well as elastomer and thermoplastics". The additional limitation rendered the claim novel over the alleged prior use but resulted in the disclosure being insufficient.

Disclaimers

A disclaimer is a form of claim limitation. It is an amendment to an already existing claim comprising the incorporation of a "negative" technical feature. Typically, this will entail excluding specific embodiments or areas from a general feature. A disclaimer is allowed if what remains once the disclaimed material has been subtracted from the claim is clearly supported; that is, the disclaimer does not add matter contrary to s.76(2). An amendment to a claim by the introduction of an "undisclosed" disclaimer, where neither the disclaimer as such nor the subject matter excluded by it was disclosed in the application as filed, may be allowable providing certain criteria are met (see 14.127). These criteria were set out by the EPO Enlarged Board of Appeal in joined cases G1/03 (*Disclaimer/PPG*) and G2/03 (*Disclaimer/Genetic Systems*) [2004] 8-9 OJEPO 413 and [2004] EPOR 33. The Board later confirmed in G2/10 (*Disclaimer/SCRIPPS*) that if the criteria for allowing an undisclosed disclaimer were met the subject matter remaining in the claim after the introduction of the disclaimer would still need to be disclosed in the application as filed.

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- 14.127 The Board held that an undisclosed disclaimer is allowable in the following circumstances:
 - a) Delimiting a claim against an anticipation published after the priority date. Where a novelty objection is raised under section 2(3), an undisclosed disclaimer may be allowed to distinguish between an application and the s.2(3) prior art. The purpose of a disclaimer excluding a conflicting application is merely to take account of the fact that different applicants are entitled to patents in respect of different aspects of inventive subject matter. The disclaimer splits the invention as a whole into two parts: in respect of the identical part, it preserves the rights of the first applicant; for the rest, disclosed for the first time in the later application, it attributes the right to the second applicant;
 - b) Delimiting a claim against an anticipation in an unrelated field that the skilled person would never take into consideration (i.e. an accidental anticipation). This occurs when a piece of prior art would be disregarded by the skilled person, either because it belongs to a technical field remote from that of the invention, or because its subject matter suggests it would not help to make the invention. An undisclosed disclaimer may be allowed to distinguish an application from prior art such as this, even if cited under s.2(2). Take, for example, a claimed invention that concerns a large group of chemical compounds with certain properties which are advantageous for a specific use. One single compound within that group turns out to be known for a completely different use and, therefore, only properties irrelevant to the new use are known. A disclaimer may be used to prevent that one single compound from presenting a bar to patenting the group. A disclaimer cannot be used to delimit a claim against an anticipation that is not accidental;
 - c) Delimiting a claim against subject matter excluded from patentability for non-technical reasons, such as methods of treatment of the human body or inventions contrary to public morality For example, a method of avoiding offspring of a certain sex would be contrary to public morality when applied to humans, but not when applied to cows. If the claims are directed broadly to mammals, an undisclosed disclaimer may be used to exclude human beings and so avoid objection under s1(3). A disclaimer that excludes subject matter not eligible for patent protection may only serve the purpose of removing such specific legal obstacles. It is unlikely that a disclaimer can be used to disclaim excluded matter in general in order to meet to the requirements of novelty, inventive step, clarity and support, which all claims must satisfy;

Undisclosed disclaimers cannot be used to delimit a claim against non-working embodiments. If a claim is directed to a large number of alternatives, some of which do not work, then either the specification will contain sufficient criteria for finding appropriate alternatives over the claimed range or there are problems relating to the sufficiency of disclosure of the invention or the level of inventive step. A disclaimer is inappropriate for dealing with either of these situations. Furthermore, the disclaimer should not remove more than is necessary either to restore novelty or disclaim excluded subject matter. A disclaimer that was relevant to assessment of inventive step or sufficiency of disclosure would add subject matter and would not be allowed. The approach in G1/03 was affirmed by the Board in G1/16. In this decision, the Board also held that an undisclosed disclaimer "must not provide a technical contribution to the subject matter disclosed in the application as filed. In particular, it may not be or become relevant for the assessment of inventive step or for the question of sufficiency of disclosure".

The decision of the Board was considered in *M-Systems Flash Disk Pioneers Ltd v Trek Technology (Singapore) Pte Ltd* (BL O/318/06), where amendment by undisclosed disclaimer was held in principle to be allowable to limit a claim in the light of conflicting prior art under s. 2(3), although the Hearing Officer was unable to exercise discretion to allow the amendment on other grounds. In *Sudarshan Chemical Industries Ltd v Clariant Produkte (Deutschland) GmbH* [2014] RPC 6 the Court of Appeal upheld the view of the lower court that the disclaimer resulted in a monopoly of ambiguous and uncertain scope and, having considered the board decision in G1/03, that it resulted in the disclosure of added matter. It was held that, far from the prior art disclosure being in a remote technical field, the prior art was in fact the most directly relevant earlier disclosure and the starting

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point from which the invention of the patent in suit had been made. In other words the circumstances in this case were not those described in 14.127 b) above.

Clarity

- 14.128 A claim is bad if it contains internal contradictions. The EPO Technical Board of Appeal has held that a claim to a composition containing, *inter alia*, 40-95% of polyamide was not clear since, even if the other essential constituents were present in the minimum quantities specified the maximum amount of polyamide that could be present was 89% (Decision T02/80; OJEPO 10/81).
- A claim should not include vague or equivocal forms of wording which leave the reader in doubt as to the exact scope of a feature. Examples of this are relative terms such as "thin", "wide", "strong". If such terms appear in a claim it is usually necessary to have them either defined or excised. No objection arises, however, if the relative term has a recognised meaning in the art, eg "high-frequency amplifier", and this is the meaning intended. The term "predetermined" may need consideration: it may be meaningful in some contexts, e.g. to distinguish between fixed and variable values, but meaningless in other contexts, e.g. where all comparable values are fixed. In Nikken Kosakusho Works v Pioneer Trading Co. [2006] FSR 4, a tool chuck had "an annular groove of predetermined depth", and it was held that this phrase was objectionable and in itself implied nothing about either the criteria for choosing the depth, or the range of values it should have. On the other hand, in Folding Attic Stairs Ltd v Loft Stairs Co. Ltd. [2009] FSR 24, the Patents Court held that a claim to a manufacturing process wherein an element was spaced at "a preset distance" from another element was meaningful in the context of the claim; it meant the spacing between these elements was selected by the manufacturer with a specific aim as described in the specification. The term "predetermined size" in the same claim was also held to be clear in context. Hence, if it is clear from the description that these factors are essential to the performance of the invention, they should be made explicit when clarifying the claims.
- 14.129.1 Although the claims are interpreted in the light of the description, it was held in *IGT/Acres Gaming Inc.'s Application* [2008] EWHC 568 that if a claim seems to bear a meaning that is, in fact, inconsistent with its real meaning when read in the context of the whole document, the claim is obscure and open to objection under s.14(5)(b) because the reader may be misled as to its scope.
- 14.130 Generalising expressions such as "substantially" or (applied to numerical data) "about" should be construed, both as regards the extent of the monopoly and the relationship between the invention and the prior art, according to the subject-matter and the context. They may be allowable if they do not render the scope of the claims indeterminate. In *PLG Research v Ardon*, [1995] RPC 287 Aldous J. applied the *Catnic* principle in holding that "substantially uniplanar" did not exclude an insubstantial departure from uniplanarity due, for example, to features inherent in manufacture. "Uniplanarity" should be judged on the basis of the eye of the skilled addressee, who would judge a departure by its size and quality. On the other hand, where such generalising expressions are inappropriate, eg a reference to "an alkyl group containing about five carbon atoms", objection should be raised.
- 14.131 The question as to whether such terms as "back", "front", "above", "upwardly", are allowable or whether they introduce uncertainty into the claim, must be decided upon the facts of the case. Particular care is needed when for example the location of a feature of the invention is defined by reference to apparatus not forming part of the invention claimed or even by reference to a person using the invention, although there will be many instances when such references are rendered clear by the inclusion of expressions such as "when in use", or "when held by an operator".
- 14.132 Expressions such as "preferably", "for example", "such as" or "more particularly" should be objected to if they cast doubt on the scope of a claim.
- 14.133 A claim whether independent or dependent, can refer to alternatives provided that this does not make the claim obscure or difficult to construe (see also 14.164).

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However, such claim formulations should be avoided if, by reason of the large number of alternatives, the generality of the claim is impossible to search in its entirety. Markush claims are an example of this type of claim: such claims set out a number of alternatives (possibly using words such as "selected from the group consisting of ..."). They are often used in chemical cases as a way of setting out various functionally-equivalent alternatives in one or more parts of the chemical compound being claimed.

- 14.134 A claim whose wording suggests that it is appendant to a preceding claim, so that it purports to incorporate all the features of the preceding claim, but which on inspection is found not to be properly so appendant (since, for example, it states that a feature of the preceding claim is omitted or replaced by a different feature, so that the claim is not fully limited by the terms of the preceding claim) may be open to an objection of inconsistency. However a claim which expressly states that it is directed to a modification of the subject-matter of an earlier claim and particularises the modification may be acceptable, provided the scope of the claim is clear. Care should be taken to ensure that a search carried out in respect of a claim which is modified in this way by a later claim has covered the matter claimed in the later claim. (See also 14.164).
- 14.135 When a claim includes reference letters or numerals used in the description and drawings these should not influence the construction of the claim, but should be taken as a helpful identification of features in the specific embodiment which may help a reader orient himself at the stage when he is trying to work out what the patent is about (as held in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2010] RPC 8, and confirmed in *Jarden Consumer Solutions (Europe) Ltd v SEB SA & Anor* [2014] EWCA Civ 1629). The only restriction brought about by the inclusion of such reference letters or numerals is that the claim must be interpreted so as to include the specific example (*Rodi and Wienenberger AG v Henry Showell Ltd*, [1966] RPC at page 453). No objection should be raised to the presence of the references. (In contrast applicants for patents under the EPC or the PCT are urged, by Rules 43(7) and 6.2(b) of the respective treaties, to use references in their claims. The PCT rule goes on to say that such references may be removed by a designated Office for the purposes of publication; this is not the practice of the UK Office).
- 14.136 Although ideally it should be possible to ascertain the scope of any claim of a specification without recourse to other documents, (and certainly without recourse to evidence of what a patentee intended a claim to mean see *Glaverbel v British Coal Corporation and anr* [1995] RPC 255), the inclusion of a reference to an earlier specification as one of the integers of a claim is not completely precluded. The overriding consideration is the clarity of the claim. A reference to a feature "as described in" an earlier document will not normally be clear in scope. It should also be remembered that if the reference is to a claim of an earlier patent specification, this may subsequently be amended, thereby altering the scope of the claim under consideration. The availability of the other document and inconvenience to a reader should also be borne in mind; in particular, objection should always be raised if the document referred to is in a foreign language. (Whether a reference can be replaced by matter from an earlier specification depends on its date of publication see 14.85).
- 14.136.1 Claims defined by an industry standard which could change over time should generally be objected to under clarity. This was discussed in paragraphs 26-28 of the Hearing Officer's decision in *Bilgrey Samson Ltd's Application*, BL O/577/01.
- 14.137 Since a trade mark is indicative of the origin of goods rather than of their content or composition, the use of a Trade Mark in a claim should generally only be permitted where the applicant is able to show that its use is unavoidable and does not introduce ambiguity. However, in limited circumstances such as when trade marks relate to internationally agreed standards which specify the technologies identified by those trade marks, for example Bluetooth and WiFi, these trade marks may be allowable.

[If a Trade Mark is used in a claim, RC12 should be added to RC11 (see 14.100-14.101, 19.25-19.26). Senior Examiners may decide to allow a reference to a Trade Mark in a claim without consulting their Deputy Director but Examiners

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should only allow such references with the concurrence of their senior officer.]

14.138 Claims containing two or more sentences have always been resisted on the grounds of ambiguity. In *Leonard's Application* [1966] RPC 269, it was held that claims consisting of disjunctive sentences would of necessity give rise to uncertainty as to the precise scope of the monopoly sought, but a claim was eventually allowed directed to "an automatic change speed transmission having all the following characteristics in combination" followed by numbered paragraphs (each a separate sentence) setting out the characteristics of the transmission.

CoP

14.139 Claims directed to "Any novel matter ..." or which are similarly directed are unacceptable and should not be filed as they serve no useful purpose: in particular such claims cannot be relied upon to form the sole support for claiming a broad scope of protection in a subsequent divisional application. These claims should be ignored at the search stage and their removal should be required before the application proceeds to grant.

14.139.1 [Moved to 14.144]
14.139.2 [Moved to 14.144]
14.139.3 [Moved to 14.144.1]

CONCISENESS

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- 14.140 The requirement that the claims shall be concise refers to the claims in their entirety as well as to the individual claims. The number of claims must be considered in relation to the nature of the invention the applicant seeks to protect. In *Contra Vision Ltd's Patent* (BL O/079/00) a request to amend the claims was refused partly on the grounds that the proposed amendments would have resulted in sixty-eight independent claims and a four-fold increase in the total number of claims, and thus the claims would not have been concise. A lengthy statement of claim in which the wording of one claim is repeated to an unnecessary extent is open to objection (*Bancroft's Application* 23 RPC 89). It follows that a statement of claim is not allowable if it is framed on the American system to include a long series of claims which are independent of each other yet almost identical in subject-matter. Multiple independent claims of slightly varying but overlapping scope also open up the need for analysis of subject matter common to those independent claims, with the result that plurality of invention may be found (see 14.157-14.168).
- 14.141 Each claim should cover some area of subject-matter not the subject of another claim, and objection should be raised when two or more claims are coterminous. While the Courts will if possible construe the claims so as to give a different meaning to each one, if little or no difference can be found between two of the claims, this affords no ground for departing from the reasonable and natural meaning of the language.

SUPPORT BY THE DESCRIPTION

- 14.142 The words "supported by the description" were new in the 1977 Act, replacing the 1949 Act requirement that the claims had to be fairly based on the matter disclosed in the specification. In *Schering Biotech Corp's Application* [1993] RPC 249 Aldous J felt that it was not right to rely on cases decided under the "fairly based" requirement and emphasised the importance of coming to the right decision since a patent, when granted, cannot be attacked on this ground (see 14.152).
- 14.142.1 The view of the EPO Technical Board of Appeal in *AgrEvo UK Ltd* (T 939/92 OJEPO 6/96) was that "support by the description" means that the technical features stated in the description as being essential features of the described invention must be the same as those used to define the invention in the claims, for otherwise the claims would not be true definitions but mere descriptions. This view that support is purely

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a drafting matter does not clearly correspond, for example, with the view of Aldous J in Schering Biotech Corp's Application [1993] RPC 249 (see 14.149). Thus, until such time as the courts endorse the EPO's interpretation of support in AgrEvo UK Ltd, the guidance given below should be followed.

14.143 Most claims are generalisations from one or more particular examples. The extent of generalisation permissible is a matter which must be judged in each particular case in the light of the relevant prior art. Thus an invention which opens up a whole new field is entitled to more generality in the claims than one which is concerned with advances in a known technology. A fair statement of claim is one which is not so broad that it goes beyond the invention nor yet so narrow as to deprive the applicant of a just reward for the disclosure of his invention. The applicant should be allowed to cover all obvious modifications, equivalents to and uses of that which he has described. In particular, if it is reasonable to predict that all the variants covered by the claims have the properties or uses the applicant ascribes to them in the description he should be allowed to draw his claims accordingly.

14.144 Where there is any serious inconsistency between claims and description, amendments to remove this will be required. For example:

- The description may state, or may imply, that a certain technical feature not mentioned in the main claim is essential to the performance of the invention. In such a case, the claims should normally be amended to include this feature. If however the applicant can show convincingly that it would be clear to a person skilled in the art that the description was incorrect in suggesting that the feature in question was essential, and if the main claim which implies (by omission) that the feature is not essential was present on the date of filing, amendment of the description may be allowed instead.
- Another form of inconsistency is where the description and/or drawings include one or more embodiments of the invention which appear to fall outside the subject-matter covered by the claim (eg the claims all relate to a control system employing an electric servo-motor and one of the embodiments employs a hydraulic servo-motor as an alternative). Here again either amendment of the claims or of the description and drawings is required to remove the inconsistency and thus avoid any possible uncertainty which could arise later as to the meaning of the claims. This can also occur where a particular part of the description or the drawings does not exemplify the invention claimed, for example where it is included to explain the invention or for comparison or where it relates to prior art, this should be made clear. This issue can arise, for example, where the description refers to 'aspects / features / clauses / summaries of the invention' which are not consistent with the claimed invention.
- The description sometimes includes general statements which suggest that the scope of protection is broader than the claims. For example that 'the invention includes any novel combination of features in the description' or 'the invention should be taken to include any modifications, whether novel or not'. In this case, amendment will be required so that the description does not cast doubt on the scope of the invention claimed.

14.144.1 The test set out in <u>Actavis UK Limited and others v Eli Lilly and Company [2017] UKSC 48</u>, is for determining whether certain equivalents fall within the scope of protection of the claims. This test does not mean that all equivalents are protected by the claims. Therefore any general statement within the description stating that the scope of protection of the claims includes all equivalents is not allowable (see 125.18.6).

14.145 Where certain subject-matter is clearly disclosed in a claim of the application as filed, but is not mentioned anywhere in the description, it is generally permissible to amend the description so that it includes this subject-matter. When however original claims filed later than the filing date of the application contain matter not present in the description, such matter will need to be deleted. Objection should be raised under s.14(5)(c), rather than under s.76(2) since later-filed original claims do not constitute an amendment of the application (but any subsequently-filed claims do, see 15.54).

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- 14.146 An opening statement or 'consistory clause' setting out the nature of the invention is normally included in the description. The consistory clause may however be omitted if the description indicates explicitly or implicitly and without ambiguity the essential features of the invention. If, however, the description of the invention contains generalising statements and the specification contains an omnibus claim (see 14.124-14.125) not of the narrow form discussed in *Raleigh Cycle Co Ltd and Anr v Miller and Co Ltd*, 65 RPC 141 then an opening statement defining the invention is necessary. (In the Raleigh Cycle specification the omnibus claim was directed to a generator, "constructed, and arranged substantially as herein described with reference to and as illustrated in the accompanying drawings").
- 14.147 It is not essential for a statement of invention to be identical in wording with a main claim, but it must not be inconsistent with such a claim. If it becomes necessary for the applicant to restrict the scope of his main claim in order to meet an objection of prior publication any corresponding statement of invention should be similarly restricted as the applicant can then no longer allege the broad statement to be his invention. A claim which is wider in scope than the statement of invention may be open to objection on the grounds that it is not supported by the description.
- 14.148 The use of a compact style of consistory clause, which imports a reference to one or more claims into the statement of invention, is strongly encouraged since this avoids repetition and removes the necessity for redrafting following amendment of the claims. When the claims are read in their context as part of the description the true scope of the invention should not be in doubt. If such reference includes independent claims care should be taken that they do not import uncertainty into the description of the invention (United Shoe Machinery Application 57 RPC 71).
- 14.149 In *Glatt's Application* [1983] RPC 122 (see 14.151(a)) it was held that if claims are put forward which cover something which plainly was never within the contemplation of the invention as described in the specification then they lack support. This view was reinforced by Aldous J in *Schering Biotech Corp's Application* (see 14.142) when it was held that the correct approach was to consider the claims in the specification through the eyes of the skilled person in the art, to ascertain what is the invention which is specified in the claims, compare that with the invention described in the specification and thereafter decide whether the invention in the claims is supported by the description. Mere mention in the specification of features appearing in the claim is not necessarily sufficient support. "The word 'support' means more than that and requires the description to be the base which can fairly entitle the patentee to a monopoly of the width claimed." This approach was believed by Aldous J to be consistent with that of the EPO in *Biogen NV v Hoffmann-La Roche & Co. AG* (T301/87 OJEPO 8/90). It is also consistent with the finding of the Court of Appeal in *Biogen v Medeva* [1995] RPC 25 at p 87, regarding the implications of quoting a claim verbatim in the description.
- 14.150 If it appears that the description is inadequate to support a broad claim, it is possible to argue either that the disclosure is not clear and complete enough or that the claim is not supported by the description. In general a classical sufficiency objection (see 14.67-14.75) should be raised under s.14(3) only in the clearest cases, when the disclosure appears inadequate to support a valid claim. However where the claims are unduly broad and speculative objection may be raised either under s.14(3) as insufficiency through excessive claim breadth and/or under s.14(5) (see also 14.79-14.82). Such an objection may not be overcome by the addition of further examples or features to the specification since this is prohibited under s.76(2), however an objection to the excessive breadth of the claims under either section may be remedied by restricting the scope of the claims (See also 14.102-14.104).
- 14.151 The following are examples of cases where the relationship of the claim to the description has been considered:-
 - (a) In *Glatt's Application*, [1983] RPC 122, an article for conditioning fabrics in a laundry dryer and comprising a flexible woven or non-woven sheet having on it

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areas of fabric conditioning composition was described in a way which indicated that it was an essential feature that the material of the sheet be permeable to air. A claim which was silent as to the permeability of the sheet was held by the Patents Court to be not supported by the description (see 14.149).

- (b) In *Universite Rene Descartes* (BL O/147/88) it was decided that to insert into a claim a specific numerical example, not expressly stated in the description, would result in a claim which was not supported by the description. (With regard to the narrowing of a claim to a sub-range not specified before, see 18.69-18.69.1.)
- (c) In *A C Edwards Ltd v Acme Signs & Displays Ltd* [1990] RPC 621 and [1992] RPC 131 it was held that the invention of claim 1 (which was substantially amended pre-grant) was not directed to a different inventive concept than that disclosed in the original application. There was therefore support for the amended claim in the description. (In practice this decision may give support, in certain circumstances, for an intermediate generalisation the case related to a 7 element digital display in which any required digit could be displayed using flaps which cover/uncover the elements. As described each flap was attached to a baseboard by two studs. The originally filed claim 1 was silent in respect of the studs but the amended claim 1 included, for each flap "a stud". It was held that this limitation to claim 1 "did not disclose use of a single stud any more than did claim 1 of the application". See also 76.15-15.1).
- (d) In Raychem Ltd's Applications [1986] RPC 547 the applicant sought to amend claim 1 by deleting the final step in a process and thus claim an intermediate product. It was held that the amended claim would not be supported by the disclosure which clearly disclosed the final step as an essential feature of the invention. It was held that such a claim must also offend against Section 76 (see also 76.17).

Broad or speculative claims

14.152 An applicant does not have to restrict his claims to the specific embodiment described, but the width of the claims must be properly supported by the description of the invention in the specification (for discussion of insufficiency by excessive claim breadth see 14.79 onwards). A claim can only be supported by an enabling disclosure (Asahi Kasei Kogyo KK's Application [1991] RPC 485, at page 536). When claims are broad and speculative, in that their scope extends beyond the description to embrace possibilities the effects of which cannot readily be predetermined or assessed on the basis of what is described, and the description gives merely an indication of the full breadth of scope of the invention but no, or inadequate, directions of how to put it into practice across the range claimed, objection should be raised that such claims are not supported by the description. In Esau's Application, 49 RPC 85 a claim for apparatus for influencing substances by means of high frequency electrical energy was refused since it embraced any kind of influence on any kind of substance. Eventually the law officer allowed the claims to be redrafted to cover a process for the aggregation of fine particles from gases or liquids for the purpose of effecting their removal. The law officer's remarks on page 87, lines 42-47 about broad and indeterminate claims are invoked again in Shell Development Co's Application, 64 RPC at page 154 and in General Electric Co Ltd's Application [1961] RPC at page 24. In Schering Biotech Corp's Application (see 14.142), the judge rejected the wider of two alternative claims 1 as unsupported: whereas the invention was the use of a new insert in a vector to produce a polypeptide having a certain activity, passages suggesting that by using that new insert other inserts of unknown code and amino-acid sequence could be found did not provide a description adequate to support a claim to a monopoly covering the other inserts. It was unjustified to claim the use of all vectors producing the required result, where only one vector had been investigated. This followed the judgment in the Court of Appeal in Genentech Inc's Patent [1989] RPC 147 concerned with genetic engineering, in which Dillon L J observed (at page 236-7) "the Patent Office ought to have very clearly in mind that it is undesirable to allow claims the

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object of which is to cover a wide and unexplored field or where there is no disclosure in the specification which is in any way coterminous with the monopoly indicated in the claims." The reasons of the three judges in Genentech in finding all claims invalid differed, but they were unanimous that the reason relied on by Whitford J, ie that the claims were not supported by the description, was not a ground for revocation under s.72(1). Mustill L J observed (at page 261) that "grounds of objection have always been prone to overlap, and that the very same factors may lead to an irredeemable flaw in the patentability of the supposed invention, and to an impossibility of framing an application which complies with section 14(5)". Subsequently, in Chiron Corpn v Organon Teknika [1994] FSR 202 Aldous J observed that s.72(1)(c) could not provide grounds for attacking a claim where in essence the complaint was one of lack of support; it being important that the effect of s.72(1) should be the same as the equivalent provision applied in many other European countries. In the case of medical inventions having at their heart a medical use (see 4A.16-4A.31), the description should not only identify a condition that may be treated but also demonstrate by reference to tests that the treatment is a reality and not just a possibility (Hoerrmann's Application [1996] RPC 341, Consultant Suppliers Ltd's Application [1996] RPC 348). However, in Prendergast's Applications ([2000] RPC 446) Neuberger J emphasised that rudimentary tests would suffice and that full, detailed and rigorous testing of the drug for the proposed condition is not necessary.

14.153 In Pottier's Application [1967] RPC 170 a broad claim to: 'A process for the treatment of hydrated seedlings which comprises subjecting the seedlings to cold shock at a temperature below 0°C for a period sufficiently long to affect the size of the resulting plant', was refused, following Esau's Application (see 14.152), because the claim was broad and speculative. The treatment of sugar beet seedlings only was described. Such a claim might be permissible if it were made clear in the description that the conditions set forth in relation to that plant applied to other plants generally; but otherwise the claim would not be regarded as adequately supported unless the description gave a sufficient range of examples, relating to different kinds of plants, to enable a horticulturist to deduce how the process should be applied to virtually any plant. In Amchem's Products Inc's Patent, [1978] RPC 271, where claim 1 was directed to a process for increasing the resistance of any plant to any disease or internal malfunction by treating it with one or other of a number of specified compounds in an amount sufficient to increase the resistance, and the description referred only to protecting tomatoes, cucumbers and potatoes against particular diseases, it was held that the invention claimed had not been sufficiently and fairly described.

14.154 Claims directed to all solutions of a problem are not allowable unless invention lies in the identification of the problem. In N V de Bataafsche Petroleum Maatschappij's Application, 57 RPC 65, it was an essential feature of a claim to a process for impermeabilizing and tightening soils etc, that an aqueous dispersion of a bituminous substance forming part of a mixture caused to penetrate the soil and coagulate therein was "suitably stabilized". No general instructions were given in the specification as to how this was to be done and the claim was held to include "every method of achieving that suitable stability by achievement whereof the problem is to be solved" and to be invalid by the same reasoning as that promulgated by Lord Parker in British United Shoe Machinery Co Ltd v Simon Collier Ltd 26 RPC pages 48-51. In Chemische Fabrik auf Aktien's Application, 45 RPC 403, a claim to a chemical process using "a catalyst" and thus embracing any catalyst which would give the desired result was disallowed. In David Kahn Inc v Conway Stewart & Co Ltd [1974] RPC at pages 319-320 it was stated that "A patentee may rightly claim a monopoly wider in extent than what he had invented. If he has discovered a general principle or invented a general method and discloses one way of carrying it out, he may claim all ways of carrying it out, but he is not entitled to claim a monopoly more extensive than is necessary to protect what he has himself said is his invention. He cannot claim all solutions to a problem unless invention lies in identification of the problem".

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14.155 A claim in generic form ie relating to a whole class eg of products or machines, may be acceptable even if of broad scope, if there is fair support in the description, and there is no reason to suppose that the invention cannot be worked through the whole of the field claimed. Where the information given appears inadequate to enable the skilled person to extend the teaching of the description to parts of the field claimed, but not explicitly described, by using routine methods of experimentation or analysis, the applicant should be required to show that the invention can in fact be readily applied on the basis of the information given, over the whole field claimed, or, failing this, to restrict the claim to accord with the description. An example of this might be a claim to a specified method of treating "synthetic resin mouldings" to obtain certain changes in physical characteristics. If all of the examples described related to thermoplastic resins and the method was such as to appear inappropriate to thermosetting resins, then restriction of the claims to thermoplastic resins might be necessary.

14.156 A claim may broadly define a feature in terms of its function, even where only one example of the feature has been given in the description, if the skilled reader would appreciate that other means could be used for the same function. For example, "terminal position detecting means" in a claim might be supported by a single example comprising a limit switch, it being obvious to the skilled person that eg a photoelectric cell or a strain gauge could be used instead. In general, however, if the entire contents of the application are such as to convey the impression that a function is to be carried out in a particular way, with no intimation that alternative means are envisaged, and a claim is formulated in such a way as to embrace other means, or all means, of performing the function, then objection arises. Furthermore, it may not be sufficient if the description merely states in vague terms that other means may be adopted, if it is not reasonably clear what they might be or how they might be used.

Reach-through claims

14.156.1 "Reach-through" claims to compounds identified by an assay or screening method with particular properties, and to the downstream uses of such compounds are speculative as the claim covers all compounds possessing these properties when assayed, whether or not they have been specifically identified in the description of the patent. If the relationship between the function of the materials and their structural features is not defined, identification of all compounds from the assay with the desired properties would require substantial experimentation by trial and error to screen compounds for the desired activity. Therefore "reach-through" claims are both insufficient and unsupported by the description. Furthermore, these claims often give no information about the chemical and physical characteristics of the material possessing the desired activity screened for and will also be unclear.

UNITY OF INVENTION

s.125

14.157 Each claim of a specification defines at least one invention. However the requirements of the Act regarding unity of invention are met if the claims relate to a group of inventions which are so linked as to form a single inventive concept. The question as to whether the inventions are related in this way is not based on rigid rules but rather on broad considerations as to the degree of interdependence between the inventions claimed, and as to the state of the art concerned, as explained in the following paragraphs. The practice to be adopted for dealing with applications considered to lack unity of invention during search or substantive examination is discussed in paragraphs 17.106-17.114 and 18.37-18.41 respectively.

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14.157.1 Multiple inventive concepts should not be included in the same application if they are unrelated to the extent that they will inevitably give rise to a plurality objection.

14.158 When considering unity of invention, regard should be had to the

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underlying inventive concept of each of the inventions claimed. This concept may be expressed in different ways (see 14.159) and may be implicit rather than explicit. Regard may be had to the purpose and/or result of each invention. One criterion which would be suitable for some sets of claims would be to determine whether the common subjectmatter of the claims is novel and involves an inventive step. Other criteria are referred to in the subsequent paragraphs. The lack of novelty or the obviousness of the common subject-matter may be established by citing documentary evidence, but this is not necessary, at least in the first instance, if the common matter is clearly known or obvious. Specifications forming part of the state of the art by virtue of s.2(3) may not be used to demonstrate that common subject-matter is not new.

- r.16 14.159 Inventions should be treated as being linked so as to form a single inventive concept where there exists between the inventions a technical relationship which involves the same or corresponding "special technical features", i.e. features which define a contribution which each of the claimed inventions, when considered as a whole, makes over the prior art. The inclusion of any one of the following combinations of claims of different categories in the same application should be permitted:
 - in addition to an independent claim for a product, an independent claim for (a) a process specially adapted for the manufacture of the product, and an independent claim for use of the product; or
 - in addition to an independent claim for a process, an independent claim for (b) an apparatus or means specifically designed for carrying out the process; or
 - in addition to an independent claim for a product, an independent claim for a process specially adapted for the manufacture of the product and an independent claim for an apparatus or means specifically designed for carrying out the process.

This list of combinations of claims in different categories (process, product, use, apparatus) is not exhaustive, and other combinations should be considered on their merits.

Examiners should use their discretion to determine whether the claims in 14.159.1 question share a single inventive concept, any doubt being resolved in favour of the applicant. In Dow Chemical Company's Application (BL O/175/83) the hearing officer concurred with the view expressed in EPO Decision T110/82 (OJEPO 7/83) that one of the determining factors is the equitable levying of fees between applicants. However the fact that the subject-matter of two claims cannot be covered by a single search does not necessarily demonstrate that unity of invention is lacking. On the other hand if a single search suffices on a borderline case the benefit of any doubt can be resolved in favour of the applicant.

14.160 Plurality of invention is not a ground on which a patent may be revoked, nor may any person, in any proceedings, raise such an objection to the claims of a patent as granted or as amended after grant (see 26.01).

Claims to separate articles which are inter-related, for example, by 14.161 being characterised in that they are to be used together, may be regarded as linked to form a single inventive concept. This would be the case with separate claims to two parts of an electrical or other coupling, or to a housing and to contacts to be mounted in the housing, provided they were specifically adapted for one another and have no further obvious In particular separate claims may be justified to parts which may be manufactured or sold separately, such as a rupturable container of fuel and a burner adapted to pierce the container when mounted on it; or a container of chemicals to be sprayed which is adapted to be mounted on a carrier, and such a carrier specially adapted for receiving the container; or to a new form of cable and to a sheath stripper particularly adapted to deal with this cable. Another example where there is unity of invention would be a transmitter and receiver which were adapted to be used together, for example by

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s.72 s.26 employing a particular novel method of encoding or modulating the signal; however a transmitter and a receiver intended for use with it would be regarded as separate inventions if they could also be used with known receivers or transmitters.

14.162 When a specification discloses a number of distinct surgical, therapeutic or diagnostic uses for a known substance or composition, separate claims to the substance or composition for the respective uses are not, as a general rule, regarded as lacking unity of invention, if there has not been any previous medical use of the substance or composition.

14.163 The fact that the inventions defined in independent claims may be directed to solving the same problem or to implementing the same idea, or that separately claimed processes may lead to the same product, may not be sufficient in itself to confer unity of invention. In particular the fact that a class of chemical intermediates has been prepared solely in order to be converted to particular products may not demonstrate that there is a single inventive concept linking claims to the intermediates and the products. The EPO Technical Board of Appeal held in Decision T35/87 (OJEPO 4/88) that it is necessary for unity of invention between intermediates and end-products that groups of intermediates prepared and oriented towards the end-products be technically closely interconnected with the latter by sharing an essential structural element. Therefore, if intermediate and final products include a common structure which can be considered to be novel and involve an inventive step then claims to the products can relate to a single inventive concept even though separate searches for the products may be necessary.

14.164 There is normally no question of plurality of invention when one claim is within the scope of another, whether by repeating the wording of it or by being dependent on it, even though the additional matter in the narrower claim would have been capable of being claimed as a further invention. Where however a claim is presented as dependent on another but in fact is not limited to the invention of the other claim, for example, by directing a claim to an apparatus as suitable for use in a claimed system, or by stating that one or more integers of the other claim are omitted or are replaced by other features, there is the possibility of plurality of invention. Likewise when alternatives are specified in a single claim, the claim should be mentally rewritten as a series of independent claims which can then be assessed for unity of invention in the usual way. A plurality objection may also be raised if an independent claim is clearly unduly broad and speculative and not new or inventive, and is apparently merely a device for giving an impression of unity of invention between otherwise unrelated dependent claims (see 17.66 and 17.110).

14.165-167 [deleted]

14.168 Where an applicant has discovered a useful property in a group of chemically related compounds, some of which are known, claims to the new use (subject to the provisions of s.4A(1)), to compositions containing the compounds for such use, and to any of the compounds that are novel per se and to their method of preparation, are considered to form a single inventive concept provided that all of the compounds, whether novel or known, possess the common characterising property giving rise to the use.

Section 14(7)

The purpose of the abstract is to give technical information and on publication it shall not form part of the state of the art by virtue of section 2(3) above, and the comptroller may determine whether the abstract adequately fulfils its purpose and, if it does not, may reframe it so that it does.

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The abstract

s.14(2)(b) and (c)

14.169 The abstract is not part of the specification, and it is clear from s.125(1), which refers to the claims being interpreted by the description and any drawings contained in the specification, that it cannot be used to give assistance in determining the extent of the protection conferred by the claims. The form and content of the abstract are governed by r.15.

s.97(1)(a) s.15(5)(a) 14.170 If an abstract fails to meet any requirement of r.15 then it may be amended by the examiner, using the power given to the comptroller by s.14(7). Although amendments made by the examiner do not form a part of the application as filed, it is the amended form of the abstract that is included in the published 'A' document, see 16.08. (There is no appeal to the Patents Court from a decision of the comptroller under s.14(7)). If however the abstract as filed clearly fails to meet the dictionary definition of an abstract (ie a brief statement of the chief points of a larger work), for example when it is little more than a title, then objection should be raised that no abstract has been filed and the applicant asked to remedy this. If the time allowed for filing the abstract (see 15.50) has already expired (including any extension allowed under r.108), the application will be taken to have been withdrawn (see 15.55).

[An objection that the applicant has failed to file anything that meets the dictionary definition of an abstract should only be raised in the clearest cases. The desirability of giving every help to private applicants should be borne in mind.]

r.15

14.171 The purpose of the abstract is to provide technical information about the patent application, and so the abstract should reflect the content of the specification. However, in reality, matter is sometimes disclosed in an abstract which is not disclosed in the specification as filed. Following the decision of the Patents Court in Abbott Laboratories Ltd. v Medinol Ltd [2010] EWHC 2865 (Pat) it is important to note that the specification cannot be amended to incorporate such matter from the abstract into the description or claims, whether or not the abstract was filed on the day of filing. This decision (which overturns previous Office practice as established in ARMCO Inc's Application BL O/84/85 - see 76.08.2) has major implications for applications in which the abstract contains significant material not disclosed elsewhere in the application. In Abbott Laboratories Ltd. v Medinol Ltd. Arnold J held that s.14(7) should be interpreted as meaning that the purpose of the abstract is to give technical information only (by reference to the similar Art.85 EPC and associated EPO case law), and so is irrelevant for the purpose of determining the disclosure of the application as filed. The disclosure of the abstract, even if filed on the date of filing, cannot therefore be considered for the purpose of determining under s.76 whether an amendment adds matter extending beyond the disclosure of the application as filed. It is not possible to incorporate this material into the description or claims by subsequent amendment, and so it will not be possible for the applicant to claim this matter, or to rely on this disclosure to provide support for the claims or to overcome an objection of insufficiency. The applicant should therefore be informed of this situation and its implications as soon as possible, so that they may have the opportunity to withdraw and re-file the application with the matter in question included in the specification.

In addition, Arnold J said that the purpose of the abstract is to provide a summary of the disclosure of the specification, and so if it does not mean the same thing as the specification then it must be assumed to be an inaccurate summary. Therefore, when reframing the abstract, the examiner should delete any material which does not appear elsewhere in the application, regardless of whether the abstract was filed on the day of filing or later.

[Inclusion of material in the abstract but not in the specification is most likely in applications from private applicants, and so examiners dealing with applications from private applicants should be particularly alert to this possibility.]

[Applications from private applicants are sent to the Private Applicant Unit (PAU)

(see 17.03). PAU examiners will scrutinise abstracts to determine whether they contain matter not present elsewhere in the application. If the PAU examiner becomes aware that there is a significant disclosure in the abstract which is not present elsewhere in the application, then they may issue a letter to the applicant under the ABS or ABCSE procedure as set out in 17.94.5-9. This letter should give the applicant the options to withdraw the application and re-file (with a refund of the search fee), or to continue with the application.]

[Where a private applicant case has been sent to an examination group, this problem is most likely to come to light when the search examiner scrutinises and if necessary re-frames the abstract. If the search examiner discovers significant material in the abstract which is not disclosed elsewhere in the application, he should inform the applicant of this problem and its implications as soon as possible. This may be done by including an appropriate warning in the search letter. However, if the matter disclosed solely in the abstract is likely to be critical for the grant of a patent, then it may be more appropriate to issue an ABS or ABCSE letter.]

- 14.171.1 It appears to follow that a consequence of the decision that the abstract is to be ignored when considering the disclosure of the application is that an applicant cannot rely on matter contained solely in an abstract for the purposes of claiming priority. (See 5.20-5.25)
- 14.172 It follows from s.14(7) that subject-matter in the abstract but not in the specification can only be cited against an invention which has a priority date later than the date of publication of the application containing the abstract.
- CoP 14.173 The abstract must have a title which encapsulates the invention r.15(1) disclosed in the specification. The abstract title is important to the public since it is the title which appears in the Journal in the lists of applications published and which is used in the Names of Applicants Index.

[If there is no abstract title the search examiner should provide one in PROSE for translation into COPS without raising objection under r.15(1). It is not necessary to add the abstract title to the page containing the abstract. No other title should be entered, and because of restrictions inherent in COPS, the title should not exceed 158 characters (including spaces) or include subscripts, such as present in chemical formulae. No abstract title (or anything else in lieu of the title) should be entered in PROSE if an abstract has not been filed.]

CoP 14.174 The abstract title can be different from the title given to the application on filing. The latter is unlikely to make a suitable abstract title if, as is generally the case, it is expressed in broad terms to avoid disclosure of the invention in the Journal before the application itself is published. If the abstract title is unsuitable (for example if it is too long or too vague) the examiner should amend it. Examples of titles which are regarded as

unsuitable are

- (a) any title including such expressions as "improvements in or relating to" or "and the like"
- (b) titles such as "chemical compound" or "control circuit", which give little or no indication of the invention
- (c) over-long titles which are apparently intended merely to indicate that the specification contains claims in certain categories (process, apparatus etc), eg "Gas-permeable seamless pipe structure and method and apparatus for production thereof", or "Method of bleeding a hydraulic system and means therefor"
- (d) over-long titles which contain matter, for example relating to possible fields

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of application of the invention, more properly to be found in the body of the abstract

- (e) titles including a trademark (see 19.24).
- 14.174.1 When amending an abstract title to make it an effective search tool, care should be taken to avoid adding matter not in the specification. Before amending an abstract title, the search examiner should read enough of the specification to be certain that the alterations are accurate and that the amended title encapsulates the disclosed invention.
- r.15 14.175 The text of the abstract should comply with r.15(2), (3) and (7), which read:-
 - (2) The abstract must contain a concise summary of the matter contained in the specification.
 - (3) That summary must include—
 - (a) an indication of the technical field to which the invention belongs;
 - (b) a technical explanation of the invention;
 - (c) the principal use of the invention.
 - (7) The abstract must not contain any statement on the merits or value of the invention or its speculative application.
 - 14.176 The abstract should be primarily directed to that which is new in the art to which the invention pertains. Clearly an abstract which describes only the background or prior art or does not adequately reflect the technical disclosure in the specification is inappropriate. If the invention is in the nature of a modification to a known apparatus, process, product or composition, the abstract should, while making clear the context of the invention, be directed to the technical features of the modification. If the invention is of a basic nature the entire technical disclosure may be new in the art and the abstract should be concerned with the entire disclosure. In either case it should be clear from the abstract where the inventive contribution to the technical field lies by indicating this in the opening sentence(s). The main specifics about the invention and how it can be practised should then be set out.
 - 14.177 The abstract should be drafted so that it constitutes an efficient instrument for the purposes of searching and disclosure in the particular technical field, in particular by making it possible to assess whether there is a need to consult the specification itself. The scope of the abstract, and the words used in it, should be selected to ensure that retrieval from electronic databases is likely when searching similar applications at a later date.
 - 14.178 The check list in the "WIPO Standard ST.12/A" provides a useful guide for the writer or reviser of an abstract. It indicates that, provided that the specification contains the information, the abstract should include the following:-
 - (a) where the invention is an article, its identity, use, construction, organisation and method of manufacture;
 - (b) where the invention is a chemical compound, its identity (structure if appropriate), method of preparation, properties and uses;
 - (c) where the invention is a mixture, its nature, properties, use, essential ingredients (identity, function), proportions of ingredients (if significant), and preparation;

CoP

CoP

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- where the invention is a machine, apparatus or system, its nature, use, construction, organisation and operation;
- (e) where the invention is a process or operation, its nature and characterising features, material and conditions employed, product (if significant), and the nature of a relationship between the steps, if more than one.
- where the disclosure involves alternatives, the abstract should deal with (f) the preferred alternative and identify the others if this can be done succinctly; if this cannot be done, it should mention that they exist and whether they differ substantially from the preferred alternative.

This checklist is for guidance only. In particular the content of the abstract should be determined by the new technical disclosure of the specification rather than by the nature of the claims.

- 14.179 Where features are merely preferred or optional, the abstract should avoid any implication that they are essential to the invention. If the disclosure involves alternatives, the abstract should deal with the preferred alternative and identify the others, if this can be done succinctly; if this cannot be done, it should mention that they exist and whether they differ substantially from the preferred alternative. Where the claims relate to more than one invention, the subject matter of the further inventions should be included in the abstract, even though no search may yet have been carried out in respect of these inventions.
- 14.180 Where the specification contains extensive numerical data or tables, eg relating to physical properties or compositions, the presence of such data, and their nature, should be indicated in the abstract, if this can be done briefly.
- The general nature of a chemical compound or composition should be given as well as the use thereof, eg "the compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics". For processes, the type of reaction, reagents and process conditions should be stated, generally illustrated by a single example. Wherever applicable, the chemical formula should be given which, among all the formulae contained in the specification, best characterises the invention.

[When a search examiner wishes the abstract to be accompanied by a formula (other than one which can be typeset in normal typescript), he will generally have to provide a copy for use in preparing the front page of the 'A' publication.

For this purpose, the examiner should provide a document on the dossier containing a copy of the formula in question from a suitable page of the description or claims. This document may be created and imported onto the dossier electronically; or alternatively, created manually and subsequently scanned on to the dossier. A minute should also be added to the dossier giving clear instructions to Formalities concerning the document's inclusion in the publication sub-file.

[Deleted]

The quality of the copy of the formula will be checked in Publishing Section for suitability for reproduction and a fresh copy will be made there if necessary. The above action is of course unnecessary if the abstract already includes an acceptable representation of the formula or a suitable formula drawing (see 15A.09) is available.

r.15(2) 14.182 An abstract should normally contain not more than 150 words, as it is unlikely to be considered to be concise if it extends beyond 150 words. However, if a longer text is considered essential, there is space on the front page which will accompany the published specification for approximately 200 words. Abstracts should therefore

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contain 200 words at the very most (including any reference numerals). Unnecessary phrases such as "the invention relates to" or "and the like" may be deleted, and an unduly long introductory statement which only indicates what is old and well-known may be curtailed or deleted. While the removal of such superfluous matter is of particular importance when the abstract is longer than 150 words, it may also be deleted even if the abstract is short.

14.183 It is not necessary for the abstract to indicate the kind of protection sought by the claims. Thus for example if an apparatus has been described in the abstract and the specification includes claims to a method of using the apparatus and/or to an article produced by the apparatus, there is no need for the abstract to indicate this if the technical features of the method and article are implicit in the description of the apparatus.

CoP

- 14.184 The legal phraseology or the sentence structure used in patent claims, should be avoided in abstracts. Thus an abstract that is identical to, or closely resembles, an independent claim should not be filed, nor should an abstract use words commonly associated with patent claims such as "said" and "means".
- 14.185 The search examiner must keep in mind that the abstract is an important search tool and if it is unsatisfactory for that purpose he should amend it. A critical appraisal of the abstract by the search examiner is therefore necessary although this should not involve a rigorous analysis to determine how far r.15 is complied with. He should not attempt extensively to rewrite it for simply stylistic reasons. Thus if an abstract does not reflect the main contribution to the art in an application (eg where the claim is heavily anticipated or badly drafted) the search examiner should amend the abstract to incorporate that contribution. It may also be necessary to add to an otherwise adequate abstract one or two phrases to ensure that it reflects all of the matter in the application which has been classified including any further inventions.

[Any required amendments should made to the copy of the abstract provided on PROSE.]

[Deleted]

- 14.186 When reframing an abstract to make it an effective search tool, care should be taken to avoid adding matter not in the specification (but see 14.171 for the procedure where the abstract as filed includes matter not present in the specification). Before amending an abstract, the search examiner should read enough of the description to be certain that the alterations are accurate. The minimum to be read depends on what is necessary for the search examiner to obtain a clear understanding of the essential nature of the invention. Where a statement of the background of the invention is included in the abstract it should not normally be deleted, since it will frequently help to explain the solution provided by the invention.
- 14.187 The search examiner should resist the temptation to amend an abstract which adequately fulfils its purpose merely because he would have written it differently. Nor should subject-matter be deleted merely because it does not appear to be useful search material in the heading(s) in which the application is classified. In particular, matter relating to the use of the invention may appear to be of no relevance to the s.17 searcher, but may well be useful to other readers.

r.15(4)-(6)

14.188 Drawings particularly for the abstract are not required and should not be filed. The applicant is required to indicate on the abstract which figure, or, exceptionally, figures of any drawings of the specification should accompany the abstract when published. If he has not done so it is up to the search examiner to decide which figure(s) should be used and to record this as outlined in 14.190. The search examiner may decide that one or more figures other than those suggested by the applicant may be used instead or additionally if he considers that they better characterise the invention. Normally not more than one figure should accompany the abstract. Exceptionally two figures may be used provided that, when sufficiently reduced in size to be accommodated

on the front page of the application, they, together with the reference characters thereon, would still be readable.

[No objection should be raised under r.15(4) in the event that no figure has been indicated on the abstract. In such circumstances the search examiner should decide upon a suitable figure.]

14.189 It should be clearly apparent from the abstract what the or each accompanying figure represents. To aid identification of features mentioned in the abstract, relevant reference numerals which appear in the selected figure(s) should be freely used in the abstract. Numerals which appear only in other drawings should normally not be used, although exceptionally, a numeral which is considered necessary for an understanding of the abstract but appears only in these other drawings, may be referred to. Such reference should be bracketed, eg (29, Fig 16), without any additional wording such as "see" or "not shown". When this expedient is adopted it should be ensured that reference numerals which do appear in the abstract drawing(s) are without brackets.

14.190 The search examiner should revise or check the abstract and record the number of the figure which is to accompany it (see 14.188) on the abstract itself as well as in the "Fig. Ref." field on PROSE (see below). If no figure is to accompany it, he should record this.

[The figure number should appear separately on the page to the text of the abstract. It is not necessary to put brackets around either the figure number or the application number, although this may be done to provide additional clarity.

[The figure(s) to accompany the abstract should be recorded using PROSE by entering the figure number(s), the word "FIG" where it is a single unnumbered figure, the abbreviation "RTA" (ie 'refer to the abstract') when special instructions are needed or the word "None" when no figure is to accompany the abstract.

In some instances (particularly chemical cases), a figure or formula may be included in the abstract itself, rather than separately within the drawing pages. In these cases, the abbreviation "RTA" should be recorded on PROSE, and no further information need be added to the abstract page itself; in such situations do **not** write "None" or "No Figure" either in PROSE or on the abstract text page.

In exceptional cases where part of a figure or a combination of two or more figures is required for the abstract, a document containing a copy of the relevant figure(s) should be provided on the dossier and annotated appropriately. This document may be created and imported onto the dossier electronically; or alternatively, created manually and subsequently scanned on to the dossier. A minute should also be added to the dossier giving clear instructions to Formalities concerning the document's inclusion in the publication sub-file.]

[Deleted]

14.191 Amendments to the abstract submitted before s.16 publication should be taken into account by the search examiner when deciding on the text to be published. Since however when the specification of the patent is published after grant it is not accompanied by an abstract, amendments to the abstract filed after s.16 publication serve no purpose, although of course they remain on the file and are open to public inspection. If however the applicant draws attention to an error in the published abstract which is such as to render the abstract wrong or misleading in a material respect, an erratum may be issued provided that the error arose during publication or during reframing of the abstract by the search examiner. (See 16.33).

[Section 14(8) Repealed.]

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[14.193-14.198 Deleted]

Section 14(9)

An application for a patent may be withdrawn at any time before the patent is granted and any withdrawal of such an application may not be revoked.

Withdrawal

14.199 An intimation of withdrawal will not be acted on by the Office unless it is clear and unqualified and in writing, and from a person with the authority to make the withdrawal. The withdrawal request may be by paper or electronic communication.

14.199.1 Directions prescribing the form and manner in which email messages withdrawing applications should be delivered to the Office were published in the PDJ No.5946 on 7 May 2003 and came into effect from 8 July 2003. These directions are reproduced in full in the "Relevant Official Notices and Directions" section of this Manual. Email withdrawal requests should be titled "Withdrawal of patent application number GBYYXXXXX.X" and sent to withdraw@ipo.gov.uk and include in the main body of the message a clear statement of withdrawal and indication that the sender is authorised to make the withdrawal. This email address should not be used for other proceedings under the Act or any other correspondence relating to business carried out by the Office. The email should be in plain text (RFC822-compliant); messages in MS-TNEF/RTF or HTML formats and messages that are encrypted or digitally signed will not be accepted. If an email request does not comply with the directions, the Office may treat the message as not having been delivered. The time and date of receipt of the email message will be taken as the time/date stamp the message receives when it enters the Office internal email system, which will not be the exact time/date it was sent. A return email message will be sent by the Office to confirm receipt of the withdrawal request; the request cannot be treated as being delivered unless this acknowledgement has been sent. (See also 14.205)

[When an application has been withdrawn (or has been refused or treated as having been withdrawn or refused) the Formalities manager should add the appropriate label to the cover of the dossier, add "Fmls comp – Terminated" action to the dossier, and carry out the appropriate COPS action (so that, regardless of whether or not the application has been published under s.16, the termination is advertised in the Journal).]

[Deleted]

[Where on any application for which a valid notification of withdrawal is received, there is a Form 9 (and fee) already lodged but no copy of the external search report on file and/or a Form 10 (and fee) already lodged but no copy of the first substantive examination report on file, then before taking any other action the formalities examiner should refer the application to the appropriate Deputy Director for any action required in the examining group. The application should then be referred back to the relevant formalities manager for completion of the termination action as set out above and refund of the Form 9 and/or form 10 fee(s) in appropriate circumstances (see 14.207).]

14.200 In General Motors Corporation (Longhouse's) Application [1981] RPC 41 a letter withdrawing the application was written, on instructions from the applicant company in the United States, by a technical assistant under the control of the authorised agent (both being employees of the applicant). Subsequently, the applicants having changed their minds, the authorised agent wrote requesting reinstatement of the

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application. Refusing the request, the hearing officer held that the technical assistant had the implied authority, by virtue of his employment, to make the withdrawal. In *Siemens Medical Systems Inc.'s Application* (BL O/063/00) it was held that withdrawal takes place as of the date on which the withdrawal request is filed, and not on the date that the Register is updated to show the withdrawal.

14.201 When there is more than one applicant a request for withdrawal will not be effective if made by only some of the applicants unless it is clear that the remaining applicants have given them the express authority to do so.

14.202 It is not necessary for a request to use the words "withdrawal" or "withdrawn"; it is sufficient if the statement expresses, in whatever terms (for example by referring to "abandonment") positive intention to terminate the application forthwith. However a statement of intention, such as that the applicant is no longer interested in prosecuting his application, is not sufficient. For example, an applicant may state that he does not intend to file a request for substantive examination; such an indication is not binding on him, and he may change his mind and file the request at any time within the prescribed period. Similarly an applicant may indicate that he does not intend to reply to a report issued under s.18(3). In such cases no specific action should be taken, the application being left to await further action by the applicant or until it is, in due course of time, treated as having been withdrawn or refused.

14.203 If the applicant or agent has indicated that he does not intend to proceed (or some such non-committal wording), but has not unequivocally and in writing withdrawn the application, and some course of action by the Office, such as search, Apublication, substantive examination or grant, is pending, he should be asked to indicate in writing his clear intentions. If no clear withdrawal is forthcoming the application will proceed. If the applicant or agent indicates over the telephone that he wishes to withdraw an application, he should be told to express his intention in writing. If no letter or email is received the request will not be acted on.

14.204 If at any time the applicant or agent purports to effect a conditional withdrawal, he should be requested to file an unqualified statement of withdrawal, failing which the application is regarded as still in being.

14.205 If an application is withdrawn before preparations for its publication have been completed it will not be published under s.16(1) (see 16.07). Thus if an applicant wishes to prevent publication of his application he must unequivocally withdraw it before preparations for publication have been completed (see 16.02). The directions prescribing the form and manner of delivery of email messages to the Office to withdraw applications (see 14.199.1) state that if an application is to be withdrawn in time to prevent publication, the email message must be received by the Office up to 23.59 on the day before preparations for publication are complete; if the email messages is received after that time, it will be too late to prevent publication. If a letter requesting that an application be withdrawn and not published is received too late to prevent publication and it appears likely, even if not explicitly stated, that the applicant intended to withdraw only if publication were not going to take place, he should be asked to state clearly his intentions.

[When a request for withdrawal is received for an application already in the A-publication cycle, the divisional publication liaison officer should be contacted immediately. When a request for withdrawal is received before publication but after preparations for publication are complete (as determined by 16.02), the relevant formalities group will issue an appropriate letter depending on whether or not withdrawal appears to be conditional on prevention of publication. In each case subsequent action will depend on any response from the applicant.]

14.206 Likewise if he wishes to withdraw his application before grant he must do so before the issue of the letter informing him of the grant. If a written request for withdrawal is received in the Office before the issue of the grant letter but not in time to

r.107

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prevent issue of the letter, then the grant may be rescinded (see 18.89-90).

[When a written request for withdrawal is received for an application already in the grant cycle, the publication liaison officer for your division should be enlisted immediately. The publication liaison officer will call a meeting of all interested parties to decide whether withdrawal is appropriate, and take the necessary steps to effect withdrawal, including communication with the applicant to formally rescind the grant by letter when the grant letter has been sent.]

14.207 If an application in respect of which Form 9A or Form 10 has been filed is withdrawn before the report under s.17 or s.18 respectively is issued, the fee paid may be refunded. Such a refund is however a matter of discretion and not a right.

[The refund is authorised by the appropriate formalities group.]

14.208 A withdrawn application may be used for the purposes of claiming priority for a later application, subject to the provisions of the Act (see 5.04).

Section 14(10)

Subsection (9) above does not affect the power of the comptroller under section 117(1) below to correct an error or mistake in a withdrawal of an application for a patent.

14.209 This subsection was added by the Regulatory Reform (Patents) Order 2004, and establishes that, although section 14(9) provides that a withdrawal may not be revoked, the withdrawal may be corrected under the provisions of section 117. This provision came into force on 1 January 2005 and applies to applications filed both before and after this date. If the application in question had been published under section 16 and the fact of withdrawal had also been published, special provisions apply (sections 117(3), (4) and 117A).

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Section 15: Date of filing application

- This section states the conditions which are necessary and sufficient for an application to be accorded a filing date, sets out the circumstances in which an application may be re-dated to a later date, makes provision for divisional applications and specifies further conditions which must be fulfilled before an application can proceed. Time limits and other provisions relating to these matters are prescribed in rr.18-22.
- Section 15 was amended by the Regulatory Reform (Patents) Order 2004 15.01.1 (S.I. 2004 No. 3204) to incorporate the principles of Articles 5 and 6 of the PLT. The amended section applies to applications initiated on or after 1 January 2005 by the filing of documents which comply with the requirements of s.15(1). The relevant rules were amended with effect from this date by the Patents (Amendment) Rules 2004 (S.I. 2004 No. 3205). For applications initiated by documents that met the relevant requirements of the former section 15(1) on or before 31 December 2004, unamended sections 14(1) 15, 17 and 18 of the Act and the Rules continue to apply. The Patents Rules 2007 (SI 2007) No. 3291) have replaced the Patents Rules 1995 (as amended) with effect from 17 December 2007.

Section 15(1)

Subject to the following provisions of this Act, the date of filing an application for a patent shall be taken to be the earliest date on which documents filed at the Patent Office to initiate the application satisfy the following conditions-

- (a) the documents indicate that a patent is sought;
- the documents identify the person applying for a patent or contain information sufficient to enable that person to be contacted by the Patent Office; and
- (c) the documents contain either
 - something which is or appears to be a description of the invention for which a patent is sought; or
 - a reference, complying with the relevant requirements of rules, to an earlier relevant application made by the applicant or a predecessor in title of his.

Section 15(2)

It is immaterial for the purposes of subsection (1)(c)(i) above-

- whether the thing is in, or is accompanied by a translation into, a language accepted by the Patent Office in accordance with rules;
- whether the thing otherwise complies with the other provisions of this Act and with any relevant rules.

r.12(1) 15.02 Normally the indication that a patent is sought will be given by the completion of Patents Form 1. This is designated a formal requirement, but it is not r.25(1)(a) necessary that it be explicit in order for a date of filing to be accorded. If the documents

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filed contain an implicit indication, however informal, which makes it reasonably clear that an attempt is being made to file an application for a patent then s.15(1)(a) can be regarded as having been complied with. The indication must, however, be in English or Welsh (at least to the extent that it is apparent to a literate person acquainted only with the English and/or Welsh language that a patent is sought).

The applicant is sufficiently identified if the name and address given are adequate to meet the customary requirements of postal delivery. The address may be anywhere in the world. Other information (such as a phone number) instead of an address may be sufficient identification to grant a filing date (but see 15.03.1). Where there is more than one applicant each must be adequately identified.

r.12(2) r.12(3) 15.03.1 The applicant's name and address should normally be given at the time of filing, but failing that a date of filing can be accorded when the application contains sufficient information to enable the applicant to be contacted. Where an application which does not include both the applicant's name and address is accorded a date of filing, the applicant must be notified of the failure, and the comptroller may refuse the application if the applicant does not file the missing information within two months of issue of the notification. The name and address (or other means of contacting the applicant) must be in English or Welsh to the extent that it is useable by a literate person acquainted only with the English and/or Welsh language.

[Where Parts 2 and 4 of Form 1 do not, between them contain enough information to enable the applicant to be contacted, contact information in Part 12 may be good enough, but where there is doubt the advice of Legal Section should be sought.]

s.7(1)

15.04 If the application is made in the name of a firm or other organisation which is not a corporate body this will not prevent it being accorded a filing date, provided the organisation is adequately identified. The formalities examiner should however require that one or more persons (that is, individuals or corporate bodies) be named at part 2 of Form 1.

15.05 Provided a document contains at least a small amount of technical information it will be regarded as complying with s.15(1)(c), and failure to comply with, for example, s.14(3) or r.14 will not prevent a filing date being accorded. If the description fails to comply with any formal or substantive requirement of the Act or Rules, objection will be raised sooner or later and the applicant given an opportunity to rectify the matter. It is therefore in the interest of the applicant to ensure that, at the time of filing, the description is not flawed in such a way that rectification would not be possible. For example, no amendment is allowed which would result in the description disclosing matter not either present at or referred to on the filing date.

[In the rare event that although a filing date has been accorded, it transpires that what has been filed cannot conceivably be called a description, the filing date should be cancelled.]

15.06 There is no requirement to pay a filing fee as a prerequisite to an application being accorded a date of filing. For details of payment of the application fee required for preliminary examination, see 14.02 and 14.04.17.

Disclosure

1. Description, Language of Description

15.06.1 In order to qualify for a date of filing something that is or appears to be a description will normally be required. Providing that the remainder of the application is in English or Welsh (i.e. with names and addresses etc. intelligible to and useable by a literate person acquainted only with English and/or Welsh) an application can qualify for a date of filing if the description (or what appears to be the description) is neither in English

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or Welsh nor compliant with rules such as r.14. The wording "something that appears to be a description" in s 15(1)(c)(i) reflects the wording "a part which, on the face of it, appears to be a description" of the PLT, and caters for possibility of that part of the application being in non-Roman notation.

r.12(8) r.12(9) 15.06.2 Where a date of filing is accorded to an application comprising a foreign-language description, the applicant must be notified of the failure to comply with r.14(1). The comptroller may refuse the application if the applicant fails to file a translation into English or Welsh within two months of such a notification.

2. Reference to an earlier application

r.17(1)

15.06.3 Article 5(7) of the PLT requires Contracting Parties to accept, for the purposes of according a date of filing only, a reference to an earlier application as a replacement for the description, and this is reflected in s.15(1)(c)(ii). Where such a reference is made the application number, date of filing and country of filing must be stated in part 9 of Form 1.

s.15(10)(b) r.17(2) r.22(3) r.108(1) r.108(5)(7) r.17(3) r.112(1)

r.112(2)

15.06.4 The application will be treated as withdrawn if the disclosure contained in the reference fails to be substantiated by the filing of a certified copy of the earlier application (and, if that copy is not in English or Welsh, by an accompanying translation) within the four months (extendable at the discretion of the comptroller, see 123.34 to 123.41). Applicants must bear in mind any difficulties which may be inherent in obtaining the necessary certified copies and translations within the time allowed. Where, however, a copy of the earlier application in question is available to the comptroller, the comptroller will make and certify the necessary copy and place it on the file without the applicant needing to request or pay for it.

r.22(1) r.108(2)-(7)

15.06.5 The application will also be treated as withdrawn if a description (in English or Welsh) is not filed (as required by s.15(10)(b)(i)) before the expiry of the period prescribed in r.22(1). This period is extendable once by two months as of right under r.108(2) and further extendable in tranches of two months at the discretion of the comptroller under r.108(3)-(7) (see 123.34 to 123.42). Rule 22 is listed in Part 3 of Schedule 4, so if a request for extension (or further extension) is not received before expiry of the requested extension, the application must be treated as having been withdrawn (see 123.34-41). A description must be filed in addition to the certified copy of the earlier application, and must be filed even where the earlier application is available to the comptroller. Where the description required by s.15(10)(b)(i) contains matter additional to that contained in the earlier application to which reference was made, s.76(1A) will not allow the application to proceed unless or until that matter has been removed from the description. Whether or not there is any added matter is a matter of fact which will have to be determined comparing the description against the certified copy (or, where relevant, the translation of the certified copy). Except in the clearest of cases (e.g. when the description is manifestly a complete photocopy of part or all of the certified copy) the document should be referred to an examiner to make the comparison.

Section 15(3)

Where documents filed at the Patent Office to initiate an application for a patent satisfy one or more of the conditions specified in subsection (1) above, but do not satisfy all those conditions, the comptroller shall as soon as practicable after the filing of those documents notify the applicant of what else must be filed in order for the application to have a date of filing.

15.06.6 Where an application fails to meet the requirements for being given a date of filing, the comptroller must notify him of that failure and state the reason.

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Section 15(4)

Where documents filed at the Patent Office to initiate an application for a patent satisfy all the conditions specified in subsection (1) above, the comptroller shall as soon as practicable after the filing of the last of those documents notify the applicant of-

- (a) the date of filing the application, and
- the requirements that must be complied with, and the periods within which they are required by this Act or rules to be complied with, if the application is not to be treated as having been withdrawn.

15.06.7 Where an application meets the requirements for being given a date of filing, the comptroller must notify the applicant of that date, and must also notify the applicant of anything that still requires to be filed and for which the sanction for failing to file it within the time prescribed is that the application will be treated as withdrawn. applications (including divisional applications) are initiated by documents complying with section 15(1), these notifications will be embodied in the document receipts issued by Document Reception.

s.89A(3)15.06.8 For international applications, the application fee is set at nil, but there is instead a national phase entry fee. As soon as the requirements of s.89A for national phase entry are met, preliminary examination and search can be carried out. In this case the notifications required by s.15(4) will be included in the formalities report rather than in the filing receipt.

Section 15(5)

Subsection (6) below applies where-

- an application has a date of filing by virtue of subsection (1) above; (a)
- (b) within the prescribed period the applicant files at the Patent Office-
 - (i) a drawing, or
 - part of the description of the invention for which a patent is (ii) sought, and
- that drawing or that part of the description was missing from the application at the date of filing.

Section 15(6)

Unless the applicant withdraws the drawing or the part of the description filed under subsection (5)(b) above ("the missing part") before the end of the prescribed period-

- (a) the missing part shall be treated as included in the application; and
- the date of filing the application shall be the date on which the missing part is filed at the Patent Office.

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Section 15(7)

Subsection (6)(b) above does not apply if-

- (a) on or before the date which is the date of filing the application by virtue of subsection (1) above a declaration is made under section 5(2) above in or in connection with the application;
- (b) the applicant makes a request for subsection (6)(b) above not to apply; and
- (c) the request complies with the relevant requirements of rules and is made within the prescribed period.

Section 15(8)

Subsections (6) and (7) above do not affect the power of the comptroller under section 117(1) below to correct an error or mistake.

General Considerations: Missing Drawings and Missing Parts of the Description

15.07 Subsections (5) to (8) provide for missing drawings and parts of the description to be filed after the date of filing, and are intended to reflect the provisions of a.5(6) of the PLT. Unless or until the terminology is further clarified by case law, it should be considered that a part is missing only when it is evident from inspection of the documents on file that the description or drawings are manifestly incomplete. The page numbering may be discontinuous, or there may be a mismatch between the number of pages of text alleged to have been filed and the number actually present. In the case of drawings there may either be a discontinuity in sheet/Figure numbering or the absence of a drawing listed in the description.

15.07.1 Where, upon performing the preliminary examination, the formalities examiner finds that a drawing referred to in the description, or a part of the description, appears to be missing this must be formally notified to the applicant in the preliminary examination report as required by s.15A(4) and (9) (see 15A.23). The examination should be no more rigorous than is necessary to check for missing pages, missing sheets of drawings, or the absence of individual Figures listed in the description. There is no requirement to read and construe the text of the description (other than to identify the drawings that are listed).

15.07.2 Preliminary examination is not always performed soon after the date of filing, and although there is no statutory requirement for document reception to notify the applicant of any parts missing from an application at the time it qualifies for a date of filing, it is nevertheless in the applicant's interest that he should be informed as soon as possible of any such defects. For this reason document reception should, as a matter of best practice and good customer relations, continue to report to the applicant any missing matter that is noticed when document reception procedures are being carried out.

Time Limits

s.15(6)(a)

15.07.3 Where a drawing or a part of the description is missing from an application on the date of filing, the missing material can be filed at any time before expiry of the period prescribed in r.18 (which is either at any time up to the preliminary examination per r.18(1) or, if the absence of the missing matter is notified with the preliminary examination report under s.15A(9), within two months of the date of issue of that notification per r.18(2)). When missing matter is filed within the allowed period, then the matter shall be treated as

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included in the application, unless the applicant requests in writing that the missing material is withdrawn before the remainder of that period has expired.

15.07.4 The period prescribed by r.18(1) can be extended in accordance with r.108(2) or (3) (see 123.36.5-123.36.8). The period prescribed by r.18(2) can be extended at the comptroller's discretion in accordance with r.108(1) (see 123.36.9). The effect of these time periods and extensions is that missing material may be filed at any time up to the issue of the preliminary examination report. Once the preliminary examination report has been issued, then if the absence of the missing matter is notified in the report, the applicant has 2 months to file the missing material, and this period may be extended at the Comptroller's discretion. If the preliminary examination report has been issued, but the report does **not** refer to the missing matter, the applicant may file the missing matter within two months of the report on filing Form 52 together with the appropriate fee. At the Comptroller's discretion, this period may be further extended on filing a further Form 52 and fee.

Re-dating

15.08 Unless s.15(7) applies the date of filing the application must be amended to be the date on which the missing part was filed. Re-dating as a consequence of including missing matter is the only circumstance in which an application may be re-dated to a date later than the originally accorded filing date.

15.08.1 With respect to drawings, s.15(5) and (6) can only be applied where a drawing referred to in an application was not present in any form in the application at the filing date of the application; an application cannot be re-dated when formal drawings are filed to replace informal drawings which had been filed on the filing date. (If a late-filed formal drawing differs materially from an originally-filed informal drawing the only remedy lies in replacing the formal drawing with one which is in agreement with the drawing originally filed). The expression "any drawing" has been held to mean "any figure" (Alps Electric Co's Application (BL O/12/90)). In the case of a divisional application filed without a particular drawing, the date on which the application was initiated may be re-dated under s.15(6) to the date on which the missing drawing is filed. This does not affect the date which the application may be treated as having as its date of filing under s.15(9), allowance of which is determined in the normal way after the question of re-dating has been settled. (However, the change in the date on which the application was initiated may result in failure to comply with the period specified in r.19, but an extension of the period may be allowed in two month tranches, if considered appropriate, by exercise of the comptroller's discretion under r.108(1) and (5)-(7)).

15.09 Section 15(8) states that s.15(6) and (7) do not affect the comptroller's discretion under s.117(1) to correct an error or mistake. Thus, if all of the requirements of s.117 and r.105 have been met (see 117.03-09), it is possible for the comptroller to permit a drawing which was omitted by mistake from the documents originally filed with an application to be filed later without loss of the original filing date. Requests to this effect should be considered on their merits, see 117.10.

15.10 If on preliminary examination (see 15.07.1) it is found that a part of the description or a drawing referred to in the application has not been filed at all, a letter should be issued specifying a period of two months for filing the missing material, the application then being re-dated to the date on which the missing material is filed. However, sight should not be lost of the possibility that, rather than re-date, the applicant might prefer to use the defective application to provide priority for a subsequent application, which includes the missing part(s), so preserving the date for the disclosure present in the original, defective application (subject of course to the provisions of s.5).

[If a part of a description or drawing has been filed late, LFB should be used, if it has not been filed at all, LFA should be used. After the formalities examiner has issued the appropriate letter and on completion of preliminary examination he should refer the case to the search examiner. The formalities examiner should

r.18(2)

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create a minute to draw the search examiner's attention to the invitation to redate. If the re-dating will or might invalidate a declaration of priority this should also be drawn to the search examiner's attention. It is for the search examiner to decide whether to carry out the search immediately or whether it would be more sensible to wait until the applicant has had the opportunity to respond to the invitation to re-date. For example, there may be no point in deferring the search if the applicant is unlikely to re-date, perhaps because the missing part is unimportant and re-dating would result in loss of priority. On the other hand, it may well be sensible to wait if there is a fair risk that the application will be withdrawn and used to provide priority for a new one. If the search examiner decides to defer the search, the COPS status should be set to 2 - "Out for ABS" and an appropriate diary entry should be entered in the PD electronic diary. This entry should state the examining group after the application number in the format GB0000000.0 – EX00. A diary action should also be added to the PDAX dossier.]

15.11 While a formal report under s.15(5) or (6) will normally only issue after preliminary examination, if the formalities examiner becomes aware before the filing of this form that a drawing is missing an informal notice should be issued informing the applicant of the options available from these subsections.

[This will normally only occur with private applicant cases. LFAA should be used.]

- 15.12 If, after re-dating, the new filing date is more than twelve months after a declared priority date then the claim to priority must be relinquished and the declared date cancelled, but see 15.16.1 and 2.
- 15.13 The applicant must be notified in writing whenever an application has been re-dated, and, if applicable, that the declared priority date has been cancelled.
- 15.14 Where the absence of missing matter is notified in the preliminary examination report, the period of two months allowed for filing the missing material and/or withdrawing the late-filed missing material may be extended at the Comptroller's discretion in accordance with r.108(1) (see 123.36.9). If no reply or extension request is received within the two month period, or if a reply indicates that the applicant does not intend to avail himself of the opportunity to re-date, the missing matter and all references to it should be treated as omitted from the application. Instructions for publication should be provided to include on the front page of the published application a notice (see 16.29) that no copy of the particular drawing(s) or part of the description was included in the application as filed. Where the missing part or drawing is filed, it is not included in the published application s.16 but is open to public inspection after publication.
- Where missing matter is treated as omitted, the specification as filed and published under s.16(1) is to be read skipping any missing pages of description or any reference to an absent figure (or a reference character in it which does not occur also in a figure which is present). For example, if Figures 2-4 are absent, a passage which reads "The cam 31 shown in Figures 2-4 controls the feed and is driven by the link shown in Figures 1 and 3 operated by the crank 33 shown in Figure 1" notionally reads "A cam (31) controls the feed and is driven by the link shown in Figure 1 operated by the crank 33 shown in Figure 1"; "31" is included if it occurs in a figure other than 2-4. If the specification when so read fails to comply with s.14(3) and/or (5) objection should be raised during substantive examination. Unless the applicant voluntarily amends the specification to delete those references which are to be treated as omitted, their deletion should be sought. (Such deletion should be requested in the substantive examination report. However, removal of references in the claims can be requested before s.16 publication).
- 15.16 If the applicant seeks to amend the specification after s.16 publication by filing or reinstating an omitted drawing, this may be allowed, provided it meets the requirements laid down for the timing and nature of amendments (see 19.13-19.22), in

s.76(2)

r.18

s.118

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particular that it must not add subject-matter (see 76.09).

Avoiding re-dating where there is a claim to priority

- r.18(4) 15.16.1 Where a declaration of priority is present on the date of filing, s.15(7) allows that r.18(4)(b) s.15(6)(b) shall not apply providing that:-
- r.18(4)(a) (a) the applicant requests that it shall not apply;
- r.18(5)(a) (b) the request is made in writing (i.e. in a letter or e-mail) before expiry of r.18(5)(b) the period for filing the missing part(s) or drawing(s);
 - (c) the request identifies where the missing matter in question is contained in the priority application (or applications):
 - (d) all the missing material is contained in the priority application (or applications); and
 - (e) copies of the relevant priority applications, either certified or otherwise verified to the satisfaction of the comptroller, are filed within either sixteen months from the declared priority date or four months from the date of the request that s.15(6)(b) should not apply.

[Where there is any doubt as to whether the disclosure of late-filed allegedly missing drawings or parts of the description are contained in the priority application (or applications) the matter should be referred to an examiner.]

15.16.2 Where the Office has access to a copy of the (or each) priority application, the comptroller will make and certify the necessary copies.

Section 15(9)

r.18(7)

r.18(6)

r.112

Where, after an application for a patent has been filed and before the patent is granted -

- (a) a new application is filed by the original applicant or his successor in title in accordance with rules in respect of any part of the matter contained in the earlier application, and
- (b) the conditions mentioned in subsection (1) above are satisfied in relation to the new application (without the new application contravening section 76 below).

the new application shall be treated as having, as its date of filing, the date of filing the earlier application.

15.17 Section 15(9) was introduced by the Regulatory Reform (Patents) Order 2004; the wording of this provision is identical to the previous section 15(4) in existence before the Order came into force on 1 January 2005. It allows for applicants to file, in certain circumstances, a new application (commonly referred to as a "divisional application") which takes the date of filing of an earlier application (commonly referred to as a "parent application"). A divisional application under s.15(9) is made by inserting the application number and filing date of the parent application in part 6 of Patents Form 1. Section 15(9) does not exclude the possibility of a divisional application itself giving rise to a divisional application. Thus no objection should be raised simply because an application claims the date of an earlier divisional application. Where this is the case, the "earlier application" referred to in s.15(9) and r.19 will be the earlier divisional application, and so when deciding if the conditions of r.19 are fulfilled, it is the status of this application

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and not that of the parent application from which the earlier divisional application derived that should be considered (see 15.19). The later divisional application will then take the filing date of the earlier divisional application, which, if validly claimed, will be the filing date of the original parent application.

[Examiners in particular should be aware of the different procedures which apply when processing divisional applications. As well as the detailed guidance contained in the following paragraphs, reference should be made to the examiners' aide-memoire and checklist for divisional applications (see 15.58).]

- r.19(3)
- 15.18 The requirement that such an application must include a request for antedating means that such a request must be made at the time of filing; there is no provision for converting an ordinary application into a divisional application after filing (P's Application [1983] RPC 269).
- r.19(2)(a)
- 15.19 A divisional application may not be made if the parent application has been refused, withdrawn or taken to be withdrawn or treated as having been withdrawn, if s.15(9)the period prescribed for putting the parent application in order has expired, or if a patent has been granted on it.
- r.19(2)
- Subject to the overriding considerations in 15.19 a divisional application 15.20 may be made at any time up to the date three months before the compliance date (as prescribed by r.30). If the compliance period (i.e. the period for putting the application in order, as prescribed by r.30) is extended under rules 108(2) or 108(3), then the three month deadline for filing a divisional application is calculated from this extended period.
- r.30(3)(b)r.2(2)r.108(4)
- r. 30(2)(b)

The compliance period for putting a divisional application in order generally expires at the same time as the compliance period for the earlier application, whose date of filing is to be treated under s.15(9) as the date of filing of the divisional Consequently, in accordance with rule 2(2), if the compliance period prescribed on the earlier application has been extended under rule 108, this extended compliance period will apply - as the unextended compliance period - to any divisional applications filed on or after the date that the period was extended.

If the compliance period prescribed on the earlier application is set under rule 30(2)(b) this compliance period will also apply to any divisional applications (see also 18.47, third paragraph in square brackets). However, if the compliance period prescribed on the earlier application is later extended under rule 108, that extension will not apply to any divisional applications which have already been filed; a separate request will be required to extend the compliance period for any such divisional applications. When a divisional application is filed before the first examination report on the parent has been issued, the compliance date of the divisional is undefined until this first examination report is issued.

- CoP
- In view of the fixed time period for placing an application in order prescribed by r.30, divisional applications should be filed early. For example, if all possible search reports under s.17(6) have been issued, it is helpful for applicants to come to early decisions as to what inventions are to be pursued in divisional applications and to file these applications promptly, filing the same number of divisional applications as there are inventions requiring protection since it is undesirable for divisional applications to raise further plurality of invention issues.
- r.108(1)
- The comptroller has discretion to extend the period of time allowed under rule 19 for filing a divisional application. However, this discretion will normally be exercised only if the applicant shows that the circumstances are exceptional and that he has been properly diligent (Penwalt Corporations's Application (BL O/72/82); International Barrier Corporations's Application; Kokusai Denshin Denwa's Application (BL O/9/83); Luk Lamellan und Kupplungsbau GmbH's Application [1997] RPC 104.

The comptroller also has discretion to extend the compliance period of a parent

Page 9 of 23 January 2019 application under rule 108(3) to allow a divisional application to be filed within the period prescribed by rule 19. This discretion will normally be exercised only if the applicant shows that the circumstances are exceptional and that they have been properly diligent (see <u>Fergusson's Application</u>, <u>BL O/272/09</u> and <u>Knauf Insulation's Application BL O/098/13</u>).

It was held by the Patents Court in <u>Kiwi Coders Corporation's Application [1986] RPC 106</u> that an appeal against a decision to refuse the allowance of a divisional application will succeed only if it is established that the comptroller's discretion was exercised wrongly in principle, i.e. there was some error in approach. It is not sufficient that somebody else might have reached a different conclusion upon the same facts. The hearing officer had held that although a fresh citation had been raised in the second report on the parent application, the citation did not require or suggest the splitting out of subject matter and consequently did not provide justification for the comptroller to permit filling well beyond the period allowed.

In Anderson's Application (BL O/297/02) the hearing officer held, on the facts of the case, that the comptroller should not exercise discretion to extend the period for filing a divisional application. He then rejected an argument that to refuse late filing of the divisional application was to deny the applicant his rightful property in contravention of his human rights. The applicant had been given ample opportunity to patent his invention, so there had been no limitation of access to the patent system and no deprivation of property within the meaning of UK patent law and the general principles of international law enforced by the Human Rights Act 1998.

A divisional application may, but need not, make a declaration of priority where one is made in the parent application. However, a divisional application may not make a declaration of priority which is not also made in the parent application. It should not be overlooked that where a declaration of priority has been made in the parent application for matter forming the invention of the divisional application, then failure to make the same declaration in the divisional application will mean that the parent application will, when published, form part of the state of the art under s.2(3) for the divisional application. If a priority declaration on a divisional is not made or is determined to be invalid, there may be implications for the novelty of the divisional application, as demonstrated in Nestec SA & Ors v Dualit Ltd & Ors [2013] EWHC 923 (Pat) (see 5.25.1-5.25.3).

[If a divisional does not make a claim to priority when one is present on the parent, formalities should contact the applicant to establish if this is intentional or an error.]

15.23 In a case where the application specified in the declaration of priority is one for a UK (national) patent, is an international application filed at the Office, or is any other application of which a copy is on the file of another UK (national) patent application (eg the parent application) r.8(4)(c) in conjunction with r.112 relieves the applicant from the necessity to request or pay for a certified copy. Where the copy of the priority application is in a foreign language, there is no routine obligation to file a translation, but the applicant may be directed to do so under rule 9(1) if the examiner thinks necessary. Where a translation is required, there is no obligation that it must be verified.

A divisional application must be filed by the original applicant for the parent application or by his successor in title. Where more than one applicant is named in the parent application, it is possible for the divisional application to be made by only some of the original applicants. Where the applicants in the parent and divisional applications differ and no explanation is either apparent or submitted the formalities examiner should raise an objection; the application cannot proceed as a divisional if the provisions of s.15(9) have not been complied with. A divisional application may be filed, after the death of an applicant on the parent application, in the name of the personal representative of the deceased. The EPO Legal Board of Appeal in *Trustees of Dartmouth College's Application* (J 2/01 [2005] OJEPO 88 and [2004] EPOR 54) held that for an application filed jointly with two or more applicants, the right to file a divisional application was only

r.6(5)

r.8(2)

available to the registered applicants jointly, and not to one of them alone or to fewer than all of them.

r.31(5)(b)

15.25 If one of several applicants for the parent application no longer has any interest in or right to the invention of the parent application, that application may be amended by making a written request (see 19.09).

15.25.1 If, following amendment of a parent application, the applicant wishes to delete the name of an inventor, the procedure described in paragraph 13.18.1 should be followed.

r.10(1) r.10(2) r.21 15.26 Where any applicant in the divisional application is not an inventor, Form 7 must be filed, even if this has already been done in respect of the parent application. This must be done within two months of filing the divisional application, or, if is expires later, within the time allowed for filing this form for the parent application (see 13.11).

r.106(2) r.22(5) r.22(6) PR Sch. 4, Parts 2 and 3 A request for preliminary examination and search, together with the search fee, must be filed in respect of every divisional application, even if the invention to which it relates has already been the subject of a further search under s.17(6), on the parent application (see 17.111-17.114). In such a case however the comptroller may refund the whole or part of the search fee paid in respect of the divisional application (see 15.47-49). The Form 9A and the search fee should be filed within two months of filing the divisional application or within the period allowed for doing this in respect of the parent application, whichever expires later (see 15.50). This period may be extended in accordance with r.108(2) or (3) and (5)-(7) (see 123.34-41). However, if the divisional application is initiated within the last six months of the compliance period (including any extensions) (see 20.02-20.02.1) then the period for filing the Form 9A and fee expires on the date on which the divisional application is initiated. In this case, the period may be extended in accordance with r.108(1) and (5) to (7) (see 123.34-41).

r.28(5) PR Sch. 4, Parts 2 and 3 15.28 A request for substantive examination (Form 10) must be filed by the later of a) two months after filing the new application or b) two years from the declared priority date, or, where there is no declared priority date, two years of the date to be treated as the filing date. This time limit may be extended in accordance with r.108(2) or (3) and (5) to (7) (see 123.34-41). However, as with the search request, if the divisional application is initiated within the last six months of the compliance period (including any extensions) (see 20.02-20.02.1) then the period for filing the Form 10 and fee expires on the date on which the divisional application is initiated. In this case, the period may be extended in accordance with r.108(1) and (5) to (7) (see 123.34-41).

15.28.1 A divisional application on which Forms 9A and 10 have been filed together should be subject to combined search and examination. This applies even if no actual search is required because the claims of the divisional application have already been searched as part of the parent application.

CoP

An application filed under s.15(9) containing additional matter not disclosed in the earlier application may be filed, but shall not be allowed to proceed under s.15(9) unless it is amended so as to exclude the additional matter (see 76.02). It is therefore unnecessary to take the precaution of filing identical claims to the parent application in a divisional application to secure a filing date. This practice is discouraged as amendment of the claims will be necessary (see 15.31), and the search examiner will have no discretion but to defer the search (see 15.36) or issue a search report under s.17(5) in respect of the first invention claimed, even if this is identical to the parent application (see 15.38). An alternative remedy to the removal of the additional matter in a divisional application lies in the relinquishment of the request for divisional status (see 19.11). The search/ substantive examiner should object to the presence of additional subject matter either as a preliminary objection or at the time of the search or examination report, as set out in 15.35 or 15.45.

15.30 There is no need for the claims of the divisional application to be of the same scope as claims which were directed to the same subject-matter in the parent

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application; nor need there have been equivalent claims in the parent application. If a claim in a divisional application is broader in scope than an equivalent claim originally present in the parent application, this does not necessarily mean that the divisional application contains additional disclosure; this must be decided on the facts of the case (see 76.16-76.20). If however the objection arises under s.14(5)(c) instead of s.76(1) the divisional status is not impugned (see 76.21). Where the parent application specified a range and a claim in the divisional claims a sub-range, see 18.69-18.69.1.

s.18(5)

15.31 The parent and divisional applications or two or more applications divided from the same parent, may not claim the same invention (see 18.91-18.97.1).

CoP

15.32 In a parent or divisional application, there is no requirement to remove description appearing in the other application or for inclusion of a cross-reference if matter is described which is claimed in the other application. However, as for any other application, it should be considered whether the presence of extraneous description which does not relate to the invention claimed in the particular application may cast doubt on the scope of the claims. It is therefore helpful for the description and drawings of a divisional application to be filed in a form appropriate to the application, e.g. in terms of identification of the embodiments relevant to the claimed invention.

PROCEDURE IN EXAMINING GROUPS

Preliminary examination

15.33 Whether or not an application is allowed to be antedated determines the date when it should be published, and the time allowed for filing priority documents, Forms 7, 9A and 10, and for putting the application in order. Therefore where the formalities examiner has reported that an application is made under s.15(9), it is necessary for the search examiner, before doing anything else with the case, to consider whether all the conditions set out in s.15(9) and r.19 have been met. However, if a drawing referred to in the application is not filed with the application then the procedure under s.15(5), (6) and (7) concerning the possible re-dating of the date on which the application was initiated should be dealt with before consideration of whether the application can be treated as having an earlier date of filing under s.15(9) (see 15.08-16). If antedating is not allowable then it is possible for the application to proceed with its date of filing as the filing date (in which case a request to amend Form 1 should be made in writing, see 19.11).

15.34 When a divisional application is filed with less than three months remaining on the compliance period (but earlier than the date of issue of the grant letter), the first question to be decided is whether or not discretion under r.108(1) should be exercised to allow the application to proceed under s.15(9) (see 15.21). This matter should be disposed of before any further proceedings on the case, including any consideration as to whether amendment is necessary under s.76(1), take place. If no, or inadequate, reasons as to why the late filing should be allowed are given initially, a suitable explanation should be sought, only a short time being allowed for a reply. If a convincing response is not forthcoming, a hearing should be offered. The applicant should be informed that proceedings on the application will not continue until the question as to whether the late filing will be allowed has been settled.

[The decision whether to allow the late filing may be taken by a Senior Examiner, who may also offer a hearing when a convincing reason for the late filing is not forthcoming. If an application seeking divisional status is received after the "parent" has been marked in order for grant and the grant letter has not yet been produced, the formalities examiner should set back the status of the case on COPS (for the search examiner to reinstate when appropriate) and minute the file to this effect. If the grant letter has already been produced but not issued, the formalities examiner should defer issue of the grant letter but should not take any action on COPS until the search examiner has indicated whether the parent

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should be withdrawn from the grant cycle. Where issue has already occurred, no further action can be taken as a divisional cannot be filed after grant of the parent.

15.35 The search examiner should not make an exhaustive analysis of the parent and divisional applications, but should investigate them sufficiently to come to a prima facie view as to whether s.76(1) has been complied with. If it has not, search should be deferred and a preliminary objection raised, requiring excision of the additional matter (unless the applicant can satisfy the examiner that there is no such matter present) before the application can proceed. The period allowed for response to the objection should normally be one month (extendable as-of-right by two months or until the expiry of the s.20 period - see 117B.01-05). However, if it is clear that the added matter is not relevant to the search, the search may be made and objection to the added matter issued simultaneously with the search report (see also 15.39 and 15.45).

[If search and/or examination are deferred EL24 should be used to make a preliminary objection. SC15 should be used to issue the objection to added matter with the search report. The Examination Support Officer should be instructed as to what is the correct processing status to be recorded. If EL24 issues the status should be set as "out for ABS/ABCSE". If added matter is present and search (or CSE) is performed see 15.39.]

15.36 The search examiner may also defer search and examination of a divisional application not fulfilling the points laid out in the Code of Practice by requesting the filing of an amended specification before performing the search. The applicant should be informed which points of the Code are not met, and a period of one month should normally be allowed for filing an amended specification.

Search

15.37 Since, where it is determined that the antedating is allowable, the application will in many cases already be due for publication, a divisional application should, as far as possible, be given on receipt priority over other applications for search and publication. Where however the application, on the basis of the divisional date, is very close to the compliance date, it must be treated, in preference to all others, as a matter of urgency (see 15.20.1).

A search report under s.17(5), accompanied by a copy of each document 15.38 cited (see 17.104.1), should be issued in the same manner as for an ordinary application. The fact that no actual search has been carried out on a particular divisional application, either because the initial search on the parent application was sufficiently wide to comprehend the invention of the divisional application, or because the invention had been the subject of a further search under s.17(6) on the parent application, does not render the issuing of a formal search report unnecessary. If the claims of the divisional application lack unity of invention the search report should be in respect of the first invention, even when a report in respect of this invention has already issued in connection with the parent application, since there is no discretion to do otherwise (see 17.106). If the parent application was an international application, it will be necessary to carry out a search unless it can be confidently deduced that the international search on the parent must have comprehended the divisional invention, but in any event a search report must be issued. If the claims were amended in response to an objection under s.76(1) and the search was done in respect of the amended claims, a notice to that effect should be included on the front page of the published A document (see 16.29).

[To obtain such a notice on the front page, the examiner should add a minute to the dossier instructing Formalities of the exact wording of the notice. An appropriate message should also be sent to the relevant Formalities Group/Examiner alerting them to the minute on file, see 16.29.]

S.16 Publication

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CoP

s.16(1)

15.39 The requirement that an application should be published "as soon as possible after the end of the prescribed period" (see 16.01) is construed as meaning as soon as is reasonably practicable after such date and, of course, applies equally to a divisional application. However, publication cannot occur until any added matter detected at that stage has been deleted from the application, under s.76(1) (see 15.35, 16.08 and 76.02). What is published under s.16(1) is not the application as so amended but the application as filed, ie including the additional matter. The divisional application should normally be sent for publication after search and as soon as at least 16 months and 3 weeks from the priority or filing date has elapsed, and before substantive examination, provided this is not due.

[Processing status 3 "Searched – Do not s.16 publish yet" should be used when added matter has been found in a divisional application. The examiner should also add a minute to the file noting where added matter is present and that the processing status has been changed. Once the added matter has been removed the processing status 5 "May be s.16 published" should be used.]

15.40 Full consideration of whether ante-dating is allowable is made at the substantive examination stage; at search stage (where the divisional does not undergo combined search and examination) only a *prima facie* assessment of added matter is made (see 15.35). Therefore when a divisional application is sent for publication before substantive examination is completed, allowance of ante-dating is only provisional. In such cases, instructions for publication should be provided to include a notice (see 16.29) on the front page of the application to the effect that the filing date accorded is provisional and is subject to ratification or amendment.

[The formalities examiner should be alerted to the need for an appropriate notice to appear on the front page of the published A document by a minute added to the dossier.]

r.31

15.41 If however the application is due or overdue for substantive examination when the search has been made, the search examiner should proceed to carry out the substantive examination, the report of which should be issued at the same time as the search report. When amendments have been filed the search report should relate to any amended claims if the amendments are allowable or to the original claims if the comptroller's consent to the amendments is withheld and the amendments would not have substantially affected the search strategy (see 17.35). Similarly, the substantive examination should be carried out on the basis of the original application or the application as amended, depending on whether the comptroller consents to the amendments. If the comptroller's consent is withheld, the objections to the amendments should be explained in the examination report.

[SE4 should be used in the case of a report under s.18(3). If there is plurality of invention, RC6 and RC6A should be added to the examiner's combined search and examination report. In the case of a report under s.18(4), an SE5 can be issued only if the divisional is pre-publication, if invention in suit was clearly claimed in the published parent and if the parent was published for at least three months. The SE5 letter gives a two month period for reply. If an SE5 is issued, the examiner should set a two month diary action for the application. Whenever a diary is set, a diary action should also be added to the PDAX dossier. If the application remains in order after the diary returns, the examiner should send a minute to the examiner assistants asking them to issue an intention to grant letter (an EL34 or EL34F – see 18.86.2).

[Where the examiner has no objections to the application and the invention in suit was not clearly claimed in the parent, SE3 should issue indicating that a report under s.18(4) that the application complies with the Act and Rules will not normally be issued until three months after the application has been published; that such delay is to allow for third parties to be given the opportunity to file observations under s.21 and for the search to be updated (if necessary).

However, in the case of a divisional filed very close to the compliance date, there may not be sufficient time remaining to allow the usual three month period after publication for s.21 observations. Even if the invention of the divisional was not clearly claimed in the published parent application, the issuing of the intention to grant letter on the divisional cannot be delayed beyond the compliance date in order simply to allow for the expiry of this three-month period (for the procedure in this situation see 18.07.2 – second square bracket). If a divisional is filed late such that it will be published after the end of the compliance period, a modified EL32 should be issued and a diary entry should be created for the return of the file shortly after publication. The EL32 should be modified as required, for example: to note that the delay is to wait for the application to be published and to remove any reference to updating the search. When the diary returns, the examiner should send a minute to the examiner assistants asking them to issue an intention to grant letter (an EL34 or EL34F – see 18.86.2).

[Any allowable amendments filed before combined search and examination should be acknowledged using SC1.

[The fact that COC action (consequent on the filing of Form 23) has yet to be taken is not an outstanding formal requirement and, thus, does not prevent the examiner from issuing a s.18(4) report or from marking the application in order for s.16 publication (see 15.42).]

15.42 If formalities are complied with for s.16 publication, the application should then be sent for publication. If formalities have not been complied with, the applicant will have been informed that the application cannot be published until the outstanding requirements have been met.

Substantive examination

(See also 15.41-15.42).

- s.18(5)

 15.43 During the substantive examination, the substantive examiner should not only satisfy himself that there is no added subject matter in any part of the application, but also that there is no conflict of claims between the parent and divisional applications (see 18.91-18.97.1). Likewise if two or more applications are divided from a single parent, then their claims must not be in conflict.
 - 15.44 If at the first substantive examination stage a divisional application satisfies all the requirements of s.15(9) the allowance of the divisional date should be notified in the first report under s.18; if it does not, then notification of the allowance of antedating should be deferred until compliance is obtained.

[RC21 should be used in a report under s.18(3) or s.18(4) to notify the applicant of the allowance of the divisional date. If allowance is deferred until grant, EL21 should be issued before the application is forwarded to grant.]

15.45 If an objection that a divisional application as filed contains added matter is raised at substantive examination, it may be included in the report under s.18(3). However, if the nature of the added matter is such that it seems unlikely that the application will be pursued, a preliminary objection may be made and full examination deferred (see 15.35). If the application is withdrawn or refused, a request for the refund of the fee paid on Form 10 should be allowed if no report under s.18 has been issued.

[If examination is deferred EL24 should be used to make a preliminary objection. The Examination Support Officer should be clearly instructed to book the application as an 'Amendment before Examination' (see also 15.35). RC24 should be used to make the objection to added matter in the s.18(3) report.]

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15.46 A parent application may be substantively examined early (provided Form 10 has been filed) and at the same time as a divisional undergoes combined search and examination unless the applicant or his agent agrees otherwise. When the parent application and the divisional application are processed together in this way, the same period for response to reports under s.18(3) should be set for both applications. If the examination of the parent application is deferred until after combined search and examination of the divisional application, the period for response to a report under s.18(3) on the divisional should be set to match that period which would have been applicable for a first response on the parent application (see 18.49). One application may be sent for grant before the other, however if amendment of the outstanding application subsequently resulted in conflict this would then need to be cured by amendment of that application, unless amendment is applied for under s.27 in respect of the granted application.

[Normally, a notification of intention to grant letter (EL34 or EL3) should be issued and the application sent to grant as soon as it is in order, irrespective of the state of the remainder of the family. However, an application may be held back where appropriate, for example if there is conflict of claims with another family member which is not yet in order or if it is not clear whether the current scope of another family member which is not yet in order conflicts with the claims of the application which is in order.

[The PROSE clause for objecting under s.14(5)(d) in the first instance (RC6) warns the applicant that there will be no automatic reminders of the deadline for filing a divisional.]

[When a plurality objection has been overcome but a divisional application has not been filed, PROSE clause RC26 may be inserted into the subsequent s.18(3) report to inform the applicant of the deadline for filing a divisional application. This clause should be used at this stage regardless of whether a divisional has been foreshadowed or not.]

[Following the introduction of notifications of intention to grant on 1 October 2016, the practice of "foreshadowing" the filing of a divisional application (i.e. indicating that a divisional application is likely to be filed in the future) has no effect. The examiner should therefore take no further action in response to such a foreshadowing. The notification of intention to grant will always provide the applicant with at least one month's advance notice of grant, during which time a divisional application may be filed (as long as it is filed at least three months before the compliance date) or other actions taken. The date given in the intention to grant letter is not a specified period and is therefore not subject to the two-month as-of-right extension. The application should be sent to grant shortly after this date if no actions have been taken since issue of the intention to grant letter (see 18.86.1-18.86.3).]

[In the exceptional circumstance of a request for accelerated examination being acceded to in respect of a member of the family, the formalities examiner should be instructed to process that member for grant before the other member(s). Any conflict would need to be cured by amendment of the outstanding application, unless amendment is applied for under s.27 in respect of the granted application. For grant of a family member, see 18.87.]

r.108(2), 15.46.1 Rule 108(2) and rule 108(3) can be used to extend the compliance period after the intention to grant letter has been issued, see 18.86.5.

Requests for refund of fees

r.106

15.47 The comptroller has discretion to remit the whole or part of the search fee paid in connection with a divisional application which relates to an invention in respect of which a search fee has already been paid on the parent application. A request for remission of the search fee must be made in writing by the applicant to the comptroller.

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When an applicant appears to be entitled to a refund and it appears most unlikely that s.17(8) would need to be invoked after a refund had been made, a refund can be made before the divisional application is in order for grant. If on the other hand, an early refund seems inappropriate, eg because the need for a supplementary search under s.17(8) cannot be ruled out, consideration of a request for a refund should be deferred and reconsidered later, normally when the application is in order for grant.

15.48 When considering an application for a refund of the search fee, the general principle of one search fee per patent application should be followed. Therefore, if two (or more) search fees have been paid on the parent application, and the parent and divisional applications relate to different ones of the inventions searched for on the parent application, a refund should normally be given. If the parent application is an international application made under the PCT, a refund of the search fee paid on the divisional application should only be given if more than one search fee was paid during the national phase of the parent application, and one of those fees covered the invention being searched in the divisional application. If just one search fee was paid during the national phase then no refund is given. The number of search fees paid to the International Search Authority is not a consideration.

15.49 If the searching necessary on the divisional application has been restricted at all stages to the "top-up" search and to any further searching consequent upon the premature termination of the relevant further search on the parent application, the full search fee paid on the divisional application should be refunded unless this results in the payment of fewer search fees than the total number of parent and divisional applications in the patent family. Furthermore, no refund should be made if a search becomes necessary due to amendment of the claims of a divisional application. If, in view of the search made, the request is refused the examiner should inform the applicant so. If only one search fee has been paid on the parent application (and hence only the first invention specified in its claims has been searched), a refund of the search fee paid on a divisional application should not be given even if the divisional application is for the first invention of the parent. There is no appeal from a decision of the comptroller to refuse a refund.

[The substantive examiner should minute the file to indicate whether or not the request for a refund may be allowed. If a request for refund of the search fee paid in a divisional application is allowed before the application is in order, the substantive examiner should issue EL8 or ELC8, as appropriate, and instruct the appropriate formalities group to arrange for an early refund. On the other hand, if consideration of a refund request is deferred, the examiner should issue ELC9. If and when the refund is allowed, the appropriate formalities group should be asked to attend to it.

[Although no refund is given, a search for a second invention in a divisional application should be made without requiring an additional search fee when a search report has issued in respect of the first invention in the divisional application, despite this invention already having been searched in connection with the parent application (see 15.38), and a further search becomes necessary for the second invention sometime later upon deletion of the first invention.]

Section 15(10)

Where an application has a date of filing by virtue of this section, the application shall be treated as having been withdrawn if any of the following applies-

(a) the applicant fails to file at the Patent Office, before the end of the prescribed period, one or more claims and the abstract;

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- (b) where a reference to an earlier relevant application has been filed as mentioned in subsection (1)(c)(ii) above-
 - (i) the applicant fails to file at the Patent Office, before the end of the prescribed period, a description of the invention for which the patent is sought;
 - (ii) the applicant fails to file at the Patent Office, before the end of the prescribed period, a copy of the application referred to, complying with the relevant requirements of rules;
- (c) the applicant fails to pay the application fee before the end of the prescribed period;
- (d) the applicant fails, before the end of the prescribed period, to make a request for a search under section 17 below and pay the search fee.

r.22(1) r.22(2) r.22(7)(a) r.22(7)(b)

15 50 Where there is no declared priority date, the claims, abstract, application fee, request for search (on Form 9A) and the search fee must all be filed not later than twelve months from the date of filing. Where, instead of filing a description, a reference is made under s.15(1)(c)(ii) to an earlier application, s.15(10)(b)(i) also requires the description to be filed within this period. Where there is a declared priority date these elements (including, where relevant, a description filed under s.15(10)(b)(i)) must be filed before expiry of whichever is the later of twelve months from the earliest priority date or two months from the date of filing. The periods specified in r.22(1) and (2) are listed in Part 2 of Schedule 4 of the Rules. They may therefore be extended once by two months as of right under r.108(2), and further extensions (in tranches of two months) may be granted at the discretion of the comptroller under rr.108(3) to (7). So as to provide a clear demarcation between extension of time under r.108 and reinstatement under s.20A, these Rules are also listed in Part 3 of Schedule 4, and if a request for extension (or further extension) is not received before expiry of the requested extension, the application must be treated as having been withdrawn (see 123.34-42). Once extension is not longer available, reinstatement under s.20A may be requested.

r.22(3) r.108(5) r.108(7) 15.51 Where a reference is made under s.15(1)(c)(ii) to an earlier application, s.15(10)(b)(ii) requires that a certified copy of the application referred to (accompanied, if necessary by a translation) must be filed within the four months if the application is not to be treated as withdrawn. This period can be extended under r.108(1) and (5)-(7) in tranches of two months (see 123.36.10-123.41) at the discretion of the comptroller in cases where there is a genuine difficulty in obtaining the necessary certified copy within the time prescribed.

r.22(5) r.22(6) PR Sch. 4 Parts 2 and 3 15.52 In the case of an application which claims an earlier filing date under s.8(3), 12(6), 15(9) or 37(4), the claims, abstract, application fee, request for search and search fee must be filed within two months of making the application or within the relevant period for the earlier application - whichever is the later. This period is extendable once by two months as of right under r.108(2), and then in two month tranches at the discretion of the comptroller under rr.108(3) and (5) to (7), provided the request is received before the expiry of the requested extension (see 123.34-41). If this extension is no longer available, reinstatement under s.20A may be requested. However, if the application is filed within the last six months of the compliance period (including any extensions), the claims, abstract, application fee and the search request and fee must be filed at the time of making the application.

15.53 In the case of an application which has been converted from an application for a European patent (UK), the period for paying the application fee, filing Form 9A, paying the search fee and filing Form 7 is governed by r.58(4), (see s.81); in the case of an international application the application fee is nil, and the period for filing Form 9A and paying the search fee is governed by r.68(3) (see 89A.12 and 89A.18).

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s.14(5)(c)

15.54 Although the Act provides for the claims to be filed later than the description, they must of course be supported by the description as originally filed. If no claims were present on the filing date of the application, then when claims are filed for the first time this does not constitute amendment of the application. However once the application contains at least one claim, the subsequent filing of claims (except by way of correction under s.117) does entail amendment of the application and is governed by r.31.

s.16(1) s.118(3)(b) r.55 15.55 If the claims, abstract, application fee, request for search, search fee, and where a reference under s.15(1)(c)(ii) is made, a description and certified copy of the application, have not all been filed by the end of the respective prescribed periods, the application is taken to be withdrawn. It is not published, but the fact that it has been withdrawn is advertised in the Journal. It may continue to serve as a basis for a declaration of priority in respect of a later application, subject to s.5(2), (2A) and (3).

r.22

r.108

r.10

[Where no claims and/or an abstract have been filed within the period prescribed by r.22 and the two-month period in which an extension could be requested on Patents Form 52 under r.108(2) has expired, the application is taken to be withdrawn. It is not possible for any extension to be granted once this two-month period has passed (r.108(7)). A standard letter (WR4) is issued by the Formalities Manager warning of the intention to advertise the application as taken to be withdrawn. Similar considerations apply where a Patents Form 7 has not been filed within the period prescribed by r.10. For termination procedure, see 14.199.1.]

Once the application has been treated as withdrawn through failure to file any of the claims, abstract, application fee, request for search, search fee, and, where a reference under s.15(1)(c)(ii) is made, a description and certified copy of the application, reinstatement under s.20A is the only option remaining available. In particular, the deletion of an incorrect claim to priority as a correction under section 117 is not allowable, even if allowance of the deletion would mean that time for filing a request for search still remained (*Payne's Application* [1985] RPC 193); see also 117.19.

Section 15(11)

In this section "relevant application" has the meaning given by section 5(5) above.

15.57 Where a reference is made under s.15(1)(c)(ii) to an earlier application, that earlier application may be either an application for a patent under the 1977 Act or an application made in a convention country. The definition of what is a relevant application is the same as for s.5 of the Act (see 5.30).

Annex to section 15 of the Manual - Divisional applications

15.58 Section 15 of the Manual refers at various points to the processing of divisional applications. In particular, references are to be found from 15.17 to 15.49.

[Examiners in particular should be aware of the different procedures which apply when processing divisional applications. Of particular help will be the examiners' aide-memoire and checklist for divisional applications, which are reproduced below. Neither the aide-memoire nor the checklist is intended to be exhaustive. More detailed guidance is given in the paragraphs of the Manual referred to in square brackets.

[DIVISIONAL APPLICATIONS: EXAMINERS' AIDE-MEMOIRE

When a purported divisional is filed

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1. There are various basic formal requirements which must be satisfied if an application is to qualify as a "divisional". These matters are considered by the appropriate formalities group [15.17-15.19, 15.22-15.24].

Has it been filed in time?

- 2. This is the first thing for the examiner to decide (unless a drawing has been omitted). If the requirements of s.15(9) and r.19 are not met, there can be no progress as a divisional [15.33].
- 3. R.19 sets out the time periods within which a divisional can usually be filed. Put simply, a divisional can be filed as-of-right on a parent providing that the parent has not been granted or terminated, and the divisional is filed at least three months before the compliance date (including any extensions) [15.19-15.20].
- 4. If lodged outside these periods, an application can still be admitted as a divisional filing, but only at the comptroller's discretion. This requires exceptional circumstances and a diligent applicant [15.21, 15.34]. However, a divisional cannot be filed after grant [15.19].

Added matter

- 5. S.15(9) means that a divisional cannot be allowed to proceed unless amended to exclude any detected additional matter [15.29, 76.02, 76.19]. The usual criteria are used to determine whether or not matter has been added [76.03]: for example, the presence in a divisional of claims having a different scope from, or no equivalent in, the parent does not necessarily mean that matter has been added. An objection under s.14(5)(c) should not be confused with one under s.76; the former does not impugn divisional status [15.30].
- 6. At the search stage, if this is separate from substantive examination, a prima facie view is taken by the search examiner on the added matter question. If added matter is judged to be present, its excision may be requested before the application is allowed to proceed, the search being deferred; EL24 is sent and one month allowed. An alternative if the added matter is not relevant to the search is to do the search and object to added matter in the search letter using SC15 [15.35]. The implications of added matter for publication under s.16 are given in para 11 below.
- 7. Since the search examiner's view is not definitive, the substantive examiner needs to satisfy himself/herself on the point [15.43]. If added matter is judged to be present, full examination may be deferred if the application is not likely to proceed, sending EL24 and allowing one month for reply. Otherwise the full examination is conducted and objection raised using RC24 [15.45].

Allowing divisional status

8. Once ante-dating is allowable, by virtue of the requirements of s.15(9) and r.19 being met (see above), the applicant should be informed using RC21. If a search or examination letter is issuing before it is allowable, notice that compliance is awaited should be given [15.44].

The search

9. The search itself is performed as usual, unless combined with examination (see paras 17-20 below). Issue of a search report on a divisional cannot be dispensed with even if the search has been covered by that on the parent [15.38]. Consideration of a request for a refund of the search fee [15.47-15.49] may be given now unless it appears likely that s.17(8) might need to be invoked, in which

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case final consideration should be deferred until just before grant (see para 20 below). ELC8(EL8)/ELC9 can be used to notify allowance/deferment respectively of such a request.

Publication

- 10. Publication cannot occur until any added matter detected at that stage has been deleted from the application. However, what is published is not the application as so amended but the application as filed, ie including the added matter [15.39, 16.08, 76.02].
- 11. In addition, special instructions for publication may need to be given if:
 - publication is before allowance of the divisional date (e.g. because substantive examination has not yet taken place), to say that the filing date is provisional [15.40].
 - amended claims have been filed in response to an objection under s.76(1). This is an examiner's free text entry [15.38, 16.29].
- 12. [deleted]

Substantive examination

- 13. It is not necessary (though it is of course allowable) to include cross-references between parent and divisional applications. Nor is there any specific requirement that disclosure should not be unnecessarily duplicated between the applications. However, it should be considered whether description of matter which is not relevant to the application in suit throws any doubt on the scope of the claims [15.32].
- 14. To comply with s.18(5) parent and divisional claims should not conflict. Special care is needed with omnibus claims [15.31, 18.91-18.97.1].
- 15. Reply periods to s.18(3) reports should be set having regard to the expiry of the compliance period, which is the later of 4½ years from the priority/filing date of the earlier case, whose date of filing is to be treated under s.15(9) as the date of filing of the divisional, or 12 months from the date of issue of the first s.18 report on this earlier case (see also para 17 below).

Combined search and examination

- 16. If Forms 9 and 10 have been filed on the same day or shortly one after the other with a request for combined search and examination, the search and examination are combined. If the examination report is one under s.18(3) a single combined search and examination report should issue using SE4. Where the examiner has no objections to the application just the search report or a single combined search and examination report should issue using SE3 or SE5 depending on whether the invention claimed in the divisional was claimed and published in the parent application [15.41]. If amendments have been filed before issue of the search report the appropriate version of SC1 should be added [15.41]. ELC5 should also be added to the covering letter of the first s.18 report on a divisional when the first s.18 report on the relevant earlier case issued more than 3½ years from its priority/filing date (see also para 16 above) [18.47, 20.02].
- 17. Post-"A"-publication COPS statuses, eg 9 and 10, must not be set until after "A"-publication is complete.
- 18. If the first substantive examination report on a late-filed divisional is under s.18(4),

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grant cannot be accelerated by waiving the usual two-month period as it is necessarily delayed until after s.16 publication [18.81].

In order stage

- 19. Any outstanding request for a refund of the search fee can be determined now and the applicant notified of the outcome (see para 10 above) [15.47-15.49].
- 20. Applications do not normally have to be held back from grant until the remainder of the family is in order. However an application may be held back where appropriate, for example if there is conflict of claims with another family member which is not yet in order. [15.46].
- 21. Even if the invention of the divisional was not clearly claimed in the published parent application, the issuing of the intention to grant letter on the divisional cannot be delayed beyond the compliance date in order simply to allow for the expiry of the three-month period for third-party observations. [15.41].

[DIVISIONAL APPLICATIONS: EXAMINERS' CHECKLIST

There are various basic formal requirements for a divisional, which the formalities examiner assesses. [15.17-15.19, 15.22-15.24]

- 1. Has the divisional been filed in time? [15.19-15.21, 15.33-15.34]
- 2. Is there any added matter? Are SC15/EL24/RC24 necessary? [15.29-15.30, 15.35, 15.43, 15.45, 76.02-76.03, 76.19]
- 3. Is ante-dating allowable? Is RC21 necessary? [15.44]
- 4. Is a search fee refund due? Is ELC8(EL8)/ELC9 necessary?
- 5. Publication:
- 6. a. is it due?
 - b. what is to be published?
 - c. are any special instructions for publication needed?
 - d. has the applicant been told?

Is any description of matter included which is relevant to the claims of the parent but not the divisional and casts doubt on the scope of the claims? [15.32]

- 7. Is there claim conflict, eg of omnibus claims? [15.31, 18.91-18.97.1]
- 8. Is combined search and examination appropriate? Which of SE3, SE4 or SE5 is necessary? Is ELC5 necessary? [15.41, 18.47, 20.02]
- 9. When does the compliance period expire, and what should the s.18 report reply deadline be? [15.20.1]
- 10. Don't set post -"A"-publication COPS statuses until "A"- publication is complete.
- 11. Before issuing an intention to grant letter:
- 12. a. is there any possibility of conflict with other applications in family?

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b. have 3 months elapsed from publication if claims were not in parent?

[NB: issuing of the intention to grant letter on the divisional cannot be delayed beyond the compliance date solely to allow for the expiry of the 3-month period - 15.41]

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Section 15A: Preliminary examination

15A.01 This section sets out the conditions necessary for an application to proceed to preliminary examination, makes provision for carrying out the preliminary examination and for reporting the results. Rules 23, 24 and 25 are particularly relevant to this section.

Information security: a reminder

- s.118(2)

 15A.01.1 The preliminary examination of UK patent applications is carried out before A publication, and so most of the guidance in this section relates to pre-publication actions. Before A publication, the application, the preliminary examination report, and any other documents or information concerning the content of the application (other than that prescribed under s.118(3)) must be protected and must not be communicated to anyone outside the Office other than the applicant or his designated representative see 118.16-118.16.1 for further guidance on these issues.
 - 15A.01.2 More generally, in all cases, whether pre-or post-publication, formalities examiners should ensure that any communications (including telephone conversations) are directed to the intended recipient.

[Where correspondence from the Office is reported as never having arrived at its intended destination, or is reported as being misdirected or delayed, this fact should be recorded by sending a minute to the relevant formalities group with any relevant details.]

Section 15A(1)

The comptroller shall refer an application for a patent to an examiner for a preliminary examination if -

- (a) the application has a date of filing,
- (b) the application has not been withdrawn or treated as withdrawn; and
- (c) the application fee is paid.
- s.15(10)(c)

 15A.02 The payment of the application fee will initiate preliminary examination. There is provision to pay the application fee on Form 1 and on Form 9A although it is not a requirement for the fee to be filed with these forms. If the application fee is paid independently of these forms it is suggested that it be accompanied by non-statutory form AF1.
 - 15A.03 The time allowed for filing the application fee is prescribed in r.22(7), (see 15.51 15.53). The preliminary examination should be carried out by the formalities examiner as soon as possible after the application fee has been paid and a letter should be issued (see 15A.20) if there are any outstanding objections.
 - [Security Section should carry out a coarse allocation of applications to the appropriate Formalities Group Manager. The Formalities Group Manager should in turn finely allocate cases on which a search fee has been filed to the appropriate classification heading and forward these cases to the formalities group associated with that heading.]
 - [The formalities examiner making the preliminary examination should complete the appropriate parts of the formalities checklist and enter any appropriate amplifying comments in a minute added to the dossier. If a procedural

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requirement is outstanding, a letter should be sent to the applicant. A report in a minute added to the dossier may also be addressed to a specific person, for example the search examiner, and may be by way of explanation or reminder.

[When before publication, all the formal requirements have been met, the formalities examiner should add the appropriate action to the dossier.]

[Private applicants' cases]

[Any application filed without the services of an agent should be identified by addition of the appropriate label to the cover of the dossier. The formalities examiner should normally issue an LFEPA (if the application fee has been filed) letter immediately, but should consult the Private Applicant Unit (PAU) first if the application is considered to be a 'no case' (i.e. an application which cannot be given a filing date due to lack of technical description).

[Where an application is identified as a 'no case', the PAU examiner will issue a 'No Case Letter', informing the applicant of the requirement to file a technical description in order to establish a filing date. Where fees have been filed with such an application, the unspent fees should be refunded and the applicant informed either by phone or in the 'No Case Letter'. PAU desk notes provide further guidance on the process.

[More information on preliminary examination processes for private applicants is provided in Chapter 15 of the <u>Formalities Manual</u>.]

Section 15A(2)

On a preliminary examination of an application the examiner shall -

- (a) determine whether the application complies with those requirements of this Act and the rules which are designated by the rules as formal requirements for the purposes of this Act; and
- (b) determine whether any requirements under section 13(2) or 15(10) above remain to be complied with.

15A.04 The formal requirements are those designated by r.25(1), namely the requirements of r.12(1) and r.14(1)-(3). The formalities examiner should therefore establish whether a properly-completed Form 1 has been filed (see 14.04 - 14.25) indicating an address for service (see 14.04.13), and whether or not the drawings and other documents comply with the formal requirements of r.14 (see 14.26-14.57). The preliminary examination should also establish whether action under s.15(3) is necessary, and whether the requirements of rr.6-9 (see 15A.13 - 15A.17) and rr.10(1) and 10(2) (see 15A.11 - 15A.12) have been met. If any requirements in relation to s.13(2) or 15(10) are outstanding these should also be determined. If it is established as a result of this preliminary examination that there is no outstanding objection, the application should be reported "Formalities complied with for A-publication".

[Where the specification of a patent application concerning biological material discloses a sequence, the formalities examiner should also check that it includes a sequence listing, in accordance with rule 13(2). If a sequence listing has not been provided then the preliminary examination report should specify a period of 2 months from the date of the report within which the applicant must provide the sequence listing. Although this is not a formal requirement designated by r.25(1), the comptroller may refuse the application if the sequence listing is not provided within the period specified. If there is any doubt as to whether an application falls under these circumstances then the formalities examiner should consult the

r.13(2)-(7)

r.23(1)

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THE SPECIFICATION

15A.05 If the pages of text of the specification do not conform with the formal requirements of r.14, the formalities examiner should itemise the outstanding requirements (see 15A.20).

In view of the propensity of some private applicants to add matter or even totally redraft a specification, objection under r.14 against a private applicant's specification should not normally be raised. If unavoidable, any necessary typing or other essential remedial action for the purposes of s.16 publication may be undertaken in the Office unless this is clearly impossible (see 14.30). Where such remedial action has been taken, the appropriate notice should be inserted on the front page (see 16.29). The applicant should be advised of the retype and a copy of the typed pages included.]

15A.06 If the drawings are formal, that is to say, they comply with the formal requirements, r.14(3) then, provided they were present on the filing date of the application, they should be annotated appropriately in the TOC. Any additional copies should also be annotated appropriately. (For the procedure when formal drawings are filed late following the initial filing of informal drawings, see 15A.22; for the case where a drawing not present in any form on the filing date is subsequently filed, see 15A.23).

> 15A.07 If the drawings are informal, that is, if they fail to comply with the formal requirements of r.14, a report to this effect should be made, detailing the deficiency unless it is clear that the drawings filed were intended only as an informal version. Informal drawings should be annotated appropriately in the TOC.

15A.08 [deleted]

15A.09 A drawing containing formulae which appear in the text of the specification (see 14.31) is rarely needed. If such a drawing has been filed but is not to be used in publishing the A document, no action is necessary and it should be left in the correspondence part of the file. If the drawing is required, if it complies with the Rules it should be annotated appropriately. Such drawings do not need to be in duplicate, and any further copies should also be annotated appropriately. Any discrepancy between the drawing and the formulae in the text should be drawn to the attention of the search examiner. If, in the search examiner's opinion the text is wrong, and the drawing correct, and the drawing was present on the date of filing the application, no action should be taken before substantive examination; the drawing is used in preparing the published application and may be used for the abstract. If the search examiner considers that the text is correct and the drawing wrong, or cannot form an opinion, the applicant should be asked to provide a drawing agreeing with the text. (If formula drawings were supplied later than the filing date of the application, see 15A.22).

If the search examiner is sure that, where there is a discrepancy, the text is correct and the drawing wrong, he may correct the drawing and so inform the applicant. Publishing Section should be given suitable instructions where a formula drawing is to be used in producing the A document.]

15A.10 If the application is an international application (UK) the formal requirements of rr.12(1) and 14 are regarded as having been met if the requirements of the corresponding rules of the PCT have been met. Rule 12(1) is equivalent to r.53.1 PCT and r.14 is equivalent to r.11 PCT. According to section 81(3)(c), any document filed with the European Patent Office under provisions of the EPC corresponding to sections 2(4)(c), 5, 13(2) or 14 shall be treated as having met the requirements of those sections. Rule 12(1) is equivalent to r.41(1) EPC and r.14 is equivalent to r.45(1),(2),(3) and r.49 EPC.

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r.25(3)

FORM 7

r.10(4)

15A.11 The formalities examiner should determine whether the questions in part 7 of Form 1 (see 14.04.16) have been properly completed, and, if correctly completed should report whether Form 7 has been filed, properly completed and with any necessary further copies

(see 13.15).

r.10(3)

15A.12 If it is found that Form 7 is outstanding or if there appears to be a defect in the Form, and the end of the 16 month period (see 13.11) is near, the applicant or agent should be notified at once. If an applicant is required to file a Form 7 on the basis of the answers to the questions in part 7 of the form 1 and the applicant fails to file Form 7 within the prescribed period the application is taken to be withdrawn (see 13.13). The prescribed period in the case of a divisional application is determined by r.21 - see 15.26).

PRIORITY DOCUMENTS

r.24(1) s.120(2)

r.7 r.24(2)-(3) 15A.13 If a declaration of priority has been made at part 5 of Form 1 (see 14.04.14) the formalities examiner should determine whether the filing date of the application is within the period of 12 months from any priority date so declared (always remembering that if the period of 12 months expired on an excluded day or on a day which is certified as one on which there was an interruption under r.110(1), see 123.43, the period is extended to include the first following day which is not excluded or certified, and the period may also be extended under r.111, see 123.46-47). If it is not, the applicant should be informed that the claim to priority is not valid and be advised if a request for late declaration of priority under s.5(2B) may be applied for. Where it is not possible to claim the priority date declared, the applicant must provide a corrected date for which a valid priority claim is possible within two months of being notified by the formalities examiner, otherwise the declaration will be disregarded.

r.112 r.8(2) PR Sch. 4, Part 2

15A.14 The formalities examiner should determine whether the file number of the or each application from which priority is claimed has been supplied, either on Form 1 or subsequently. If a copy of the priority claim application is available to the office the formalities examiner should obtain a copy of the application for the dossier (see 15A.18 -15A.19). Where the priority claim application is not available the formalities officer should determine if a certified copy of the application has been filed within the prescribed period of 16 months (extendible in accordance with r.108(2) or (3) and (4) to (6), see 123.34-41) from the earliest declared priority date. Where priority is claimed from more than one application, all the certified copies must be filed within this period. Where no certified copies of the application have been filed the formalities examiner should report this and should also report if an application from which priority is claimed is not an application for a patent under the Act, an international application filed at the Office or any other application supplied to the Office in support of a declaration of priority on another application made under the Act (see 15A.20). (For the periods allowed for filing priority documents when the application in suit is one for a European Patent (UK) converted under s.81, or is an international application see 5.10; for the periods in respect of a divisional application see 15.23).

r.8(1)

15A.15 When such a copy is filed, it must be established that it is of a "relevant application" (see 5.30) from which priority can legitimately be claimed, and that the document is consistent with the details given on Form 1. If there is a discrepancy an explanation should be sought from the applicant. If there is an error in the declaration of priority on Form 1, an application to correct it should normally be made in writing. If the wrong priority document has been filed, or if details on it are clearly incorrect, a replacement (duly certified) should be requested and must be filed before the end of the prescribed period; if it is filed later, a written request for its admission as a correction under s.117 should be filed.

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[If there is a discrepancy between the declaration of priority on Form 1 and the priority documents the agent should be contacted by telephone (followed by written confirmation) to establish where the error lies. If only the file number on Form 1 is wrong then it may be corrected in the office, provided that the error is notified within 16 months of the earliest declared priority date, since the applicant is allowed to supply the file number at any time within this period. If the fault lies in the priority document and the prescribed period has already expired, the matter must be referred via the Formalities Manager to the divisional Head of Admin.]

15A.16 If a page of text or drawing is apparently missing from the priority document the formalities examiner should ask the applicant whether or not the document is in agreement with the application, of which it purports to be a copy, as filed. If it is, no further action is necessary. If it is not, a replacement (duly certified) should be requested if the prescribed period has not expired. If that period has expired, the applicant can seek the admission of such a replacement as a correction under s .117.

[If the priority document is deficient and the prescribed period has already expired, the matter must be referred via the Formalities Manager to the divisional Head of Administration.]

s.5(2) r.3 r.26(1) 15A.17 If, after 18 months from the earliest declared priority date, any required certified copy of a priority application has not been filed, the claim to priority in respect of that application is relinquished and the application will then proceed with its own filing date as priority date, or, where not all of several declared dates have been relinquished, with the earliest remaining priority date. Time limits and other dates, including the date on which publication is due, are reckoned from the new priority date. The applicant must be notified of the loss of any declared claim to priority and of the reason for this. Even if a claim to priority is relinquished, any related priority documents should be kept in the open part of the file so as to be available for inspection under s.118.

[The appropriate standard letter should be issued warning of the intention to cancel the declaration or date of priority, and giving two weeks for any observations which might justify extension of the relevant period under r.108(3). In the normal case, after the two weeks has ended, the application should be referred with an explanatory minute to the Formalities Manager. The Formalities Manager will authorise the cancellation of the relevant priority details, annotate Form 1 appropriately and add an explanatory minute to the PDAX dossier and carry out, or arrange for, the appropriate COPS action. On a PCT application, the Formalities Manager will add an explanatory minute to the PDAX dossier and amend the WIPO print and NP1 and carry out, or arrange for, the appropriate COPS action. The formalities examiner must also inform the applicant by issuing LFH.]

[Deleted]

[A minute on the PDAX dossier should direct the search examiner's attention to the new priority date.]

Priority claimed from an application filed at the Office

15A.18 If priority is claimed from a UK application, an international application filed at the Office or any other application supplied to the Office in support of a declaration of priority in a UK application, and the UK or international application has been withdrawn by the applicant or has been treated as withdrawn because the period prescribed by r.22(2), (together with a two month extension possible under r.108(2)) has expired without Form 9A and the search fee being filed, documents may be transferred from the earlier application to serve as priority documents for the application in suit. When priority is claimed from an earlier UK application itself only documents present on the filing date of

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the earlier application may be so transferred; in particular, later filed claims or late-filed drawings may not be transferred. A full set of these documents must remain on the file of the earlier application.

[In the case of a UK application the documents to be transferred are a copy of the Form 1 (prepared by the formalities examiner) and a copy of all other documents (and only those documents) submitted on the filing date of the earlier application. Care must be taken to ensure that there still remains on the file of the earlier application a complete set of documents representing copies of those transferred. Thus, in accordance with the above:-

the claims, abstract and drawings thus transferred must be those submitted on the application date. If none was filed on the application date no such transfer can occur; claims, abstract, or drawings filed after the application date (including formal drawings following initially-filed informal drawings) must not be transferred.

[When documents are transferred from one application to another, the Dossier Action Log must be updated on each dossier. The TOC should be annotated to advise the examiner as to whether the/each priority case has been searched.]

15A.19 [deleted]

Section 15A(3)

The examiner shall report to the comptroller his determinations under subsection (2) above.

s.15A(2)(b) r.23(2) 15A.20 A letter should be issued following the preliminary examination setting out any objections arising therefrom. If the specification does not comply with r.14, or if any other formal requirement has not been met, the report should set out the precise grounds of objection. If it is clear that drawings which are informal are only intended as such, a statement that formal drawings should be filed will suffice. The applicant should be requested to rectify these deficiencies within 15 months of the priority date or, where there is none, of the filing date. If this period has already or nearly expired a period of two months should be allowed for compliance. If any other matters are outstanding, for example, if a priority document has not been filed and the time for filing it has not expired, or if Form 7 is not yet on file, a reminder to this effect should be included in the report.

[It is usual for any objection arising out of the preliminary examination to be conveyed to the applicant by standard paragraphs and issued directly by the formalities examiner. If however the circumstances demand it, any outstanding procedural requirements may be communicated to the applicant by "first" letter or by telephone followed by a confirmatory telephone conversation report. A first letter must be authorised by the Formalities Manager and will issue under his name. If, exceptionally, an outstanding formal requirement is conveyed for the first time by a communication using other than standard paragraphs, that communication must specify a period in which the applicant should comply with the requirement: it must also state that unless the applicant complies within the period specified, the comptroller may refuse the application after giving the applicant an opportunity to be heard in the matter.]

[A copy of a standard letter, of a telephone conversation report or of a first letter must be made available on the "open to public inspection" part of the file.]

15A.21 When replacement pages of text are filed, the formalities examiner should check that they are in exact conformity with those originally filed and that they comply with the formal requirements and should incorporate them into the application. The published

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application should carry a notice (see 16.29) stating that it takes account of replacement documents filed later than the application. If, however, the original text was illegible (as distinct from merely difficult to read) the matter should be referred to the search examiner (see 16.09).

[If the replacement pages are acceptable, new versions of the relevant documents should be assembled for the dossier. The latest versions of the claims and description should be annotated appropriately. See also 15A.22.]

15A.22 When formal drawings are filed, whether or not in response to an Official request, in a case where the drawings present on the filing date were informal, they should be checked by the formalities examiner for conformity with the informal drawings. Any discrepancy which appears prima facie (that is, without requiring undue investigation) to be material should be resolved before publication. Otherwise, the matter can be deferred for resolution at the substantive examination stage (see also 18.08). The consideration of discrepancies in formal drawings is a matter for the search examiner. The drawings should be annotated as in 15A.06 (the originally-filed informal drawings being regarded as a third copy). The published application should bear a notice (see 16.29) stating that the original drawings were informal and that the published drawings have been prepared from a later-filed formal copy. If formula drawings (see 15A.09) have been filed later than the filing date of the application and are to be used in producing the published application the formalities examiner should check that they agree with the formulae in the specification, any discrepancy being reported to the search examiner, and instructions for publication should be provided to include a notice that such drawings were filed late.

[When replacement formal drawings are received the formalities examiner should check that they are identical to the informal drawings on file. Once the formalities examiner is satisfied that there is no discrepancy between the drawings and that all other requirements are met, the application should be sent for publication at the appropriate time without further referral to the search examiner (assuming the search report has issued). However, the search examiner should be consulted if the formalities examiner is unsure as to whether the later filed formal drawings are identical to those originally filed or has any doubt that what purportedly has been filed are formal or replacement drawings. Responsibility for deciding to raise the matter of any discrepancy with the applicant or agent will then rest with the search examiner, but it is the role of the formalities examiner to request replacement drawings if the search examiner determines they are needed. If the search examiner decides to defer until substantive examination the question as to whether any such discrepancy is material, he should add a minute to the dossier to alert the substantive examiner to the situation.]

[If formal drawings or replacement pages are filed outside the period specified, an extension of time may be allowed. An automatic extension of two months to the specified period can be allowed on receiving a request in writing before the end of the period as extended. If the period has already been extended by two months a further extension of time may be allowed but this request must be accompanied by an explanation of the cause of delay. Any such request should be referred to the Formalities Manager for consideration. Any request made to extend a specified period after the two month automatic extension period has expired should also be referred to the Formalities Manager]

Section 15A(4)

If on the preliminary examination of an application it is found that-

(a) any drawing referred to in the application, or

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r.109

(b) part of the description of the invention for which a patent is sought,

is missing from the application, then the examiner shall include this finding in his report under subsection (3) above.

r.18(2) s.15(6)(b) 15A.23 The formalities examiner should check during the first preliminary examination that all drawings referred to in the description or claims were present (in either formal or informal versions) on the filing date of the application and that all the pages of the description are numbered consecutively. If such a drawing is missing or it appears that a page is missing this should be reported in the preliminary examination report. The report should state that the missing part should be filed within two months of the date of notification. Subsequent filing of missing drawings or pages will lead to the application being re-dated unless there is a claim to priority and an application to avoid re-dating is allowed (see 15.07 to 15.16).

Section 15A(5)

Subsections (6) to (8) below apply if a report is made to the comptroller under subsection (3) above that not all the formal requirements have been complied with.

Section 15A(6)

The comptroller shall specify a period during which the applicant shall have the opportunity-

- (a) to make observations on the report, and
- (b) to amend the application so as to comply with those requirements (subject to section 76 below).

Section 15A(7)

The comptroller may refuse the application if the applicant fails to amend the application as mentioned in subsection (6)(b) above before the end of the period specified by the comptroller under that subsection.

Section 15A(8)

Subsection (7) above does not apply if-

- (a) the applicant makes observations as mention in subsection (6)(a) above before the end of the period specified by the comptroller under that subsection, and
- (b) as a result of the observations, the comptroller is satisfied that the formal requirements have been complied with.

15A.24 If an applicant has been notified at least once that a requirement designated as formal by r.25(1) has not been complied with, and no satisfactory response has been received within the period specified (see 15A.20), a report should be issued stating that unless the applicant submits observations or requests a hearing within one month the

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application will be refused under s.15A(7). If no satisfactory response is received within this period, or if, following a hearing, the matter is decided against the applicant, a decision should be issued formally refusing the application

[If the period specified in FL1 has elapsed without a satisfactory reply having been received, a letter drafted in some such terms as the following should be issued:-

Care must be taken when preparing the letter, using the above as a base, to ensure that the correct requirement is inserted. The official letter must be authorised by the Formalities Manager. Where the formal requirement remains outstanding after expiry of the period specified in the Official Letter issued as above, the application is refused. Where the refusal is undisputed, a decision of refusal should be prepared and submitted through the Formalities Manager to the divisional Head of Admin for approval and signature. Cases where refusal is disputed should be submitted through the Formalities Manager and divisional Head of Administration to the appropriate Senior Legal Adviser in Legal Section for a hearing.]

Section 15A(9)

If a report is made to the comptroller under subsection (3) above-

- (a) that any requirement of section 13(2) or 15(10) above has not been complied with; or
- (b) that a missing drawing or part of the invention has been found to be missing,

then the comptroller will notify the applicant accordingly.

r.10(3) r.22(7) 15A.25 Any requirements of section 13(2) or 15(10) which have not been complied with within the prescribed periods (as extendible under r.108(2)) will be reported to the applicant in warning letter WR4. The formalities manager should issue the letter at the appropriate time.

15A.26 Failure to respond to any finding under s.15A(4) that a part of the application appeared to be missing at the time of filing will result in a letter being issued by the formalities manager stating that the missing part has not been filed and that the application will proceed in the form that it was originally filed.

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Section 16: Publication of application

Section 16(1)

Subject to section 22 below and to any prescribed restrictions, where an application has a date of filing, then, as soon as possible after the end of the prescribed period, the comptroller shall, unless the application is withdrawn or refused before preparations for its publication have been completed by the Patent Office, publish it as filed (including not only the original claims but also any amendments of those claims and new claims subsisting immediately before the completion of those preparations) and he may, if so requested by the applicant, publish it as aforesaid during that period, and in either event shall advertise the fact and date of its publication in the journal.

s.130(5) r.26(1) r.26(2) References in the Act to publication of an application are to publication under s.16, the publication consisting of the application as filed including the original claims and also any amendments of those claims and any new claims subsisting immediately before the completion of preparations for publication (see 16.02). The application is published as soon as possible after the expiry of the period of eighteen months from the declared priority date or, where there is none, the filing date. On the publication date an "A document" is made available consisting, as far as possible, of (a) the specification as published; (b) a front page bearing certain bibliographic data, classification information, a list of the documents cited in the search report under s.17, the abstract and any drawing selected to accompany the abstract; and (c) a copy of the external search report(s). The bibliographic data will not contain an inventor's name if the comptroller has accepted an application from the inventor to waive his right to be mentioned (see 13.03). See 89A.14-89A14.2 regarding PCT applications entering the national phase under section 89.

[Deleted]

s.118(2)

16.02 The determination as to when preparations for publication have been completed is made on a case by case basis. The hearing officer in Peabody International's Application [1986] RPC 521 applied the guidance given by the Court of Appeal in Intera Corporation's Application [1986] RPC 459 that preparations have been completed when the print-out of the application data and the specification have been allocated to one of the printing contractors and are ready to be sent to or collected by him from Publishing Section. Following subsequent computerisation, the nearest equivalent point in the procedure is now selected. Unless accelerated publication is requested (see 16.04), a letter issued with the search report gives an estimated date soon after which the preparations for publication of the application will be completed. This letter mentions that the applicant will receive a further letter at this time giving the date of publication, publication number and exact date when the preparations for publication will be completed (the PPC date). The letter with the search report also advises the applicant that any amended or new claims for inclusion with the published application or any request to withdraw the application so as to prevent publication must be filed before the PPC date since it is not possible to withdraw an application from publication on or after this date. This letter should not be relied upon as a reminder if the applicant wishes to withdraw the application before publication. If accelerated publication has been requested, it is unlikely that there will be sufficient time after issue of the search report to file amended or new claims for inclusion with the published application or to request withdrawal before publication because the preparations for publication will be completed very soon after issue of the report. Unless accelerated publication is requested, completion will be at least sixteen months and three weeks after the declared priority date or the filing date and at least four weeks after the date of issue of the search report. The fact of publication is advertised in that issue of the Patents Journal which is published on the same date as the application, since information about the application may not be disclosed before the date of publication (except for the bibliographic information which may be published earlier

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under s.118(3)(b), see 118.18).

s.118; r.51

16.03 On the date of publication the file on the application becomes open to public inspection, as does the relevant entry in the Register. In particular, any amendments to the claims which were filed too late to be included in the published application and any amendments to the description or drawings, are published on that date by being open to public inspection, as is any matter omitted (other than under s.16(2) - see 16.34-16.37) from the A document, for example, in the circumstances referred to in 16.27. In addition, certain documents are available free of charge on the Office website through Ipsum, the Office's online patent information and document inspection service.

16.04 S.16(1) permits the publication of an application before the expiry of the period prescribed by r.26(1) at the request of the applicant. When such a request is made, an application should be sent for publication as soon as the necessary formal requirements have been complied with and a report under s.17(5) has been issued. The application is thus accelerated in that it is placed at the head of the queue waiting to pass through the publication cycle. It is not necessary to give a reason for wanting accelerated publication.

[A case on which accelerated publication has been requested should have the appropriate label applied to the cover of the dossier by the Formalities Examiner. Formalities should check the action log and minute sheet on PDAX for an indication that the application has been diarised to return to the examiner after publication. If such a diary entry is present formalities should update it so that the case returns at the appropriate time after accelerated publication.]

[There are no established Office procedures for providing "instant" publication of an application, or for shortening the 5-week A-publication cycle. To make the most of the 5-week cycle, Formalities need to generate "Ready for A Publication" by the end of Wednesday. DIS PRO should be checked by the examiner on the following day to make sure that the case has been picked. If "Ready for A picklist" is still displayed, contact PD/A3 immediately.]

s.22(3)(a)

16.05 An application on which, for security reasons, directions prohibiting publication have been imposed will not be published until such directions have been revoked.

r.8

Where there is a declared priority date the claim to priority is relinquished if the file number of the priority application and priority document is not filed within sixteen months (extendible in accordance with r.108(2) or (3), see 123.34-41), unless this requirement does not apply (see 5.08 to 5.10). If this occurs the applicant should be so informed and the declaration on Form 1 amended and COPS updated. If the priority date so lost is the earliest or only date declared then the time when publication becomes due will be correspondingly later (see 16.01). An application should not be sent for publication until either the priority document has been filed or the priority date has been lost. Thus the filing of a priority document towards the end of the prescribed period will cause an application to be sent late for publication (see 16.31) and will thus delay publication under s.16 until after the end of the normal eighteen month period. Publication should not however be delayed solely because a translation (when needed) of a priority document has not been filed.

s.118(3)(b); r.55 16.07 If an application has been withdrawn or treated as withdrawn or has been refused (either under s.15A(7) or, after a hearing following a preliminary objection (see 17.96.2), under s.18(3)) before the completion of preparations for publication, it will not be published, nor, subject to the exceptions provided for in s.118, will any of the documents become open to public inspection. However, the termination will be advertised in the Journal.

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CONTENT OF THE PUBLISHED APPLICATION AND "A DOCUMENT"

The application as filed

s.130(4)

The application must be published as filed, that is, in the state in which it was on the filing date. Therefore if any of the documents originally filed is subsequently replaced by another, for example because the original did not comply with formal requirements, the new document must conform essentially with the original. (See 14.30 for private applicant cases and 15A.22 for the situation where there is a discrepancy between formal and informal drawings). The A document will carry a notice (see 16.29) that replacement documents or drawings or formulae, as the case may be, were filed later than the filing date. (If the examiner has reframed the abstract (see 14.170-191) then the A document includes the abstract in its amended form instead of as originally filed.) A divisional application which as filed discloses additional matter may under s.76.(1) proceed following exclusion of the additional matter (see 76.02). However it should be published under s.16(1) as filed, that is including the additional matter (see also 15.35 and 15.39).

16.09 If the formalities examiner is unable to establish that the text of a replacement page is identical with that originally filed he should refer the matter to the search examiner. If the search examiner confirms that the original text is literally illegible (as distinct from merely difficult to read) then square brackets should be placed around the text replacing the illegible matter in the copy of the document to be published, and the front page should carry a notice, in addition to the notice referred to in 16.08, to the effect that matter so shown was submitted after the filing date to replace defective text. If no legible replacement for illegible matter is filed, arrangements should be made to omit it from the A document and to insert on the front page a notice that this has been done. In view of the serious consequences for the applicant which may follow an allegation that the application as filed contained illegible matter, the procedure referred to in this paragraph should be followed only when the examiner is satisfied that the original matter cannot be deciphered.

[When the search examiner wishes illegible matter which has not been replaced by legible matter to be omitted from the A document, he should send the case to the appropriate formalities group for retyping and/or blanking out as appropriate.]

16.10 In deciding the "as filed" state of an application, account should be taken of any documents relating to the application which were present in the Office at the close of business on the date of filing (or in the case of a divisional application, on the date of lodging of that application). Any such document or set of documents tending to complete an otherwise deficient application should be incorporated into the application, as should any alterations to the specification, whether in the form of replacement pages or proposed in a letter. If the resulting specification does not comply adequately with formal requirements (see 15A.05) objection should be raised under s.15A(3), making it clear what form of the application is being objected to.

16.11 Where two versions of a document were present on the filing date and the only difference is that one is formal and the other informal, then the formal version should be regarded as the effective one; the informal copy should be marked "surplus". Where there is a difference in substance between two versions of the same document, then, if the applicant has given explicit instructions, or if it is implicit or obvious which version is intended to be definitive, the application should be reconstituted accordingly.

[If the formalities examiner is in doubt how to proceed he should consult the Formalities Manager and, if necessary, the divisional Head of Administration or relevant Deputy Director. If he is unsure the case should be referred to the Divisional Director. If he considers that the applicant's intention is in doubt he should select which appears to him to be the most appropriate version and

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proceed as in 16.12.]

16.12 If the applicant's intention regarding amendments or different versions of the same document is in doubt he should be informed which version appears to the Office to be most appropriate and that, unless he indicates clearly his intentions within a specified short period (generally one month), that version will be treated as definitive. When the application is subsequently reconstituted (whether after a reply or not), the applicant should be informed in writing of the course taken.

[Letter SL11 should be used in the first instance, and SL12 to inform the applicant of the action eventually taken.]

16.13 [Deleted]

16.14 Where the description as filed is in a foreign language and is not accompanied by a translation, see 15.06.1-2. If a translation is filed, the A document will carry a notice (see 16.29) that the specification was originally filed in a foreign language.

Later-filed claims

16.15 The published application includes not only the specification in the state in which it was on the date of filing but also original claims filed later than the filing date within the period prescribed by r.19(1) and (3). The front page of the A document should carry a notice (see 16.29) that the claims were filed later than the filing date of the application, but the actual date on which the claims were filed will not be referred to in the published application.

Amended or new claims

Amendments to original claims, or new claims, are also included in the published application, provided they are filed before preparations for publication have been completed. (The actual date on which they were filed is not material and is not mentioned in the A document). Since the publication is required to include, in addition to original claims, only those amended or new claims which subsist immediately before completion of preparations for publication, any amended or new claims which have been in the meantime further amended or cancelled are not included. The amended or new claims are included in the A document if they are available in a suitable form for direct reproduction with the original description and claims. For this purpose, it is necessary for all the changes to appear on fresh pages which are self-explanatory and do not rely on instructions in a covering letter. The first such page should preferably be suitably headed, eg "Amendments to the claims". If suitable pages are not received by the time preparations for publication are completed the amended or new claims are omitted from the A document but published by inclusion in the file laid open to public inspection: a notice on the front page of the A document indicates that amended or new claims unsuitable for reproduction have been filed.

[To obtain the footnote re omitted amendments to the claims, an appropriate free text entry should be entered on COPS.]

- 16.17 As a consequence of the wording of s.16(1), if a prohibition order under s.22 is revoked but the application is published under s.16 only after substantive examination the published application will include both the claims in their original form and (if they have been amended) the claims of the application as in order for grant.
- 16.18 When amendments to the claims, or new claims, are filed they should be checked and collated for inclusion in the A document by the formalities examiner. Amended or new claims are to be published with the original claims only if the changes to the claims are filed as fresh pages meeting the requirements of r.14 and Schedule 2. The applicant or agent should be informed of any deficiency but publication should not be delayed to await any response. The formalities examiner should consult or refer the

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application to the search examiner for advice when necessary.

[No attempt should be made to edit new sets of claims to avoid unnecessary repetition of the wording of the original claims nor add explanatory text. Furthermore, unless new claims are received before the search (see 17.35), they should not be considered for any lack of clarity as to the precise effect of the changes on the existing claims until substantive examination. Applicants and agents are now encouraged to provide a heading identifying the fresh pages as relating to changes to the claims.

When new or amended claims are filed the formalities examiner should check that they meet the requirements of r.14 and Schedule 2 and annotate them with "Incorporate after A Pub" in the TOC on the dossier. If the new or amended claims are not a complete set, the document assembler should be used to create a full set, the pages of new or amended claims and external search report being renumbered as appropriate. After publication, the amended claims should be annotated "Working Copy" in the TOC by the formalities examiner.

If on receipt of new or amended claims (a) the search report has not yet issued, (b) a report, such as letters SL2 or SL2PA, that no search is possible has already issued, (c) new or amended claims have already been filed, (d) there is a gap in the numbering of the new or amended claims, or (e) there is reason to doubt that what has been filed are new or amended claims, the application should be referred to the heading or search examiner.]

16.19 Unless amended or new claims are filed under r.31(5)(a) before search, no attempt should be made to establish whether they introduce new subject-matter. Amended or new claims allowed under r.31(5)(a) or filed at the applicant's own volition under r.31(4) are published as filed, subject to the omission of matter under s.16(2).

Other amendments, corrections or alterations

s.118 16.20 Any amendments to the specification other than the claims are not included in the A document, although they do become open to public inspection on the publication date.

r.31(5)(b)

16.21 Any amendment to the Request for Grant (Form 1) is however included, r.49 provided that a written notification or Patents Form 20 (required for a correction of a name), as appropriate, setting out the proposed amendment has been filed before preparations for publication have been completed (see 19.05-19.12 and 32.06); the front page of the A document will bear an appropriate notice (see 16.29) eg that such amendment has been made under r.31(5) or under r.49(1). (If the amendment concerns the declaration of priority the date on which the application is due to be sent for publication may need to be revised - see 16.01).

[Where a footnote regarding amendments made under r.49(1) is required, an appropriate free text entry should be entered on COPS.]

16.22 If it is requested that the application proceed in the name of a person other than the or an original applicant, for example because the application has been assigned under s.30, or because the original applicant has died and the application is to proceed in the name of the deceased's personal representative, then, provided the change has been effected before preparations for publication have been completed, the A document will reflect the change and will carry an appropriate footnote (see 16.29). (See also 19.09).

16.23 If correction of a clerical error (see s.117) is sought and allowed before completion of preparations for publication, the application will be published as corrected and the A document will bear a notice (see 16.29) that a correction has been made. Except in the case of a name (where correction must be requested on Form 20), an error

r.105(1) r.49(1)

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may be rectified merely by written notification (see 117.03); if no form has been received in the case of a request for correction of a name, the examiner should ask by telephone that it be filed. Reasonable time should be allowed for this, although a case should not be retained on this account for long after it is due to be sent for publication. If no Form (or suitable evidence) is forthcoming the application should proceed to publication uncorrected, and the matter may be dealt with afterwards.

- 16.24 If an application contains an applicant's or agent's identifying reference to another application filed on the same day or earlier under the 1977 Act, the search examiner should supplement it by the application number, even if it is necessary to telephone the applicant or agent to ascertain the number. All other references are published as filed.
- 16 25 The comptroller may, of his own volition, amend the specification contained in an application in order to acknowledge a registered trade mark (see 19.23-19.26).
 - Since the Office is under a statutory obligation to publish an application in 16.26 the conditions in which it was filed, subject only to the derogation of s.16(2), if an application contains matter accompanied by wording suggesting that the copyright is owned by a person other than the applicant, then it must still be published as filed.

Computer programs, biological sequence listings and other bulky ancillary material

Computer programs, and nucleic acid or protein sequences listings, ancillary to the main text and extending over many pages are unduly burdensome to include in the published specification. This is also the case with other extensive material clearly ancillary to the main text. Therefore if an application contains such a program, sequence listing or material, it is normally omitted from the A document at the discretion of the examiner, although of course it remains part of the published application and becomes open to public inspection on the publication date (see also 24.04). A notice referring to the omission should be included on the front page (see 16.29). If however the search examiner considers that the program or other material would facilitate a ready understanding of the invention it may be included in the A document.

[If the program or other ancillary material is to be omitted from the A document the examiner should minute the file to instruct Formalities which pages of the application are not to be included. The minute should also instruct Formalities that the appropriate common standard text (see 16.29) relating to computer programs et al is to be included on the front page of the A document. If other material is to be omitted, the minute should include details of an appropriate nonstandard text.]

If the pages of a computer program, sequence listing or other ancillary material do not comply with r.14 and Schedule 2 the formalities examiner should report accordingly, but no objection should be raised unless the pages are to be included in the A document or are unsuitable for reproduction in response to requests on Form 23 after publication. (If the applicant retains the pages in the specification, objection should be made during substantive examination).

FINAL PROCEDURE

When one or more notices is to be included on the front page of the A document, the formalities examiner and/or the search examiner should give appropriate instructions.

[Where appropriate, the search examiner should add a minute to the dossier instructing Formalities which of the standard texts (see the "Notices for front page of 'A' document" form in annex 8A of the formalities manual) are to be included on

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s.19(2)

the front page of the A document. When necessary, a minute should also be added to the dossier outlining the exact wording of any non-standard texts to be inserted. A PSM message should then be sent to the appropriate Formalities Group/Examiner. This data will subsequently be inputted to COPS for preparation of front page data. Note that, the text of pre-printed notices should not be altered in any way, save the non-standard text relating to drawings omitted under s.15(5) or (6) which requires completion.]

[As part of the pre-A publication checks, formalities examiners should check all documents and consider if personal or sensitive information contained therein should be redacted for Ipsum. After publication, formalities examiners should check all incoming documents as they are received and redact as necessary.]

[The Enhance feature on PDAX may be used to redact any personal information, either at the head or foot of the correspondence or in the body of the text. Once this has been done, "set handle" is applied to the redacted version and the redacted document is annotated as "OLFI" to enable post–publication display of the letter on Ipsum.]

16.30 When the search examiner sends the application for issue of the search report and of any documents cited thereon (see 17.104, 17.104.1) or of a report that a search would serve no useful purpose he should normally authorise publication of the application, regardless of whether this is yet due, whether or not there are any outstanding formal objections and whether formal or formula drawings are awaited. He should not however authorise publication if the abstract is awaited.

[The search examiner should record the appropriate COPS processing status in PROSE. Processing status 5 "May be s.16 published" will apply to the majority of completed searches and CS&Es (including divisionals). It applies when the application will be in order for A-publication with respect to the examiner's requirements once the search report is ready to be issued. It also applies to PCT national phase applications which have been classified and are ready for republication. This status should also be used when an application is in order for publication having previously had a status recorded as processing status 2 (see 18.47) or 3. Processing status 3 "Searched – Do not s.16 publish yet" should be used when a formal search or CS&E has been carried out but for some reason the examiner needs to see the dossier again before it is sent for publication. This is most often used when no abstract has yet been filed.]

16.31 If formalities have been complied with and unless accelerated publication is requested (see 16.04), the application should be sent for publication 16 months and 3 weeks after the earliest declared priority date or, where there is none, the filing date, provided that 4 weeks have elapsed since issue of the search report. When accelerated publication is wanted the application should be sent for publication immediately because the normal 4 week wait after issue of the search report is taken to be waived.

[On receipt of the application the formalities examiner will use COPS to check the date of intended publication. The formalities examiner will either accept this date or overtype with "today's date" for accelerated publication. Once this COPS action has been completed the application enters the A-publication queue. At the start of the publication cycle the appropriate applications are picked and transferred to Publishing Section.]

[Deleted]

16.32 If formalities have not been complied with or if the 16 months and 3 weeks has not yet passed (provided accelerated publication is not requested) publication should be deferred, the application being sent for publication at the appropriate time and after any objections have been met without, in general, being referred to the examiner. Applications should however be referred to the search examiner if necessary upon the filing of

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amendments or formal drawings or formula drawings (see 15A.22, 16.09 and 16.18), or if a letter needing the examiner's attention or a request for further search is received. In such circumstances, the documents selected for publication may need amending before publication.

[Deleted]

[Once all the formalities are complied with, the application should be transferred to Publishing Section or enter the A-publication queue, or the application should be referred to the search examiner, whichever is appropriate.

[When the search examiner has dealt with any such matters referred to him after issue of the search report (see the second sentence of 16.32), then he should refer the application to the appropriate formalities group, after setting the appropriate COPS status if he has not already done so (see list in 18.47). The formalities group will resume responsibility for forwarding the application to Publishing Section at the appropriate time.]

Correction of printer's errors

16.33 If the A document contains a printer's error, whether in the specification, the bibliographic or classification data or in a footnote (see 16.29) or in the search report, it may be corrected by the issue of an erratum. In this context, "printer's error" is interpreted broadly to embrace any error originating within the Office or during the publication process. However, it does not extend to errors made elsewhere, such as by the applicant. (See also 14.191).

[An erratum should not be issued to correct an error in the specification which is detected by the search/substantive examiner unless the error is significant, in the sense that it misleads or introduces doubt. An erratum should be issued for an error in the specification which is notified by the applicant or by a member of the public or for any error in the bibliographic or classification data or the footnotes or for an omitted footnote. An erratum should also be issued whenever an error is found in an external search report or when an additional citation is found before A-publication (see also 17.105), but where in each case it is too late for the amended or corrected external search report form to be incorporated in the A document. No erratum is necessary in respect of citations found after A-publication.

[As soon as a search/substantive examiner appreciates that the classification assigned to an A document is erroneous and/or does not reflect fully the disclosure of an inventive concept or other significant disclosure, the COPS record should be amended to indicate the classification that the document should have carried at the date of A publication.

[When the search/substantive examiner detects a significant error in the specification or any other error requiring correction, the relevant formalities group should be instructed to arrange for the production and issue of an erratum. Where the correction relates to classification or field of search bibliographic data, is in the text of the specification or abstract, or is complex, the search/substantive examiner should give precise instructions concerning the content and location of each deletion and insertion before referring the case to the formalities group. When errors are brought to the attention of a formalities group other than by search or substantive examiners, the formalities group will not normally consult the relevant examiner except in respect of technical matters.]

Section 16(2)

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The comptroller may omit from the specification of a published application for a patent any matter -

- (a) which in his opinion disparages any person in a way likely to damage him, or
- (b) the publication or exploitation of which would in his opinion be generally expected to encourage offensive, immoral or anti-social behaviour.
- 16.34 While the search examiner should not specially look for material of the kind referred to in s.16(2), where he becomes aware of such matter which is in his opinion both evident and blatant he should take steps to see that it is withheld from publication. The published specification will contain a statement at the place(s) concerned that "certain matter has here been suppressed from publication under Section 16(2)". If a specification is either completely offensive or is so riddled with offending matter that publication of any text would appear ridiculous, the whole of the specification may be suppressed. Care should be taken that any matter which it is considered should be omitted under s.16(2) is not only absent from the A document but also will not become open to public inspection after the publication date. Rule 51(2)(d) provides the same power in respect of documents other than the published application (see 118.07).
 - [If formalities notice matter which may require omission under s.16(2) the document code should be changed to CONFIDENTIAL and the document annotated as "Not Open to Public Inspection". A minute should be added to the dossier clearly and unequivocally identifying the matter to be suppressed and the reasons for it being withheld from publication. A PDAX message should then be sent to the examiner.
 - [If the examiner becomes aware of matter which may require omission under s.16(2) he should immediately ask formalities to change the document code and annotate accordingly.
 - [The Deputy Director should be consulted and the examiner should use the "Enhance" function on PDAX to blank-out the matter concerned. Once this has been done the redacted version should be annotated appropriately and given the appropriate document code (e.g. DESC). The original version should retain the document code CONFIDENTIAL and should not be made public following publication.]
 - [If the highlighted material is not considered offensive or libellous, and may therefore be open to public inspection, the examiner should write a minute to formalities asking them to reinstate the original document code, remove any annotation and set public following publication.]
- 16.35 Statements which are critical of prior inventions (whether identified, eg by reference to specific patents, or not) should be regarded as falling within the scope of s.16(2)(a) only if they are explicitly disparaging of a person (natural or corporate) or if by very clear implication they reflect adversely on the character or competence of any person. Mere statements that prior inventions are in some way unsatisfactory cannot be omitted under s.16(2)(a).
- 16.36 The question as to what would be considered to encourage offensive, immoral or anti-social behaviour is discussed in paragraphs 1.41-1.45.
- s.97(1)(b)

 16.37 Although there is no appeal from a decision of the comptroller under s.16(2), the applicant should be informed that matter is to be omitted under this subsection from his application as published. The substantive examiner may be required to consider whether the matter may be restored before grant.

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No useful search possible: reasons

- a) No useful search possible because the invention is obscure
- b) No useful search possible because the invention is not patentable
- c) No useful search possible when the invention is not novel or is obvious

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FINAL PROCEDURE

DOCUMENTS FOUND OR CONSIDERED IN FULL AFTER ISSUE OF THE SEARCH REPORT

SECTION 17(6)

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17.01 This section sets out the conditions necessary for an application to proceed to search, makes provision for carrying out the search and for reporting the results, provides that in some instances a search may not be performed or may not be completed, specifies how the search shall be conducted in the case of an application which relates to more than one invention, and authorises the performance of supplementary searches. Rule 27 is particularly relevant to this Section.

Information security: a reminder

- s.118(2) 17.01.1 The initial search at least for UK patent applications is carried out before A publication, and so most of the guidance in this section relates to pre-publication actions. Before A publication, the application, the search report, and any other documents or information concerning the content of the application (other than that prescribed under s.118(3)) must be protected and must not be communicated to anyone outside the Office other than the applicant or his designated representative see 118.16-118.16.1 for further guidance on these issues.
 - 17.01.2 More generally, in all cases, whether pre-or post-publication, formalities examiners should ensure that any communications (including telephone conversations) are directed to the intended recipient.

[Where correspondence from the Office is reported as never having arrived at its intended destination, or is reported as being misdirected or delayed, this fact should be recorded by sending a minute to the relevant formalities group with any relevant details. Use of r.111 to extend a deadline may only be authorised by the relevant Head of Administration (see 123.47.1).]

Section 17(1)

The comptroller shall refer an application for a patent to an examiner for search if, and only if-

- (a) the comptroller has referred the application to an examiner for preliminary examination under section 15A(1) above;
- (b) the application has not been withdrawn or treated as withdrawn:
- (c) before the end of the prescribed period-
 - (i) the applicant makes a request to the Patent Office in the prescribed form for a search; and
 - (ii) the fee prescribed for the search ("the search fee") is paid;

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- (d) the application includes-
 - (i) a description of the invention for which a patent is sought; and
 - (ii) one or more claims; and
- (e) the description and each of the claims comply with the requirements of the rules as to language.
- r.27(1) 17.02 The request for search must be made on Patents Form 9A; the time r.22(2) allowed for filing this is prescribed in r.22(7), (see also 15.52 15.53). Any further search under s.17(6) or supplementary search under s.17(8) on an application should be requested on Patents Form 9 (for applications filed before 1 January 2005) or Form 9A (for applications filed after this date).
 - 17.03 Before the application is sent to an examiner for search the requirements of s.17(1) must have been met, this includes the payment of any excess claims fees. The excess claims fee is part of the search fee therefore it follows that if the excess claims fee is not paid, the Patents Form 9A is considered not to have been filed.

[If any application does not meet the requirements of this section, on payment of the Application Fee, these will be requested in a preliminary examination report issued under s.15A by the Formalities Examiner (see 15A.20). Once the requirements of section 17(1) have been met, the Formalities Examiner will send the application to the appropriate examining group via the ESO.

[The application should be inspected immediately upon receipt in the examining group to ensure that it has been correctly allocated. Any case found to be incorrectly allocated should be transferred as quickly as possible. This should be done by direct enquiry on the part of the Deputy Director or of the search examiner in charge of the heading to which the case has been allocated. Difficult re-allocations should be settled between Deputy Directors. When transfer has been agreed to a heading in another examining group, a minute titled "ALLOCATED [HEADING] [GROUP]", should be added to the dossier and the appropriate PDAX message should be sent to the Examination Support Officer in the search examiner's group. The Examination Support Officer will then send a PDAX message to the Examination Support Officer responsible for the correct heading. Since it is for the search examiner to decide the subject matter to be searched, the dossier minute should indicate which headings have been considered and the subject matter for which search is or is not appropriate.]

[Private applicant cases

[Applications from private applicants are typically dealt with by the Private Applicant Unit (PAU). Unless the application has been identified as a potential 'no case' (see 15A.03), most applications from private applicants will be sent to PAU after preliminary examination in the normal way. PAU examiners will consider whether the application is insufficient under s.14(3), or clearly unpatentable under s.1(1)(c) or (d) because it lacks industrial applicability or falls within one of the excluded categories. If the PAU examiner considers that the application has no patentable content for one of these reasons, then the applicant should be sent a letter under the action before search (ABS), or action before combined search and examination (ABCSE), procedure described in full at 17.94.5-9, informing him of the shortcomings, and giving him the option to withdraw (with a refund of the search fee) or continue with the application.

[Otherwise, the PAU examiner will perform a search sufficient to identify documents relevant to novelty and inventive step. If the application contains subject matter that requires specialist knowledge, PAU examiners will consult with the relevant examination group, or transfer the case to that group.

[If the search provides strong evidence of a lack of novelty or inventive step, and

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combined search and examination has been requested, the PAU examiner may defer the substantive examination and offer the applicant the option of withdrawing their application and receiving a refund of their examination fee.

[Further information on PAU workflow and process can be found in PAU desk notes.]

[If it appears that an invention is not patentable but may be suitable for some other form of protection, care should be exercised in suggesting this to applicants. It is important not to imply that such protection will be obtainable, nor to indicate that the subject-matter is appropriate to an application for design registration, without first referring the matter to Designs Section. If, e.g.: because of urgency, the opinion of Designs Section is not obtained, then the advice given to the applicant should be in general terms, e.g.: that it may be possible to take advantage of some other form of protection such as that afforded by design registration or copyright; the pamphlet "How to register a design" being enclosed.]

17.04 [deleted]

17.05 The search should be undertaken as promptly as possible, not only so that the application may be sent for publication in due time (see 16.31) but also so that the applicant can have an early opportunity to consider the search report and any documents cited (see 17.104.1). He will then be in a position to decide whether to take any action, such as the filing of amended claims or withdrawal, before preparations for publication have been completed. Moreover an applicant who files an application either without a declaration of priority or with some of the twelve-month priority period remaining may want to receive the search report in sufficient time to enable him to decide whether to file abroad under the International Convention.

[The aim should be for a search to be done as soon as possible. Where a backlog of work begins to build up a search examiner should ensure that his Deputy Director is made aware of the situation. The Deputy Director should make it one of his primary objectives to ensure that the work of searching is fairly and reasonably distributed among the members of his group.]

17.05.1 If the applicant has requested for an accelerated search to be performed, this should have been marked clearly to ensure prompt action is taken. Requests for acceleration should be in writing, and may be made electronically using the Office's online patent filing services (as a covering letter). It is possible for an examiner to exercise discretion to accept an acceleration request by email; however this practice should not be encouraged. A request for an accelerated search, examination or CSE should be allowed if an adequate case specific reason is given; requests giving no (or inadequate) reasons should be refused. Where requests for accelerated search and publication are made at the same time, but the request for accelerated search is refused, the request for accelerated publication should also be refused. Once search has been completed in the usual timescales, the applicant may again request accelerated publication. Awareness of a potential infringer, a need for a faster processing to secure an investor, or a need for a granted patent in order to subsequently request accelerated processing under the Patent Prosecution Highway (PPH) at another office (see 18.07.1 for details of PPH processing at this Office) are likely to be accepted as adequate reasons for acceleration. These reasons are also set out in paragraph 6.2 of the Patents Fast Grant Guidance. In addition, where the applicant requests acceleration in order to take advantage of the Patent Box, the applicant should explain how a delay in grant would have a significant cash flow impact because of its effect on eligibility for the Patent Box; however, detailed financial records are not normally required. (A significant cash flow impact would be one which might affect solvency of the company or its ability to obtain significant financing or to continue with investment or research programmes). For Green Channel requests, the applicant must state in writing which action(s) they wish to accelerate, and provide an appropriate explanation of how their application relates to a "green" or environmentally-friendly technology. Examiners should not conduct any detailed investigation into such Green Channel explanations, but should refuse Green Channel requests if they are clearly unfounded, for example if the application relates to a perpetual

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motion machine.

What constitutes an adequate reason for acceleration may depend, in part, on 17.05.2 the applicant's actions. For example, any delay in filing the Form 9A may be taken into account, particularly if acceleration is being requested in order to obtain a search report before the end of the priority year, and filing a timely Form 9A earlier in the year would have achieved this. Where search and examination would normally be combined, similar considerations should be made when deciding whether to allow accelerated treatment, and if this is acceded to, both the search and examination of the application should be performed at the same time. The applicant should always be informed as soon as possible whether the request has been accepted or refused, and a record of this decision and its reasons should be placed on the dossier. If the request has been accepted, the search (or combined search and examination) report should be issued in a timescale which is in line with any existing Agency targets. If the search/CSE report is itself issued immediately then there is no need to send a separate acknowledgement, but an indication should be included in the covering letter to confirm that processing has been accelerated. It should be assumed, unless an explicit request is made, that accelerated publication is not required. A regular Notice to this effect appears in the Journal. (See 18.07.3 concerning a request for confidentiality relating to accelerated processing of an application.)

[A case on which accelerated search has been requested should be identified by the appropriate dossier cover label and an acceleration PDAX message. A GREEN CHANNEL label should also be added to the dossier cover where the acceleration request is under the <u>Green Channel</u>, and this should be recorded on <u>COPS</u> using the function Record Green Channel Patent Application (REC GRE). The examiner in charge of the classification heading concerned may decide whether to allow such requests]

17.06 A request for refund of the search fee is normally acceded to if it is received before a report under s.17(5) has been issued. This refund is a matter of discretion; it is not a right. Where a refund is requested after an ABS letter has been issued see 17.94.9, and see 17.96 where a refund is requested after the issue of a report under s.17(5)(b).

[The request should be dealt with by the formalities group; if the application has already been sent to an examining group the group should be informed immediately. A search report should not be issued after receipt of a request for a refund, even if the search has already been performed.]

[Sections 17(2) and 17(3) Repealed]

17.07 These subsections which covered preliminary examination of an application ceased to have effect when the Regulatory Reform (Patents) Order 2004 (S.I. 2004 No. 2357) came into force on 1 January 2005. For applications filed after this date, preliminary examination is covered by s.15A. For applications filed before 1 January 2005, preliminary examination is still performed under sections 17(2) and 17(3). The procedure for preliminary examination is described in 15A.01 et.seq.)

17.08 to 17.29 [deleted]

Section 17(4)

Subject to subsections (5) and (6) below, on a search requested under this section, the examiner shall make such investigation as in his opinion is reasonably practicable and necessary for him to identify the documents which he thinks will be needed to decide, on a substantive examination under section 18 below, whether the invention for which a patent is sought is new and involves an inventive step.

17.30 The search examiner must therefore put himself in the position of the substantive examiner and consider what kind of evidence he would require in order to make an objection of lack of novelty or inventive step (see also s.3). At the same time he may also

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need, in order to carry out the search, to come to an opinion on such matters as clarity of the claims and unity of invention. Also, although the search under s.17(4) is concerned solely with providing evidence touching on whether the invention satisfies the conditions for patentability set out in s.1(1)(a) and (b), it may in some cases be necessary at this stage for the search examiner to form an opinion as to whether the invention is excluded from patentability on other grounds. The search examiner should however act on these opinions only to the extent that this is necessary in order to carry out the search (but see 17.67, 17.94-17.98.1). Views formed at this stage do not bind the substantive examiner.

17.31 It is not possible, given the wide variation in nature and scope of protection sought in different applications, the great variety of technical subjects and the wide divergence between classification systems in different subject-matter areas, to give more than general guidance as to how the search is to be performed. The search examiner is required to make "such investigation as in his opinion is reasonably practical and necessary", and while what is set out in the following paragraphs will apply to most applications, an unusual case may require an unconventional approach.

PREPARING FOR THE SEARCH

Assessing the invention

- 17.32 In order to carry out his statutory duty the search examiner must read as much of the specification as is necessary to obtain a clear understanding of the essential nature of the invention. The main claim itself may give a guide to this, particularly if it is in the two-part form prescribed by Rule 43(1) EPC and Rule 6.3 PCT, with a preamble setting out the state of the art followed by a statement of what characterises the invention. (This type of claim is also sometimes referred to as the Germanic form of claim or, in the US, a Jepson claim). A discussion in the specification of the prior art and/or of the problem to be solved by the invention may also provide, in conjunction with the main claim, a good guide to the essential nature of the invention. Neither the search examiner nor the substantive examiner is however bound to accept the applicant's assessment of what constitutes the inventive step.
- 17.33 Where there is no discussion of the prior art in the specification the search examiner will have to rely on his own knowledge to form an opinion as to what the invention is. If he is unable to do this a preliminary search may be necessary before the nature of the invention can be established with reasonable certainty.
- The extent to which it is necessary to read the description and the dependent claims will therefore depend on the case. Although the search examiner need not study all the details of the description, he should consider them to the extent that this is necessary to understand the workings of the invention, the problem to be solved, the way in which this solution is arrived at, and whether all of the features specified in the main claim as characterising the invention are in fact technically essential in the sense that the invention could not be performed without them, or whether some could, without ingenuity, be replaced by equivalents or be omitted altogether (see 14.114-14.116.2). It is also necessary to establish whether there is unity of invention (see 14.157-14.168), particularly where there are two or more independent claims (but see 14.164); if there is not unity the search must be directed to the first invention claimed (see 17.106 and 17.107). See 19.23-19.26 for practice relating to trade marks in patent specifications.
- 17.34.1 For cases where the original claims were filed after the filing date of the application, the search examiner should also make a prima facie judgement of whether they are supported by the description. If support is clearly lacking (e.g. the claims include additional features not present in the description, or the scope of the claims is broader than the original teaching in the description), amendment will in due course be necessary to comply with s.14(5)(c) (see 14.145). The examiner should therefore direct his search to what the claim might reasonably be expected to cover after amendment (see 17.36). It is essential that this is drawn to the applicant's attention at the search stage (see 17.83.2) in order for the

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applicant to decide how he wishes to proceed, since this defect may have serious consequences if significant amounts of technical disclosure are unsupported.

[A minute should be placed on the dossier to state whether late-filed claims are supported or not. If unsupported, the internal search report form should make clear if/how the search has been restricted. Where the claims contain additional features not in the original description, clause SC5 (at search stage) or SC6 (at CS&E) should be used. Private applicant versions of both these clauses are available (SC5PA and SC6PA).]

r.31(5)(a) s.117(1) 17.35 The applicant is allowed to amend the specification with the comptroller's consent before being informed of the search report, although only corrections under s.117(1) or amendments to the claims will be published in the A specification (see 16.20-16.23). When amendments are proposed before the search, the search examiner should consider their allowability, having regard to ss. 14(3), 14(5) and 76, and consent to those found allowable. Where relevant, an allowable amendment should be taken into account in determining the search strategy. If, during combined search and examination, a proposed amendment is found not to be allowable but would not, in any event, affect the search strategy, the amendment should be refused and the applicant advised accordingly, with reasons. Where search only is being undertaken and either it is impracticable for the search examiner to determine the allowability of a proposed amendment, or he considers that it is not allowable, consent should be withheld and the applicant advised that, pending consideration of the amendment at the examination stage, the amendment will be treated as a voluntary amendment filed under r.31(3) on the date of issue of the search report (see 19.15-19.19). If the proposed amendment is not allowable and would have affected the search strategy substantially, consideration should be given to consulting the applicant to determine whether the search should proceed in respect of the invention claimed in the application as filed. Amendments filed before A publication and unable to be published in the A specification will be incorporated in the specification and laid open to public inspection after A publication.

[The appropriate version of SC1 will usually serve to advise an applicant that consent has been given under r.31(5)(a) to an amendment filed before issue of the search report. Where search only is being undertaken and consent to an amendment filed before issue of the search report has been withheld, the other version of SC1 may be used to inform the applicant that the amendment will be treated as a voluntary amendment filed under r.31(3) and that it will be considered later at the examination stage.

[Purported claims which cannot be regarded as claims within the meaning of s.14 (eg claims to a sum of money), or claims which have clearly been filed on the wrong case may be replaced and if such replacement claims are filed within the prescribed period (see 15.50), they may be regarded as original claims for the purposes of the search.]

Matter to be searched for

17.36 The search should ideally cover all the subject-matter to which the claims are directed, or to which they might reasonably be expected to be directed after amendment (see also 17.34.1 and 17.83.2). On the other hand the search must be limited by what is practicable and reasonable. The completeness of any search is limited by the inevitable imperfections of any classification system and its implementation, and the vagaries of search words, and a complete search may not be justified, bearing in mind that the cost must be kept within reasonable bounds. The search examiner should therefore do his best within the time that is reasonably available to minimise the likelihood of failing to find existing highly relevant documents.

s.125

17.37 Although sometimes the subject-matter to be searched for will be based on what is defined in claim 1, as interpreted with due regard to the description (see 17.34), there are many instances in which a somewhat broader search will be necessary. This would be the case if there were a later, broader, independent claim linked to it by a single

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inventive concept, for example if claim 1 were directed to apparatus, defined narrowly, and a later claim to a method, defined more broadly. Also there may be a later claim which is formally dependent on, but is not within the scope of, the main claim (see 14.164), or there may be a specifically described embodiment, or a generalising statement in the description, which is not consistent with claim 1 (see 14.144). It is desirable that account be taken of such matters at the search stage in order to minimise the need for further searching at the substantive examination stage should the main claim be broadened on amendment. Moreover, it will usually be necessary for the matter to be searched for to be broader than claim 1 in some respects in order to cover inventive step as well as novelty (see also 17.50).

- 17.38 If what is claimed constitutes a novel application of what can be shown to be a known technique, material or structure, chosen for properties useful in the claimed field, the search will need to be directed to establishing whether there is anything in the prior art which points towards its use in the field in question, or whether it has been recognised as a generally available option in circumstances where the need for those properties arises. If either of these circumstances applies, or if it can be argued that the technique, material or structure and its properties would form part of the common general knowledge of the skilled person in the field in question, then the relevant disclosure(s) should be cited for lack of inventive step. The onus is then put on the applicant at substantive examination to argue that the skilled person in that field would be unaware of, or have reason to disregard that technique, material or structure.
- 17.39 If all or part of what is claimed is functionally equivalent to that which is known in the particular field, search should be directed to establishing this equivalence, unless it appears to be sufficient to rely on common general knowledge. If however the differences between what is known and what is claimed are matters of design having no functional significance it will normally be sufficient to assume that such differences do not provide a basis for establishing an inventive step, and no extensive search should be made for the non-significant differences.
- 17.40 If the claim is directed to a compound defined by a general chemical formula, the search should primarily be directed to finding compounds falling within the scope of the claim (preferably those described in the worked examples), and secondarily to discovering documents which disclose generic formulae overlapping the generic formula claimed. When citing documents disclosing generic formulae, citations relating to the same purpose as the application being searched should be cited in preference to those where a different use is envisaged.
- 17.41 If an invention is defined by reference to parameters (of a material or composition) which are not usually specified in the documents searched, and also by reference to a method of producing the material or composition, a search for the method per se may suffice. If the claim does not specify a method, reference data may be utilised to identify materials likely to possess the specified parameters, with a search then being made for such materials, and/or a search may be made for disclosures of prior art materials akin to those exemplified in the application and which might reasonably be expected to possess the required properties. Prior disclosures of such likely anticipations should be cited and the onus of distinguishing the invention thus put upon the applicant. The same procedure may be used if difficulties arise with the use of parameters in a method claim. (See also 2.18-2.20, 3.88-3.93 and 14.121).
- 17.42 If the search examiner is of the opinion, after considering the whole specification, that the claims as they stand do not clearly define the invention, when for example because of an inappropriate choice of wording or terminology the claims in fact define something different from what has been described or unwittingly embrace matter which is well known, then the search should primarily be directed to what the search examiner perceives to have been invented. Documents may be cited against the claim as presently worded, but undue time should not be spent in finding "paper citations" which are likely to be rendered irrelevant when the claims are clarified.

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No special effort need be made to carry out a complete search in respect of an unduly broad or speculative claim (see 14.152-14.156). The search should be directed to that aspect of the claim which is supported by the description and which it is thought likely will form the subject of the claim if it is amended in response to an objection to its undue breadth. For example if an electrical servosystem is described and the claims also embrace a fluid pressure system, but it is not apparent from the description how a non-electrical system would be made, extension of the search beyond the electrical field would not normally be justified. If it is not possible to predict what is likely to be claimed after amendment or if an unduly broad and speculative claim appears to be merely a device for giving an impression of unity of invention, then the search examiner should use their judgement to decide the best course of action to follow as set out in 17.110.

Acknowledged prior art

17.44 If the specification acknowledges specific prior art, identified by document reference, the search examiner should consider the documents referred to, preferably before beginning the search, unless it is reasonably certain from the context that such documents are unlikely to be relevant to the issues of novelty and inventive step. Such declared prior art is often the most relevant available and may render the invention claimed obvious, or even, on occasion, anticipate it. Any such documents considered to be relevant should be reported in the same way as documents found as a result of the search. (See also 17.91)

[Where copies of acknowledged prior art documents are needed, they should be ordered at the first opportunity. However, where it is clear that the delay in obtaining the copies is going to be excessive, the search examiner may perform the search before receiving them. The action taken by the search examiner with regard to such documents and copies thereof should be recorded on the internal search report. If a document subsequently becomes available to the search examiner after issue of the external search report and proves to be relevant, then the search examiner should send a copy of it to the applicant together with SL5 or SL5B, as appropriate.]

- 17.45 If the search examiner is unable to obtain through normal channels a copy of an apparently relevant document he should contact the agent or applicant and make an informal request for a copy. (In the case of a reference to a German Gebrauchsmuster, the abstract (available in the Science Reference Library) should first be consulted). Such a request should still be made by the search examiner even if the search has already been done before the normal channels are exhausted or is likely to have been done before the request is answered. If the agent or applicant is unwilling to comply, or if to wait for him to do so would unduly delay s.16 publication, the matter should not be pursued. A formal request should not be made, nor should a translation of a foreign language document be asked for (see also 18.10, 89B.11). If the document is not available to the search examiner when the application is due to be sent for publication it may be included in the search report if the reference in the specification indicates that the document may be citable.
- 17.46 Documents said to be relevant which are referred to in a letter from the applicant or agent should be dealt with in the same way as prior art referred to in the specification.
- 17.47 Unidentified prior art referred to in the specification which appears to be relevant to the issues of novelty and inventive step should not be included in the search report, although it may be noted on the internal search report and considered at substantive examination (see 18.67).

Using the results of an earlier search

17.48 If the application claims priority from an earlier UK application the report of any search carried out on the earlier application should be inspected. (Even if it is merely necessary to update the previous search no refund of the search fee should be made).

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[It is necessary for the search examiner to be aware of any search performed on the earlier application. Therefore, if such a search has been carried out, the formalities examiner should annotate Form 1 and send the appropriate message to the search examiner. The examiner may import the ISR of the priority case into a dossier. If the earlier ISR is imported, then the examiner should ensure that the earlier ISR document is clearly distinguished from that of the application in question by appending the annotation "ISR of related case". The copy function can be used to copy it across to the new dossier in which case it will retain its original document code. If no search has been made on the earlier application Form 1 should be annotated accordingly.]

[Deleted]

17.49 Likewise in the case of a divisional application the search done on the parent application should be consulted, see 15.38. (For refunds in such cases, see 15.47-49). It may also be useful to inspect the search report of an earlier pertinent application referred to in the specification or found in the course of the search.

PERFORMING THE SEARCH

- When the search examiner is satisfied that he has understood the essential nature of the invention he should draft a statement of the critical matter (search statement), any non-essential limitations in the claims being ignored (see 17.34, 17.36-17.37, 17.42-17.43, 17.53 and 17.57). The statement should as far as practicable be such that if no anticipation of it is found it can confidently be concluded that what is claimed is both new and inventive (see also 17.58). That is, if the critical matter is novel the invention claimed cannot be said to be obvious.
- 17.51 The search for the critical matter should then be made. The search examiner must use his knowledge and experience to formulate a search strategy, deciding which databases or other sources could contain citable documents and establishing the order in which these should be searched, taking into account all available classification systems and suitable search words. This decision depends not only on the technical character of the critical matter (whether corresponding to a broad concept of wide application or whether highly specific in a narrow technical field), but also on the manner in which the search material is organised.
- 17.52 When formulating the search strategy account should be taken both of the likelihood of search in a given area being fruitful and of the amount of effort needed to search that area. Thus search having a low (but finite) chance of success in a particular area may be justified if the search would be short, but not if a disproportionate amount of time would be necessary, and may even be done before a considerably longer but potentially more fruitful search.
- 17.53 If possible, the search statement and search strategy should be determined provisionally before beginning the search. Since the critical matter depends not simply on what is disclosed and claimed but also on its relationship with the state of the art, the search examiner must always be prepared to revise both during the search, and in some cases a preliminary search may be necessary before either can be decided upon.

Field of search

17.54 Although any matter (subject to certain specified exceptions), including prior use, which forms part of the state of the art (see s.2) may be cited in support of an argument that an invention is not new or does not involve an inventive step, for the purposes of the investigation under s.17(4) the search examiner is only required to consider documentary evidence. There are no limits as to where the prior disclosure was published. Publication anywhere in the world becomes effective on the date on which it takes place. This publication date must (except in the case of an application forming part of the state of

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the art by virtue of s.2(3)) be earlier than the priority date of the invention being searched. For search purposes, the priority date is that indicated in accordance with 17.74.

In considering internet disclosures, the search examiner should cite any documents which are considered to be highly relevant, even if no publication date can be established or there is a possibility that the document was published later than the priority date of the invention being searched. Such documents should be cited under category X or Y with an accompanying note in the covering letter to say that a 'publication' date cannot be established but that the disclosure appears highly relevant and there may well be a related patent application which does form part of the state of the art (see 17.83). When updating the search, the examiner should search for such corresponding patent applications. Where the application in suit has not been published the examiner should not contact the owner or author of any such prior art in an attempt to establish a publication date. Following publication of the application in suit examiners may contact a third party author if they feel such action is appropriate, however consideration should be given to the efficient processing of the application and unnecessary investigation should be avoided.

The documentary evidence may also include descriptive matter, published subsequently to the relevant priority date, but indicating that the invention was known before that date. Thus the search report may include a document containing a description of the invention together with a statement that it was used publicly before its priority date or that an oral description thereof was made public, e.g. in a lecture before a learned society, before that date (see 2.27). Non-documentary evidence of prior use should not formally be cited at this stage. However, if the search examiner is aware, either from personal experience or from information from another examiner or from a member of the public (see 21.12-21.13), of an instance of prior use which is apparently destructive of the novelty or inventive step of the invention claimed, all the relevant facts should be communicated to the applicant - provided sufficient circumstantial details of the prior use are available to enable the applicant to make his own independent enquiries. Therefore a vague or anecdotal allegation of prior use should not be pursued. (See also 18.24 for the procedure at examination stage).

[The letter accompanying the search report should be used for bringing an instance of prior use to the applicant's attention. In no circumstances should the search examiner offer to make the anticipatory matter (or a drawing or photograph of it) available to the applicant or to third parties, unless provided by a member of the public. This is in order to avoid the involvement of the examiner in his personal, as opposed to his official, capacity in the patent proceedings.]

17.55 The search examiner consults documents available through online databases and may supplement this search with an internet search and/or a search through paper documents held in the Office. Online databases include patent databases (such as the European Patent Office Documentation (EPODOC) and Derwent World Patents Index (WPI) databases) and non-patent literature databases, which often cover specialist areas of technology. The choice of databases and tools used to perform the search will depend on the subject matter of the application, and should be based upon the examiner's judgement of where relevant prior art is likely to be found.

[The search should not rely exclusively on CPC classification terms as there can be a delay between publication of non-EP/US patent documentation and its classification in CPC, and not all national document collections are classified to that scheme (for example most JP, KR and CN patent publications are not classified to the CPC). Therefore, unless the search is deliberately curtailed (see 17.83(d), 17.83(e) and 17.117), a search should also cover documents only classified to IPC (either directly or by word-only searching). The examiner should also consider whether a FICLA and/or FT search would be appropriate.]

17.55.1 Where a patent document is found during the search which is relevant for novelty and/or obviousness, the examiner should consider whether to perform a citation search on that document, to identify documents cited against it, and to identify other patent documents against which it has been cited. While such a citation search is normal practice

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for relevant patent documents (ie those which are to be cited as "X" or "Y"), this may depend on the factors such as the overall relevance of the document, the numbers of documents cited against it and the circumstances of the case; for example, if there are numerous novelty citations it is unlikely to be useful to perform citation searches to identify yet further relevant documents. Similarly, when a published case equivalent to the application in suit is found, citations on that case should generally be checked. This is discussed further in the discussion of the top-up search (see 17.115) as such equivalents will not normally be published at the time of the initial search.

[Citation searches can be carried out using COMBI, and noted in the internal search report. For citation search against family members of the application in suit, see 17.115]

17.56 As a matter of course and as necessary, to establish common knowledge in an art for the purpose of establishing the presence or absence of an inventive step the search may extend to other readily accessible published information e.g. standard text books and technical review articles. If, in any particular case, the search examiner is aware of a relevant prior publication, he should include it in the search report.

Search strategy

17.57 The areas most likely to contain the most relevant documents will normally be those relating to the technical subject with which the invention, or specific embodiments of it, is concerned. However if the critical matter is of broad application but is claimed narrowly, it may be appropriate first to search disclosures of general applicability, and it may then be unnecessary to extend the search to areas more specifically concerned with the particular manufacture claimed. For example if the claim were directed to a vehicle body or container comprising a particular structural joint, but the critical matter appeared to consist of the joint per se then the primary search would be in the areas relating to such joints. The search examiner should keep a look-out for any documents disclosing the use of similar joints in vehicle bodies or containers or in an art close enough for the document to be used in conjunction with a disclosure of the joint per se to show that it would not be inventive to use particular joints in this way. If an anticipation of the critical matter has been found, extension of the search to those areas concerned with the higher level of organisation (in this case vehicle bodies or containers) may not be necessary, particularly if a supporting document of the kind referred to in the preceding sentence has been found. This would also be the case even if no anticipation of the critical matter had been found if it could be said with reasonable certainty that if a document disclosing the joint per se did exist it would be found there.

17.58 If the invention is a prima facie new organisation for which documents would need to be found showing it to be known or obvious as a whole if an objection were to be sustainable, then a single search in the fields most relevant to such an organisation will generally suffice, and there will not normally be any point in searching at different levels of organisation. If the invention appears to be a non-inventive combination, for example a particular element in a particular machine, a search to establish whether the combination is known should be made as a matter of course, unless in the search examiner's opinion the chances of finding an anticipation are remote. If no such anticipation is found or searched for, search should be considered for the element and the machine per se, and/or for documents which could be used to argue the non-inventiveness of the combination by showing that the particular element is a conventional option in the relevant technical field. For example if a central heating boiler having a particular fuel spraying nozzle were claimed, and a disclosure of the same nozzle in an engine were found, a further document describing similar nozzles in a way which implied that they could be used in both boilers and engines would be highly relevant. Separate search statements should be written for the respective searches, which may need to be carried out in different headings. If both the element and the machine are sufficiently well known for this to be asserted without documentary evidence, and the obviousness of making the combination can be argued from common general knowledge, then the novelty search may suffice.

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- 17.59 In some circumstances it may only be feasible to make a novelty search, ie a search limited to the claimed context even though the characterising part of what is claimed is not peculiar to that context. This could arise if the claim were directed to the use of a generally applicable technique in a specific context but where the available classification and search words do not provide a way of feasibly searching for that technique in general and the searcher is unable readily to identify the various contexts in which it may find use.
- When the search examiner considers that a search might usefully be made in an area which is the field of expertise of another examiner, he should consult and take advice on where to search and the likelihood of finding relevant documents. The results of these consultations should be recorded on the ISR. Consultation should be restricted to whatever is necessary for the other examiner to understand what the search need is, and a second analysis of the case by the other examiner should be avoided unless the latter has reason to believe (eg because of his greater experience) that it would be useful. The primary examiner should normally make the whole of the search himself. Exceptionally the application may be sent to another examining group for search, eg where the examiner consulted thinks that it would be more economical or convenient for him to do the search himself. It must however always be remembered that avoidance of delay is of the utmost importance and cases should be sent to another examining group for search instead of being done by the primary search examiner himself only when the time allowable for completion of the search is adequate.
- 17.61 The search examiner should beware of an ex post facto approach to the subject of obviousness when deciding to extend the search to arts not mentioned in the application. The question to be answered is not, given the invention, in what fields might it be applied, but, given the problem to be solved by the invention, in what analogous arts would it be reasonable for the skilled person to seek the solution (see also s.3).

Reconsidering strategy during the search

- While searching for the critical matter the search examiner should keep in mind the nature of any evidence which would be needed, in conjunction with an anticipation of the critical matter, to support an argument of lack of inventive step. If an anticipation of the critical matter, but not of every feature of the claimed invention, has been found, the search examiner should consider whether to search for supporting evidence elsewhere.
- 17.63 If the novelty and inventiveness of the main claim cannot be impugned there is no point in making a special search for the subject matter of dependent claims. It is however as well to note any disclosure of the subject matter of a dependent claim which is found while searching the main claim, since this could become useful if material citable against the main claim were either found later on in the same search or came to light subsequently.
- 17.64 The search strategy should be reviewed on finding documents which demonstrate either that the invention of the main claim lacks novelty or is obvious or, when there is more than one independent claim, that the claims relate to more than one invention (see 17.88). It should be borne in mind that while several documents may produce a stronger argument that something forms part of the common general knowledge (for assessing inventiveness) than a single document, in the case of an objection of lack of novelty a multiplicity of citations may be merely redundant.
- 17.65 The search examiner should attempt to anticipate in what way the claim is likely to be amended. Often amendments will take the form of combining one or more of the dependent claims with the main claim; in other cases the search examiner may be able to tell, from his knowledge of the art and the results of his search, that a feature described but not brought out in the claims is likely to be used on amendment to characterise the invention. If the direction of amendment can be predicted with any reasonable confidence, the search should be focussed on finding documents of potential relevance to possible amended claims. However, no search is necessary for claims which merely add features which are trivial or

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conventional.

17.66 If it is not possible to predict what is likely to be claimed after amendment, the search examiner should use his judgement to decide the best course to follow. The aim should be to minimise the need for searching at the substantive examination stage, but there is no point in performing at the search stage any search for which there is a strong possibility that the effort will prove to have been misdirected. If the invention of the main claim is shown to be not novel or inventive, and a complete search in respect of it is not practicable, and the dependent claims diverge from it, for example in order to embrace different embodiments, so that while in form the claims relate to a single invention, in practice they do not, several courses are possible: see 17.110 and 14.164.

Other documents found

17.67 The search examiner should also, while searching for documents which bear on the questions of novelty and inventive step, note any documents which may be relevant for other reasons, for example conflicting UK or European (UK) applications (see 18.91-18.97.1, 73.05-73.12) or documents which support a view that the invention is non-patentable on other grounds or cast doubt on the validity of the claim to priority (for example suggesting that the priority document was not the first relevant application), or which illustrate the technical background or contribute to a better understanding of the invention. Such documents should be cited as "A" unless they are also relevant for the novelty or obviousness of the searched invention (see 17.80). No special search should however be made for such documents unless there is a good reason in a particular case for doing so.

Section 17(5)

On any such search the examiner shall determine whether or not the search would serve any useful purpose on the application as for the time being constituted and -

- (a) if he determines that it would serve such a purpose in relation to the whole or part of the application, he shall proceed to conduct the search so far as it would serve such a purpose and shall report on the results of the search to the comptroller; and
- (b) if he determines that the search would not serve such a purpose in relation to the whole or part of the application, he shall report accordingly to the comptroller;

and in either event the applicant shall be informed of the examiner's report.

THE SEARCH REPORT

17.68 In the normal case, where the examiner has been able to carry out a search, a report identifying the relevant documents and indicating why they have been cited is sent to the applicant. The documents are also listed on the front page of the published Adocument which also includes a copy of the external search report(s).

[That information which is to constitute the search report to the applicant (see 17.69-17.82) should be recorded within the upper and lower tables of the internal search report. Information which is intended solely for the substantive examiner (see 17.86-17.93) should be recorded outside these tables. The search report to the applicant should not include an excessive number of citations. Where a very large number of items has been found, the search examiner is expected to use his judgment and select the most relevant. If it is difficult to determine which are the most relevant, normally only examples should be cited and the applicant so informed by adding a passage to the search report letter before the paragraph about other search results (see 17.83). The number of items cited should not in general exceed twelve unless there is a special reason for more, although a larger number can of course be noted outside the tables of the internal search report.

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[The Deputy Director or subclass examiner, after due consultation, should arrange for an appropriate early response to issue following enquiries from the agent or private applicant regarding the date of issue of the search report. Any letter confined to such an enquiry is forwarded by the formalities examiner direct to the relevant group Deputy Director. The method and substance of the response should be determined according to the particular circumstances: in general, the response should be by letter rather than telephone (plus telephone report), and may be issued by the appropriate Formalities Manager. When it is possible to make a relatively accurate estimate the response should specify the anticipated month of issue. In other circumstances it may be appropriate to be less precise eg to indicate that the report is not likely to issue before a specified date (month). In any event, the response should indicate the telephone number of a named contact.

[In most cases, publication of an external search report does not require any action on the part of the search examiner. However see 16.33 and 17.105 for action to be taken if the search examiner becomes aware of an error in the external search report or of an additional citation after the external search report has issued.

[Search report covering letters SL1, SL1A, SL3, SE1 and SE3 include a request for disclosure of details of search results from other patent offices on the same invention. This request covers official search reports only, but excludes reports issued by WIPO or the EPO, reports with no citations, or those already supplied on an earlier GB patent application. The request is active for reports issued before the first response made to a report under section 18 issued on the application, or two months after the date of a report under section 18(4) where no response is made to this report.

[Private applicants' cases

[The search examiner should use SL1PA to act as the covering letter for the external search report. The Preliminary Examination Report (using LFEPA) should be issued only if there are any formalities objections. Paragraphs may be added to the search report covering letter before the paragraph about other search results (see 17.03 and 17.83) and the search examiner should satisfy himself that the letter and any enclosures will make a coherent whole. The procedure for obtaining copies of cited documents for issue with the external search report is outlined in 17.104.1. Where there is plurality of invention on a private applicant case, SC13 can be used. Where there is no standard private applicant letter or clause available, other standard letters and clauses may be used where appropriate, with modification to suit the individual case if the search examiner sees fit. SC17PA should be included to recommend the use of a patent attorney or other professional advisor.]

Field of search

The search examiner should identify the field of search by entering the appropriate details in the "Field of Search" table in the internal search report. Only current IPC terms and (if used) terms from the final edition of the UK Key (edition X) can be entered. When a search is made through documents classified under the IPC, CPC or FICLA, the relevant IPC sub-class(es) should be indicated in the "IPC" entry - eg G03B, G06F. In the rare instances that the search was limited only by search words and was not limited to any IPC or CPC sub-classes, the "IPC sub-class" box should be left blank. The "UKC" entry should be used if the search has been conducted through documents classified on the UK Key (whether GB patent documents or otherwise). Only the heading(s) searched should be recorded under the "UKC" entry - eg G3N, H2F.

[Details of the field of search are entered into the "Field of Search" table by opening a dialogue box while editing the internal search report in Word; this is done by clicking on the 'Add-Ins' tab and then selecting 'Maintain FOS'. There are two input fields for Other Field Of Search: The 'Other Field Of Search for this ISR' is used by PROSE to record the other field of search specific to the current ISR, while the 'Other Field Of

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Search total for the case on OPTICS' is that which is to be stored on COPS. This is because COPS only has one free text field for this information and different searches conducted on a case may include different fields of search. For the first ISR on a case the examiner should enter the same data in each field. For each subsequent ISR at the 'A' stage, the first field should be filled with the details specific to that ISR, while the second field should be filled with an accumulation of the data for all the ISRs up to that point, but should not contain any duplication. When the examiner enters the details for a second ISR, for example, the second field will already be populated with the data recorded for the case from the first ISR and so all the examiner need to add to the second field are further "other" fields of search, such as databases not searched in the first search. The examiner should enter the appropriate text (see 17.71) or right click to display standard texts for selection.

[Fuller details on the field of search should be entered outside the "Field of Search" table - usually under the heading "Other details about field of search". For the UKC, a heading and any classifying terms searched in it should be recorded here - eg H2F (F3C, F3D). For a search of documents under the IPC or CPC, more detail should be given, including sub-classes, sub-groups and all CPC terms searched - eg E05B 1/00, 1/0007, 1/003, 1/04. Other details given may include any search using terms from earlier editions of the UKC or IPC, or an explanation if the CPC classifications have no suitable IPC equivalent at sub-group level.

[Deleted]

17.70 If the search has been stopped at a certain date because the search examiner considers that no relevant documents would be found earlier than that date, for example because of the nature of the technology used in the invention, there is no need to tell the applicant. If however the search has been discontinued for some other reason (usually because sufficient relevant documents have already been found) then the applicant should be informed (see 17.83).

17.71 Databases used and document collections searched should be recorded under the Field of Search entry "Online & other databases". Online databases should be recorded using the standard database names e.g. EPODOC, WPI, INSPEC. When fulltext searching is conducted, this should be listed as "Patent Fulltext". Those database names which are also registered trademarks are acknowledged as such in the standard database names document but not in the search report. If an internet search has been performed, this should be recorded as such in the external search report, but names of individual search engines that are used for the search should not be listed unless they have been accessed through a subscription and are not freely available. If however only one or two websites have been looked at, then the Internet should not be listed on the external search report because this may lead to the impression that a significant internet search has been conducted.

[Databases should also be recorded using PROSE. For further information on internet references, see the Internet Searching Manual.]

17.72 [Deleted]

Claims searched

17.72.1 The search report also includes an indication of the claims in respect of which the search has been done. In general, all claims dependent on a main claim which has been searched should be listed by number provided none falls outside the scope of the main claim (eg by virtue of specifying omission of some feature(s) of the main claim). Where a dependent claim introduces a feature which is not trivial or conventional, this claim should still be listed in the claims searched. However, if the search examiner considers that further searching in respect of this feature may be required at a later stage then the applicant should be warned in the covering letter. Independent claims and claims dependent upon them should also be listed by number when they fall within the scope of the search made. If the claims searched have been amended in wording or numbering from those originally filed, their date

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of filing should also be stated in the "Claims searched" box.

[The indication of claim(s) searched should be consistent with the indication as to which claim(s) the cited documents are considered relevant (see 17.77).]

17 72 2 Where there is lack of unity, then claims relating wholly to second or further inventions should not be included in the "claims searched". Claims relating to a first invention and also dependent upon claims to subsequent inventions should be listed in the "claims searched" along with an indication that only a partial search has been performed in respect of these claims. In addition, independent claims should not be searched if they relate to subject matter wholly unpatentable under s.1(2), s.1(3) or s.4A (see 17.94 and 17.107). However, claims which are unpatentable under s.1(2), s.1(3) or s.4A as worded but which could form the basis of a patentable claim - for example, method of treatment claims which could be converted to a valid second medical use claim - should be searched if they fall within the first invention. Claims which are completely unsupported and of indeterminate scope (for example, "reach-through" claims to compounds identified by an assay or screening method - see 14.156.1) should not be searched. A brief explanation in the internal search report and search letter as to why the claim was not searched should be included in the internal search report and search letter. Occasionally applications contain totally indeterminate claims, for example, directed to "any novel matter disclosed". Such claims should be disregarded at the search stage; no reference need be made to them in either the external search report or the accompanying letter.

[In the "claims searched" the examiner should record "(in part)" after any claims which have been partially searched because they relate to a first invention and also depend upon independent claims to subsequent unsearched inventions]

Documents cited

17.73 The search examiner should report primarily those prior publications - including those acknowledged in the application - which could prove useful to the substantive examiner when constructing an objection based on lack of novelty or of inventive step. He should be generous in his assessment of what the substantive examiner might consider relevant and particularly in the absence of category X or Y documents should also include documents illustrating background art, see 17.80. The examiner should always cite at least one document in the first search report on an application, unless — exceptionally — he considers that the invention relates to a wholly new field of technology and so no relevant documents of any kind can be found. If a document of the kind referred to in 17.67 is included, the reason for its inclusion should be referred to in a supplementary report in the search letter (see 17.83).

[The first two columns of the lower table of the internal search report headed "Ref" and "Location" are for the convenience of the search examiner, who can include in the first of these a private shorthand reference code to readily identify a citation and, in the second, the source or location where the cited document is to be obtained or found. The information in these columns will not be carried over to the external search report.]

[In the exceptional case that no relevant documents have been cited, "None" should be inputted in the citation field of the ISR]

17.74 Whether or not a given document forms part of the state of the art in the case of an invention may depend on the priority date of the invention, and also on that of the matter in the document. The priority date may differ for different parts of the matter disclosed in an application or for different aspects of the invention (see 5.20-5.24). The search examiner should however treat the actual filing date of the application being searched as though it were the priority date of all the matter present. In this way, if it should transpire that an invention is not entitled to a priority date which has been declared, or if the applicant should relinquish his priority date, this will not cause him to be confronted with a citation of which he had been left unaware. In order to decide whether a published application should be included in the search report by virtue of s.2(3), the potential citation should be treated as

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though all the matter in it were entitled to the earliest priority date declared. All this is without prejudice as to what may be the true priority date of matter in either the application being searched or in the potential citation. (For the practice at substantive examination see 18.14-18.16).

17.75 The citations should be listed according to relevance, starting with any category X documents, followed by category Y documents and lastly category A documents. The documents within each category should also be listed with the most relevant (eg the one relevant to most claims) first. The relevant passages for consideration in each document should normally be indicated (see 17.81). In the absence of any significant priority (eg where all the documents are category A), UK patent specifications should be listed first, followed by EP specifications, PCT pamphlets, foreign patent specifications in country code order and finally non-patent literature.

[Details on citation formats in PROSE can be found online].

17.76 [Deleted]

Further information

17 77 An indication of why each document has been included in the search report should be given by assigning a category indicated by a code letter (eg X, Y or A - see 17.78-17.80). The claims to which it is considered relevant should also be indicated, as should pertinent passages wherever possible (see 17.81). The relevance of the document to each claim (except for any relating to a second or subsequent invention where there is not unity of invention, see 17.106 to 17.110) should have been investigated and all of the claims affected should be listed on the search form, as far as it is reasonably practicable to do so. In cases which are complex or obscure or have a very large number of claims, it may not be practicable to consider all of the claims in sufficient detail for every claim affected to be identified. In any event, at least those claims (or those of the claims which relate to the first invention where there is not unity of invention) which are independent or which appear prima facie to relate to new or important features or the characterising features of particular embodiments, rather than merely reciting standard prior art features, should have if possible received particular attention and be listed if appropriate. While the substantive examiner will be guided by the search examiner's assessment of the citations, he is not bound by it, and may take a different view after his more detailed consideration of the whole specification.

[All claims listed against cited documents in the search report should be included in the list of claims searched. A supplementary report should issue in the form of an appropriately headed passage in the search letter (before the paragraph about other search results) if only a partial search was made in respect of any claims so listed (see 17.72.1). Examiners should consider and report on the relevance of citations to appendant claims only to the extent that it is reasonably practicable so to do. Where it has not been practicable to consider all of the claims, it is acceptable to qualify listed claims with "at least". Consideration should then be given to including comments in the internal search report form (ISRF) and search letter explaining the extent to which the relevance of the citations to the claims has been considered. However, a bare reference to "claim 1 at least" (i.e to one independent claim only) should be avoided in all but exceptional circumstances e.g. where the scope of the invention is extremely unclear or there are a very large number of claims.]

17.78 Category X is to be used to indicate a document which is relevant when taken alone. It may disclose (or imply - see 18.22) all the features specified in a claim, i.e. may demonstrate lack of novelty. Alternatively, it may of itself indicate a lack of inventive step - for example, where the difference between what is claimed and the disclosure of the document is considered to be non-inventive or to be common general knowledge, or where features of two embodiments can be combined to show all the features of what is claimed. The essential point about a category X document is that it can be used without the support of other documentary evidence to attack patentability. It should be indicated as relevant to

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those claims whose novelty or inventive step is impugned by the document standing alone.

17.79 Category Y is to be used to denote a document which is relevant when combined with another document and which will therefore form one limb of an obviousness argument. If a category Y document is listed against a claim, it follows that at least one other document of this category must also have been listed against that claim. A document may be assigned both categories X and Y. In this regard a document may be X category in respect of one or more claims and Y category in respect of a different claim or claims; or may be both X and Y category against a single claim eg because it is relevant to lack of inventive step both as taken alone (in the light of common general knowledge) and when combined with another document cited under category Y.

[Each document should be listed only once on the search report and, if it is relevant under both categories X and Y, "X, Y" should be indicated against it. The "Claims" column should be completed by inserting "X: " and the numbers of the claims affected under that category in one group and inserting "Y: " and the numbers of the claims affected under that category in a second group.]

- 17.80 Category A is for documents indicating technological background and/or state of the art. No search is made for such documents, and if the normal search reveals documents in category X and/or Y it will not usually be necessary to cite background art as well. However, if the search reveals nothing in category X and/or Y, one or more documents representing the most relevant background art should normally be cited under category A, whether these are revealed by the search or otherwise, eg acknowledged in the application. Documents cited for other purposes may also be assigned category A but the reason should be given in a supplementary report in the search letter, see 17.83. Such purposes include those referred to in 17.67 (and in particular include citation to support an objection under s.1(2) which, prior to the introduction of category A, was assigned category X). The search examiner may also include any other document which he feels is relevant to the application and should be brought to the attention of the applicant, but does not merit category X or Y. Where a search has been made for the common matter of two or more independent claims in order to ascertain whether the inventions are linked to form a single inventive concept, only documents which appear relevant under s.1(1)(a) or (b) to the (or the first) invention claimed should be designated X or Y; other documents found may be designated A (see 17.83,17.106 and 17.109). There is no bar on citing category A documents as well as category X or Y documents although, since category X and category Y can each be taken to subsume category A for most purposes, it is unlikely to be appropriate to assign code A in addition to code X or Y to citations of category X or Y. The listing of claims and pertinent passages against cited documents may be dispensed with for category A documents but may be done where the search examiner considers it would be helpful. Only claims which fall within the scope of the search (at least in part) should be listed against cited documents, claims relating to second or subsequent inventions should not be listed (see 17.72.1 and 17.77).
- 17.80.1 Category & may be used to indicate cited documents which are members of the same patent family (eg GB and foreign equivalent) or otherwise correspond. Corresponding documents should only be listed where their inclusion enhances the search report, eg by providing the English text, by bringing matter into the s.2(2) field, or by disclosing or claiming different aspects of the invention.
- 17.81 Relevant passages of cited documents should always be indicated (other than for category A documents, where this is optional, see 17.80) except where this is clearly impracticable, for example where there are many separate and equally relevant passages throughout a document or where the document is short and its relevance is self-evident. Such an indication will not in any way restrict the substantive examiner, who will be free to rely on any part of the document in order to support an objection.
- 17.82 Citations in the s.2(3) field or whose effectiveness depends on their priority date and/or that of the application in suit (see 17.74) should be indicated by further code letters. These are:-

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- P document published on or after the priority date but before the filing date of the application in suit. Such a document would lie in the s.2(2) field if the invention were not entitled to the priority date requested. On the other hand, if the claim to priority were sustained, the document would be either in the s.2(3) field or outside the state of the art. If a late declaration of priority is filed after search, then documents cited in the search report may no longer form part of the art (see 18.14). That is, a citation may become a 'P' document (although this will not be indicated on the search report) as a result of the late declaration of priority.
- E UK patent application, or European or international application designating the UK, which has a filing or priority date earlier than, but a publication date the same as or later than, the filing date of the application in suit. Such a document is therefore prima facie in the s.2(3) field but may be rendered nugatory if the applicant can sustain his own priority date and/or attack that of the document listed. Such a document should be listed only if it impugns the novelty of the invention, since there is no possibility of it being in the s.2(2) field and documents in the s.2(3) field are not relevant to obviousness.

Since these codes convey only supplementary information a document to which they are assigned should of course also be categorised as X, Y or A (see 17.78-17.80).

Supplementary report

- 17.83 In some cases it may be necessary for the search examiner to add observations, which should be as concise as possible, to the letter which accompanies the search report. Thus, a brief explanation should be added to the letter as a supplementary report:-
- (a) if the claims lack unity of invention but it is thought that it would not be self-evident to the applicant why this is so (NB the fact that the examiner considers that the claims relate to plural inventions should **always** be reported where this is the case, whether or not further explanation is needed see 17.106-17.110);
- (b) if the search examiner is not confident that the applicant will be able to deduce the way in which cited Y category documents are to be combined merely from information (eg identified relevant passages) provided in the search report;
- (c) if a document is cited which does not bear on novelty or obviousness or does not represent the most relevant background art (see 17.73 and 17.80);
- (d) if the search examiner has conducted only a partial search, for example because documents found in the search demonstrate that the invention of the main claim lacks novelty and inventive step, and it is not apparent in what way the applicant might amend, or because the claims are insufficient due to excessive claim breadth (see also 14.79-14.82, 17.83(e) and 17.117);
- (e) if the documents cited are examples only of relevant prior art, in which case the supplementary report should also give a warning (when appropriate) that a further search may be necessary at the substantive examination stage. In some circumstances it may be useful to include an explanation as to why particular documents have been cited, for example because they show a particular embodiment or demonstrate the wide breadth of a speculative claim;
- (f) why an independent claim has not been searched when it relates to an excluded invention under s.1(2);
- (g) where the categories X or Y have to be omitted from the search form because an application is so obscure;

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- (h) where documents which may be relevant have been revealed by an online database search but only an abstract has been seen and there will be some delay in obtaining the complete document for the search examiner to inspect. The search report should include an indication of the likely relevance of the complete document where possible;
- r.27(2) i) where documents which may be relevant have been revealed by an online database search and the complete document is unavailable, where a document is available as a library loan only, or where copyright allows for in-office use only and no copy can therefore be provided to the applicant;
 - (j) where the search examiner has determined that the claims do not clearly define the invention, and so has searched what he perceives to be the invention when taking the application as a whole (see 17.42);
 - k) where the search examiner considers that the application may relate to matter excluded under section 1(2) but where action as described in 17.83.4 or 17.94.5-17.101 is not appropriate (see 17.94.2-17.94.3);
 - I) where a 'publication' date for an internet disclosure cannot be established but the disclosure appears highly relevant (see 17.54).

[The supplementary report should be one or more appropriately headed paragraphs added to the search report covering letter before the paragraph about other search results. In the case of an application from a private applicant, SC3PA should be added if it is necessary to indicate the interpretation which has been put upon unclear claims in order to carry out the search. If the matter cited completely anticipates the entire subject-matter of an application from a private applicant SC4PA should be added. SC14 or SC14A should be added to report documents revealed by an online database search but unseen. Where partial searches only have been conducted in respect of some claims see 17.72.1 and 17.77.]

17.83.1 Where the search report has been issued on the basis of an abstract as in 17.83(h) above, the examiner should analyse the full document when it becomes available and send a copy or copies to the applicant as soon as possible (whether it is then considered relevant to the invention or not). An accompanying letter should confirm, or not, the relevance of the document and should include any information which would if known have been included on the search report, or indicate any differences between what was indicated on the search report and the document's actual relevance as appropriate (see also 17.105-17.105.2). An amended search report should be issued if there is a significant difference between the indicated likely relevance and the actual relevance of the document and the application has not yet been published. The examiner should enter particulars as necessary on the internal search report and COPS using PROSE. If copies of a document prove to be unobtainable, the applicant should also be informed.

[The application should be diaried for one month to safeguard against the order for references going astray. This should be done by creating an entry in the PD electronic diary system and adding the diary action to the dossier in PDAX. This diary entry should state the examining group after the application number in the format GB0000000.0 – EX00. SL14 should be issued when a document previously cited on the basis of an abstract is considered not relevant to the claims after the full document is available.]

17.83.2 If search in respect of later-filed original claims is restricted in the circumstances discussed in 17.34.1, then the applicant should be advised accordingly in a supplementary report in the letter which accompanies the search report and informed that amendment to the claims will be necessary in due course.

Where the claims contain additional features not in the original description, clause

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SC5 (at search stage) or SC6 (at CS&E) should be used. Private applicant versions of both these clauses are available (SC5PA and SC6PA).]

Examination Opinion

17.83.3 While conducting the search, if major issues are identified in the application that will require considerable amendment if the application proceeds to substantive examination, the issue of an examination opinion should be considered by the search examiner where combined search and examination is not being conducted. This examination opinion is non-statutory, but may form the basis of the first examination report under s.18(3) at substantive examination (see 18.47.1).

17.83.4 Examples of situations where the issue of an examination opinion will be appropriate include complete or extensive anticipation of the subject matter disclosed, broad speculative claims where there is no clear indication of how the applicant may wish to proceed, complex independent claims with overlapping scope relating to a number of separate inventions, and inventions falling within excluded categories. However, in the case of plurality of a more limited extent, an examination opinion should not be issued for this reason alone. Furthermore, under some circumstances (e.g. excluded inventions), action prior to search, or issue of a report under s.17(5)(b) in addition to the examination opinion may be more appropriate (see 17.94-17.101).

[The search examiner should use search letter SL1A as a covering letter for the search report and accompanying examination opinion. This letter invites amendment before substantive examination and informs the applicant that the examination opinion will form the first report under section 18(3) if the points in the opinion are not addressed.]

[The examination opinion should include clauses selected from EC1 to EC8, which may be supplemented by further explanation if necessary or for clarification. Where plurality of invention is present, in addition to using clause EC6 (where plurality alone would justify an examination opinion) or EC8 (where the examination opinion is being issued for another reason), clause SC13 should be used in the search letter (see 17.108).]

[For private applicant cases major issues such as those exemplified above may be detailed in a supplementary report in the search letter rather than an examination opinion (see also 17.83). Alternatively an examination opinion may be issued to a private applicant if the examiner feels it is appropriate.]

International Exhibitions

If an applicant, at the time of filing an application, purports to inform the comptroller under r.5(1) of the display of the invention at an international exhibition the search examiner should ascertain whether the exhibition cited by the applicant is an international exhibition within the meaning of s.2(4)(c). If the exhibition cited does comply with the statutory requirement (see 2.41), the search examiner need take no further action except to note the fact on the internal search report. If it does not, a paragraph should be added to the letter accompanying the search report informing the applicant that the exhibition cited by him is not an international exhibition within the meaning of s.2(4)(c), and that the admitted display of the invention will be taken into consideration by the substantive examiner during substantive examination in due course (see 18.23). No reference to the display should be entered on the external search report, but again a note of it should be made on the internal search report.

[Deleted]

17.85 [Moved to 17.72.2]

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The internal search report

The search examiner should record on the internal search report any information which is likely to be of use to the substantive examiner. This should not include matters which are self-evident from the specification or otherwise, but should provide a record of the thoughts and strategy of the search examiner which would not be apparent to another, or even to himself at a later date. This should as a minimum include a statement of the critical matter (see 17.50), details of the classification terms searched (including CPC and IPC subgroups), and a list of the documents found. If comments such as "further search may be necessary" are made, then informative reasons should be given. Full details of the online search strategy should also be recorded, either in the internal search report or a stand-alone document. The way in which each document is relevant under an identified strategy should be clear: this is particularly important with regard to documents listed as examples. If comments such as "best of many" are made, then a clear indication of the criterion used in the selection should be given. If on the other hand documents cited are examples only, then this should be clearly stated. Multiple citations, showing more or less the same features, should not be made. If the reasons for the particular form of the search statement are not readily apparent from the claims searched, for example if the search has been cast more broadly or has been restricted, for the reasons discussed in 17.36-17.37 and 17.42-17.43, then a suitable explanation should be given. Where there is more than one search statement or strategy, it should be made clear which one produced each of the documents listed. If any part of the search has been deferred the reasons for this should be clearly explained. If some thought has been given as to whether to search using a particular heading, or to consult the examiner in charge of another heading, and it has been decided not to do so, then this should also be noted.

[The online search strategy may be recorded either in the internal search report, or in an OSS (Online Search Strategy) document on PROSE. This may be done using a history print (from the HI command on EPOQUE) or a print-out of the full strategy, but however it is recorded it should be clear what has been searched and which documents have been viewed.]

[It is not necessary for the search examiner to make comments in every case in respect of:

plural invention if there is only one independent claim

technical subject

problem(s) addressed

any subject-matter assumed, without search, to be common general knowledge

documents found

further search.

[Where a search reveals a large number of citable documents and examples (whether "best of many" or "examples only") are cited, not only should this be recorded on the internal search report for the benefit of the substantive examiner but also the applicant's attention should be drawn to the situation in a supplementary report in the search letter (see 17.83).]

17.87 [Deleted]

17.88 If the specification contains obscurities and it has been necessary for these to be interpreted in a particular way in order for the search to be performed, this should be made clear on the internal search report (as well as in a supplementary report in the search letter, see 17.83).

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- 17.88.1 If the application contains more than one independent claim, a comment on plurality should always be included on the internal search report, even if it is considered that the claims relate to a single inventive concept. If the search examiner considers that the claims lack unity of invention then this should be recorded, together with an explanation if necessary, and it should be made clear to which invention the search relates. If it has been decided to treat a group of inventions as being so linked as to form a single inventive concept this should be noted, together with the reason if this is not self-evident.
- 17.89 The substantive examiner is entitled to assume, in the absence of any indication to the contrary, that all documents found which fall within the terms of the search statement and within the databases searched have been recorded. If many such documents were found and only a selection has been cited, this should be made clear (see 17.83(e) and 17.86). In such cases, it may sometimes be useful to record on the internal search report those documents which were not selected for citing in the external search report. If any such documents are recorded, they should be accompanied by an indication of why they are relevant.

[No document should be cited which cannot properly be justified. However, since it is for the substantive examiner to decide whether claims are novel and inventive, doubt at the search stage should be resolved in favour of citing.]

- 17.90 If a specification published after the declared priority date of the application in suit has been noted, the search examiner should, unless he has grounds for believing that the exercise would be fruitless, determine whether or not there is a foreign or European equivalent with an earlier publication date.
- Any other document found in the course of the search which is likely to prove useful to the substantive examiner, for example a document relating to a subordinate claim for which no special search has been made (see 17.63) or relevant for reasons referred to in 17.67, should also be noted, together with the reason, for consideration by the substantive examiner. No document lying outside the scope of the search statement should be listed without explanation, since this would leave uncertain the true extent of the search performed. Where any prior art specifically referred to by the applicant has been inspected, the result should be noted. Finally, any relevant instance of prior use which is known to the search examiner should also be noted (see 17.54).
- 17.92 [Deleted]
- 17.93 While the search examiner should not spend time delving into matters in the specification which are not necessary for the performance of the search and ancillary duties (see 17.102) any such matters which are noticed and are likely to be of relevance to the substantive examiner should be briefly noted.

SEARCH WOULD NOT SERVE A USEFUL PURPOSE

- 17.94 Section 17(5)(b) directs the examiner to determine whether or not a search on an application would "serve any useful purpose", and if it would not, to report accordingly. This situation may arise if the specification is so unclear that a meaningful search is simply impossible. Alternatively, although a search might be possible, it may be considered that there is no prospect of obtaining a valid patent and so the search would not serve a useful purpose. For example, this might be the case if the specification was considered to be classically insufficient under s.14(3), and/or because it is not patentable by virtue of s.1(1)(c) or (d).
- 17.94.1 However, the effect of section 17(5) as a whole is that if a search would serve a "useful purpose" in relation to any part of the application, then one should be carried out, at least in relation to that part. Since the aim must always be to keep to a minimum any searching done subsequent to the initial search stage, cases in which a report is made under s.17(5)(b) will be relatively rare (unless the claimed invention is clearly not patentable by

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virtue of s.1(1)(c) or (d) – see 17.98). In many instances where a search could be performed more efficiently if the scope of the invention were made clearer, it nevertheless remains practicable for a search to be performed without amendment of the claims. In such a case the search examiner should do his best to glean from the claims and description what appears to be the invention, at least to a sufficient extent to enable a partial search to be performed, as provided for by s.17(5)(a). In any such instance the search letter should include a supplementary report explaining the scope of the search, and giving reasons – see 17.72.2 and 17.83.

17.94.2 If there is plurality and the first claimed invention appears to be wholly excluded under s.1(2), but one or more subsequent inventions are not excluded, then the search should be directed to the first non-excluded invention – see 17.107. If there are multiple independent claims that form a single inventive concept and claim 1 relates to subject matter excluded under s.1(2), the examiner is able to search any matter which could form the basis of a non-excluded claim.

Where it is considered that the or each claimed invention is excluded from patentability, but there is a possibility that the claims may be amended to define a non-excluded invention supported by the disclosure and it is readily apparent what this invention would be, a search should be directed to this invention and the applicant should be informed of the search examiner's views (in a supplementary report in the search letter, see 17.83); see also 17.94.8. The examiner should only seek to identify such a "searchable" invention as far as it is efficient and practical to do so. Where a "searchable" invention cannot be readily identified and no saving amendment is obvious the examiner should consider the strategies discussed below (see 17.94.8 and 17.98 in particular).

Strategies at search stage where it appears that a search would serve no useful purpose

17.94.3 Section 17(5) states that the examiner should determine whether or not a search on an application would serve any useful purpose, and if it does not, to report accordingly. However, a formal report under s.17(5)(b) is not the only option available at search stage for applications where there appear to be significant patentability issues, and it may not be the most appropriate option, at least initially. If the claimed invention appears to be unpatentable under s.1(1)(c) or (d), but it can be searched and the examiner considers that the objection might be successfully disputed or avoided by amendment, the applicant should simply be informed when the search report is issued that the potential objection will need to be fully considered if and when substantive examination is performed.

17.94.4 However, if the search examiner considers that the entire application clearly has no patentable content, then he should consider the most effective way to deal with the application. This will depend, in most applications, on the nature of the potential objection(s) and whether the applicant is professionally represented or not. The search examiner can consider several options:

- a) action before search (ABS sometimes also referred to as "amendment before search");
- b) issue of a report under s.17(5)(b);
- c) issue of a substantive examination report under s.18(3) before search (the "Rohde & Schwartz" procedure but this should only be done in very limited circumstances).

These options are not mutually exclusive; it is possible to use the ABS procedure prior to issuing either a s.17(5)(b) report or s.18(3) report.

a) Action Before Search (ABS)

17.94.5 If, in the examiner's opinion, the application has no patentable content, and it is considered likely that the applicant would wish to simply withdraw the application and receive a refund of the search fee once that opinion is communicated to him, then the best option is likely to be issue of a letter suggesting action before search (ABS), or, if appropriate, action before combined search and examination (ABCSE). However, the search examiner

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should not respond to a request for a further search under s.17(6) by issuing an ABS letter (see 17.111). An ABS or ABCSE letter should state the examiner's view that there is no likelihood of a patent being granted, and clearly and simply set out the reasons why the examiner considers that the invention is not patentable, or is classically insufficient (see 14.67-14.75), or lacks novelty and/or inventive step, together with any documents illustrating this. The letter should also:

- a) Set a period (usually one month, but can be longer if appropriate) for response;
- b) advise the applicant that he can either:
 - (i) withdraw the application, in which case the search fee will be refunded. The letter should inform the applicant that in order to withdraw the application the applicant should write to the Office stating clearly his wish to withdraw the application; or
 - (ii) request that the application proceeds.

and;

c) clearly state what will happen if no response is received from the applicant within the specified period. This should make it clear to the applicant that a search report will be issued after the end of the specified period if no response is received from the applicant, and the application is not withdrawn. If it is considered likely that this report will be a report under s.17(5)(b) stating that a search would serve no useful purpose, then the letter should clearly warn the applicant of that likelihood. The letter should also make it clear that once a search report is issued there will be no refund of the search fee.

Where the application is considered to lack sufficiency under s.14(3) or to be unpatentable under s.1(1)(c) or (d), the ABS letter should normally be followed by a report under s.17(5)(b) if no response or withdrawal request is received from the applicant.

[If an ABS or ABCSE letter is issued, the COPS status should be set to "Out for ABS"/"Out for ABCSE", an appropriate diary entry created in the PD electronic diary system and a diary action added to the dossier in PDAX (taking into account any asof-right extension to the reply period that might be requested). The diary entry should state the examining group after the application number in the format GB0000000.0 – EX00.1

[If the application is from a private applicant, then it will normally be considered by the Private Applicant Unit (PAU) – see 17.03. If the PAU examiner considers that the application is clearly insufficient or unpatentable, or clearly lacks any novelty, then an ABS or ABCSE letter should be sent to the applicant as outlined above. Only one ABS or ABCSE letter should ever be sent to an applicant, and so if the applicant has either not responded, or responded with an indication that he wishes to proceed with the application, then the applicant should **not** be sent a further ABS/ABCSE letter.]

17.94.6 In response to the letter, the applicant may provide amendments and/or arguments to address the issues raised in the ABS/ABCSE letter. Where such arguments and/or amendments are received the search examiner should carefully consider them and decide whether to issue a search report under s.17(5)(a) (or combined search and examination report), or issue a report under s.17(5)(b) that a search would serve no useful purpose. The examiner should not issue another letter requesting action before search.

17.94.7 This procedure may also be useful for applications which are very clearly lacking in novelty and/or inventive step in their entire content. In such cases, it may be helpful to perform a very rudimentary search to identify a small number of documents which illustrate this, and a copy of each of the documents should be sent with the letter. Again the letter should set out the options for the applicant, including withdrawal with a refund of the search fee, set a period for response, and state what action will be taken if no response is received. If the search examiner considers that the invention lacks novelty and/or inventive step but is otherwise patentable and could be searched, then if the application is not withdrawn the

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ABS/ABCSE letter should be followed up with a search report under s.17(5)(a) (or combined search and examination report) rather than a s.17(5)(b) report (other than in the very rare situation described in 17.101).

17.94.8 A similar procedure may also be used if it is considered that, while the claims as drafted are not patentable, there is a possibility that a claim defining a patentable invention could be supported by the disclosure, but it is not clear what this would be. In this case, a letter requesting amendment before the search is carried out may be sent to the applicant. Again, the letter should set a date for response and should clearly set out what the search examiner's action will be if no satisfactory response is received.

17.94.9 The examiner may refer to the Code of Practice in a letter requesting action or amendment before search. However, it should be noted that non-compliance with the Code of Practice is not in itself justification for a report under s.17(5)(b).

[SC16 should be used when referring to the Code of Practice at the search stage, inserting the number of the relevant point of the Code].

[If the application is withdrawn and a refund of the search fee is requested, the request should be referred to the examiner by formalities. The request for a refund should be accepted unless the period specified for response to the ABS/ABCSE letter has expired and the examiner has already initiated work on a search report (under either s.17(5)(a) or (b)).

b) Report under s.17(5)(b) that a search would serve no useful purpose

17.94.10 If the examiner has determined that a search would clearly serve no useful purpose in relation to making an application for a UK patent, and either an ABS letter is not considered appropriate, or a letter has been issued and no satisfactory response has been received, then (unless the *Rohde & Schwartz* procedure is adopted) he should report this in a letter to the applicant under s.17(5)(b). The letter should be accompanied by an examination opinion (see 17.83.3) (for a search) or an abbreviated exam report (for a CSE – see square brackets of 17.94.11 and 18.47.2), outlining the reasons why the search would serve no useful purpose. If, having considered the facts of the case, the examiner feels that issue of an examination opinion is inappropriate, the reasons for not performing a search should instead be detailed in the search letter.

For private applicants either an examination opinion should issue or alternatively the letter under 17(5)(b) should provide a brief explanation of the reasons why the search would serve no useful purpose (reports under 17(5)(b) to private applicants will be relatively rare as ABS or ABCSE action will usually be most appropriate in the first instance, see 17.94.5-17.94.9). In all cases the applicant should be informed that if amended claims are submitted, then the examiner will reconsider whether a search can be made.

17.94.11 If, following amendment, the search examiner still considers that a search would serve no useful purpose, then he should avoid entering into lengthy correspondence at this stage and should suggest that the matter is dealt with at substantive examination or the applicant should be offered a hearing. If the application is unsearchable because it lacks patentability, the hearing may deal with that substantive matter too - see 17.98-17.98.1.

[When no search has been made because one would have served no useful purpose, this should be recorded on the internal search report through the Field of Search entry on PROSE, which will transmit this information into COPS.]

[The report under 17(5)(b) should take the form of letter SL2 and be accompanied by an OPINION document (In private applicant cases, SL2PA should be used and the OPINION document is optional. If an OPINION document is issued, the SL2PA letter and checklist should be modified to refer to the OPINION document. If no OPINION document is issued, an explanation why the search was not completed should be included in the SL2PA). In combined search and examination cases SE2 (SE2PA)

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should be issued along with an abbreviated examination report including a brief explanation of the reasons why no search has been performed. These letters offer the applicant the opportunity to submit amended claims. For further details on the procedure where combined search and examination is requested but the search would serve no useful purpose, see 18.47.2]

[No external search report should issue, not least so that Formalities can rely on the absence of an external search report on file as a signal that any new or amended claims should be referred to the search examiner (see 16.18). Insofar as no search report will have issued no search report should be included with the published Adocument.]

[For a search or CSE on a case which has not been published, a response to a report under 17(5)(b) would preferably be considered within one month. This is because if the examiner decides to carry out a search as a result of the response it is preferable that the application is published with the search report. For a CSE on a case which has been published, a response should be considered within the usual amendment target; if a search is required, it should also be completed within this timescale and preferably at the same time as the consideration of the response.]

[For a search, if a response to a report under 17(5)(b) does not convince the examiner that the claims are now searchable, the examiner can respond by way of the SL6 letter. The SL6 can be edited to include brief reasons, although lengthy correspondence should be avoided. If a hearing takes place at this stage, a s.18(3) report can be issued as a pre-hearing report (see 18.79-18.80.1). If such a response is received on a CSE then it should be processed in the same way as a normal amendment, i.e. with further examination reports issued, culminating in the offer of a hearing if necessary.]

If, following a report that a search would not serve a useful purpose, searchable amended claims, or observations which convince the search examiner that a meaningful search is possible in respect of the original claims, are received before the application has entered the actual publication cycle under s.16, then the search should be carried out. If no response to such a report has been received by the time the application is due to be sent for publication by the search examiner (see 16.31) then, provided the application has not been refused following a preliminary objection (see 17.96.1-17.96.4) it should be sent for publication in the usual way. The front page of the published document will indicate, in the place provided for documents cited, that no search was possible. If a response enabling a meaningful search to be made is received after the application has been sent for publication, the search should be carried out as soon as practicable in order to give the applicant as much time as possible to decide on his subsequent course of action. If the application has been sent for publication but it has not entered the actual publication cycle then a search may be carried out as normal.

[The amendments should be added to the dossier by Index and Scanning and annotated appropriately, and a PDAX message sent to the examiner.]

[If a search is subsequently performed the search examiner should create a fresh internal search report and an external search report. A report of a search in respect of amended claims should be accompanied by letter SL3 (to which SC13 should be added if there is plurality of invention) together with a copy of any citations (see 17.104.1). The search should normally be carried out as soon as possible; if the search is carried out before the case is picked for publication, the Examination Support Officer will add a "P" to the external search report in the table of contents. However if COPS has selected the application for publication from those in the A-publication queue when the amended claims are placed on the file, the search on the amended claims should be deferred until after publication. In these circumstances the amended claims should normally be put on the file at Publishing Section by the publication liaison officer, and will be published if the preparations for publication are not complete

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(as determined by 16.02).]

17.96 No refund is made following issue of a report under s.17(5)(b) indicating that no search has been performed on the grounds that it would not serve a useful purpose (see also 17.06). As discussed above, if it is considered likely that the applicant will wish to withdraw and seek a refund once he becomes aware of the search examiner's opinion, then the search examiner should consider sending an ABS letter instead. However, if it appears that the applicant would be fully aware of the possible objections, then there is little to be gained by adding an extra round of correspondence.

c) Report under s.18(3) before search ("Rohde & Schwartz")

17.96.1 Issuing an examination report under s.18(3) before a search is conducted is very rarely considered to be appropriate, because this option will normally result in a hearing officer having to issue a decision, but it may be done in exceptional circumstances. This approach may only be considered where the search examiner is in no doubt before a search is commenced that the, or each, invention claimed is not patentable by virtue of s.1(1)(c) or (d), or s.14(3), and is equally convinced that the disclosure is such that it could not possibly support any allowable claim. A report under s.18(3) may be issued even though no request for substantive examination has been filed and regardless of whether the other requirements of s.18(1) are met - see *Rohde and Schwarz's Application* [1980] RPC 155.

17.96.2 Where such action is taken, no report should be made under s.17(5). Instead, a reasoned report under s.18(3) should be made giving the search examiner's opinion that the application should be refused. This report can be brief in stating the reason why the application should be refused. For example, it is not necessary to write a detailed argument on why an invention that is contrary to physical laws will not work when this is clear from reading the application. The report should add that if the application is withdrawn a refund of the search fee will be made (see 17.06). If the matter is not resolved (either because the applicant submits arguments which do not dispose of the matter or because there is no response) then a hearing should be offered and a hearing officer's decision issued in the usual way. In order to efficiently resolve the objection resulting in issue of the s.18(3) report, examiners should avoid entering into protracted correspondence with the applicant.

[The examiner should consult their group head before issuing a report under s.18(3) before search. Where an examiner issues a report under s.18(3) before search, a period of four months should be set for reply in the first instance. A "Diary" entry should be created in the PD electronic diary so that the application will return to the examiner in 6 months (to take into account a possible two month extension of the reply period). A diary entry should also be created for any subsequent exam reports. Each diary entry should state the examining group after the application number in the format GB0000000.0 – EX00, and a corresponding diary 'action' should also be added to the PDAX dossier.]

[At the appropriate time, in order to avoid protracted correspondence, a letter should be issued by the examiner saying that he is minded to refuse the application and offering a hearing. The applicant should be given one month to indicate whether he wishes to be heard in the matter, a diary entry should again be created so that the application returns to the examiner even if no response is received. If the applicant does not wish to heard (or does not respond), then a hearing officer will decide the matter on the papers.]

[It should be noted that if, after consulting a group head, an ex-officio objection is made under s.18(3) in the circumstances mentioned above, the report containing that objection is considered to be the first report under s.18(3) for the purposes of determining the compliance period. If the application does proceed to normal substantive examination, every effort should be made to ensure that substantive examination is not unduly delayed since the applicant is deprived of the potential benefit of r.30(2)(b).]

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An ABS letter may be sent to an applicant which effectively gives the applicant the choice of withdrawal with a refund of the search fee, a report under s.17(5)(b) or a s.18(3) report before search. In this case, the search examiner may inform the applicant before a report under s.17(5) is issued that whilst the application would seem to give rise to an objection under s.1(1)(c) or (d), or s.14(3), the matter will not be pursued prior to substantive examination unless within two months the applicant indicates a wish to have the matter resolved immediately. If the applicant so indicates, the objection should be pursued under s.18 as indicated in 17.96.1. If the applicant does not take the opportunity either to have the matter settled immediately or to withdraw the application, a report under s.17(5)(b) should then be issued indicating that because no patentable subject matter is disclosed it is not apparent what could be usefully searched, and the application sent to await A-publication in the usual way. There is no entitlement to a refund of the search fee after issue of the search report.

17.96.4 Another situation where an application may be refused without performing a search is on the grounds of estoppel by record where the application is for the same invention as an earlier application which has been refused by the courts or the comptroller, as occurred in *Ward's Applications* (BL O/143/02 and BL O/055/06).

[A letter should be issued by the examiner offering the applicant the opportunity to withdraw and have his search fee (and, if paid, the substantive examination fee) refunded (see 17.06). The letter should state that he is minded to refuse the application if no withdrawal is made, and a hearing should be offered. The applicant should be given one month to indicate whether he wishes to be heard in the matter. If he does not wish to heard (or does not respond), then a hearing officer will decide the matter on the papers.]

No useful search possible: reasons

a) No useful search possible because the invention is obscure

17.97 A report under s.17(5)(b) (preceded, if appropriate, by an ABS/ABCSE letter) should generally be made if obscurities in the specification are such as to render a meaningful search impossible, or to make the scope of the invention so uncertain that the search is likely to be incomplete. The search examiner should however avoid entering into dialogue with the applicant or agent regarding possible amendments or about other matters which should be dealt with at the substantive examination stage. No report should be made directing attention to alleged defects or obscurities if, despite these, the search examiner has been able to perform what is reasonably likely to be a complete search.

b) No useful search possible because the invention is not patentable

17.98. A report under s.17(5)(b) (preceded, if appropriate, by an ABS/ABCSE letter), or an examination report under s.18(3) before search, should generally be made if the, or each, invention claimed is clearly not patentable by virtue of s.1(1)(c) or (d) (for example if the invention relates to a pure business method), or by virtue of s.14(3) (for example, in the circumstances set out in 4.05 and 14.79). In CFPH LLC's Application [2006] RPC 5, Peter Prescott QC (sitting as a Deputy Judge in the Patents Court) confirmed at paragraph 96 that it will not always be necessary for an examiner to carry out a search before he or she can determine whether the invention is new and not obvious (and susceptible of industrial application) under the description "an invention" (in the sense of Article 52):

"In order to identify what is the advance in the art that is said to be new and nonobvious the Patent Office may rely on prior art searches. But in my judgment it is not invariably bound to do so. It will often be possible to take judicial notice of what was already known. Patent Office examiners are appointed because they have a professional scientific or technical training. They are entitled to make use of their specialist knowledge. Of course the letter of objection will state the examiner's understanding of the technical facts in that regard, and thus the applicant will have the

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opportunity to refute it in case there has been a mistake."

Furthermore, in <u>Shopalotto.com Ltd's Application [2006] RPC 7</u> (see 1.22), it was held that the question of whether the claimed invention includes a contribution outside the list of excluded subject matter may be answered notwithstanding the fact that there has been no novelty search in relation to the invention. Pumfrey J pointed out the distinction between the scope of contribution and the area in which the contribution is made and added that there comes a point where the relevant matters are so notorious that a formal search is neither necessary nor desirable and the Comptroller is entitled to use common sense and experience.

17.98.1 It should be noted that "useful purpose" means serving a useful purpose in relation to making an application for a UK patent. A search does not serve a "useful purpose" within the meaning of s.17(5)(b) merely because it may help the applicant with a decision on whether to file in a country in which the equivalent application is not excluded from patentability.

17.99-17.99.2 [Moved to 17.96.1-17.96.3]

17.99.3 [Deleted]

17.99.4 [Moved to 17.96.4]

17.100 [Moved to 17.94.2]

c) No useful search possible when the invention is not novel or is obvious

17.101 Whenever the search examiner takes the view that an invention claimed is not novel or is obvious, documents demonstrating this should be selected and cited if this is at all possible. If, exceptionally, this view can be supported from common general knowledge but the search examiner considers that it would be impossible, or that a disproportionate amount of time would be necessary, to find such documents, a report to this effect should be made under s.17(5)(b), preceded, if appropriate, by an ABS letter. In general, such a report will not be appropriate in respect of any claim when a search has been made on another claim and the claims are considered to relate to a single inventive concept. Thus, for example, independent claims and claims dependent upon them should be listed as having been searched when they fall within the scope of the search made (see 17.72.1).

FINAL PROCEDURE

17.102 The search examiner should also check, and if necessary reframe, the abstract (see 14.169-14.191) and classify the disclosure on both the IPC and CPC (even if an abstract has not been filed). The search examiner must therefore study the specification in whatever detail is necessary to carry out these tasks, in order to minimise errors on the published document, even though this may be time-consuming, particularly where relatively deep indexing systems are in use. The classification and/or index should normally be assigned in the light of the search, and classification of what is obviously old should be avoided. All significant technical disclosure should be classified and/or indexed, including any second or subsequent inventions, even though it may not have been the subject of a search and even if the same disclosure in a co-pending application is being given the same classification/index. The search examiner must see that any subclass examiner who may need to assign a supplementary classification has been consulted, and should make a record of such consultation by the addition of a minute to the PDAX dossier.

[The abstract title should be entered into the 'Abstract Title' field in the Details area on PROSE, and the figure to be used with the abstract should be entered into the 'Fig. Ref.' field as well as on the Abstract itself. ClassTool should be used to enter IPC and CPC classification data.]

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- 17.103 While the search examiner should not check those matters which are the responsibility of the formalities examiner, if he comes across an apparent omission or error on the part of the formalities examiner he should draw it to his attention.
- 17.104 When the search examiner has completed his report on the search and his other duties (see 17.102) the application should be sent for issue of the search report and search letter (see 17.83).

[After preparation of the report, a message should be sent to the Examination Support Officer from the examiner, either directly or via a message to their Revising Officer, depending on whether the examiner is revised or not. The Examination Support Officer will then print the reports and covering letters, and ensure that the relevant documents are imported into the PDAX dossier. The printed reports and covering letters should be placed together with any cited documents and sent to the post room for issue to the applicant.]

[Deleted]

[(For the issue of the search report on a divisional application, see 15.41-42).]

17.104.1 Issuing copies of citations is at the discretion of the Comptroller (see rule 27(2)). The default is for search reports issued by the Office to be accompanied by a copy of any non-patent literature (NPL) cited and an English language abstract of any cited foreign language patent document or NPL citation. Applicants are able to request, on Form 9A, that a copy of any cited patent document is also provided. The applicant will not be able to later 'opt in' to receive paper copies of patent documents. However, the option remains for a paper copy of any foreign language document to be issued to the applicant should they have difficulties obtaining a copy on the Internet. In general full copies of citations are provided except for the rare case that the cited document is of such a thickness that provision of only the most relevant sections is justified. In citing an NPL disclosure which cannot be obtained in time, the search examiner may initially rely on an abstract only. However a copy of the source document should be obtained and sent to the applicant as soon as possible. Where a cited document is not in English, machine translations of the cited document should not normally be issued to the applicant because they cannot be relied upon for accuracy and (depending on the source) there may be contractual and copyright restrictions. If a free translation can be obtained (e.g. through the website of another patent office), reference may be made to this source e.g. by URL. If the examiner feels it is nevertheless necessary to send a machine translation (and there are no copyright or contractual restrictions to doing so) a clear explanation of the status of the translation should be provided. In particular, it should be explained that the translation is machine-generated and therefore should not be relied upon as being definitive, but is being provided to be helpful for the applicant. Conversely, the search or substantive examiner may use a machine translation which he is unable (e.g. for contractual or copyright restrictions) to share with the applicant. In such cases, if the applicant disagrees with the examiner's interpretation of the disclosure then it is ultimately the applicant's responsibility to provide an explanation of his view. It should be remembered that it is the foreign language disclosure itself which forms the citation, not the translation. Translations are merely used to assist in understanding the prior art.

[The situation regarding abstracts is as follows:

- (a) if the search examiner does not have a copy of the NPL source document, (whether because it is not needed or it is unavailable), then the abstract alone issues to the applicant;
- (b) if the search examiner has a copy of the NPL source document as well as the abstract and the source document is not in English, then both the source document and the abstract are copied to the applicant.
- (c) abstracts of any foreign language patent documents are issued to the applicant. Where the applicant has requested copies of all citations the foreign language patent

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r.27(2)

document will accompany the abstract.

[In the case of cited documents with over 50 pages the search examiner should generally indicate for the benefit of the Examination Support Officer which pages are to issue (the front page should always be included) by annotating the checklist. The option remains for the search examiner to direct that a full copy should issue, if deemed necessary.]

[If a machine translation is to be issued to the applicant the copyright notice from the provider should be included. K-PION translations should <u>not</u> be provided; however a reference to the online KIPRIS service – which is free for use by the public - may be added to the search report (e.g. by URL).]

17.104.2 The application will then proceed to publication in due course (see 16.29-16.32) unless in the meantime it is withdrawn or refused.

[The search examiner should record the appropriate COPS processing status in PROSE (see 16.30).]

DOCUMENTS FOUND OR CONSIDERED IN FULL AFTER ISSUE OF THE SEARCH REPORT

17.105 The applicant should be sent a copy (or copies) of any non-patent literature (NPL) (and patent documents only when they have been requested on Form 9A) which the search/substantive examiner has become aware of after issue of the search report and which would have been included in the report had it been found during the search, or considered in full after citing the abstract in the search report (see also 17.83.1 and 17.75 square bracket note (d)). Where a copy of the patent document is not to issue, the applicant should nevertheless be informed of the citation. If the search examiner becomes aware of or considers the document before substantive examination, then the applicant should be immediately notified of the document so that he may decide whether to proceed with substantive examination, although this will not normally be done if it is a newly published document added to the files since the date of the search. A document found after issue of the search report and after the filing of amended claims and which anticipates the original rather than amended claims should nevertheless be communicated to the applicant. If the date of completion of preparations for publication has not passed, an amended external search report should be issued and the new document will be included on the front page of the published application. If the date of completion of preparations for publication has passed, an amended search report is not issued and the new document will only be mentioned on the front page of the specification published after grant (see also 18.85).

[When a search examiner becomes aware of a citation after the external search report has issued, the publication status of the application should first be checked on COPS using the "Display Processing Status" (DIS PRO) function. If the application is not yet ready for A publication, the search examiner should prepare amended internal and external search reports, and enter the new citation using PROSE. Depending on the circumstances in which the citations came to the notice of the search examiner, the Field of Search may, of course, also require updating on the internal and external search reports. The amended external search report, together with copies of the additional citation (see 17.105.2), should be issued under cover of SL5B, in which the new citation is identified. The amended search report should also be identified as such. The date of search on the amended report should correspond with that on the original report, but a suitable qualification may be added if necessary eg the date of any additional search. The Examination Support Officer should remove "P" from the original search report in the PDAX dossier in question but leave as open to public inspection, and mark the new search report as "P" allowing it to be published.

[When a search examiner's attention is drawn to an error in an external search report after the report has issued but before preparations for A-publication are complete (eg a citation has been wrongly identified), a similar procedure to that outlined above should

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be followed, except that the aim is to produce a corrected report for issue to the applicant, together with a copy of the correct citation(s), where appropriate (see 17.105.1), under cover of SL5C and for publication with the A-document, and to correct any corresponding error in the internal search report form.

[If it is too late for a corrected external search report to be published with the A-document then SL5D should be issued (together with a copy of the correct citation(s) where appropriate (see also 17.105.1)), and the formalities examiner should be advised to issue an erratum in respect of both the corrected external search report and any corresponding errors on the A front page (see also 16.33). After the application has been A-published, the citations should be corrected in COPS (using the "Record Citations" (REC CIT) function).

[If an applicant or agent is warned by telephone that an amended or corrected report is being issued it is not necessary to send a telephone report as well as the appropriate letter. See 18.11 for the procedure adopted if the substantive examiner becomes aware of a citable document when substantive examination is due.]

17.105.1 Where the search examiner is made aware by the applicant of a document that has been cited in a search report for a patent application on the same invention made in another patent office, consideration of the documents cited should be deferred until substantive examination. An amended search report should not be issued (see 18.64 for when substantive examination has already been performed).

[The foreign search report or letter received from the applicant mentioning the cited documents should be placed on the open part of the file. A minute should be added to the PDAX dossier and the appropriate PDAX message sent to the substantive examiner.]

17.105.2 Documents cited by the IPO after issue of the search report are copied to the applicant where appropriate (see 17.104.1). In the case of international applications under s.89, copies of additional documents cited by the UK search/ substantive examiner are provided but not copies of the documents cited in the International Search Report, Supplementary International Search Reports (if any), or the International Preliminary Report on Patentability.

[It is the examiner's responsibility to ensure that the Examination Support Officer is instructed to send copies of newly cited documents to applicants:

where NPL documents are cited for the first time at the substantive examination stage;

where patent documents are cited for the first time at the substantive examination stage and the applicant previously requested that they be sent paper copies of cited patent documents by ticking the box on Form 9A;

where a source document for a cited abstract has been obtained;

where the wrong document has previously issued;

where on an international application under s.89, documents are cited by the UK examiner which were not included in the international search report.]

Section 17(6)

If it appears to the examiner, either before or on conducting a search under this section, that an application relates to two or more inventions, but that they are not so linked as to form a single inventive concept, he shall initially only conduct a search in relation to the first invention specified in the claims of the application, but may proceed to conduct a search in relation to another invention so specified if the applicant pays the search fee in respect of the application so far as it relates to that other invention.

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PLURALITY OF INVENTION

The question as to whether there is unity of invention (see 14.157-14.168) should always be considered whenever there are two or more independent claims in addition to any omnibus claim (but see 14.164); the answer to this question will usually be quickly apparent and should always be recorded on the internal search report (see 17.88.1). When it is clear that the claims relate to more than one invention or inventive concept then the search must be directed to the first invention specified in the claims, which will generally be the invention of claim 1 or of a group of claims whose scope embraces claim 1 (see also 17.37). Section 17(6) allows no discretion in this matter. The search must be directed to the first invention encountered when the claims are read in numerical sequence (see Hollister Inc's Application [1983] RPC 10), even if the claims are filed out of sequence. If it only becomes apparent after a partial or full search that unity of invention does not exist, this lack of discretion prevents the acknowledgement, in the "claims searched" or in the citation table, of any search other than that relating to the first invention. Nevertheless, prior art common to the first invention and any other invention(s) can be cited as background art relevant to the first invention if it is considered desirable in establishing the grounds for noting a plurality of inventions (see 17.80). The examiner may advise the applicant of prior art relevant to further inventions in a supplementary report in the search letter, but should make clear to the applicant that the further invention has not been searched. If the first invention of a divisional application is the same invention as in the parent, see 15.38.

[The extent and results of a search, as they relate to invention(s) beyond the first, should be recorded on the internal search report for the benefit of any search examiner called on to search the further invention(s) (see 17.86).]

17.107 As noted above, s.17(6) requires the examiner to search this first invention. However if the first invention claimed is excluded under s.1(2) but later claims define one or more not excluded inventions, the examiner is able to search the first of these (see 17.94.2). This is because s.1(2) is clear that matter which is excluded under that provision is not considered an "invention" at all. If it is clear that the first invention is excluded under s.1(2), this should be reported to the applicant in the search letter, exam opinion or CSE examination report as appropriate.

r.27(3) CoP 17.108 When the search examiner has reported that the claims relate to two or more inventions not linked by a single inventive concept, the comptroller must notify the applicant of this fact. Those claims or groups of claims which are considered to constitute separate inventions should be identified in an accompanying letter or the examination report if the search and substantive examination are combined. In the latter case the report should make it clear that the notification of more than one invention is made under s.17 to keep open the opportunity for the second and any further inventions to be searched under s.17 (see 18.41). The letter or report should also indicate that the search has been directed to the first of the inventions. If it is not possible to state precisely how many inventions are specified in the claims, but it is nonetheless clear that unity of invention is lacking, for example in a case with a large number of overlapping independent claims, or where there are obscurities in the claims, or where a lengthy analysis of the claims, more appropriately done at substantive examination, would be needed, a report to this effect may be made. Where it is not practicable to identify all the claims encompassed by the first inventive concept, claim 1 of the application may be searched by the search examiner. Where excessive amounts of time would be incurred to identify the exact number of inventive concepts in an application, a clause may be inserted into the search letter, asking the applicant to identify the separate inventive concepts when requesting a further search under s.17(6).

[Plurality of invention should be indicated by the addition of SC13 to SL1 before the paragraph about other search results or by adding RC6 and RC6A to a combined search and examination report issued with SE1 or SE4 (see 15.41).]

17.109 In some cases it will be evident why the search examiner has reported

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that there is plurality of invention. Where this may not be immediately apparent, for example where prior art found during the search demonstrates that the matter linking two or more claims is not novel or inventive, or where a single claim embraces more than one invention (see 14.164), a specific report to this effect should be included in the letter or examination report accompanying the search report. Any such prior art should be designated A in the search report as described in 17.80, unless it is also relevant for novelty or inventive step in respect of the searched invention.

17.110 If a group of claims formally has unity of invention because one of them embraces in scope all the others, and it transpires that the invention of this claim is not novel or inventive, the search examiner should if practicable complete the search on this claim. If such a course is clearly not reasonable, for example if this claim is unduly broad and speculative and is apparently merely a device for giving an impression of unity of invention, then the search examiner should decide what appears to be the most efficient course. The search examiner may decide to read the main claim as notionally amended by combination with each of these dependent claims and search the invention which is then encountered first; in such a case the search examiner should indicate in the letter accompanying the search report that there is plurality of invention and add a brief explanation of the reason for this (see also 14.164). Alternatively he may perform a partial search in respect of the main claim, or, if the substance of the main claim is so blatantly well known or is so nebulous that search for it would serve no useful purpose and the claim is clearly an artificial attempt to give an impression of unity to differing inventions, he may defer the search altogether (see 17.94.5-17.94.9).

Further search

r.27(4) r.27(5) r.27(6) r.108(1) 17.111 If the search examiner has reported plurality of invention, a further search may be requested in respect of a second or subsequent invention which was present in the claims at the time of the main search. However, further searches under s.17(6) are carried out at the comptroller's discretion. A request for a single further search should normally be fulfilled. However, where multiple further searches are requested, the examiner should use their judgement to decide how many to perform. The filing of a large number of further searches is undesirable – for efficiency and fairness the examiner should consider carrying out fewer searches than requested. (Further searches are not to be confused with supplementary searches under s.17(8) of an application which has been amended or corrected, see 17.120-17.123). A further Form 9A (or Form 9 see 17.02) and search fee must be filed for each such search requested, and this must be done at least three months before the end of the compliance period (including any extensions). A form 9A filed for a further search request is not subject to additional excess claims fees. The period for filing the form and fee may be extended at the comptroller's discretion.

[Where fewer searches have been carried out than have been requested, this should be noted in a minute. The applicant should be made aware that the examiner has not carried out (all of) the requested further searches, and that a refund will be issued on any unsearched Form 9A. The examiner should send a minute to Formalities asking them to refund the fee.]

[A further search should normally be carried out concurrently with "primary" searches received in the group at the same time, whether or not the application has been published. During the 5-week period of the publication cycle, COPS is locked and so won't accept any changes to bibliographic data or processing status. It is therefore not possible to generate an internal or external search report in the usual way (as nothing can be entered into the "citation" and "field of search" tables), and so if the further search is likely to be due during the publication cycle it is advisable to issue it before it enters the cycle. The initial search letter (eg SL1 or SE1) provides (under the heading "publication") an estimated date after which the preparations for publication will be completed – the case will generally enter the publication cycle shortly after that date, and so this may be used to estimate the date from which COPS will be locked. Of course, the actual searching can be done during the publication cycle, and the case remains available on PDAX. If the search is urgent (for example if it has been

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accelerated) and so has to be done during the publication cycle, then the search results will need to be communicated to the applicant without completing a conventional search report. This may be done by creating a miscellaneous letter giving information about the claims searched, the citations and the field of search as free text, and enclosing copies of any citations. The case should then be diaried to a date after publication and a full search report created at this time in the usual way.]

[A report of a further search should be accompanied by letter SL4 and a copy of any additional citations (see 17.104.1). When further search is carried out before A-publication the resulting external search report will be published together with the original external search report. To ensure that this happens, the Examination Support Officer imports the later search report and marks it as "P" in the PDAX dossier allowing it to be published. The Examination Support Officer will then retrieve the sub-file and add a copy of the later search report, again marking the report as "P" allowing it to be published.]

[The search examiner should not respond to a request for a further search under s.17(6) by issuing an ABS letter (see 17.94.4-17.94.9) requesting amendment or other action before search]

17.112 If carrying out searches on more than one invention simultaneously the results of all the searches may be reported on a single search report providing it has been made clear in a letter or report what the different inventions are and the search report makes clear to which claims each document is relevant.

17.113 The practice of filing more than one Form 9A and search fee before the initial search report has issued is undesirable, since it amounts to an admission that the claims have been filed in the knowledge that they do not comply with s.14(5)(d). In this situation the normal course of action should be to search only the first invention. In which case, for efficiency, the search examiner may also decide to assess plurality only to the extent needed to search the first invention. However, the search examiner has discretion to carry out all searches and fully assess plurality. Any assessment of plurality should be made without reference to the applicant's actions. If multiple searches are carried out the search letter heading should be modified to refer to both section 17(5) and 17(6). If after carrying out a full assessment of plurality it turns out that the claims have unity of invention, a single search should be made and the fees for the superfluous Form(s) 9A should be refunded.

[Where the search examiner has carried out fewer searches than have been requested, this should be noted in a minute. The applicant should be made aware that not all requested searches have been completed, that unsearched Form 9As will be refunded, and (where applicable) that a full assessment of plurality has been deferred. The examiner should send a minute to Formalities asking them to refund any unsearched Form 9A fees.]

17.114 When Patents Form 9A (or Form 9, see 17.02) is filed requesting a further search and the relevant subject-matter is dealt with by an examining group other than that in which the original search was performed, the further search can be carried out in the other group if desirable for quality and/or efficiency.

Section 17(7)

After a search has been requested under this section for an application the comptroller may at any time refer the application to an examiner for a supplementary search, and subsections (4) and (5) above shall apply in relation to a supplementary search as they apply in relation to any other search under this section.

17.115 A supplementary search will generally be necessary as part of the substantive examination in order to detect any relevant documents which have been published since the original search (although see 89B.12-89B.12.3 for specific points relating to s.89 cases). This "top-up" search will also normally include a check for published

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equivalent cases, both to identify any application which is potentially in conflict with the application in suit (and which might therefore give rise to action under s.18(5) or s.73(2) – see 18.91-18.97.1 and 73.05-73.12), and to identify any further citations raised against these equivalents (see 18.10.1-18.10.4). The examiner may take into account how closely the claims of the equivalent application resemble those of the application in suit, and the apparent relevance (from the category, if stated) of the equivalent's citations. A supplementary search of this type may not be necessary where the initial search is performed at such a time as to be effectively a "top-up" search, for example where the first search on a divisional is performed later than 21 months from the priority date.

Whilst the application of CPC terms to EPODOC abstracts may occur several months later than 21 months from the priority date (see also 17.118), databases should be sufficiently up to date at about 21 months to conduct a search for prior art falling in the s.2(3) field provided that the search relies on IPC terms. Note that in any case, a search cannot be considered complete unless it involves search of both CPC and IPC (see 17.55). Where a priority claim is invalid or relinquished, a top-up search before 21 months from *filing* may not uncover all relevant s.2(3) prior art because some documents may not yet be published.

Online databases should also be up to date three months from the priority or filing date of an application for prior art in the s.2(2) field. A top-up search should cover the period of at least 6 months before the original search date, to account for the time taken to classify published documents to CPC collections. If a document found lies in the field defined by s.2(3), consideration should be given as to whether there may be an earlier-published equivalent (see also 17.90). The examiner should ensure that a complete search in respect of at least s.2(2) art has been made before grant because only applications forming part of the s.2(3) field can be cited under s.73(1) after grant.

[If a priority date has already been determined as a result of the practice described in 18.15, then the examiner should take this into account when deciding when to carry out a top-up search for s.2(3) art. That is, if a priority claim is valid, then databases should be sufficiently up to date at about 21 months after the priority date. If the priority claim is invalid then the top-up for s.2(3) art should be delayed until at least 21 months after the *filing* date. If the priority date has not been determined, then the examiner should bear in mind that the priority claim may be invalid when carrying out a top-up search for s.2(3) art. The examiner should then decide the most effective course of action, which may be for example to: delay the top-up until 21 months from *filing*, check the priority claim, or continue on the basis that a top-up 21 months from the declared priority is appropriate.]

[A top-up internal search report should be generated on PROSE to record details of the updated search. It should normally be sufficient to update a search at the first substantive examination stage only, unless that examination occurs very early (eg as a result of combined search and examination or a request for accelerated examination). The search statement used and the files searched need be recorded only if different from the search being updated. However, a record should always be made of the search strategy used, even if it is the same as the strategy used in the original search. This can either be recorded in the top-up search report or in an OSS (Online Search Strategy) document in PROSE. Any newly-cited documents should be recorded on the report and the Examination Support Officer instructed to issue them (see 17.104.1, 17.105.2). If the search is further updated before grant, a further top-up internal search report should be produced, and the Examination Support Officer should be instructed as above as to which documents are to issue if further citations are found. A further updating search is necessary only to the extent that the first updating search was incomplete.]

[When conducting a top-up search the examiner should use the FAMI+REFI preparation on EPOQUE to identify equivalents and the documents cited against them. In addition, online file inspection may provide further details of the significance of a citation; see 18.10.4. A note should be made on the top-up search reporting whether or not such citations have been checked and – if not – the reasoning why not.]

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[The FAMI+REFI preparation will also identify the CPC classifications that have been applied to the case by the EPO/USPTO. If this check reveals CPC classifications that were not searched during the original search, these should be recorded in the internal top-up search report and the examiner should consider whether the search needs to be extended accordingly. If the examiner considers extension of the search is not necessary, they should include an explanation on the top-up search report.]

[Patent examiners should only use the top-up internal search report for notes relating to the search. Any other notes, for example recording the examiner's decision to drop an objection, should be added as a minute to the PDAX dossier.]

[If a top-up search is carried out at the same time as finding the application in order for grant, the examiner should create an internal search report (ISR-TOP) and associated checklist. The examiner should then send a "ISSUE RELEVANT EL34 (OR EL3) LETTER AND TOP UP SEARCH" message to the EA GRANT mailbox as described in 18.03.6, 18.81 and 18.86.2.]

17.116 This supplementary search may be deferred if thought appropriate, for example if much relevant prior art has already been cited and no amendment has yet been made, or if the first examination report is only a preliminary one (see 18.48), or if the claims are obscure; a note to this effect should be made on the internal search report and the applicant informed accordingly.

17.117 It will also be necessary to perform a search under s.17(7) if the search has been wholly or partially deferred under s.17(5), or if it is discovered on examining the specification that the search already performed under s.17(4) was deficient, for example if it transpires that the true scope of the invention is broader than had been thought, or if the specification has been amended in a way not anticipated by the original search strategy (see also 17.120-123 regarding the possibility of a fee for such a supplementary search). The course and results of such a search should be recorded on a top-up internal search report.

[The Examination Support Officer should be instructed to issue any newly-cited documents (see 17.104.1, 17.105.2).]

17.118 When an application is sent to grant before 21 months or the substantive examiner is not otherwise satisfied that the supplementary search is complete for art in the s.2(3) field, the application should be diaried for return at some appropriate date after grant for the search to be completed and the applicant informed accordingly. If a document forming part of the state of the art by virtue of s.2(3) comes to the notice of the substantive examiner after the issue of a report under s.18(4), action may be taken under s.73(1) after grant (see 73.02-73.03).

[To ensure the applicant is informed, the examiner should send a minute to the EA asking them to include the relevant post grant top-up search clause in the intention to grant letter.]

[The examiner should create an entry in the PD electronic diary system and add the diary action to the dossier in PDAX. The diary entry should state the examining group after the application number in the format GB0000000.0 – EX00.]

[Online databases will usually be sufficiently up to date in respect of s.2(3) art in addition to s.2(2) art at about 21 months from the priority date of the application. Examiners should use their judgment as to whether the top-up search made is likely to be complete.]

[A top-up internal search report (ISR-TOP) should be generated on PROSE to record details of the updated search. Any additional fields of search or documents should be recorded in the free-text areas of the ISR-TOP. A checklist for the post grant top-up search report should be generated instructing the ESO to import the ISR-TOP.]

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17.119 [deleted]

Section 17(8)

A reference for a supplementary search in consequence of -

- (a) an amendment of the application made by the applicant under section 18(3) or 19(1) below. or
- (b) a correction of the application, or of a document filed in connection with the application, under section 117 below,

shall be made only on payment of the prescribed fee, unless the comptroller directs otherwise.

- Subsection (8) was added by the CDP Act along with s.18(1A). Where, before or during substantive examination, the substantive examiner considers that a supplementary search is necessitated by an amendment or correction in respect of an application, an extra fee is payable under s.17(8) and s.18(1A). This is not to be confused with a further search under s.17(6) at the request of the applicant for a second or subsequent invention which was claimed in the application as filed and identified in the search report, see 17.111-114. Section 17(8) applies to amendments made either in response to the substantive examiner's report or of the applicant's own volition, as well as to corrections.
- 17.121 If a supplementary search is required a request for a further search fee may be considered in the following situations:
 - i) A correction is made that alters what has to be searched and so necessitates a change to the search statement;
 - ii) An amendment shifts the scope of the main claim to include features of the description which were justifiably not searched. For example, where searching these features would not have been practical within a single search, or would have required undue additional searching (bearing in mind 17.32), if the search examiner communicated the scope of search clearly to the applicant, a further search fee request may be considered if the amended claims are no longer within the scope of the search. If the amendment could have readily been predicted then a request is unlikely to be justified;
 - iii) Where a plurality objection was raised in the initial search report, international preliminary search report or written opinion and the applicant deletes the first claimed invention, resulting in claim 1 becoming an unsearched invention. If multiple inventions remain in the application, any searches of later inventions should be dealt with in accordance with s.17(6).
- 17.122 A request for a further search fee is not appropriate in the following circumstances:
 - To overcome an unfortunate choice of search areas or search statement by the search examiner;
 - ii) When the amended claim remains within the scope of the original search statement;
 - iii) When the sole reason for the further search fee is that the original search was truncated;
 - iv) When the sole reason for the further search is a decision by the Examiner to extend the search to more relevant areas. For example, where reclassification has created a highly relevant place not available at the search stage, or other classification terms have been applied to the published document by the EPO;

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- v) Where the applicant broadens a claim to achieve consistency with the description (for example so that an embodiment falls within the scope of the claim) but there was no comment from the search examiner that the original search was not widened to take account of the description (see 17.37), and the applicant could have reasonably expected such a comment.
- r.27(6) 17.123 Where action is taken under s.18(1A), see 18.03.2-03.6, and a fee for a supplementary search is paid, it should be accompanied by a fresh Form 9A (or Form 9, see 17.02) completed accordingly. A form 9A filed for a supplementary search request is not subject to additional excess claims fees. A search report is in due course issued reporting the result of the supplementary search.

[The Examination Support Officer should be instructed to issue any newly-cited documents (see 17.104.1, 17.105.2).]

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18.01 This section sets out the conditions necessary for an application to proceed to substantive examination, makes provision for carrying out the examination and reporting the result, provides for the applicant making observations on the report and if necessary amending the application, specifies that a patent may then be granted or refused, and finally deals with the case of conflicting applications from the same applicant. Time limits and other provisions relating to these matters are prescribed in rr.28, 29 and 30.

Information security: a reminder

- s.118(2)

 18.01.1 Combined search and examination actions are generally carried out before A publication, and accelerated examinations may also be performed before A publication. The guidance in this section therefore relates in part to pre-publication actions. Before A publication, the application, the search, examination or combined search and examination report, and any other documents or information concerning the content of the application (other than that prescribed under s.118(3)) must be protected and must not be communicated to anyone outside the Office other than the applicant or his designated representative see 118.16-118.16.1 for further guidance on these issues.
 - 18.01.2 More generally, in all cases, whether pre-or post-publication, formalities examiners should ensure that any communications (including telephone conversations) are directed to the intended recipient.

[Where correspondence from the Office is reported as never having arrived at its intended destination, or is reported as being misdirected or delayed, this fact should be recorded by sending a minute to the relevant formalities group with any relevant details. Use of r.111 to extend a deadline may only be authorised by the relevant Head of Administration (see 123.47.1).]

CODE OF PRACTICE

- 18.01.3 The Code of Practice (the second part of which can be found below) identifies best practice points for patent applicants and agents, which if followed widely will lead to savings and efficiencies in the Office, and consequently to better service and better value. Examiners and other Office officials may on occasion draw the Code to the attention of the applicant or agent, and may ask for it to be complied with before the case is processed further if that would be more efficient.
- 18.01.4 However, it is not to be expected that best practice can always be adhered to. The Office has no right to demand compliance with the Code of Practice because the Code is advisory only and has no legal force.
- 18.01.5 If an application does not comply with one of the points of the Code of Practice then this does not necessarily justify an objection under the Patents Act or Rules. For example, an application having more than one independent claim in one category would not comply with code point 1e, but this would not usually justify an objection under s.14(5)(b). When drawing attention to non-compliance with the Code of Practice, examiners should therefore make it clear whether they are also raising a formal objection under the Act or Rules.

[CODE OF PRACTICE FOR APPLICANTS AND AGENTS

Prosecuting patent applications

This part of the Code of Practice relates to the prosecution of patent applications. The process of examination and amendment of patent applications ideally proceeds by eliminating objections until the application can be granted. To expedite the granting of an application, the

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substantive examiner will attempt to indicate all objections in the first report issued under s.18(3). The main exception to this will occur where only major objections (such as patentability issues) are raised and minor matters are deferred until the major points have been settled. This process of eliminating objections minimises the time taken conducting a comprehensive review of the specification as it will generally only be necessary to decide whether or not the amendments or arguments advanced meet the objections raised. However, for this process to be efficient for both sides it is necessary that the following points are observed.

POINT 6: Responding to the examiner's objections

- a A full response should be made to each and every objection raised in an examination report through amendment and/or argument so as to progress the application towards grant (see 18.63 to 18.63.3).
- b When objections are to be met by amendment, an appropriate explanation should be provided, in particular, as to how the amendment meets the objection and how it is supported by the specification as originally filed (see 18.63 to 18.63.3).
- c Amendments must neither add new technical disclosure, nor broaden the scope of claims beyond the disclosure as originally filed (see 76.04 76.23).
- d Pages showing the amendments, in manuscript or distinctive type, should be filed in addition to the clean replacement pages for the specification (see 18.61).
- e Consequential amendment of the description may be deferred until the independent claims have been agreed upon (see 18.52).
- f The Office recommends the use of electronic filing when submitting amended pages or arguments in response to the examiner's objections, whether the original application was filed electronically or not. See https://www.gov.uk/apply-for-a-patent.

POINT 7: Time issues in patent processing

The efficiency of the patent granting process depends in no small part on the timeliness of the Office as well as of applicants and agents. The Office will set a timetable for the various stages in processing a patent application to grant, by setting periods for responding to various Office letters and reports. Applicants and agents should use their best endeavours to act within the periods for response that will be specified. Requests for extensions of those periods for response will be considered if made in the recommended way and in accordance with the legislation relating to extensions of time. Requests for processing to be accelerated will also considered if made in the recommended way.

- a Action should be taken within a period specified for response; and not delayed until the last day if that is avoidable.
- b A request for extension of a period for response should be made in a timely manner. The request may be e-mailed to the dedicated <a href="mailto:patential-gate-nailto:paten
- c A request for accelerated processing of search or examination should be supported by an adequate reason that is peculiar to the circumstances of the case (see 17.05.1-2 and 18.07 - 18.07.3).

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- d When time is short, the covering letters or fax header sheets accompanying responses to Office actions should be marked "URGENT" (see 18.72.1).
- e Notification of withdrawal of an application *must* reach us before the date on which preparations for publication are completed if it is wished to prevent publication: the publication process does not permit later withdrawals (see 14.205).
- f Voluntary amendments should be filed early (see 19.13).

POINT 8: Filing divisional applications

- a Divisional applications should be filed early as time is limited under rule 30 (see 15.20.2).
- A divisional application should have a single claimed invention (or inventive concept) that is distinct from that of the parent application (see 15.20.2 and 15.29).
- c The description and drawings of the divisional application should be provided in a form appropriate to the invention of the divisional application, and irrelevant material excised (see 15.32).
- d Amendments already known to be required at the date of filing of the divisional application should be made (see 15.32).

If the above points are not met on filing a divisional application, suitable amendments should be filed as soon as possible (see 15.36).

POINT 9: Forms and formalities after filing

• a Information about changes should be notified promptly and by the recommended method. Global changes affecting more than one patent application should be notified by one communication, with a list of the patent application numbers (or patents) appended. The distinction between amendment and correction should be appreciated (see 19.03), and where a correction is proposed, sufficient evidence demonstrating that the correction was the applicant's intention at the time of filing should be provided (see 117.19). Supporting proof where needed should be adequate to establish and verify the circumstances.

Change of address (only): a letter will suffice for this, whether it is amendment or correction (see 19.05, 117.03).

Change of agent: Form 51 is used for this amendment (see 14.04.12).

Appointment of an agent for the first time (after the filing date): Form 51 is used.

Amendment or correction of other data on the application form: Form 20 is used for correction of an applicant's name, and may require supporting proof. All other amendments or corrections should be made in writing (see 19.05 - 19.12 and 117.17 - 117.21).

Amendment of name (ownership) in the Register. Form 20 is used and may require supporting proof (see 32.06).]

Section 18(1)

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Where the conditions imposed by section 17(1) above for the comptroller to refer an application to an examiner for a search are satisfied and at the time of the request under that subsection or within the prescribed period -

- a request is made by the applicant to the Patent Office in the prescribed form for a substantive examination; and
- (b) the prescribed fee is paid for the examination;

the comptroller shall refer the application to an examiner for a substantive examination; and if no such request is made or the prescribed fee is not paid within that period, the application shall be treated as having been withdrawn at the end of that period.

- r.28(1) 18.02 The request for substantive examination must be made on Patents Form 10. r.28(2) This, together with the prescribed fee, including any excess pages fees, must be filed within six months of the date of publication of the application under s.16, unless the application falls into one of the categories referred to in (a)-(d) below:-
- for an application which claims an earlier date of filing under s.8(3), 12(6), r.28(5) 15(9) or 37(4), Form 10 and the fee must be filed within two months of filing the application or, if it expires later, within two years of the declared priority date, or, where there is no declared priority date, within two years of the date treated as the date of filing:
 - (b) for an application not falling within (a) above whose publication under s.16 has been prohibited or delayed because of a direction made under s.22(1) or (2), Form 10 and the fee must be filed within two years of the declared priority date, or, where there is no declared priority date, of the date of filing;
 - for an application which has been converted from one for a European patent (UK) the period is governed by r.60, (see 81.17);
 - (d) for an international application for a patent (UK), the period is governed by r.68(4), (see 89B.09).

In the case of an application in category (a), (b), (c) or (d), the period prescribed for filing Form 10 and the fee can be extended in accordance with r.108(2) or (3) together with r.108(5) to (7), see 123.34-41.

[The COPS records are combed weekly. Applications which have between two weeks and three weeks remaining of the prescribed six month period for filing Form 10 are identified on the "Form 10 Picklist". (The "Form 10 Picklist" cannot identify applications which fall into categories (a) - (d) listed in 18.02). Any applications on which Form 10 and fee are not filed are selected by COPS on the "Form 10 Time Limit Report" one month and seven weeks after the expiry of the prescribed period. Such applications should be checked by the relevant Formalities Manager to confirm termination. (For termination procedure, see 14.199). For applications not identified by the "Form 10 Picklist" but on which Form 10 has yet to be filed, the formalities examiner should identify those where the period for filing Form 10 has not expired. The file should then be diaried using the PD diary. If Form 10 is not subsequently filed in time, the application should be passed to the relevant Formalities Manager to confirm termination.]

18.03 Form 10 and the examination fee, including any excess pages fees can be filed at any time before the end of the prescribed period; it may be filed at the time of making the application if the applicant so wishes. Applications on which Forms 9 or 9A (see 17.02) and 10 have been filed on the same date (apart from PCT s.89 cases where an international search report has been communicated to the Office) will receive combined search and examination before publication under s.16, unless the applicant has explicitly stated in writing

r.28(3)

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that this is not wanted. If an applicant has initially filed only Form 9 or Form 9A and later requests combined search and examination in writing when filing Form 10, the request for the combined procedure should be met if possible. However, in such cases the search and examination can only be combined if the examiner is aware of the request before beginning the search. A request for a refund of the examination fee and also of the search fee for combined search and examination cases is normally acceded to if it is received before issue of the substantive examiner's report. However, the examination fee is not refunded if following combined search and examination a search report under s.17(5) has issued and the examination has been performed but no report under s.18 has issued (see 18.84.1). In all cases such refunds are a matter of discretion, not a right.

[A COPS flag for combined search and examination will be set automatically to 'YES' if Forms 9 or 9A and 10 are logged with the same filing date. The formalities examiner should identify those applications on which both Form 9 or 9A and Form 10 have been filed on the same date (other than PCT s.89 cases where an international search report has been communicated to the Office). The combined search and examination will be identifiable by the appropriate cover label and PDAX message. However, it will not be necessary to label the dossier cover if the applicant has stated either on Form 10 or in a separate letter that combined search and examination is not wanted. In this case, the formalities examiner should set the combined search and examination flag to 'NO', and add a minute to the PDAX dossier explaining the situation to the examiner.

[In the event of Form 10 being filed after Form 9 or 9A with a written request for combined search and examination, the formalities examiner should check whether the search report has issued. If it has already issued, the applicant should be informed, as indicated later in this paragraph, that the request was received too late. On the other hand, if the search report has not issued, the formalities examiner should arrange without delay for the Form 10 to be put on file and for a minute to be added to the PDAX dossier. The formalities examiner should also place the appropriate label on the dossier cover and send the appropriate PDAX message to the substantive examiner to make him aware that combined search and examination has been requested. The combined search and examination COPS flag should also be set to 'YES'. On receipt of a labelled file in the examining group, the Examination Support Officer should check with the search examiner to see whether the search has been started. If it has not, the examiner in due course should carry out the examination at the same time as the search. In the remote event of the Form 10 and the written request being received during a search, the search examiner can opt, depending on the stage reached, to carry out the examination or defer it until the normal examination stage. Whenever the examination is not carried out the applicant should be informed by the formalities examiner or the search examiner, as appropriate, that the request for substantive examination was received too late to allow combined search and examination and that substantive examination will occur in due course after s.16 publication. The applicant should also be informed that accelerated examination will be considered if requested and a reason for the request is given in writing. If necessary, the combined search and examination flag on COPS should also be changed from 'YES' to 'NO'. The request for a refund should be dealt with by the appropriate formalities group with the examining group being informed immediately. An examination report or combined search and examination reports should not be issued after receipt of a request for a refund, even if the report or reports have already been prepared. 1

Section 18(1A)

If the examiner forms the view that a supplementary search under section 17 above is required for which a fee is payable, he shall inform the comptroller, who may decide that the substantive

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examination should not proceed until the fee is paid; and if he so decides, then unless within such period as he may allow -

- (a) the fee is paid, or
- (b) the application is amended so as to render the supplementary search unnecessary,

he may refuse the application.

18.03.1 Subsection (1A) gives powers to the comptroller where an applicant's action makes a supplementary search necessary at the substantive examination stage. Section 17(8) provides for the payment of a fee for such a search (see 17.120-123).

18.03.2 If, before or during substantive examination, the substantive examiner reports that a supplementary search is necessitated by an amendment or correction as referred to in 17.120-123, the applicant may be so informed in a letter giving a specified period to pay the fee or amend the application so as to remove the need for the search or submit observations, and warning that the application may otherwise be refused. Where such an amendment is submitted but fails to remove the need for the search, the matter is pursued until either a satisfactory amendment is filed or the fee is paid, or it becomes evident that the dispute cannot be resolved.

Senior Examiners may decide whether to take action under ss.17(8) and 18(1A), without reference to their Deputy Director; Examiners should consult their senior officer as to the appropriate decision. Such action should be initiated by issuing EL27 in which the period specified for response should normally be two months. This period may need to be reduced if the application is approaching the end of the compliance period; if there is less than 6 months remaining of the compliance period the reply period should not be set at longer than 1 month. Appropriate timeframes should be decided by the examiner if less than 3 months of the compliance period remain. When issuing EL27, the case examiner should create a "Diary" entry in the PD electronic diary for return of the file to him on a specified date which should be 5 months from the date on which he writes the instructions. The diary entry should state the examining group after the application number in the format GB0000000.0 - EX00. A diary action should also be added to the PDAX dossier. Instructions should be given for the diary entry to be cancelled if a response is received before the "bring forward" date. If amendments are unsatisfactory or the applicant disputes the need for the search, or search fee, the matter should be pursued by letter or telephone (confirmed in writing) with the aim of swift resolution so that the normal examination process can commence or continue without undue delay. If no response is received the examiner should write or telephone (confirming in writing) to enquire if it is the applicant's intention not to proceed, emphasising that if no action is taken the application will be treated as refused at the end of the compliance period. It should be made clear that genuine reasons for the late-filing should accompany any subsequent response. The case examiner should be named and a contact telephone number provided in all letters to the applicant or his agent.]

18.03.3 Where a further search is performed, at the request of the applicant, for a second or subsequent invention which was claimed in the application as filed and which was identified in the search report, section 17(6) rather than section 17(8) applies and the procedure is that set out in 17.111, etc. If, however, amendment to remove plurality of invention results in the deletion of claims to an invention which was searched at the search stage in favour of an invention which was present at that stage but which was not so searched, a search fee under section 17(8) should be required if a further search is then necessary at substantive examination.

[A search for a second invention in a divisional application should be made without requiring an additional search fee when a search report has issued in respect of the first invention in the divisional application, despite this invention already having been

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searched in connection with the parent application (see 15.38), and a further search becomes necessary for the second invention sometime later upon deletion of the first invention.

18.03.4 If an applicant files another search fee in anticipation of the amendments made necessitating a further search under section 17(8) and the substantive examiner does not consider such a search to be necessary, then a refund of the fee paid should be made, even if no specific request therefor has been made by the applicant.

18.03.5 If, following the issue of the letter referred to in 18.03.2, there is such an unresolved dispute and/or if the fee is not paid or any other requirement of this provision is not met, a hearing is offered. If the hearing officer decides that examination should not proceed until the fee is paid or the application amended, he should specify a period (normally two months) for payment or appropriate amendment. If neither action is taken within the specified period he may refuse the application.

[A hearing may be offered by Senior Examiners but Examiners should consult their senior officer as to the appropriate decision. The hearing should be taken by the Deputy Director (see also 18.03.2).]

18.03.6 When the appropriate fee has been filed, together with a Form 9 or 9A, the substantive examiner performs the supplementary search. A search report is issued; this may accompany a s.18 examination report.

[If the search report is issued with a s.18 report, an ISR-SUPP bundle with SE6 or SE7 should be used as appropriate; SL7 should otherwise be used (in an ISR-SL7 bundle). Any newly-cited documents should be issued at the same time (see 17.104.1, 17.105.2).

[If an SE7 is issued as a first examination report, the first tick-box should be selected in PROSE. The second tick-box will only be available, and should be ticked, if the examination report is a first examination report and is being issued more than 3 years, 6 months after the earliest date. This will ensure the appropriate text is included in the letter, and set a reply period of two months. If the application has already been published the examiner should set a diary for three months time.

[If an SE7 is issued as a second (or later) examination report, neither tick box should be selected in PROSE. This will set a reply period of one month. If the application has already been published, the examiner should set a diary for five weeks.

[In either case, where an SE7 is issued and the application has *not* been published, a diary should instead be set for three months after publication. Whenever a diary is set, a diary action should also be added to the PDAX dossier.

[If the application is still in order for grant when the case returns to the examiner, the examiner should send a message to the EA GRANT mailbox. On receiving the message, the EA should then issue the appropriate intention to grant letter (see 18.81 and 18.86.2 for detail on the intention to grant process).]

Section 18(2)

On a substantive examination of an application the examiner shall investigate, to such extent as he considers necessary in view of any examination carried out under section 15A above and search carried out under section 17 above, whether the application complies with the requirements of this Act and the rules and shall determine that question and report his determination to the comptroller.

18.04 After Form 10 has been filed but before sending the application to an examining group for substantive examination, the formalities examiner should examine any new pages for compliance with r.14 and Schedule 2. Any objections should be reported in a

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form suitable for inclusion in the letter which constitutes the examiner's report under s.18(3) (see 18.47).

[18.05 Deleted]

18.06 The application should be forwarded to the examining group responsible for the classification heading where the primary search had been performed or if the application is destined for combined search and examination, the file should be sent for allocation to the appropriate group as indicated in 17.03. It may be transferred by mutual agreement to a different heading before substantive examination if, for example, it had transpired during the search that the other heading would be more suitable, or if amendment of the specification has rendered transfer appropriate, or if subject-matter has been transferred on reclassification. The substantive examiner should aim to deal with cases allocated to him within 18 months of their s.16 publication date but he should normally examine these cases in order of their priority dates, unless the application qualifies for combined search and examination, in which case the search and examination should be done so that the search report and any report under s.18(3) can issue within six months of the date of filing of the Form 9 or 9A (for divisional applications see 15.41-15.42).

[When an application which qualifies for combined search and examination is received in an examining group, it will take its normal place amongst pending searches (unless accelerated search has been requested - 17.05.1-2).]

[Examiners in particular should be aware of the different procedures which apply when processing combined search and examination cases. Reference should be made to the examiners' aide-memoire for combined search and examination cases, which is issued to all examiners and is reproduced in 18.98.]

18.07 A request for accelerated substantive examination of an application, which the applicant should mark appropriately to ensure prompt action, may be allowed provided that the request:

- a) gives adequate reasons why acceleration is needed (see 17.05.1-2 or paragraph 6.2 of the Patents Fast Grant Guidance);
- b) meets the requirements for acceleration through the "Green Channel" (see 17.05.1-2 or paragraph 6.2 of the <u>Patents Fast Grant Guidance</u>);
- meets the requirements for acceleration under the PCT(UK) Fast Track (see 89B.17);
 or
- meets the requirements for acceleration under the Patent Prosecution Highway (PPH) (see 18.07.1).

Requests for acceleration should be in writing, and may be made electronically using the Office's <u>online patent filing services</u> (as a covering letter). It is possible for an examiner to exercise discretion to accept an acceleration request by email; however this practice should not be encouraged. If the request is made before publication, the applicant should indicate whether or not publication before the end of the 18 month period prescribed under s.16 is also requested. (In the absence of any such indication, the applicant should be contacted to clarify whether accelerated publication is required.) A regular Notice to this effect appears in the Journal. Requests giving no, or inadequate reasons should be refused. (See also 18.87).

[On receipt of a request for accelerated examination, Formalities should add the Accelerated Examination label to the cover of the dossier and send the message Acc Exam to the group ESO. A GREEN CHANNEL label should also be added to the dossier cover where the acceleration request is under the <u>Green Channel</u>, and this should be recorded on COPS using the function Record Green Channel Patent Application (REC GRE).

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[On receipt of an Accelerated Exam message the examiner should consider the request as a matter of urgency, and report to the applicant/agent whether it is allowable. This should be done either by letter or by telephone (followed up by a report). In the event that the request is allowed, an indication should be given, with reference to any existing Agency target, of when the examination report can expect to be issued. If the application is in the publication cycle an examination report can still issue – see 18.64 square brackets.

[EL29, modified as appropriate, may be used to communicate a refusal of accelerated examination. EL30 or SC19 (when issuing a search report), modified as appropriate, can be used to inform the applicant that the request for accelerated substantive examination has been allowed and that substantive examination will take place immediately but that no report under s.18(4) will normally issue until at least three months after the application has been published under s.16. EL33 should then be sent if the substantive examination has been carried out and reveals no objection. When the substantive examiner has done the substantive examination and identified objections, and if EL30 or SC19 has not issued previously, ELC30 should be included in his report to confirm allowance of the request. See 18.07.2 for the situation where an examination report is likely to be issued earlier than three months after publication. In the rare event that the examination report itself is issued immediately, then it will of course not be necessary to issue a separate letter indicating allowance of the acceleration request, however an indication should be included in the covering letter to confirm that processing has been accelerated.

[At the point when the request is allowed or disallowed, the examiner should ensure that PAFS records the correct action type against the case and that the appropriate PDAX message exists for the case.

[Where an acceleration request is allowed, the PAFS action should be correct, but the examiner should always confirm what PAFS actions are open and, if they are not correct, include in the checklist accompanying the letter or report appropriate instructions to the ESO. The examiner should ascertain whether there is a "normal" Exam message in the appropriate heading team mailbox, and if there is close and delete it. They should then send the message ACC [HEADING] EXAM, setting the relevant date, to their own Group Personal mailbox, or that of the examiner who will carry out the action. The relevant date should be that of the date stamp on the applicant or agent's letter requesting acceleration, the examination being due two months from this date. If the examiner doing the examination is not the heading examiner then the ESO should be asked to transfer the relevant PAFS booking.

[Where an acceleration request is not allowed, the PAFS action will need to be changed, and the ESO should be asked to do this in the checklist accompanying the letter or report issued to the applicant or agent. Typically the checklist should include 'Please change the PAFS booking from Accelerated Examination to Examination with a significant date equal to the earliest date of this application'. The examiner should ascertain whether there is a "normal" Exam message in the appropriate heading team mailbox. If there is then no further action needs to be taken. However, if there is not, the checklist accompanying the letter or report issued to the applicant or agent should include an instruction to the ESO to send a "normal" Exam message to the appropriate heading team mailbox, with the date in the message being the earliest date for the application.]

18.07.1 A request for accelerated processing of an application under the Patent Prosecution Highway (PPH) will be allowed providing the relevant PPH requirements are met. These requirements are available online from the <u>Patent Prosecution Highway</u> web pages. The examiner should consider the work of the Office of First Filing/Examination but is not bound to follow the actions of that Office. Any objections under UK patent law should be raised as normal.

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[On receipt of a request for accelerated processing under the PPH, formalities should add the Accelerated Examination label and the PPH label to the cover of the dossier. Once all normal Formalities actions have been carried out, the ESO should send a PDAX message ('PPH REQUEST') to the PPH mailbox instead of the relevant heading mailbox (any further action will be advised by the PPH Administration Team).

[A member of the PPH Administration Team will determine whether the request for PPH processing is allowable and record this in a minute for the heading examiner. A member of the PPH Administration Team will inform the applicant of the allowability of the PPH request. Once the PPH Administrator has placed the minute on the PDAX dossier and recorded the PPH request they will send a suitably annotated PDAX message to the appropriate PDAX heading mailbox.

[When starting work on an application which has been accelerated under the PPH, the examiner should refer to the guidance provided in the minute from the PPH Administration Team. If there is no minute but a PPH request has been made the PPH Administration Team should be contacted immediately by emailing PPH@ipo.gov.uk.]

A report should issue confirming whether the request is allowable or not (see 18.07 and 18.07.1). If a request for accelerated substantive examination is allowed, the report should state that substantive examination will proceed as quickly as possible, but that no report under s.18(4) will normally issue until at least three months after the application has been published under s.16 so as to allow time for third parties to file observations under s.21 and for updating the search (see 18.85 - 2nd square bracket). The "3-month rule" does not necessarily apply to divisional applications. In a divisional application, if the invention claimed was clearly claimed in the published parent application, giving third parties at least three months to file observations under s.21 in respect of that invention, then the "3-month rule" can be waived. In the case of a divisional filed very close to the end of the compliance period, there may not be sufficient time remaining to allow the usual three month period after publication for s.21 observations. Even if the invention of the divisional was not clearly claimed in the published parent application, the issuing of the intention grant letter on the divisional cannot be delayed beyond the end of the compliance period in order simply to allow for the expiry of this three-month period. In this case the examiner should delay the issue of an intention to grant letter to allow as much time as possible for s.21 observations to be filed (without delaying beyond the end of the compliance period). In the case of s.89 applications, if the corresponding international application has been published by WIPO (see 89B.04), then a report under s.18(4) may not be issued until at least 2 months after the application has been republished so as to allow adequate time for third parties to file observations under s.21 after the application has entered the national phase (National Starch and Chemical Investment Corporation's Application BL O/34/96). Where the s.89 application has entered the national phase early and accelerated publication under s.16 has occurred (see 89A.20.1), the usual "3-month rule" (from the date published by the IPO) applies. For further details on accelerated examination of s.89 applications, see 89A.21. For accelerated processing under the PCT(UK) Fast Track, see 89B.17.

[In the case where the 3-month rule has been waived (or reduced) in relation to a divisional application, a minute should be put on file confirming this.]

[Where there is insufficient time remaining to allow the full 3-month delay after publication for s.21 observations, and so a shorter delay is used, a diary entry should be created for return of the file before the end of the compliance period and, if the delay is more than one month, a modified EL32 should be issued. The EL32 should be modified as required, for example: to note that the delay will be less than three months after publication and (if appropriate) to remove any reference to updating the search.]

18.07.3 Any request for confidentiality relating to accelerated prosecution, for instance where such prosecution has been requested because of alleged infringement, should be

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considered in the light of the general guidance given in 118.13, but the request itself and the general reason for it should be on the open file.

r.31(5)(a)

Substantive examination should be carried out using the main copy of the specification; the duplicate must remain unchanged as a record of the specification as filed. When substantive examination occurs after s.16 publication, any amendments filed before substantive examination should be incorporated into the specification, and the examination be conducted on the basis of the amended specification (cf 18.63-18.70). The amendments should be incorporated into the description, claims and/or drawings as appropriate, and each of these new documents annotated as "WORKING COPY". For applications undergoing combined search and examination before s.16 publication, the examiner doing the search and examination should consider whether any amendments filed before issue of the search report may be allowed. If they are allowable the search and examination should proceed on the basis of the application as amended (17.35, 19.19.1). Amended or new claims should be included in the published application as normal (16.16-16.19). Applications where the original claims were filed after the filing date should be treated on combined search and examination as outlined in 17.34. If formal drawings were filed later than the application date they may nevertheless be used for the examination, but if a detail of a drawing becomes a point of issue the informal drawings should be consulted since any discrepancies of detail may not have been detected in the preliminary examination (see 15A.22).

[The substantive examiner should, at each action, scan all correspondence from applicants or agents to ensure that all matters raised have been dealt with bearing in mind the substantive examiner's overall responsibility for the application. If, when proposed new claims are filed, it is not clear which previous claims (if any) have been superseded the agent (or applicant) may be telephoned to ascertain the position before examination is made.

[Amendments allowed before the issue of the search report should be acknowledged at the time of combined search and examination using the appropriate version of SC1.

[The examiner should also pay particular attention to documents sent to Index and Scanning for importing onto the open part of a dossier. Although the substantive examiner generally has to identify and explain his objections without reference to any annotations he may have made, he may where he finds it difficult to do otherwise, explain his objections more fully by annotating a photocopy of selected pages from the specification which he can attach to the report which is to be issued, though this practice should be regarded as exceptional. A second photocopy, similarly annotated, must be associated with the file copy of the report. The substantive examiner should send the annotated photocopied page with a completed proforma to Index and Scanning who will import the page into the dossier and send the requested message to the examiner.]

s.1(1) s.14(3) 18.09 In particular the substantive examiner must establish whether the application relates to a patentable invention (see ss.1-4), whether the invention is disclosed in a manner which is clear and complete enough to enable it to be performed (see 14.58-14.90), and whether the claims define the invention and are clear (see 14.108-14.139), are concise (see 14.140-14.141), are supported by the description (see 14.142-14.156) and relate to a single invention or inventively-linked group of inventions (see 14.157-14.168). The substantive examiner should therefore study the specification to whatever extent is necessary to see

whether these requirements have been met.

s.14(5)

18.09.1 In <u>Macrossan's Patent Application [2006] EWHC 705 (Ch)</u>, Mann J held that each patent application must be measured against the requirements of the law and on the basis of its own facts; any particular application stands and falls on its own merits. Earlier patents can be used to gain some assistance on a particular case, but to rely on previous patents as some sort of benchmark would be to give the earlier patent in time a primacy which the legislation does not warrant. In deciding whether or not an application complies with the

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requirements of the Act and Rules, the facts of the case should be decided on the balance of the evidence available.

As Mann J indicated in <u>Macrossan's Patent Application [2006] EWHC 705</u> (Ch), any doubt should be resolved in the applicant's favour only if the doubt is substantial. This could arise if the examiner's assertions as to the common general knowledge have been challenged and expert evidence would be needed to establish the position, or if the date of a prior disclosure has been challenged and the examiner does not have access to material that would confirm the date. Certainly the examiner is not required to meet the criminal burdenof-proof standard in raising and pursuing an objection. If the examiner is minded to maintain an objection, but there may be substantial doubt on an issue of fact which would determine patentability, the test applied in Blacklight Power Inc. v The Comptroller-General of Patents [2009] RPC 6 should be used (see 4.05.1). In this case, the judge held that the examiner should consider whether the evidence provided by the applicant gives rise to a reasonable prospect that, if the issue were to be fully investigated at trial with the benefit of expert evidence, it would be resolved in the applicant's favour. This case concerned industrial applicability and sufficiency where the claimed invention relied on a scientific theory of doubtful validity. However, the test could also apply to other questions of doubt which would be addressed in court by the use of expert evidence. This could include the determination of inventive step where a prima facie objection of obviousness is contested on technical grounds (see 3.67-3.69), and the determination of the publication date of an internet citation (see 18.09.3-18.09.5 below).

18.09.3 When assessing the relevance of an internet disclosure at the substantive examination stage, a document should be cited at first instance unless the examiner is certain that it falls outside the state of the art. If the applicant contests the publication date the examiner should decide the matter on the balance of probabilities based on the evidence available. Such evidence may include a publication date provided on the webpage itself, the cached date from a search engine (which provides a date <u>by which</u> the webpage must have been published), and the "WayBackMachine" on archive.org. Evidence from sources such as archive.org, while not conclusive, may provide justification for an examiner's view that there is little doubt as to the date of disclosure (see also 17.54).

18.09.4 The standard of proof required for assessing the publication date for internet citations has been considered both in EPO Board of Appeal decisions and in Office decisions. Although the Board of Appeal in T 1134/06 *Konami Corp.* decided that for an internet disclosure to be cited as prior art, its date of publication would need to be proved "beyond any reasonable doubt", in *HSBC France's Application* BL O/180/09, the hearing officer held that the date of an internet disclosure should be decided on the balance of probabilities. This followed from previous UK case law on prior use (e.g. *Kavanagh Balloons Pty Ltd v Cameron Balloons Ltd* [2004] RPC 5 – see 2.29.1):

"As the EPO's approach to prior use forms the basis of the Technical Board of Appeal's decision in T 1134/06, I do not consider that I am bound to follow the EPO's reasoning in this case. Rather it seems to me more appropriate, in line with UK cases in this general area such as *Kavanagh Balloons*, that the date and contents of internet disclosures be assessed on the balance of probabilities, just as it is for cases of alleged prior use or, for that matter, dating any other categories of prior disclosure."

18.09.5 In *Ranger Services Application* BL O/362/09 it was held that a publication date established on archive.org was sufficient to demonstrate, on the balance of probabilities, a date of publication before the priority date of the application. In addition, EPO guidance issued in 2009 (Official Journal EPO 8/9 2009) states:

"...the balance of probabilities will be used as the standard of proof, as generally applied by the boards of appeal. According to this standard, it is not sufficient that the alleged fact (e.g. the publication date) is merely probable; the examining division must be convinced that it is correct. It does mean, however, that proof beyond reasonable doubt ("up to the hilt") of the alleged fact is not required."

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It further notes that the fact that archive.org is not a complete archive does not detract from its credibility and the legal disclaimers contained in the site should not be taken to reflect negatively on the accuracy of the service. This guidance reduces the burden of proof required by the EPO and brings its practice more into line with that of the Office.

CONSIDERING THE SEARCH REPORT

r.113(5)-(6)

18.10 The substantive examiner should then study the search report, including any document noted but not cited. Although any views expressed by the search examiner, either concerned with novelty or obviousness or with any other subject, should be carefully considered, the substantive examiner is not bound by these views and must make up his own mind as to what objections, if any, should be raised. While the search examiner will have resolved any doubt about the relevance of a document in favour of citing it, the substantive examiner should only cite if the document supports at least a prima facie objection. On the other hand the examiner may decide to cite a document noted by the search examiner but not included in the search report under s.17(5), for example where the documents cited were merely examples selected from a large number found, or any other document which has come to his notice (but see 18.11). Where the examiner has become aware of an apparently relevant document in a foreign language, he should check whether there is an English language equivalent. If not, the substantive examiner should use his judgment regarding the necessity for a text in English, making use of what he can glean from the foreign language document including any drawings and an English language abstract if available. The applicant can be asked informally to provide a copy of the text of the document in English if he has it, but a formal request for a translation should not be made except possibly in the case of a document cited in an international search report, international preliminary report on patentabilty or international preliminary examination report (see 89B.11 and rule 113(5)-(6)). Conversely the examiner may exceptionally provide a copy of a translation of a foreign language document to the applicant but is not obliged to do so (as per 17.104.1).

[If the substantive examiner decides not to cite a category X and/or Y document which had been included in the search report, a minute should be added to the PDAX dossier to record his decision. Such a minute is unnecessary in respect of A category documents included in the search report.

[The substantive examiner should ensure that any newly-cited documents are issued as appropriate (see 17.104.1, 17.105.1).

[If a substantive examiner requires a translation of a foreign language document which he has been unable to obtain by other means, consideration may be given to procuring one. This may be arranged by an Examination Support Officer. This should rarely be necessary and if it is it should be possible to identify key passages for translation instead of the whole document.]

Family matching, checking equivalents, and online file inspection

18.10.1 There are often reports and citations associated with equivalent applications. At any stage, when equivalents are found, examiners should use their judgement to decide which of these reports and citations to consider. Online file inspection can be used to find these reports and may provide further details of the significance of a document cited against an equivalent (see 18.10.4).

First substantive examination

18.10.2 When first examining a UK application or PCT application, the substantive examiner should identify any equivalent applications and list these on the internal search report (as per 17.115). The claims of EP, WO, and GB equivalents should be considered in order to assess whether conflict arises (see 17.115 and 18.91-18.97.1). When there is an EP or WO equivalent, the examiner should also complete a search comparison form.

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18.10.3 The composition of a patent family may change over time. Therefore examiners should check if any further equivalents have come to light since the check made at first substantive examination. As a minimum, this check should be made just before issuing an intention to grant letter, but may also be useful when issuing a second (or later) examination report. The examiner should also consider checking the online file, and legal status (eg whether granted or not), of any equivalent applications (see 18.10.4). At this stage it is possible that new documents have been cited against an equivalent, or an equivalent may have been granted with narrower claims. In addition, the first examination report for an equivalent may have become available, if it was not previously. It is often useful to carry out a final check, before grant, of the legal status and online file of any EP and US equivalents.

Online file inspection

18.10.4 Reports and citations associated with equivalents, and the legal status of equivalents, can often be found using online file inspection.

[For EP equivalent cases, the <u>European Patent Register</u> online file inspection facility may provide further details of the significance of a document cited against the equivalent. For US equivalents, the <u>USPTO's PAIR</u> online file inspection facility may be used. Other offices are increasingly introducing online file inspection and online machine translation. Where reports on AU and CA equivalents are considered by the examiner the applicant should be informed that work from either the Australian or Canadian office has been considered. When checking an equivalent granted US patent, the substantive examiner should also consider whether the granted claims have been significantly restricted or clarified in comparison to the claims of the application in suit. Where it appears that the granted claims, if made to the application in suit, would distinguish the invention from the prior art and be prima facie allowable, RC 13 should be used to mention this to the applicant.]

Uncovering new citations after search

18.11 Ideally an applicant should not be confronted during substantive examination with a document which could have been included in the search report but was not. Nevertheless the overriding consideration is the validity of an eventual patent, and if such a document demonstrates that the invention claimed is not novel or is obvious it must be cited.

[Whenever a new document is cited, even if only referred to as an example of common general knowledge, it should be included in an internal search report.]

[Whenever a document which could and should have been cited earlier is cited for the first time in a s.18 report, an apology should be made on behalf of the Office. In general no reason for the oversight should be offered, though if the document was cited against a corresponding application or patent of the same patent family or if it has come to light as a result of reclassification this should be mentioned. In no circumstances should the blame for the mistake be attributed. On the other hand, when citing for the first time a document which was not previously relevant but has become so as a result of amendment of the specification, this fact may be pointed out. If this citation is made as a result of a partial search, and further searching is likely to be necessary, this should also be mentioned. Furthermore, if a citable document is found as a result of updating search to comply with s.2(3) then this should be mentioned in the s.18 report.

[If the substantive examiner discovers such a citable document and considers it so relevant that the applicant may not proceed with the application, there being nothing to indicate that the applicant must already be aware of the document, he may defer issue of the s.18 report and instead cite the document using SL5, adding the relevant information regarding the document ie category and relevant passages/claims. The optional last paragraph of SL5 should be included if appropriate. This gives the

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applicant two months in which to withdraw the application before issue of the report. For all cases, the examiner may wish to set a diary reminder in the PD electronic diary for two months after the issue of SL5. This entry should state the examining group after the application number in the format GB0000000.0 – EX00. A diary action should also be added to the PDAX dossier.

[The applicant should be provided with a copy of any non-patent literature (NPL), English language abstracts of foreign language patent documents and, where these have been requested by ticking the box on Form 9A, any patent documents cited after issue of the search report (see 17.104.1, 17.105.2). Furthermore, a copy of the source document (where appropriate) should be similarly provided for the applicant whenever it is substituted for an abstract at the substantive examination stage.]

Further search (see also 18.03.1-18.03.6)

18.12 Normally no further searching should be necessary, beyond updating the original search (17.115-17.117; for s.89 cases, see 89B.12-89B.12.3). The search examiner will have set out a statement of the critical matter and indicated in which databases and classification areas the search has been carried out. Even if the substantive examiner is surprised by the fact that few (or no) documents have been listed, he should assume (in the absence of any indication to the contrary) that the report of the search includes all anticipations of the critical matter present in the areas searched, although if he knows of a particular relevant document omitted from the report he may cite it. Nor should the search be extended to other databases or classification areas unless there is very good reason for doing so. On the other hand the substantive examiner will have studied the specification more closely than the search examiner and if it transpires that the statement of critical matter was inadequate, or if any of the circumstances referred to in paragraph 17.117 applies, then a further search may be necessary. This could also be the case if reclassification has created a highly relevant place. not available at the search stage and likely to contain documents not covered by the original search, to search for the particular critical matter. If classification terms have been applied to the published document by the European Patent Office, it will normally be desirable to ensure that the field of search includes at least those terms which apparently relate to the critical subject matter (as opposed to supplementary material which might also have been classified). The applicant should be informed if the search has been extended to a field which was not referred to in the search report.

[Any additional fields of search or citations arising from "top-up" or further searches should be recorded on a top-up internal search report in PROSE; furthermore any newly-cited documents should be issued by the Examination Support Officer together with the examination report (see 17.104.1, 17.105.2).

[Unless action has been taken under ss17(8) and 18(1A), a further Form 9 (or Form 9A see 17.02) and search fee can only be accepted if the search examiner has reported that the application relates to two or more inventions, and then only in respect of claims present in the application at the time of the main search. Following a search report on the first of two inventions identified by the search examiner on an application, the applicant may cancel the searched claims and file a Form 10 together with a further Form 9 or Form 9A in respect of the remaining claims. In such a case the fee paid on the further Form 9 or Form 9A is not refunded; however, the further search can be carried out in advance of substantive examination. If, in such a case, Form 9 or Form 9A is not filed, it may be requested under ss.17(8) and 18(1A) at the substantive examination stage (see 18.03.3). When a search report has been issued in respect of the first invention in a divisional application, despite a report in respect of this invention having already issued in connection with the parent application - see 18.03.3.]

18.13 If documents have been cited at the search stage and no amendment has been made, it is up to the substantive examiner to decide whether to carry out at once any

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further searching which is necessary or whether to defer it. If any necessary further search is deferred, the applicant should be informed.

Priority dates: Section 2(3)

18.14 As a result of the practice referred to in paragraph 17.74 the search report may include documents which may or may not in fact form part of the state of the art, depending on what is the priority date of the invention under examination and/or of the potentially citable matter. Further such documents may be found in the course of updating the search. In addition, if the applicant files a late declaration of priority (see 5.26.1) after search, the search report may resultantly include documents which no longer form part of the state of the art (see 17.82). The examiner should therefore consider whether the documents in the search report still form part of the state of the art. A document cannot be disregarded as a citation simply because the application in suit claims priority from it (see 5.25.2 and 5.26 and 15.22). At examination the practice set out in paragraphs 18.15 to 18.20 should be followed when a potential citation was published on or after the declared priority date or filing date of the application being examined.

If the potential citation is a UK patent application, or a European or international application designating the UK, and demonstrates lack of novelty, a prima facie determination of the priority date of the invention under examination (see 5.20-5.25.2) should be performed if possible. Normally only a cursory examination of any priority documents will be necessary. If any priority documents (or verified translations or declarations - see 5.11) have not yet been filed then the matter should provisionally be resolved against the applicant. Similarly, if there is any other doubt about the matter, either because it can be argued that the invention is not supported by the disclosure in the priority document, or because the priority document contains a reference which suggests that it might not be the earliest relevant application (for example if it is a US continuation-in-part or if it contains a reference to an earlier application), then the matter should provisionally be resolved against the applicant. If a prima facie priority date cannot be determined or if the prima facie priority date is later than the earliest declared priority date (or, where there is none, the filing date) of the potential citation, then the latter should be formally cited. No attempt should be made at this stage to establish the priority date of the invention in the citation. If the dates are such that there is a possibility that the applicant may be able to show that the priority date of his invention is not later than that of the cited matter by establishing or arguing for his own declared date and/or by attacking that of the citation, he should be invited to do so; if he does, then the substantive examiner will have to determine any priority date in question. If the applicant amends to remove the objection of lack of novelty, and the citation could be used to demonstrate the absence of an inventive step, the matter should then be considered as in paragraph 18.16.

Because of the provisions of s.78(5A) an application for a European patent (UK) remains citable under s.2(3) even if it, or the designation of the UK in it, is withdrawn or deemed to be withdrawn. Under the EPC all European patent applications filed on or after 13 December 2007 designate all Contracting States (including the UK) automatically at the date of filing. Every European patent application will therefore become a European patent (UK) application. Section 78(5A) further provides that removal of the UK designation before publication of the European patent (UK) application does not prevent the matter contained in the European patent (UK) application becoming part of the state of the art by virtue of section 2(3). Every European patent application filed after 13 December 2007 will therefore enter the state of the art by virtue of section 2(3) once published. For European patent applications filed prior to 13 December 2007, removal of the UK designation before publication will continue to prevent the matter contained in those applications from forming part of the state of the art by virtue of section 2(3).

r.9(4)

[RC1 should be used for formally making the citation (see 18.47). If the dates are such that the applicant may be able to argue that the priority date of his invention is earlier than that of the cited matter, RC1A should be added. If there is a possibility that the applicant will be able to show that the priority date of his invention is earlier

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than that of the cited matter by filing a translation of his priority document (or an equivalent declaration - see 5.11) then RC1C should be added instead.

18.16 If the potential novelty citation is a document other than a UK patent application or a European or international application designating the UK then it should be formally cited provided that its publication date is earlier than the prima facie priority date (determined as in 18.15) of the invention under examination. Similarly, if the citation is a UK patent application or a European or international application designating the UK, but is to be used to argue lack of inventive step but not lack of novelty, then it should also be formally cited provided that its publication date is earlier than the prima facie priority date (determined as in 18.15) of the invention under examination. If the applicant in his response asserts that the priority date of his invention is in fact not later than the publication date of the citation the substantive examiner will have to determine the question.

r.9(4)

[Formal citation should be made using RC1 or RC3 as appropriate (see 18.47), and the appropriate one of RC1B or RC3A should be added. If there is a possibility that the applicant will be able to show that the priority date of his invention is earlier than the publication date of the cited matter by filing a translation of his priority document (or an equivalent declaration - see 5.11) then RC1D or RC3B should be added instead.]

r.8(1), (2)

- 18.17 If, in order to determine the priority date of the invention under examination, the substantive examiner needs to consult a document referred to in the priority document, he should ask the applicant to provide a copy, with a translation if necessary. If it transpires that the document in question is in the office on the file of another application, the examiner should consult that file. If the priority application number and document itself if required (see 5.08 to 5.10) has not been provided and there is still time to do so, confirmation of the priority date must be deferred until the document is provided.
- 18.18 If it becomes necessary to consult the priority documents of a cited European (UK) application and, exceptionally, it proves impossible to obtain a copy before the end of the compliance period, the applicant should be informed that the examiner does not have immediate access to the priority documents and may have to resume action after grant. Similarly, the applicant should be informed of possible action after grant if a translation of a priority document or declaration needed to establish the priority date of a cited EP(UK) application has not yet been filed (see 73.02).

[Copies of priority documents (other than UK applications) of cited EP (UK) applications and of translations, if any, of the priority documents into one of the three official languages of the EPO can be obtained from the <u>European Patent Register</u> online file inspection service (queries about the <u>European Patent Register</u> should be directed to CIMS (Document Supply) on ext 4329). When the priority date of the EP (UK) application cannot be established in time, and the applicant is so informed at the same time as citation is made, RC22 should be used (or RC22A if there are other objections outstanding); if citation has already been made, EL22 should be used. RC22A should also be used when there should be plenty of time left for obtaining copies of the priority documents from the EPO.]

18.19 When it appears to the substantive examiner that the application under examination should be cited against the potential citation, he should take steps to ensure that the matter is taken into account by the relevant examiner.

ss.89(1) and 89B(2) r.66(1), (2) 18.20 An international application can form part of the state of the art by virtue of s.2(3) only if it has fulfilled the conditions for entry into the national phase (see 2.30 and 89B.04) or if s.79(2) is satisfied in the case of an international application treated under the EPC as an application for a European patent (UK) (see 79.03). If at the time the potential citation is under consideration it is not possible to establish whether these conditions have been met, the potential objection should nonetheless be brought to the applicant's attention. However, no formal objection can be raised until it has entered the national or regional phase designating GB. In the event that no objections remain save that a PCT application would

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anticipate one or more claims but that it has not yet entered the national or regional phase, the application may be sent to grant and action taken under section 73(1) if and when it does so

[COPS can be used to determine whether an international application has entered the national phase. The necessary information can be accessed using the DIS EQU function and entering the WO number. The resulting display of a UK number indicates that the international application has entered the national phase. The European Patent Register can similarly be used to determine whether an international application has entered the regional phase. The latest dates by which an international application would normally be recorded on the relevant database as having entered the national or regional phase are as follows:

COPS – UK designated: 34 months after the priority date or, if none, the filing date

<u>European Patent Register</u> – EP(UK) designated: 40 months after the priority date or, if none, the filing date.

[If the international application has not entered the national or regional phase at the time of writing the examination report, RC43 should be used to warn the applicant of the potential citation. The PROSE system will then generate a CAV2C caveat form to monitor the progress of the potential citation. At the appropriate time, the examiner will be sent the completed CAV2C form, which will indicate either that the international application is now citable under s.2(3) (having entered the national or regional phase) or that it is not citable (having never entered either the national or regional phase). The examiner can then take the appropriate action, which may be after the grant of the patent - see 73.02-73.04. Where the application is a PDAX dossier the examiner should record the details as an action. The Examination Support Officer will print out the caveat form and send it to the Caveat section. When the caveat form is returned to the examiner, the outcome should be recorded as a further action in PDAX. If further details are required they can be added to a minute and/or a copy of the actual caveat form and the form sent to Index and Scanning with a request to import the caveat into the dossier.]

Common general knowledge; non-documentary disclosure

The search report is concerned solely with documentary evidence, though in some cases the substantive examiner may be able to argue (at least in the first instance) that an invention claimed is not novel or is obvious on the basis of common general knowledge which is sufficiently well-known not to need documentary support, either on its own or in combination with any documents cited (see 3.45 and 3.62).

18.22 Common general knowledge can in some cases be regarded as implicit in the disclosure of a cited document, so that while certain essentials of a claim being considered may not be explicitly disclosed in the citation, it may be possible to argue that an earlier invention would, as a matter of normal practice, be performed in a way falling within the scope of the claim under consideration. This would have the effect that the prior document may then be cited on the grounds of lack of novelty rather than in support of an obviousness objection (though it may be advisable to explain the reasoning behind such an objection). It also renders citable such a document which forms part of the state of the art by virtue of s.2(3).

18.23 If it is found that an admitted display of the invention not within s.2(4)(c) has occurred or that in respect of a display falling within s.2(4)(c), no written evidence under r.5(4) and (5) has been filed within the prescribed period (see 2.40), and the matter displayed thus appears to fall within the state of the art as defined in s.2(2), objection should be raised under s.1(1)(a) or (b) as appropriate.

Prior use

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18.24 If the substantive examiner is aware, either from personal experience or from information from another examiner (see 17.54 and 17.91) or from a member of the public (see 21.12-21.13), of an instance of prior use which is apparently destructive of the novelty or inventive step of the invention claimed, all the relevant facts should be communicated to the applicant, provided sufficient circumstantial details of the prior use are available to enable the applicant to make his own independent enquiries. For example it might be reported that an article having particular features was produced by a named manufacturer, under a particular name or identifying reference, or that such an article was purchased by a named person at an identified shop on or about a specified date. If prima facie evidence of prior use is put to the applicant he must respond (Zannetos's Application, BL O/119/96). A vague or anecdotal allegation of prior use should however not be pursued. (For details of the standard of proof required in cases of alleged prior use, see 2.29.1).

[If the applicant does not admit prior use and is unwilling to amend it will not normally be possible to pursue the matter. In no circumstances should the substantive examiner offer to make the anticipatory matter (or a drawing or photograph of it) available to the applicant or to third parties, unless provided by a member of the public. This is in order to avoid the involvement of the examiner in his personal, as opposed to his official, capacity in the patent proceedings. Any request or demand that an examiner should give evidence as to prior use, whether orally or by affidavit or statutory declaration, should be referred to the Director of Patents.]

EXAMINATION FOR INVENTIVE STEP

18.25	[moved to 3.48]
18.26	[moved to 3.49, 3.64-3.65]
18.27	[moved to 3.66]
18.28	[moved to 3.54]
18.29	[moved to 3.50, 3.60]
18.30	[moved to 3.62]
18.31	[moved to 3.63]
18.32	[moved to 3.70]
18.33	[moved to 3.71]
18.34	[moved to 3.55, 3.69]
18.35	[moved to 3.57, 3.64]
18.36	[moved to 3.68]

PLURALITY OF INVENTION

18.37 The substantive examiner must consider whether the claims relate to a single invention or group of inventively-linked inventions (see 14.157-14.168). He should take into account any views expressed by the search examiner (see 17.106-17.110) but is not bound by these and must make up his own mind on the subject; he should hesitate however before raising objection if the search examiner has considered the question and decided that the claims do have unity of invention.

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[The substantive examiner should consider offering an apology on behalf of the Office when raising an objection to plurality of invention if the search examiner decided the same claim represented a single invention.]

18.38 When there is plurality of invention, the substantive examiner should decide which of three courses of action to take at the first action under s.18. The course of action adopted should be that which is likely to be the most efficient in the particular circumstances of the case. Firstly, the examiner may decide to perform the full substantive examination at that stage. If substantive examination is performed an objection to the lack of unity of invention should be incorporated in the report. Secondly, the examiner may decide to defer consideration of claims relating to a second or subsequent invention. If so, the applicant should be informed accordingly. If no search has yet been performed in respect of the second or subsequent invention, the applicant should be reminded of this fact. Thirdly, substantive examination may be deferred entirely and a preliminary report issued under s.18(3) - see 18.39.

[The aim should be to perform the full substantive examination if it is practicable to do so. Consideration of the novelty or obviousness of claims relating to a second or subsequent invention should be deferred if the claims in question have not been searched. However consideration in other respects should be deferred only if the amount of time or the difficulty involved in considering all of the claims is likely to be excessive.

[Objection to plurality of invention should generally be made formally using RC6 (or RC6PA for private applicants). If however the fault appears to lie merely in infelicitous drafting of the claims, and the specification does not appear to disclose separate inventions, and it is thought undesirable to encourage division, RC6 need not be used or the reference in it to division may be omitted. The reference to division should also be omitted if less than three months of the compliance period remains and so the deadline for filing a divisional application under r.19 has passed. RC6 should not be used if it seems likely that plurality is present but it is difficult to disentangle the inventions specified in a large number of independent claims or the claims are too obscure. In this case the report should contain some other reference to s.14(5)(d) and/or use of its wording. RC7PA should be added to RC6PA if division is to be suggested to private applicants. RC6A should be added if only the first invention has been searched.]

CoP

The examiner may consider deferring substantive examination entirely when more than one invention has been searched and it is not clear which invention the applicant is likely to pursue, or when none of the inventions has been searched, or when claims are of an unduly complex nature not meeting the points laid out in the Code of Practice. Where a formal objection arises under s.14(5)(d), a preliminary report should be issued to this effect. RC16 may also be added to this preliminary report to refer to points in the Code of Practice. The applicant should be informed that further substantive examination is deferred until the application has been amended to meet this objection. Where no formal objection arises under s.14(5)(d), RC16 should be used to refer to points in the Code of Practice. The period specified for response under s.18(3) should be four months unless the substantive examination has been combined with the search, when the period for response should be set to expire two years after the priority date, or if none, the filing date. The period specified for the next report under s.18(3) should be two months or set to expire two years after the priority date, or if none, the filing date, if this is later for combined search and examination cases. Except for applications where the "3 month rule" can be waived (see 18.07.2), no s.18(4) report should be made until 3 months after s.16 publication.

[Deferred examination should arise only if consideration of all of the claims would involve an inordinate amount of work. If the application is in order as a result of amendment in response to a preliminary report of plurality of invention, EL3 should not be issued, since the preliminary report constitutes a report under s.18(3). (See also 18.47).

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[If the claims are amended in response to a plurality objection so that they no longer relate to plural inventions, objections are outstanding and no divisional application has been filed, PROSE clause RC26 may be inserted into the subsequent s.18(3) report. It is irrelevant whether the applicant has foreshadowed a divisional application or not, see 15.46.]

18.40 For a combined search and examination case, in the situation where it would be possible to perform the search but the examination is to be deferred for the reasons set out above, then both the search and examination should be deferred.

[The procedure set out in 17.94.10 should be followed, with a suitably modified version of SE2 (SE2PA) being sent to the applicant.]

r.27(3)-(6)

A further Patents Form 9 (or Form 9A see 17.02) and search fee can only be accepted if the search examiner has reported that the application relates to two or more inventions, and then only in respect of claims present in the application at the time of the main search (see 17.111). If plurality is first reported in a report under s.18(3), issued after the search report under s.17, a further Form 9 or Form 9A and search fee should not be accepted even if the claims now sought to be searched were in the application as filed; at this stage the applicant should be asked to amend to overcome the objection. However, a further Form 9 or Form 9A and search fee can be accepted when the search and examination are combined and it is made clear in the substantive examination report, issuing with the search report, that plurality is notified under s.17 (17.108). In such a situation, if a response to the examination report has been received then the examiner should conduct a re-examination taking into account the results of the further search. If no response to the examination report has been received then it is open to the examiner to decide whether it would be most efficient to conduct a re-examination in light of the further search results, or to await a response to the outstanding examination report. Re-examination at the time of conducting the further search may be particularly appropriate if the compliance date is close. If the search examiner has reported plurality of invention and the applicant has filed one or more further Forms 9 or Form 9A, but the substantive examiner decides not to raise, or, having raised, decides to withdraw, a plurality objection in respect of claims which the search examiner has indicated related to more than one invention, a request for a refund of the fee paid on the further form(s) should be acceded to. Such a refund is made as a matter of discretion and not as a rectification of an irregularity under r.107; it should not be given where withdrawal of the objection is due to amendment of the claims. If, on the other hand, amendment to remove plurality of invention involves deletion of claims to an invention which was searched at the search stage in favour of an invention present at that stage but not searched, a search fee under s.17(8) should be required if a further search is needed at substantive examination, see 18.03.3. See also 18.12.

OTHER ASPECTS OF EXAMINATION

r.12 The specification should commence with a short and appropriate title and should continue with the description (including a list of any drawings) and the claims, in that order (see 14.48-14.51). The substantive examiner should also consider whether those requirements of r.14 and Schedule 2 which are not designated as formal requirements (see 14.54, 14.57) have been complied with. Beyond that, the form of the specification is a matter for the applicant, provided that s.14(3) and (5) are complied with.

[RC10 may be used to object to an inappropriate title. If the grant title exceeds 158 characters, the examiner must seek the applicant's agreement to a shorter one (because COPS cannot accept longer titles). Although this is best done during the course of the normal substantive examination process, if it has been overlooked until the application is ready to proceed to grant, the agent's/applicant's agreement to a shorter title should be still sought by telephone at that stage (see also 18.86).]

18.43 Objection should be raised under s.14(5)(a), (b) or (c) if the claims contain obscurities or ambiguities or are not clearly consistent with the description. Attention should be focused principally upon the main claim(s). The extent to which appendant claims are

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scrutinised at substantive examination is a matter for the substantive examiner's judgement; much will depend on the number of claims and their particular appendancies. The following principles are given for guidance:

- (a) If a main claim appears to define a patentable invention all that is generally required with regard to its appendant claims is to check that they are supported by the description (particularly where they were filed later than the application see 14.145) and to detect any blatant errors or any matters which cast doubt on the scope of the claims, such as a claim which is formally dependent on another but is not within its scope (cf 14.134). Minor matters which would not lead a skilled reader to misconstrue a claim or which would not be pursued if no amendment were forthcoming, should not be raised.
- (b) When objection is to be raised to the main claim on grounds of lack of novelty and/or inventive step, and
- (i) the substantive examiner can conclude, after considering the search report (and any other prior art known to him), that objection also arises in respect of some or all of the appendant claims, he should report accordingly;
- (ii) the substantive examiner readily identifies an appendant claim on which he has found no objection on this account, he should include the fact, explicitly or by implication, in his report, without committing the Office for the future since there may be pertinent prior art not known to the examiner;
- (iii) it is not clear to the substantive examiner what amendment of the main claim is likely to be made to meet the objection, examination of some or all of the appendant claims (and any further searching) may be deferred.
- (c) The applicant should always be able to deduce from the substantive examiner's report which claims have been considered by the examiner and with what result, and of which claims consideration has been deferred.

It should be remembered that an omnibus claim may be an independent claim and must be considered separately (see 14.124-14.125).

[Time should not be wasted on detailed checking of appendant claims; for example, the effect of complex appendancies does not need to be established. A cursory inspection of claims filed originally with the application will often suffice if the main claims are acceptable.]

- CoP
- 18.43.1 In instances where the claims do not meet the points laid out in the Code of Practice, the substantive examiner may consider deferring full substantive examination. Where a formal objection arises, a preliminary report under s.18(3) should be issued objecting under s.14(5)(a), (b) or (c). RC16 may also be added to this preliminary report to refer to points in the Code of Practice. The applicant should be informed that further substantive examination is deferred until the application has been amended, and/or comments have been made by the applicant, to meet the objections raised. The procedure is otherwise as in 18.39. Where no formal objection arises under s.14(5)(a), (b) or (c), RC16 should be used to refer to points in the Code of Practice.
- s.76(2)

 18.44 Objection should be raised to any obscurities which hinder the understanding of the invention or cast doubt upon the scope of the claims, or to any passage which is inconsistent with the claims (see in particular 14.144-14.148). Objection should be made under s.14(5) in preference to s.14(3) where this is possible (see 14.102-14.105). Where appropriate a warning should be added that any amendment to meet the objection must not add subject-matter. Minor matters which would not lead a skilled reader to misconstrue a document or which would not be pursued if no amendment were forthcoming should not be raised.

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(For references in the specification to other documents, see 14.93-14.96; to prior art, see 14.91-14.92; to Trade Marks, see 14.97-14.101, 14.137).

[No more of the description should be read in detail than is necessary, for example to establish sufficiency and support for the claims. Objection should not be made to consistory clauses merely because they are not in literal agreement with the main claims. If the examiner considers it helpful to suggest what form of amendment would be regarded as satisfactorily meeting an Official objection, he should think carefully about the suggestion before making it. Examples of minor matters which should not be raised are inconsequential incorrect or missing reference numerals or leading lines, missing words, repeated phrases, and spelling errors.]

s.76(2) s.14(5)(c) s.76(2) 18.45 Objection must be raised if amendments to the specification result in the application disclosing matter which extends beyond that disclosed in the application as filed (see 76.03-76.23), or if amended claims are not supported by the description as filed (see 14.142-14.156). Original claims filed after the date of filing the application should be treated in this latter way (see 14.145); in either case a warning should be given against adding subject-matter to the description.

[Added matter introduced by amendments submitted before, or in response to, the substantive examiner's first report may be objected to using RC9.]

18.46 As far as substantive examination is concerned, the claim to priority should not be questioned unless it becomes necessary to do so in considering the viability of a potential citation (see 18.14-18.16).

Section 18(3)

If the examiner reports that any of those requirements are not complied with, the comptroller shall give the applicant an opportunity within a specified period to make observations on the report and to amend the application so as to comply with those requirements (subject, however, to section 76 below), and if the applicant fails to satisfy the comptroller that those requirements are complied with, or to amend the application so as to comply with them, the comptroller may refuse the application.

18.47 If it is found, either at the first substantive examination or following subsequent amendment, that there are objections outstanding, the examiner's report to the comptroller is issued to the applicant and should specify the period within which a response should be made. The report should usually deal first with fundamental matters such as patentability (other than questions of novelty or obviousness) and unity of invention (see 18.37-18.40), if they arise, then raise formally any objections based on lack of novelty or inventive step (see 3.48-3.71), and thereafter deal with lack of clarity and inaccuracies and inconsistencies in the claims and description in order of importance (see 18.42-18.45). The object should be to present the objections in a logical order. The report should also include any report from the formalities examiner (see 18.04). The specification is not returned to the applicant with the report.

[When the application leaves the examining group, the appropriate processing status should be recorded on PROSE.

The most common COPS processing statuses are listed below for convenience:

- 2: Out for ABS should be used when search has been requested but is being deferred awaiting action from the applicant ("Action Before Search") see MoPP 17.03 & 17.94.5-9. It should only be recorded provided no formal search has been carried out (and no decision that no search is possible has been made).
- 3: Searched Do not s.16 publish yet should be used when a formal search or CS&E has been carried out but for some reason the examiner needs to see the file again before it is sent for publication. This is most often used when no abstract has yet been filed.

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- 4: No search possible applies when the formal search report is to the effect that no search was performed.
- 5: May be s.16 published will apply to the majority of completed searches and CS&Es (including divisionals). It applies when the application will be in order for A-publication with respect to the examiner's requirements once the formal search report is ready to be issued. It also applies to PCT national phase applications which have been classified and are ready for republication. This status should also be used when an application is in order for publication having previously had a status recorded as in 2 or 3 above.
- 8: Out for ABE should be used when examination has been requested but is being deferred awaiting action from the applicant ("Action Before Examination").
- <u>9: Disposed of In Order</u> should be used when an intention to grant letter has issued, including when the application is in order at first examination. This status should not be used until after "A"-publication is complete.
- <u>10: Disposed of Not in Order</u> should be used where the application is not in order at first examination. This status should not be used until after "A"-publication is complete.
- <u>11: Awaiting applicant's response</u> generally applies when amendments which do not put the application "in order" have been received and so a further examination report is issued to the applicant. This status should **not** be used if status 9 or 10 has not been previously set.
- 12: Ready for Grant should be recorded once the application is finally in order, all "B" stage revision of the COPS data has been completed, and the date given in the intention to grant letter has passed. (This status also applies to an application which has been recalled from grant (see below) but is again in order for grant.)
- 13: Not Ready for Grant is used when an application which has been recorded as Ready for Grant needs to be recalled. It is essential to act promptly when using this status, otherwise publication may have gone too far to allow automatic intervention. This status may be recorded by the Publication Liaison Officer in Formalities.

[Unless the search and examination have been combined or an abbreviated examination report (see 18.47.1) is issued, the first report under s.18(3) should be issued under cover of examination letter EL1. If the report is issued 31/2 years or more after the earliest date of the application, the letter should normally specify a period for reply of two months. For reports issued less than 31/2 years after the earliest date, the letter should normally specify a reply period of four months (see 18.49). Subsequent s.18(3) reports should be issued using EL2, specifying a period of two months or less for reply (see 18.49) and making reference to the date of the agent's letter replying to the previous report. For combined search and examination, the report should issue with SE1 or SE4. Furthermore, if the examination letter is issued within three months of the end of the unextended compliance period, ELC1 should be added. If it is issued in the two months extension obtained by filing Form 52, ELC2 should be added. If it is issued within two months after the end of the compliance period so that filing of Form 52 is necessary, add ELC3. If the examination letter is issued after the end of the extended compliance period letter EL5 should issue (see also 20.06).

R.30(2)

When the first report (or in the case of a divisional application, the first report on the earliest 'parent' application) is issued later than three years and six months from the earliest date, then ELC4 (or ELC5 for the divisional) should be added to EL1. This reminds the applicant that the unextended period for getting the application in order will expire twelve months from the date of issue of the first report (or, in the case of a divisional application, twelve months from the date of issue of the first report on the earliest 'parent' application). Provided that the relevant checkbox is ticked confirming that this is the first examination report for the case, PROSE will add the ELC4 letter clause automatically during creation of EL1 letters created more than 3 years and 6 months from the earliest date. As discussed above, for such letters, the period for response should normally be set to the PROSE default period of 2 months. If ELC4 is not added during creation of the letter it can still be added to the letter after creation. If ELC4 was omitted from a first examination letter issued later than three years and six months from the earliest date, then the applicant or agent should be informed of the correct compliance date at the earliest possible opportunity, and the examiner should arrange for the compliance date to be set correctly on COPS. If this mistake becomes apparent at the second examination, then a clause should be added to the EL2 letter to inform the applicant that the normal unextended period allowed for

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complying fully with the requirements of the Act will end 12 months after the date that the first substantive examination report was sent.

[Whenever the specification includes amendments not previously reported on, RC8 or SC1, as and when appropriate (see 18.08), should usually be the first item in the report, indicating the date of the letter which accompanied the amendments. When documents are formally cited in support of an objection of lack of novelty or inventive step, RC1 or RC3 should be used (or RC5 if the claims are obscure), with RC1A, RC1B, RC1C, RC1D, RC3A or RC3B added if appropriate (see 18.15-18.16).

[Documents cited or otherwise referred to in a s.18(3) report should be itemised by number etc, and passages considered to be relevant by the substantive examiner should also be identified, so that the report is complete without recourse to the search report under s.17. References to published or reported judgments and decisions should fully and clearly identify the report etc in question in the normal way, such as in the Table of Cases of this Manual.

[The examiner should produce the examination (covering) letter and the s.18(3) report using numbered paragraphs and descriptive sub-headings as appropriate. Examination letter clauses should be inserted in the examination letter after the paragraph relating to the need to file amendments or make observations on the report.

[The examination report should not refer (except in certain limited cases relating to divisional applications) to objections which might arise if a presently unpublished application by the same applicant (or otherwise) that the examiner may be aware of were to be published. In these circumstances the examiner should create a minute and raise the objection if and when the other application is published. See 118.16

[After preparation of the s.18(3) report and examination (covering) letter, the substantive examiner should send the appropriate PDAX message to their revising officer, Deputy Director or Examination Support Officer, as appropriate. Any additional instructions to the Examination Support Officer should be written on the checklist in Prose. The Examination Support Officer should then import the examination report(s) and covering letter(s) into the dossier and issue the required copies of each to the applicant.

[When a substantive examiner forwards a case for issue of a preliminary report (see 18.39, 18.43.1, and 18.48), he should send the appropriate PDAX message to his Deputy Director.

[When, during substantive examination, a letter is to issue which does not embody a report under s.18 (eg an answer to an agent's enquiry, or the offer of a hearing), the substantive examiner should ensure that the letter is headed "Patents Act 1977", the application number is identified and, if appropriate, the latest date for reply is specified.

18.47.1 If an examination opinion identifying major defects (see 17.83.3) has been issued at search stage and no response has been filed, the first report under s.18(3) should take the form of an abbreviated examination report (AER) which essentially reproduces the examination opinion. For international applications entering the national phase where the International Search Report or International Preliminary Report on Patentability (IPRP) indicate that major amendment is required, if the examiner is in agreement, an AER based upon information in these reports should either be issued at the same time as reviewing the IPC and applying the CPC classification prior to re-publication of the application (see 89A.14.1) or when national phase examination takes place (see 89B.15.1). Where an AER is issued, the top-up search should be deferred (if required – see 89B.12.1) until the application has been amended.

[Letters EL1A or EL1B should be used to accompany an abbreviated examination report (AER), while letter EL1C itself acts as an AER. The reply period is usually two

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months for EL1A (AER issued following no response to an examination opinion), and four months for EL1B (AER issued for PCT applications without an international preliminary report) and EL1C (AER based upon an international preliminary report on patentability). A shorter reply period for EL1B and EL1C may be specified by the examiner if this is considered more appropriate. Where the EL1C letter is issued more than 3 years and 6 months from priority, the reply period should be two months. The AER should use clauses selected from EC1 to EC8. If an AER based on an examination opinion or an International Preliminary Examination Report is issued more than 3 years and 6 months from the priority or filing date, ELC4 should be added to the EL1A or EL1C letter to set the correct compliance period; PROSE will do this automatically if the relevant checkbox is ticked.]

[As the first action under s.18(3), the issue of an abbreviated examination report (AER) should be booked out as a completed examination (see 89A.14.2).]

18.47.2 For applications that qualify for combined search and examination but for which search would not serve a useful purpose (see 17.94-17.101), an abbreviated examination report should be issued. This combined report under s.17(5)(b) and s.18(3) should inform the applicant of the reasons why the application has not been searched. Once the report is issued there will be no refund of the search or examination fee, therefore consideration should be given as to whether action before combined search and examination or action under s.17(5)(b) is most appropriate (see 17.94.5).

[Letter SE2 should accompany the AER. The period specified for reply should be set to expire two years after the priority date, or if there is none, the filing date. The heading of the AER should be edited to read "Combined Search Report under Section 17(5)(b) and Abbreviated Examination Report under Section 18(3)".]

18.48 Occasionally the substantive examiner may decide that the specification is so obscure that useful examination is impossible. In such a case, he should report to this effect under s.18(3), stating briefly the nature and extent of the obscurity and saying that further examination is deferred pending amendment. In such a case the period specified for reply should be four months or for combined search and examination cases set to expire two years after the priority date, or if there is none, the filing date (see 18.49).

PERIOD SPECIFIED FOR RESPONSE

18.49 Under s.18(3) the comptroller has power to refuse an application where the applicant fails to file a satisfactory response to an official report within the period specified therein. This period is set at the examiner's discretion, but there are certain standard periods which should normally be set unless the circumstances dictate otherwise. Our practice on periods of response for first examination reports is set out in a Practice Notice issued on 6 December 2010, and reproduced in the "Relevant Official Notices and Directions" part of this Manual. For first examination reports (other than combined search and examinations) issued less than 3½ years after the earliest date of the application, the standard period for response is four months from issue of the examination report. Where the first examination report is issued 31/2 years or more after the earliest date of the application, the standard period for response is two months from the date of issue of the examination report. The reason for this shorter period for response is that in these cases the applicant has only 12 months to get the application in order, and so a longer response period is likely to lead to a very compressed timetable in subsequent actions, particularly as such periods are extendible as-of-right by 2 months - see 18.53. These norms of four months and two months are not rigid ones, and longer or shorter periods may be set if the circumstances warrant it; for example, first examinations issued very close to 3½ years after the earliest date also clearly give rise to the same risk of problems with a compressed timetable for getting the case in order.

Second or subsequent examination reports have a standard response period of two months, although again this should be altered if the circumstances require it. Thus the period of two months could be increased to three months if a major objection was inadvertently not

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previously raised, or if a document is cited for the first time. Alternatively a shorter period may be set if only minor objections are made in a second or later examination report. It is imperative that the remaining compliance period is considered when setting response periods for further examination reports. When the unexpired portion of the normal compliance period is less than twice the appropriate s.18(3) period, only one half of the remaining time should be specified rounded down to the nearest month or, when less than six months remain, down to the nearest week. In this latter case the period should be specified in weeks and not in fractions of a month. When less than six weeks remain, the substantive examiner should use his discretion.

For combined search and examination cases (other than divisional applications – see 15.46) the period for response to a first report under s.18(3) should be set to expire two years after the priority date, or if none, the filing date. The periods set for response to any further reports under s.18(3) should normally be two months (following the approach described above), unless any such period would expire before the date previously set for reply to the first report. In that case the period once again should be set to expire two years from the priority date, or if none, the filing date. It is possible for a late declaration of priority to be made (see 5.26) after a combined search and examination report has issued, in which case the examiner should reissue the report under s.18(3) bearing a reply-by date calculated from the newly declared priority date. The relevance of citations should not be re-assessed at this point but will need to be considered when a response to the report is received. Where s.21 observations are filed near to the end of the compliance period, that period may be extended as described in 20.02.1 and, if so, the report should inform the applicant of the extension and the period for response should be set accordingly.

[When the specified period is to differ from the default period set by PROSE, the substantive examiner should determine the correct period and adjust the latest date set for reply accordingly.]

18.50 Occasionally a further report under s.18(3) may be sent raising additional points before a reply to an earlier report is received. This may happen if an agent's letter crosses with the report or if a further citation is found. When this occurs the applicant should not only be informed of the period for reply to the further report but also be reminded of the period for reply to the earlier report. When the two reports are on the same or related matters it is preferable that the two periods should be arranged to expire at the same time. Thus, if there is sufficient of the period already specified remaining, the period for reply to the further report may be set to expire at the end of the period already specified for the earlier report. Alternatively, in appropriate cases, the first period may be extended to the end of the period specified for the further action. Only exceptionally should the period specified in respect of the further action expire before the end of the period specified for the earlier action.

18.51 [Deleted]

CoP

Although s.18(3) gives the comptroller the power to refuse the application if 18.52 he is not satisfied that any objections have been overcome, this power will not be exercised where the applicant has made, within the specified period, an attempt to advance the case towards a final decision as to its allowability; this attempt can be argument, amendment, a request for hearing or a request for interview. Merely filing requests for further searches under s.17(6) does not address objections raised under s.18, and therefore is not an attempt to advance the case. Similarly where a report under s.18(3) is accompanied by the offer of a hearing, a response which merely declines the offer is not an attempt to advance the case (see also 18.80.1). Normally a proposal to amend the claims only (leaving consequential amendment of the description and drawings to be done when the claims are settled) would be regarded as such an attempt. A request to defer amendment of the description until the independent claims have been agreed upon should therefore be considered favourably. If however the response to the examination report is such that it cannot be regarded as such an attempt the applicant should be warned in writing that refusal is contemplated unless the outstanding matters are addressed within two months of the expiry of the period for reply originally specified (or the compliance date if that is sooner). If this fails to elicit a satisfactory response, he should be formally advised that it is proposed to refuse the application as

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provided by s.18(3), but that before this is done he will be given an opportunity to be heard in the matter, and a hearing may be appointed (see 18.79-18.80 for the relevant guidance). If no reply is received to the offer of a hearing the application may be allowed to lapse at the compliance date (see 18.79 and 20.03 for further details).

18.52.1 If a third party requests in writing that an application be refused because the applicant has failed to file a satisfactory response to an official report within the period specified therein (taking into account all possible extensions of time), the applicant should be advised that since they have failed to respond within the period for response the comptroller proposes to refuse the application. The third party's letter should also be drawn to the applicant's attention. A final decision to refuse an application should be made with regard to all the facts of the case, and the applicant should therefore be offered the opportunity to provide reasons for their lack of response and/or request a Hearing. See procedure in 18.54.

18.52.2 If, however, an enquiry is received from a third party, merely asking whether the application will be refused, the comptroller should respond to the third party to inform them of the compliance date of the application in question and that our normal practice would be to treat the application as refused at the compliance date if no response has been received from the applicant.

Extension of the period (an aide-memoire is provided in Annex B)

r.109(2) s.117B(3) r.109(1) s.117B(4) s.123(3A) An automatic extension of two months (or to the end of the compliance period, as prescribed by rule 30 for the purposes of section 20, if this expires sooner) to the period set in an official report can be obtained by requesting it in writing (see also 18.53.1). The request must be received before the end of the period as extended. Only one extension of this type is available. Further extensions may be available at the examiner's discretion if an automatic two month extension has already been granted. Any request for a further extension must be made before the end of the period as already extended and an adequate reason must be given (see 18.56-18.57.1). Under Rule 109 of the Patents Rules 2007, there is no longer a requirement for a request for a further extension under s.117B(4)(b) to be made in writing. However this may be required if the examiner feels that a written request is appropriate in the circumstances. A discretionary extension of one month (in addition to the automatic two months) may be granted readily however any longer or further extensions should be accompanied by a very good reason. Evidence to substantiate any reason given can always be requested if considered necessary.

[When an automatic extension of two months is requested the formalities examiner should create a minute noting that a request has been made, and add it to the dossier. If the request is filed within the two month period the application will be processed in the normal way. Where a response to an examination report is made outside the extended period the application should be referred to the substantive examiner for consideration. He may exercise the discretion provided by section 18(3) to accept the late response rather than moving to refuse the application.]

[A request for a further extension is referred to the substantive examiner, who should not hesitate to consult his Deputy Director. In reaching a decision whether or not to exercise discretion to extend the period, each case should be considered on its own merits and the contents of 18.54-18.57.1 should be regarded as guidelines rather than rigid rules. The request should normally be answered by telephone or by electronic mail and a minute (or the telephone report or email) added to the dossier. A concise report of the telephone conversation should always be sent and a copy placed on the open part of the file. A report of an email correspondence need not be sent unless specifically requested or if it is necessary to clarify the reasons for refusing an extension, but a record of the email exchange should be placed on the open part of the file. The report should clearly state the extension allowed or the reason(s) for refusal which should be carefully worded bearing in mind the possibility of appeal against a decision to refuse. If the report is necessarily lengthy it is preferable to issue

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a letter instead of a telephone or email report. In all cases, the reason for the request should appear on the open file, eg in the applicant's or agent's letter or s.18 report or telephone or email report. When, after a period for reply under s.18(3) has been specified, the criteria used for determining the period are changed (for example the compliance period is extended or one of the norms set out in paragraph 18.49 is altered) such that if the new criteria has been applied a longer period would have been specified, a request by the applicant for an extension of time to make the specified period up to the longer period should be allowed.]

18.53.1 Requests for extensions of time may be made by email and the Comptroller has directed that such requests be made to the email address patent@ipo.gov.uk. The Office does not guarantee to recognise requests sent to any other email address.

[All requests sent to the 'pateot' email address will receive an automated acknowledgment confirming receipt: requests for an automatic extension will receive no further response because the act of validly requesting the extension is all that is necessary for it to be obtained; when a request for a discretionary extension is received, the Examination Support Officer will send the appropriate PDAX message to the substantive examiner for consideration. Email requests will be noted and imported into the dossier by the Examination Support Officer. They will also check to see if the request has been made on time and that it appears to come from the applicant or appointed agent. If a request is made out of time or apparently not by the applicant or his representative then the procedure of the following paragraph should be followed.]

s.101 s.20A 18.54

18.54 When a reply is received after the expiry of the specified period and the automatic extension period of two months has passed, the reason, if not already given, should be asked for. If no reason is forthcoming the late response cannot be accepted. Where a reason is provided, the examiner may exercise discretion under s.18(3) to accept the late response, even though no extension to the specified period can be granted. Discretion should be exercised favourably if the examiner is satisfied that the failure to respond was unintentional at the time that the specified period expired. This is consistent with the statutory test that applies to requests for reinstatement under s.20A (see 20A.13-16 for guidance on the meaning of unintentional). However, there is no statutory requirement that the failure to respond must have been unintentional in order for the late response to be accepted, and thus the discretion accorded by s.18(3) may be exercised in appropriate circumstances even if this criterion is not met.

18.54.1 After considering the matter (see 18.56-18.57.1) the substantive examiner should report either that the application should be allowed to proceed or that the application should be refused for non-compliance with s.18(3) within the specified period. If the substantive examiner is minded to refuse the application, the applicant should be forthwith informed of the fact and told that, if he wishes, an opportunity will be given to hear him in the matter. A month should be given for reply. If no reply is received the application will be treated as refused under s.18(3) at the end of the compliance period. Where however the applicant asks to be heard, the Deputy Director will take the hearing and may decide either to refuse the application or to allow it to proceed subject to such conditions as he thinks fit. Where an application is refused, and a hearing has taken place, the applicant should be notified in a formal written decision signed by the Deputy Director acting for the comptroller.

[When a reply is received outside the automatic two month extension period and no request for extension is received, the formalities examiner should add a minute to the dossier and send the appropriate PDAX message to the substantive examiner, who should if necessary consult their group head. In the interests of uniform practice, consultation with the Divisional Director should be freely resorted to. If the two month extension period is exceeded by not more than a de minimis period and the reason given for late response is acceptable the application should be allowed to proceed. If however, the date is substantially exceeded the reason for the late reply should, if not already given, be asked for. If no adequate reason is forthcoming, a report under

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s.18(3) should issue informing the applicant that the application will be refused unless observations are forthcoming or a hearing is requested.]

18.55 It should be borne in mind that the periods normally specified for response to the first s.18(3) report were determined having regard to all normal conditions, including the availability of an automatic two month extension. While every case must be decided on its merits, the decision in <u>Jaskowski's Application</u>, [1981] RPC 197, furnishes some guidance in this matter. In that case the applicant's agent sought an extension on the grounds that delays were inevitably caused by the need to consult US Patent Attorneys who in turn had to seek instructions from the applicant. The hearing officer, in refusing the request, stated "s.18(3) clearly gives the comptroller discretion to extend the specified period but unless a coach and horses is to be driven through the subsection he must have some adequate reason for exercising that discretion which is peculiar to the particular applicant or application in suit. I can see nothing abnormal in the chain of communications in this case... which could be regarded as an adequate reason for extending the specified period".

r.109(2)

It follows that factors which may be considered normal in relation to all or particular categories of application, eg, the distance of applicant's location from the UK, the complexity of the subject matter of the application or objections thereto, absence on business or holiday (see Decker's Application BL O/10/96), and a preference of the applicant to defer response until reports of parallel applications abroad have been received do not constitute good grounds for an extension of the specified period; on the other hand, extreme complexity or remoteness, such incidents as illness of or serious accident to applicant or agent, also fire and explosion, wars, revolutions, etc, and natural calamities, which destroy documents or dislocate normal operations, may do so. Further, when it is necessary for the applicant to adduce technical evidence an extension may be allowed in appropriate cases. In McDonald's Application (BL O/71/96), after expiry of the normal period for putting the application in order, the agent requested allowance of a late response to a first s.18(3) report on the grounds that the applicant had been awaiting the results of searches and examinations on corresponding applications filed elsewhere, that he (the agent) was unfamiliar with examination procedures before the Office and that there had been delays because of overseas travel and family illness. In refusing the request the hearing officer noted that family illness might provide an adequate reason but took no account of it because this difficulty arose well outside the period set for response and none of the other reasons put forward for the delay up to that point were sufficient. Extensions of time to await the issue of reports on corresponding applications were also refused in Smart Card Solutions' Applications [2004] RPC 12. In this case, the hearing officer did not consider that the potential cost savings to the applicant as a small business in avoiding separate responses to the UK and PCT applications by deferring response until issue of the International Search Report an adequate reason for extension as this was not peculiar to the applicant. The hearing officer also pointed out that the public interest should be protected "by ensuring that any uncertainty involving a patent application is resolved as quickly as possible" by not allowing the examination process to be drawn out without good reason for the delay. A particular category of adequate reason is that the applicant is a German firm which has the inventor as an employee and which does not wish to proceed with the application but by German law is obliged to give the employee the opportunity of proceeding with the application on his own behalf, within a mandatory period before terminating the application. A further, but restricted, category of adequate reason is that where an applicant requests an extension of a specified period (possibly of several months) to carry beyond the date of expiry of the nine months opposition period running in respect of a granted European Patent (UK) equivalent and has indicated that he will not proceed with the UK application if no opposition to the European Patent (UK) equivalent is entered. Provided that sufficient of the compliance period would still remain in order to deal with any objections outstanding on the UK application if it should have to proceed, the request may be allowed to avoid an unnecessary waste of Office and the applicant's time. So far as delays in (or failures of) communication services are concerned, some protection to applicants may be afforded by r.111, under which ad hoc interruptions and dislocations to a communication service by which documents may be sent and delivered (including the postal service, electronic communications, and courier services) may justify an extension to a period of time specified in the Act or Rules.

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[Where correspondence from the Office is reported as never having arrived at its intended destination, or is reported as being misdirected or delayed, this fact should be recorded by sending a minute to the relevant formalities group with any relevant details. Use of r.111 to extend a deadline may only be authorised by the relevant Head of Administration (see 123.47.1).]

- 18.57 In *Jaskowski's Application*, (see 18.55) the agent was seeking an extension without having received instructions from the applicant. The hearing officer indicated that it is the applicant's responsibility to respond to the examiner's report. However a failure on the part of the agent to respond within the specified period may be an adequate reason if the failure was due to an exceptional factor as exemplified in paragraph 18.56. It may also be an adequate reason if it is established on the evidence filed that the failure to take appropriate action was due to the fault of the agent.
- 18.57.1 It is however recognised that even a well-organised system will break down occasionally. An isolated slip in office procedure by the applicant, his agent or his servants may be a good ground as would unusual congestion of urgent work. Account may also be taken of temporary difficulties, such as financial problems faced by an applicant, with a view to avoiding early refusal of an application against the longer term best interests of the applicant. Nevertheless, further extensions of time beyond the automatic two months available (see 18.53) should be the exception rather than the rule. Consequently, the following should be taken as a guideline:
 - (a) A reason should always be required, but a single further extension of up to a month will generally be given even if the reason is not one of the sort which would be acceptable according to 18.56 above.
 - (b) Additional requests for extensions of time (whether at the same action or a later one) require a very strong reason and should normally be no longer than a week or the minimum required to overcome the problem encountered.
 - (c) Extensions of time should be refused or require evidence where an agent or applicant consistently requests extensions to the period for response without good reason being given.
- 18.58 The length of further extensions in addition to the automatic two month extension is in many cases indicated by the reason for making the request; otherwise a month's extension is generally appropriate for a further extension. The substantive examiner should, of course, always take into account how much of the compliance period remains.
- 18.59 If a request for an extension is refused, the applicant may request a hearing. If the hearing officer refuses to allow the extension and the specified period has expired the application will be refused under s.18(3). If the period has not expired at the time of the hearing, or if no hearing is requested, no action should be taken until a response to the outstanding objections is received (see 18.53). If no response is received before the compliance date the application will be treated as having been refused (see 20.03) unless both an extension of the compliance period under r.108(2) or (3) and (4) to (7) (see 123.34-41) and an extension of the s.18(3) reply period are sought and granted.
 - [Where extension of the compliance period is sought under r.108(3), the Deputy Director should decide that question together with the request for extension of the s.18(3) reply period. The Deputy Director should feel free to consult the Deputy Director of PD/CL about the decision under r.108(3).]
- 18.60 In order that applicants who simply respond outside the automatic two month extended period should not have an advantage over those who request an extension of time before the end of the extended period, it is essential that the question of an extension should be treated as distinct from that of the content of the response, and should be settled before any amendments and/or observations submitted are considered.

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s.101 s.20(1)

RE-EXAMINATION

Amendments

CoP

18.61 Normally the applicant or agent responds to a report under s.18(3) by filing amendments, and/or observations. Amendments may be filed in electronic form if they are submitted via the Office website, or using the secure online filing system provided by EPO Online Services if the filer has completed the enrolment procedure for that service. Office policy is that amended pages should not be accepted by email. While it is possible under section 124A(3) to exercise discretion to accept documents submitted by email, this should only be allowed in exceptional circumstances and should not be encouraged. amendments should normally be in the form of new pages or sheets of drawings to be incorporated into the specification. It is helpful if a further copy of the amended pages is provided indicating the changes made either in manuscript on the original pages or using standard word-processing features since this aids identification by the examiner of the changes and where support is provided for them in the description. However minor amendments may be submitted in manuscript on photocopy pages or may be requested in a letter and be effected by the substantive examiner, provided they can be regarded as de minimis (see 14.37-38). Minor amendments to drawings, eg the insertion of a reference numeral, which can be regarded as de minimis may also be effected by the substantive examiner if requested in a letter and in accordance with 14.28 and 14.40-45. Amendments may also be submitted informally, with a view to filing retyped pages when the allowability of the amendments has been confirmed; this practice should not normally be continued in subsequent actions. When no other matters are outstanding and the substantive examiner asks for new pages to be filed, one month should be specified for reply (unexpired compliance period permitting).

[Care must be taken to ensure that all letters etc are placed on the correct file. Where there are inter-partes proceedings in relation to a patent application (principally proceedings under s.8, 10 or 12) there is a separate Litigation Section file for those proceedings. In such cases, there should be a warning label on the dossier cover and a warning sheet in the dossier table of contents.

[Amended or new claims received before the preparations for publication are completed are included in the published application (16.16-16.19, 19.15-19.16). To ensure that the application as filed is published, any amendments of the description, drawings or claims should be annotated appropriately in the table of contents. The substantive examiner should not enter amendments on the original specification before s.16 publication. As with any application on which amended or new claims are filed before the completion of preparations for publication, the formalities examiner should carry out the necessary checks on the new or amended claims. The amended claims should be annotated and a PDAX message, which includes the date on which the amendments were received in the Office, sent to the substantive examiner. The examiner may make manuscript amendments once the application has been published.

[Any replacement pages filed after publication should be imported into the dossier by Index and Scanning. The formalities examiner will create a new description, claims and or drawings, which will be appropriately labelled, before the case is sent to the substantive examiner. Duplicate new pages should be kept with the letter which accompanied them.

[When retyped pages are filed solely to meet the requirements of r.14 and Schedule 2, either at the first response or following deferment permitted by the substantive examiner, they should be checked by the formalities examiner for textual consistency with the pages they replace. If the formalities examiner is in doubt as to the authentic text against which to check he should refer the file to the substantive examiner who should either identify the correct text or, if he prefers, carry out the

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necessary check himself. The formalities examiner will not check the text of the replacement pages when they incorporate amendments which have not previously been written into the specification, or when they have been filed in response to a report containing substantive as well as r.14 objections; in these cases it will be necessary for the substantive examiner to determine whether or not there is added matter or errors.

[The substantive examiner should decide whether any discrepancies noted during checking, either by himself or the formalities examiner, are such as to require a further report under s.18(3). If they are merely minor typographical errors or omissions to which the de minimis rule can be applied he may ignore them or correct them with the applicant's agreement. Otherwise, new pages should be requested.]

[Any incoming correspondence on published applications should be checked by the formalities examiner, who should redact certain personal or sensitive information from documents which may be made available for online inspection via Ipsum (the Office's online patent information and document inspection service). In addition, if the substantive examiner becomes aware of any personal information in any incoming correspondence received after 1 March 2011, he should redact it as necessary. The Enhance feature on PDAX may be used to redact any such personal information. Once this has been done, the following steps need to be taken: "set handle" the redacted version; annotate it as "OLFI", remove any OLFI annotation from the interim or original version of the letter (and close any interim version); and send a SET PUBLIC message to the formalities group team mailbox and save or close the dossier.]

18.62 Where the amendments do not meet the substantive objections, the substantive examiner should use his discretion in deciding whether to allow compliance with r.14 to be deferred further, having regard to the nature and extent of the amendments required and the unexpired compliance period remaining. If further deferment is allowed, the examiner should include in his next s.18(3) report a reminder that the r.14 objections are outstanding and that compliance will be required as soon as the substantive objections have been met. If, on the other hand, no further deferment is to be permitted, the examiner should state in his s.18(3) report that all further amendments must be filed on new pages complying with r.14.

[In the case of private applicant cases, if after a request the applicant fails to submit pages complying with r.14 and Schedule 2 and the application is otherwise in order for grant, the application should be referred to the Formalities Manager to approve any necessary retyping in the Office. The applicant should be advised of such retyping and informed that the application will proceed to grant unless an objection to what has been done is lodged within four weeks.]

s.76(2) CoP 18.63 The form of the amendments is entirely a matter for the applicant, so long as they do not add subject-matter. However, a full response should be made to each and every objection raised in an examination report through amendment and/or argument so as to progress the application towards grant. (For amendment other than in response to an examiner's objections, and the timing of such amendments, see 19.13-19.22).

CoP

18.63.1 Where objections are to be met by amendment, an appropriate explanation should be provided, in particular, how the amendment meets the objection, and how it is supported by the specification as originally filed. The covering letter accompanying the amendments should explain how each objection has been overcome. Where major objections related to novelty, inventive step and other patentability issues have been raised, the letter should point out where support for the amendments lies and give reasons why the amended claims overcome the objections, for example, by stating what is considered to constitute the inventive step in the independent claims.

CoP

18.63.2 If the applicant considers an objection in an examination report to be unfounded, detailed reasons which adequately address the issue should be provided in the response. In particular, when responding to an objection to lack of inventive step, the

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response should assist the examiner in understanding the perspective of the skilled person at the priority date of the invention. Rebuttals which include comments such as "the invention is not obvious because no-one has done it before" and "the examiner has fallen into the trap of ex post facto analysis" and provide no technical information to enable the examiner to determine what would have been obvious to the person skilled in the art will not adequately address the objection.

18.63.3 The application may formally contain only one set of claims at any one time. Applicants sometimes file auxiliary sets of claims, which are alternative claims filed in addition to the main set of claims, for consideration in the event that the examiner has objections to the main claim set. An examiner is under no obligation to consider such auxiliary claims, but may be prepared to consider one or a small number of auxiliary claim sets if the examiner considers that they help the efficient processing of the application towards grant. It should be borne in mind that these auxiliary claims do not overcome any objections until the amendment is formally effected. Where an applicant suggests alternative claim wording without filing formal replacement pages, amendment will only be effected when replacement pages are formally filed. Where the applicant provides clear instructions informing the examiner that an auxiliary set of claims, in the form of replacement pages, should be treated as formally filed if the main claim set is found objectionable, the examiner may make the amendment to incorporate these claims without additional replacement pages being filed, but only after he has confirmed this course of action with the applicant or agent eg by telephone. The examiner should record the outcome of any such telephone conversation with the applicant or agent (see 18.74-18.78). Where more than one claim set is filed close to the compliance date but not examined until afterwards and the main claim set is objectionable, the application will not meet the requirements of the Act, since it is not possible to effect the amendment once the compliance period has expired (see Fisher Rosemount Systems' Application BL O/238/12). In this situation the examiner will only be able to consider such auxiliary claims if Patents Form 52 is filed to extend the compliance date.

18.64 The examiner should consider a response to a s.18(3) report within half the time remaining of the compliance period. That is, within that time, the examiner should either issue a further report under s.18(3) (or other correspondence concerning outstanding matters), or send the application forward to grant. For example, if (when the applicant's response is received in the office) two years remain until the compliance period ends, then the examiner should re-examine the application within one year. If eight months remain, then re-examination should take place within four months.

[Where an application has undergone accelerated examination or accelerated CSE, any amendments received by the latest date for response should be processed as a matter of urgency, and at the latest within one month of receipt. Such amendments should be sent to the examiner as an 'URGENT AMENDMENT' on PDAX, with the high priority marker set. Where the as-of-right extension to the latest date for response has been requested and amendments for an accelerated examination or CSE are received during the extended period for filing a response (or later) it will be assumed that the applicant is no longer interested in expediting the prosecution of their application. In this circumstance amendments will be processed within the usual unaccelerated timescales.]

Where, prior to receiving the response to the first s.18(3) report on the application, the substantive examiner is made aware by the applicant of any document cited in a search report for a patent application on the same invention made in another patent office that has not previously been considered, the document should be considered by the examiner as soon as possible after it has been received unless the response to the s.18(3) report is due imminently. An amended s.18(3) report should be issued if the document would give rise to a further objection. Even when the response is received before s.16 publication, the formalities examiner should refer the file to the appropriate examining group.

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Whether before or after s.16 publication, if the substantive examiner finds that the objections have not been met or that there are further objections, he should write a further report to be issued to the applicant (but see 18.73).

Consideration should be given as to whether the search previously made is adequate, and so whether any necessary supplementary search should be performed (see 17.115-17.117). The examiner should also consider checking if any further equivalent cases have come to light since any previous check, and consider checking the status of these (and any previously identified equivalents) using online file inspection (see 18.10.3-18.10.4). If any amendment or correction made by the applicant necessitates a supplementary search, an additional search fee may be payable under s.17(8) and s.18(1A) before substantive examination proceeds any further, see 17.120-123 and 18.03.1-03.4. If, either at this stage or after a subsequent action, there are no outstanding objections the application should be sent for grant provided that the "3 month rule" is satisfied in appropriate circumstances (see 18.07.2, 18.85-18.86).

[During the 5-week period of the publication cycle, COPS is locked and so won't accept any changes to bibliographic data or processing status. However, an examination report can still be created and signed-off during this period; the checklist should set a COPS processing status of "Do not change processing status". If there are any additional citations, these should be mentioned in the examination report, but any copies that are sent with the report will need to be manually ordered since an internal top-up search report cannot be generated; the checklist should also alert the ESO to the new citations. If this situation arises the case should then be diaried to a date after publication and any additional citations or fields of search entered directly to PROSE and a COPS update then performed.]

18.65 When the applicant has restricted his claims to meet an objection to lack of novelty or of inventive step then, for the purpose of determining whether the objection has been met, the new claims must be looked at in the same way as they would have been if the specification had originally been filed with those claims. It is not sufficient for the applicant to add to his anticipated claim a feature disclosed in an example in the specification but which is no more than one of the alternative ways which the person skilled in the art would regard as available to him for carrying out the known concept originally claimed.

- s.125(1) 18.66 If the applicant argues that there is a distinction between his invention and the prior art, the substantive examiner should make sure that this distinction is reflected in the claims. If anything falling within the scope of a claim is known or obvious, that claim is bad.
- s.2(2)

 18.67 An objection of lack of novelty or of inventive step based, wholly or in part, on a statement of prior art in the description should not be withdrawn solely because the applicant amends or deletes the statement, unless an adequate reason is given. For example if an applicant who has stated that a particular practice is known in the art now wishes to amend or withdraw that statement because he asserts that the practice was not publicly known and thus did not form part of the state of the art, then this assertion must be categorical and unambiguous and supported by evidence.
- s.125(1)

 18.68 Objection must be raised when, as a result of amendment, there are specifically-described embodiments or statements in the description which are not consistent with the claims, since doubt is thrown on the scope of the claims. It is up to the applicant how this objection is overcome; normally the simplest course will be to delete the subject matter which is now outside the scope of the claims, but the matter may be retained provided it is made clear in the description that the matter does not constitute an embodiment of the invention. This could be the preferable course in a case where embodiments falling within the claims are partly described by reference to such matter; in such a case care must be taken that any omnibus claim does not embrace this matter. The title should be consistent with the invention claimed.
- s.14(5)(c) 18.69 Consideration should be given as to whether claims which have been s.76(2) amended are supported by the description (see 14.142-14.156) and whether they entail added

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subject-matter (see 76.04-76.23). Applicants may seek to restrict the claims of an application having a proportion or property expressed as a range of values to a sub-range within the original range. (The same situation arises where the original range is in a parent application and the sub-range in a divisional). In assessing amendments which restrict the scope of independent claims, examiners should be aware of the potentially very serious consequences for the applicant should such amendments be held – post-grant – to add matter. In this situation s.76(3)(b) would prevent amendment to remove the additional matter, as this would extend the protection conferred by the patent; this is potentially an "inescapable trap" (G 01/93 Advanced Semiconductor Products, OJEPO 8/94 – see 76.27).

18.69.1 There have been various approaches to assessing whether a restricting amendment to a claim is supported or adds matter. At one extreme is the view that the mention of a range is the implicit disclosure of every item falling within the range, and accordingly any sub-range can be claimed if the requirements of Section 1(1) are met since there would be support for it. At the other extreme is the view that no sub-range can be claimed unless there was mention in the application as filed of the values concerned as end points of a preferred range. Pending guidance from the courts for practice under the 1977 Act, examiners should not adopt either extreme as an automatic rule of thumb approach suitable for all cases but should decide each case on its own merits by considering whether the sub-range claimed is supported by the description and does not extend the matter disclosed. The view point should be that of a skilled person reading the document. This will involve considering what is said about the values; it is not a question of just looking for any mention of a value but rather of assessing the teaching of the document about it. It will be necessary to consider the original disclosure closely to ascertain whether there is a sufficient disclosure to support values within the sub-range e.g. whether there is reference explicit or implicit to the special advantages obtained when values are selected in the sub-range. The above guidance only applies to considerations of support for an amended claim (or claim of a divisional application). The requirements of novelty and inventive step will also have to be met. The very nature of this approach is such that detailed rules to be rigidly applied in all circumstances cannot be given. Advice should therefore be freely sought from the relevant DD or head of examining group. In exceptional cases advice may also be sought from Legal Section.

s.14(5)(d) 18.70 Objection will have to be raised if, as a result of amendment, the claims lack unity of invention.

s.19(2)

18.71 If, after objection has been raised, the applicant refuses or omits to acknowledge a Registered Trade Mark (see 14.70), the substantive examiner should amend the specification to acknowledge the Mark and inform the applicant that he has done so (see 19.24). If however the use of the Trade Mark is objectionable (see 14.137) the objection should be maintained.

[For procedure, see 19.24.]

CoP

18.72 The process of examination and re-examination in response to the agent's or applicant's replies continues until the substantive examiner is satisfied that the application complies with all requirements of the Act, or that a point is reached where disagreement between the applicant and the examiner is such that a hearing must be appointed and the matter resolved, or the application is withdrawn or refused. In the usual event, where the substantive examiner (or Deputy Director after a hearing) is satisfied that no further objections are outstanding, the grant of a patent follows automatically (see 18.85-18.86).

[If an amendment or argument is made that means that an objection is no longer relevant, the examiner should add a minute to the PDAX dossier explaining why the objection has been dropped.]

18.72.1 Letters and faxes filed close to the end of the compliance period should be marked prominently "URGENT - compliance period expires on (date)"

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[To identify applications near to the end of the normal compliance period, a warning label will be displayed on the dossier cover of applications with four months or less to the end of the compliance period, and the appropriate PDAX message should be sent to the substantive examiner.

[Deleted]

[If a substantive examiner requires urgent action on a file not covered by an Urgent label, then the substantive examiner should ensure that any PDAX message sent has the appropriate urgent warning at the beginning of the message.

[Deleted]

It also sometimes occurs when time is short that a letter is filed direct with the substantive examiner by the applicant or agent. If the letter is accompanied by a copy thereof and it is requested that the copy be endorsed and returned to serve as a receipt, the substantive examiner should glance at the two letters to check that they are the same and then endorse the copy by hand before returning it. (Some agents have adopted the practice of filing copies of letters for use as receipts; they are normally stamped and returned.) In some instances where letters are not accompanied by a copy, the agent or applicant merely asks in the letter for its receipt to be acknowledged. This is normally done automatically by the formalities examiner and the issue of the receipt is indicated by a hand-written number at the bottom righthand corner of the letter. If this action should ever have been omitted, the substantive examiner should ask the appropriate formalities group to arrange for it to be done. Where such a letter is filed direct with the substantive examiner, he may instead make a photocopy for endorsement by hand as above. The substantive examiner can send the letter to formalities who should forward it to Index and Scanning for incorporation into the dossier.]

Interviews and telephone conversations

r.51

18.73 Any objections at all which need to be raised at the first substantive examination should be set out in writing (except where the only objection is that a Trade Mark has not been acknowledged - see paragraph 18.82). When an objection needs to be raised in a subsequent action however, the examiner may attempt to resolve the matter either over the telephone or at an interview. Recourse to the telephone should particularly be considered if there is something clearly amiss with the application (e.g. the wrong pages have been filed), the applicant or agent has particularly welcomed telephone contact, or it seems likely from the written exchanges that the examiner and the applicant or agent may be at cross-purposes. A telephone or interview report which sets out the remaining objections to grant of the patent application, and specifies a period for response, can itself constitute a report under section 18(3); there is no requirement to create a separate s.18(3) report and covering letter. If the telephone or interview report is intended to be a report under s.18(3) then for the avoidance of doubt this should be explicitly stated in the report.

[In the case of a private applicant, an interview may be suggested using ELC19PA.]

[Anyone is entitled under s.22 of the Welsh Language Act 1993 to have legal proceedings held in Wales conducted in Welsh without advance notice. If the applicant or his agent insists on conducting an interview in Welsh the substantive examiner should obtain the services of an interpreter. ARD hold a list of Office personnel willing and able to act as interpreters in Welsh.]

18.74 A record should be made of anything said or agreed during an interview or telephone discussion which might materially affect or throw light on the prosecution of the application, and should ideally be brief. It should not contain non-essential information, or comments which the applicant or the agent wish to make off the record and which are not germane to the conclusion reached. The record will be open to public inspection and should,

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together with the other papers on the open part of the file, present a continuous narrative of the proceedings. It should state the outcome of the discussion - for example, that a particular amended form of claim was accepted. If thought appropriate the reasons should be briefly indicated - for instance if it has been agreed that a particular form of claim is distinguished from the cited prior art, but it is not self evident why this should be so. When an objection is withdrawn as a result of fresh or further argument put forward in the discussion, the record should briefly outline the argument. If the applicant or agent puts forward an argument but indicates that he does not wish it to be made public, he must be told that it must either be recorded or disregarded. Amendments or arguments put forward during the discussion which are subsequently withdrawn or become irrelevant during the course of the same discussion need not be recorded.

[Comment by the agent which might be interpreted as critical of the applicant (or vice versa), or anything critical of a third party, should not be recorded. Time should not be spent in trying to obtain an agreed record of the discussion.]

- 18.75 Any document cited and withdrawn during the course of a single discussion should nevertheless be recorded (see 18.85) unless the discussion revealed its citation to have been misconceived, eg based on a misunderstanding.
- 18.76 As discussed above (18.73), a telephone or interview report can itself constitute a report under section 18(3). Whether or not this is the case, if further action has been agreed at the end of the discussion, for example if the agent is to seek the applicant's agreement to an amended claim, or is to make consequential amendments to the description, or if the substantive examiner has promised to put an argument in writing, this should be made clear in the record, as should any time limit set.
- 18.77 As a general rule a copy of the record should be sent to the applicant or agent with whom the discussion was held, who should be informed that any disagreement he may have should be communicated in writing.

[It should be apparent from the open part of the file whether or not a copy of the record has been sent to the applicant. In any event a reference to the record should be entered as a minute on the dossier. The substantive examiner should adopt whatever method appears most suitable for communicating a record of an interview or telephone conversation to the agent or applicant. In most cases, this will be a report of the telephone conversation (quoting the agent's file reference and addressed to the applicant, c/o the agent in the usual way). However other procedures may sometimes be appropriate; for example a paragraph indicating that a requested amendment has been made could be added to a letter or report. Exceptionally in the case of interviews, the need to communicate a record may be avoided by obtaining the signature of the agent or applicant to a minute of the interview which is then placed on the open part of the file.]

18.78 Any doubt about whether to make a record of a discussion should be resolved in favour of making the record.

Failure to reach agreement

s.101

18.79 Where the substantive examiner is unable to obtain a satisfactory response, an offer of a hearing should be made. Under most circumstances, an offer should not be made until an objection is repeated, or the application is close to the end of the compliance period with unresolved matters outstanding. Note that it is desirable for a hearing to take place before the compliance period ends, see the considerations in the square bracket below. Where the compliance period has been extended under r.108(2) and a response filed at or very near the end of the extended period fails to overcome the outstanding objections, it may be necessary to issue EL5 (see 20.06). However, for applications relating to methods of doing business with major patentability objections, a hearing may be offered upon receiving the first response from the applicant if the examiner remains of the opinion that there is no prospect of a patent being granted. Since the comptroller must give to a party to any proceeding before

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him an opportunity to be heard before exercising adversely any discretion, the offer of a hearing is a prerequisite to refusing an application under s.18(3). If no reply is received to the offer the application may be allowed to lapse at the compliance date (see 20.03). (For hearings, see 101.02-101.07 Chapter 4 of the <u>Tribunal Patents Manual</u> and Chapter 6 of the <u>Patent Hearings Manual</u>).

[Before offering a hearing, the examiner should consider the following factors:

- (i) the length of time remaining until the compliance date;
- (ii) the number of times an objection has been made;
- (iii) the total number of s.18(3) reports issued;
- (iv) whether genuine progress is being made towards grant; and
- (v) whether there is a saving amendment.]

[Examiners should consult their group head before offering a hearing. Normally the offer will be made in writing, if time permits, by including a paragraph in the covering letter and/or the exam report. Where the matter is urgent however the offer should first be made by telephone and then confirmed in writing unless the applicant or agent agrees to the immediate appointment of a hearing. The applicant should be informed that if they choose to respond to the offer of a hearing with further amendments or arguments but do not request to be heard then their application may be passed to a Hearing Officer for a decision on the papers (see 18.80). A date for response should be set.]

[The examiner should include in the checklist accompanying the letter instructions to the ESO to include a hearings guidance leaflet when issuing the letter if the hearing is for an unrepresented applicant. A link to an <u>online copy</u> of the leaflet can be included in the letter if appropriate.]

18.79.1 After the offer of a hearing has been accepted, the examiner should issue a final communication to the applicant, otherwise known as a pre-hearing report. This report should define all the issues to be considered at the hearing and should introduce no new objections. All the relevant arguments for each issue should be set out and any precedent cases should be referred to. It must also adequately brief the hearing officer and any assistant on the case without the need for any further report. Any outstanding matters or actions that have been deferred and will need to be addressed after the hearing if the application is not refused should be mentioned in this communication.

[As well as the content noted above, the pre-hearing report should include full analysis using the appropriate legal tests, a summary of the applicant's arguments, how the claim has been construed, any issues that have been deferred (i.e. whether the search and/or exam is complete) and any details of the compliance date and extensions if relevant.]

[If the applicant requests to be heard the examiner should arrange the hearing by creating a minute addressed to Litigation Section requesting that a hearing be appointed and sending a PDAX message to the HEARINGS team mailbox entitled "Please see hearing request". Where less than two months of the unextended compliance period remain, the minute should instruct the hearings clerk to arrange the hearing as soon as possible.]

18.80 An applicant, instead of taking up an offer of a hearing may seek to continue filing observations or amendments which the examiner considers do not satisfactorily meet the objections. If this occurs near to the end of the compliance period the examiner may consider it most efficient to respond with a further report under s.18(3). The accompanying exam letter should reiterate the offer of a hearing and include appropriate reminders of the compliance date as detailed in 18.47. Exam letter EL5 may be used if the report is issued after the end of the extended compliance period (see 20.06). If the compliance period has passed, but has not been extended, an EL5 letter (modified as appropriate) may be used to tell the applicant that the application will be treated as having been refused unless he submits

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observations and/or requests a hearing to demonstrate that the application was in fact in order (or requests an extension of the compliance period under r.108).

However, where the offer of a hearing was made early in the examination process and no saving amendment appears possible, it is desirable to avoid multiple unproductive amendment rounds which do not progress the case towards grant. In such instances the applicant should be told in a letter that the application does not meet the requirements of s.18(3) and that a formal decision as to whether the application should be refused will be issued unless a hearing is requested or the application is withdrawn. The applicant should be informed that the application will be passed to a Hearing Officer for consideration two weeks after the date of the letter. The letter should also define all the issues to be considered in the Hearing Officer's decision, setting out the relevant arguments on each one. It must also adequately brief the hearing officer and any assistant on the case without the need for any further pre-hearing report.

[Once two weeks have passed since the date of the letter, the examiner should create a minute addressed to Litigation Section requesting that the application be forwarded to a Hearing Officer for a decision on the papers and send a PDAX message to the HEARINGS team mailbox entitled "Please see decision request".]

18.80.1 If the offer of a hearing is refused and no further amendment or argument is provided the response cannot be considered an attempt to advance the case. The applicant should therefore be warned in writing that refusal is contemplated unless the outstanding matters are addressed within two months of the expiry of the period for reply originally specified (or the compliance date if that is sooner). If further arguments or amendments are filed in response to this letter and the applicant continues to decline the offer of a hearing, the procedure set out in 18.80 should be followed.

Section 18(4)

If the examiner reports that the application, whether as originally filed or as amended in pursuance of section 15A above, this section or section 19 below, complies with those requirements at any time before the end of the prescribed period, the comptroller shall notify the applicant of that fact and, subject to subsection (5) and sections 19 and 22 below and on payment within the prescribed period of any fee prescribed for the grant, grant him a patent.

APPLICATION IN ORDER AT FIRST EXAMINATION

r.31(4)(a) r.19 r.108(1) r.30A

18.81 Provided that at least a full search under s.2(2) has been made for documents published before the priority date of the invention and that an adequate opportunity has been given for s.21 observations (see 18.07.2 for discussion of the exceptions to the "3-month rule"), when it is found at the first substantive examination that the application, whether as filed or as subsequently amended, complies with the requirements of the Act and Rules then the applicant must be informed of this fact. In the same report he is informed that voluntary amendments and/or a divisional application may be made within two months of the date of the letter. This letter acts as a notification of intention to grant and indicates that the application will be sent for grant shortly after the two-month period has expired. No divisional application or voluntary amendments can be made once the application has been granted (and, in addition, after the two-month period has expired voluntary amendments can only be made with the consent of the comptroller). The application is not normally sent for grant until the two-month period has expired (see 18.84). However, if in response to the report the applicant confirms in writing that he wishes to waive the opportunity to file any divisional applications or amendments, the pre-grant procedure (see 18.85-86) instead commences forthwith. The facility for expediting grant by waiving the two-month period does not extend to late-filed (eq divisional) applications where grant is necessarily delayed until after s.16 publication. It is not possible for the applicant to request a delay to grant.

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[If the application is found to be in order at first examination, the substantive examiner should carry out the pre-grant steps set out in 18.86 and send a PDAX message with the text "ISSUE RELEVANT EL3 LETTER" to the EA GRANT mailbox, including as a recipient the Examiner Assistant for their examining group. If the examining group does not have an Examiner Assistant then the recipient field should be left blank. On receiving this message, the EA should then issue an EL3 or EL3F (if excess fees are due).]

[Where amendments have been filed, they should be acknowledged.]

[ELC4 should be added when a first s.18 examination report is issued more than 3 years and 6 months after the earliest date; PROSE will add the ELC4 letter clause during creation of the EL3 or EL7 letter if the relevant checkbox is ticked, as discussed in 18.47. Similarly, ELC5 should be added to a first examination report on a divisional application when the first report on the parent application was/is issued later than 3 years 6 months from the parent's earliest date. The use of these clauses will ensure that the compliance date is set correctly on COPS and will also inform the applicant of the compliance date (see 20.02).

[In the situation where a top-up search is carried out at the same time as finding the application in order see 17.115.]

s.19(2)

18.82 Where the only objection outstanding at the first examination is that a Registered Trade Mark, while allowable, is unacknowledged, the substantive examiner should amend the specification to acknowledge the Trade Mark, inform the applicant that he has done so and (for non-combined search and examination cases) issue a report as in paragraph 18.81.

[The procedure for both non-CS&E and CS&E cases is set out in 19.24-19.26.]

18.83 If amendments are filed within the prescribed two-month period the amended specification should be re-examined in the same way as a specification amended after a report under s.18(3). If as a result of the amendments the specification no longer complies with the Act and Rules a report under s.18(3) should be issued, specifying four months for reply provided sufficient of the compliance period remains. For the procedure to be followed when amendments are filed, see 19.18.

r.108(1)

18.84 If after the end of the two month period the application has not been amended, or, if amended, it is still in order, it should be sent for grant (see 18.85-18.86.3). The two-month period is prescribed by r.31(4)(a) and therefore cannot be automatically extended by two months under s.117B(3), as that section applies only to periods specified by the comptroller. However, a request for a discretionary extension of the two-month period may be made under r.108(1) and should be allowed if accompanied by an adequate reason. This request may be filed retrospectively. The criterion applied in determining the adequacy of the reason should be the same as that applied when considering a request for an extension of the period specified for response to a report under s.18(3) (see 18.56-18.57). Where a convincing reason is not provided, or the reason relates to the applicant's desire for more time to file a divisional application, the extension should be refused. If such an extension is allowed, grant should be delayed.

18.84.1 The substantive examiner should defer issuing an examination report under s.18(4) if he finds no objections to the application when the first substantive examination is made before the search under s.2(2) has been completed for documents published before the priority date of the application and before an adequate opportunity has been given after s.16 publication for observations under s.21 (see 18.07.2 for situations where the three month period after publication can be waived). This is most likely to occur when combined search and examination has been requested, and the first substantive examination reveals no objections. The applicant should be informed that while the initial stage of the s.18 investigation has not revealed any objections, the investigation cannot be completed and a report under s.18 cannot

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issue until three months after publication, when the examiner will have considered the outcome of a supplementary search under s.17(7) and any third party observations filed under s.21. The application should not be sent to grant until after a report under s.18 has issued (see 18.84.2). The substantive examiner should diary the file for return at an estimated date three months after s.16 publication, using the PD electronic diary. A diary action should also be added to the PDAX dossier.

[When no objections are raised at the first examination stage following combined search and examination, the search report should be issued with SE3. SE3 does not constitute a report to the comptroller or the applicant under s.18 and does not set any period for response. Any supplementary report on the search should be added to SE3 under an appropriate sub-heading but before the passage about publication of the application.]

18.84.2 On return of the file under the diary system the substantive examiner should update the search and consider any voluntary amendments made by the applicant and any third party observations. If no objections are found at this time, a first substantive report under section 18(4) should be issued following the procedure set out in 18.81-18.84. On no account should the application simply be sent for grant.

18.84.3 On the other hand if there are one or more objections, for example as a result of amendments or the top-up search, a first substantive report under s.18(3) should be issued following the procedure set out in 18.47-18.80, although the period set for reply to the first or any subsequent reports should not expire earlier than two years from the priority date, or if none, the filing date. The date for completing the first substantive examination report may be deferred at the applicant's request, without a reason being necessary, to approximately the date on which other applications, which are of the same date, normally become due for first examination under s.18.

FINAL PROCEDURE

As soon as there are no objections outstanding, the search is complete in respect of s.2(2) art and third parties have had an adequate opportunity to file observations under s.21, the substantive examiner should ensure that the recorded bibliographic data (classification, cited documents, field of search) required for publication of the granted specification are correct and up to date. If less than 21 months have elapsed from the priority date or the substantive examiner is not otherwise satisfied that the search is complete in respect of s.2(3) art, the application should be diaried for return after grant in order to complete this search and the applicant should be informed accordingly (see 17.118). An entry should be created in the PD electronic diary system, and the substantive examiner should remember to add the diary action to the dossier in PDAX.

[Before marking an application in order for grant, the examiner should check if any further equivalent applications have become available, and consider checking the status of these (and any previously identified equivalents) using online file inspection (see 18.10.3-18.10.4).

[Except as noted in 18.07.2 no application should be marked in order for grant until three months after s.16 publication so as to allow the opportunity for s.21 observations and a top-up search. If during this period the substantive examiner is content that previous objections have been resolved and no new ones arise, they should add a minute to the dossier accordingly, and create an entry in the PD electronic diary for return of the file at an estimated date three months after publication so that the search can be updated. A diary action should also be added to the PDAX dossier. If the diary entry is for more than one month from the date of receipt of the last response by the applicant, the examiner should also issue EL32 to acknowledge the response. Any third party observations filed in the intervening period should be copied to the applicant and considered by the examiner without delay.

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[For revision of classification, see 18.86. Any document cited (formally or otherwise) or new field searched which was not listed on the A document should be recorded on PROSE as soon as possible, for eventual inclusion on the front page of the B document. For procedure when action deferred to await filing of a divisional application, see 15.46.]

s.14(9) s.19 18.86 The examiner should then complete the necessary pre-grant steps before marking an application in order for grant.

[When the substantive examiner is satisfied that there are no objections outstanding and that the application may go forward to grant, he should add a minute to the PDAX dossier explaining why major objections were dropped (perhaps due to an amendment or an argument made by the agent or perhaps because the examiner has reconsidered the matter). The examiner should either add the title "In Order – for grant" to the minute to that effect or add an "In Order – for grant" action. (The abstract is not published as part of the granted patent; therefore no revision or amendment of the abstract by the substantive examiner is necessary at this stage. Moreover if amendment to the abstract is filed no action should be taken except as referred to in 14.191).

[The examiner should enter the grant title and update the field of search, classification and citations in PROSE. The full data for COPS that has to be entered (or revised) on PROSE to allow the case to proceed to grant and 'B' publication is:

- Grant title
- Applicant's reference
- Field of Search
- Citations
- IPC and CPC classification

[All IPC and CPC classification symbols should be revised to ensure they are current and appropriate at B stage, due to possible changes to classification schemes and/or amendments giving rise to changes in the identified invention information. Where necessary, such revision will include the entry of new classification symbols.

[ClassTool should be used to revise/enter IPC and CPC classification data.

[Field of search and citations might already have been entered into PROSE and COPS, e.g. if an ISR-TOP has been created and signed off on PROSE previously. To record that there are no additional fields of search, the examiner should select the 'Other' field of search tab on PROSE, right-click in the grey space, select 'Edit', right click in the white area and select 'Record no additional fields for B'.

[The title from the first page of the latest version of the specification should be entered into the Grant title field in the Details area on PROSE. The applicant's reference field should also be corrected if it is different from that in the most recent correspondence from the applicant.

[The examiner should ensure that the 5 data markers have been activated at the bottom right of the PROSE screen.

[If the grant title exceeds 158 characters the examiner must seek the applicant's agreement to a shorter one (because COPS cannot accept longer titles). If the application is otherwise ready to proceed to grant, this should be done by telephone (see also 18.42).

[For those cases where classification has still to be considered, made or revised in another heading, the case should be forwarded to the formalities group for grant via

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the appropriate examining group for such action. When an application is to be routed through one or more further groups for revision of supplementary classification before grant, it should be made clear in a minute that the application is merely in transit from one group to another. Only the final marking to Formalities should refer to grant. The application should not be referred back to the primary group for any classification checking except when special circumstances arise.

It is the substantive examiner's responsibility to see that the documents going forward for grant have been properly assembled. The specification sent to Publishing Section should contain only those pages which are to form part of the published B document, the Formalities Examiner having placed a "P" against the documents ready for B publication and marked them each as "Working Copy". Any necessary renumbering of the pages will be carried out by the formalities examiner before grant (see 14.34). If one or more, but not all, of the figures on a sheet of drawings have been cancelled, Publishing Section will blank out the cancelled figures. In order to ensure that this is done, the substantive examiner should add a minute to the PDAX dossier highlighting which figures are to be cancelled. It is possible that the specification going forward for grant will still contain a heading or other redundant wording on pages of new or amended claims filed for inclusion in the A document, if they have not been superseded by replacement pages during substantive examination. Since the B publication should not contain such extraneous matter, Publishing Section will blank it out. In order to ensure that this is done, the substantive examiner should add a minute to the dossier.

[Where a request for amendment is filed after the case has been sent for grant but before issue of the grant letter (also known as the B-publication letter), action should be taken as in 14.206 mutatis mutandis. Grant should if possible be stopped to allow the request to be dealt with, but if it is too late to prevent production or issue of the grant letter it may be necessary to rescind grant. The need to rescind grant should if possible be avoided by dealing with the request sufficiently quickly for the granted patent (including any amendment allowed) still to be published on the date foreshadowed in the grant letter.]

18.86.1 If the application was found to be in order for grant at first examination, and remains in order after the relevant period has passed (see 18.84), the application should be sent for grant.

[The examiner assistant should check if new documents have been filed, if not they should set the COPS status to "12 – Ready for Grant" on PROSE and forward the case onto Formalities for "Grant". If there are new documents filed, then the examiner assistant will check with the examiner whether the application can proceed to grant and record the situation in a minute. However if a divisional is filed, there is no need to withhold the parent application from proceeding to grant. If an EL3F was issued, the examiner assistant will also check if the grant fee has been paid.]

[If the grant fee is not paid by the deadline in the EL3F the Examiner Assistant should issue a reminder letter to the applicant. This letter will remind the applicant of the need to pay the grant fee and inform them that as they have missed the deadline a Form 52 and fee is now required for them to do so. The 2 month response date provided in the EL3F letter is a prescribed period set by rule 30A of the Patents Rules for paying the grant fee. This period can be extended by 2 months 'as of right' by filing a Form 52 and fee. Further extensions are possible but are subject to the comptroller's discretion. If the fee remains unpaid and no further extensions are available the application will be terminated by formalities once the compliance date has expired. Once terminated the applicant may apply for reinstatement in the usual way (see section 28).]

18.86.2 If the application is found to be in order for grant at a later examination stage, then an intention to grant letter should be issued by the examiner assistant.

r.30A

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[In the situation where a top-up search is carried out at the same time as finding the application in order see 17.115.]

[The examiner should send an "ISSUE RELEVANT EL34 LETTER" message to the EA GRANT mailbox, including as recipient the Examiner Assistant for their examining group. If the examining group does not have an Examiner Assistant then the recipient field should be left blank.]

[The examiner assistant will check whether any grant fees are due and create either an EL34 EL34F bundle. This will include the intention to grant letter and checklist. They should then send an "Intention to grant checklist" message to the ESO.]

[The EL34F bundle should only be created by the Examiner Assistant if the number of excess pages or claims have increased since the filing of the Form 9A and Form 10. If this is the case a grant fee will be requested in the EL34F letter based on the increase in excess claims or excess pages.]

[The ESO should action the checklist to issue the intention to grant letter and update PAFS and COPS (to status 9: Disposed of – In Order).]

[The team of Examination Assistants will be provided with a list of applications on which an EL34 or EL34F letter has issued. Applications will appear on the EL34 list 5 weeks after the EL34 has issued, whereas applications requiring a grant fee will appear on the EL34F list 10 weeks after the EL34F has issued, as the applicant has 2 months in which to pay their grant fee. If no new documents have been filed since the issue of either the EL34 or the EL34F letters, and the grant fee has been paid in respect of the latter, the Examiner Assistant should update COPS to status 12: Ready for Grant and send a "Grant checklist" message to the relevant Formalities group. If new documents have been filed, the Examination Assistant will check with the examiner whether the application can proceed to grant and record the situation in a minute.]

[If the grant fee is not paid by the deadline in the EL34F the Examiner Assistant should issue a reminder letter to the applicant. This letter will remind the applicant of the need to pay the grant fee and inform them that as they have missed the deadline a Form 52 and fee is now required for them to do so. The 2 month response date provided in the EL34F letter is a prescribed period set by rule 30A of the Patents Rules for paying the grant fee. This period can be extended by 2 months 'as of right' by filing a Form 52 and fee. Further extensions are possible but are subject to the comptroller's discretion. If the fee remains unpaid and no further extensions are available the application will be terminated by formalities once the compliance date has expired. Once terminated the applicant may apply for reinstatement in the usual way (see section 28).]

[The EL34 notification of intention to grant is different to the EL34F in that it does not specify a period in which an action must be taken, but simply notifies the applicant of the fact grant is going to take place within a particular timescale. It follows that no as-of-right extension is available to the date given in these letters.]

[If a written request is received from the applicant to send the application to grant sooner than the date indicated in either the EL34 or EL34F (thus waiving the opportunity to file any divisional applications or voluntary amendments) and any grant fee due has been paid, an "Early grant request" message should be sent to the EA GRANT mailbox. The Examiner Assistant will instigate grant action without delay by taking the steps outlined above. This action should only be taken where a request for accelerated grant is received after the intention to grant letter has been issued. Requests received before the intention to grant letter has been issued or requests to forgo the issue of an intention to grant letter must be denied (by an Examiner Assistant) and the applicant should be advised (by an Examiner Assistant) that grant

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can be brought forward only if requested in writing after the issue of the intention to grant letter.]

18.86.3 A grant letter is then issued informing the applicant under s.18(4) that the application complies with the requirements of the Act and Rules and that a patent is therefore granted. The date of this letter is the date of grant for all provisions of the Act prior to s.25(1); in particular, the application may not be withdrawn or amended on or after this date (for amendment of a granted patent, see s.27). In the same letter, the applicant is informed of the date when notice of the grant will be published in the Journal. This practice was confirmed by the Hearing Officer in ITT Industries Inc's Application [1984] RPC 23 (see especially page 27 line 20 onwards).

18.86.4 No application should be sent to grant without first having a notification of intention to grant issued. This is true even for applications which are found in order for grant near or after the compliance date.

[The EL34 is the notification of intention to grant letter that is most likely to be issued near or after the compliance date. There is no need for examiners to modify the letter in this situation, as it is written such that it is correct even if the compliance date is imminent or has passed. However, see 73.07 if conflict is found at the point of issuing an intention to grant letter.]

[The date in the EL34 should not be altered from its default of one month. This can mean that the latest date for reply is after the compliance date. This is not a problem because an application can be sent to grant after the compliance date.]

r.108(2), r.108(3) 18.86.5 Rule 108(2) and rule 108(3) can be used to extend the compliance period after the intention to grant letter has been issued, providing the application has not been sent to grant. Therefore it would be good practice for the applicant to request any extension to the compliance period before the date set out in the intention to grant letter. If the compliance period is extended in this way, the application will still be sent to grant in the timescale set out in the notification of intention to grant letter however such an extension to the compliance period may allow actions such as a divisional to be filed on time.

18.87 All applications when placed in order for grant enter the next grant cycle within a week. During each grant cycle, which lasts five weeks, the various grant procedures outlined in 18.86 and 24.01-24.04 take place. If an applicant has requested accelerated examination and desires grant for a particular date, and the request for the former is accepted by the substantive examiner, an effort should be made to achieve B-publication (see 24.04 and 25.02) by the desired date but it will be impossible to guarantee to do so. The applicant should be told that publication will, if possible, occur by the requested date and should also be told if it proves impossible to do so.

[Any case which has undergone accelerated substantive examination, should be identified by the appropriate label on the dossier cover. If grant by a particular date has been requested, a PDAX message should be sent to the substantive examiner alerting him to the request outlined in the minute. When the case is in order, after updating the data in PROSE, the examiner should check with the publication liaison officer for their division whether that date can be met. If it cannot, it should be noted that there are no established Office procedures for providing "instant" grant of a patent, or for shortening the 5-week B-publication cycle. To make the most of the B-publication cycle, Group ESOs and Examination Assistants need to set "Ready for Grant" by the end of Thursday. DIS PRO should be checked by the examiner on the following day to make sure the case has been picked. If "Ready for B picklist" is still displayed, contact PD/A3 immediately.]

ACTION AFTER ISSUE OF A REPORT UNDER S.18(4)

18.88 As a consequence of the terms of s.18(4), once a notification of intention to grant has issued (see 18.81 and 18.86.2) informing the applicant that his application complies

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with the requirements of the Act and Rules then, unless the application has in the meantime been amended in such a way that it no longer complies, a patent must be granted. Grant cannot be withheld because prior art subsequently comes to light (e.g. because of action within the Office, as the result of observations from a third party, or where the applicant makes the office aware of documents cited against a patent application for the same invention made in another patent office) which casts doubt on patentability. (Nokia Mobile Phones (UK) Ltd's Application - [1996] RPC 733). If there is no doubt that new prior art found by the examiner would have given rise to a major objection the applicant should be informed of it since he may wish to amend either before grant (if the grant letter referred to in 18.86.3 has not yet issued) or after grant. Likewise any third party observations should be copied to the applicant (see 21.15, 21.16). The applicant should be informed that grant will be delayed for two months (in order to give him time to decide whether to amend) unless he requests earlier grant. If the applicant chooses not to amend, the new prior art should not be listed on the front page of the B publication since this might suggest that it had been properly considered and the application considered acceptable over it. If any of the new prior art forms part of the state of the art by virtue of s.2(3) and is citable against lack of novelty, the applicant should be warned that action may be taken after grant (see 73.02). If a divisional application is filed on the application in suit, see 15.46.

Limited circumstances in which grant or a s.18(4) report may be rescinded

r.107 r.33(5) 18.89 The legislation provides no possibility to rescind grant or a s.18(4) report other than in circumstances where there has been an irregularity in Office procedure falling within the terms of r.107. Requests from applicants to rescind grant simply in order to allow the filing of voluntary amendments or a divisional application cannot therefore be acceded to if there has been no such irregularity. Applicants should be advised of possible actions open to them after grant, for example, amendments under section 27. Irregularities in the grant procedure which may justify rescinding grant may occur when:

r.33(4)

- (i) third party observations, which the examiner considers give rise to a well-founded objection, were received before issue of the intention to grant letter, but too late to prevent its issue; or
- (ii) a request by the applicant to withdraw the application or to file voluntary amendments was received in the Office prior to issuing the grant letter, but too late to prevent its issue; or
- (iii) the examiner agreed that amendment to the description could be attended to at a later date pending the examiner's acceptance of the claims, but the case was then inadvertently marked in order for grant before such amendments were made.

18.90 If it is necessary to rescind grant or a notification of intention to grant made under s.18(4), the examiner should issue a letter stating that the report under s.18(4) was made in error and is rescinded. If the grant letter has issued (see 18.86) it will also be necessary to cancel the grant. A report should then be made under s.18(3) setting out the objection and specifying two months (or six months if the examiner's report under s.18(4) was the first report under s.18) for reply, unless the time available makes a shorter period appropriate; this may be increased to four months if major amendment is required and sufficient of the compliance period remains. If s.21 observations were filed near to the end of the compliance period, that period may have been extended as described in 20.02.1.

[Cancellation of the grant may only be initiated by contacting the publication liaison officer, who will call a meeting of all the interested parties (see 14.206). The letter rescinding the grant letter and/or report made under s.18(4) should identify the writer and provide a contact telephone number. A fresh report should be made for communication to the applicant. When the remaining time is so short as to require urgent action, the applicant should if possible be given forewarning by telephone to provide opportunity for the filing of Patents Form 52.]

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Section 18(5)

Where two or more applications for a patent for the same invention having the same priority date are filed by the same applicant or his successor in title, the comptroller may on that ground refuse to grant a patent in pursuance of more than one of the applications.

s.130(1) s.89(1) s.78(2) s.73(2)

- 18.91 For this subsection to have effect the conflicting applications must be applications for patents under this Act, including international applications designating the UK which have entered the national phase as domestic applications under the provisions of s.89. It does not apply to conflict with an application for a European patent (UK), since this is not treated as an application under the Act for the purposes of s.18(5); such conflict can only be dealt with under s.73(2) when each of the relevant patents have been granted (see 73.05-73.09).
- 18.92 The stricture of s.18(5) applies not only when the conflicting applications have identical applicants or groups of applicants, but also when the applications have an applicant in common, or when an applicant in one case derives his right to be granted a patent from a person who is an applicant in the other case, for example by assignment or by contract of employment, or in any other way.
- 18.93 For the grant to be refused on an application which conflicts with another, the priority dates in question must be the same, including the case where one application claims priority from the other, or where one is divided from the other and claims the same priority. It should be borne in mind that it is the priority dates of the respective inventions (see 5.20-5.24) which must be considered, rather than the declared priority dates of the applications. (If the priority dates of the respective inventions are not the same, then one may form part of the state of the art in respect of the other; if so, appropriate action under s.18(3) or s.73(1) should be considered).
- 18.94 Conflict between applications should be drawn to the attention of the applicant as soon as it is detected (but not before the first substantive examination), since it is desirable that the matter be dealt with before any of the patents has been granted, so that the applicant may decide how he wishes the conflict to be resolved, for example by amending to distinguish the inventions from one another or by deciding which application should proceed. Once a patent has been granted on one of the applications, for example if one application is accelerated (see 15.46 last square bracket), conflict can still be avoided either by amendment of the outstanding application or by amendment under s.27 in respect of the granted patent, since an amendment under s.27 has effect retrospectively from the date of grant. However, the situation cannot be saved by surrendering the granted patent, since this action is not retrospective (IBM Corporation (Barclay and Bigar's) Application [1983] RPC 283). There is no provision for dealing with a conflict between patents having the same priority date and granted to the same applicant, other than in the particular circumstances dealt with by s.73(2).
- 18.95 The tests for determining under s.18(5) whether two UK applications relate to the same invention are the same as for deciding under s.73(2) whether a UK patent conflicts with a European patent (UK). The phrase "for the same invention" under both s.18(5) and s.73(2) is regarded as embodying the long-standing principle that the same monopoly should not be granted twice over. Thus it covers not only the situation where respective applications contain claims explicitly including all of the same features (including the case where these are claims dependent on quite distinct main claims) but also where the claims differ in their wording but their scope does not differ in substance. The examiner should consider whether the dependent claims result in the same invention as any of the claims in the other application, once the features set out in both the independent claim and dependent claim(s) are taken into account. The degree of overlap which is allowable must be decided on the facts of the case, having regard to the state of the art, and the applicant may be able to show that there is a significant distinction between apparently conflicting claims.

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18.96 <u>Maag Gear Wheel and Machine Co Ltd's Patent</u> [1985] RPC 572 was a decision of the comptroller which related to an objection under s.73(2). In this case, which concerned a pivoted pad journal bearing for a shaft, each of the features contained in claim 1 of the UK patent was specified, though in slightly different terminology, in claim 3 of the European patent (UK). However, claim 1 of the European patent (UK) (to which claim 3 was appendant) included additional "pad geometry" features not to be found in the claims of the UK patent. The hearing officer observed that, even though claim 1 of the UK patent was not explicitly limited to the pad geometry of claim 1 of the European patent (UK), that pad geometry was the only construction described and illustrated in the UK patent. Thus, he construed claim 1 of the UK patent as protecting a journal bearing including that pad geometry and accordingly found claim 1 (and its appendant claims 2 to 5 and omnibus claim 6) of the UK patent to be directed to the same invention as that claimed in claim 3 of the European patent (UK).

In <u>IBM Corporation (Barclay and Bigar's) Application [1983] RPC 283</u>, before the comptroller, a claim to a solution containing a compound in a concentration "less than 0.03M and sufficiently low to give a perceptively lighter colour", and a claim to a solution containing the same compound in a concentration "less than or equal to 0.02 Molar", were also held to be for the same invention. In this case, although the wording of the claims differed, the wording of the claims led to the same result (because in order for the concentration in question to give the required perceptively lighter colour it would have to be less than or equal to 0.02M) and the scope of the claims therefore did not differ in substance.

In <u>Marley (UK) Ltd's Patent [1994] RPC 231</u> the Court of Appeal decided that the correct construction of s.73(2) was the literal one that the UK patent may be revoked if the claims of the UK and European (UK) patents are for the same invention. The court found that a claim to a product will conflict with a claim to the same product as produced by a specific process. In Marley, claim 1 of the UK patent related to concrete articles made of a particular composition and having particular qualities whilst claim 8 of the European patent (UK) related to such concrete articles, but produced by a particular process. Balcombe LJ held that claim 1 of the UK patent was for the same invention as claim 8 of the European patent. It is perhaps worth noting that, after the House of Lords' judgment in <u>Kirin-Amgen Inc v Hoechst Marion Roussel Ltd [2005] RPC 9</u>, such a "product-by-process" claim would be construed as a claim to the product (see 14.120.1), thus also leading to the conclusion that the UK and European (UK) patents related to the same invention.

In <u>Arrow Electric Switches Ltd's Applications 61 RPC 1 (1944)</u>, it was decided under the 1949 Act that where the respective UK patent applications were directed to distinct inventions A and B, it is allowable for one of the applications to contain a claim to the combination of A and B. (However, it would not have been allowable for both applications to contain such a claim.) In this case, one application was a divisional of the other application, as a consequence of a plurality objection. Invention A was an electric switch and invention B was a means for operating an electric switch. The question of double jeopardy from infringement arising out of a single act was considered by Morton J. in the Arrow case and he concluded that it would be unduly hard on inventors if protection for the combination A and B were denied because its unauthorised use could result in a suit under both the patents.

In <u>Kimberley-Clark Worldwide Inc's Patent</u> (BL O/279/04), in relation to s.73(2), claims comprising feature A in the UK patent were held not to be the same invention as the claims in the European patent (UK) comprising features A and B. In the case in question the hearing officer considered that the inclusion of feature B in the European patent (UK) lead to a difference in substance between the two claims, and therefore no revocation action was taken. In <u>SeeReal Technologies SA (BL O/261/12)</u> the Hearing Officer, when assessing conflict between claim 1 of a divisional application and claim 1 of the parent application, confirmed the practice followed in <u>Kimberley-Clark Worldwide Inc's Patent</u> (BL O/279/04). The decision in <u>SeeReal Technologies SA (BL O/261/12)</u> also highlighted the importance of claim construction when assessing conflict, with reference to <u>Maag Gear Wheel and Machine Co Ltd's Patent</u> [1985] RPC 572.

The assessment of conflict under sections 18(5) and 73(2) is unaffected by the judgment in Koninklijke Philips Electronics n.v. v Nintendo of Europe GmbH [2014] EWHC 1959 (Pat)

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because this judgment is directed only to the discretion to allow post-grant amendments (see 75.05.1).

18.97.1 The EPO Technical Boards of Appeal in T 1790/12 and T 879/12 held that a divisional application with second medical use claims of the form "Substance X for use in the treatment of disease Y" did not conflict with a parent application with "Swiss-type" second medical use claims of the form "The use of substance X in the manufacture of a medicament to treat disease Y". Although s.18(5) and s.73(2) are not derived from provisions of the EPC, in view of this EPO case law, no objection should be raised under s.18(5) or s.73(2) to conflict between applications including the new form of second medical use claim and granted GB or EP patents which protect the same medical use solely through Swiss-type claims (see 4A.27.1).

Annex A to section 18 of the Manual - Combined Search and Examination

18.98 Sections 17 and 18 of the Manual refer at various points to the process of combined search and examination. In particular, references are to be found at 17.35, 17.94.10, 17.108, 17.115, 18.03, 18.06, 18.08, 18.39-41, 18.47-49, 18.82, 18.84.1-18.84.3 and 19.26.

[Examiners in particular should be aware of the different procedures which apply when processing combined search and examination cases. Of particular help will be the examiners' aide-memoire for combined search and examination cases, the contents of which are reproduced below.

[COMBINED SEARCH AND EXAMINATION (CS&E): AIDE-MEMOIRE

Identifying CS&E cases

- 1. The COPS CS&E flag is automatically set to YES when Forms 9 & 10 are filed on the same day. If Forms 9 and 10 are filed together but the applicant states that CS&E is not wanted, or if, before the search is started, Form 10 is filed after Form 9 with a written request for CS&E, CHA CSE is used to reset the flag appropriately. CHA CSE is also used to reset the flag to NO on all searched PCT cases filed with Forms 9 and 10.
- 2. All CS&E applications are identified by the appropriate label on the dossier cover.
- 3. Where a request for CS&E is made too late the applicant is informed and if necessary the CS&E flag is reset to NO using CHA CSE.

Action on arrival in an examining group

4. Combined Search and Exam is recorded on PAFS when a CS&E case is booked into an examining group but only after consultation with the examiner when CS&E has been requested late. CS&E cases take their place with applications awaiting search unless accelerated search and examination has been requested (see 20, below).

Search & First Substantive Examination

5. Where examination reveals objections the search and examination reports are issued together with SE1 (SE1PA) setting a latest date for reply 2 years from the priority/filing date. Before the case is booked out the appropriate value is set for the COPS status field (normally either 5 - "May be s.16 published" or 3 - "Searched but not 5"). When the case is booked out PAFS will count 2.9 work units.

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- 6. Where examination does not reveal any objection only the search report is issued with SE3 (SE3PA). Before the case leaves the group the appropriate value is set for the COPS status field. The case counts as 2.9 work units when booked out and is diaried for return to the examiner 3 months after A-publication.
- 7. When the file is diaried back to the examiner three months after A-publication the search is topped up and any voluntary amendments considered. A first examination report is then issued under s.18(4) using EL3 (EL3F) or under s.18(3) using EL1 (EL1PA) with RC8, if appropriate, as the case may be. On no account should the application simply be sent for grant. The latest date for reply is based on the normal 2 months for EL3 (EL3F) and the later of 4 months from the date of the letter or 2 years from the priority/filing date for EL1 (EL1PA).

Acknowledgement of Registered Trade Marks

8. The examiner should check at first examination stage whether any unacknowledged terms are registered trade marks. If the examination has not revealed any objections, the examiner should amend the specification to acknowledge the mark (see 19.23-19.26) and inform the applicant by adding SC2 to SE3 (SE3PA). If other objections are to be raised, the applicant should be asked to acknowledge the mark, using RC11 added to the first s.18(3) report.

Amendments

- Amendment before the issue of the search report is allowable with the Comptroller's consent and account should be taken of any such amendment during CS&E.
- 10. New or amended claims filed voluntarily or as part of a full response to the examination report before preparations for publication are complete are published in the A-document in the normal way.

11. [Deleted]

- 12. A response to an examination report received after A-publication is considered in the normal way.
- 13. If a further examination report is issued the period for reply is set to expire two years from the priority/filing date or after the normal four or two months, whichever is later.
- 14. No application is to be marked In Order until three months after A-publication. If all earlier objections are met before this date, then the file is diaried for return to the examiner at the end of that period. EL32 is issued if the diaried date is for more than one month ahead.

A-publication

15. On publication the main COPS processing status for CS&E cases is set automatically to 10 - "Disposed of - not in order". This is reset using REC PRO at the next COPS action if it does not reflect the true status of the case.

Third party observations

16. Any third party observations are copied to the applicant immediately. With applications diaried because no objections are outstanding the examiner also considers them without delay. On applications where a response to an examination report is awaited the examiner has the usual option of deferring consideration until the response is filed.

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Extension of periods specified at CS&E stage or later

17. Requests for extension of the period for reply given in a substantive examination report should be treated in the normal way. If requested, on cases where no examination report is issued at CS&E, the issue of the first s.18 report can be deferred until applications not subject to CS&E are expected to receive their first s.18 examination.

Top-up searches

- 18. Examiners complete the search for s.2(2) art and if possible also for s.2(3) art as soon as practical and certainly before issue of EL3 (EL3F) or in other circumstances immediately before grant. Online databases are generally sufficiently up to date 3 months from the priority/filing date for the s.2(2) field and 21 months from the priority/filing date for the s.2(3) field.
- 19. Where an application is sent to grant before 21 months or the s.2(3) search is otherwise not complete, the examiner diaries it for return at some appropriate time after grant to complete the search. Any s.2(3) objection arising is made under s.73(1) in the normal way.

Accelerated search and examination

20. The normal procedure for accelerated search should be followed but with the examination done at the same time as the search.

Early grant

21. This depends on the applicant requesting accelerated publication (which is handled normally), otherwise the procedure is the same as with any other CS&E case.

Divisional applications

22. If a divisional application qualifies for CS&E the search and examination are done together even if this was not the case for the parent application and /or the search has effectively been done following a request on the parent. If the parent application has not been substantively examined this may be done at the same time as the divisional (provided Form 10 has been filed) unless the applicant or agent agrees otherwise. The need to delay grant for 3 months after publication can be waived, in accordance with normal practice, if the divisional invention was claimed in a sufficiently earlier published parent.

Refunds

23. Normally no refunds should be made if the search and examination reports or just the search report have been issued.]

Annex B to section 18 of the Manual - Extensions of time aide-memoire

18.99 The following aide-memoire for examiners reflects the practice described in 18.53-18.60.

EXTENSIONS OF TIME: SUBSTANTIVE EXAMINATION REPORTS

An as-of-right extension of two months, or until the compliance date if sooner, is available to the period for reply specified in s.18 examination reports. The extension:

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- must be requested in writing, preferably in the covering letter accompanying the response or, alternatively, by email to pateot@ipo.gov.uk (telephone requests are not allowable).
- may be requested retrospectively up to the expiry of the extended period.
- is available only once for any given report round.
- must be for two months, or until the compliance date if sooner, whether or not it is needed or wanted; extensions for shorter time periods are not available.

An extension further to the as-of-right extension may be requested but:

- is only available if the as-of-right extension was requested.
- the request must be made before the expiry of the period as extended by right.
- is discretionary, but one single extension of up to one month on a given period is generally allowable.
- does not usually need to be requested in writing.
- must give an adequate reason; if no reason is given, one should be asked for.
- may be requested at the same time as the as-of-right extension.
- must take into account how much time is left of the compliance period.

Requests for additional further extensions:

- must be made before expiry of the period as already extended.
- require a strong reason to be allowed.
- should be for the minimum required (normally < 1 month) to fix the problem.

Where a late reply is received and no extension is available because the period for requesting an extension has expired, the reply should be referred to the examiner:

- If no reason is given for the late reply, the examiner should ask for one; if no reason is forthcoming, the application will be refused.
- If a reason is given, the examiner should consider it and decide whether to exercise the discretion provided under section 18(3) to accept the late reply (despite it falling outside the specified period).

Administrative points:

- Requests for all extensions (i.e. as-of-right and discretionary) may be emailed to pateot@ipo.gov.uk an automatic reply will be sent. We do not guarantee to recognise requests sent to any other email address.
- Requests for extensions emailed direct to examiners should be handled as follows:

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email requests for as-of-right extensions should be forwarded to formalities to be put on file. You have discretion whether or not to reply but if you do, you should encourage the agent to use the pateot@ipo.gov.uk service.

in the case of a discretionary request, you should consider the request and respond, ensuring copies of all correspondence are placed on file.

- No telephone requests for as-of-right extensions are allowable encourage agent/applicant to use above dedicated email address rather than write a letter.
- Replies to requests for discretionary extensions may be dealt with by telephone or in writing but ensure audit trail is complete. In all cases, a complete record (letter, telephone or email report) of events and reason for the request must be on file.

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Section 19: General power to amend application before grant

19.01 Provisions relevant to this subject are laid down in r.31.

Section 19(1)

At any time before a patent is granted in pursuance of an application the applicant may, in accordance with the prescribed conditions and subject to section 76 below, amend the application of his own volition.

r.107 s.25(1) To be effective a request to amend must be received before the issue of the letter informing the applicant that a patent has been granted (see 18.86). If it is received before that date but too late to prevent issue of the letter the grant may be rescinded; the request should then be considered as described in paragraphs 19.20-19.22. If the request is received on or after that date it is too late to amend the application; amendment of the specification of the patent may be sought after the date of publication of the notice of grant in the Journal (see 27.04). It is additionally necessary for the request to be received while the application is still in being; an application apparently cannot be amended after it has been treated as withdrawn through failure to meet a formal requirement or otherwise terminated, even if allowance of the amendment would allegedly have the effect of avoiding termination (eg by relinquishing a claim to priority, see 19.11, and thus apparently giving more time for Form 9A to be filed). This is because amendment takes effect ex nunc as explained in 19.04 and, in addition, it appears that the general power to amend under s.19 cannot be used to circumvent the specific requirements of other sections of the Act (cf *Payne's Application* [1985] RPC 193, see 117.19).

Amendments and corrections

Although the ordinary dictionary definitions of these words overlap, and the terms may often be employed interchangeably in normal parlance, they are used in the Act and Rules in quite distinct and specific senses, and it is convenient at this point to discuss in general terms the difference between them. Correction is the alteration of a document so that it may better express the intention the drafter had at the time of drafting, including the case where an agent drafting a document has misconstrued his instructions. If the alteration is sought because the drafter has become aware of new facts, or because circumstances have since changed, or because he has changed his mind, then this is not correction but amendment.

[Whenever a request to effect an alteration is made informally in a letter rather than formally on the appropriate form, it should be borne in mind that the applicant may not have used the term "amend" or "correct" in these precise ways. If the applicant's intentions are not clear both options may if necessary be pointed out and the difference explained, but care should be exercised against suggesting either option in a case where it would appear prima facie not to be open.]

r.105(3) s.27(3) s.75(3) 19.04 Correction of an application or the specification of a patent or of any document filed in connection therewith is governed by s.117, and takes effect ex tunc, that is, the document is deemed always to have been in the state in which it is after the correction. If the correction sought is in a specification then it is necessary to show that it may properly be dealt with as a correction, but once this is established there is no impediment to the making of the correction; in particular the question of whether subject-matter is added or the protection conferred is extended by the alteration does not arise (*Rock Shing Industrial Ltd v Braun AG*, BL O/138/94). In contrast, amendment of an application or of the specification of a patent must comply with the requirements of s.76(2) or (3), (see 76.04-27). Amendment of an application is governed by s.19 and takes effect ex nunc, that is, from the time the amendment is made; amendment of the specification of a patent is carried out under s.27 (or under s.75 if done while there are pending proceedings

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in which the validity of the patent may be put in issue) and is deemed to have had effect from the date of grant.

AMENDMENT OF THE REQUEST FOR GRANT

r.31(5)(b) r.31(6) r.49 19.05 An application to amend the request for grant (Patents Form 1) must (except as stated below) be made in writing, giving a reason for the amendment. This may be filed at any time before the applicant is sent the letter informing him that a patent has been granted (see 18.86), but must be received before preparations for publishing the application under s.16 have been completed if the change is to be included in the published application. In such a case the published application will carry a notice to the effect that the publication reflects an amendment to the request for grant effected under r.31. A request to change a person's address or address for service must be made in writing by that person, see 32.06.

r.31(5)(b) r.49(2), (4) r.113(1) 19.06 Any request to amend a name must be made on a Patents Form 20, as such a change must be effected under s.32(2)(d) and in accordance with r.49(2). Patents Form 20 can also be used to notify the IPO of address changes. However, if only an address has changed, it is allowable for a request to update the address on record to be made in writing. (Form 20 should also be used for correction of a clerical error in a name - see 117.17). Where the comptroller has reasonable doubts about whether the alteration should be made, the person making the request will be informed of these doubts and may be required to supply proof to support his request. In the case of a corporate body any proof required should be in the form of a document from the appropriate companies registration authority, such as (for the UK) a certificate from Companies House, or (for the USA) a State Certificate, or (for Germany) an extract from the Handelsregister, For France or Belgium a copy of the gazette or commercial paper in which the change of name was advertised should be supplied. If a change of name has already been recorded at the EPO, a copy of EPO Form 2544 (giving notice of the change made in the Register of European Patents) will be accepted. Whenever the proof is in a foreign language it should be accompanied by a verified translation. In the case of a natural person whose name has been changed, eg by Deed Poll, it is sufficient to give particulars of the issue of the gazette or newspaper in which the change has been advertised.

[Where a change of name is accepted, the name is crossed out using Enhance and the new name inserted.]

r.49(5)

19.07 Changes in the applicant's name, address or address for service will be effected in the Register. If the request to amend is received in time the amendments will be included in the published application (see 19.05).

[Where there is any doubt as to an applicant's name, address or address for service, COPS and PROSE hold the definitive version of the Register.]

19.08 If the change in name or address had taken place at the time the application for a patent was filed (so that Form 1 was incorrect at the time it was filed), then alteration of it is not amendment but correction and must be effected under s.117 (see 117.17).

19.09 Provided that Form 7 has not yet been filed, the addition or deletion of an applicant or the substitution of one applicant for another, for example because of assignment of the application or the death of an applicant, may be effected by a request in writing. (This may also necessitate an amendment of Part 8 of Form 1 (see 14.04.16-17)). Reasons for making the amendment should be provided in writing. Supporting evidence (or sworn statement(s) indicating the consent of the party or parties affected by the change) is required and the statements made on a subsequent Form 7 must be consistent with the amendments made and the reasons given. If however Form 7 has already been filed, any assignment of the application or other change in ownership must be notified under s.30.

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19.10 A request to amend the title of the invention on Form 1 is generally allowable, although consideration should be given to the issues raised in 14.51. It is acceptable for amendment of the Form 1 title to result in a discrepancy between the Form 1 title and the title on page 1 of the specification (see 14.49).

[The formalities examiner should forward such a request to the relevant examiner, adding a minute to the PDAX dossier, to draw the examiner's attention to the request. If the examiner allows the request, they should create a minute and send the appropriate PDAX message to the formalities examiner who will effect the changes using the "Enhance" function in PDAX and ensure that the appropriate COPS action is taken.]

19.11 If the application includes a declaration of priority (see 14.04.14) or claims an earlier date of filing (see 14.04.15) either of these may be relinquished by a request to amend Part 5 or Part 6 of Form 1. (It should be remembered that abandonment of the claim to an earlier filing date may necessitate relinquishment of a claim to priority). The proposed amendment may arise as a consequence of an objection made under s.18(3), whether to meet that objection or in anticipation of a further objection which would arise as a result of the action taken, for example where a declaration of priority is deleted consequent on division following an objection of plurality of invention. In all cases, including when a request is made to relinquish divisional status following a preliminary objection (see 15.34-15.35), the request to amend Form 1 should be made in writing, giving a reason for the amendment. For making a declaration of priority after filing a Form 1, see 5.07 to 5.07.3.

[A request for the deletion of a declaration of priority must be referred with an explanatory minute to the relevant Assistant Head of Administration via the Formalities Manager. The Assistant Head of Administration will authorise the amendment, alter Form 1 using the "Enhance" function in PDAX and then update the history action log.]

19.12 The applicant must always be informed whether or not an application to amend the request for grant has been allowed.

AMENDMENT OF THE SPECIFICATION OF AN APPLICATION

s.18(3) r.31 r.66A CoP s.76(2) 19.13 In addition to having the right to amend the specification in order to overcome an official objection, the applicant may make amendments for reasons of his own. Such voluntary amendments may however only be made as provided for by r.31 or r.66A (see 19.15-19.16; 19.20), and it is preferable for voluntary amendments to be kept to a minimum and filed as early as possible. No amendment is allowable which results in the application disclosing any matter which extends beyond that disclosed in the application as filed (see 76.03-76.23). (For the procedure for effecting amendments, see 18.61-18.62).

[19.14 Deleted]

Amendment as of right

r.31(3) s.16(1) 19.15 Between the dates of issue of the search report and of the first substantive examination report the applicant may, of his own volition, amend the specification, for example to take account of documents cited in the search report. There is no restriction on the number of times this may be done, and this right is not affected by the issue of an examination opinion with the search report (see 17.83.3 and 17.83.4). The amendments are deemed to be effected at the time they are filed, but are not considered by the substantive examiner, for example to see if they add subject-matter, until the first substantive examination. Any amended or new claims subsisting immediately before preparations for publication have been completed are included in the published application (see 16.16-16.19).

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- r.66A
- 19.15.1 Where an international application under the PCT has entered the UK national phase and an international search report was issued during the international phase, the applicant may amend the specification of his own volition from the date of national phase entry until the date the first examination report is issued. Where no international search report has been issued by the time the application enters the UK national phase, the period within which the applicant may amend voluntarily starts from the date of issue of the UK search report or the international search report (whichever is issued first).

r.31

- 19.16 After the issue of the first substantive examination report the applicant may, in addition to amending to meet any objections raised in that report, amend the specification once for reasons of his own. If the first report is made under s.18(3), the voluntary amendments must be filed at the same time as the applicant replies to that report except that if the first substantive examination report is issued before the preparations for publication of the application have been completed, the applicant may also amend the specification of his own volition before he replies to the report. Any amended or new claims subsisting immediately before preparations for publication have been completed are included in the published application (see 16.16-16.19). On the other hand if the first report is made under s.18(4) any amendments must be filed within two months of the issue of the report.
- 19.17 The opportunity to amend the specification as of right following a first report under s.18(3) is therefore expended when any considered reply is made, whether consisting of amendments to meet the substantive examiner's objections, the setting out of proposals to meet those objections, or the submission of arguments intended to rebut them, and regardless of whether the reply is complete, or whether it is made before the end of the period specified in the report. Thus, for example, if a reply is made proposing amendments to the claims but deferring consequential amendments, this terminates the period for voluntary amendments as of right under r.31(4), and any further amendments not required by the substantive examiner must be made with the consent of the comptroller under r.31(5)(a), (see 19.20). However a mere request or a query in response to the report under s.18(3) does not have this effect, and the option to file voluntary amendments remains open until a considered reply is made within the period specified.
- 19.18 If, following a first report under s.18(4), allowable amendments are filed before the expiry of the two month period the amendments should be acknowledged and the application should be sent for grant in the timescale previously indicated (see 18.85-18.86). If however, amendments are filed which are not allowable, so that a report is then issued under s.18(3), this report counts as a second report, and any subsequent voluntary amendments must be made with the consent of the comptroller under r.31(5)(a), (see 19.20). On the other hand if a first report under s.18(4) is rescinded under r.107 (see 18.89-18.90), then the report under s.18(3) replacing it is regarded as the first report and voluntary amendments as of right are allowed when reply is made to it, even if voluntary amendments had already been made within the period allowed by the original s.18(4) report.

[If the examiner determines that amendments filed within the two months period are allowable, they should send a PDAX message with the text "ISSUE RELEVANT EL4 LETTER" to the EA GRANT mailbox, including as a recipient the examiner assistant for their examining group. If the examining group does not have an examiner assistant then the recipient field should be left blank. On receiving this message, the EA should then issue an EL4 or EL4F (if there are outstanding grant fees). If there are no grant fees outstanding, the EL4 should be accompanied by a GRANT checklist. The EA should set the application ready for grant and send a "GRANT CHECKLIST" message to Formalities. If the response date in the intention to grant letter has not yet expired, the EA should instead use an EL4P checklist to accompany the EL4. The EA will subsequently set the application ready for grant and send a "GRANT CHECKLIST" message to Formalities once the date in the original intention to grant letter has expired. An EL4F should be accompanied by an EL4P checklist.]

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[If the amendments have decreased the number of excess pages or excess claims and consequently the applicant has overpaid, the EA should send a PDAX message to Formalities instructing them to issue a refund of the overpayment. The EA should at the same time continue to prepare the application for grant. The EA should send a "GRANT CHECKLIST" message to the relevant Formalities group, unless the date given in the original intention to grant letter has not expired (see above). There is no need to wait for the refund to be issued before sending the application to grant.]

[If the grant fee is not paid by the deadline in the EL4F the Examiner Assistant should issue a reminder letter to the applicant. This letter will remind the applicant of the need to pay the grant fee and inform them that as they have missed the deadline a Form 52 and fee is now required for them to do so. The 2 month response date provided in the EL34F letter is a prescribed period set by rule 30A of the Patents Rules for paying the grant fee. This period can be extended by 2 months 'as of right' by filing a Form 52 and fee. Further extensions are possible but are subject to the comptroller's discretion. If the fee remains unpaid and no further extensions are available the application will be terminated by formalities once the compliance date has expired. Once terminated the applicant may apply for reinstatement in the usual way (see section 28).]

[If the voluntary amendments are not allowable, an examination report under s.18(3) should be issued. Once the objections raised in the s.18(3) report have been addressed, the examiner should ask the EA to issue a further intention to grant notification should be issued (an EL34 or EL34F), see 18.86.2.]

19.19 The comptroller has no power to refuse amendments submitted under r.31(3) or (4) to be made. However, any amendment which does not comply with s.76(2) or which gives rise to any other objection under the Act or Rules should not be allowed to stand. The amended specification should be considered by the examiner as described in 18.64-18.70. The amendments take effect on filing; hence if no response is received within the specified period to an objection to such an amendment it is not permissible to send the unamended application forward for grant.

[RC9 may be used to object to added matter in a specification amended under r.31(3) or (4).]

Amendment with the consent of the comptroller

Before issue of the search report

s.117(1) 19.19.1 Under rule 31, amendment of the specification before the examiner's search report under section 17(5) is issued is only allowable if the comptroller requires or consents to that amendment. Otherwise the specification will remain in its unamended state. The search examiner should normally consider the allowability of any amendments proposed before the search is done, having regard to ss.14(3), 14(5) and 76 (see 17.35). Amendments made to the specification other than corrections under s.117(1) or to the claims will not be published in the A specification (see 117.13). They will however be incorporated into the specification and become open to public inspection when the application is published (see 16.20).

After response to the first report under s.18

r.31(5) 19.20 Once the opportunities for amendment as of right (see 19.15-19.16) have r.31(6) passed, the applicant may make amendments which are not in response to an Official objection only with the consent of the comptroller and provided that they are received before issue of the letter informing the applicant that a patent has been granted (see 18.86 and 19.02). The application to amend should be made in writing, giving a reason for the amendment, unless the applicant can satisfy the substantive examiner that the amendment is calculated to meet an objection that the examiner should have raised. The comptroller's

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consent is not normally withheld if the amendments appear to be allowable.

19.21 Until consent is given to the amendments the specification remains in its unamended state. Consent is not granted until the amendments are in an allowable state. The applicant should not be left uncertain whether the amendments have been received and considered. Accordingly, if the amendments were filed after a reply to a report under s.18(3) and no further report under s.18(3) is to issue, and there has been no communication with the agent or applicant concerning the amendments, he should be notified of their allowance. On the other hand, if the specification without the proposed amendments is in order and the amendments give rise to objection a report to this effect should be made, and two months be specified for reply. If no response is made within this time the (unamended) application may be sent for grant.

[Allowable amendments filed after a reply to the final report under s.18(3) should be acknowledged as in paragraph 19.18. On the other hand if, while the amendments are allowable, a further report under s.18(3) is to issue, RC8 should be added to the report. RC9A may be used to object to additional matter in the proposed amendments when the application is not otherwise in order, and EL9 may be used where the unamended application is in order (RC9 should not be used in either of these circumstances). Where a report solely dealing with objections to proposed amendments under r.31(5)(a) is to be sent, it should be headed "Patents Act 1977: Report on amendments" (and not "Patents Act 1977: Examination report under section 18(3)") and an appropriate period for reply should be specified.]

[The EL9 should have a reply date of 2 months. The examiner should reconsider any further amendments in response to the EL9 within 3 weeks of receiving them, this is to ensure the minimum possible delay to grant. If the applicant responds to the EL9, and the application is resultantly found to be in order for grant, the examiner should follow the procedure in 19,22.1 so that the application is sent on for grant by the examiner assistants. The examiner should also minute the file for the attention of the examiner assistants stating that the amendments are now allowable (sending a "PSM" message to the EA GRANT mailbox). If a response to the EL9 is received and the proposed amendments are still not allowable, then the examiner should use their judgement whether to send the application to grant in the unamended state (following the same procedure as when there is no response see below) or whether they issue a further EL9. If no response is received within the time period, the examiner assistants will prepare for the application to be sent to grant in its unamended state, checking that any excess fees have been paid. If any required fees have been paid, the examiner assistants will then message formalities to perform the grant check. If any fees have not been paid, the examiner assistant should issue the standard reminder letter (with a deadline of two months from the original EL9 deadline.]

[Where fees are filed in response to an EL9 letter, but no substantive response has been made, formalities should check the correct amount has been paid and close the application down. Unless the applicant has requested early grant Formalities do not need to send a "FORM 34 PAID" message to the EA in this instance as the application will appear on their EL9 list after 10 weeks. Once the application appears on the EA's list they must check whether any grant fee remains outstanding. If no grant fee is due they should prepare the application to be sent to grant in its unamended state. A "GRANT CHECKLIST" message should then be sent to the relevant formalities group who will carry out the final grant check.]

Ilf grant fees remain outstanding, the EA should issue a reminder letter to the applicant. This letter will remind the applicant of the need to pay the grant fee and inform them that as they have missed the deadline a Form 52 and fee is now required for them to do so. The 2 month response date provided in the EL9 letter is a prescribed period set by rule 30A of the Patents Rules for paying the grant fee. This period can be extended by 2 months 'as of right' by filing a Form 52 and fee. Further extensions are possible but are subject to the comptroller's discretion. If the

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fee remains unpaid and no further extensions are available the application will be terminated by formalities once the compliance date has expired. Once terminated the applicant may apply for reinstatement in the usual way (see section 28).]

19.22 If, however, a request to amend is received after the end of the compliance period (at which time the application must have been reported as complying with the Act and Rules, otherwise it would have been treated as having been refused) the amendment should be allowed only if it does not necessitate substantial re-examination or further search and would not unduly delay grant; a request to restrict the claims to avoid late-found prior art should, if effective for this purpose, be allowed.

19.22.1 If the application was found in order at second or later examination, then amendments can only be made with the consent of the comptroller. The intention to grant letter sets out that such voluntary amendments must be made before the date given. However, amendments received after this date should still be considered so long as they are received before grant. In some cases the date in the intention to grant letter may be later than the compliance date. This is not a problem because it is possible to make voluntary amendments after the compliance date, see 19.22. The amendments must be accompanied by reasons, and their allowance is at the comptroller's discretion.

[If the substantive examiner finds the voluntary amendments are allowable they should minute the file to state the application is in order for grant and send a PDAX message with the text "ISSUE RELEVANT EL4 LETTER" to the EA GRANT mailbox, including as a recipient the examiner assistant for their examining group. If the examining group does not have an examiner assistant then the recipient field should be left blank. On receiving this message, the EA should then issue an EL4 or EL4F (if there are outstanding grant fees). If there are no grant fees outstanding, the EL4 should be accompanied by a GRANT checklist. The EA should set the application ready for grant and send a "GRANT CHECKLIST" message to Formalities. If the date in the intention to grant letter has not yet expired, the EA should instead use an EL4P checklist to accompany the EL4. An EL4F should be accompanied by an EL4P checklist.]

[If the amendments have decreased the number of excess pages or excess claims and consequently the applicant has overpaid, the EA should send a PDAX message to formalities instructing them to issue a refund of the overpayment. The EA should at the same time continue to prepare the application for grant. The EA should send a "GRANT CHECKLIST" message to the relevant formalities group unless the date given in the original intention to grant letter has not expired (see above). There is no need to wait for the refund to be issued before sending the application to grant.]

[If the grant fee is not paid by the deadline in the EL4F the Examiner Assistant should issue a reminder letter to the applicant. This letter will remind the applicant of the need to pay the grant fee and inform them that as they have missed the deadline a Form 52 and fee is now required for them to do so. The 2 month response date provided in the EL34F letter is a prescribed period set by rule 30A of the Patents Rules for paying the grant fee. This period can be extended by 2 months 'as of right' by filing a Form 52 and fee. Further extensions are possible but are subject to the comptroller's discretion. If the fee remains unpaid and no further extensions are available the application will be terminated by formalities once the compliance date has expired. Once terminated the applicant may apply for reinstatement in the usual way (see section 28).]

Section 19(2)

The comptroller may, without an application being made to him for the purpose, amend the specification and abstract contained in an application for a patent so as to acknowledge a registered trade mark.

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Registered trade marks

(The allowability and acknowledgement of trade marks in specifications is discussed in paragraphs 14.97-14.101, 14.137).

19.23 Under the Trade Marks Act 1994, registered trade mark includes service mark.

19.24 While in general no attempt should be made at the search stage to check for trade marks, if the search examiner comes across a term in the specification or abstract which he knows, or can readily establish, to be a registered trade mark he should amend the specification or abstract to acknowledge the mark and inform the applicant that he has done so. S.19(2) does not extend to authorising the comptroller to amend the title on Form 1 to acknowledge a registered trade mark. That title, complete with any unacknowledged trade mark, is published in the Patents Journal (see 14.04.10). The abstract title (see 14.173-14.174) should not normally contain a trade mark, but if this is unavoidable then the trade mark must be acknowledged.

[The search examiner should insert "(RTM)" after the trade mark using the "Enhance" function in PDAX or add an "RTM" document to the bundle in PROSE. Where the "RTM" document is used in PROSE, the examiner will need to edit it to include the identified trade mark(s). In either case the search examiner will need to add a minute to the dossier. However, there is no need to make this insertion if the symbol ® is already present. SC2 should be added to SL1 or SL2 before the paragraph on publication.]

[If any RTMs are added or removed after A-publication a second RTM document will be needed before grant. Formalities will automatically only include the most recent RTM document in the B-publication. If this is not to be the case then formalities should be informed by a minute. Any RTM document on the dossier which is not to be included in the B-publication should be appropriately annotated.]

19.25 At substantive examination (when it is not performed at the same time as the search), if the examiner suspects that an unacknowledged term may be a registered trade mark, he should check whether or not it is (see 14.100 for the procedure). If the use of the trade mark is not objectionable (see 14.137) and the application is otherwise in order the substantive examiner should amend the specification to acknowledge the mark and inform the applicant, in the report under s.18(4), that this has been done. If the application is not in order, the examiner should ask the applicant, in the report under s.18(3), to acknowledge the trade mark. If the applicant subsequently refuses or omits to acknowledge the mark, the substantive examiner should do so and inform the applicant.

[If the application is otherwise in order, the examiner should insert "(RTM)" as per 19.24. The applicant should be informed by referring to the acknowledged trade mark in EL3. If the applicant is to be asked to acknowledge the trade mark, RC11 should be added to a s.18(3) report. If the examiner needs to acknowledge a trade mark either because the applicant refuses or omits to do so, the examiner should add SC2 to the report to inform the applicant of the fact.]

19.26 For combined search and examination cases, the examiner should check at first examination stage whether any unacknowledged terms are registered trade marks (see 14.100 for the procedure). If the examiner comes across such an unacknowledged registered trade mark in the specification or abstract, he should either add an "RTM" document to the PROSE bundle or insert "(RTM)" after the trade mark (see 19.24). If the use of the trade mark is not objectionable (see 14.137) and the examiner has no other objections, he should inform the applicant that the specification or abstract has been amended to acknowledge the mark. If other objections are to be raised and the "RTM" document has been used, the examiner should also ask the applicant, in the report under s.18(3), to acknowledge the trade mark, as this provides an opportunity for the applicant to

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acknowledge the mark themselves in amended pages.

[If there are no other objections, the examiner should insert "(RTM)" as per 19.24. The applicant should be informed by adding SC2 to SE3 before the paragraph on publication. If there are other objections and the applicant is to be asked to acknowledge the trade mark, RC11 should also be added to the s.18(3) report.]

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Section 20: Failure of application

20.01 Rule 30 is relevant to this section. This rule sets out the compliance period, ie the period for putting an application in order.

Section 20(1)

If it is not determined that an application for a patent complies before the end of the prescribed period with all the requirements of this Act and the rules, the application shall be treated as having been refused by the comptroller at the end of that period, and section 97 below shall apply accordingly.

r.30 r.2(2) r.108(4) 20.02 The period prescribed for the purposes of this subsection (and for s.18(4)) is the compliance period. The compliance period is (i) four years and six months calculated from the declared priority date or, where there is none, from the filing date of the application; or (ii) twelve months calculated from the date that the first substantive examination report is sent to the applicant, whichever expires the later. Where the first substantive examination report is not sent to the applicant before the expiry of the period set out at (i) above, that period is extended to such date as that report is sent to the applicant and the period set out at (ii) then applies. The above periods, set out in r.30, ensure that applicants always have time in which to complete prosecution of their applications, and ensure that the application does not lapse if the first s.18 report does not issue until after $4\frac{1}{2}$ years.

However, r.30(3)(a) specifies that where the application claims an earlier date of filing under s.8(3), 12(6) or 37(4), the period is either (i) the period prescribed by r.30(2) in relation to the earlier application, or is (ii) eighteen months from the actual date of filing, whichever period expires the later.

Furthermore, under r.30(3)(b), in the case of a divisional application filed under s.15(9) the compliance period expires at the same time as the compliance period prescribed for the earlier application. Any extension made under rule 108 to the compliance period prescribed on the earlier application will also apply to any divisional applications filed on or after the date that the period was extended, in accordance with r.2(2). The compliance period for any such divisional applications will therefore be the period as extended. However, if the compliance period prescribed on the earlier application is later extended, that extension will not apply to any divisional applications which have already been filed; a separate request will be required to extend the compliance period for any such divisional applications.

The period for putting any application in order may be extended in two month tranches in accordance with r.108(2) or (3) and (4) to (7), see 123.34-41. The period may also be extended by the provisions of s.20(2) (see 20.08 - 20.10). For the periods in the case of divisional applications, in the case of new applications filed under s.8(3), 12(6) or 37(4), or in the case of European patents (UK) converted under s.81 also see 15.20.1, 8.25.1, 12.16.1, 37.17.1 and 81.19 respectively.

[ELC4 should be added to the covering letter when the first report under s.18 is issued later than three years and six months from the priority or filing date. For the procedure if ELC4 was omitted from a first examination letter issued later than three years and six months from the earliest date, see 18.47, 3rd indented paragraph.]

[ELC5 should be added to the covering letter of the first s.18 report on a divisional application when the first report on the parent application was issued later than three years and six months from the priority or filing date. It should also be used in the covering letter for a subsequent s.18(3) report on such a divisional application if it was not used at the time of the first report.]

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r.30(4)

20.02.1 R.30(4) provides for an automatic extension of the prescribed period when observations under s.21 are filed near to the end of the period and give rise to a report under s.18(3). Where the date of the letter embodying that report is within three months of the end of the existing compliance period, the compliance period becomes three months from the date of the letter. This applies only to the first s.18(3) report based on those particular observations, if there is more than one such report.

[ELC6 should be used in the examination (covering) letter to inform the applicant of the extension of the period following s.21 observations.]

20.02.2 In Anning's Patent Application [2007] EWHC 2770 (Pat), it was held that the compliance period is a period during which the requirements of the Act and Rules must be complied with. It does not impose any additional requirement on the applicant. Therefore it follows that the compliance date does not roll over to the next working day if it falls on a non-working day, since it is not of itself a deadline for doing anything under the Act. See 120.07.

20.03 Outstanding applications are periodically checked to detect those on which a reply to a report issued under s.18(3) is overdue where the compliance period has nearly expired. A letter is sent to the applicant forewarning of the intention to refuse each such application under s.20(1) and giving the applicant an opportunity to submit any observations which might affect refusal. When the compliance period has expired, the application is forwarded to the relevant formalities group for refusal to be authorised. If it is found at that time that the forewarning letter has not been sent, another letter forewarning of the intention to refuse is sent before refusal is confirmed, allowing one week for the applicant to submit any observations. When refusal has occurred, it is advertised in the Journal.

[The COPS records are combed weekly and applications that are 4½ years from the declared priority date or filing date and have a certain processing status are identified on the "Section 20 Pick List". The selection is verified by the formalities groups who should confirm eg whether a Section 18(3) report has been issued to which no reply has been received or indeed whether the report issued in the first place. If it is ascertained that a reply to a Section 18(3) report is overdue a standard letter (WR1) with a copy on file should be issued, forewarning the applicant of the intended refusal. If a reply is not overdue at the time of vetting, the appropriate COPS action should be taken, but if the reply subsequently becomes overdue the letter (WR1) should then be sent.

[After 4½ years have elapsed from the declared priority date or filing date, those applications are selected by COPS on the "Section 20 Time Limit Report" and the relevant Formalities Manager takes appropriate action for treatment as refused under s.20. All such applications should have had the standard letter issued and a copy placed on file. If it is detected that the letter (WR1) has not been issued, the Formalities Manager should issue the alternative forewarning letter (WR2) before sending the file to the relevant Formalities Manager. The Formalities Manager should then therefore not only verify that the application should be treated as refused but also check that one of the letters has been issued (see below if it has not) and that no response which would prevent treatment as refused has been subsequently received.

[The Formalities Manager should add the appropriate label to the PDAX dossier cover and add a minute to the dossier. Where the application is a paper case the Formalities manager should sign the square on the flap of the shell after verifying that the application is being correctly terminated. (If for example it is found that the application had been incorrectly stored after amendments had been filed, the case should be referred to the Divisional Director; it may be possible to exercise discretion under r.107 to extend the prescribed period.) The Formalities Manager should then annotate the file accordingly, carry out the appropriate COPS action

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(so that the termination is advertised in the Journal) and forward the file to Nine Mile Point.

[If it is discovered that a letter (WR1 or WR2) has not been issued the Formalities Manager should, after verifying that the application should be treated as refused, arrange for the alternative letter (WR2) to issue. After allowing time for any response, the Formalities Manager should arrange for action as in the last sentence of the preceding paragraph.]

20.04 Treatment of the application as having been refused at the end of the prescribed period is mandatory if it fails to comply with any requirement of the Act and Rules within that period. It follows therefore that if a hearing is necessary to resolve a disagreement this should if possible be held and a decision be given and communicated to the applicant before the end of the prescribed period. (The reasons for the decision may be given later if necessary.) It is then possible for the applicant to amend within the period (including any extension by virtue of s.20(2) - see 20.08 - 20.10) in order to meet the terms of an adverse decision. If however the hearing is held after the end of the period it may only be for the purpose of deciding whether or not the application was in order at the end of the period. If it is decided that it was not, then it is not possible to amend to rectify any faults unless the period is extended under r.108(2) or (3). Under these circumstances, the comptroller may consider that, for the benefit of the applicant, a period of less than the minimum fourteen days' notice of a hearing usually given is appropriate, if this would otherwise lead to the hearing being held after the end of the prescribed period. The wishes of the applicant should however be taken into account.

20.05 It is also in an applicant's own interest, when filing amendments near the end of the prescribed period, to mark the covering letter URGENT, prominently and boldly and preferably in red.

20.06 If a response filed within the prescribed period fails to put an application in order, but it is not possible to elicit a further response or to arrange a hearing before the end of two months after the expiry of the normal compliance period (ie the period prescribed by r.30 as extended by r.108(2)), the applicant should be told that the application will be treated as having been refused unless within fourteen days he submits observations and/or requests a hearing to demonstrate that the application was in fact in order (or requests an extension of the compliance period under r.108(3) to (7), see 123.34-41).

[EL5 may be used.]

20.07 Provided that an application was in order at the end of the compliance period there is no statutory bar to its being amended after the end of that period; the opportunity to amend an application is only terminated by the issue of the letter informing the applicant that a patent has been granted. (See 19.22.)

Section 20(2)

If at the end of that period an appeal to the court is pending in respect of the application or the time within which such an appeal could be brought has not expired, that period -

- (a) where such an appeal is pending, or is brought within the said time or before the expiration of any extension of that time granted (in the case of a first extension) on an application made within that time or (in the case of a subsequent extension) on an application made before the expiration of the last previous extension, shall be extended until such date as the court may determine;
- (b) where no such appeal is pending or is so brought, shall continue until the end of the same time or, if any extension of that time is so granted, until the

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expiration of the extension or last extension so granted.

CPR 63.17 CPR 52.6(1) CPR 52.6(2) 20.08 The time allowed for bringing an appeal is governed by Part 52 of the Civil Procedure Rules and the Practice Directions supporting CPR 52. The comptroller will normally use the discretionary power provided by CPR 52.4(2)(a) to direct that notice of appeal must be filed at the court within 28 days after the date of a decision. However, a different period can be set where appropriate. Where the appeal notice has not yet been filed, an application to extend the period for appeal can be made to the comptroller, per Aujla v Sanghera [2004] EWCA Civ 121. However, once the notice of appeal has been filed, any request for extension must be made to the appeal court. The parties cannot themselves extend the appeal period by agreement.

When a decision is given before the end of the compliance period (see 20.02) and at the end of that period the time (including any extension granted by the Court or the comptroller) allowed for bringing an appeal is still running, the period for putting the application in order is automatically extended, for all purposes, until the end of that time. Therefore, if an adverse decision on a substantive matter is given less than 28 days from the end of the compliance period, and the comptroller has directed that any appeal must be filed within 28 days after that decision, the applicant has 28 days (plus any extension granted by the Court or the comptroller) from the date of the decision in which to submit amendments with a view to meeting the terms of the decision. If no appeal is brought within this time, this opportunity to amend ends automatically at the end of this time. If there is an appeal the Court may prescribe a period within which amendments may be made.

20.10 Any extension of the prescribed period which is given under r.108 applies only to the period as prescribed by r.30, and is not in addition to any extension arising by virtue of s.20(2). Thus, for example, a substantive decision given 14 days before the end of the prescribed four years six months has the effect of extending the period by 14 days; a request on Form 52 extends the original period by two months, i.e. the extensions run concurrently.

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Section 20A: Reinstatement of applications

20A.01 This section specifies the circumstances for reinstatement of a patent application which has been either refused or treated as having been refused or withdrawn because the applicant failed to do something within a period prescribed or specified for doing that thing. The relevant procedures are prescribed in rule 32. This section was introduced by Regulatory Reform (Patents) Order 2004 which came into effect on 1 January 2005, and applies to patent applications filed both before and after that date.

Section 20A(1)

Subsection (2) below applies where an application for a patent is refused, or is treated as having been refused or withdrawn, as a direct consequence of a failure by the applicant to comply with a requirement of this Act or rules within a period which is -

- (a) set out in this Act or rules, or
- (b) specified by the comptroller.

Subject to the requirements of section 20A(2), the exclusions of section 20A(3) and a request being made in accordance with the rules, section 20A provides for reinstatement of an application which has been refused or treated as having been withdrawn because an applicant has failed to comply with a requirement with respect to the application within a period prescribed or specified for complying with that requirement. In *Anning's Patent Application* [2007] EWHC 2770 (Pat) the applicant had failed to reply to a substantive examination report within the period specified in the report and had taken no action in response to a subsequent letter informing him that his application would be treated as refused if he did not reply by the end of the compliance period. The application was subsequently treated as refused under s.20(1) at the end of the compliance period. Pumfrey J held that the "failure to comply" that led to the application being treated as refused was the failure to respond to the examination report, not the failure to place the application in order for acceptance within the compliance period. He stated:

"The letter [informing the applicant that no reply to the examination report has been received and warning that the application will be treated as refused at the end of compliance period] does not itself either require any act to be done or extend the period of time for doing that act, and is for this reason not within s.20A: and in my judgment the prescribed period under s.20(1) is merely the period during which the requirements of the Act and Rules must be complied with. It imposes no additional requirement on the applicant".

It therefore follows that an application may not be reinstated if the only failure by the applicant has been a failure to comply with s.20(1) (see also 20A.11.1).

Section 20A(2)

Subject to subsection (3) below, the comptroller shall reinstate the application if, and only if -

- (a) the applicant has requested him to do so,
- (b) the request complies with the relevant requirements of rules; and
- (c) he is satisfied that the failure to comply referred to in subsection (1) above was unintentional.

r.32 20A.03 An application for reinstatement shall be made on a Form 14. The reason PR Sch 4, why the applicant failed to comply with the time allowed should be stated on the form and

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Part 1 should be supported by evidence. A reinstatement request must be filed within 12 months beginning immediately after the date on which the application was terminated. This period may not be altered.

The outstanding requirements may be filed at the same time as the request Form 14. However, this is not strictly necessary as a further period for filing documents and fees will be provided for if reinstatement is allowed.

[If a Form 14, fee or supporting evidence is not included with a reinstatement request, the formalities manager should contact the applicant/agent and instruct them to file the omitted documents within 14 days; otherwise the application will remain withdrawn. When a Form 14 has been filed the formalities manager should record the request on COPS using function REGFIL, which will create a Journal entry.]

20A.05 [Deleted]

r.32(7)

r.32(8) r.32(9) 20A.06 For guidance on what is meant by "unintentional" for the purposes of section 20A, see 20A.13.

20A.07 If, after considering the applicant's reasons for reinstatement and the supporting evidence, the comptroller concludes that a case has not been made out, then the applicant is informed by letter. The letter will explain why the comptroller has reached his conclusion and will advise the applicant that, unless within one month he requests a hearing, the request for reinstatement will be refused. If no request for a hearing is received within this time, a formal decision is issued refusing reinstatement. If the Office receives a formal written notification within that time that the request has been formally withdrawn, then only an acknowledgment of receipt of the notification is issued. If, on the other hand, the applicant asks for a hearing within the time allowed then a hearing must be held, following which either a decision refusing the request is issued or a conditional offer of reinstatement is made. There is no provision for a request for reinstatement to be opposed.

[If no reply is received within the one month specified in the Office's letter refusing reinstatement, the formalities manager should record the decision on COPS using function REG F14 which will create a Journal entry. Any fees paid on un-actioned forms, such as Forms 9A and 10 should be refunded.]

Section 20A(3)

The comptroller shall not reinstate the application if -

- (a) an extension remains available under this Act or rules for the period referred to in subsection (1) above; or
- (b) the period referred to in subsection (1) above is set out or specified -
 - (i) in relation to any proceedings before the comptroller;
 - (ii) for the purposes of section 5(2A)(b) above; or
 - (iii) for the purposes for a request under this section or section 117B below.

20A.08 This subsection precludes the comptroller from reinstating an application if it is still possible to extend a period. Rule 108 curtails (but does not exclude) the retrospective availability of extension for certain prescribed periods. The subsection also prescribes those periods to which subsection (1) does not apply, namely: (i) periods which relate to *inter*

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partes proceedings before the comptroller; (ii) the period of two months prescribed by rule 7(1) for the purposes of filing a late declaration of priority under section 5(2); (iii) the twelve or two month period prescribed by rule 32(1) for requesting an extension of a period under section 20A; and (iv) the two month period prescribed by rule 109(2) for requesting an extension under section 117B of a period specified by the comptroller.

[If after receiving a request for reinstatement, it is established that an extension of time is still available, the applicant/agent should be informed as soon as possible].

Section 20A(4)

Where the application was made by two or more persons jointly, a request under subsection (2) above may, with the leave of the comptroller, be made by one or more of the persons without joining the other.

20A.09 Where an application has been filed in the name of two or more applicants, it is permissible, subject to the comptroller's agreement, for one of them to apply for a reinstatement without joining the others.

Section 20A(5)

If the application has been published under section 16 above, then the comptroller shall publish notice of a request under subsection (2) above in the prescribed manner.

r.32(4) 20A.10 If the application for which reinstatement is requested has been published, the comptroller is required to publish a notice of the reinstatement request in the Patents Journal.

Section 20A(6)

The reinstatement of an application under this section shall be by order.

Section 20A(7)

If an application is reinstated under this section the applicant shall comply with the requirements referred to in subsection (1) above within the further period specified by the comptroller in the order reinstating the application.

Section 20A(8)

The further period specified under subsection (7) above shall not be less than two months.

r.32(10)

20A.11 The order for reinstatement will specify that reinstatement is allowed subject to the applicant, within a specified period, meeting the requirements under the Act or rules which they failed to comply with, leading to the application being refused, or treated as having been refused or withdrawn. The specified period will normally be two months from the date of the order but a longer period may be provided. If the request for reinstatement has been published in the Journal, the final decision allowing or refusing the request is also advertised in the Journal and noted in the Register.

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[If it is decided to allow reinstatement the formalities manager should inform the applicant/agent in writing and issue the order. The Head of Administration or formalities manager should record the decision on COPS using function REC F14 which will create the Journal entry and change the processing status of the application.]

20A.11.1 In *Anning's Patent Application* [2007] EWHC 2770 (Pat), Pumfrey J held that the "failure to comply" that led to the application being treated as refused was the failure to respond to the examination report, not the failure to place the application in order for acceptance within the compliance period (see 20A.02). It follows that where an application is treated as refused at the end of the compliance period due to failure to respond to an examination report and is subsequently reinstated, section 20A(7) provides the applicant with a further period to respond to the examination report. In *Ali et al's Patent Application* BL O/264/10 the hearing officer considered *Anning* and the wording of section 18(3), and concluded that the requirement which the applicant must be given a chance to meet following reinstatement in these circumstances is the requirement in section 18(3) to make observations or amendments which bring the application into compliance. Section 20A(7) provides a power to specify a period for that requirement to be met, and to do that properly it is necessary to specify both a new period for responding to the examination report and a new period for overall compliance.

[If reinstatement is allowed in these circumstances, the order for reinstatement should specify both a further period for responding to the examination report and a further period for compliance.]

Section 20A(9)

If an application fails to comply with subsection (7) above the application shall be treated as having been withdrawn on the expiry of the period specified under that subsection.

If the applicant fails to comply with any outstanding requirements referred to in the order for reinstatement within the two months specified in the order, the application shall be treated as withdrawn on the expiry of that two month period.

Meaning of unintentional

20A.13 There is no definition in the Act or rules as to what is meant by "unintentional" as it applies for determining whether to allow a request for reinstatement of a patent application. In Sirna Therapeutics Inc's Application [2006] RPC 12, which related to a request to make a late declaration of priority under section 5(2B), the hearing officer observed that the requirement to show an intention to file an application in time differed from the test of "continual underlying intention to proceed" that was applied in Heatex Group Ltd's Application ([1995] RPC 546) in deciding whether to exercise discretion favourably to allow a period of time to be extended under rule 108 (see 123.37). However, case law under rule 108 may be of relevance in analysing the evidence to establish the applicant's intentions. In Anning's Application (BL O/374/06), which related to a request for reinstatement under section 20A, the hearing officer took a similar approach and warned against the danger of going beyond the clear meaning of the statute. He interpreted "unintentional" according to its normal English meaning. In this case the hearing officer held that although there was a continual underlying intention to proceed it did not follow that the failure to reply to an examination report was unintentional.

20A.14 Sirna Therapeutics Inc's Application [2006] RPC 12 and Anning's Application (BL O/374/06) established that the "continual underlying intention" test in Heatex is <u>not</u> applicable in determining the meaning of the word "unintentional" (in section 5(2B) or section 20A).

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- 20A.14.1 In *Green's Application* (BL O/087/09) the applicant was unable to pay the prescribed fee required to enter his international application into the national phase, due to severe financial difficulties. The hearing officer held that, despite the applicant's underlying intention to enter the application into the national phase, the decision not to pay the prescribed fee in time was a *conscious* one based on his knowledge of his impecunious state, and as such the failure to comply could not have been *unintentional*.
- In *Matsushita Electric Industrial Co. v Comptroller General of Patents* [2008] EWHC 2071 (Pat), which concerned a request for restoration under s.28, Mr. Justice Mann gave some guidance on the level of evidential burden required to "satisfy" the Comptroller that the failure in section 28(3) was "unintentional". The applicant in that case chose not to file any evidence beyond a bald assertion of the statute that the failure to pay the renewal fee on time was unintentional. It argued that that was all the statute required to satisfy the comptroller. It was held by the Judge that a mere assertion that the failure to pay the renewal fee was unintentional is not sufficient to enable the Comptroller to determine that the requirements of s.28(3) are fulfilled. He said:
 - "...the Act requires a judgment to be formed by the Comptroller so that he can be satisfied of the relevant matters. A judgment usually has to be made on the basis of evidence... The evidence required in any particular case where satisfaction is required depends on the nature of the enquiry and the nature and purpose of the decision to be made... A significant matter requires significant proof. I repeat, the Act does not require a statement that the failure to pay fees was unintentional. It requires the Comptroller to be satisfied of that fact."
- 20A.16 It is clear from this judgment that while there is no universal rule as to what level of evidence has to be provided to satisfy the comptroller of the unintentional lapse in section 28(3), and by implication in sections 5(2B) and 20A, some evidence above and beyond a bald assertion of the law is required.

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Section 20B: Effect of reinstatement under section 20A

20B.01 This section sets out the rights that are accorded to third parties upon reinstatement of a patent application under section 20A. The section is analogous to section 28A which prescribes similar rights on restoration of a patent.

Section 20B(1)

The effect of reinstatement under section 20A of an application is as follows.

Section 20B(2)

Anything done under or in relation to the application during the period between termination and reinstatement shall be treated as valid.

Section 20B(3)

If the application has been published under section 16 above before its termination anything done during that period which would have constituted an infringement of the rights conferred by publication of the application if the termination had not occurred shall be treated as an infringement of those rights -

- (a) if done at a time when it was possible for the period referred to in section 20A(1) above to be extended, or
- (b) if it was a continuation or repetition of an earlier act infringing those rights.

Section 20B(4)

If the application has been published under section 16 above before its termination and, after the termination and before publication of notice of the request for its reinstatement, a person -

- (a) began in good faith to do an act which would have constituted an infringement of the rights conferred by publication of the application if the termination had not taken place, or
- (b) made in good faith effective and serious preparation to do such an act,

he has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the reinstatement of the application and the grant of the patent; but this right does not extend to granting a licence to another person to do the act.

Section 20B(4A)

The right conferred by subsection (4) does not become exercisable until the end of the period during which a request may be made under this Act, or under the rules, for an extension of the period referred to in section 20A(1).

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Section 20B(5)

If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (4) above may-

- (a) authorise the doing of that act by any partners of his for the time being in that business, and
- (b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.

Section 20B(6)

Where a product is disposed of to another in exercise of a right conferred by subsection (4) or (5) above, that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the applicant.

Section 20B(6A)

The above provisions apply in relation to the use of a patented invention for the services of the Crown as they apply in relation to infringement of the rights conferred by publication of the application for a patent (or, as the case may be, infringement of the patent).

"Patented invention" has the same meaning as in section 55 below.

20B.02 Subsections (3) to (6) give protection to persons who take steps to work an invention which is the subject of a terminated patent application before notice of a request to reinstate the application is published (see 20A.08). If they take these steps after the end of the period during which the patent applicant can request an extension of time, then they are free not only to continue what they have started without infringing the reinstated application, but also to pass their rights to work the invention to others (but not license others to work the invention). Subsection (4A) was inserted by the Intellectual Property Act 2014 on 1 October 2014 to make clear that these "third party rights" do not begin until the end of the period during which the patent applicant can request an extension of time to the period they had failed to meet. Subsection (6A) ensures that the Crown is not liable for payment of compensation to the patent proprietor for Crown use if it takes steps to work an invention which is the subject of a terminated patent application before notice of a request to reinstate the application is published.

Section 20B(7)

In this section "termination", in relation to an application, means -

- (a) the refusal of an application, or
- (b) the application being treated as having been refused or withdrawn.

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Section 21: Observations by third party on patentability

Rule 33 is relevant to this section. Where third party observations are filed at the International Bureau in relation to a PCT application, see 89B.16.

Section 21(1)

Where an application for a patent has been published but a patent has not been granted to the applicant, any other person may make observations in writing to the comptroller on the question whether the invention is a patentable invention, stating reasons for the observations, and the comptroller shall consider the observations in accordance with rules.

r.33(1) 21.02 Any written communication relating to an application (whether sent by conventional or electronic mail) which is received from any person other than the applicant or the agent responsible for the application should be forwarded to the relevant examiner assistant. The Formalities Examiner should send the appropriate PDAX message to the s.21 observations PDAX mailbox. An examiner assistant will check this mailbox and should ensure that the communication is acknowledged and is copied to the applicant, but acknowledgement by letter is not necessary where the dedicated email address is used (see 21.02.1) since a reply is sent automatically from this address. Although s.21 refers to observations on patentability, i.e. bearing on whether or not the invention fulfils the conditions of s.1(1), in practice it is generally desirable to send to the applicant a copy of any letter received from a third party informant which purports to relate to an application, so that he may have prior notice of a document which may be laid open to public inspection. The same procedure applies if observations are filed prematurely (i.e. before s.16 publication of the application in question). When premature observations relate to patentability, the

s.21 if and when the application is published. If termination action has been taken or is appropriate when any such letter is received, receipt should be acknowledged and the letter should merely be copied to the applicant and placed on the file. Providing the terminated application has been published, the letter will be open to public inspection.

> 21.02.1 Directions made under section 124A prescribing the form and manner in which observations under section 21 may be submitted using electronic media came into force on 25 May 2005. These Directions were published in PDJ No. 6056 on 15 June 2005 and are reprinted in full in the "Relevant Official Notices and Directions" section of this Manual. The Directions require observations to be sent by email to address section21@ipo.gov.uk or to be delivered on digital media. Observations sent electronically to any other address may be treated as not filed, but should not generally be treated in this way if they comply with the other conditions in these Directions and are successfully received at an email address within the Office. Observations received at the dedicated email address will be acknowledged by an automatic email reply. This email mentions that if the observations can be treated as made under section 21, they will be forwarded to the examiner for consideration, placed on the open part of the file, and a copy sent to the applicant.

> applicant should be informed that the observations will be treated as having been filed under

It is the responsibility of the relevant examiner assistant to ensure that the third party documentation is correctly shown on IPSUM. This will include checking for and redacting personal data as appropriate. Examiner assistants are directed to the PDAX Information Centre for details of PDAX procedures for handling s.21 observations. It is also their responsibility to check for potentially offensive or libellous material (see 21.03). It is therefore the examiner assistant's responsibility to ensure that the correct documents are made open to public inspection and the OLFI annotation is added as appropriate.]

[The examiner assistant should acknowledge the communication (unless it is anonymous or the observations were sent to the dedicated email address for receiving section 21 observations, in which case a reply will have already been

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s.124A(3)

sent) and send a copy to the applicant.

[Anonymous observations should so far as possible be treated the same as those from named informants. When copying the observations to the applicant, the examiner assistant may add a sentence pointing out that they were filed anonymously. However, where a third party files observations which are not anonymous, but requests anonymity, the examiner assistant should write to the third party giving them the opportunity to withdraw their observations so that they are not made available and are not considered under s.21. If no response is received within two weeks the observations should be processed under s.21 in the normal way.

[Provided that the observations bear, at least in part, on patentability and have been received in the Office after s.16 publication but before the date of issue of the grant letter, EL18 (which also includes information regarding s.21 observations) should be sent to the informant unless an email reply has been sent from the dedicated section 21 email address and EL23 (or ELC23, see 21.06) to the applicant. If the observations do not relate to patentability (or, regardless of whether they relate to patentability, are received when termination action has been taken or is appropriate) EL18B should be sent to the informant and EL23C to the applicant, but EL18B should not be sent if the dedicated section 21 email address has been used. (For the case where observations have been received on or after the date of a (first or final) report under s.18(4), see 21.15, and 21.16).

[If observations relating to patentability are filed before s.16 publication of the application in question, EL18 should be modified using the text of EL18A. At the same time, the observations should be copied to the applicant using EL23B. If the observations do not relate to patentability (or, regardless of whether or not they relate to patentability, are received when termination action has been taken or is appropriate) EL18B should be sent to the informant (unless the dedicated section 21 email address has been used) and EL23C to the applicant together with a copy of the observations.

[Any observations going to matters other than patentability should be referred by the examiner assistant to the relevant Deputy Director or Head of Examining Group. It may be appropriate to bring another relevant section of the Act to the attention of the informant, eg s.8 if the observations appear to relate to entitlement, but care is necessary to avoid any implication that the Office requires the party to take action under that section or guarantees the outcome of any such action.]

[If a complaint about the processing of an application is received from a third party, the complaint and the Office's response should be copied to the applicant.]

21.02.2 Observations on patentability filed in relation to one application can, where appropriate, be considered in relation to any other application relating to the same invention. In particular, where observations filed on an earlier application from which a later application claims priority appear relevant to the later application because it relates to the same invention, the applicant should be so advised, and the observations should be copied to the applicant if not previously copied. If the earlier application is unpublished, the observations may nevertheless be copied onto the open file of the later application.

r.33(2) r.51(2)(d) 21.03 If however observations filed by a third party informant contain libellous or obscene matter, the text both as communicated and as placed on the open file, should have the offending remarks omitted. The informant's observations should merely be acknowledged, while the letter sent to the applicant should be modified to indicate that some non-relevant matter has been deleted from the enclosed copy of the observations.

[Examiner assistants are directed to the PDAX Information Centre for details of PDAX procedures for handling s.21 observations]

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[Offensive or libellous material should not be open to public inspection or be made available via IPSUM. If an examiner assistant identifies or is made aware of potentially offensive or libellous material they should ensure that the document is not open to public inspection. The examiner assistant should consult their Deputy Director or Head of Examining Group when potentially faced with such material and where there is agreement, the offensive or libellous material should be redacted before the document can be made open for public inspection. If it is determined that there is no offensive or libellous material present, the relevant documents should be made open to public inspection.]

[If the examiner assistant notices potentially offensive or libellous material in a document filed, they should ensure that the document is <u>not</u> set as open to public inspection. Where the case requires another action (e.g. search, exam or amendment) the standard message for that action should be sent as normal by the formalities examiner.

[For handling confidential or sensitive information in observations see 21.05]

r.33(3)

21.04 The 2007 Rules make specific provision with regard to the copying of documents referred to in the informant's letter. In general, documents referred to in observations should be copied to the applicant unless the document is clearly readily available to the applicant or photocopying is impractical. However, it is at the comptroller's discretion whether to send the applicant a copy of any document received from the third party and referred to in the observations. If other materials (eg samples) have been sent with the letter the applicant should be informed that they are available for inspection in the Office.

[If a copy of a document sent with an informant's letter is requested under rule 48 (using Form 23), it should be supplied.]

r.33(1),
21.05 Documents or other materials which are filed by the informant under s.21 must normally remain on the open file of the application in question. Hence if a third party informant sends such material to the Office with a view to its being used in this way, but requests that the material be returned to him in due course, he should be informed that either the material must remain on file or that it will be returned to him without being considered under s.21. Having regard to the terms of r.33(1) it would appear that observations on patentability should be sent to the applicant irrespective of any request under r.53 that the observations be treated as confidential. However it is possible for parts of the observations to be treated as confidential to the extent that they are not laid open to public inspection on the file. The examiner assistant should refer any requests for confidentiality under r.53 to the relevant head of examining group who will consider the issue of public interest (see 118.13). However, objections to patentability should only be made on the basis of documents which are open to public inspection.

[Documents filed with a letter containing observations under s.21 should be put on the open part of the file. Documents or samples which cannot be readily accommodated on the file should be placed in a box file or other suitable container and a minute added to the dossier stating where the box file is stored.]

[Correspondence from third parties containing observations under s.21, and any associated documents, should be checked by the examiner assistant, who should redact certain personal or sensitive information from documents which may be made available for online inspection via Ipsum (the Office's online patent information and document inspection service).]

[Examiners are directed to the PDAX Information Centre for details of PDAX procedures for handling s.21 observations]

21.06 Where the observations are received after the issue of a report under s.18(3), they should be copied at once to the applicant; it is up to the examiner to decide

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whether to accompany them by a further report under s.18(3) taking account of the observations (see 18.50), or whether to defer such action until a reply is received to the outstanding report. Where late-filed observations give rise to a report under s.18(3), the compliance period may be extended as described in 20.02.1.

[When sending the copy of the observations to the applicant at the same time as the report under s.18, ELC23 should be incorporated in the covering letter to the s.18 report instead of sending EL23.]

r.33(4) r.33(5)

Observations on patentability which are received before a report under s.18(4) has been issued should be considered by the examiner, who must make up his own mind whether on the balance of probabilities they support a sustainable objection. For example, he should consider any alleged prior art in exactly the same way as he would if it had been found in the course of the search under s.17. If the date at which any alleged prior art was published, used or otherwise made available to the public is not given or cannot be established (eg by following the procedure in 21.13 if it is felt that the informant is likely to be aware of the date), no objection should be raised. If an objection does arise the examiner should normally express this in a report under s.18(3) in his own words, rather than as a commentary on the observations. If however an examiner fully agrees with well-argued observations he may raise an objection of lack of novelty or inventive step by formally citing the relevant documents and then drawing the applicant's attention to the supporting argument as set out in the observations. If, in the examiner's view, no objection arises, no comment on the observations is necessary. If the application is in order for grant, the applicant should be informed that it will not be sent for grant for two months (in order to enable him to file voluntary amendments) unless he requests that it be sent earlier.

[When a substantive examiner makes a formal objection based on material provided by a third party, the matter should not be dropped unless the applicant makes a response sufficient to counter the objection. While in general no comment on the observations should be made when the examiner is not raising an objection arising out of them, if it becomes necessary to refer to the observations, for example because of a specific query from the applicant, a comment that the observations have been taken into account in framing the s.18(3) report may be made. Reasons for not raising objections should be briefly recorded as a minute.]

- 21.08 S.21 requires the informant to state reasons for his observations. If no reasons are (explicitly) stated the observations should nevertheless be acknowledged, be put on the open file, and the applicant sent a copy. The examiner should also consider the observations, which may be constituted, for example, merely by a list of specifications, and act upon them as he considers appropriate. If reasons for the "observations" are not stated the examiner should not ask the third party for any.
- 21.09 When the documents referred to by a third party are numerous and/or lengthy the examiner should do his best to identify those portions likely to be relevant to novelty or obviousness. Exceptionally, if the examiner is unable to identify the relevant passages, the third party may be requested to do so, but, if he does not, the matter should not be pursued with him.
- 21.10 If a communication giving the results of a search in another Office is received from a foreign agent apparently acting for the applicant in another country, it should be acknowledged and copied to the applicant. The contents of the communication should be treated as in paragraphs 17.44 and 17.46.

[EL18B and EL23C should be used.]

21.11 When any document of which the Office is informed by a third party has been formally cited (as distinct from the applicant being merely notified of it under r.33(1)), then it should be included in the search report on the front page of the specification (see 18.85).

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[Any document cited (formally or otherwise) which was not listed on the A document should be recorded as soon as possible on COPS and on the internal search report (see 17.105, 18.11). When a document previously merely notified is subsequently formally cited, the substantive examiner should send the applicant a copy of it together with the relevant s.18 report.]

- An allegation of prior use received from a third party should be treated as described in paragraph 18.24.
- 21.13 If an applicant denies material facts contained in observations made under s.21, for example an allegation of prior use or prior publication, and it is thought probable that the informant could provide evidence to substantiate his allegation, then it is possible to invite him to do so. This procedure may also be used if an examiner considers that s.21 observations give insufficient information to justify action on novelty or obviousness grounds but that there is a strong probability that further information could be provided by the informant enabling the objection to be made. The informant would also be approached for evidence or information concerning the date of publication of a highly relevant document which he has supplied. However such action should not be taken unless the information already available provides a clear indication both of the need for the further information and also of the likelihood that the third party will be in a position to supply it. Moreover, any such invitation to the informant should not be a direct request for evidence or information; it should instead be indicated that an objection cannot be raised or pursued unless such material is available. Applicants must accept that the onus is on them to demonstrate that they are entitled to grant but care should always be taken not to take any action which could imply that the informant is a party to the proceedings (see 21.18-21.19). If an allegation by the informant is supported by an affidavit or statutory declaration, then any denial by the applicant should also be sworn.

[The Deputy Director should be consulted before approaching the third party. A request for further information or evidence should invite a response within a specified period (eg two months); if no response is received within this period the matter should not be pursued.]

ACTION AFTER ISSUE OF A REPORT UNDER S.18(4)

r.33(5)

21.14 Observations from a third party can be considered by the examiner only if they have been received in the Office before a report under s.18(4) has been issued. If they were received before the issue of such a report but too late to prevent its issue, and they give rise to a fresh objection, the report may be rescinded and action taken on the observations (see 18.89). If in this case the examiner instead concludes that no fresh objection arises from the observations, he should inform the applicant that they have been considered but no objection will be raised, and the report should not be rescinded. Action may also be taken if the report under s.18(4) has been rescinded for another reason.

[EL23A should be sent to the applicant to communicate the observations when no objection results. However, if fresh objections arise and the case has been sent for grant, the publication liaison officer of the relevant division should be contacted immediately. See also 18.89. If, on the other hand, fresh objection arise and the case has not been sent for grant, cancellation of grant is not necessary.]

r.33(1) 21.15 If the observations were received in the Office on or after the date of issue of a report under s.18(4), then (unless the report is rendered nugatory by the applicant filing, under r.31(4)(a) amendments which are not allowable (see 19.18)), the third party should be informed that, because of the terms of r.33(5), the observations cannot be considered by the examiner. However, it is not necessary to inform the third party in this instance if the observations have been sent to the dedicated email address (see 21.02 and 21.02.1). If the observations were received in the Office after the end of the compliance period but before issue of a report under s.18(4) the third party should be similarly informed (although in this

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case the observations may need to be considered if the compliance period is subsequently extended.) In both cases the observations should be copied to the applicant in the usual way. It is up to him to decide whether to amend the specification (but see 21.17). The applicant should be informed that grant will be delayed for two months (for the purpose of giving him time to decide whether to submit voluntary amendments) unless he requests that it be granted earlier.

[EL18B, should be sent to the informant.]

[When observations are received after an intention to grant letter, the examiner assistant should issue an EL23D letter to the applicant, along with the observations. The EL23D letter delays grant by two months (from the date the letter is issued) to give the applicant an opportunity to file voluntary amendments in response to the observations. The examiner assistant should diary the application to return in two months and one week from the date the EL23D is issued. If within two months the applicant responds with amendments, these should be dealt with as in 19.17-19.21. If the applicant does not respond within two months, when the diary returns the examiner assistant should send the case on for grant by updating the status to 11: Ready for Grant and sending a "Grant checklist" message to the relevant formalities group. At the same time, the examiner assistant should minute the case with a request for the examiner to check whether s.73(1) action is needed as a result of the prior art referred to in the observations. The examiner assistant should then send a 'Please see minute' PDAX message to the examiner.]

21.16 If the observations were received in the Office on or after the date of issue of the grant letter (see 18.86), then the informant must be told that, since they were received after grant, they cannot be taken into consideration under s.21 but that they will be open to public inspection under s.118(1). However, a written acknowledgement should not be sent to the informant where a reply email has already been sent from the section 21 dedicated email address (see 21.02 and 21.02.1). A copy of the observations should be sent to the applicant "for information" (see 21.02). Any letter from the applicant commenting on the observations will also be placed on the open file.

[EL18B, suitably amplified, should be sent to the informant and EL23C to the applicant.

[Third parties contemplating filing s.21 observations sometimes enquire about the likely date of issue of the grant letter. If an intention to grant letter has issued they should be informed that it is too late to file observations under s.21 (see 21.14). If it has not, they are entitled to no further information as to likely timescales and should merely be advised to file the observations as soon as possible.]

21.17 Where observations received too late to be acted upon by the examiner (see 21.15, 21.16) indicate that the invention may lack novelty by reason of a document forming part of the state of the art by virtue of s.2(3), then proceedings under s.73(1) may need to be initiated after grant (see 73.02-73.03). It is desirable that the applicant be warned of this possibility.

Section 21(2)

It is hereby declared that a person does not become a party to any proceedings under this Act before the comptroller by reason only that he makes observations under this section.

21.18 The receipt of the communication from the third party should be acknowledged (see 21.02 and 21.02.1), and, in a case where the observations have been received too late to be considered by the examiner (see 21.15-21.17), the third party should be informed of this fact. Beyond this, he has no right to be kept informed of the progress of the application, or of the reason for action taken (or not taken) by the examiner. If he

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attempts to discuss the matter directly with the examiner he should be told that, by virtue of s.21(2), he has no status in the proceedings.

21.19 An informant can find out whether his observations have been acted upon by consulting the open file. If he is not satisfied with any action taken he may always supplement his observations. If, either in these circumstances or before making any observations a third party enquires as to the manner in which, for example, an allegation of prior use should be communicated to the Office he should be told that the form of observations made under s.21 is entirely a matter for the informant.

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SECURITY AND SAFETY

Section 22: Information prejudicial to national security or safety of public

22.01 This section gives the comptroller the power to prohibit the communication of information disclosed in an application filed at the Office, specifies how such an application is to be dealt with by the Office, lays down how prohibition directions are to be reviewed by the Secretary of State, confers certain rights on an applicant where grant of a patent is prevented by such a direction, and finally specifies penalties for failure to comply with such a direction. S.22 applies to all applications filed at the Office, whether filed under the 1977 Act or filed at the Office in its capacity as a Receiving Office under the EPC or the PCT. It also applies to applications under the 1949 Act, except that where such an application was, on the date (1st June 1978) on which the 1977 Act came into force, already the subject of directions under s.18 of the 1949 Act, those directions continue in force; if and when directions on such an application are revoked any patent is published and granted under the 1949 Act (unless the application is withdrawn in which case it is neither granted nor, following paragraph 1 of Schedule 5 to the CDP Act, published). S.22 was amended by the Patents Act 2004 with effect from 1 January 2005, which substituted the original term "the defence of the realm" with "national security" throughout this section, without any intended change of scope. The 2004 Act also amended s.22(6) to remove references to the United Kingdom Atomic Energy Authority (UKAEA).

22.02 The term "Secretary of State" when used in a statute means "one of her Majesty's Principal Secretaries of State" (Interpretation Act 1978, Schedule 1).

Section 22(1)

Where an application for a patent is filed in the Patent Office (whether under this Act or any treaty or international convention to which the United Kingdom is a party and whether before or after the appointed day) and it appears to the comptroller that the application contains information of a description notified to him by the Secretary of State as being information the publication of which might be prejudicial to national security, the comptroller may give directions prohibiting or restricting the publication of that information or its communication to any specified person or description of persons.

Section 22(2)

If it appears to the comptroller that any application so filed contains information the publication of which might be prejudicial to the safety of the public, he may give directions prohibiting or restricting the publication of that information or its communication to any specified person or description of persons until the end of a period not exceeding three months from the end of the period prescribed for the purposes of section 16 above.

22.03 Every application filed at the Office, is, once it has passed through Document Reception and New Applications (or has been filed securely - see 22.07), scrutinised by an examiner in Security Section, who is supplied with a list of material, the publication of information about which might be prejudicial to national security. If such information is disclosed, the application is removed from the general stream of applications and directions are given under s.22(1) prohibiting the publication of the application and the communication of its contents. Similar directions are given under s.22(2) if the information disclosed is such that its publication might be prejudicial to the safety of the public. In this case no general guidance is given by the Secretary of State, and the decision as to what falls into this category is a matter for the comptroller.

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- 22.03.1 Every application arriving in an examining group will therefore have been screened by Security Section and usually no further checks under s.22 are needed. However, if an examiner becomes aware that material potentially relevant to s.22 has subsequently been placed on file, for example in correspondence from the agent or by amendment (whether allowable under s.76 or not), the examiner should refer the application to Security Section in Room G.R70 for advice.
- 22.04 Directions under s.22(1) continue in force until revoked (see 22.14), while directions under s.22(2), unless confirmed (see 22.13), automatically lapse at the end of the period of twenty-one months from the priority date or, where there is no priority date, the filing date of the application.
- s.97(1)(c) 22.05 In neither case is there any appeal from a decision by the comptroller to issue prohibition directions.
 - 22.06 Although prohibition directions initially impose a blanket prohibition against any disclosure of the patent application and information therein, permission may be sought from the comptroller for disclosure to specified persons. If granted such permission will impose conditions on the persons so specified; thus they should not without specific authorisation disclose the information to any other person. Permission must be sought for filing corresponding applications abroad (see 23.04).
 - Although all applications are inspected by Security Section, anyone filing an application, knowing that a Government department or a foreign government wishes its contents to be kept secret, or the contents of which relate to a classified Government contract, should file the application at Room G.R70, Concept House, and not to the usual Front Office. Such applications may be filed by hand at the Newport or London office, in envelopes marked "For the attention of GR70", but only between the hours of 9am and 5pm. The receptionist should be informed that the application is for GR70 rather than the usual Front Office. Documents which might include information of relevance to national defence or security should not be filed by facsimile transmission. In respect of a filing connected with a classified Government contract the application should be accompanied by a notification of the number of the contract together with the name and address of the Government agency involved in the contract.
 - Documents involved in applications subject to prohibition directions under Section 22(1) must be despatched under security rules; Room G.R70 will always advise on this procedure. If such documents are being despatched to the Office, the envelope should be clearly marked "for attention of Room G.R70" and should be addressed to Room G.R70, Concept House, Cardiff Road, Newport, South Wales, NP10 8QQ.

Section 22(3)

While directions are in force under this section with respect to an application -

- (a) if the application is made under this Act, it may proceed to the stage where it is in order for the grant of a patent, but it shall not be published and that information shall not be so communicated and no patent shall be granted in pursuance of the application;
- (b) if it is an application for a European patent, it shall not be sent to the European Patent Office; and
- (c) if it is an international application for a patent, a copy of it shall not be sent to the International Bureau or any international searching authority appointed under the Patent Co-operation Treaty.

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Section 22(4)

Subsection (3)(b) above shall not prevent the comptroller from sending the European Patent Office any information which it is his duty to send that office under the European Patent Convention.

22.09 For as long as prohibition directions are in force an application for a patent under the Act is dealt with by an examiner in Security Section. Search and substantive examination are carried out in the usual way (for the period allowed for requesting substantive examination, see 18.02), but the application is not published, and at no stage is it mentioned in the Journal. When it appears to the examiner that the application is in order, a formal report indicating that the application complies with the Act and Rules is issued under s.18(4). The application does not however, proceed to publication and grant whilst the prohibition directions remain in force.

EPC r.37(2) EPC a.135 s.81 An application for a European patent which is filed at the Office is not forwarded to the European Patent Office while it is the subject of prohibition directions. If as a consequence it does not reach the European Office before the end of fourteen months from the declared priority date or, where there is none, the filing date, the European application is deemed to be withdrawn. The applicant may then apply for the application to be converted to one for a patent under the Act (see 81.03-06) and/or, subject to the comptroller's permission, (see 23.04) to appropriate foreign applications.

PCT a.27(8) PCT rr. 22.1(a), 15.6(iii), 16.2(iii)

22.11 Likewise an international application filed at the Office which has attracted prohibition directions is not forwarded to WIPO or to the International Searching Authority. An international application subject to prohibition directions is no longer treated as such and must enter the national phase early if it is to proceed. Any international and search fees paid will be refunded to the applicant. There is no provision for the application to be converted to one for a patent under the Act although as soon as the conditions of s.15(1) are complied with a filing date under the Act may be accorded.

Section 22(5)

Where the comptroller gives directions under this section with respect to any application, he shall give notice of the application and of the directions to the Secretary of State, and the following provisions shall then have effect -

- (a) the Secretary of State shall, on receipt of the notice, consider whether the publication of the application or the publication or communication of the information in question would be prejudicial to national security or the safety of the public;
- (b) if the Secretary of State determines under paragraph (a) above that the publication of the application or the publication or communication of that information would be prejudicial to the safety of the public, he shall notify the comptroller who shall continue his directions under subsection (2) above until they are revoked under paragraph (e) below;
- (c) if the Secretary of State determines under paragraph (a) above that the publication of the application or the publication or communication of that information would be prejudicial to national security or the safety of the public, he shall (unless a notice under paragraph (d) below has previously been given by the Secretary of State to the comptroller) reconsider that question during the period of nine months from the date of filing the application and at least once in every subsequent period of twelve months:

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- (d) if on consideration of an application at any time it appears to the Secretary of State that the publication of the application or the publication or communication of the information contained in it would not, or would no longer, be prejudicial to national security or the safety of the public, he shall give notice to the comptroller to that effect; and
- (e) on receipt of such a notice the comptroller shall revoke the directions and may, subject to such conditions (if any) as he thinks fit, extend the time for doing anything required or authorised to be done by or under this Act in connection with the application, whether or not that time has previously expired.

Section 22(6)

The Secretary of State may do the following for the purpose of enabling him to decide the question referred to in subsection (5)(c) above -

- (a) where the application contains information relating to the production or use of atomic energy or research into matters connected with such production or use, he may at any time do one or both of the following, that is to say,
 - (i) inspect the application and any documents sent to the comptroller in connection with it:
 - (ii) authorise a government body with responsibility for the production of atomic energy or for research into matters connected with its production or use, or a person appointed by such a government body, to inspect the application and any documents sent to the comptroller in connection with it;

and

(b) in any other case, he may at any time after (or, with the applicant's consent, before) the end of the period prescribed for the purposes of section 16 above inspect the application and any such documents:

and where a government body or a person appointed by a government body carries out an inspection which the body or person is authorised to carry out under paragraph (a) above, the body or (as the case may be) the person shall report on the inspection to the Secretary of State as soon as is practicable.

When directions under s.22(1) or (2) have been given with respect to an application the Secretary of State must be so informed, and must advise whether or not it should continue in force. Such advice will not be tendered in advance of the Secretary of State (usually, in practice, the Ministry of Defence) inspecting the application. inspection is however done immediately if the application contains information relating to the production or use of atomic energy or research into matters connected with such production or use, and the Secretary of State may authorise a government body with responsibility for the production of atomic energy or for research into its production or use, or a person appointed by such a body to inspect the application. (See also 22.27-22.29). Otherwise the inspection cannot take place until after the expiry of eighteen months from the declared priority date or, where there is none, the filing date, unless the applicant gives permission for an earlier inspection. It is therefore advantageous, if early consideration for revocation of the directions is desired, to complete and return to Room G.R70 Concept House together with a copy of the specification the Form of Assent to Inspection which is despatched with the letter sent to the applicant stating that the order has been imposed. Even when early revocation is not being sought, it is desirable to acknowledge receipt of the letter imposing the directions.

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- 22.13 If the Secretary of State informs the comptroller that in his opinion the application contains information the publication of which would be prejudicial to the safety of the public, then the direction given under s.22(2) are confirmed. They then do not lapse, but continue in force until revoked.
- 22.14 If the Secretary of State notifies the comptroller that publication of the information is not considered prejudicial the directions given under s.22(1) or (2) are revoked. The application then proceeds as described in 22.19-22.23.
- 22.15 If on the other hand the Secretary of State decides that publication would be prejudicial to defence or public safety, so that the prohibition directions given by the comptroller continue in force, then he must periodically reconsider his decision. This must be done within nine months of the application being filed, and at least once a year thereafter (but see 22.12). The applicant is not informed when such reconsideration has taken place, but it is open to him at any time to enquire whether directions could be revoked. If and when it is decided that publication would no longer be prejudicial, the procedure in 22.14 is followed.
- The letter notifying revocation of prohibition directions on an application may indicate that any subsequent application claiming priority from it may nevertheless need to be scrutinized. In such cases Room G.R70 Concept House should be informed of any such subsequent application made in this office, preferably by means of a letter stating whether there are changes in the specification compared with that of the earlier application. If they are at all substantial, the changes should be shown on a copy of the later application or the relevant parts thereof. The same procedure should be followed **before** making such subsequent applications abroad (with or without benefit of priority) under the EPC, PCT or national routes (see also 23.03). Correspondence with Room G.R70 Concept House on these and other matters not germane to the examination of the application will not be placed open to public inspection. It should be noted that failure to mention the existence of an earlier application for the same or similar matter when priority is not claimed can sometimes lead to unnecessary prohibition.
- s.16(1) 22.17 Following revocation of prohibition directions an application for a patent under the Act will normally be published under s.16 as soon as practicable, and details of the application will be published in the Journal. It will not be so published however if it is withdrawn before the prohibition directions are revoked or preparations for publication have been completed (see 16.07).
 - 22.18 [not used]

Procedure after directions have been revoked

22.19 When prohibition directions are revoked before a search has been carried out, the application is sent either for search in an ordinary examining group or to await the filing of Form 9A and/or claims; it then proceeds in the normal way (see 17.02 et seq).

[When the directions are revoked in this situation, the application is forwarded to the appropriate Formalities Manager; it is then either forwarded after fine allocation to the appropriate examining group or (if it is a paper case) put in store to await filing of the outstanding document(s).]

22.20 If the directions are revoked after issue of a search report but before issue of a substantive examination report the application is sent to the appropriate examining group. The group examiner should consider the search which has been carried out by Security Section and should perform an additional search if he is reasonably sure that it would yield more pertinent prior art; any relevant document so discovered should be dealt with as described in 17.105 - 17.105.2. The application should then be classified and sent for s.16 publication (see 17.102, 16.30), and will then proceed as an ordinary application being dealt with in the appropriate examining group.

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[An additional search will not often be required; no work units may be claimed in respect of such a search.]

22.21 If the directions are revoked after issue of a substantive examination report but before the application is in order, the application should be sent at once for publication, after following the procedure described in 22.20. In addition to the text of the specification as filed, the published application should include the claims in their current form if this differs from that originally filed. Substantive examination is then continued, either by the Security Section examiner who prepared the first examination report or, if thought appropriate, by the examiner responsible for the subject-matter concerned.

[Unless the specification has remained unamended, the security examiner should annotate the appropriate description and claims in the table of contents in PDAX. If the drawings have been amended a copy of the unamended formal drawings as filed should also be annotated in the table of contents.

If the application is a paper case, the security examiner should place a copy of the specification, flagged "TO BE PRINTED AS 'A' DOCUMENT", in front of the original specification in the shell. If the abstract has been reframed, the reframed original copy of the abstract should replace any duplicate copy in the duplicate specification during production of the 'A' document. Also, a copy of the claims in their current form if this differs from that on filing should be attached to the duplicate specification. If the drawings have been amended a copy of the unamended formal drawings as filed should be flagged "TO BE PRINTED IN 'A' DOCUMENT" and attached to the specification sent for publication.

The above preparations for "A" publication are made by the examiner in security section; any subsequent changes therein should be made only after consulting the security examiner. When in due course, the application is returned for completion of the substantive examination, the examiner who is completing the examination should ensure that the set of documents is properly re-assembled and that the duplicate copy of the abstract, if removed as above, has been returned to its correct position (paper cases only).]

- As a result of the directions having been in force, it may be necessary to extend the compliance period using the discretion conferred on the comptroller by s.22(5)(e). Such discretion should not be exercised earlier than necessary in a particular case. It should be noted that discretion under s.22(5)(e) can be exercised only after the prohibition directions have been revoked. It is not regarded as enabling the comptroller to resuscitate an application which, when the prohibition was revoked, had already been treated as having been withdrawn or refused, for example through failure to file Form 9A or Form 10 in time or through not being in order at the end of the compliance period.
- When the prohibition directions are revoked after an application has been put in order, it should first of all be published under s.16, after following the procedure described in 22.20. As a consequence of the wording of s.16(1) the published application should include both the text of the specification as filed and the claims in their final form, if different. The application should then proceed to grant (see 18.85-18.86).

[For s.16 publication procedure, see 22.21. When in due course the file is returned to the examiner for revision of the classification prior to B publication, he should see that the documents going forward for publication have been properly assembled.]

Section 22(7)

Where directions have been given under this section in respect of an application for a patent for an invention and, before the directions are revoked, that prescribed period expires and the application is brought in order for the grant of a patent, then -

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- (a) if while the directions are in force the invention is worked by (or with the written authorisation of or to the order of) a government department, the provisions of sections 55 to 59 below shall apply as if -
 - (i) the working were use made by section 55;
 - (ii) the application had been published at the end of that period; and
 - (iii) a patent had been granted for the invention at the time the application is brought in order for the grant of a patent (taking the terms of the patent to be those of the application as it stood at the time it was so brought in order); and
- (b) if it appears to the Secretary of State that the applicant for the patent has suffered hardship by reason of the continuance in force of the directions, the Secretary of State may, with the consent of the Treasury, make such payment (if any) by way of compensation to the applicant as appears to the Secretary of State and the Treasury to be reasonable having regard to the inventive merit and utility of the invention, the purpose for which it is designed and any other relevant circumstances.
- Thus if an application was brought in order within the compliance period and, while a prohibition order was still in force, was used for the services of the Crown, that use is to be treated as though the patent had been granted and published, and the applicant and other parties have the rights provided for in ss.55-59. Moreover if the prohibition direction has caused hardship the applicant may be awarded reasonable compensation.

Section 22(8)

Where a patent is granted in pursuance of an application in respect of which directions have been given under this section, no renewal fees shall be payable in respect of any period during which those directions were in force.

r.37, r.38

22.25

No renewal fees are payable either in respect of years preceding that in which the direction is revoked or in respect of the year during which it is revoked. The first renewal date in respect of which fees are payable will be the first anniversary of the date of filing following revocation of the direction, or three months after the date of grant, whichever is the later. The period within which fees for subsequent years must be paid is governed by r.38.

Section 22(9)

A person who fails to comply with any direction under this section shall be liable -

- (a) on summary conviction, to a fine not exceeding the prescribed sum; or
- (b) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine, or both.
- 22.26 It should be noted that a failure to comply with a direction under s.22 (or with the requirements of s.23(1)) is a criminal offence. A notice drawing attention to these matters appears prominently in every issue of the Patents Journal.
- 22.26.1 The Magistrates' Courts Act 1980 amended s.22(9) to set the maximum fine on summary conviction as the "prescribed sum". The reference to "indictment" in (b) is treated

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as a reference to "information" for the Isle of Man only (S.I. 2003 No. 1249).

APPENDIX

Euratom Treaty

22.27 The treaty requires the Office to carry out certain obligations as regards atomic energy patent applications. Patent applications relating to atomic energy subject matter are separated by the Treaty into two categories:-

Article 16(1): specifically nuclear matters

Article 16(2): other atomic matters directly connected with and essential to the development of nuclear energy within the Community.

The purpose behind these obligations is to assist in building up at the European Commission a confidential information bank. The Commission is not authorised to use an invention without either the consent of the applicant or obtaining a compulsory licence under Articles 17 to 23 of the Treaty. The text of the Treaty is given on pages 162 to 268 of Part II of the Treaty of Accession to EC and Euratom (Cmnd 5179).

22.28 In the case of Article 16(1) the applicant is asked for his consent to the communication of the contents of the specification to the European Commission. If such consent is not forthcoming within two months, the Commission is notified by the Office of the existence of the application. The Commission may then ask to see the specification and this request is passed on by the Office to the applicant. Failing the applicant's agreeing to this request, the Office must however forward a copy of the specification to the Commission within 18 months of the filing date unless by then the application has been withdrawn.

22.29 For applications falling within the category of Article 16(2) the Office is merely required to notify the European Commission of the existence of the applications, and this is done about 17 months after filing the application, without reference to the applicant.

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Section 23: Restrictions on applications abroad by United Kingdom residents

Section 23(1)

Subject to the following provisions of this section, no person resident in the United Kingdom shall, without written authority granted by the comptroller, file or cause to be filed outside the United Kingdom an application for a patent for an invention if subsection (1A) below applies to that application, unless -

- (a) an application for a patent for the same invention has been filed in the Patent Office (whether before, on or after the appointed day) not less than six weeks before the application outside the United Kingdom; and
- (b) either no directions have been given under section 22 above in relation to the application in the United Kingdom or all such directions have been revoked.

Section 23(1A)

This subsection applies to an application if -

- (a) the application contains information which relates to military technology or for any other reason publication of the information might be prejudicial to national security; or
- (b) the application contains information the publication of which might be prejudicial to the safety of the public.
- S.23 refers to residence and not to citizenship or nationality. If a person normally resident in the United Kingdom lives abroad for a period of several months, he will be regarded for the purposes of s.23 as having ceased to be a United Kingdom resident during this period. On the other hand, a person normally resident abroad but temporarily resident in the United Kingdom or a person who is not a United Kingdom citizen but has a residential address here is considered to be subject to s.23. Any United Kingdom resident temporarily travelling abroad is considered to be bound by the requirements of s.23 during his travels. Furthermore a United Kingdom resident employed by a foreign organisation is subject to s.23 irrespective of any term of his employment contract requiring an initial foreign filing of a patent application relating to an invention arising out of such employment. Additionally even when a United Kingdom resident is a joint inventor with a foreign resident or seeks to be a joint applicant therewith in relation to a foreign application, the requirements of s.23 should be complied with.
- 23.01.1 According to the Interpretation Act 1978, "person" includes a body of persons corporate or unincorporated. Thus the "person" referred to in s.23(1) includes not only the inventor who must be a natural person or persons, but also the applicant which could be a company. The words "file or cause to be filed" mean that this person could also be an agent responsible for preparing a patent application for first filing outside the United Kingdom.
- Subsection (1A) was inserted by the Patents Act 2004 and came into force on 1 January 2005. The strictures of s.23(1) only apply to applications that contain information relating to military technology or other information whose publication might be prejudicial to national security or the safety of the public. A UK resident who wishes to file such an application abroad must therefore either file an application at the Office and then wait six weeks (after which, provided no direction has been given under s.22 (see 22.03), applications may be made abroad without further formality) or else must have written

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permission from the comptroller. Persons wanting such permission should apply direct to Room G.R70, Cardiff Road, Newport, South Wales, NP10 8QQ either by letter or, if more urgent attention is required, personally. A notice drawing attention to these matters appears prominently in every issue of the Patents Journal.

23.03 An offence may be committed if, notwithstanding that an application has been filed at the Office which is not the subject of prohibition directions (whether because it did not attract them or they have been revoked), a subsequent application is made abroad based upon but containing matter not disclosed in the application as filed at the Office. It should be ensured, therefore, that any such subsequent application does not contain additional descriptive matter where s.23(1A) applies without written prior authority from the comptroller (see 22.16).

Even when an application is the subject of a prohibition direction it may be permitted to form the basis of applications in foreign countries having reciprocal arrangements with this country. An example of such an arrangement is the NATO "Agreement for the mutual safeguarding of secrecy of inventions relating to defence and for which applications for patents have been made" (Cmnd 1595). Details of the very special procedures for such conversions and foreign filings will be provided after permission has been granted to file abroad. Such requests should be sent directly to Room G.R70, Cardiff Road, Newport, South Wales, NP10 8QQ.

Section 23(2)

Subsection (1) above does not apply to an application for a patent for an invention for which an application for a patent has first been filed (whether before or after the appointed day) in a country outside the United Kingdom by a person resident outside the United Kingdom.

23.05 Thus where an application has been filed abroad by a person (see 23.01.1) who is not a UK resident, further applications for the same invention may be filed in other countries by a UK resident without the prior approval of the comptroller.

Section 23(3)

A person who files or causes to be filed an application for the grant of a patent in contravention of this section shall be liable -

- (a) on summary conviction, to a fine not exceeding the prescribed sum; or
- (b) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine, or both.

Section 23(3A)

A person is liable under subsection (3) above only if -

- (a) he knows that filing the application, or causing it to be filed, would contravene this section; or
- (b) he is reckless as to whether filing the application, or causing it to be filed, would contravene this section.

23.06 It should be noted that a failure to comply with the provisions of s.23(1) (or

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with a direction given under s.22) is a criminal offence. However, s.23(3A) limits culpability of the offence to where a person knows that filing an application or causing it to be filed would contravene s.23, or where he is reckless as to whether filing the application or causing it to be filed would contravene this section. Therefore, a person acting in good faith who mistakenly believes that the restrictions in s.23 do not apply to a patent application will not be guilty of a criminal offence.

23.07 The maximum fine on summary conviction corresponds to that applicable under s.22(9) (see 22.26.1). The reference to "indictment" in (b) is treated as a reference to "information" for the Isle of Man only (S.I. 2003 No. 1249).

Section 23(4)

In this section -

- (a) any reference to an application for a patent includes a reference to an application for other protection for an invention;
- (b) any reference to either kind of application is a reference to an application under this Act, under the law of any country other than the United Kingdom or under any treaty or international convention to which the United Kingdom is a party.

Thus no application for a utility model or any other form of protection of an invention may be sought abroad, either under the laws of another country or under the EPC or the PCT, without first complying with the requirements of s.23(1) (see 23.02). UK residents wishing to file applications under the EPC or PCT without first filing a UK application can meet the requirements of s.23(1) by filing their applications at the Office in its capacity as Receiving Office under these treaties. If, however, they wish to file at any other Receiving Office and s.23(1A) applies to the application, they must seek the prior written approval of the comptroller.

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PROVISIONS AS TO PATENTS AFTER GRANT

Section 24: Publication and certificate of grant

Section 24(1)

As soon as practicable after a patent has been granted under this Act the comptroller shall publish in the journal a notice that it has been granted.

At the same time as the applicant is informed, in a "grant" letter, that grant has taken place (see 18.86) he is notified of the date on which it will be advertised in the Journal. This is generally several weeks after the date of the "grant" letter.

s.77(1) 24.02 A European patent (UK) is advertised in the Journal on the date on which its grant is mentioned in the European Patent Bulletin.

Section 24(2)

The comptroller shall, as soon as practicable after he publishes a notice under subsection (1) above, send the proprietor of the patent a certificate in the prescribed form that the patent has been granted to the proprietor.

r.34 24.03 The certificate includes the name of the proprietor of the patent, the date of filing the application and is dated with the date that the patent took full effect i.e. the date that the entry for grant shows in the journal and the B document is published. A notice on the back of the certificate reminds the proprietor of his responsibility for setting up effective arrangements for paying renewal fees (see 25.06-25.08).

[The Office may provide replacement certificates of grant either to correct an error on an original certificate or to replace one that has been lost. Return of the original certificate is not required. Replacement of old-style certificates will be with certificates in the current style.]

Section 24(3)

The comptroller shall, at the same time as he publishes a notice under subsection (1) above in relation to a patent publish the specification of the patent, the names of the proprietor and (if different) the inventor and any other matters constituting or relating to the patent which in the comptroller's opinion it is desirable to publish.

Section 24(4)

Subsection (3) above shall not require the comptroller to identify as inventor a person who has waived his right to be mentioned as inventor in any patent granted for the invention.

24.04 The specification is reproduced directly from the typescript of the specification as in order. It is published accompanied by a front page bearing the same publication number as the published application (A document) but followed by B, and this document is often referred to as the B document. The front page also carries the same bibliographic data as the A document, a list of all documents cited as relevant to the issues

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of lack of novelty or of inventive step, either in the search report or in subsequent proceedings, and revised classification data. It includes the date on which the patent was published, which is the effective date of grant (see 25.02-03). It does not include an abstract. See 13.03 for suppression of inventor details. Computer programs, sequences and other ancillary material omitted from the A publication (see 16.27) should also be omitted from the B publication.

24.04.1 If the B document contains a printer's error, whether in the specification, the list of citations, or in the bibliographic or classification data, it may be corrected by the issue of an erratum. In this context, "printer's error" is interpreted broadly to embrace any error originating within the Office or during the publication process. However, it does not extend to errors made elsewhere, such as by the applicant. An erratum should not be issued to correct an error in the specification which is detected by the Office unless the error is significant, in the sense that it misleads or introduces doubt. An erratum should be issued for an error in the specification which is notified by the applicant or by a member of the public or for any error in the bibliographic or classification data. See 16.33 for procedure.

a.98 EPC 24.05 European patents (UK) are published by the EPO on the date on which the mention of grant is published in the Bulletin.

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Section 25: Term of patent

25.01 This section specifies when a patent begins to have effect, how long it may continue in force, and what must be done to keep it in force. Further requirements concerning renewals are set out in rr.36 to 39 and 41. The section applies to both patents granted under the 1977 Act and European patents (UK).

Section 25(1)

A patent granted under this Act shall be treated for the purposes of the following provisions of this Act as having been granted, and shall take effect, on the date on which notice of its grant is published in the journal and, subject to subsection (3) below, shall continue in force until the end of the period of 20 years beginning with the date of filing the application for the patent or with such other date as may be prescribed.

- s.77(1) 25.02 Thus the effective date of grant for the purposes of all provisions of the Act subsequent to s.25(1) is the date on which the specification of the patent was published and the notice of grant appeared in the Journal (or, in the case of a European patent (UK), the grant was mentioned in the Bulletin).
 - 25.03 This date is later than the date on which a patent was granted (see 18.86, 24.01), and which is the date effective for all provisions of the Act prior to s.25(1). This was confirmed by the Hearing Officer in *ITT Industries Inc's Application* [1984] RPC 23 (see especially page 27 line 20 onwards). There is thus an interval of several weeks during which the provisions relating to an application have ceased to apply but those relating to a granted patent do not yet have effect. For example, since s.19 is a provision prior to s.25(1), an application cannot be amended once a patent has been granted, but the specification of the patent cannot be amended until after publication of the notice of grant, because s.27 is a provision subsequent to s.25(1). Similarly, if a question of entitlement is referred to the Comptroller between the date on which the grant letter is issued and the date of publication of the notice of grant, then no immediate action can take place under either of sections 8 or 37. Instead, the question is treated as having been referred under s.37 on the latter date see 8.03.1.
- s.130(1) 25.04 The twenty-year term of the patent is measured from the date of filing. In the case of a patent granted in pursuance of a UK application, this is the date accorded under s.15. In the case of a European patent (UK) or a patent granted on an international application, the date of filing is that accorded under a.80 EPC or a.11 PCT respectively.
 - 25.04.1 A notice in the Journal dated 22 July 1992 makes clear that from the date of that notice patent expiry dates recorded on the Register, announced in the Journal and recorded in official renewal information, would be based on the interpretation of relevant provisions of the legislation that the full term expires on the day before the anniversary of the filing date of the application; and that this change in procedure applies only to the expiry of a patent and not to the lapsing of a patent due to non-payment of a renewal fee. Thus a 20 year period that starts on 4 November 1992 ends on 3 November 2012.
 - 25.04.2 Although the term of a patent may not be extended beyond the prescribed 20 year period, a medicinal product or plant protection product protected by a patent may be protected for a further period of up to five years from the expiry of the patent at the end of the twenty year term by the grant of a supplementary protection certificate (see supplementary protection certificate pages).

Section 25(2)

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A rule prescribing any such other date under this section shall not be made unless a draft of the rule has been laid before, and approved by resolution of, each House of Parliament.

25.05 Hence although s.25(1) authorises the making of a rule prescribing that the term of a patent be measured from a date other than the filing date, any such rule must be made by affirmative resolution. No such resolution has so far been made.

Section 25(3)

Where any renewal fee in respect of a patent is not paid by the end of the period prescribed for payment (the "prescribed period") the patent shall cease to have effect at the end of such day, in the final month of that period, as may be prescribed.

- r.37(2) 25.06 If it is desired to keep a patent in force after the end of the fourth year from the date of filing, renewal fees must be paid for each succeeding year (but see 25.08). r.38(2)Successively increasing amounts are prescribed for each year after the fourth, and the fee for each year should normally be paid within the period of three calendar months ending on the last day of the month in which the renewal date falls. For example, if a patent is filed on 10 May 2003 and granted on 17 June 2006, renewal fees are due on 31 May each year, starting in 2007, and can be paid any time in March, April or May of each year (but see 25.07, 25.08).
- r.37(3)25.07 If, in the case of a patent granted under the Act, the notice of grant has not been published in the Journal by the end of three years and nine months from the date of filing, then any renewal fees which have become due (including any fees due in respect of preceding years) can be paid at any time up to the end of the third calendar month after the month in which the date of grant falls. For example, if a patent is filed on 20 April 2002 and granted on 16 November 2006, the renewal fee which would have been due for payment on 30 April 2006 may be paid any time up until 28 February 2007. The fifth anniversary falls on 20 April 2007, so the renewal fee for the following year would be due on 30 April 2007 and may be paid any time in February, March or April of that year.
- Renewal fees to keep a European patent (UK) in force beyond four years 25.08 a.86 EPC from its date of filing are payable to the Office only in respect of each year following the year in which mention of the grant was published in the Bulletin. (Fees in respect of years up to and including the year in which mention of grant is published are paid direct to the EPO). Where a renewal fee becomes due within three months after publication of the mention of grant, it may be paid up to the end of the third calendar month after the month in which the date of grant falls. If the comptroller is not notified of an address for service for the proprietor of a European patent (UK), then the proprietor's address on the register will be treated as the address for service even if that address is outside the United Kingdom (see also 77.05).
- a.112a EPC 25.08.1 Where a European patent (UK) has been revoked by the EPO Board of Appeal and is subsequently restored by the Enlarged Board of Appeal following a petition r.41A for review under EPC Art.112a, any renewal fees which fell due whilst the patent was revoked are payable within a two-month period following the restoration. See 77.12.1 for further details.
- 25.09 In addition to the renewal fee, Form 12 must also be filed within the same r.36(3)period (preferably at the same time). A certificate of payment will be issued once the fee is r.36(5)received and/or a report detailing errors if the payment is incorrect. Details of the renewal arrangements effective from 1 November 1999 were published in a supplement to the Patents and Designs Journal of 20 October 1999.
 - The amount of the fee due is that which is prescribed at the time payment is made (but see 25.14). As a consequence of the stipulation that the fee be paid within the period of three calendar months ending on the last day of the month in which the anniversary

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r.37(4)

s.77(5A)

of filing falls, it is not possible to circumvent an increase in the prescribed fees by earlier payment.

Anyone may pay the renewal fees on a patent - there is no requirement that this be done either by the proprietor or with his agreement.

Section 25(4)

If during the period ending with the sixth month after the month in which the prescribed period ends the renewal fee and any prescribed additional fee are paid, the patent shall be treated for the purposes of this Act as if it had never expired, and accordingly -

- (a) anything done under or in relation to it during that further period shall be valid:
- (b) an act which would constitute an infringement of it if it had not expired shall constitute such an infringement; and
- (c) an act which would constitute the use of the patented invention for the services of the Crown if the patent had not expired shall constitute that use.

Section 25(5)

Rules shall include provision requiring the comptroller to notify the registered proprietor of a patent that a renewal fee has not been received from him in the Patent Office before the end of the prescribed period and before the framing of the notification.

- r.39(2) 25.12 Within six weeks after the end of the period allowed for paying a renewal fee (see 25.06-25.08) the comptroller must, if the fee is still unpaid, send to the proprietor a notice reminding him that payment is overdue and of the consequences of non-payment (except the timescales are different where fees are payable under s.77(5A) see 25.12.1 below). This notice is sent to the last address specified for this purpose by the proprietor or, if no such address was given, to the address for service which is entered in the register.
- r.39(2) 25.12.1 In the situation where a European patent (UK) has been revoked by the EPO Board of Appeal and is subsequently restored by the Enlarged Board of Appeal, and renewal fees are payable under s.77(5A), the comptroller must send such a notice within six weeks of either (i) the end of the renewal period or (ii) the date on which the Office receives notification from the EPO of the restoration of the patent, whichever occurs later.
- s.25(4)

 25.13 The period allowed for payment of a renewal fee (see 25.06-25.08) may be extended by up to six months on payment of the fee appropriate for the length of extension sought and completion of the appropriate part of Form 12. If the renewal fee is paid within this extended period, the patent is treated as though it had not expired (but see ss.58(5) and 62(2)). If however the renewal fee is not paid by the end of six months from the time when it was due, the patent is regarded as having expired on the anniversary of the filing date, and is so advertised in the Journal. For example, if a patent is filed on 10 May 2003 and granted on 17 June 2006, renewal fees are due on 31 May each year, starting in 2007, but may be paid late any time up to the end of November (with a late payment penalty). If a fee is not paid for any given year, the patent will be deemed to cease on 10 May of that year. The Register is endorsed "Patent ceased".
- r.36(2) 25.13.1 If outstanding renewal fees due under s.77(5A) are not paid within either r.41A the two-month period for paying the renewal fee following the restoration or the six-month extension discussed above, the European patent (UK) will be deemed to have ceased at

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the end of the final day of the two-month period following the restoration by the Enlarged Board of Appeal.

- When the renewal fee is paid in the extended period, the amount due is that which was prescribed at the end of the normal period. The amount of the fee for the extension is however that due at the time it is paid.
- r.41(2) 25.15 If the renewal fee has not been paid (together with the fee for any extension) within six months of the end of the normal period allowed, then within a further six weeks the comptroller must send to the proprietor a further notice informing him that the patent has now lapsed and informing him of the possibility of applying for restoration (see s.28). This notice must be sent to the address specified by rule 39(3) (see 25.12).

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Section 26: Patent not to be impugned for lack of unity

Section 26

No person may in any proceeding object to a patent or to an amendment of a specification of a patent on the ground that the claims contained in the specification of the patent, as they stand or, as the case may be, as proposed to be amended, relate -

- (a) to more than one invention, or
- (b) to a group of inventions which are not so linked as to form a single inventive concept.
- s.18(4) s.14(5)(d)
- 26.01 Before a patent is granted the examiner must have reported that the application complied with all the requirements of the Act and Rules, including the stipulation that the claims should have unity of invention. S.26 makes clear however that even if the examiner has wrongly decided that there is unity, the grant is in no way invalidated. Nor may an opponent to an application to amend under s.27 or 75 object that a proposed amendment would introduce plurality of invention. Moreover this matter may not be argued in any other proceedings, for example in an application for judicial review.
- 26.02 S.26 is not regarded as fettering the comptroller's discretion to refuse or allow amendment under s.27 or 75. Nonetheless it is not the practice of the Office to withhold consent to an amendment solely because the amended specification would relate to more than one invention.

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Section 27: General power to amend specification after grant

s.77(1) 27.01 This section is concerned with the amendment, at the request of the proprietor, of the specification of a granted patent, including a European patent (UK), provided that there are no proceedings pending in which the validity of the patent may be put in issue (see 27.21). (Amendments where the validity of the patent may be put in issue are covered by section 75). Prescribed regulations are set out in r.35 and Part 7 (Proceedings heard before the Comptroller). (For the distinction between amendment and correction see 19.03-19.04).

27.02 Amendment during revocation proceedings initiated by the comptroller is effected under s.73 and is not governed by the rules relating to amendment under s.27 or s.75 (see also 27.05.2 and 73.10).

Section 27(1)

Subject to the following provisions of this section and to section 76 below, the comptroller may, on an application made by the proprietor of a patent, allow the specification of the patent to be amended subject to such conditions, if any, as he thinks fit.

INITIAL PROCEDURE

- r.35(1) 27.03 An application to the comptroller for leave to amend the specification under this section must be made in writing. The proposed amendment should be identified and the applicant must also state the reasons for seeking the amendment (see 27.07). In particular, if the amendments are intended to distinguish the invention claimed from any published prior art which might invalidate the patent, this should be disclosed and the prior art identified. A copy of any document referred to by the applicant, or a translation thereof, may be called for. Where the amendments are intended to distinguish the invention from prior use, an outline of the nature of the prior use and when the proprietors became aware of it should be disclosed, but more detailed information regarding the prior use is not normally required.
- r.35(2)27.03.1 If it is reasonably possible, the proposed amendment and the reasons for it shall be set out and delivered to the comptroller in electronic form or using electronic communications. Directions prescribing the form and manner for electronic delivery of applications to amend under s.27 were published in the PDJ No. 5938 on 12 March 2003, and came into force with the Patents Act 1997 (Electronic Communications Order) 2003 (S.I. 2003 No. 512) on 1 April 2003. Electronic delivery should be made either by email to litigationamend@ipo.gov.uk entitled "Proposal to amend under s.27", or on an electronic carrier (such as floppy disk or CD-R) delivered to the Office and accompanied by an identifying letter. Text produced using well-known word processing packages or filed in PDF format will be accepted, and if filed by email, this may be provided as an attachment. It is preferable for the text to use conventional word-processing editing features to set out the amendments on the original version of the text to distinguish the changes to the text. If the text cannot be read by the Office, it will be treated as not delivered, and the applicant will be contacted with a view to making alternative arrangements. The Office will not accept email messages for the purpose of amendment under s.27 at any email address other than that given above, neither will email messages in MS-TNEF/RTF or HTML formats nor messages that are encrypted or digitally signed be accepted. It is expected that where word-processing facilities are available and have been used for preparation of patent specifications, it will be "reasonably possible" for amendments under s.27 to be submitted by electronic delivery.

[The application to amend is examined in Restoration and Post Grant Section (RAPS) to see that it is formally in accordance with the Act and Rules. This examination includes checking:

(i) that reasons for making the amendment have been given;

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- (ii) that any prior art referred to has been adequately identified;
- (iii) whether the Office is aware of any pending proceedings in which the validity of the patent may be put in issue.]

[RAPS should report any formal defects to the applicant and request copies of any documents referred to which have not been provided and which are not available to the Office. A translation of any document not in English should also be requested under r.113. A period of one month should be allowed for reply.]

- s.25(1) 27.04 An application to amend under this section cannot be considered until the s.77(1) date on which the notice of the grant of the patent is published in the journal, or, in the case of a European patent (UK), is mentioned in the European Patent Bulletin, and the proprietor should be so informed if an application is received before that date.
- r.35(3) 27.05 Where it is considered necessary for clarity, the Office may request the filing of a copy of the unamended specification on which the amendment is shown marked up. In the case of a European patent (UK) specification published in English by the EPO, the general procedure is the same as for a UK specification. Since the authentic text is in English translations of any amendments to the claims into French or German will not be required, and will not be advertised or published. If the EP(UK) specification is instead in French or German, translations into English of the part of the specification proposed to be amended and of the part as proposed to be amended are also required. The comptroller may require a translation of the entirety of the specification if this is necessary to determine allowability of the amendments. Where no full translation has been filed or called for the applicant should be advised by RAPS that a translation of the whole specification may be required later, for example during any opposition proceedings to the amendment (see 77.13-77.15).

27.05.1 If a European patent which designates the UK is amended during opposition proceedings before the EPO, and the decision of the EPO is that the patent should be maintained in its amended form, the amendments automatically apply to the European patent (UK), see 77.08-09. Action under s.27 with regard to those amendments is not required. Where amendment under s.27 of a European Patent (UK) is sought before the nine months allowed for opposing the patent has expired or when there is an opposition outstanding, the possibility exists that the specification may be amended before the EPO. In such circumstances the proprietor or agent is given the option of either (a) staying the request until the opposition period has expired or the opposition proceedings have been settled or (b) proceeding with the request under s.27 on the understanding that the desired amendment may be negated as a result of subsequent amendment before the EPO.

[Where an application is made to amend a European patent (UK), RAPS should ascertain on COPS or the <u>European Patent Register</u> whether (a) the period for opposing the patent has expired and whether any opposition has been entered and (b) whether any application for central amendment of the patent at the EPO has been made and whether any amendment has been allowed. Where necessary the proprietor or agent will be given the option of staying the request.

[Deleted]

27.05.2 Where a European patent designating UK relates to the same invention as a UK patent, amendments to the UK patent may be submitted under s.27 in order to remove the conflict and so avoid revocation of the UK patent under s.73(2). Furthermore, in *Henry Reed v Sir James Laing & Sons Ltd* (BL C/74/96) Laddie J allowed amendment of the European patent (UK) under s.27 to avoid s.73(2) conflict even though the EP(UK) patent had lapsed see 73.10.

s.118(1) 27.06 A preliminary notice is inserted in the Journal giving only the publication number and title of the specification and the proprietor's name. The preliminary notice will state that, unless the application to amend is abandoned, a further notice will be made which

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will announce the amendments as open to opposition, and that meanwhile the proposed amendments may be inspected in the Office.

[RAPS should arrange for preliminary advertisement of the application, and should then refer the case to the Deputy Director in charge of the subject matter to which the specification relates.]

EXAMINATION OF THE AMENDMENTS

Exercising discretion

27.07 The examiner to whom the application is referred should determine whether the reasons given for making the amendments are sufficient. The reasons must be such that it can be established that the amendments effect a proper cure for any defect they are intended to rectify. The allowance of amendments under s.27 is a matter for the discretion of the comptroller and the onus is on the patentee to make full disclosure of all matters material to the exercise of this discretion (Hsuing's Patent [1992] RPC 497). Thus, unless full particulars of legitimate reasons are given (see 27.03) discretion should not be exercised in favour of allowing the amendments. The comptroller is entitled to know before making his decision whether it is mere whim or necessity which has driven the proprietor to seek leave to amend (Clevite Corporations Patent, [1966] RPC 199). Although the Clevite judgment was under the 1949 Act, its relevance under the 1977 Act has been confirmed by the hearing officer in Waddingtons Ltd's Patent [1986] RPC 158. The hearing officer also supported the view that the allowability of a request to amend under s.27 is discretionary and compliance with s.76 is not itself necessarily sufficient and where amendments are proposed to distinguish the invention from prior art it is necessary for the comptroller to have particulars of that prior art so that he may take it into account in the exercise of his discretion. He held that the omission from s.27 of any specific requirement for full particulars does not therefore mean that such particulars can never be demanded.

s.27(6) 27.08 In considering whether to allow an application to amend, the examiner or deputy director considering the application shall have regard to relevant principles under the European Patent Convention (see 27.32 and 27.32.1). For example, the EPO do not consider the behaviour of the patent proprietor when exercising discretion in allowing amendments. According to s.27(6), the behaviour of the patent proprietor will therefore no longer be an issue to be considered in the UK when deciding whether to allow an amendment to be made under section 27. This effect was explicitly confirmed by Floyd J in <u>Zipher Ltd v Markem Systems</u> Ltd & Anr [2008] EWHC 1379 (Pat):

'It follows that if I am to have regard to the principles applicable under the EPC, the discretion which I have to refuse amendments which comply with the Act has been limited. Considerations such as those formerly considered relevant to the discretion, such as the conduct of the patentee, are no longer relevant.'

Allowability of the amendments

27.09 When the amendments are proposed to distinguish the invention from specified prior art they must be such that the invention is both novel and involves an inventive step having regard to the specified prior art when considered in the light of common general knowledge and of the prior art taken into account during examination of the application for the patent.

27.09.1 In <u>BL O/531/16</u>, the hearing officer stated that case law establishes that an opponent cannot advance arguments which challenge the validity of the patent beyond that suggested by the patentee (see 27.28). The hearing officer also reinforced the view that an examiner is allowed to take into account their own background knowledge when deciding whether to exercise the comptroller's discretion to allow the amendments and is entitled to take into account the prior art cited during examination of the application.

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27.10 [Deleted]

s.76(3)

- 27.11 The amendments must not add matter nor must they extend the protection conferred by the patent (see 76.24). Nor must they introduce any other objection into the specification; for example the description and claims must continue to be clear. Although s.14(5) does not provide grounds for revocation of a patent once granted, objections to noncompliance with s.14(5) can be raised if the patentee applies to amend his claim (judgment of Dillon LJ in Genentech Inc's Patent [1989] RPC 147 at pages 248-249). Objection is however not raised against proposed amendments on the ground that the claims as amended would lack unity of invention (see 26.02). An application under s.27 to amend the specification of a granted European patent (Philips Electronic and Associated Industries Ltd's Patent [1987] RPC 244) by (a) deleting French and German translations of the claims, (b) deleting reference numerals in the claims and (c) adding an omnibus claim to bring the specification into conformity with UK practice was opposed as regards (b) and (c) on the grounds that these amendments would extend the protection conferred by the patent, contrary to s.76(2)(b) of the Patents Act 1977 at the time (now s.76(3)(b)). The hearing officer considered that the law under the 1949 Act, whereby reference numerals in claims are to be regarded as helpful, rather than restrictive, is unchanged in the 1977 Act, and that deletion of the numerals did not give rise to objection under s.76(2)(b) of the Patents Act 1977 at the time (now s.76(3)(b)) (see also 14.135). He also held that with the functional form of claim 1 in the present case, there was a distinction over that in Rotocrop International Ltd v Genbourne Ltd [1982] FSR 241 in which it was held that an omnibus claim, even though tied to claim 1, covered obvious modifications of the illustrated structure. The addition of an omnibus claim of independent form was not objectionable in this case. As regards (a), since the authentic text of the claims in this case was the English version, the translations fulfilled no useful function in the UK and there was no reason to refuse to delete them. Hence changes (a) and (b) which concerned only presentational matters were allowed at the same time as substantive amendment (c); but whether presentational changes alone would have been allowed as amendments under s.27 was undecided.
- 27.11.1 Since 6 April 2017 it has not been possible to amend a granted patent to insert an omnibus claim (see 14.124). However the presence of an omnibus claim in a granted patent is not a ground for revocation.

Procedure

27.12 Any objections to the amendment should be reported to the applicant. Where amendments consequential to those proposed appear necessary this should be pointed out in the report. Two months will be specified for reply. The examination of proposed amendments to EP(UK) specifications is based on the English text.

[The examiner should report in a minute whether the reasons given for making the amendments are sufficient and whether the amendments are allowable (or -strictly speaking - prima facie allowable, since the amendments are subject to advertisement and opposition; see 27.24-27.31). The examiner should then send a PDAX message to the Deputy Director of the subject matter. The Deputy Director will forward the case to RAPS who will contact the applicant. Each amendment or group of amendments should be dealt with separately. If any amendment or group of amendments is not regarded as prima facie allowable the objection should be stated in a form which is suitable for inclusion in an official letter, which will be sent over the signature of a member of RAPS but will give the name and telephone number of the examiner. RAPS will inform the applicant of the latest date for response and will deal with requests for extensions of time periods. The letter may include PC1 advising the patentee of the form in which any further amendments should be submitted.]

Where the further amendment proposed is of a simple nature and small in amount, it may be submitted in a letter and (in appropriate cases) incorporated by the examiner in the original amended copy or the agent may call at the Office to effect the further amendments. In these circumstances the further amendments should be in a different colour and the copy should be annotated e.g.: "further amendments in green effected by examiner

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(or agent) on (date)". When the further amendment is extensive, a published copy, showing the whole of the amendments, should normally be provided. If the specification is heavily amended or lengthy and the further amendment only affects some of the pages, these pages only need be submitted. The date of filing should be annotated on each page. Further amendments to EP(UK) specifications that are not in English should be submitted in accordance with 27.05. Where amendments have initially been submitted electronically, further amendments should also be filed by electronic means.

27.14 If the examiner considers the amendments not to be allowable, and agreement is not reached a hearing should be offered. If a hearing is to be offered the Deputy Director should inform RAPS who will contact the applicant. If some but not all of the proposed amendments appear to be allowable, this should be reported to the applicant, who must be given an opportunity to decide whether to proceed with the allowable amendments or to withdraw all of the proposed amendments (again, subject to the offer of a hearing). If the applicant requests to be heard he should be informed that an ex parte hearing will be appointed subject to advertisement in the Journal of notice of the proposed amendment and absence of opposition (see 27.17).

[A Deputy Director takes any ex parte hearing.]

s.101

r.75

27.15 The comptroller has discretion to allow withdrawal of an application to amend (Upjohn Co (Beal's) Patent, [1973] RPC 77) but the application cannot be withdrawn after the determination of the allowability of the amendments by the comptroller (Emulsol Corporation's Application, 57 RPC 256). The point of "determination" is taken to be the date of issue of the letter informing the applicant that the amendments are either allowed (after the amendments have been effected or a new specification has been provided -see 27.18), or refused. If some but not all of the proposed amendments appear to be allowable, this should be reported to the applicant, who must be given an opportunity to decide whether to proceed with the allowable amendments or to withdraw all of the proposed amendments. Prior to this point, the comptroller has discretion to accept a withdrawal request. However, where he is of the view that the amendments submitted cure a defect that has been identified, discretion is likely to be exercised to refuse the request to withdraw. Where withdrawal of an application to amend has been refused, the amendments submitted do not cure the defect in the patent and the applicant fails to submit alternative amendments which will cure the defect, the application to amend must also be refused. The fact that the patentee has sought to withdraw his application to amend and that this withdrawal request has been refused should be recorded in the register, in addition to the normal entries relating to the application to amend and refusal to allow the amendment. Where amendments submitted do cure the defect, the applicant should be informed that the amendment application will progress as usual notwithstanding his wish to withdraw.

[Suitable wording for the additional register entry concerning refusal to allow withdrawal should be provided by the examiner.]

- 27.16 When the examiner considers that the amendments appear to be allowable (subject to any opposition) the actions set out in 27.12 should be taken. RAPS will arrange for a notice to be made in the Journal declaring that the amendments are now open to opposition. The notice will state that copies of the amendments and the reasons for it are available by application to the RAPS, and, if amendments have been filed electronically, details of the amendments can also be viewed through the website.
 - 27.17 If on the other hand no agreement has been reached and the matter is to be decided at a hearing, notice of the proposed amendments may be advertised in the Journal, the advertisement making clear that the question of the allowability of the amendments has not yet been determined, but that if it proves to be acceptable in the form proposed, a further advertisement will not be made. If no notice of opposition is received within the prescribed period (see 27.25) an ex parte hearing will be held. If the proposed amendments are accepted essentially unchanged they should be effected without further delay, but if the amendments approved differ materially from those originally proposed, a further notice announcing a new opposition period will be made, and the decision is an interim one (see

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27.29). If the decision of the hearing is to refuse the amendments this fact must be advertised.

FINAL PROCEDURE

r.35(6) 27.18 When, either in the absence of opposition or following the conclusion of opposition proceedings, the form of the amendments to be accepted is decided upon, either the amendments may be effected in the original specification in the Office, or the applicant may be called upon to provide, within a specified period, a new specification complying with Schedule 2 to the Rules and incorporating the amendments, including any amended drawings. Such a new specification should be required whenever the amendments are extensive or confusing. In the case of a EP(UK) specification, the amendments are entered in the file copy onto the authentic text (and also onto the translation of the claims if the authentic text is not in English) by RAPS if this is practicable. However if the amendments are extensive or would be confusing bearing in mind that the file copy will have been printed in comparatively small print a new specification as amended and prepared in accordance with Schedule 2 to the Rules should be required under rule 35(6). Once the amendments have been effected or a new specification has been provided, the applicant for amendment should be informed by letter that the amendments are allowed.

[RAPS will decide whether or not to require a new specification under r.35(6). If the amendments are to be effected in the Office, this should be done by RAPS.]

Where a fresh specification has been supplied as referred to in paragraph 27.18, the original specification is not cancelled but certificates are placed on the dossier for both old and new specifications. The certificate relating to the old specification will read:

'This specification has been amended under Section 27 of the Patents Act, 1977, the proprietor of the patent having been notified of the decision to allow the amendment on [date] and the present form is shown in a new specification attached hereto, filed under rule35(6).

The certificate relating to the new specification will read:

'This specification, filed under rule 35(6), is a true copy of the specification as amended under Section 27 of the Patents Act, 1977, the proprietor of the patent having been notified of the decision to allow the amendment on [date]'.

If the amendments are instead effected in the original specification this will bear a certificate reading:

[RAPS should prepare the certificate(s) for the signature of the Deputy Director. Where a new specification has been filed, RAPS should also check that it is in fact an exact copy of the specification as amended, and create a minute to confirm that the check has been made and to point out any apparent discrepancies. The final responsibility lies with the Deputy Director who should, when satisfied, confirm that the signed certificate(s) may be placed on file. Should allowability be determined at a hearing, the date on which the application to amend was allowed will be the date of the decision.

When the specification has been amended, that fact is advertised in the Journal. When the advertisement appears or shortly thereafter, the amended specification is published accompanied by a front page carrying a "C" designation and including the bibliographic data (updated if necessary) of the B specification together with an endorsement that the patent has been amended or, in the case of an EP(UK) specification, amended for the UK. Any orders for copies of the amendments received before the C document is available

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are retained and dealt with when it becomes available. If further amendments lead to second and further C publications, these carry designations C2, C3, etc. In the case of an amended EP(UK) specification, the country code given at the top of the C front page is EP/UK.

[On forwarding an amended specification to Publishing Section, RAPS will indicate any changes in the bibliographic data from those on the front page of the B specification. RAPS also indicate the date on which the amendment(s) is/are allowed. In preparing the C front page, Publishing Section should take the relevant data from the front page of the B document unless RAPS have indicated a change. A suitable footnote should be provided to indicate any changes. In the case of an amended EP(UK) specification the layout of the C front page is changed from that of the front page of the B document and is instead much the same as that of the front page of the B or C document of a domestic patent.]

Section 27(2)

No such amendment shall be allowed under this section where there are pending before the court or the comptroller proceedings in which the validity of the patent may be put in issue.

Proceedings in which validity may be put in issue are defined in s.74(1) (see 74.03), and while they are pending amendment can only be made under s.75. It was decided in *Lever Bros' Patent* [1955] RPC 198 that proceedings are "pending" until the period for appeal has expired and any appeal has been determined. Where the proceedings are concluded by a consent order, they are normally "pending" until the court approves the order (*Critchley v Engelmann* [1971] RPC 346); see also 75.12.1. Proceedings are not regarded as pending merely because a writ has been issued, but are considered to have begun only when it has been served (*Foseco International Ltd's Patent*, [1976] FSR 244). For the situation where amendment under s.27 of a European Patent (UK) is sought before the nine months allowed for opposing the patent has expired or when an opposition is outstanding, see 27.05.1.

[A check is made as part of the formal examination of the application to amend. See 27.03.1]

27.21.1 If proceedings in which validity may be put in issue are instituted while an application to amend under s.27 is pending, the application to amend should normally be stayed pending resolution of those proceedings. However, where an opposition to the application to amend has been filed and the applicant has not filed a counter-statement within the prescribed period, the application should normally be treated as withdrawn rather than stayed (see 27.26).

Section 27(3)

An amendment of a specification of a patent under this section shall have effect and be deemed always to have had effect from the grant of the patent.

Hence the issue of infringement between grant and amendment is to be decided upon the claims of the amended patent (but see s.62(3)). If an act would have infringed these claims then infringement may be considered to have taken place, even though the patent before amendment may have been invalid; conversely if the amended claims would not have been infringed then infringement is considered not to have occurred, even though the claims before amendment may have been both valid and infringed.

Section 27(4)

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The comptroller may, without an application being made to him for the purpose, amend the specification of a patent so as to acknowledge a registered trade-mark.

27.23 Under the Trade Marks Act 1994, a reference to a registered trade mark includes a service mark. If it comes to the notice of the Office that a term used in the specification of a patent is a registered trade mark and this fact has not been acknowledged in the specification, the proprietor should be so informed and advised that before a decision is made whether to amend the specification he has a period of two months in which to submit any comments. If the proprietor replies that the term is not in fact a registered trade or service mark the matter will have to be determined, but the validity of the mark is not material.

[See under 14.70 for the procedure to check whether a word is a registered mark. The necessary acknowledgement of the registered trade or service mark should be effected by amendment in the original specification by RAPS. The procedure set out under 27.18 to 27.20 should be followed.]

Section 27(5)

A person may give notice to the comptroller of his opposition to an application under this section by the proprietor of a patent, and if he does so the comptroller shall notify the proprietor and consider the opposition in deciding whether to grant the application.

Any person may oppose an amendment; there is no need for an opponent to show a locus standi (*Braun AG's Application* [1981] RPC 355), nor even for an agent to identify an opponent for whom he is acting (*Sanders Associates' Patent* BL O/89/81).

PR part 7 r.75 r.76(3)(c) r.108(1)

r.82

Notice of opposition should be given on Form 15 which should be filed in duplicate within four weeks of the date of the advertisement in the Journal announcing the amendments as open to opposition (see 27.16, 27.17). Except where proceedings are pending before the court or comptroller in which validity is put in issue (see 27.21 - 27.21.1), this period may not be extended. The notice should be accompanied by a copy thereof and a statement of grounds (in duplicate). This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 - 123.05.13.

If, having been notified of the opposition, the applicant for amendment does not file a counter-statement he will under r.77(9) be treated as supporting the opponent's case. In that event, the applicant for amendment should be informed in an official letter that, subject to comments within a specified period (normally 14 days), the applicant will forfeit the right to take any further part in the opposition proceedings. A copy of the official letter should be sent to the opponent. In Norsk Hydro's Patent [1997] RPC 89 (decided under r.40(4) of the Patents Rules 1995 which required the applicant to file a counter-statement if he wished to continue with the application) it was held that the comptroller had jurisdiction to allow a request for extension to the period retrospectively as a matter of discretion. In the particular instance it was not appropriate to exercise that discretion because at the material time (the end of the specified period) it was not evident that N did not wish the application for amendment to be withdrawn.

[Tribunal is responsible for sending the respective copies to the applicant and the opponent.]

27.26.1 Any offer of alternative amendments should be made in the counter-statement, with the applicant for amendment making it clear whether the offer is a firm one or is conditional upon an adverse finding on the originally requested amendments. Such alternative amendments should be submitted in accordance with the procedure set out in 27.13.

27.27 The comptroller may give such directions as he thinks fit with regard to the subsequent procedure. Thus, if the alternative amendments are significantly different from the

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original ones, a further notice announcing a new opposition period should be made in the Journal (see 27.17), making it clear whether they supersede or are conditional upon the refusal of the amendments previously open to opposition. In any case, the opponent(s) to the amendments as originally requested should be given the opportunity to file a supplementary statement opposing the new amendments and setting out the grounds for so doing. Any objection to the alternative amendments by the Office should also be reported as outlined in 27.12. If a form of amendment acceptable to the parties and the Office is not arrived at, the matter will need to be decided at a hearing (see 27.29).

[The alternative amendments offered should be referred to the Deputy Director in charge of the subject matter to which the specification relates. amendments are significantly different from those originally requested, the Deputy Director should defer his consideration until after the new amendments have been advertised. Hearings on opposed s.27 proceedings are taken by a Divisional Director.

27.27.1 Following the hearing officer's decision in Intel Corporation's Patent [2002] RPC 48, the evidence rounds are generally reversed, so that the applicant for amendment will normally have the first evidence round. The hearing officer - while accepting that in opposed amendment proceedings both sides have a substantial onus to discharge - could see no good reason why the evidence rounds should differ from the normal procedure in the Patents Court for opposed amendments under s.75. He also made clear that the possibility remains of requiring the opponent(s) to go first if circumstances justify that, or of requiring the first two evidence rounds to be conducted in parallel.

- 27.28 Both in the notice of opposition and supporting statement and in any subsequent proceedings the opponent must address himself solely to the allowability of the proposed amendments, and may not attack the validity of the patent as it would be after amendment, except that if the amendments have been sought in order to remove an admitted defect casting doubt on the validity of the patent, the opponent may argue that the proposed amendments are not adequate to remove the defect (James Gibbons Ltd's Application [1957] RPC 158, Bridgestone Tire KK's Patent - BL O/166/92). The opponent may not object that the proposed amendment would introduce plurality of invention (see 26.01).
 - The fact of allowance or refusal of the amendments is advertised in the Journal. If the form of the amendments eventually found acceptable differs materially from the original form, the decision allowing them should be an interim one, and an advertisement announcing the provisionally allowed amendments as open to opposition should be made. In Clear Focus Imaging Inc. v Contra Vision Ltd (Patents Court, 16 November 2001, unreported) Jacob J emphasised that the decision to re-advertise or not is pre-eminently a matter of discretion of the hearing officer. Furthermore, he noted that re-advertisement is not ordered in the interests of any existing opponent to the amendment; it is done to alert other potential opponents. Neither is it ordered to account for latecomers who, had they known, might have wished to oppose the amendments from the outset.
 - Under the 1949 Act the opponent was not normally required to pay costs, whatever the outcome of the opposition (see BTH Co Ltd's Patent, 53 RPC 255). However the ordering of an opponent to pay costs is clearly envisaged by section 107 in view of the specific reference to section 27(5) in section 107(4)(c) which provides that an opponent who neither resides or carries on business in the United Kingdom may be required to give security for costs.
 - 27.31 Where an opposition to the amendments has been properly launched by the filing of Form 15 accompanied by a supporting statement, but the opponent subsequently withdraws at any stage, the comptroller nevertheless takes account of matters raised by the opponent in deciding whether discretion to allow amendment should be exercised (Ministry of Agriculture, Fisheries and Food's Patent, BL O/11/92). If no agreement is reached with the applicant, an ex parte hearing is held as described in 27.17.

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s.74(2)s.26

[The matters raised by an opponent prior to the withdrawal of an opposition should be considered by the hearing officer, if one has been appointed (see 27.14), or otherwise the Deputy Director originally charged with the assessment of the amendments (see 27.12).]

Section 27(6)

In considering whether or not to allow an application under this section, the comptroller shall have regard to any relevant principles under the European Patent Convention.

Section 27(1) confers on the comptroller discretion to allow or refuse an amendment to the patent. Articles 105a(1) and 123 EPC also confer on the EPO discretion to allow or refuse an amendment of the European patent. The comptroller continues to have discretion to allow or refuse an amendment, but in exercising that discretion, section 27(6) requires the comptroller to have regard to any relevant principles which are applicable to amendment or limitation proceedings under the EPC. These may include relevant regulations made under the EPC, any relevant guidelines produced by the EPO, and decisions of the Opposition Division and Boards of Appeal. This should ensure that, as far as possible, there is consistency in approach as regards post-grant amendment in national proceedings and before the EPO. The EPO do not consider the behaviour of the patent proprietor when exercising discretion in allowing amendments. The intended effect of section 27(6) is that the behaviour of the patent proprietor will no longer be an issue to be considered in the UK when deciding whether to allow an amendment to be made under section 27. This effect was confirmed by Floyd J in Zipher v Markem (see 27.08 and below).

27.32.1 In *Zipher Ltd v Markem Systems Ltd & Anr* [2008] EWCH 1379 (Pat), Floyd J summarised the position under the EPC as follows:

- i) in opposition proceedings, appropriateness of the amendments to the proceedings, their necessity and procedural fairness are the main, perhaps only, factors considered relevant to the discretion to allow amendment:
- ii) in central amendment proceedings, compliance with the procedural requirements gives rise to a right to have the patent limited in accordance with the request.

These are therefore the factors which should be taken into account when considering whether or not to allow an amendment under this section.

In central limitation before the EPO it is only necessary to meet the procedural requirements in order for a patent to have its claims centrally limited. There is no assessment of novelty or inventiveness of the proposed claims in this process and it has been argued that these aspects should not be considered for amendments under section 27 since section 27(6) requires the comptroller to have regard to relevant principles under the EPC. However, amendment under section 27 in the UK is still subject to the comptroller's discretion and although central limitation is a similar process to amendment under section 27 it is not an identical process. The main differences between the two processes are that i) no reason need be supplied for central limitation at the EPO while rule 35(1)(c) requires a reason to be provided for amendment under section 27, ii) there is no opportunity for third party opposition to central limitation while section 27(5) provides for third party opposition to the proposed amendments and iii) the EPC requires that the claims are a limitation of the granted claims while section 27 does not have such a requirement (though section 76 essentially means that they must be). Section 27 still gives the comptroller discretion to allow or refuse an amendment provided he has had regard to the relevant EPO principles. As long as he has exercised his discretion reasonably and judicially there is no reason why he should not exercise that discretion. Having given regard to the principles of the EPC with respect to central limitation and having sufficiently distinguished the two processes, the reasonable conclusion is that the lack of discretion for the EPO to refuse a central limitation request meeting the formal requirements does not limit the comptroller's discretion to refuse an amendment under section 27 on the basis of lack of novelty or inventiveness of the proposed

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amendment.

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Section 28: Restoration of lapsed patents

This section specifies the circumstances under which a patent which has lapsed through failure to pay renewal fees may be restored. It governs patents granted under the 1977 Act and European patents (UK) which have lapsed due to failure to pay renewal fees due to the Office (see 25.08-25.08.1 and 25.13-25.13.1). Relevant procedures are prescribed in r.40. The Regulatory Reform (Patents) Order 2004, which entered into force on 1 January 2005 amended this section by replacing the previous condition for restoration, namely "reasonable care" with "unintentional". The latter standard applies to patents that ceased (as defined by section 25(3)) on or after 1 January 2005. For patents that ceased before 1 January 2005, the comptroller will continue to apply the standard of "reasonable care".

Section 28(1)

Where a patent has ceased to have effect by reason of a failure to pay any renewal fee, an application for the restoration of the patent may be made to the comptroller within the prescribed period.

Section 28(1A)

Rules prescribing that period may contain such transitional provisions and savings as appear to the Secretary of State to be necessary or expedient.

r.40(2), (4), 28.02 An application for restoration should be made on Form 16, on which should be stated the reasons for the application. These must be supported by evidence, and if that evidence does not accompany the application then the comptroller will specify a period r.81 within which it must be filed. r.108(1)

> 28.03 A mere attempt to pay the renewal fees does not constitute an application for restoration (Dynamics Research and Manufacturing Inc's Patent, [1980] RPC 179); Electricité de France (EDF)'s Patents, [1992] RPC 205).

r.41 Once the extended period for paying renewal fees has expired the Office 28.04 is obliged to draw the attention of the proprietor to the provisions of s.28 (see 25.15). In Daido Kogyo KK's Patent, [1984] RPC 97 discretion was exercised under r.100 of the Patents Rules 1995 to allow an application for restoration to be filed out of time since this reminder had not been issued at the proper time. In view of this, the Court of Appeal recommended that all applications for restoration, even though apparently too late to have effect, should be entered in the Register (see 28.05.1).

r.40(1) 28.04.1 The prescribed period under s.28(1) is thirteen months after the end of the period specified in section 25(4) and cannot be altered. For example, if the anniversary of the filing date of the patent falls on 10 May, the renewal fee will be due by 31 May each year. If the renewal fee for 2006 is not paid by 30 November 2006 (i.e. the end of the six month period specified in section 25(4)), the patent will be treated as ceased on 10 May 2006. The thirteen month period allowed to make an application for restoration will begin on 1 December 2006 and expire on 31 December 2007.

Section 28(2)

An application under this section may be made by the person who was the proprietor of the patent or by any other person who would have been entitled to the patent if it had not ceased to have effect; and where the patent was held by two or more persons jointly, the application may, with the leave of the comptroller, be made by one or more of them without joining the others.

28.05 By virtue of the reference to "any other person who would have been entitled", an application for restoration may be made by a person who has acquired the

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(5)

Sch 4, Part

patent after it has lapsed, for example by assignment (*Border's Patent BL O/157/79*). If the assignment has not been entered in the Register, proof of ownership must be provided as part of the evidence to which 28.02 refers. A potential proprietor, to whom the patent would later be assigned if it were to be successfully restored, is not "any other person who would have been entitled" (*Vause's European Patent BL O/278/00*).

Section 28(2A)

Notice of the application shall be published by the comptroller in the prescribed manner.

r.40(1), (2) 28.05.1 An application for restoration is advertised in the Journal and noted in the register. The advertisement constitutes the notice required by subsection (2A) and concludes the period referred to in s.28A(4), see 28A.03.

Section 28(3)

If the comptroller is satisfied that the failure of the proprietor of the patent -

- (a) to pay the renewal fee within the prescribed period; or
- (b) to pay that fee and any prescribed additional fee within the period ending with the sixth month after the month in which the prescribed period ended,

was unintentional, the comptroller shall by order restore the patent on payment of any unpaid renewal fee and any prescribed additional fee.

- r.40(6)-(8) If, on consideration of the statements in the application for restoration and of the supporting evidence, the Office comes to the conclusion that a case has not been made out, then the applicant is sent a "minded to refuse" letter containing reasons for the conclusions drawn. The applicant is given one month to respond to this letter and to provide further evidence if applicable. If no further evidence is supplied, or if the evidence does not convince the Office to change its opinion, a further letter is issued advising the applicant that, unless within a further one month he requests to be heard, the application for restoration will be formally refused. If no request for a hearing is received within this time, a formal decision is issued refusing to order restoration of the patent unless the Office has been formally notified in writing that the application has been withdrawn, in which case only an acknowledgement of receipt of the notification is issued. If the applicant asks for a hearing within the time allowed, then he must be given an opportunity to be heard, following which either a decision refusing the application is given or a conditional offer of restoration is made. An order restoring the patent is issued when the conditions, which include the payment of fees due (see 28.07), have been met. There is no provision for an application for restoration to be opposed.
- r.36(4)
 28.07 If it is decided, with or without a hearing, that the patent may be restored, the applicant must first file Form 12, together with the unpaid renewal fees. The comptroller will specify a period within which the form and fees must be filed (usually two months of notification of the decision being sent to the applicant). This specified period may be extended under section 117B and rule 109, see 117B.01-0.5. A formal order is then issued restoring the patent.
- r.40(9) 28.08 The final decision allowing or refusing restoration is advertised in the Journal and noted in the Register. Similar action is taken when applications are formally withdrawn. If there is some doubt as to whether a notification is intended to be a withdrawal, the Office informs the applicant that it intends treating the notification as a withdrawal and, unless within one month the Office hears to the contrary, the Register will be noted accordingly.

Meaning of unintentional

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- 28.09 As with the more stringent standard of "reasonable care" (see 28.10 to 28.16), there is no definition in the Act or rules as to what is meant by "unintentional" as it applies for determining whether to allow a request for restoration. In Sirna Therapeutics Inc's Application [2006] RPC 12, which related to a request to make a late declaration of priority under section 5(2B), the hearing officer observed that the requirement to show an intention to file an application in time differed from the test of "continual underlying intention to proceed" that was applied in Heatex Group Ltd's Application ([1995] RPC 546) in deciding whether to exercise discretion favourably to allow a period of time to be extended under rule 108 (see 123.37). However, case law under rule 108 may be of relevance in analysing the evidence to establish the applicant's intentions. In Anning's Application (BL O/374/06), which related to a request for reinstatement under section 20A, the hearing officer took a similar approach and warned against the danger of going beyond the clear meaning of the statute. He interpreted "unintentional" according to its normal English meaning. In this case the hearing officer held that although there was a continual underlying intention to proceed it did not follow that the failure to reply to an examination report was unintentional.
- 28.09.1 Sirna Therapeutics Inc's Application [2006] RPC 12 and Anning's Application (BL O/374/06) established that the "continual underlying intention" test in Heatex is <u>not</u> applicable in determining the meaning of the word "unintentional" (in section 5(2B) or section 20A and it follows, in section 28(3) either).
- 28.09.2 In *Matsushita Electric Industrial Co. v Comptroller General of Patents* [2008] EWHC 2071 (Pat), [2008] RPC 35, Mr. Justice Mann gave some guidance on the level of evidential burden required to "satisfy" the Comptroller that the failure in section 28(3) was "unintentional". The applicant in that case chose not to file any evidence beyond a bald assertion of the statute that the failure to pay the renewal fee on time was unintentional. It argued that that was all the statute required to satisfy the comptroller. It was held by the Judge that a mere assertion that the failure to pay the renewal fee was unintentional is not sufficient to enable the Comptroller to determine that the requirements of s.28(3) are fulfilled. He said:
 - "...the Act requires a judgment to be formed by the Comptroller so that he can be satisfied of the relevant matters. A judgment usually has to be made on the basis of evidence... The evidence required in any particular case where satisfaction is required depends on the nature of the enquiry and the nature and purpose of the decision to be made... A significant matter requires significant proof. I repeat, the Act does not require a statement that the failure to pay fees was unintentional. It requires the Comptroller to be satisfied of that fact."
- 28.09.3 It is clear from this judgment that while there is no universal rule as to what level of evidence has to be provided to satisfy the comptroller of the unintentional lapse in section 28(3) (and by implication in sections 5(2B) and 20A), some evidence above and beyond a bald assertion of the law is required.

Meaning of reasonable care

28.10 For patents that lapsed before 1 January 2005, the standard of "reasonable care" applies when determining whether a patent should be restored, i.e. the comptroller will need to be satisfied that the proprietor took reasonable care to see that the renewal fee was paid within the prescribed period or that the renewal fee and any prescribed additional fee were paid within the six months immediately following the end of that period. In deciding whether or not a proprietor took reasonable care it is appropriate to bear in mind the direction given by the judge in *Continental Manufacturing & Sales Inc's Patent* [1994] RPC 535:

"The words 'reasonable care' do not need explanation. The standard is that required of the particular patentee acting reasonably in ensuring that the fee is paid."

28.11 The proprietor is reminded at the time of grant of the need for setting up effective renewal arrangements (see 24.03), and the reminder issued under r.39 (see 25.12)

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is not intended to be a substitute for such a system but to alert the proprietor to a breakdown in his own system. However in *Ling's Patent* and *Wilson's and Pearce's Patent*, [1981] RPC 85, it was held that it was reasonable for an individual in a small way of business who has taken upon himself to pay renewal fees without professional assistance to rely on these reminders. Similarly, in *Frazer's Patent*, [1981] RPC 53, it was held that a "reasonable lone patentee" who had put his patent affairs in the hands of his solicitor had exercised due care, and the failure of the solicitor to pay renewal fees was a circumstance beyond the proprietor's control; for a person in this situation the normal rule that a principal stands in the shoes of his agent did not apply. However, a company of some size owning several patents might be expected to have on its staff a person responsible for dealing with patent matters, and the failure to do so indicates a lack of reasonable care (*Societe Minerve SA's Patent*, BL O/55/82). In *Marbourn's Patent* (BL O/376/99) restoration was allowed where a previously effective system within a company broke down following restructuring of the company as a result of decisions which could not reasonably have been foreseen by the director responsible for ensuring that the patent was renewed.

While the placing of responsibility for renewal fees in the hands of a professional adviser may be considered to amount to reasonable care (Frazer's Patent - see 28.11), the Patents Court agreed that a proprietor who had entrusted the payment of renewal fees to a person holding a licence under the patent had not shown sufficient care to justify restoration (Lichtenstein's Patent, BL O/152/83, BL C/34/84) (although this was decided on the facts of the case and may not always be so); the same is true where the task is left to staff employed by the proprietor who are inadequately instructed or supervised (Zarach's Patent, not reported; Tekdata Ltd's Patent, [1985] RPC 201 and Luthy's Patent, not reported) or to one of the co-proprietors (Ho and Wang's Patent, BL O/152/87). In Textron [1989] RPC 441, the House of Lords held that the patentee must, in each case, take reasonable care in the selection of an agent or servant and in the instructions and arrangements for payment. When placing the responsibility for payment of renewal fees in the hands of others, the proprietor is expected to have checked that an effective renewal system is in place and that a dependable address is provided to which reminders can be forwarded (University of Chicago's Patent, BL O/44/91). Nevertheless, in Pritchard's Patent (BL O/104/96) a proprietor who paid insufficient attention to reminders from his agent and failed to pay a renewal fee in time was held not to have exercised reasonable care. In Gram's Patent (BL O/412/99) a proprietor acting for himself in renewals matters following a dispute with his representatives was held to have taken reasonable care, despite his mistaken belief that he could pay the renewal fee up to six months after the end of the month in which the anniversary of filing fell, because of a unique set of circumstances which led him towards that belief and the fact that the reminder notice which would have disabused him of this notion was not forwarded to him by his representatives. The allocation to a trusted and hitherto reliable employee of the task of checking the payment of renewal fees was held to be a reasonable system for ensuring their payment. Following Textron, the Patents Court ordered restoration of Sony Corporation's Patent ([1990] RPC 152), holding that Sony exercised reasonable care by operating a system whereby competent agents were responsible for paying renewal fees and in extraordinary cases the matter came before a competent employee part of whose duty it was to take the appropriate steps. That employee made a mistake which was contrary to his duties and therefore outside the control of Sony; they could not be reasonably expected to ensure that it would not happen. In the case of a corporate proprietor regard should be given to the words of Lord Oliver in Textron at page 453, lines 31-44, when deciding who should be regarded as the "proprietor by his directing mind" for the purposes of s.28(3). However, a failure by a senior employee responsible for patent matters (and serving for that purpose as the "directing mind" of the proprietor) was held, following Textron, to constitute lack of reasonable care (British Broadcasting Corporation's Patent, BL O/49/89).

28.13 In *Ling's Patent* and *Wilson's and Pearce's Patent* (see 28.11) it was observed that if a proprietor were to fail to notify the Office of a change of address, then failure to receive the statutory notice would undoubtedly be his fault. Likewise a proprietor who takes his patent affairs out of the hands of the agent who has prosecuted the application but fails to provide the Office with an address for service or an address for renewal reminders (see 25.12) will be regarded as not having exercised reasonable care (*Convex Ltd's Patent*,

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[1980] RPC 423; Francis' Patent, BL O/154/82). The same is true of a person who does not inform an agent acting for him of a change of address (*Nakumura's Patent*, BL O/121/84; *Samuels' Patent*, not reported) or of a temporary absence (*Whiteside's Patent*, BL O/44/84; *Singleton's Patent*, not reported).

- Restoration may be allowed where a proprietor who has set up a reasonable system for paying renewal fees is prevented by ill health from playing his part in the system (*Mead's Patent*, [1980] RPC 146) although being stressed and run-down has been found inadequate to justify restoration (*Linkrose Ltd's Patent*, BL O/117/90). The Office would expect claims that ill health was the reason for not paying a renewal fee to be supported by medical evidence. However, an application will not be successful even if it is demonstrated that failure to pay in time was due to difficult personal circumstances if the proprietor has not shown reasonable care in the first place by setting up a system (*Warwick's Patent*, BL O/150/82). Similarly, in *Marcel J Paulus's Patent* (BL O/73/95) (upheld on appeal) restoration was refused because the renewal system put in place by the proprietor collapsed completely when he died and no alternative arrangements for maintaining the patent were introduced even though at least one member of the family knew of the existence of the patent.
- 28.14.1 The fact that a proprietor has set up a system which is reasonable for the renewal of patents in general will not necessarily justify restoration. In *The Cement and Concrete Association's Patent*, [1984] RPC 131 a system which had worked adequately for other patents failed to alert the person responsible for deciding whether to pay renewal fees to the fact that the proprietor was under an obligation to a licensee to keep the patent in force; the Patents Court held that, whatever the merits of the system in general, there had not been reasonable care in the case of the particular patent in suit. The failure to pay renewal fees was the result of a conscious decision, albeit one made in ignorance of important facts. Similarly, employing a computer system which did not cater for a date of grant close to the renewal date of *Halcon's Patent* (BL O/94/85) did not amount to reasonable care.
- 28.15 In Atlas Powder Co's Patent [1995] RPC 357 (upheld on Appeal) Aldous J concluded that s.28 is not there to alleviate proprietors from decisions not to pay the fees, even though such proprietors may have taken reasonable care to come to a correct decision. Thus a proprietor who decides not to pay a fee cannot have his patent restored. He will not have taken any care to see that the fee was paid even though he may have taken reasonable care to decide whether to pay the fee. It makes no difference if the decision not to pay a renewal fee was based on facts subsequently shown to be incomplete or inaccurate (also Walters' Patent, BL O/105/91). This is in line with the intention of the 1977 Act to impose on the proprietor the need to take a greater degree of care to see that the fee was paid than was required under the 1949 Act where all the proprietor had to show was that failure to pay the fee was unintentional. In Lermer Gmbh's Patent (BL O/14/96) it was alleged that the person who had ordered that the patent should not be renewed had exceeded his authority. Restoration was refused because the applicant for restoration failed to establish whose responsibility it had been to decide whether to renew and so had not shown that there had been an effective system in place to ensure payment of the renewal fee.
- 28.15.1 In Ament's Application [1994] RPC 647 the Patents Court rejected a long-standing practice of the Office in regarding the inability of a proprietor to pay a renewal fee because of lack of funds and the attendant absence of any attempt to pay the fee as amounting to lack of reasonable care to see that the fee was paid. It was held that comments made by the Appeal Board in Radakovic (J/22/88 OJEPO 5/90 applied with equal force to section 28(3) as they did to Article 122 EPC [1973]. These comments were to the effect that for "all due care" to be proven it must be clear that the financial difficulties were genuine and were due to circumstances beyond the reasonable control of the applicant, and it was also necessary for the applicant to have shown diligence in seeking financial assistance. The onus is on the applicants for restoration to establish that they wanted to pay the fee and had exercised reasonable care to ensure that they were in a position to pay (in Ament's Application sufficient evidence was not provided). That may require seeking

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financial assistance and in appropriate cases taking reasonable care to avoid impecuniousity. The comptroller has no discretion to waive fees or to provide periods for their payment other than those provided in the Rules (*Halpern & Ward's Patent*, BL C/14/93; *EPS Research's Patent*, BL O/53/92).

The responsibility for taking reasonable care to see that renewal fees are paid falls to the actual proprietor (at the time the fees could have been paid), and not to the registered proprietor if different. Thus if the patent is assigned, the obligation passes to the new proprietor, irrespective of whether or not the assignment is registered (Whiteside's Patent, BL O/44/84). It is the responsibility of a person acquiring a patent to take steps to discover the true position regarding renewals (Advocat Giovanni Gozzo AB's Patent (BL O/150/95), Uniworld Trade and Finance Establishment's Patent, not reported). In Latchworth Ltd's Patent (BL O/112/96) where the applicant company had been struck off the Companies Register and dissolved, causing ownership of the patent to pass to the Crown a few days before it was granted and to remain so for the entire period that the renewal fee could have been paid, restoration was refused because there was no evidence to demonstrate that the Crown took reasonable care to see that the renewal fee was paid and the indications were that the Crown would not take any such care in the circumstances. Failure to make adequate arrangements at change of patent proprietorship on takeover or transfer of assets was also found to involve lack of reasonable care in the unreported decisions on Reiss Engineering's Patents (BL O/180/86), Dytap Revetments' Patent (BL O/76/87), Triten Corp's Patent (BL O/65/88), BWS Management's Patent (BL O/113/90) and Fisher Westmoreland's Patent (BL O/151/90).

Section 28(4)

An order under this section may be made subject to such conditions as the comptroller thinks fit (including a condition requiring compliance with any provisions of the rules relating to registration which have not been complied with), and if the proprietor of the patent does not comply with any condition of such an order the comptroller may revoke the order and give such directions consequential on the revocation as he thinks fit.

28.17 If it is considered that, in the circumstances of a particular case, the protection given to third parties by s.28A(4) to (6) (see 28A.03) is not adequate, an order for restoration may vary the provisions of those subsections. In *Daido Kogyo KK's Patent* [1984] RPC 97, where the Court allowed an application for restoration which had not been entered on the Register since it had apparently been lodged out of time (see 28.04), the Court of Appeal upheld an order making it a condition of restoration that the protection given to anyone who takes steps to begin to work the invention should be extended until the time when the order was actually made.

28.18 Subsections (5) to (9) concerning the effect of restoration were repealed, and replaced by section 28A, by the CDP Act.

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Section 28A: Effect of order for restoration of patent

28A.01 Section 28A concerns the effect of an order by the comptroller for the restoration of a patent under s.28(3).

Section 28A(1)

The effect of an order for the restoration of a patent is as follows.

Section 28A(2)

Anything done under or in relation to the patent during the period between expiry and restoration shall be treated as valid.

28A.02 [deleted]

Section 28A(3)

Anything done during that period which would have constituted an infringement if the patent had not expired shall be treated as an infringement-

- (a) if done at a time when it was possible for the patent to be renewed under section 25(4), or
- (b) if it was a continuation or repetition of an earlier infringing act.

Section 28A(4)

If after it was no longer possible for the patent to be so renewed, and before publication of notice of the application for restoration, a person -

- (a) began in good faith to do an act which would have constituted an infringement of the patent if it had not expired, or
- (b) made in good faith effective and serious preparations to do such an act,

he has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the restoration of the patent; but this right does not extend to granting a licence to another person to do the act.

Section 28A(5)

If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (4) may -

(a) authorise the doing of that act by any partners of his for the time being in that business, and

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(b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.

Section 28A(6)

Where a product is disposed of to another in exercise of the rights conferred by subsection (4) or (5), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent.

28A.03 Subsections (4) to (6) give protection to persons who take steps to work an invention which is the subject of a lapsed patent before notice of an application for restoration is published (see 28.05.1). They are free not only to continue what they have started without infringing the restored patent, but also to pass their right to work the invention to others (but not to license others to work the invention). However, this protection does not apply to steps taken during the six months period of grace under s.25(4) in which late renewal is still possible. Subsection (3) provides that steps taken during that grace period will still infringe, and that steps taken during the period between expiry and restoration which are a continuation or repetition of earlier infringing ones are also infringements.

Section 28A(7)

The above provisions apply in relation to the use of a patent for the services of the Crown as they apply in relation to infringement of the patent.

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Section 29: Surrender of patents

s.77(1) 29.01 This section provides for the surrender of patents, including European patents (UK), and for opposition by a third party to an offer to surrender. Procedures are prescribed by r.42 and Part 7 – Proceedings before the Comptroller.

Section 29(1)

The proprietor of a patent may at any time by notice given to the comptroller offer to surrender his patent.

r.42 29.02 Notice of an offer by a proprietor to surrender his patent should be given in and r.75 writing. The offer must then be advertised by the comptroller in the Journal.

29.03 The offer to surrender should be accompanied by either (a) a declaration that no infringement or revocation action relating to the patent is pending before the court; or (b) if such action is pending, full particulars of the action in writing. Where a revocation action is pending before the court, the comptroller may stay any consideration of the offer to surrender and order the proprietor to inform the court that an offer to surrender has been made (Dyson Ltd's Patent [2003] RPC 24 and [2003] RPC 48). Genentech Inc's patent (BL O/360/14) related to an offer to the comptroller to surrender a patent, where a revocation action was pending before the court. The patentee had already informed the claimant in the revocation action, as well as the court itself, of the offer to surrender. In addition, the court had issued a judgment stating the patentee had "applied to the UK IPO and surrendered the ... patent. Therefore there is no patent and no reason to continue the [revocation] action in relation to that patent". It was therefore clear that all parties had proceeded on the basis that the patent had been surrendered. In addition, no one opposed the offer to surrender. The hearing officer therefore determined that the offer to surrender could be accepted prior to the resolution of the revocation proceedings. More generally, the hearing officer found that if it is clear that the court, the claimant and patent holder in a revocation action are all aware that an offer of surrender has been made to the comptroller, and have proceeded on the basis that it has taken effect, then that offer to surrender should be accepted without the need to wait for the resolution of the revocation proceedings (subject to advertisement of the offer, and subject to any opposition being satisfactorily dealt with). For procedure where a revocation action is pending before the comptroller when the offer to surrender is made, see 72.36-72.39.

Section 29(2)

A person may give notice to the comptroller of his opposition to the surrender of a patent under this section, and if he does so the comptroller shall notify the proprietor of the patent and determine the question.

r.76(3) 29.04 Any person who wishes to oppose the surrender must do so on Form 15 r.108(1) within four weeks from the date of the advertisement. This period may not be extended. There is no need for an opponent to have a *locus standi*.

PR part 7 29.05 The Form should be accompanied by a copy and a statement of grounds (in duplicate) This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.13.

29.06 If proceedings to revoke the patent are pending before the comptroller the opposition to surrender will normally be stayed pending the outcome of the revocation action (see 72.36-72.39).

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Section 29(3)

If the comptroller is satisfied that the patent may properly be surrendered, he may accept the offer and, as from the date when notice of his acceptance is published in the journal, the patent shall cease to have effect, but no action for infringement shall lie in respect of any act done before that date and no right to compensation shall accrue for any use of the patented invention before that date for the services of the Crown.

s.73(4) 29.07 If the comptroller accepts the offer to surrender this takes effect *ex nunc*. Consequently although no action can be taken in respect of an infringement which has taken place before the date on which the acceptance is advertised in the Journal, any royalties or other monies already paid to the proprietor cannot be recovered. Moreover since a prima facie valid patent will have been in existence for a period of time, however short, up to the surrender, an offer to surrender will not automatically terminate revocation proceedings (see 72.36). In addition, surrender of a European patent (UK) will only obviate revocation of a national patent with which it is in conflict if the offer to surrender is made before the date on which the notice of grant of the national patent appears in the Journal; see 73.11-12.

[If no revocation proceedings are pending and the offer to surrender is not opposed, an acceptance of the offer to surrender should be prepared by Restoration and Post Grant Section (RAPS) and sent for signature to the Deputy Director of the group to which the subject-matter of the patent belongs. If he decides that the patent may properly be surrendered, then after signing the acceptance he should return the case to RAPS for the acceptance of the offer to be advertised.]

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PROPERTY IN PATENTS AND APPLICATIONS, AND REGISTRATION

Section 30: Nature of, and transactions in, patents and applications for patents

30.01 The nature of patents and applications as property, and transactions which may be made therein, are laid down in this section, except that it does not extend to Scotland where s.31 applies instead.

30.02 According to s.30, particularly sub-sections (1), (3) and (4), any patent or application is personal property; the patent or application and rights therein vest by operation of law in the same way as any other personal property.

s.77(1) 30.03 Section 30 applies in relation to not only 1977 Act patents and applications s.78(2) but also granted European patents (UK) and applications for European patents (UK).

Section 30(1)

Any patent or application for a patent is personal property (without being a thing in action), and any patent or any such application and rights in or under it may be transferred, created or granted in accordance with subsections (2) to (7) below.

Section 30(2)

Subject to section 36(3) below, any patent or any such application, or any right in it, may be assigned or mortgaged.

- s.36(3) 30.04 A patent or application or right therein may be assigned or mortgaged provided that, where two or more persons are proprietors of or applicants for a patent, all of the proprietors or applicants have consented (subject to ss.8, 12 and 37 (which relate to the determination of questions about entitlement to applications and patents) and to any agreement in force).
- s.130(1) 30.05 The term "right" in relation to any patent or application includes an interest in the patent or application; it has also been held to extend to the right to file a future application (see 130.22.1). Any reference to a right in a patent includes a reference to a share in the patent. A "mortgage" includes a charge for securing money or money's worth.

Section 30(3)

Any patent or any such application or right shall vest by operation of law in the same way as any other personal property and may be vested by an assent of personal representatives.

Section 30(4)

Subject to section 36(3) below, a licence may be granted under any patent or any such application for working the invention which is the subject of the patent or the application; and

(a) to the extent that the licence so provides, a sub-licence may be granted under any such licence and any such licence or sub-licence may be assigned or

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mortgaged; and

(b) any such licence or sub-licence shall vest by operation of law in the same way as any other personal property and may be vested by an assent of personal representatives.

30.06 Following the death of the proprietor or applicant, a patent or application or right therein or licence or sub-licence thereunder may be vested by an assent of personal representatives and can thus be disposed of in the same way as any other personal property (see 32.10 for registration procedure).

s.36(3) 30.07 The grant of licences etc as detailed in s.30(4), where two or more persons are proprietors of or applicants for a patent, again requires the consent of all of the proprietors or applicants (subject to ss.8, 12 and 37 (which relate to the determination of entitlement to applications and patents) and to any agreement in force).

Section 30(5)

Subsections (2) to (4) above shall have effect subject to the following provisions of this Act.

Section 30(6)

Any of the following transactions, that is to say -

- (a) any assignment or mortgage of a patent or any such application, or any right in a patent or any such application;
- (b) any assent relating to any patent or any such application or right;

shall be void unless it is in writing and is signed by or on behalf of the assignor or mortgagor (or, in the case of an assent or other transaction by a personal representative, by or on behalf of the personal representative).

Section 30(6A)

If a transaction mentioned in subsection (6) above is by a body corporate, reference in that subsection to such a transaction being signed by or on behalf of the assignor or mortgagor shall be taken to include references to its being under the seal of the body corporate.

30.08 Subsection (6) defines the form which certain transactions must take to avoid being treated as void for the purposes of the section. This subsection was deregulated by the Regulatory Reform (Patents) Order 2004 which replaced the requirement that a transaction must be signed by all parties to the transaction with a requirement that it only has to be signed by the assignor. The amended subsection applies to all transactions done outside Scotland and signed on or after 1 January 2005. Transactions done before that date will need to be signed by all parties to the assignment. See 30.05 with regard to the meanings of "right" and "mortgage" in the Act. In Hartington Conway Ltd's Patent Applications [2004] RPC 6, where the right in question was the right to file a future application, it was held that s.30(6) applied prior to filing a patent application and would therefore bite on assignments made at that time.

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Section 30(7)

An assignment of a patent or any such application or a share in it, and an exclusive licence granted under any patent or any such application, may confer on the assignee or licensee the right of the assignor or licensor to bring proceedings by virtue of section 61 or 69 below for a previous infringement or to bring proceedings under section 58 below for a previous act.

30.09 An assignment or exclusive licence may also transfer rights under ss.58 (with regard to previous Crown use), 61 and 69 (with regard to previous infringement) to the assignee or licensee.

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Section 31: Nature of, and transactions in, patents and applications for patents in Scotland

31.01 In Scotland, the nature of patents and applications as property, and transactions which may be made therein, are laid down by s.31 instead of by s.30. The provisions of the two sections are similar.

s.77(1) 31.02 Section 31 applies in relation to not only 1977 Act patents and applications s.78(2) but also granted European patents (UK) and applications for European patents (UK).

Section 31(1)

Section 30 above shall not extend to Scotland, but instead the following provisions of this section shall apply there.

Section 31(2)

Any patent or application for a patent, and any right in or under any patent or any such application, is incorporeal moveable property, and the provisions of the following subsections and of section 36(3) below shall apply to any grant of licences, assignations and securities in relation to such property.

- s.130(1) 31.03 A patent, application or right therein or thereunder is thus "incorporeal moveable property" in Scotland. The term "right" includes an interest in the patent or application. Any reference to a right in a patent includes a reference to a share in the patent.
- s.36(3) 31.04 Licences (including sub-licences), assignations and securities may be granted subject to s.31(3) to (7) and provided that, where two or more persons are proprietors of or applicants for a patent, one of them does not grant a licence or assignation or cause or permit security to be granted over the patent or application without the consent of the other or others (subject to ss.8, 12 and 37 (which relate to the determination of questions about entitlement to applications and patents) and to any agreement in force).

Section 31(3)

Any patent or any such application, or any right in it, may be assigned and security may be granted over a patent or any such application or right.

Section 31(4)

A licence may be granted, under any patent or any application for a patent, for working the invention which is the subject of the patent or the application.

Section 31(5)

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To the extent that any licence granted under subsection (4) above so provides, a sub-licence may be granted under any such licence and any such licence or sub-licence may be assigned and security may be granted over it.

Section 31(6)

Any assignation or grant of security under this section may be carried out only by writing subscribed in accordance with the Requirements of Writing (Scotland) Act 1995.

31.04.1 Section 31(6) was amended by the Requirements of Writing (Scotland) Act 1995. Where an assignment is done in Scotland the transaction document need only be signed by or on behalf of its granter at the end of the last page, rather than by or on behalf of all parties.

Section 31(7)

An assignation of a patent or application for a patent or a share in it, and an exclusive licence granted under any patent or any such application, may confer on the assignee or licensee the right of the assignor or licensor to bring proceedings by virtue of section 61 or 69 below for a previous infringement or to bring proceedings under section 58 below for a previous act.

31.05 Section 31(7) is virtually identical to s.30(7), see 30.09.

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Section 32: Register of patents, etc

32.01 The maintenance of a register of patents is required by this section which also provides for the making of rules relating to registration, correction of errors in the register, public inspection and copying of the register and other actions connected with the register. Rules 44-50 are the rules in question. Subsections (9) to (11) concern the status as evidence of the register of patents, comptroller's certificates and certified copies of entries in the register or of documents etc. Rules 46 and 48 prescribe the procedure for obtaining such certificates and copies etc.

s.77(1) s.78(4) s.89 Sch. 2 32.02 The section applies to applications for patents under the Act, including international applications (UK) which have been published under the PCT and entered the UK national phase (and are therefore treated as published under s.16), and to patents granted under the Act or under the EPC. Section 32 and the rules thereunder do not impose any requirements as to the registration of applications for European patents (UK). However, copies of entries relating to such applications in the European register of patents are entered in the register, see 32.07.

32.03 [deleted]

Section 32(1)

The comptroller shall maintain the register of patents, which shall comply with rules made by virtue of this section and shall be kept in accordance with such rules.

Section 32(2)

Without prejudice to any other provision of this Act or rules, rules may make provision with respect to the following matters, including provision imposing requirements as to any of those matters -

(a) the registration of patents and of published applications for patents;

Patents and published applications

- r.44(1) 32.04 An entry is not made in the register in respect of an application for a patent r.44(2) until the application is published under s.16. Upon such publication, the following are entered in the register:-
 - (a) the name and address of the applicant or applicants;
 - (b) the name and address of the person or persons stated by the applicant or applicants to be believed to be the inventor or inventors, unless the comptroller has accepted an application under r.11(1) for the inventor to waive his right to be mentioned (see 13.03);
 - (c) the title of the invention;
 - (d) the date of filing and the application number of the application for the patent;
 - (e) the date of filing and the application number of any application declared for the purposes of s.5(2) and the country it was filed in or in respect of;

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- (f) the date on which the application was published;
- the address for service of the applicant or applicants. (g)
- 32.05 The following are also entered in the register, as soon as practicable after r.44(3)-(6) the event to which they relate:
 - the date of filing of the request for substantive examination; (a)
 - the date on which the application is withdrawn, taken to be withdrawn, (b) treated as having been withdrawn, refused or treated as having been refused;
 - (c) the date on which the patent is granted;
 - the name and address of the person or persons to whom the patent is granted if different from the entries made in accordance with item (a) of 32.04:
 - the address for service if different from the entry made in accordance with item (g) of 32.04;
 - (f) certain matters in connection with a request for an opinion under s.74A, see 74A.01-13
 - notice of any transaction, instrument or event referred to in s.32(2)(b) or s.33(3), see 32.08.
- Such other particulars as the comptroller may think fit may be entered in the register at any r.44(7)time after s.16 publication. In addition to the matters referred to above and in 32.07, 32.08, 32.11 and 32.12, an entry is made on cessation of a patent under s.25(3); on the reference to the comptroller of a question or application under s.10 or 12(4) (disputes between joint applicants), s.11(5) or 38(5) (justification for grant of licence or its period or terms), s.13(1) and/or 13(3) (mention as inventor), s.27 (amendment of specification after grant), s.28 (restoration of patent), s.29 (surrender of patent), s.46 or 47 (licences of right), s.48 (compulsory licence), s.61(3) (infringement of patent), s.71 (declaration of non-infringement), s.72 (revocation of patent) or s.117 (correction of specification after grant); and on appeal to the Patents Court, Court of Appeal or House of Lords. Where appropriate, the outcome of the above events is also recorded in the register (but see 32.12 for proceedings in the courts).

A copy of an entry in or extract from the register should be requested on Patents Form 23.

Rule 49(1) provides that any person may request that a correction or change be entered in the register or made to any application or other document filed at the Office in respect of his name or his address, or that a correction be made to his address for service. This rule encompasses alterations to reflect changes that have occurred in names or addresses (such as a change in the applicant's name; see also 19.06-07) as well as corrections of typographical errors in names or addresses (see 117.17). A request to correct or change a name should be made on Patents Form 20. The correction or change of an address or the correction of an address for service may be advised by means of any written notification; it is not necessary to use a Patents Form, although Form 20 has been designed with this use in mind. The register is altered accordingly if the comptroller is satisfied that the request should be allowed. If the comptroller has reasonable doubts about whether he should make the correction or change, he must inform the person making the request of the reason for his doubts and he may require that person to file evidence in support of the request. The type of evidence required is described in 19.06. There is no need to request correction of the register where a body corporate has become a "public limited company" or "plc" (or the Welsh equivalent of either) with its name otherwise unchanged. Under the Patents (Companies Re-registration) Rules 1982, references to the name in the register (and in any application to the comptroller and in any other record kept at, or any document issued by, the Office and relating to patents) are treated from the date of the change as

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r.46

r.49

references to the new name. (If a request to amend the applicant's name on Form 1 is allowed, the register is amended in the same respect, see 19.07.) Similar provisions do not apply for conversions under the Limited Liability Partnership Act 2000 and its associated Regulations; transfer to a limited liability partnership (LLP) would be regarded as an assignment rather than a change of name, and would require recording in the register (see 32.08 to 32.12).

[Form 20 and accompanying documents to correct or change a name should be sent to Register Administration for action if it is indicated in part 4 of the form that correction under s.32(2)(d) is requested as a result of a change in a name. However, if correction of a typographical error is being requested under s.117, Form 20 and accompanying documents should be sent to Formalities (for pre-grant cases) or Restoration and Post Grant Section (RAPS) (for post-grant cases) for action.

[The Assignments Assistant should enter details of each patent or patent application in the Section's Record Book, giving each a different job number. The serial numbers of all patent or patent applications should be entered on the Report Sheet, as should any discrepancy between the existing name on the Register and the identification of that name in the application. The fact that an application under s.30 or s.32 has been filed should be entered on the COPS register for all patents or applications executed under the Patents Act 1977 or at the EPO. The files for ungranted cases are also endorsed. PDAX dossiers will have an "ASSIGNMENT" section created.

[When a change of name is requested, the Register and Form 20 should be checked to ensure that the original name is given consistently throughout. Supporting evidence should not routinely be requested unless some reasonable doubt exists as to the accuracy or veracity of what is presented, and if evidence is requested, the applicant must be informed what the doubt is. If proof is requested. the adequacy of the proof that is supplied should be considered and, if it is inadequate, a stock letter should be sent to the agent or applicant pointing out the deficiency. The change of name should have taken place after the filing date of the patent application, failing which the agent or applicant should be advised to consider applying for a correction of a clerical error, if that is applicable. If the change is allowed, the name in question should be altered in the Register on COPS. The agent or applicant should be informed by letter that alteration has been effected and a report sheet should be completed. For paper cases, the change of name folder should be placed at the back of the file in question or, if the change relates to more than one patent, the documents should be placed on the file of the highest publication number available. PDAX dossiers have an "ASSIGNMENT" section for such changes.

[In respect of all ungranted 1977 Act cases, the old name on Form 1 should be struck out and replaced by the new name in red capital letters. The alteration on Form 1 should be endorsed with "F20" and the date of receipt of the form and initialled. Form 20 should be signed and dated by the actioning officer.]

32.07 The comptroller is not required to keep entries in the register relating to published but ungranted applications for European patents (UK). The Register of European Patents, kept by the EPO under article 127 of the EPC should be consulted for information on such applications.

Section 32(2)

(b) the registration of transactions, instruments or events affecting rights in or under patents and applications;

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Transactions, instruments or events affecting rights

r.44(6)

32.08 The register contains notice of any transaction, instrument or event referred to in s.32(2)(b) or s.33(3). An agreement to assign, which operates in English law to create and vest in the buyer an immediate equitable interest, may thus be entered in the register as a transaction affecting rights in a patent but this is not itself an assignment or any of the other transactions, instruments or events specified in s.33 (*Coflexip Stena Offshore Limited's Patent* [1997] RPC 179).

r.47

32.09 An application to register, or to give notice to the comptroller of, any such transaction, instrument or event should be made on Patents Form 21 accompanied by the appropriate fee. The fact that such an application has been received is recorded in the register (when the application for a patent has been published). Rule 47 requires that such an application should include evidence establishing the transaction, instrument or event. Thus the form should be signed by or on behalf of the person or persons making the application, to confirm the changes to the rights affected by the transaction, instrument or event and that any necessary stamp duty has been paid (see below). If the Form is signed by or on behalf of at least the assignor, mortgagor or grantor of a licence or security, the application will normally be taken to include sufficient evidence to register the transaction, instrument or event. In such cases the comptroller will not normally require any additional evidence. However, he may require further evidence if the particular circumstances warrant it. In any case, further evidence sufficient to establish the transaction, instrument or event should accompany the form if (a) in the case of an assignment it is not signed by or on behalf of the assignor, or (b) in the case of a mortgage or the grant of a licence or security, where the mortgagor or grantor is not the applicant, it is not also signed by or on behalf of the mortgagor or grantor. For any documentary evidence not in English, a translation must be supplied.

r.113(1) r.113(2)

For discussion of the registration of transactions by co-owners of a patent, see 36.07.

The requirement for stamp duty to be paid on an instrument exclusively for the sale, transfer or other disposition of intellectual property (as defined in section 129(2) of the Finance Act 2000) was removed with effect from 28 March 2000 (by s.129 of the Finance Act 2000). Stamp duty remains chargeable on instruments which deal in part with intellectual property and in part with other property on which stamp duty is payable, as set out in Schedule 34 to the Finance Act 2000. If the applicant or other party enquires as to whether stamp duty is payable in relation to a transaction relating in part to intellectual property and in part to other property or in any other circumstances, e.g. in respect of transactions outside the UK, it will normally be necessary to advise that the enquiry should be referred to HM Revenue & Customs (HMRC).

In the case of a published application for a patent, details of a transaction, instrument or event may be recorded even if the application has been refused or withdrawn.

s.30(1),(2) r.55(g) If Form 21 relates to an unpublished application for a patent, details of the transaction, instrument or event concerned are published in the journal. If there is a change of ownership of the application, that is recorded on the Patents Form 1 in the application file. PDAX dossiers should have the Form 1 annotated and a minute added to the dossier.

In the case of a granted patent, details of a transaction, instrument or event may be entered on the register even if the patent has lapsed for non-payment of fees. These details may not be registered in respect of a revoked patent since revocation has effect ex tunc and the patent is therefore deemed never to have been granted. However, any register entries made prior to revocation remain on the register as a historical record. Similarly if a patent has been deemed void ab initio no recordal is possible.

When the Office is aware that there are proceedings before the court in which the ownership of the patent is at issue, the applicant for registration should be informed that the Office

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proposes to stay the application on Form 21 pending the final outcome of those proceedings unless the applicant provides evidence that the court is content for the substitution of the parties (under the procedure governed by Rule 19.4 of the Civil Procedure Rules) or supplies evidence that the other party consents to the registration. Where there are pending entitlement proceedings before the Comptroller, the request to register an assignment should be referred to the Hearing Officer. Unless special circumstances apply, the Hearing Officer should contact the claimant to determine if he is content with the registration. If the claimant is not content, the registration should be stayed until proceedings have been settled, but the fact that the request was made should be recorded on the register. In the case where the Office is aware of any proceedings before the court or the comptroller where ownership is not in issue, registration will normally be effected, save that for inter partes proceedings before the comptroller, the Hearing Officer should be alerted. Here, registration will have an impact on the proceedings because it is likely to change one of the parties, but this will have to be dealt with by an application for substitution or addition of a party.

The same procedure applies in relation to granted European patents (UK). Thus an application to register any transaction, instrument or event in respect of a granted EP(UK)should be made on a Form 21. A copy of EPO Form 2544 (notice of a change in the register issued by the EPO) is sufficient as the documentary evidence required by rule 46 in certain circumstances to support a Form 21. Although the EPO continues to record assignments up to the end of the opposition period (under EPC rule 85), this does not avoid the need for a Form 21 to be filed. For the purpose of recording assignments and other transactions in the register, the effective date of grant is the date on which notice of grant is published in the Bulletin (see 25.02).

[Forms 21 and any accompanying documents to register assignments etc should be referred to Assignment Section for action.

[In Assignments Section, an Assignments Assistant should check that the correct form and fee have been presented and advise the agent or applicant of any error. Cashier Section should hold the form (but not any supporting documents) and a note of the error until it is rectified. The Assignments Assistant should enter details of each application in the Section's Record Book, giving each patent or patent application affected a different job number. The serial numbers of all applications or patents affected should be entered on the Report Sheet, as should any discrepancy between the name and address of the assignor on the form or any transaction document and in the Register. The fact that an application under s.30 or s.32 has been filed should be entered on the COPS register for all patents or patent applications executed under the Patents Act 1977 or at the EPO. The files for ungranted cases are also endorsed. PDAX dossiers not yet published will have the "ASSIGNMENTS" section of the dossier completed.

[The contents of the Assignment Section (PDAX dossiers) or folder (paper cases) should be examined to check that the assignor is empowered to do so, that the patentee is the same as the one shown on the Register sheet, that any documents are dated and signed, any documents have been translated, any copies certified etc. If there is any deficiency, the agent or applicant should be informed of it in the standard letter. A suitable entry should be made in the Section's Record Book at this stage and again when a reply is received. Cases where there is doubt as to whether to effect registration while other proceedings are in train should be referred up. When all requirements are met, the Register should be altered accordingly. PDAX dossiers should have the "ASSIGNMENTS" section of the dossier completed. For paper cases, the assignment folder should be placed at the back of the file of the application or patent in question or, if the change relates to more than one patent, the documents should be placed on the file of the highest publication number available.

[The above procedure is for assignments but procedure is generally the same for mergers, licences, agreements and mortgages.]

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[The procedure in relation to a European patent (UK) is generally the same as for a domestic patent. If there is found to be no Register entry for the number quoted, a request should be made to the European Patent Filing Department to obtain a print-out. If that shows that the patent is granted and designates the UK, the matter must be referred back to the European Patent Filing Department to investigate the absence of the data and arrange for the necessary register to be created. Once that is done the request is entered in the Register and the normal procedure follows; if it does not designate the UK, the documents should be returned to the applicant giving the reason; or, if the patent is still in the application stage but designates the UK, the applicant should be advised that the matter should be referred to the EPO for registration. Prior to grant, European patents (UK) do not have a file in the UK. Files are raised as required. In the event of proceedings before the comptroller, a request for the file should be made to ensure that a file is not already in existence before a new file is raised. Suitable shells for such files may be obtained from the European Patent Filing Department.]

- 32.10 In the case of a deceased owner of a patent or application or right therein, a certified copy of the probate or letters of administration is required. The executor named therein should then complete an assignment as though he were the owner but where the executor and beneficiary are the same person or the named beneficiary is to be entered as the new owner a copy of the will or a signed statement by the executor is required. For overseas owners a personal representative who is resident in the UK must be appointed.
- r.44(7) 32.11 Provided that the patent application in question (or its UK equivalent) has been published under s.16, an entry is made in the register on the reference to the comptroller of a question under s.8(1) (determination before grant of questions about entitlement to a patent), s.12(1) (determination before grant of questions about entitlement to a foreign or convention patent) or s.37(1) (determination of right to patent after grant). For a s.12(1) reference relating to an application for a patent other than a European patent (UK), the entry is made under the UK equivalent (ie application for a UK national patent or EP(UK)) if such exists. Where a decision is issued in relation to any of the above, the outcome is recorded in the register.
 - 32.12 Where any order or direction has been made or given by the court, for example -
 - (a) transferring a patent or application or any right in or under it to any person;
 - (b) that an application should proceed in the name of any person; or
 - (c) revoking a patent;

the person in whose favour the order is made or the direction is given should send the comptroller written notice thereof accompanied by an office copy of such order or direction. The register is then rectified or altered accordingly. (Where the order or direction refers to amendment of a specification, see 75.13).

Section 32(2)

- (ba) the entering on the register of notices concerning opinions issued, or to be issued, under section 74A below:
- r.44(5), (7) 32.12.1 An entry is made on the register when -
 - (a) a request for an opinion under section 74A(1)(a) or (b) has been received;
 - (b) a request has been refused or withdrawn;

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- (c) an opinion has been issued; or
- (d) the comptroller thinks other particulars concerning opinions or requests should be entered.

Section 32(2)

(c) the furnishing to the comptroller of any prescribed documents or description of documents in connection with any matter which is required to be registered;

Furnishing of documents in connection with registration

32.13 Documents may be required in order to give grounds for a requested insertion or amendment of an entry in the register, see 32.06, 32.07, 32.09, 32.10, 32.12 and 32.14.

Section 32(2)

(d) the correction of errors in the register and in any documents filed at the Patent Office in connection with registration;

Correction of errors in register etc

- r.50 32.14 Correction of an error in the register or in any document filed in connection with registration must be requested in writing, accompanied by sufficient information to identify the nature of the error and the correction requested (see 32.06 if the requested correction is due to a change in a name, address or address for service). Written explanation of the reasons for the request or evidence in support of it may be called for in order to satisfy the comptroller that there is an error. If the comptroller is so satisfied, such correction as may be agreed between himself and the proprietor of the patent or applicant is made.
 - 32.14.1 The scope of the Comptroller's powers under r.50 was considered in <u>Virgin Atlantic Airways Ltd v Jet Airways Ltd [2013] R.P.C. 10</u>. A request had been made to the Office under r.50 to remove Virgin's European Patent (UK) from the register because, it was claimed, the UK designation was not valid on account of events that had taken place at the EPO pre-grant. The request was dismissed by the hearing officer in <u>BL O/281/11</u>. On appeal, the Patents Court held that the procedure under r.50 was only suitable for corrections of the kind likely to be agreed with the proprietor of (or applicant for) the patent. The Comptroller's power to make corrections under r.50 therefore did not extend to corrections of the kind sought in this case.

Section 32(2)

(e) the publication and advertisement of anything done under this Act or rules in relation to the register.

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Notices concerning register

r.45

32.15 The comptroller may arrange for the publication and advertisement of such things done under the Act or Rules in relation to the register as he may think fit. This is done by means of notices in the Journal.

Section 32(3)

Notwithstanding anything in subsection (2)(b) above, no notice of any trust, whether express, implied or constructive, shall be entered in the register and the comptroller shall not be affected by any such notice.

Section 32(4)

The register need not be kept in documentary form.

Register in non-documentary form

32.16 Subsection (4) (together with subsection (8) providing for inspection and copying of material on the register in non-documentary form) enables part(s) or all of the register to be kept in non-documentary form, in particular on a computer.

Section 32(5)

Subject to rules, the public shall have a right to inspect the register at the Patent Office at all convenient times.

Public inspection of register

r.46 s.32(8)(a) 32.17 The register (or entries or reproductions of entries in it) is available for inspection by the public at the Office in Newport or London between the hours of 9am and 5pm on weekdays, other than Saturdays and days which are specified as excluded days for the purposes of s.120. Register details are also available from the Online Patent Information and Document Inspection Service (Ipsum) on the Office website – see www.ipo.gov.uk/p-ipsum.htm. A copy of an entry in or extract from the register should be requested on Patents Form 23 accompanied by the appropriate fee. In the case of a non-documentary part of the register, the right of inspection is a right to inspect the material on the register.

Section 32(6)

Any person who applies for a certified copy of an entry in the register or a certified extract from the register shall be entitled to obtain such a copy or extract on payment of a fee prescribed in relation to certified copies and extracts; and rules may provide that any person who applies for an uncertified copy or extract shall be entitled to such a copy or extract on

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payment of a fee prescribed in relation to uncertified copies and extracts.

Section 32(7)

Applications under subsection (6) above or rules made by virtue of that subsection shall be made in such manner as may be prescribed.

Section 32(8)

In relation to any portion of the register kept otherwise than in documentary form-

- (a) the right of inspection conferred by subsection (5) above is a right to inspect the material on the register; and
- (b) the right to a copy or extract conferred by subsection (6) above or rules is a right to a copy or extract in a form in which it can be taken away and in which it is visible and legible.

Copies of entries; extracts

s.32(8)(b)
32.18 Copies of entries in the register and extracts from the register are obtainable, on application, in either certified or uncertified form. In the case of a non-documentary part of the register, both forms must be made visible and legible and able to be taken away.

Certified

- s.32(13) 32.19 A certified copy or extract, i.e. one certified by the comptroller and sealed with the seal of the Office, should be requested on Patents Form 23 accompanied by the appropriate fee (see 32.20). It constitutes evidence in accordance with subsections (11) and (12). Section 32(6) makes mandatory the supply of certified copies of or extracts from the register. The restrictions in r.51 (see 118.07) apply to the supply of copies and extracts.
 - 32.20 In order to obtain a certificate (see 32.22) or certified copy or extract which will constitute evidence in accordance with s.32(10) or (11), the greater of the two fees specified for Form 23 should accompany the form. A separate certificate (accompanied by the relevant copy or extract if one has been requested) bearing the Office seal and stating the matter certified is then provided.
 - 32.20.1 When requesting certified copies, a separate Form 23 should be used for each patent or patent application.

Uncertified

- An uncertified copy or extract should be requested on Patents Form 23 as prescribed by r.46(3) and r.48, see 118.08-09. The restrictions in r.51 (see 118.07) apply to the supply of copies and extracts.
- 32.21.1 A single Form 23 may be used to request uncertified copies relating to more than

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one patent or patent application. However, certified and uncertified copies should not be requested on the same form.

32.21.2 An electronic uncertified copy of documents from a published UK patent or patent application can be requested using the online Form 23 service available via http://www.ipo.gov.uk/p-apply-online-uk-uncertified-checklist.htm. However, it is not possible to use the online service to request a paper uncertified copy, and it is not possible to request an electronic uncertified copy by filing a paper Form 23.

Section 32(9)

The register shall be prima facie evidence of anything required or authorised by this Act or rules to be registered and in Scotland shall be sufficient evidence of any such thing.

Section 32(10)

A certificate purporting to be signed by the comptroller and certifying that any entry which he is authorised by this Act or rules to make has or has not been made, or that any other thing which he is so authorised to do has or has not been done, shall be prima facie evidence, and in Scotland shall be sufficient evidence, of the matters so certified.

Certificate of comptroller

r.46(3)

32.22 Such a certificate certifying that an entry in the register has or has not been made or that a certain thing has or has not been done should be requested on Patents Form 23 accompanied by the appropriate fee (see 32.20). The certificate bears the real or facsimile signature of an authorised officer on behalf of the comptroller. The restrictions in r.51 (see 118.07) apply to the information which may be given.

Section 32(11)

Each of the following, that is to say -

- (a) a copy of an entry in the register or an extract from the register which is supplied under subsection (6) above;
- (b) a copy of any document kept in the Patent Office or an extract from any such document, any specification of a patent or any application for a patent which has been published,

which purports to be a certified copy or a certified extract shall be admitted in evidence without further proof and without production of any original; and in Scotland such evidence shall be sufficient evidence.

Copies and extracts as evidence

32.23 Subsection (11) lays down the status as evidence of not only a certified copy or extract from the register (see 32.18-20) but also a certified copy of any document kept in the Office or extract therefrom, any patent specification or any published patent

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application. Such copies or extracts of documents etc, are obtainable as set out in 32.19-20. In the case of a document not open to public inspection, a copy or extract thereof is not supplied unless the person requesting it is entitled thereto, e.g. in the case of an unpublished patent application he is the applicant or his agent. Where a requested item cannot be supplied, the person is so informed, normally by telephone, and the fee paid for that item may be refunded.

[Section 32(12) Repealed.]

32.24 This subsection has been repealed by the Youth Justice and Criminal Evidence Act 1999, with effect from 14 April 2000.

Section 32(13)

In this section "certified copy" and "certified extract" mean a copy and extract certified by the comptroller and sealed with the seal of the Patent Office.

Section 32(14)

In this Act, except so far as the context otherwise requires -

"register", as a noun, means the register of patents;

"register", as a verb, means, in relation to any thing, to register or register particulars, or enter notice, of that thing in the register and, in relation to a person, means to enter his name in the register;

and cognate expressions shall be construed accordingly.

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Section 33: Effect of registration, etc on rights in patents

Assignments and other transactions, instruments or events affecting rights in or under patents and applications may be entered in the register of patents once the patent application in question has been published. Also, where the comptroller is notified of such a transaction, instrument or event prior to the application being published, the comptroller may, in accordance with rule 55(g), make that information public. An application to register, or to give notice to the comptroller of, any such transaction, instrument or event should follow the procedure prescribed by r.47, see 32.08-10. Section 33 concerns the effect of such registration or giving of notice on the rights in question.

s.77(1) s.78(2) s.78(3)(f) 33.02 Section 33 applies in relation to not only 1977 Act patents and applications but also granted European patents (UK) and applications for European patents (UK). Registration of an application for a European patent (UK) in the Register of European Patents kept by the EPO is treated as registration under the 1977 Act, see 32.07, 78.06 and 78.07.

Section 33(1)

Any person who claims to have acquired the property in a patent or application for a patent by virtue of any transaction, instrument or event to which this section applies shall be entitled as against any other person who claims to have acquired that property by virtue of an earlier transaction, instrument or event to which this section applies if, at the time of the later transaction, instrument or event -

- (a) the earlier transaction, instrument or event was not registered, or
- (b) in the case of any application which has not been published, notice of the earlier transaction, instrument or event had not been given to the comptroller, and
- (c) in any case, the person claiming under the later transaction, instrument or event, did not know of the earlier transaction, instrument or event.

33.03 The transactions, instruments or events (hereinafter termed "transactions etc") to which this section applies are defined by s.33(3). A person acquiring the property in a patent or application by virtue of any such transaction etc is entitled as against any other person who claims to have acquired that property by virtue of an earlier such transaction etc if two conditions are met at the time of the later transaction etc. One condition is that the earlier transaction etc was not registered or (if it relates to an unpublished application) notice of the earlier transaction etc had not been given to the comptroller. The other condition is that the person claiming under the later transaction etc did not know of the earlier one.

Section 33(2)

Subsection (1) above shall apply equally to the case where any person claims to have acquired any right in or under a patent or application for a patent, by virtue of a transaction, instrument or event to which this section applies, and that right is incompatible with any such right acquired by virtue of an earlier transaction, instrument or event to which this section applies.

33.04 The entitlement to which s.33(1) refers applies even if the right claimed under a later such transaction etc is incompatible with a right acquired under an earlier one.

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Section 33(3)

This section applies to the following transactions, instruments and events -

- (a) the assignment or assignation of a patent or application for a patent, or a right in it;
- (b) the mortgage of a patent or application or the granting of security over it;
- (c) the grant, assignment or assignation of a licence or sub-licence, or mortgage of a licence or sub-licence, under a patent or application;
- (d) the death of the proprietor or one of the proprietors of any such patent or application or any person having a right in or under a patent or application and the vesting by an assent of personal representatives of a patent, application or any such right; and
- (e) any order or directions of a court or other competent authority -
 - (i) transferring a patent or application or any right in or under it to any person; or
 - (ii) that an application should proceed in the name of any person;

and in either case the event by virtue of which the court or authority had power to make any such order or give any such directions.

Section 33(4)

Where an application for the registration of a transaction, instrument or event has been made, but the transaction, instrument or event has not been registered, then, for the purposes of subsection (1)(a) above, registration of the application shall be treated as registration of the transaction, instrument or event.

If the making of an application for registration of a transaction etc has been recorded in the register (see 32.09), it is immaterial for the purposes of s.33(1)(a) whether or not the transaction etc has actually been entered in the register at the time of a later transaction etc. Thus for determining the entitlement to which s.33(1) refers, registration of the making of the application is deemed to constitute registration of the transaction etc.

33.05.1 Article 33 of Council Regulation (EC) No. 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters requires EU member states to recognise judgments given in other member states without further proceedings. This applies unless the judgment is irreconcilable with an earlier judgment between the same parties in the UK or an earlier judgment in another member state able to be given recognition. Denmark is not covered by this Regulation, but is party to the Brussels Convention, and Iceland, Switzerland and Norway are signatories of the Lugano Convention on Jurisdiction and Enforcement of Judgments in Civil and Commercial Matters, which makes similar provisions. Therefore an application to enter a court order on the register transferring a patent or application, or stating that the application is to proceed in the name of another person, made by a court in the European Economic Area, should be accepted unless it cannot be reconciled with an earlier court order.

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33.06 In Molnlycke AB and another v Procter & Gamble Ltd and others [1994] RPC 49 at page 138 the Court of Appeal rejected the argument that entry in register of a notice that a s.32 application had been filed was equivalent to registration. The purpose of subsection (4) is to secure priority for a person who claims an interest in a patent and seeks registration. It is not to substitute for the requirement of registration of the particular transaction or instrument a lesser requirement that an application has been made for registration of an unspecified transaction or instrument.

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Section 34: Rectification of register

34.01 This section relates to rectification of the register of patents by order of the court in response to an application by an aggrieved person. It authorises rules of court to provide for relevant procedures, the relevant rule being paragraph 16 of the Practice Direction supplementing CPR 63 (CPR 63PD).

s.77(1) 34.02 The section also applies to register entries relating to granted European s.78(2) patents (UK) but not to applications for European patents (UK).

Section 34(1)

The court may, on the application of any person aggrieved, order the register to be rectified by the making, or the variation or deletion, of any entry in it.

CPR 63PD para 16.1

34.03 An application for rectification should be made using a claim form, which should be served both on the other party and on the comptroller.

s.130(1) CPR 63.3(1) 34.04 The "court" means the High Court or any patents county court having jurisdiction by virtue of an order under s.287 of the CDP Act (or the Court of Session in Scotland). Patent proceedings before the High Court of England and Wales are in fact assigned to Chancery Division and taken by the Patents Court.

Rectification of the register may take the form of the making of an entry therein or the variation or deletion of an existing entry.

Section 34(2)

In proceedings under this section the court may determine any question which it may be necessary or expedient to decide in connection with the rectification of the register.

Section 34(3)

Rules of court may provide for the notification of any application under this section to the comptroller and for his appearance on the application and for giving effect to any order of the court on the application.

CPR 63PD paras 16.1 and 16.2

34.06 A copy of the claim form and the accompanying documents must be served on the comptroller, who is entitled to appear and to be heard on the application.

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Section 35: Evidence of register, documents, etc [Repealed]

35.01 The Patents, Designs and Marks Act 1986 (c.39) repealed s.35 of the 1977 Act and amended s.32 in such a way as to incorporate therein the content of both the former sections 32 and 35, and provide for computerisation of the register. These measures were brought into force on 1 January 1989 by the Patents, Designs and Marks Act 1986 (Commencement No 2) Order 1989.

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Section 36: Co-ownership of patents and applications for patents

- s.36(7) 36.01 The rights of and relating to co-owners of patents and applications are laid down by this section. Although sub-sections (1) to (6) do not refer to applications, their provisions have the same effect in relation to a filed application for a patent as they have in relation to a granted patent.
- s.77(1) 36.02 This section also applies to granted European patents (UK) and applications s.78(2) for European patents (UK).

36.03 The provisions of sub-section (1) (that each co-owner is entitled to an equal undivided share), sub-section (2) (regarding the right of a co-owner to perform an act which would otherwise amount to an infringement) and sub-section (3) (regarding the need for the consent of all co-owners to amend the specification of the patent, apply for the patent to be revoked, or to the grant of a licence or the assignment or mortgage of a share etc) do not apply if there is any agreement to the contrary.

Section 36(1)

Where a patent is granted to two or more persons, each of them shall, subject to any agreement to the contrary, be entitled to an equal undivided share in the patent.

In *Florey & Others' Patent* [1962] RPC 186, the hearing officer (when considering the Patents Act 1949 s.54(1) which contained an almost identical provision to s.36(1) regarding the entitlement of co-owners to an equal undivided share in a patent) held that, if the existence of an agreement to the contrary is not established beyond reasonable doubt, the patentees are entitled to equal shares in the patent no matter what their individual efforts amounted to in relation to the whole; and that each co-patentee is therefore entitled to an equal share in any benefits accruing from assignment of the patent. He further observed as a general proposition that "whatever their several contributions may have been, the members of a team pursuing different aspects of a research project under the direction of a team leader should, in any event, be entitled to an equal share in any benefit resulting from what must inevitably be regarded as a joint effort".

In *Patchett's Patent* [1963] RPC 90, the judge held (under the Patents Act 1949) that unless there is some subsisting agreement to the contrary, a co-patentee is entitled to receive some part of any payment made in respect of Crown use of a patented invention, and has a prima facie right to initiate a reference to the court of a dispute as to Crown use; and that so long as the rest of the co-patentees were brought into such reference, for which purpose their status as co-applicant or respondent would appear to be immaterial, the issues between the patentees and the Crown would be susceptible of complete resolution.

Section 36(2)

Where two or more persons are proprietors of a patent, then, subject to the provisions of this section and subject to any agreement to the contrary -

- (a) each of them shall be entitled, by himself or his agents, to do in respect of the invention concerned, for his own benefit and without the consent of or the need to account to the other or others, any act which would apart from this subsection and section 55 below, amount to an infringement of the patent concerned; and
- (b) any such act shall not amount to an infringement of the patent concerned.

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36.06 Section 55 referred to in s.36(2) provides that use of patented inventions for the services of the Crown does not amount to infringement (see also 36.03). In *Henry Brothers (Magherafelt) Ltd. v The Ministry of Defence and the Northern Ireland Office* [1997] RPC 693, upheld by the Court of Appeal [1999] RPC 442, Jacob J held that the term "agents" was not used in a strict sense. The patentee was entitled to exploit his invention through others. Where an independent contractor is used by one of the joint proprietors to perform an act which would be an infringement of a patent if this section did not apply, it must be considered whether the act is in substance licensing or use by the joint proprietor for his own benefit.

Section 36(3)

Subject to the provisions of sections 8 and 12 above and section 37 below and to any agreement for the time being in force, where two or more persons are proprietors of a patent one of them shall not without the consent of the other or others -

- (a) amend the specification of the patent or apply for such an amendment to be allowed or for the patent to be revoked, or
- (b) grant a licence under the patent or assign or mortgage a share in the patent or in Scotland cause or permit security to be granted over it.

36.07 See 36.03. Amendment or applying for revocation of a patent, and assignments, mortgages and the grant of licences etc under s.30(2) or (4) or, in Scotland, s.31(2), are specifically subject to the s.36(3) requirement for the consent of all co-owners. Sections 8, 12 and 37 referred to in s.36(3) relate to the determination of questions about entitlement to applications and patents and provide in s.8(1)(b), s.12(1)(b) and s.37(1)(c) for referral by a co-owner of the question whether any right in or under an application or patent should be transferred or granted to any other person. Thus the comptroller may make an order under s.37(1) which over-rides the specific provisions of s.36(3) - this was confirmed in Hughes v Paxman [2006] EWCA Civ 818; [2007] RPC 2. In this Court of Appeal judgment it was held that the comptroller can order that licences under the patent be granted if he considers that there is a deadlock situation between the co-proprietors. The comptroller has a wide discretion in such circumstances but must act rationally, fairly and proportionately having regard to all the circumstances of the case, the aim being to produce a fair commercial solution when co-owners cannot agree. On the facts of this particular case the comptroller held that there was not a deadlock situation and therefore gave no order that licences should be granted (see BL O/217/08).

Section 36(4)

Subject to the provisions of those sections, where two or more persons are proprietors of a patent, anyone else may supply one of those persons with the means, relating to an essential element of the invention, for putting the invention into effect, and the supply of those means by virtue of this subsection shall not amount to an infringement of the patent.

36.08 Under s.60(2), a person who supplies any of the means, relating to an essential element of an invention, for putting the invention into effect may thus infringe a patent for the invention, ie contributory infringement. Section 36(4) provides that such supply to a co-owner of a patent does not constitute such infringement.

Section 36(5)

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Where a patented product is disposed of by any of two or more proprietors to any person, that person and any other person claiming through him shall be entitled to deal with the product in the same way as if it had been disposed of by a sole registered proprietor.

s.130(7) s.36(7) The term "patented product" means a product which is a patented invention or, in relation to a patented process, a product obtained directly by means of the process or to which the process has been applied. In that definition, "patented invention" means an invention for which a patent is granted and "patented process" should be construed accordingly. Section 36(5) has the same effect in relation to a filed application for a patent as in relation to a granted patent and the reference to a patented product should be construed accordingly. Any such product disposed of by a co-owner can under s.36(5) be dealt with by a recipient in the same way as if it had been disposed of by a sole registered proprietor. The recipient is thus protected against any infringement proceedings which might otherwise have arisen.

Section 36(6)

Nothing in subsection (1) or (2) above shall affect the mutual rights or obligations of trustees or of the personal representatives of a deceased person, or their rights or obligations as such.

Section 36(7)

The foregoing provisions of this section shall have effect in relation to an application for a patent which is filed as they have effect in relation to a patent and -

- (a) references to a patent and a patent being granted shall accordingly include references respectively to any such application and to the application being filed; and
- (b) the reference in subsection (5) above to a patented product shall be construed accordingly.

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Section 37: Determination of right to patent after grant

This is the last of the three sections (8, 12 and 37) under which questions about entitlement to patents may be referred to the comptroller. Section 37 relates to such questions in the case of patents granted under the Act and granted European patents (UK).

s.25(1)The procedure for a reference under s.37 is prescribed by Part 7 (Proceedings heard before the comptroller) of the Patents Rules 2007 (see 123.05 -123.05.13). Questions may also be determined under s.37 as a result of a reference under s.8 (which provides for questions about entitlement to be referred to the comptroller at any time before a patent has been granted for the invention in question). This is by virtue of s.9 which provides that, if a question referred to the comptroller under s.8 has not been determined when a patent is granted, it may then be treated as having been referred under s.37. Section 37 takes effect from the date on which the notice of grant appears in the Journal; when a question is referred between the date on which the grant letter is issued and this date, it is treated as having been referred under s.37 on the date on which the notice of grant appears in the Journal (see 8.03).

> Certain effects of orders made under s.37, particularly their effects with regard to licences, are laid down by s.38.

> 37.04 Some guidance with regard to the determination of questions about entitlement is given by the judgments and decisions referred to in 8.06 to 8.09, some of which were under s.8 but others of which were under s.12 or s.37. The considerations applying to such questions under s.8, s.12 or s.37 are essentially the same.

Section 37(1)

After a patent has been granted for an invention any person having or claiming a proprietary interest in or under the patent may refer to the comptroller the question -

- (a) who is or are the true proprietor or proprietors of the patent,
- whether the patent should have been granted to the person or persons to whom it was granted, or
- whether any right in or under the patent should be transferred or granted to any other person or persons;

and the comptroller shall determine the question and make such order as he thinks fit to give effect to the determination.

s.37(5)37.05 A question concerning entitlement to a granted patent may be referred to the comptroller under s.37 by any person having or claiming a proprietary interest in a patent at any time after publication of the mention of its grant (see 25.02). However, the remedies available may be restricted if the reference is made on or after the second anniversary of the mention of grant in the journal, see 37.19-20.1.

> 37.06 [deleted]

37.07 The question (or one referred under s.8 but treated as referred under s.37, see 37.02) is normally in due course determined by the comptroller although he may instead decline to deal with it, see 37.21. The comptroller has a general power to make such order as he thinks fit to give effect to the determination, which order may if appropriate contain inter alia any of the provisions set out in subsection (2), see 37.12, or allow the making of a new application, see 37.15. The order may over-ride the specific provisions of s.36(3) - see

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36.07.

Procedure

PR part 7

37.08 A reference under s.37(1) should be made on Patents Form 2 accompanied by a copy thereof and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.13.

37.09 [deleted]

[37.10-11 Not used.]

Section 37(2)

Without prejudice to the generality of subsection (1) above, an order under that subsection may contain provision -

- (a) directing that the person by whom the reference is made under that subsection shall be included (whether or not to the exclusion of any other person) among the persons registered as proprietors of the patent;
- (b) directing the registration of a transaction, instrument or event by virtue of which that person has acquired any right in or under the patent;
- (c) granting any licence or other right in or under the patent;
- (d) directing the proprietor of the patent or any person having any right in or under the patent to do anything specified in the order as necessary to carry out the other provisions of the order.

Specific remedies available

Orders under s.37(1) may, in respect of the patent in question, inter alia (a) direct that the claimant should be on the register as a proprietor; (b) direct registration of a transaction, instrument or event in favour of the claimant; (c) grant any licence. Moreover, the existing proprietor or any person having rights in respect of the patent may be given directions as necessary to carry out the other provisions of the order (see 37.13 if those directions are not complied with). However, no order is made by virtue of s.37(2) unless notice of the reference has been given to interested parties as required by s.37(7) (such notice normally having been given by the Office).

Section 37(3)

If any person to whom directions have been given under subsection (2)(d) above fails to do anything necessary for carrying out any such directions within 14 days after the date of the order containing the directions, the comptroller may, on application made to him by any person in whose favour or on whose reference the order containing the directions was made, authorise him to do that thing on behalf of the person to whom the directions were given.

Directions not complied with

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- 37.13 If a person given directions under s.37(2)(d) fails to comply with them within 14 days, any person in whose favour or on whose reference the order containing those directions was made may apply for authority to do whatever is necessary on behalf of that person. An application under s.37(2)(d) is not included in Schedule 3 to the Patents Rules 2007. Patents Form 2 need not therefore be filed in order to start the application, which should however set out fully the facts upon which the applicant relies and the nature of the authorisation sought.
- 37.14 The Office sends a copy of the application to the person alleged to have failed to comply with the directions. The comptroller may give such directions as he may think fit with regard to the subsequent procedure, and may grant authorisation if he thinks fit.

Section 37(4)

Where the comptroller finds on a reference under this section that the patent was granted to a person not entitled to be granted that patent (whether alone or with other persons) and on application made under section 72 below makes an order on that ground for the conditional or unconditional revocation of the patent, the comptroller may order that the person by whom the application was made or his successor in title may, subject to section 76 below, make a new application for a patent -

- (a) in the case of unconditional revocation, for the whole of the matter comprised in the specification of that patent; and
- in the case of conditional revocation, for the matter which in the opinion of the comptroller should be excluded from that specification by amendment under section 75 below;

and where such new application is made, it shall be treated as having been filed on the date of filing the application for the patent to which the reference relates.

Making of new application

- s.72(2)(a) Subsection (4) provides, at the discretion of the comptroller, for the making of a new application by the claimant where the comptroller has (as well as finding that an existing proprietor of the patent was not entitled thereto) ordered conditional or unconditional revocation of the patent in question under s.72 on entitlement grounds, see 72.40. The application for revocation under s.72 on those grounds may be made only by a person who has already been found under s.37 (or by the court in an action for a declaration or declarator) to be entitled to be granted that patent or a patent for part of its content. If the revocation ordered is unconditional, the permitted new application is for the whole content of the revoked patent whereas if conditional, the permitted new application is for that part of the patent's content which should be excised (by amendment under s.75).
- r.20(2)-(4) Where the decision to make an order has not been appealed, the new r.108(1) application should be made within a period of three months calculated from the day after the order under section 37(4) was made. However, where an appeal is brought, the new application should be made within a period of three months beginning immediately after the date on which the appeal was finally disposed of. In either case, this period may be extended or shortened at the discretion of the comptroller.
- 37.17 s.76(1)The new application is treated as having been filed on the date of filing of the earlier application. However, the application requires amendment in order to proceed if it discloses matter which extends beyond that disclosed in the earlier application as filed, as discussed in 8.25.
 - 37.17.1 The compliance period for putting in order an application under s.37(4) is

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prescribed by r.30(3) and is the same as that for an application under s.8(3) or 12(6) -see 8.25.1.

37.18 An order under s.37(4) allowing the making of such a new application may be precluded by s.37(5), see 37.19. Moreover, such an order is not made unless notice of the reference has been given to interested parties as required by s.37(7) (such notice normally having been given by the Office).

Section 37(5)

On any such reference no order shall be made under this section transferring the patent to which the reference relates on the ground that the patent was granted to a person not so entitled, and no order shall be made under subsection (4) above on that ground, if the reference was made after the second anniversary of the date of the grant, unless it is shown that any person registered as a proprietor of the patent knew at the time of the grant or, as the case may be, of the transfer of the patent to him that he was not entitled to the patent.

Effect of timing of reference

- Orders under s.37 transferring the patent in question on the ground that it was granted to a person not so entitled, or under s.37(4) allowing a new application on the same ground, can be made only (with one exception) if the reference is made within a period of two years from the date of publication of the mention of grant of the patent (see 37.20.1 below). The exception to this time limit is where it is shown that a registered proprietor knew at the time of grant or, if applicable, of transfer of the patent to him that he was not entitled to the patent. It was held in *Cartwright's Patent* (BL O/74/93) that the words "not so entitled" in s.37(5) are not restricted to a reference under s.37(1)(b) but are also applicable in the case of a reference under s.37(1)(a).
- 37.19.1 The fact that a reference is not opposed does not override the limitation on the comptroller's powers imposed by s.37(5) and the consequential onus on the referrer to show that the registered proprietor knew at the relevant time that he was not entitled to a patent (*Parr's Patent*, BL O/46/94).
- s.130(7) 37.20 Subsection (5) is so framed as to have, as nearly as practicable, the same effects as the corresponding provisions of the EPC, CPC and PCT. Article 23(3) of the CPC [1989] appears to be equivalent. In *Yeda Research and Development Co Ltd v Rhone-Poulenc Rorer International Holdings Inc.* [2007] UKHL 43, the House of Lords allowed an amendment to a statement initially claiming joint ownership to claim sole ownership even though the 2 year limitation period had expired, on the basis that the original reference had been made within that period.
 - 37.20.1 The reference must be made by, at the latest, the second anniversary of the date of grant.

Section 37(6)

An order under this section shall not be so made as to affect the mutual rights or obligations of trustees or of the personal representatives of a deceased person, or their rights or obligations as such.

Section 37(7)

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Where a question is referred to the comptroller under this section an order shall not be made by virtue of subsection (2) or under subsection (4) above on the reference unless notice of the reference is given to all persons registered as proprietor of the patent or as having a right in or under the patent, except those who are parties to the reference.

Section 37(8)

If it appears to the comptroller on a reference under this section that the question referred to him would more properly be determined by the court, he may decline to deal with it and, without prejudice to the court's jurisdiction to determine any such question and make a declaration, or any declaratory jurisdiction of the court in Scotland, the court shall have jurisdiction to do so.

Comptroller declines to deal with question

CPR 63.11 37.21 The comptroller has discretion to decline to deal with a question he considers would more properly be determined by the court. The relevant procedure, subject to rule 63.11 of Part 63 of the Civil Procedure Rules, and comments on the exercise of this discretion are given in 8.28 to 8.30, and chapter 2 of the Patent Hearings Manual.

Section 37(9)

The court shall not in the exercise of any such declaratory jurisdiction determine a question whether a patent was granted to a person not entitled to be granted the patent if the proceedings in which the jurisdiction is invoked were commenced after the second anniversary of the date of the grant of the patent, unless it is shown that any person registered as a proprietor of the patent knew at the time of the grant or, as the case may be, of the transfer of the patent to him that he was not entitled to the patent.

Restriction on determination by court

37.22 Subsection (9) places a limitation (similar to that in subsection (5), see 37.19) on the power of the court to determine a question whether a patent was granted to a person not entitled thereto. The use of the phrase "declaratory jurisdiction" may refer back to the way in which it is used in subsection (8) and thus restrict the effect of subsection (9) to Scotland, but appears more likely to have the broader meaning of the jurisdiction of the court, both in Scotland and elsewhere, to make a declaration.

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Section 38: Effect of transfer of patent under s.37

38.01 Orders that a patent (ie a patent granted under the Act or a granted European patent (UK)) should be transferred from its existing proprietor(s) to specified proprietor(s) may be made under s.37. The effects of such orders on licences or other rights granted or created by the existing proprietor(s) are laid down by s.38. This section also gives certain rights to existing proprietor(s) or licensee(s) who worked the invention, or prepared to do so, before the registration of a reference under s.37, see 38.05 to 38.07.

38.02 The provisions of s.38 in relation to a patent correspond to those of s.11 in relation to an application for a patent.

Section 38(1)

Where an order is made under section 37 above that a patent shall be transferred from any person or persons (the old proprietor or proprietors) to one or more persons (whether or not including an old proprietor), then, except in a case falling within subsection (2) below, any licences or other rights granted or created by the old proprietor or proprietors shall, subject to section 33 above and to the provisions of the order, continue in force and be treated as granted by the person or persons to whom the patent is ordered to be transferred (the new proprietor or proprietors).

Where an existing proprietor is retained

This subsection applies where the effect of an order under s.37 is that the proprietor(s) to whom the patent is transferred include one or more of the existing proprietor(s). Licences or other rights continue in force as if granted by the new proprietor(s), unless the order provides otherwise and subject to s.33 (which concerns the effects of transactions, instruments or events, and registration thereof, on rights in patents).

Section 38(2)

Where an order is so made that a patent shall be transferred from the old proprietor or proprietors to one or more persons none of whom was an old proprietor (on the ground that the patent was granted to a person not entitled to be granted the patent), any licences or other rights in or under the patent shall, subject to the provisions of the order and subsection (3) below, lapse on the registration of that person or those persons as the new proprietor or proprietors of the patent.

Where no existing proprietor is retained

38.04 Subsection (2) applies instead of subsection (1) where the effect of an order under s.37 is that the proprietor(s) to whom the patent is transferred include none of the existing proprietor(s). Licences or other rights lapse on registration of the new proprietor(s), unless the order provides otherwise (but see 38.05).

Section 38(3)

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Where an order is so made that a patent shall be transferred as mentioned in subsection (2) above or that a person other than an old proprietor may make a new application for a patent and before the reference of the question under that section resulting in the making of any such order is registered, the old proprietor or proprietors or a licensee of the patent, acting in good faith, worked the invention in question in the United Kingdom or made effective and serious preparations to do so, the old proprietor or proprietors or the licensee shall, on making a request to the new proprietor or proprietors or, as the case may be, the new applicant within the prescribed period, be entitled to be granted a licence (but not an exclusive licence) to continue working or, as the case may be, to work the invention, so far as it is the subject of the new application.

38.05 Subsection (3) concerns the situation where an order is made under s.37 transferring the patent to new proprietor(s) none of whom was an existing proprietor or allowing a person other than an existing proprietor to make a new application (see 37.15 to 37.18). The Office notifies all existing proprietors and their licensees of whom it is aware of the making of the order. In that situation, an existing proprietor or licensee who before registration of the relevant s.37 reference (see 37.08) acting in good faith worked the invention in the UK or made effective and serious preparations to do so, is entitled to a non-exclusive licence to work or continue working the invention. (For the meanings of "exclusive licence" and "non-exclusive licence", see s.130(1).)

r.90(2) r.108(1) 38.06 In order to obtain such a licence, a request for its grant should be made, in the case of an existing proprietor, within two months of the date of the order mentioned in s.38(2). This period is extensible at the discretion of the comptroller.

38.07 The period and terms of the licence to be granted should comply with s.38(4), ie, be "reasonable". Any dispute regarding such period or terms or whether the person requesting the licence is entitled to one may be referred to the comptroller under s.38(5) by either party, see 38.08 to 38.10.

Section 38(4)

Any such licence shall be granted for a reasonable period and on reasonable terms.

Section 38(5)

The new proprietor or proprietors of the patent or, as the case may be, the new applicant or any person claiming that he is entitled to be granted any such licence may refer to the comptroller the question whether that person is so entitled and whether any such period is or terms are reasonable, and the comptroller shall determine the question and may, if he considers it appropriate, order the grant of such a licence.

PR part 7

38.08 The dispute (see 38.07) should be referred by filing Patents Form 2 accompanied by a copy thereof and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.13. In accordance with r.76(4)(c) the statement should set out the period or the terms of the licence which the claimant is prepared to accept or grant.

r.77

38.09 The Office sends a copy of the reference and statement to the new proprietor(s) or, as the case may be, the new applicant, and each person claiming to be entitled to a licence, other than the referrer. If any recipient does not agree to grant or accept a licence as specified he should file a counter-statement in the proceedings.

s.108

38.10 When the comptroller determines the question to which the s.38(5) reference relates he may, if appropriate, order the grant of such a licence (see 38.05).

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Without prejudice to any other method of enforcement, such an order has effect as if it were a deed, executed by the proprietor of the patent and all other necessary parties, granting a licence in accordance with the order.

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EMPLOYEES' INVENTIONS

Section 39: Right to employees' inventions

- s.130(1) 39.01 This is the first of a group of sections (39 to 43) relating to inventions made by employees. In the Act, unless the context otherwise requires, "employee" means a person who works or (where the employment has ceased) worked under a contract of employment or in employment under or for the purposes of a government department or a person who serves (or served) in the naval, military or air forces of the Crown. In relation to an employee, "employer" means the person by whom the employee is or was employed.
- s.43(1) 39.02 Sections 39 to 42 do not apply to an invention made before the appointed day (1 June 1978). Moreover, those sections do not apply to an invention made by an employee unless at the time he made it either -
 - (a) he was mainly employed in the UK; or
 - (b) he was not mainly employed anywhere or his place of employment could not be determined, but his employer had a place of business in the UK to which the employee was attached, whether or not he was also attached elsewhere.
- s.43(3) 39.03 In sections 39 to 43, unless the context otherwise requires, references to the making of an invention by an employee are references to his making it alone or jointly with any other person, but do not include references to his merely contributing advice or other assistance in the making of an invention by another employee.
- s.77(1) 39.04 Sections 39 to 43 apply in relation not only to 1977 Act patents and applications but also to granted European Patents (UK) by virtue of s.43(4). According to s.43(4) references in ss.39 to 42 to a patent and to a patent being granted are respectively references to a patent or other protection and to its being granted under any national or international law, i.e. UK law, the law in force in any other country or any treaty or international convention. A.60(1) EPC in association with aa.4 and 5 of the Protocol on Jurisdiction and the Recognition of Decisions in Respect of the Right to the Grant of a European Patent under the EPC also permits the application of s.39 to applications for European Patents (UK) where the employee is employed in the UK, subject to any agreement to the contrary insofar as the national law governing the contract allows the agreement in question.

Section 39(1)

Notwithstanding anything in any rule of law, an invention made by an employee shall, as between him and his employer, be taken to belong to his employer for the purposes of this Act and all other purposes if -

- (a) it was made in the course of the normal duties of the employee or in the course of duties falling outside his normal duties, but specifically assigned to him, and the circumstances in either case were such that an invention might reasonably be expected to result from the carrying out of his duties; or
- (b) the invention was made in the course of the duties of the employee and, at the time of making the invention, because of the nature of his duties and the particular responsibilities arising from the nature of his duties he had a special obligation to further the interests of the employer's undertaking.

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Section 39(2)

Any other invention made by an employee shall, as between him and his employer, be taken for those purposes to belong to the employee.

- 39.05 Section 39 gives criteria for determining whether an invention made by an employee belongs to him or to his employer. Where rights to such an invention are disputed by the inventor and his employer, subsection (1) lays down the circumstances in which it belongs to the employer; it otherwise belongs to the employee by virtue of subsection (2).
- 39.06 Since s.39 refers to an invention without any reference to a patent or an application for a patent, the s.125 definition of an invention as that specified in a claim cannot apply to s.39. The term "invention" in s.39 should apparently instead be construed in its broadest sense of that which has been invented, in much the same way as when considering questions about entitlement under s.8, see 8.06-8.09.
- s.39(1) 39.07 In order for the invention to belong to the employer it must, firstly, have been made in the course of the duties of the employee (which may, in subsection (1)(a), be either his "normal" duties or other duties "specifically assigned to him"). In addition, either the circumstances must have been such that an invention might reasonably be expected to result from the carrying out of his duties (subsection (1)(a), see 39.10) or he must have had as a result of his duties a special obligation to further the interests of the employer's undertaking (subsection (1)(b)).
- s.42(2) 39.08 The provisions of subsection (1) apply notwithstanding anything in any rule of law. They thus override the provisions of all other enactments except any relevant enactment of later date. Moreover, any term in a contract entered into by the employee with or at the request of the employer which diminishes his rights in inventions made by him after the appointed day (1 June 1978) and the date of the contract is unenforceable, see 42.03-04.
 - 39.09 Section 39 lays down for the first time statutory criteria for determining rights in employee's inventions; this was previously a matter of common law. The Patents Court, in *Harris' Patent* [1985] RPC 19, entertained some doubt as to whether s.39 is declaratory of the previous common law position. The Court held that, although guidance may be obtained from earlier cases as to how courts assessed the duties of the employee in a particular case and particular circumstances, and the extent and nature of an employee's obligation to further the interests of the employer's undertaking, it is the provisions of s.39 alone to which regard must be had for the law governing any employee's invention made after 1 June 1978. The Court of Appeal, in *LIFFE Administration and Management v Pavel Pinkava* [2007] RPC 30, confirmed that it is the provisions of s.39 alone to which regard must be had for the law governing an employee's invention and noted that sections 39 to 43 of the Patents Act 1977 is more favourable to the employee than the previous common law rules. There is no reason to interpret s.39 by reference to any previous law and there is no reason to imply any further condition or qualification to the requirements of s.39.
 - 39.10 The Patents Court in *Harris' Patent* also held that the expression "an invention" in s.39(1)(a) cannot mean any invention whatsoever. It is governed by the qualification that it has to be an invention that "might reasonably be expected to result from the carrying out of his duties" by the employee and, therefore, must be referring to an invention which achieves, or contributes to achieving, whatever was the aim or object to which the employee's efforts in carrying out his (normal or specifically assigned) duties were directed, i.e. such an invention as that made, though not necessarily the precise invention actually made and in question. Kitchin J in *LIFFE Administration and Management v Pavel Pinkava and De Novo Markets Limited* [2006] EWHC 595 (Pat) however cautioned against using this as a substitute for the statutory test in s.39(1)(a). If that test was satisfied, it was not relevant to say that the invention in question did not achieve the particular aim or object

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to which the inventor's efforts were directed. Moreover, the "circumstances" referred to in s.39(1)(a) are the circumstances in which the invention in question was made. The Court of Appeal, in *LIFFE Administration and Management v Pavel Pinkava* [2007] RPC 30, agreed with the conclusion of Kitchin J and rejected the submission that the words "an invention" in s.39(1)(a) should be read as "the invention" or "a similar invention". Furthermore, the invention does not need to provide a solution to a pre-identified problem.

- 39.11 When considering the normal duties of an employee, the Court in *Harris' Patent* further held that his duty of fidelity to his employer is to carry out faithfully the work he is employed to do to the best of his ability and does not assist in the formulation of the actual duties he is employed to do. In *LIFFE Administration and Management v Pavel Pinkava* [2007] RPC 30, the Court of Appeal held that although the source of an employee's duty is primarily contractual, the contract evolves in the course of time such that it is unsafe to have regard only to the terms contained in an initial written contract of employment. Furthermore, some of the terms of an employee's duties may be implied by law.
- 39.12 The special obligation of an employee to further the interests of the employer's undertaking was decisive in *Unitec Systems' Application* (BL O/143/94) where the invention lay in the field of business of a company, whose joint managing directors at the time of the invention were the patent applicants. The hearing officer held that the patent applicants were employees, even though they had not signed a contract of employment until after the invention had been made, and that therefore s.39 applied. Moreover, although he found that the invention had not been made in the course of the patent applicants' "normal" duties as required by s.39(1)(a), he held, following the guidelines set out in *Harris' Patent*, that the s.8 reference succeeded since the invention had been made in the course of the duties of the patent applicants, who were not relieved to any degree of the "special obligation" referred to in s.39(1)(b) and implicit in their titles.
- 39.12.1 In *Ultraframe UK Ltd v Fielding* [2004] RPC 24, which concerned the ownership of design rights, the Court of Appeal held that a contract of service existed if three conditions were fulfilled: 1) the servant agreed that, in consideration of a wage or other remuneration, he would provide his own work and skill in the performance of some service for his master; 2) he agreed, expressly or impliedly, that in the performance of that service, he would be subject to the other's control in a sufficient degree to make that other master; and 3) the provisions of the contract were consistent with its being a contract of service. A 100% shareholder and director who was not under obligation to be at work certain hours or to produce designs in return for a wage was not subject to a contract of service and was therefore not employed by the companies he had operated his business through. However, the Court held that he held any design rights in trust for the company through whom he was operating the business as at the time he created those design rights.

Section 39(3)

Where by virtue of this section an invention belongs, as between him and his employer, to an employee, nothing done -

- (a) by or on behalf of the employee or any person claiming under him for the purposes of pursuing an application for a patent, or
- (b) by any person for the purpose of performing or working the invention,

shall be taken to infringe any copyright or design right to which, as between him and his employer, his employer is entitled in any model or document relating to the invention.

39.13 Subsection (3) was added by the CDP Act. This provides that acts done for the purposes of patenting, performing or working the invention shall not be taken to infringe any copyright or Design Right pertaining to the invention and belonging to the employer. This prevents an employer using copyright or Design Right to frustrate an employee who

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tries to patent or exploit an invention which rightly belongs to the employee.

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Section 40: Compensation of employees for certain inventions

40.01 This is the second of the group of sections relating to inventions made by employees. It provides for the court or the comptroller to award compensation to be paid by an employer to an employee in respect of an invention made by the employee, in certain circumstances. The procedure for an employee to apply for compensation to the Patents Court or the comptroller, respectively, is prescribed by rule 63.12 of Part 63 of the Civil Procedure Rules (CPR 63) and by rule 59 of the Patents Rules 1995.

PA 2004 40.02 The concept of an employee having a statutory right to such compensation, for his invention from which his employer has derived benefit did not exist in UK law prior to the Patents Act 1977. This section was amended by the Patents Act 2004 to allow compensation to be awarded in respect of all outstanding benefits deriving from a patented invention, removing the requirement for an employee to show that the patent itself is of outstanding benefit. The amended legislation only applies to inventions for which a patent application is filed from 1 January 2005 onwards; for patent applications made prior to this date, employee compensation can only be obtained from benefits deriving from the patent (see 40.04-40.04.1).

40.03 For the applicability of s.40 and interpretation of certain terms used therein, see 39.01-04.

Section 40(1)

Where it appears to the court or the comptroller on an application made by an employee within the prescribed period that -

- (a) the employee has made an invention belonging to the employer for which a patent has been granted,
- (b) having regard among other things to the size and nature of the employer's undertaking, the invention or the patent for it (or the combination of both) is of outstanding benefit to the employer, and
- (c) by reason of those facts it is just that the employee should be awarded compensation to be paid by the employer,

the court or the comptroller may award him such compensation of an amount determined under section 41 below.

Section 40(2)

Where it appears to the court or the comptroller on an application made by an employee within the prescribed period that -

- (a) a patent has been granted for an invention made by and belonging to the employee;
- (b) his rights in the invention, or in any patent or application for a patent for the invention, have since the appointed day been assigned to the employer or an exclusive licence under the patent or application has since the appointed day been granted to the employer;
- (c) the benefit derived by the employee from the contract of assignment, assignation or grant or any ancillary contract ("the relevant contract") is inadequate

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in relation to the benefit derived by the employer from the invention or the patent for it (or both); and

(d) by reason of those facts it is just that the employee should be awarded compensation to be paid by the employer in addition to the benefit derived from the relevant contract:

the court or the comptroller may award him such compensation of an amount determined under section 41 below.

40.03.1 An application under s.40 can relate to a foreign patent, and to more than one patent, provided that any such patent is identified in the application on Form 2, see 40.09 (GEC Avionics Ltd's Patent [1992] RPC 107 and British Steel PLC's Patent [1992] RPC 117).

40.03.2 In *Fellerman's Application* (BL O/11/96) the hearing officer observed that s.40 requires the applicant for an award of compensation to apply to the comptroller (or court) with reference to the employer, not the current proprietor of the patent. Similarly, in *Price v Elf Print Media Ltd* (Patents Court, 1 February 2001, unreported, and [2001] EWCA Civ 622), an employee failed in making a claim for compensation against two former directors of his employer company, to whom the patent had been assigned by the company, since the former directors were not his employer.

s.43(7) s.40(7) Compensation (of an amount determined under s.41, see 41.03 to 41.06) to be paid by the employer may be awarded to the employee, under s.40, in either of two sets of circumstances (unless s.40(3) applies, see 40.16). Common to both sets is that the invention in question must have been made by the employee, a patent must have been granted for it (see 39.04), and the employer must have been derived benefit (i.e. benefit in money or money's worth) from the invention or the patent for it. However, for patent applications made before 1 January 2005, the benefit must derive from the patent itself (see 40.04.1). In *Kelly & Anor v GE Healthcare Ltd* [2009] EWHC 181 (Pat), [2009] RPC 12, Floyd J stated that only actual inventors (i.e. "the natural person[s] who came up with the inventive concept"), and not those who merely contributed to the invention, can be compensated. The circumstances of subsection (1) must be met if the invention belongs to the employer (see below) but those of subsection (2) must be met if it belongs to the employee (see 40.06).

40.04.1 The relationship between benefit derived from the invention and benefit derived from the patent per se was considered (under the pre-2004 Act law) by the Patents Court in Memco-Med Ltd's Patent [1992] RPC 403. It was decided that the onus of proof that the benefit was derived from the patent rather than the invention lay on the employee but may thereafter shift to the employer depending on the evidence. Aldous J acknowledged that while the benefit from a patent may be readily recognisable when the patent is licensed and royalties paid, it is more difficult to determine in cases (a) where the employer exploits the patent by manufacturing articles in accordance with the invention of the patent or (b) where the patent is not licensed and the invention is never put into practice but the patent is nevertheless of great benefit in preventing activities which would compete with those of the patentee. In answering the question whether the patent has been of benefit to the employer, Aldous J indicated that it could be useful to assume that the patent was never granted due to some failure by the Patent Agents and thereafter to decide what would have been the position of the employer. It would then be possible to ascertain the benefit from the patent by comparing the actual position of the employer with the position he would have been in if the patent had not been granted bearing in mind the benefit must be in money or money's worth.

40.04.2 Under s.40(1), the court or comptroller may award compensation only if it appears that the invention or the patent for it is, considering inter alia the size and nature of the employer's undertaking, of outstanding benefit to the employer and an award is therefore "just". In *Memco-Med Ltd's Patent* (see 40.04.1) Aldous J affirmed the views of the hearing officers in GEC Avionics' Patent and British Steel PLC's Patent (see 40.03.1) that for benefit to be "outstanding", it must be something out of the ordinary when looked at in the total context of the activities of the employer concerned and not something that one would

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normally expect to arise from the duties that the employee is paid for. Thus to assess whether the benefit is outstanding, it is necessary to look at the employer's undertaking, which may be the whole or a division of the employer's business, and ascertain the benefit to the employer taking into account the size and nature of that business and all the surrounding circumstances. In *Ian Alexander Shanks v Unilever Plc, Unilever NV and Unilever UK Central Resources Limited* (BLO/259/13) the hearing officer found that the benefit due to the patents was around £24 million over a number of years. He considered this benefit in light of the defendant's profits and turnover, the defendant's other licensing and patent activities and the defendant's activities in general. Considering the totality of the evidence the hearing officer held that the benefits arising from the patents fell short of being outstanding. The hearing officer's decision was upheld by the Patents Court in *Shanks v Unilever Plc & Ors* [2014] EWHC 1647 (Pat) and by the Court of Appeal in [2017] EWCA Civ 2.

40.04.3 The need to consider the employer's undertaking when assessing whether a patent is of outstanding benefit was also demonstrated in Kelly & Anor v GE Healthcare Ltd [2009] EWHC 181 (Pat), [2009] RPC 12, the first UK judgment to award compensation to employees under s.40. In this case, Floyd J held (under the pre-2005 form of s.40) that the patents in question were of outstanding benefit to the company, having regard to all of the circumstances, including the size and nature of the employer's undertaking. The benefits went far beyond anything which one could normally expect to arise from the sort of work the employees were doing. In particular, the benefit of patent protection is not limited to profits from sales. In this case, as well as protecting the business against generic competition, the patents were a major factor in achieving corporate deals. Floyd J went on to hold that it was just that the employees should receive an award of compensation, the fact that the employees had waited for some years before claiming being considered to be irrelevant. In this case, the fact that the patents had expired enabled the court to quantify the benefit those patents had brought to the employer. This is in contrast with previous cases under s.40, brought prior to expiry of the patent, wherein the courts have been unwilling to speculate on future benefits those patents might bring.

40.05 In *Memco-Med's Patent* (see 40.04.1) Aldous J upheld the hearing officer's earlier decision not to order discovery of documents relating to Memco-Med's sales and profits partly because the applicant had not established that the patent had played a major part in securing the sales obtained and partly since a request for discovery should be made promptly, holding that discovery should only be ordered when necessary and should be limited to those issues which on the pleadings are essential for a decision. In *Communication & Control Engineering Company Limited's Patent* 2115226 (BL O/82/93), the hearing officer followed *Memco-Med* when refusing a request for discovery not only on the grounds of lack of sufficient clarity and precision in the request but also, and more fundamentally, on the grounds that it was not in his judgment necessary for disposing of the matter, in the sense that it effectively precluded a making good of any fault at the price of further delay.

- s.40(4) 40.06 Under s.40(2), the court or comptroller may award compensation if it appears to be "just" because the benefit derived by the employee (from a contract whereby he assigned his rights, or granted an exclusive licence, to the employer) is inadequate in relation to the benefit derived by the employer. This applies notwithstanding anything to the contrary in the contract (or in any agreement applicable to the invention other than a relevant collective agreement as defined in s.40(3) and (6)).
- s.43(5) 40.07 Where the employer dies before any award is made under s.40, the benefit s.43(6) or expected benefit to him includes that to his personal representatives or any person in whom the relevant patent was vested by their assent. Where the employee dies before any such award is made, his personal representatives or their successors in title may exercise his right to make or pursue an application for compensation.

40.08 Section 41(7) to (12) provide for certain actions to be taken after an application for compensation under s.40 has been determined, see 41.07 to 41.11.

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Procedure

Application to the comptroller

PR part 7 s.40(5) r.51(3)(a) 40.09 An application to the comptroller under s.40 for an award of compensation should be made by the employee on Patents Form 2 accompanied by a copy thereof and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.13. The comptroller may decline to deal with the application, see 40.17. Documents filed at the Office in connection with the application are not open to public inspection unless the comptroller otherwise directs.

r.91 CPR 63.12

- 40.10 The application should be made within the period which begins when the relevant patent is granted and which expires one year after it has ceased to have effect. However, where the patent has ceased to have effect by reason of a failure to pay any renewal fee in time and an application for restoration is made to the comptroller under s.28, the period-
 - (a) if restoration is ordered, continues as if the patent had remained continuously in effect; or
 - (b) if restoration is refused, is treated as expiring one year after the patent ceased to have effect or six months after the refusal, whichever is the later.
- r.108(1) The period is extensible at the discretion of the comptroller.

40.11 [deleted]

40.12 [deleted]

40.13 [deleted]

Application to the court

CPR 63.12 s.130(1) 40.14 An application to the Patents Court under s.40 should be made by issue of a claim form within the period specified in 40.10. An application to the court in the UK other than England or Wales should be made to the High Court of that part of the UK or, in Scotland, to the Court of Session. The subsequent procedure is in general outside the scope of this Manual.

s.97(1)

40.15 It is also possible to appeal to the court against a decision of the comptroller under s.40. The award of costs in proceedings before the court under s.40, whether on an application or on appeal, is subject to s.106 (see 106.01-06). This requires *inter alia* that the court should have regard to the financial position of the employer and employee in determining whether to make an award of costs and the amount thereof.

Section 40(3)

Subsections (1) and (2) above shall not apply to the invention of an employee where a relevant collective agreement provides for the payment of compensation in respect of inventions of the same description as that invention to employees of the same description as that employee.

Collective agreements regarding compensation

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40.16 An employee who has made an invention cannot take advantage of the provisions of s.40(1) and (2) if he and his employer are covered by a relevant collective agreement (as defined in s.40(6)) regarding the payment of compensation in respect of such inventions. The agreement must relate to inventions of the same description as that in question and employees of the same description as the employee who made the invention in question. His rights to any compensation are then governed by the agreement instead of by those provisions.

Section 40(4)

Subsection (2) above shall have effect notwithstanding anything in the relevant contract or any agreement applicable to the invention (other than any such collective agreement).

Section 40(5)

If it appears to the comptroller on an application under this section that the application involves matters which would more properly be determined by the court, he may decline to deal with it.

Comptroller declines to deal with application

40.17 The comptroller has discretion to decline to deal with an application under s.40 (or one under s.41(8), see 41.08-10) if it appears to him that it involves matters which would more properly be determined by the court. The observations in 8.29 on the exercise of such discretion to decline to deal with questions of entitlement appear to apply mutatis mutandis here.

CPR 63.11 40.18 In such a case any person entitled to do may, within 14 days after the comptroller's decision, apply to the court by originating summons to determine the application.

Section 40(6)

In this section -

"the prescribed period", in relation to proceedings before the court, means the period prescribed by rules of court, and

"relevant collective agreement" means a collective agreement within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992, made by or on behalf of a trade union to which the employee belongs, and by the employer or an employers' association to which the employer belongs which is in force at the time of the making of the invention.

40.19 The definition of "relevant collective agreement" was amended by s.300(2), Sch 2, para 9 of the Trade Union and Labour Relations (Consolidation) Act 1992 to include a reference to this Act.

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Section 40(7)

References in this section to an invention belonging to an employer or employee are references to it belonging as between the employer and the employee.

Invention belonging to employer or employee

40.20 The references in s.40(1) and (2) to an invention belonging to an employer or employee relate to questions of ownership by one or the other in accordance with s.39. Ownership jointly with a third party or parties is not precluded.

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Section 41: Amount of compensation

41.01 This is the third of the group of sections relating to inventions made by employees, and concerns the amount of compensation to be awarded to an employee inventor by the court or the comptroller in proceedings under s.40(1) or (2), see 40.04-15. It also makes provision for further applications under s.40 after refusal to order an award of compensation, for variation of such an order and for enforcement of such an order made by the comptroller. This section was amended by the Patents Act 2004 in consequence to the changes made to section 40 to allow compensation to be awarded in respect of all outstanding benefits deriving from a patented invention, applying to patent applications made from 1 January 2005 onwards (see 40.02).

41.02 For the applicability of s.41 and interpretation of certain terms used therein, see 39.01-04.

Section 41(1)

An award of compensation to an employee under section 40(1) and (2) above in relation to a patent for an invention shall be such as will secure for the employee a fair share (having regard to all the circumstances) of the benefit which the employer has derived, or may reasonably be expected to derive, from any of the following -

- (a) the invention in question;
- (b) the patent for the invention;
- (c) the assignment, assignation or grant of -
 - (i) the property or any right in the invention, or
 - (ii) the property in, or any right in or under, an application for the patent,

to a person connected with the employer.

Section 41(2)

For the purposes of subsection (1) above the amount of any benefit derived or expected to be derived by an employer from the assignment, assignation or grant of -

- (a) the property in, or any right in or under, a patent for the invention or an application for such a patent; or
- (b) the property or any right in the invention;

to a person connected with him shall be taken to be the amount which could reasonably be expected to be so derived by the employer if that person had not been connected with him.

Section 41(3)

Where the Crown or a Research Council in its capacity as employer assigns or grants the property in, or any right in or under, an invention, patent or application for a patent to a body having among its functions that of developing or exploiting inventions resulting from public research and does so for no consideration or only a nominal consideration, any benefit

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derived from the invention, patent or application by that body shall be treated for the purposes of the foregoing provisions of this section as so derived by the Crown or, as the case may be, Research Council.

In this subsection "Research Council" means a body which is a Research Council for the purposes of the Science and Technology Act 1965.

Section 41(4)

In determining the fair share of the benefit to be secured for an employee in respect of an invention which has always belonged to an employer, the court or the comptroller shall, among other things, take the following matters into account, that is to say -

- (a) the nature of the employee's duties, his remuneration and the other advantages he derives or has derived from his employment or has derived in relation to the invention under this Act;
- (b) the effort and skill which the employee has devoted to making the invention;
- (c) the effort and skill which any other person has devoted to making the invention jointly with the employee concerned, and the advice and other assistance contributed by any other employee who is not a joint inventor of the invention; and
- (d) the contribution made by the employer to the making, developing and working of the invention by the provision of advice, facilities and other assistance, by the provision of opportunities and by his managerial and commercial skill and activities.

Section 41(5)

In determining the fair share of the benefit to be secured for an employee in respect of an invention which originally belonged to him, the court or the comptroller shall, among other things, take the following matters into account, that is to say -

- (a) any conditions in a licence or licences granted under this Act or otherwise in respect of the invention or the patent for it;
- (b) the extent to which the invention was made jointly by the employee with any other person; and
- (c) the contribution made by the employer to the making, developing and working of the invention as mentioned in subsection (4)(d) above.

Section 41(6)

Any order for the payment of compensation under section 40 above may be an order for the payment of a lump sum or for periodical payment, or both.

s.43(7) 41.03 An award of compensation should be such as to secure for the employee who made the invention a fair share (having regard to all the circumstances) of the benefit derived or reasonably expected to be derived by the employer. Benefit means benefit in money or money's worth and, where the employer has died, is determined in accordance with s.43(5) (see 40.07).

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- Where the property or any right in the invention or any patent for it or application for such a patent has been assigned or granted to another person or body, s.41(2) and (3) may be applicable to assessment of the benefit to the employer. Subsection (2) applies where it has been assigned or granted to a person connected with the employer, The effect of this subsection is that the award is based on the benefit that the employer would have been expected to derive from the transaction had that person not been connected to the employer. The test for determining whether the other party is connected to the employer is set out in s.43(8).
- 41.04.1. The Court of Appeal in Shanks v Unilever [2011] RPC 12 held that "that person" in s.41(2) refers to the actual assignee, with the same attributes as the real person, but without the connection to the employer. Therefore, if the actual assignee had not fully exploited the invention or patent, then this would be reflected in the value of the compensation. This overturned the decision of the Patents Court (Shanks v Unilever [2010] RPC 11), which had held that the assessment of this hypothetical benefit should be based on the premise that the transaction with "that person" was with a notional non-connected counterparty operating in the appropriate market at the appropriate time. At the same time, the Court of Appeal held that the compensation should take account of the actual benefit that the assignee had derived from the patent or invention to date, together with the likely future benefit if the patent is still in force. The Court rejected the argument (from the employer and assignee) that the compensation should be based on what the likely value of the transaction would have been on the open market at the time it was made, without the benefit of hindsight. It was considered that this would lead to an unjust result as in many cases the value of a patent is not known at the time of assignment.
- Matters to be taken into account in determining a fair share of the benefit are set out, where the invention has always belonged to the employer, in s.41(4) and, where the invention originally belonged to the employee, in s.41(5). *Kelly & Anor v GE Healthcare Ltd* [2009] EWHC 181 (Pat), [2009] RPC 12 was the first successful s.40 employee compensation claim in the UK. In this case, having determined the benefits of the patents to the company under the pre-2005 form of s.40, Floyd J took each of the factors set out in s.41(4) into account before deciding what was a fair and just share of the benefit for each of the employees concerned.
- 41.06 The court or the comptroller may order payment of a lump sum and/or periodical payment as compensation, to be paid by the employer. For enforcement of orders made by the comptroller for such payment, see 41.11.

Section 41(7)

Without prejudice to section 12 or section 14 of the Interpretation Act 1978 (which provides that a statutory power may in general be exercised from time to time), the refusal of the court or the comptroller to make any such order on an application made by an employee under section 40 above shall not prevent a further application being made under that section by him or any successor in title of his.

Further applications under s.40

41.07 The refusal of the court or the comptroller to order the payment of compensation under s.40 does not prevent the employee or any successor in title from making a further application under s.40. The reference to the Interpretation Act 1978 in s.41(7) replaced the previous reference to the Interpretation Act 1889, this amendment having been effected by s.25(2) of the 1978 Act.

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Section 41(8)

Where the court or the comptroller has made any such order, the court or he may on the application of either the employer or the employee vary or discharge it or suspend any provision of the order and revive any provision so suspended, and section 40(5) above shall apply to the application as it applies to an application under that section.

Variation of order for payment of compensation

- 41.08 Where the court or the comptroller has made an order for the payment of compensation under s.40, the employer or the employee may under s.41(8) apply for any provision of the order to be varied, discharged, suspended or revived. The application may be made to the court or to the comptroller.
- PR part 7 41.09 Such an application to the comptroller under s.41(8) should be made on r.51(3)(a) Patents Form 2 accompanied by a copy thereof and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 123.05.13. Documents filed at the Office in connection with the application are not open to public inspection unless the comptroller otherwise directs.
 - 41.10 The comptroller may, under s.40(5), decline to deal with the application made under s.41(8) (see 40.17-18).

Section 41(9)

In England and Wales any sums awarded by the comptroller under section 40 above shall, if the county court so orders, be recoverable by execution issued from the county court or otherwise as if they were payable under an order of that court.

Section 41(10)

In Scotland an order made under section 40 above by the comptroller for the payment of any sums may be enforced in like manner as an extract registered decree arbitral bearing a warrant for execution issued by the sheriff court of any sheriffdom in Scotland.

Section 41(11)

In Northern Ireland an order made under section 40 above by the comptroller for the payment of any sums may be enforced as if it were a money judgment.

Section 41(12)

In the Isle of Man an order made under section 40 above by the comptroller for the payment of any sums may be enforced in like manner as an execution issued out of the court.

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Enforcement of order made by the comptroller

41.11 Orders made by the comptroller for the payment of compensation under s.40 may be enforced in different parts of the UK as set out in s.41(9) to (12). Subsection (12) was added by S.I. 1978 No. 621, which has since been replaced by S.I. 2003 No. 1249.

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Section 42: Enforceability of contracts relating to employees' inventions

This is the fourth of the group of sections relating to inventions made by employees. It relates to the enforceability of contractual terms diminishing an employee's rights in connection with inventions made by him after 1 June 1978.

42.02 For the applicability of s.42 and interpretation of certain terms used therein, see 39.01-04.

Section 42(1)

This section applies to any contract (whenever made) relating to inventions made by an employee, being a contract entered into by him -

- (a) with the employer (alone or with another); or
- (b) with some other person at the request of the employer or in pursuance of the employee's contract of employment.

Section 42(2)

Any term in a contract to which this section applies which diminishes the employee's rights in inventions of any description made by him after the appointed day and the date of the contract, or in or under patents for those inventions or applications for such patents, shall be unenforceable against him to the extent that it diminishes his rights in an invention of that description so made, or in or under a patent for such an invention or an application for any such patent.

42.03 The contracts to which s.42 applies may be of any date but must have been entered into by the employee with the employer or with some other person at the request of the employer or in pursuance of the employee's contract of employment (as detailed in subsection (1)). Any term in such a contract diminishing the employee's rights in inventions (or patents for them or applications for such patents) of any description made by him after the appointed day (1 June 1978) and the date of the contract is unenforceable against him to the extent that it diminishes those rights.

Thus a contractual term cannot be enforced in a way which would deny an employee his rights to certain of his inventions as laid down by s.39, see 39.08.

Section 42(3)

Subsection (2) above shall not be construed as derogating from any duty of confidentiality owed to his employer by an employee by virtue of any rule of law or otherwise.

42.05 Any duty of confidentiality owed to his employer by an employee is not overridden or diminished by s.42.

Section 42(4)

This section applies to any arrangements made with a Crown employee by or on behalf of the Crown as his employer as it applies to any contract made between an employee and an

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employer other than the Crown, and for the purposes of his section "Crown employee" means a person employed under or for the purposes of a government department or any officer or body exercising on behalf of the Crown functions conferred by any enactment or a person serving in the naval, military or air forces of the Crown.

42.06 Section 42 is made applicable to Crown employees by subsection (4), any "arrangement" between such an employee and the Crown as his employer taking the place of a contract between an employee and his employer other than the Crown. The wording following "enactment" in subsection (4) was added by s.22 of the Armed Forces Act 1981.

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Section 43: Supplementary

This is the fifth and last of the group of sections relating to inventions made by employees. Its provisions supplement those of ss.39 to 42 and relate to the applicability and construction of those sections. The various provisions of s.43 are referred to where appropriate in the chapters on ss.39 to 42.

Section 43(1)

Sections 39 to 42 above shall not apply to an invention made before the appointed day.

Section 43(2)

Sections 39 to 42 above shall not apply to an invention made by an employee unless at the time he made the invention one of the following conditions was satisfied in his case, that is to say -

- (a) he was mainly employed in the United Kingdom; or
- (b) he was not mainly employed anywhere or his place of employment could not be determined, but his employer had a place of business in the United Kingdom to which the employee was attached, whether or not he was also attached elsewhere.

Section 43(3)

In sections 39 to 42 above and this section, except so far as the context otherwise requires, references to the making of an invention by an employee are references to his making it alone or jointly with any other person, but do not include references to his merely contributing advice or other assistance in the making of an invention by another employee.

Section 43(4)

Any references in sections 39 to 42 above to a patent and to a patent being granted are respectively references to a patent or other protection and to its being granted whether under the law of the United Kingdom or the law in force in any other country or under any treaty or international convention.

Section 43(5)

For the purposes of sections 40 and 41 above the benefit derived or expected to be derived by an employer from an invention or patent shall, where he dies before any award is made under section 40 above in respect of it, include any benefit derived or expected to be derived from it by his personal representatives or by any person in whom it was vested by their assent.

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Section 43(5A)

For the purposes of sections 40 and 41 above the benefit derived or expected to be derived by an employer from an invention shall not include any benefit derived or expected to be derived from the invention after the patent for it has expired or has been surrendered or revoked.

43.02 Section 43(5A) was added by the Patents Act 2004. This subsection ensures that when assessing benefits under section 40(1) or (2) in relation to inventions made by an employee and calculating the amount of compensation under section 41, benefits that arise after the relevant patent has ceased cannot be taken into account.

Section 43(6)

Where an employee dies before an award is made under section 40 above in respect of a patented invention made by him, his personal representatives or their successors in title may exercise his right to make or proceed with an application for compensation under subsection (1) or (2) of that section.

Section 43(7)

In sections 40 and 41 above and this section "benefit" means benefit in money or money's worth.

Section 43(8)

Section 533 of the Income and Corporation Taxes Act 1970 (definition of connected persons) shall apply for determining for the purposes of section 41(2) above whether one person is connected with another as it applies for determining that question for the purposes of the Tax Acts.

43.03 S.43(8) refers to s.533 of the Income and Corporation Taxes Act 1970 which was repealed and replaced by s.839 of the Income and Corporation Taxes Act 1988. No consequential amendment was made to s.43(8).

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CONTRACTS AS TO PATENTED PRODUCTS, ETC.

as a defence in infringement proceedings.

Section 44: Avoidance of certain restrictive conditions [repealed with savings]

- s.130(1) 44.01 This section renders ineffective certain restrictive conditions or terms of contracts for the supply of a patented product or of licences to work a patented invention or of related contracts. (By patented invention is meant an invention for which a patent is granted. Patented product means a product which is a patented invention or, in relation to a patented process, a product obtained directly by means of the process or to which the process has been applied.) It also concerns use of the presence of such a condition or term
 - 44.01.1 This section ceased to have effect for new agreements when Section 70 of the Competition Act 1998 came into effect along with the main powers of that Act from 1 March 2000. The provisions of the Competition Act are therefore effective instead to prevent restrictive practices. However a saving in The Competition Act 1998 (Transitional, Consequential and Supplemental Provisions) Order 2000 means that section 44 will continue to apply to agreements entered into before 1 March 2000. Under Section 52 of the Competition Act, the Office of Fair Trading will publish guidelines about the application and enforcement of the prohibitions contained in that Act. See also 45.01.1.
 - 44.02 The present s.44 is substantially a re-enactment of s.57 of the 1949 Act which in turn was based on s.38 of the 1907 Act. The mischief to which that s.38 was directed was to prevent a patentee from abusing his monopoly by placing restrictions on the acquisition and use of products other than the patented products (observed in the judgment of the Court of Appeal in *Fichera v. Flogates Ltd* [1984] RPC 257, see also 44.06-07, 44.10 and 44.12).
- s.77(1) 44.03 The provisions of s.44 apply in relation to not only patents granted under the 1977 Act, but also granted European patents (UK).
 - Restrictive conditions may also offend against the Treaty establishing the European Economic Community, particularly Article 81 (previously 85) thereof which prohibits agreements affecting trade between member states and preventing, restricting or distorting competition within the common market. The position with regard to provisions in patent licence agreements is also governed by EEC Regulation No. 240/96, see [1996] FSR 397.

Section 44(1)

Subject to the provisions of this section, any condition or term of a contract for the supply of a patented product or of a licence to work a patented invention, or of a contract relating to any such supply or licence, shall be void in so far as it purports -

- (a) in the case of a contract for supply, to require the person supplied to acquire from the supplier, or his nominee, or prohibit him from acquiring from any specified person, or from acquiring except from the supplier or his nominee, anything other than the patented product;
- (b) in the case of a licence to work a patented invention, to require the licensee to acquire from the licensor or his nominee, or prohibit him from acquiring from any specified person, or from acquiring except from the licensor or his nominee, anything other than the product which is the patented invention or (if it is a process) other than any product obtained directly by means of the process or to which the process has been applied;

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- (c) in either case, to prohibit the person supplied or licensee from using articles (whether patented products or not) which are not supplied by, or any patented process which does not belong to, the supplier or licensor, or his nominee, or to restrict the right of the person supplied or licensee to use any such articles or process.
- Subject to the exceptions to which 44.08 and 44.11-12 refer, any condition or term of such a contract or licence (see 44.01) is void in so far as it purports to impose any of the requirements, prohibitions or restrictions set out in s.44(1)(a), (b) and (c). These relate to the acquisition of anything other than the patented product (as defined in 44.01) and the use of articles and patented processes.
- 44.06 Subsection (1) is of a highly penal nature since it not only renders the condition or term void but also (by virtue of s.44(3), see 44.09) affords a defence to an infringer. It should therefore be construed strictly (observed in the judgment of the Court of Appeal in *Fichera v Flogates Ltd* [1984] RPC 257).
- 44.07 It was also held in *Fichera v Flogates Ltd* that s.44 is concerned only with conditions and terms which are enforceable by action for damages for breach of contract.

Section 44(2)

Subsection (1) above applies to contracts and licences whether made or granted before or after the appointed day, but not to those made or granted before 1st January 1950.

44.08 Subsection (1) applies to contracts and licences made or granted on or since 1 January 1950 (the day on which the 1949 Act came into operation) but not those made or granted previously.

Section 44(3)

In proceedings against any person for infringement of a patent it shall be a defence to prove that at the time of the infringement there was in force a contract relating to the patent made by or with the consent of the plaintiff or pursuer or a licence under the patent granted by him or with his consent and containing in either case a condition or term void by virtue of this section.

- 44.09 The presence in a relevant contract or licence of a condition or term void by virtue of s.44 is, if proved by the infringer, a defence in infringement proceedings. The contract or licence must have been in force at the time of the infringement of the patent in question.
- In *Fichera v. Flogates Ltd* (see 44.02), it was held that none of the conditions or terms offended under s.44(1), the attempted defence under s.44(3) therefore failed and the plaintiffs were entitled to an enquiry as to damages in respect of the infringement. However, an infringement action in *Chiron Corpn v Organon Teknika Ltd* [1994] FSR 202 was successfully defended because an agreement required the defendant to buy raw materials from the proprietors whether it was patented or not. Earlier in *Chiron Corpn v Organon Teknika Ltd* [1993] FSR 324 and 567 the Court of Appeal held that it was immaterial to the operation of s.44(3) that the agreement in question was governed by a foreign law.

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Section 44(4)

A condition or term of a contract or licence shall not be void by virtue of this section if -

- (a) at the time of the making of the contract or granting of the licence the supplier or licensor was willing to supply the product, or grant a licence to work the invention, as the case may be, to the person supplied or licensee, on reasonable terms specified in the contract or licence and without any such condition or term as is mentioned in subsection (1) above; and
- (b) the person supplied or licensee is entitled under the contract or licence to relieve himself of his liability to observe the condition or term on giving to the other party three months' notice in writing and subject to payment to that other party of such compensation (being, in the case of a contract to supply, a lump sum or rent for the residue of the term of the contract and, in the case of a licence, a royalty for the residue of the term of the licence) as may be determined by an arbitrator or arbiter appointed by the Secretary of state.

Section 44(5)

If in any proceeding it is alleged that any condition or term of a contract or licence is void by virtue of this section it shall lie on the supplier or licensor to prove the matters set out in paragraph (a) of subsection (4) above.

s.44(4)(a) s.44(5) s.44(4)(b) Subsection (1) does not operate to void a condition or term if (a) at the time the contract or licence was made, the supplier or licensor was willing to agree to different terms which were reasonable and excluded any offending under subsection (1) (the onus being on the supplier or licensor to prove these matters); and (b) the contract or licence entitles the person supplied or licensee to relieve himself of his liability to observe the offending condition or term, subject to three months notice and payment of compensation.

Section 44(6)

A condition or term of a contract or licence shall not be void by virtue of this section by reason only that it prohibits any person from selling goods other than those supplied by a specific person or, in the case of a contract for the hiring of or licence to use a patented product, that it reserves to the bailor (or, in Scotland, hirer) or licensor, or his nominee, the right to supply such new parts of the patented product as may be required to put or keep it in repair.

A condition or term is not made void by subsection (1) by reason only that (a) it prohibits any person from selling goods other than those supplied by a specific person, or (b) in the case of a contract for the hiring of or licence to use a patented product, it reserves the right to supply such new parts of the patented product as may be required to put or keep it in repair. The latter is wide enough to provide an exception for the replacement of worn as well as damaged parts (judgment of Court of Appeal in *Fichera v. Flogates Ltd* - see 44.02).

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Section 45: Determination of parts of certain contracts [repealed with savings]

45.01 This section provides for the termination or variation of contracts and licences relating to patented inventions when the patents concerned have ceased to be in force.

45.01.1 This section, along with section 44, ceased to have effect for most purposes from 1 March 2000 when Section 70 of the Competition Act 1998 came into force. However a saving in The Competition Act 1998 (Transitional, Consequential and Supplemental Provisions) Order 2000 means that this section will continue to apply where an application was made or notice was given under section 45(1) or (3) before that date. See also 44.01.1.

s.77(1) Sch.2, Para s.45(5) 45.02 The provisions of s.45 apply in relation to patents granted under the 1977 Act patents, including granted European patents (UK). It is immaterial whether the contract or licence was made before or after the day the section came into operation (1 June 1978).

Section 45(1)

Any contract for the supply of a patented product or licence to work a patented invention, or contract relating to any such supply or licence, may at any time after the patent or all the patents by which the product or invention was protected at the time of the making of the contract or granting of the licence has or have ceased to be in force, and notwithstanding anything to the contrary in the contract or licence or in any other contract, be determined, to the extent (and only to the extent) that the contract or licence relates to the product or invention, by either party on giving three months' notice in writing to the other party.

Section 45(2)

In subsection (1) above "patented product" and "patented invention" include respectively a product and an invention which is the subject of an application for a patent, and that subsection shall apply in relation to a patent by which any such product or invention was protected and which was granted after the time of the making of the contract or granting of the licence in question, on an application which had been filed before that time, as it applies to a patent in force at that time.

This section applies to any contract for the supply of a patented product or licence to work a patented invention, or contract relating to any such supply or licence. For the purposes of this section, the normal definitions of "patented product" and "patented invention" in s.130(1) are modified in accordance with s.45(2). After the cessation of the patent or patents by which the product or invention was protected, either party may on giving three months' notice in writing to the other party terminate the contract or licence to the extent that it relates to the product or invention.

Section 45(3)

If, on an application under this subsection made by either party to a contract or licence falling within subsection (1) above, the court is satisfied that, in consequence of the patent or patents concerned ceasing to be in force, it would be unjust to require the applicant to continue to comply with all the terms and conditions of the contract or licence, it may make such order varying those terms or conditions as, having regard to all the circumstances of the case, it thinks just as between the parties.

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CPR 63.5 45.04 It is also possible for a party to such a contract or licence to apply to the court for variation of its terms or conditions. Such proceedings must be begun by issue of a claim form. The court may vary any such terms or conditions which, in consequence of the cessation of the patent or patents concerned and having regard to all the circumstances, it considers to be unjust.

45.05 [deleted]

Section 45(4)

Without prejudice to any other right of recovery, nothing in subsection (1) above shall be taken to entitle any person to recover property bailed under a hire-purchase agreement (within the meaning of the Consumer Credit Act 1974).

Section 45(5)

The foregoing provisions of this section apply to contracts and licences whether made before or after the appointed day.

Section 45(6)

The provisions of this section shall be without prejudice to any rule of law relating to the frustration of contracts and any right of determining a contract or licence exercisable apart from this section.

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LICENCES OF RIGHT AND COMPULSORY LICENCES

Section 46: Patentee's application for entry in register that licences are available as of right

This section provides for the making of an entry in the register that licences under a patent are available as of right, thereby reducing subsequent renewal fees by half. Such entries in the register under s.46 may be made at the request of the proprietor of the patent. It is also concerned with the settlement of the terms of such licences and with proceedings for infringement of a patent under which such a licence has been granted. Section 47 makes provision for the cancellation of an entry made under this section. Procedures under s.46 are prescribed by rule 43 and Part 7 of the Patents Rules 2007.

s.53(4) s.49(4) Sections 48 to 54 relate to the making of entries that licences are available as of right (and the compulsory grant of licences without there being such an entry) by order of the comptroller. A compulsory entry made under ss.48 to 51 has the same effect as an entry made under s.46, and some of the provisions of s.46 also apply to a licence granted by virtue of a compulsory entry. According to the observations of Lord Diplock in the House of Lords in Allen & Hanburys Ltd v Generics (UK) Ltd and Gist-Brocades NV and others and the Comptroller-General of Patents [1986] RPC 203 (hereinafter known as the Gist-Brocades case), recourse may be had to the provisions of s.48(3) and s.50 to identify the policy to be achieved when settling the terms of a licence under s.46(3) (even though the Act does not specifically state this to be so), as discussed in 46.29.

46.03-04 [deleted]

The term 'licence' has been defined by Lord Diplock in his judgment in the 'Gist-Brocades' case [1986] RPC 203 at page 246 as follows: "A licence passes no proprietary interest in anything, it only makes an action lawful that would otherwise have been unlawful. In the context of the royal grant of patents for inventions it was a consent given by the proprietor of the patent to another person, the licensee, to do something that the patent entitled the proprietor of it to prevent anyone from doing except with his consent. This is the meaning which "licence" has borne throughout the UK patent legislation up to and including the Act of 1977. Apart from certain statutory prohibitions ... such a licence, at any rate where it is granted by the proprietor of his own free will, may be subject to whatever limitations or conditions the proprietor thinks fit to impose".

ss.48-51 s.24(2); r34 As Lord Diplock goes on to explain, the concept of the particular class of licences known as "licences of right" was introduced into domestic patent law by the Patents and Designs Act 1919. That Act provided that the words "licences of right" could be endorsed upon a patent and entered in the register either voluntarily at the request of the patentee or compulsorily by order of the comptroller upon the application of any interested person on the ground that there had been an abuse of monopoly rights under the patent, the legal consequences being the same whether the endorsement was made voluntarily or compulsorily. Those provisions have been reenacted in the present Act, although since this provides for issue of a certificate of grant rather than letters patent the fact that licences are available as of right is only entered in the register.

46.07 From 1st January 2012, applicants interested in licensing the inventions contained in their international applications can request the International Bureau of WIPO to make this information available on its Patentscope website. Although this will indicate that a licence of right is available for the invention contained in the international application, this will have no effect under section 46(1) of the Act when the application enters the national phase. An entry that a licence is available as of right can only be recorded on the Register once the patent has been granted. Applicants wishing to apply for an entry to be made in the Register that licences are available as of right on their international application (UK) will need to request this after the patent application has been granted as detailed in paragraph 46.08 below.

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Section 46(1)

At any time after the grant of a patent its proprietor may apply to the comptroller for an entry to be made in the register to the effect that licences under the patent are to be available as of right.

APPLICATION FOR "LICENCES OF RIGHT" ENTRY

r.43(1) s.46(3)(d) At any time after the publication in the Journal of notice of grant of a patent (see 25.02) its proprietor may apply for a "licences of right" entry to be made in the register. The application should be made on Patents Form 28. It is advisable to make the application at least ten working days (longer if other persons need to be notified, see 46.09) before renewal of the patent falls due so as to allow time for the entry to be made before that date. If the entry is not made in time, payment of that renewal fee at full rate is necessary instead of at the half rate payable after the day of the entry. Renewal fees that have already been paid cannot be refunded retrospectively following the appearance of a "licences of right" entry on the register.

Section 46(2)

Where such an application is made, the comptroller shall give notice of the application to any person registered as having a right in or under the patent and, if satisfied that the proprietor of the patent is not precluded by contract from granting licences under the patent, shall make that entry.

46.09 Form 28 includes a declaration that the applicant is not prevented by contract from granting licences under the patent. Any person registered as having a right in or under the patent is notified that the form has been filed and given a period of time (normally fourteen days) in which to make any observations; no entry is made during that period or while any observations received are being considered.

r.43(2)

When the Office is satisfied that the grant of licences is not so precluded, the entry in the register is made. Form 28 also includes a tear-off slip which is then stamped and returned to the applicant to confirm that the entry has been made. The making of the entry is announced in the Journal. Interested parties have two months in which to apply for cancellation of the entry, see 47.07, except that the proprietor of the patent can apply for cancellation at any time, see 47.03.

Section 46(3)

Where such an entry is made in respect of a patent -

(a) any person shall, at any time after the entry is made, be entitled as of right to a licence under the patent on such terms as may be settled by agreement or, in default of agreement, by the comptroller on the application of the proprietor of the patent or the person requiring the licence;

APPLICATIONS FOR COMPTROLLER TO SETTLE TERMS OF LICENCE

46.11 Applications for settlement of terms of licences under patents where owners have volunteered to make licences available as of right have been extremely rare, and only

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one such case has been reported (*Cassou's Patent* [1971] RPC 91). In that case, which arose under Section 35 of the 1949 Act, the invention was taken to reside in the use of a sterilized plastics sheath in association with a known type of injection gun used for artificial insemination purposes, and royalty was settled at 5% of the selling price of the sheaths on the basis that that seemed to be the going rate in commercial agreements of like nature. It was further decided that the licence should continue for the duration of the patent in suit.

- 46.12 In the *Cassou* case, the patentee's response to the application under section 35 included the filing of an application under section 36(1) for cancellation of the endorsement "licences of right", but it was decided that cancellation was discretionary and the discretion should not be exercised in such a way as to defeat the purpose of section 35. In the result, the licence provided for consent of the applicants (licensees) to cancellation of the endorsement.
- 46.13 There were a relatively large number of applications for settlement of terms of licences under "new existing patents". Although all such patents have now expired, similar principles will apply for other cases, such as where an application under section 48 has resulted in an entry in the register that licences are available as of right.
- PR part 7 46.14 Applications under section 46(3)(a) are initiated by filing Patents Form 2 (and a copy thereof) to start proceedings before the comptroller, the procedure for which is discussed at 123.05 123.05.13. Where (a) the applicant is the proprietor of the patent, Form 2 should be accompanied by a statement of grounds including, as appropriate, the period or terms of the licence he proposes. Where (b) the application is made by any other person, Form 2 should be accompanied by two copies of a draft of the licence he seeks. Because in the latter case the applicant does not usually have many of the relevant facts, he is thus only required to provide a draft licence. In the case of an application by any other person who is an existing licensee see 46.77.
- PR part 7 46.14.1 In case (a) the proceedings continue as set out at 123.05 123.05.13. In case (b), the comptroller must notify the proprietor that an application has been made, send him a copy of the draft licence and specify a period for the proprietor to file a statement of grounds if he wishes to contest the applicant's case. If the proprietor files a statement of grounds, the proceedings continue as if the proprietor were the claimant and the applicant the defendant; the applicant is therefore given an opportunity to file a counter-statement in response to the proprietor's statement.

[46.14.2 Deleted]

46.15 The sufficiency of the statement was at issue in Roussel-Uclaf (Clemence & le Martret's) Patent [1987] RPC 109, and in that case it was decided, after a first preliminary hearing, that although the statement was not unlike many which were filed and accepted in the absence of a challenge, it did not in fact meet the strict requirements of the old r.63(1). (R.63 of the 1982 Rules was repealed by the 1990 Rules.) The statement in that case was accompanied by a draft licence containing terms acceptable to the applicant Harris, but it simply identified the parties, the patent and the product covered by the patent, and stated that Harris wished to do all acts which but for the licence would amount to infringement. In the view of the hearing officer, whilst patentees cannot reasonably expect to find in the statement answers of a confidential nature to questions which may seem relevant, it would be reasonable for the applicants to state whether they intend to manufacture themselves or obtain the product from some other source. If the latter the intended source should be indicated, and any intentions as regards importation and exportation should also be stated, as should the form of presentation of the product. The principles on which the applicants rely in arriving at the proposed royalty should also be stated, although costs and profits need not be included in the statement. In general, the hearing officer observed that "The statement in my view must contain sufficient facts to foreshadow what is subsequently produced in the evidence". The hearing officer's views were not challenged on a first appeal in that case, but Falconer, J. did qualify the statement just quoted by saying that: "... the statement should contain a clear statement of the facts which are to be relied on and which will be proved by the evidence. In that way, if the matter is so pleaded, only then can one

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hope to keep the evidence to essential matters which on the counterstatement would turn out to be in issue". Following further preliminary hearings in that case, it was confirmed by the hearing officer that information on purchase price, selling price and anticipated profit need not be given in the statement, and that decision was upheld on appeal by Falconer, J. In the statement as finally settled, the applicants pleaded particular facts and matters on which they relied in support of their proposed royalty rate and the judge observed: "They are bound now of course by those and will not be allowed to go outside them. Those are the facts upon which they rely".

The sufficiency of the pleadings should be considered in the light of the 46.16 observation of Graham, J. in Ford Motor Co Ltd (Cuskie's) Application [1973] RPC 573 at page 576; "I think it is not right to treat a pleading in the Patent Office with that great strictness with which pleadings are treated in the High Court". That approach was adopted in Roussel-Uclaf and also in Smith Kline and French Laboratories Ltd's Patents 1338169 and 1397436 (Generics' Application) [1988] RPC 148 where the hearing officer proceeded on the basis that, since the question of whether the statement is entirely satisfactory can only be fully determined after the applicant has filed his evidence, it is only in the clearest of cases that he should intervene. In the latter case, the hearing officer did order that the statement be amended to indicate whether the applicant intended selling or exporting active ingredients per se (as well as pharmaceutical formulations) and to set out the royalty rate(s), but he refused to order amplification of the forms of presentation proposed to be marketed and the intentions regarding exportation, selling price and the particular countries they might import from. His view was that if the applicant's precise intentions are not firmed up, their only course may well be to draw their licence request very broadly, thus giving themselves the flexibility to adapt to prevailing market conditions at any time during the period of the licence. The fact that certain formulations and manufacturing routes might infringe other patents was not considered directly material to the application in suit, but was a matter for other proceedings. In Smith Kline & French Laboratories Ltd's Patents 1338169, 1395929, 1397436 and 1398426 (Harris Pharmaceuticals' Application [1990] RPC 203), the statement as filed did not refer to sub-contracting. The hearing officer held that the statement could be amended to refer to sub-contracting of packaging of the finished pharmaceutical dosage form since this fell outside the claims of the patents. The applicant also wished to subcontract the manufacture of the raw material and the making up of that material into the dosage form. Such manufacture and making up were held to fall within the scope of or infringe the claims and therefore to be acts which need to be sub-licensed. In order to pursue sub-contracting of these acts, the hearing officer held that the proposed subcontractors would have to be joined in the present application or in a fresh one with details of the intended form of sub-contract being given.

Sufficiency of pleadings has also been considered in Upjohn's Patent 46.17 1291632 (BL O/40/87; BL O/102/87), where it was decided following a first preliminary hearing that particular compounds to be imported under the licence should be specified, and that whilst the country or countries of origin should be identified the particular manufacturer(s) or town(s) need not be. Further information regarding the manufacturing process was not considered necessary, and it was also considered unnecessary to elaborate as to why no price advantage was obtained if a patented process was used. The patentees instituted a parallel infringement action against the applicants in that case and sought a stay of proceedings until the outcome of that action was known, but this was refused. The patent in suit was a divisional claiming a process and intermediates of use in preparing pharmaceutically active compounds claimed in the parent patent (the subject of a separate application under section 46), and although they were seeking a licence the applicants nevertheless declined to admit that they would in fact be infringing the divisional in working the licence under the parent, and would therefore give no undertaking to pay royalty under the (divisional) licence. In these circumstances, the patentees argued that the applicants should be put to an election: either admit infringement and pursue the application or deny infringement and withdraw the application, otherwise the application should be struck out on the ground that there was no jurisdiction to hear the case or that it was an abuse of process. Those arguments were rejected following a second preliminary hearing.

46.18 Various objections to the pleadings were also considered in *Monsanto's*

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Patent 1366379 (BL O/116/87), where evidence filed shortly before a preliminary hearing to support the patentees request for further information was not admitted. The evidence was concerned with the quality of some products which might be imported under the licence, but it was felt that this was a matter which could be raised in the counterstatement and evidence. In any case, the applicants had not had an opportunity to reply to it. As regards the importation rights sought in the statement, which were effectively unlimited, the hearing officer did not consider he had the power to require the applicants to limit themselves to particular countries at that stage, but he did envisage that further information might be required later if any issue in the evidence stages turned on the source of the product. The patent covered herbicidal compounds and compositions and the hearing officer decided that the formulations which the applicants wished to sell were sufficiently identified in the statement even though all the ingredients and their precise quantities were not specified. Proposed sales to manufacturers and formulators under the licence of one particular compound used for preparing the herbicidal compositions but not claimed per se were not seen as objectionable. It was appreciated that the purchaser would infringe the patent if he produced the claimed formulation, but that was considered to be of no concern in those proceedings. It was sufficient that the applicants were seeking a licence to cover that particular compound (even though, being a known compound, it was not covered by the claims) and were therefore protecting themselves against contributory infringement under Section 60(2).

It is established practice to allow the parties to file evidence as in other inter partes procedures. In those cases where the parties reached agreement it has been the usual practice to issue a decision ordering the grant of a licence on the agreed terms having confirmed that the terms contain nothing prima facie unlawful (see eg the unreported decision (BL O/91/87) on an application by Thomas Kerfoot & Co Ltd in respect of ICI's atenolol Patent No 1285038).

In those cases where the parties were unable to agree terms, it has become the practice to adopt the format usual in inter-partes proceedings, ie the parties are allowed a period to file evidence in support of their case in turn and the party who first filed evidence is allowed to file evidence in reply, following which a hearing is appointed. In some cases (under the old Rule 63), the applicants adopted the practice of filing their first round of evidence with their statement and requested that the patentees be directed to file their evidence with the counterstatement. This has been acceded to where appropriate, due account being taken of the decision of the House of Lords in the Gist-Brocades case (see 46.24) that hearings should not be unduly delayed.

In Roussel-Uclaf's Patent mentioned in 46.15, having decided that the statement was deficient, the hearing officer ordered the applicants to file a supplementary statement within two weeks and indicated that failure to do so would mean that the application would be deemed not to have been properly made and that the applicant would have to start afresh with a new application if the matter was to proceed further. At the same time, the hearing officer refused to allow the patentees a further three months from the date of receipt of the supplementary statement within which to file their counterstatement, but ordered, in the light of delays which had already occurred, that the latter should be filed by the end of what he regarded as a rather generous three months extension of the period originally allowed under the old Rule 63(2) for filing the counterstatement. What this meant in effect was that the counterstatement was due about one month after receipt of the supplementary statement. The hearing officer was upheld on appeal [1989] RPC 405 on this point when Falconer, J. decided that, although the hearing officer did not say as much, he was in fact applying his discretionary power to regulate proceedings before him and it could not be said that he had gone wrong in principle in taking delays into account. In the Smith Kline and French (Generics' Application) case mentioned in 46.16, the hearing officer did allow the patentees the full 3 months from the date of receipt of the amended statement to file the counterstatement, but in that case the patentees had objected promptly to the adequacy of the original statement. It was observed in the Roussel-Uclaf case that should a counterstatement not be filed by the date ordered then it would be considered that they do not take issue with the terms proposed by the applicants.

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- The question as to whether the comptroller has jurisdiction to consider an application under section 46(3)(a) until there has been a prior "default of agreement" was also considered in *Roussel-Uclaf's Patent*. In that case, the hearing officer followed the decision of Whitford, J. in *R. v The Comptroller-General, Ex parte Bayer AG* (BL C/56/85), where a similar question arose under section 35(2)(a) of the 1949 Act and it was decided that an attempt to reach agreement was not a pre-condition to making the application. On appeal, Falconer, J. upheld the decision of the hearing officer on the basis that the slight alteration of language in section 46(3)(a) did not in any way affect the reasoning of Whitford, J.
- 46.23 The patentees (Roussel-Uclaf) in the case mentioned above also sought to have the application dismissed or stayed on the grounds that it was vexatious and an abuse of the process. In particular, they argued in effect that the applicants, being a non-trading company, were only interested in obtaining a licence bestowing rights under the patent on affiliates and others not a party to the application, and that the comptroller had no jurisdiction to grant such a licence. In refusing to dismiss or stay the proceedings, the hearing officer pointed out that the applicants already had licences of right and that it could not be taken for granted that it would ultimately be found they were not entitled to the sort of licence they were seeking or that they would not be able to operate their licence even if it did not include all the provisions they would like. This decision was upheld by Falconer, J on appeal ([1989] RPC 405), when the judge confirmed that the comptroller does have the power to prevent any proceedings before him being used in any way which could properly be described as vexatious and an abuse of the process, but considered that the application had been properly pleaded and that the jurisdictional point should be decided at the substantive hearing.

[46.24 Deleted]

- Applicants are not entitled to the grant of an "interim" licence pending settlement of the terms of the substantive licence. A decision to this effect was made in *ICI's Patent 1285038 et al (Harris Pharmaceuticals' Application)* (BL O/59/86; BL C/82/86) and upheld on appeal by the Patents Court.
- 46.26 The question of the validity of the patent in suit cannot be raised in proceedings under section 46(3)(a). This was confirmed in *Schering AG's Patent 1193998* (ABM Chemicals Ltd's Application) (BL O/133/87).

SCOPE OF COMPTROLLER'S DISCRETION AS TO TERMS OF LICENCE OF RIGHT

- Although in the *Gist-Brocades* case the House of Lords was not required to decide the full scope of the comptroller's discretion to impose limitations or conditions upon a licensee of right (being only concerned with the question of whether he has power to prohibit or limit importation see 46.53-46.55.2), certain observations were made in the judgment which have guided subsequent decisions of the comptroller, the Patents Court and the Court of Appeal. In particular, Lord Diplock (see pages 248-250) and Lord Bridge of Harwich were agreed that the comptroller has a wide discretion as to the terms that are settled by him, and the only fetters of his jurisdiction are that he cannot (a) impose upon the licensee any positive obligation to do any of the licensed acts and (b) settle terms effectively debarring others from applying for a similar licence.
- 46.28 Lord Templeman, whilst agreeing that the comptroller has power to prohibit or control importation, came to the opposite conclusion to Lord Diplock on the general question of whether the comptroller has a wide discretion, while both Lord Fraser of Tullybelton and Lord Brightman reserved their opinion on the scope of the comptroller's discretion. However, subsequent decisions of the courts have so far relied on the interpretation of Lord Diplock (as indicated in 46.27).
- 46.29 Lord Diplock further observed that by virtue of section 53(4), which provides

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that entries made in the register under section 48 to 51 shall for all purposes have the same effect as entries made under section 46, recourse may be had to the provisions of sections 48(3) and 50 to identify the policy intended to be achieved by the comptroller in the exercise of his discretion.

FUNCTION OF PATENTS COURT ON APPEAL RE SETTLEMENT OF TERMS

46.30 [deleted] (see 97.03 to 97.05 for appeals to the Patents Court from the Comptroller in general).

In Allen & Hanburys Ltd's Patent [1987] RPC 327 (the salbutamol case), the original appeal to the Patents Court Whitford J (17 March 1986) overturned the comptroller's decision allowing importation (see 46.53) and, observing that the decision was a final rather than an interim decision as is generally customary in such cases, he discharged the licence, leaving the applicants free to apply for a manufacturing licence. The Court of Appeal, having regard to the fact that in the unusual circumstances of that case a radically different licence would ensue, considered that the judge acted correctly in discharging the licence, but it was confirmed that a licence takes effect from the time when terms are settled by the comptroller so, presumably, it is appropriate to issue a final decision in such cases.

46.32 The discharge by Whitford, J of the licence settled by the comptroller in the salbutamol case was not retrospective, and the Court of Appeal decided in that case that applicants may accept terms settled by the comptroller or the Court and operate the licence without prejudice to any appeal seeking more favourable terms.

SETTLEMENT OF TERMS

The following paragraphs are based on decisions of the Office and the Courts settling terms of licences of right under provisions relating to particular 1949 Act patents. Care will need to be taken if it becomes necessary to determine whether the decisions are relevant to settlement of terms of licences of right under other patents. In general, terms in the draft licences under consideration at the hearing about which the parties were agreed, or to which no objection was raised, have been taken as settled and not interfered with, provided the terms contain nothing unlawful.

Royalty

(see also 46.63 to 46.66.4)

Where an applicant had applied for settlement of terms of licences of right under two patents (*Upjohn's Patent 1291631 and Takeda Chemical Industries Ltd's Patent 1298364 (Generics Ltd's Application* BL C/49/87)), both licences being necessary for the applicant to manufacture and sell the same pharmaceutical formulations, the Patents Court held that the hearing officer had no power to determine only the total royalty under the two patents together and defer apportionment of the total between them; this would not settle the terms of either licence.

In the light of the link drawn between sections 46, 48 and 50 by Lord Diplock in the *Gist-Brocades* case (see 46.27 - 29), royalty is to be settled so as to ensure inter alia that "the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention" (section 50(1)(b)). Guidance as to the correct approach in achieving this end has been given by the Court of Appeal in two cases, namely the salbutamol case and *Smith Kline & French Laboratories Ltd's* (*Cimetidine*) *Patents* [1990] RPC 203. The approach has also been summarised by the Court of Appeal [1991] RPC 409 and the Patents Court [1990] RPC 309 in *American Cyanamid Co's* (*Fenbufen*) *Patents*. From these cases it is clear that reasonable

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remuneration will be secured by the royalty that would be agreed between a willing licensee and willing licensor for the rights to be granted under the licence. Thus the royalty is not to reflect the fact that the patentee may be thoroughly reluctant to grant any licence at all; the obligation to grant licences of right in the context of new existing patents was seen as a quid pro quo for the uncovenanted benefit to the patentee of being granted an automatic extension of his patent from 16 to 20 years.

46.35.1 The royalty which would be agreed between a willing licensee and a willing licensor is a payment only for use of the invention and is not compensation for losses the patentee may suffer by grant of the licence. In particular, quoting Lord Justice Lloyd in the cimetidine case, "one of the effects of granting a licence in a limited market is that sales made by the licensee will necessarily reduce sales which would otherwise have been made by the licensor. It was held by a majority of the Court of Appeal in the salbutamol case that a patentee is not entitled to claim, as part of his royalty, compensation for loss of such sales. This was expressed by saying that the patentee's position as manufacturer is to be ignored. The licensee is to pay a proper sum for the use of the patentee's invention, as an invention. But he is not to pay for the patentee's loss of sales as manufacturer, or to make a contribution to the patentee's manufacturing overheads". The majority view of the Court of Appeal in the salbutamol case was formed partly on the wording of section 50(1)(b) and partly by analogy with Patchett's Patent [1967] RPC 237 in which it was decided that a reasonable royalty to be paid for Crown use of an invention should be determined on the basis of what the patentee as willing licensor and the Crown as willing licensee would agree upon, "provided it is borne in mind that the only subject matter of the payment is the use of the invention".

A variety of approaches have been used in determining the royalty that would be agreed between a willing licensor and a willing licensee. However, as the Court of Appeal confirmed in the cimetidine case, the best guide to what a willing licensor and a willing licensee would agree is what other licensors and licensees have in fact agreed in existing voluntary licences for the same or similar products. Where comparison between the licence sought and existing licences is not exact, the practice has been to adjust the royalty to take account of the differences. This method was sanctioned by the Court of Appeal in the salbutamol case. The comparable licences approach to royalty determination, as well as other approaches, have been developed mainly in pharmaceutical cases. However, the general principles will often be of wider application.

In the cimetidine case, Nicholls, L.J. stressed that the various approaches to royalty determination are no more than aids and that they are to be used with due flexibility having regard to the circumstances of each case. In any event, the use of a number of approaches in one case will not always give compatible results. In the fenbufen case, the comparable licences approach indicated a royalty of around 27% whereas a section 41 calculation (see 46.39-45) suggested a figure between 47 and 54%. The comparability figure was preferred, although it was uplifted by 5% to acknowledge the unusual market circumstances in that case.

46.37.1 In the cimetidine case, the Court of Appeal in supporting the Patents Court emphasised that once a royalty figure has been determined by the use of suitable comparables, it is wrong then to modify that figure in order to bring it into line with some predetermined range, for example the range of pharmaceutical royalties so far determined in Office decisions.

46.37.2 Patentees sometimes argue that they have suffered inadequate remuneration which would have entitled them to an extension of term under section 23 of the 1949 Act. However, accountancy evidence of the kind advanced in proceedings under section 23 has not so far appeared in licence of right cases. In *The Upjohn Company's Patents 1291631 and 1291632* (*Generics Ltd's Application BL C/70/88*) concerned with the pharmaceutical triazolam, Whitford, J. stated that adequacy of remuneration is a relevant factor in royalty determination. However, it appears likely from that case that the factor will be taken into account by adoption of the willing licensor/willing licensee approach. In the cimetidine case, Falconer, J. stated that he had taken adequacy of remuneration into account in arriving at a

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royalty figure of 45%. The Court of Appeal in the same case did not refer to adequacy of remuneration, but Lloyd, L.J. made clear that comparability grounds alone would be enough to justify the figure of 45%.

46.37.3 In *Filpin Filpost Ltd v Fairfax (Dental Equipment) Ltd* (BL O/7/93) the hearing officer rejected the argument that an applicant who sold via a distributor, should not be expected to pay a royalty on income received by the distributor. It was held that to set the royalty rate solely on the price at which the applicants sold to the distributor would enable the distributor to benefit without contributing by way of a royalty to the patentee.

46.37.4 In *Interdibipack SPA & Quickpack (UK) Ltd v Francesco Torre* (BL O/146/95) the proprietor had in the past supplied the applicants with machines in accordance with the patent for sale within the United Kingdom and the applicants had developed their own UK market for them. Whilst the benefits to the proprietor of the applicants' marketing efforts in the United Kingdom were unquantifiable on the evidence, the hearing officer recognised them to the extent that, in the absence of any other convincing pointers, he decided that the appropriate royalty should be at the lower end of the normal range for mechanical inventions.

Pharmaceutical royalties

(i) Existing licences approach

Where they exist, licences entered into voluntarily by the patentee for the drug in question will carry particular weight. However, existing licences for other drugs whether or not granted by the same patentee will afford close comparability, provided there is sufficient similarity between the drugs and their positions in the market. In the cimetidine case, the Patents Court (supported by the Court of Appeal) found close comparability in licences granted by ICI for the drug atenolol. The drugs (though for treatment of different disorders) were said to be of broadly similar medical value, and both their total and generic sales were closely similar. In the fenbufen case, comparison was made with voluntary licences for naproxen and piroxicam in view of their market shares and therapeutic similarity as non-steroidal anti-inflammatory drugs.

46.38.1 In the salbutamol case and in the naproxen case (*Syntex Corporation's Patent* [1986] RPC 585), voluntary licence/supply agreements existed for the same drugs. However, only the supply agreements had actually been worked and it was decided that the effective royalty paid under the supply agreements was somewhat less than the 30% specified in the unworked licences. In the fenbufen case, the effective naproxen royalty was accepted as comparable, and the fact that the unworked naproxen licences included a more comprehensive import ban than the prospective fenbufen licence was held to be irrelevant to the comparability exercise.

46.38.2 In Allen & Hanburys Ltd's Patent 1429184 (3M Health Care Ltd's Application; not reported), a royalty derived from an existing licence was scaled down by the hearing officer because the applicants would be selling the product in a different form of dispenser from the patentees' and would therefore in part be supplying a market in which the patentees were not competing.

46.38.3 It has been consistently accepted that agreements made early in the development of a product provide no guidance as to the royalty payable under a licence of right towards the end of the life of the patent.

(ii) Section 41 approach

46.39 In the salbutamol case, the Court of Appeal decided that the approach adopted for determining royalty payable under compulsory licences granted under section 41 of the 1949 Act was of use in settling royalties under licences of right relating to

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pharmaceuticals. Section 41 gave the comptroller discretion to grant, on such terms as he thought fit, compulsory licences under patents relating to foods, medicines and surgical and curative devices, and following Geigy's Patent [1964] RPC 391 it became well established that pharmaceutical royalties should cover three elements, namely (a) an allowance for the recovery by the patentees of the cost of discovering the drug and establishing its efficiency, (b) an allowance for the recoupment of the promotional expenses incurred in creating and maintaining the market for it and (c) a reward for the patentees for their contribution to the art secured by an appropriate measure of profit upon the capital investment they have been constrained to make in the project. The sum of these three elements represented the royalty payable, expressed as a percentage of the patentee's selling price. Element (a) was obtained by expressing the patentee's current world-wide research and development expenditure as a percentage of its current world-wide sales of pharmaceutical products which were the fruits of that research. Element (b) was obtained by expressing the patentee's current promotional expenditure on the licensed product(s) in the UK as a percentage of its current UK sales of the licensed products. Element (c) was obtained by uplifting elements (a) and (b) by 22.5%.

46.39.1 Whilst accepting that section 46 was not a direct parallel to section 41, which required the comptroller to endeavour to secure that medicines etc should be available to the public at the lowest prices consistent with the patentee's deriving a reasonable advantage from their patent rights, the Court of Appeal in the salbutamol case was clear that "the three elements....are properly to be taken into account in considering, for the purposes of section 46 of the Act, the patentee's 'reasonable remuneration having regard to the nature of the invention'." In the later cimetidine case, Lloyd, L.J. emphasised that the section 41 approach is never more than an approximation.

46.40 Generally speaking, the rules laid down in the authorities under section 41 for evaluating the three elements have been followed in decisions under section 46. Thus it has been accepted as appropriate that the evaluation should be made with reference to the patentee's research, development and promotional costs and sales during the last three years for which figures are available.

In evaluating the expenditure component of element (a), formulation costs are excluded, as are central administration costs and half of the patentee's patent department costs. The costs of the patentee's medical information services should be excluded when evaluating element (a) and brought into account when evaluating element (b), but often there has not been enough information for the hearing officer to make the necessary correction, and in any case it has been accepted that it should not affect the royalty calculation significantly. The costs of Phase IV (post-product registration) clinical trials are usually left under R & D as, for example, in the fenbufen case. R & D by the patentee and an exclusive licensee in bringing a product to its current state of development should be treated as one; see Research Corporation's (Carboplatin) Patent [1990] RPC 663.

In evaluating the sales component of element (a), sales of veterinary and cosmetic products are excluded, as are sales of fine chemicals and "commodity" products which are not the fruits of the patentee's own R & D effort. Where the product is a pharmaceutical, but the patentee's only R & D contribution is to the product formulation, its sales will be excluded (see the decisions of the Patents Court and the Court of Appeal in the cimetidine case). Sales of licensed-in and bought-in products are also excluded. Otherwise, sales of all pharmaceutical products which are the fruits of the patentee's R & D effort need to be considered regardless of whether those products are currently patented or not, but provided that their sales contribute to funding the patentee's R & D; see for example the hearing officer's decision in the carboplatin case.

46.43 Prior to the decisions of the Patents Court and the Court of Appeal in the cimetidine case, it was the practice in Office decisions to apply a discount to promotional expenditure in evaluating element (b) on the basis that part of the expenditure went towards promoting the patentee's brand name rather than the generic product and was therefore not of benefit to the licensee. A major influence on the size of the discount was often evidence about the proportion of prescriptions written generically. However, the appeal decisions in

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the cimetidine case made clear that this approach was wrong and that in normal circumstances the whole of the promotional element is to be allowed. As expressed by Aldous, J. in *Eli Lilly & Co's Patent 1277137* (the cephalexin case; BL O/69/87, but quoted by the Court of Appeal in the cimetidine case):-

"The question to be asked is: what part of the promotional expenditure was incurred in creating and maintaining the market? It is not right to look at the promotion expenses and deduct the amount that is directed to advertising with a trade mark as that advertising creates and maintains the reputation of the drug and the market as a whole. That reputation, in a drug as well-known as the one in question, is available for use by a licensee even though he cannot use the trade mark and even though his sales will be limited to supplying generic prescriptions."

It was acknowledged in the cimetidine case that there can be situations in which it would still be appropriate to apply a discount to the promotional element. The Court of Appeal made clear that such a situation would exist if there were suitable evidence to show that the proportion of promotional costs attributable to the brand name market exceeded the share of that market in the total market for the drug (Lloyd, L.J. at page 242); however, the normal assumption should be that the promotional expenditure is spread evenly (Lord Justice Nicholls at page 255). In the Office decision in Allen & Hanbury Ltd's Patent 1429184 (3M Health Care Ltd's Application; not reported), issued between the decisions of the Patents Court and the Appeal Court in the cimetidine case, a discount was allowed on promotion because the licence did not cover a product form sold and promoted by the patentee (see 46.38.2).

46.45 Element (c) in the section 41 approach, ie the uplift applied to elements (a) and (b) was set at 20% in Bayer's Patent 1173862 (Generics' Application; BL O/49/86) and used in all subsequent cases until the Patents Court and Court of Appeal decisions in the cimetidine case. However, the 20% figure was a percentage on capital, and the cimetidine decisions make clear that an uplift expressed as a percentage on sales will usually, though not always, be more appropriate. According to Nicholls, L.J., the appropriate profit uplift will sometimes be the rate of return which the particular patentee normally obtains on his costs, but in other cases an uplift related to the return normally obtained in the industry as a whole may be more appropriate. In the cimetidine appeals themselves, the uplift was set at 43% and was derived from the current level of profitability of the ethical pharmaceuticals division of the patentee in that case. In the carboplatin case, an uncontested uplift of 27.6% was applied. In other cases, for example fenbufen and cephalexin, where the evidence did not allow derivation of an uplift personal to the patentee concerned, the figure of 22.5% first appearing in the Geigy case has been reverted to. That figure was endorsed as a return on sales in the cimetidine appeal decisions.

[46.46 Not used]

(iii) Profits available

This approach involves making an estimate of the likely profit available to the licensee and then looking at the way in which that profit might be divided between the licensee and the patentee. It has normally been adopted only in cases where there was some agreement between the parties on the manner in which it should be used, see eg Tanabe Seiyaku's Patent 1236467 (the diltiazem case; BL O/140/86) where the profit available was split equally between the parties. In the cimetidine case, there was no agreement between the parties, but Falconer, J. split the profit into two shares, one which gave the applicants a return on sales equal to their general level of profitability in all their trading, and another which represented the residue to be returned to the patentee as royalty. However, this use of the approach was criticised by the Court of Appeal in the same case because it made the royalty dependent upon the licensee's reasonable remuneration rather than on the patentee's as required by section 50(1)(b). It was also held to be contrary to Dillon, L.J.'s statement in the salbutamol case that applicants cannot insist on a licence which will be profitable to them however low they may choose to fix their selling price. It appears from the Court of Appeal's cimetidine decision that in general the profits available

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approach should be used only as a last resort though it may be employed as a cross check on other results by showing their consequences in terms of the profit shares the parties will receive. In *Gerber Garment Technology Inc's Patent*, BL O/99/96 the hearing officer used the profits available approach as a last resort when all other approaches proved to be unsuitable.

46.47.1 By overriding the Patents Court on the profits available approach, the Court of Appeal in the cimetidine case left untouched the assumption in other cases that different applicants under the same patent should pay similar royalties for similar licences. This is based in part on an observation by Whitford, J. in *ICI's Patent 1285038 (Harris Pharmaceuticals' Application*; BL O/59/86; BL C/82/86) and has been discussed in subsequent Office decisions, eg *Bayer AG's Patent 1173862 (Harris Pharmaceuticals' Application*; BL O/8/88). In *Smith Kline & French Laboratories Ltd's Patents 1338169 and 1397436 (Ivax Corporation and others' applications)*, the hearing officer decided that it is the percentage royalty that should be common to the applicants. The unit price royalty may therefore be different if the patentees' selling price has changed.

(iv) Equivalent daily patient's cost

46.47.2 This approach involves setting royalty by reference to the costs attaching to daily doses of comparable drugs. In *Pfizer's Patent 1257180* (BL O/78/87), the hearing officer found it to provide a useful cross-check on other approaches. In the Office decision in the fenbufen case, the approach was rejected as having little to do with questions relating to a patentee's entitlement or to matters of concern to a willing licensee and willing licensor.

(v) Basis of royalty

Following the decision of Whitford, J. in the salbutomol case, royalties payable in respect of pharmaceuticals have generally been expressed as a fixed unit price equivalent to the relevant percentage of the patentee's net selling price. Departures from the practice in Office decisions have been reversed by the courts in the triazolam case (where the drug was "white listed", ie it could only be prescribed generically) and in the cimetidine case (in respect of sales to hospitals). The practice was reinforced in the latter case in which Lloyd, L.J. said "the principle that the rate of royalty is set at a fixed price per unit quantity sold across the whole market, irrespective of variations in the patentee's selling price, is one of great importance, and should be upheld except in very exceptional circumstances." In the later carboplatin case, Hoffmann, J. confirmed that the possibility of a price cutting spiral initiated by either party was no reason for departing from the general principle. In The Procter & Gamble Company's Patent 1254465 (BL O/88/88), the hearing officer based the royalty on the licensee's price because the patentee did not market the product in question. In Farmitalia Carlo Erba SpA's Patent 1249443 (not reported), the hearing officer set the royalty as a percentage of the patentee's price because the parties were agreed on that basis.

46.48.1 In *Bayer's Patent 1173862 (Generics Ltd's Application;* BL O/49/86), a proposal by the patentees that royalty should be expressed as a percentage of the NHS Drug Tariff Price (ie the price officially established for the generic product once there are a certain number of competitive suppliers of that product) was rejected since there was likely to be a considerable delay before the Tariff Price was set.

Non-pharmaceutical royalties

(i) Mechanical

46.49 Royalties settled or agreed for licences of right under new existing patents in the mechanical field have been in the range 5 - 7% of the selling price (typically the licensees'). This follows voluntary licensing practice and is consistent with the decisions in Cassou's Patent [1971] RPC 91 (a licence of right case), Patchett's Patent [1967] RPC 237

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(a Crown use case), and various compulsory licence cases cited for example on *Ashland Oil's Patent 1190644* (BL O/35/86). In the absence of guidance from existing voluntary licences, the general approach in Office decisions has been to take 5% as a starting point and to settle a higher figure only if the licence confers benefits in addition to use of the invention. An example is the allowance of sub-licensing in *Holywell Mining Group Ltd's Patent 1297787* (BL O/47/88). Other justifications for higher royalties referred to in Office decisions include the provision of technical assistance and know-how, and the enhancement by a licensed article of the value of apparatus of which it forms a part, (see, for example, *Abraham's Patent 1302188* (BL O/186/87) and *Firma Carl Kurt Walther's Patent 1368039*).

(ii) Surgical and medical

Surgical devices are in a special category along with pharmaceuticals, and the old section 41 approach is applicable as a guide in royalty determination, see *Shiley Inc's Patent* [1988] RPC 97. That patent covered heart valves and the Patents Court settled an index-linked fixed unit price royalty equivalent to 15% of the patentee's selling price. Index-linking of the royalty was also adopted in *Hilti's Patent* (see 46.58).

46.50.1 In *Smith & Nephew's Patent 1280631* (BL O/126/87) which related to medical dressings, the parties were agreed that existing voluntary licences provided a guide without reference to section 41 considerations. The hearing officer derived a royalty from those licences (taking account of their provision for lump sum payments), but then applied an uplift on the basis that there would otherwise be insufficient recognition of the patentees' promotional expenditure in this medical field. On appeal to the Patents Court, the uplift was removed (to give a royalty of 11 1/4%) on the basis that negotiation of the existing voluntary licences would already have taken the promotional element into account.

46.50.2 In *Cyprane's Patent 1224478* (BL O/108/88), which concerned an anaesthetic vaporiser, the hearing officer noted that the vaporiser was not a surgical or curative device under section 41 of the 1949 Act. However, a section 41 approach was adopted because of similarities with pharmaceutical and surgical products, eg high promotion costs. The resultant royalty of 7.2% of the patentee's price was substantially uplifted because both parties agreed that the royalty should take account of alleged infringing activities which took place prior to the settlement of the licence.

46.50.3 In *Cabot Safety Corporation's Patent* [1992] RPC 39, the hearing officer regarded an earplug as having similarities with surgical inventions and, after taking the commercial value of the invention into account, settled a fixed sum royalty equivalent to 18%.

(iii) Agrochemicals

Bearing in mind the extensive research, development and testing involved, royalties for agrochemicals (notably herbicides) have been approached on the same general basis as those for pharmaceuticals. Thus fixed unit price royalties have been settled in all cases and section 41 calculations have been accepted as giving guidance; see eg *Schering Agrochemicals Ltd's Patent 1271659* (BL O/115/88). A profit sharing approach has so far been used only when the parties were agreed on it; see eg *Schering AG's Patent 1193998* (BL O/133/87).

(iv) Bulk chemicals

A fixed unit price royalty equivalent to 4% of the patentees' selling price was settled in *Ciba Geigy's Patent 1146173* [1986] RPC 403 relating to flame retardant plasticisers for vinyl chloride polymers. However, this was based to a certain extent on the decision to allow importation which was overturned by the Patents Court.

Importation

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46.53 In the Gist-Brocades' case (see 46.27-46.29), the House of Lords decided that the comptroller has the discretion to ban imports from countries who were not member states of the then European Community, but referred to the European Court of Justice questions regarding the banning of imports from such member states. In response to the reference, the ECJ held (Allen & Hanburys Ltd v Generics (UK) Ltd [1988] FSR 312) that a person importing from another member state should be treated the same as one manufacturing in the UK, ie the importation should only be banned by injunction or by the terms of a licence if such manufacture would be banned. This applies even if the product being imported is not patentable in the member state in which it was manufactured. Thus in all normal circumstances, imports from within the EC must be allowed. Moreover, since past ECJ cases that applied only to the EC hold good for the European Economic Area (EEA) provided that the measure judged upon has been extended to the EEA and the decision took place before 2 May 1992, imports from within the wider EEA must also be allowed. In both the Ciba-Geigy (see 46.52) and salbutamol cases, the Patents Court considered the House of Lords' Gist-Brocades' decision and decided, bearing in mind the criteria of sections 48 and 50, to ban importation because the patentees were manufacturing the products in question in the UK and meeting all demands for the product on reasonable terms, and their interests would be unfairly prejudiced by the proposed importation from outside the then EC. The meaning of "reasonable terms" has been considered in the carboplatin case.

The situation under section 46 with regard to non-European Union (EU) countries has therefore corresponded closely to that which developed under the old section 41, ie importation has been allowed when UK demand is currently met by importation, but not when there is domestic manufacture. However, in the cimetidine case, where the patentees manufactured in Ireland and met UK demand by importation from that country, the Court of Appeal referred to the ECJ the question of whether there was discrimination contrary to the Treaty establishing the European Economic Community if importation from outside the then EC was allowed when demand in the UK was being satisfied by manufacture in another member state of the then EC. The ECJ ruling ([1993] 1 CMLR 89 Generics (UK) v Smith Kline and French) was that although restrictions applied to thirdcountry (ie non-EC) imports were not covered by EC rules on free movement of goods, importation from outside the then EC in the above circumstances would affect trade between member states in a discriminatory way and so contravene articles 30 and 36 of the Treaty. On a second point of referral, as to whether importation from Spain and Portugal should automatically be allowed given that their Treaty of Accession to the European Economic Community provided that for a limited period the exhaustion of rights principle should not apply to certain types of goods put on the market in those countries, the ECJ ruled that national authorities in the other member states were entitled to restrict patent licensees from importing patented products from Spain and Portugal as long as the derogating provisions were observed.

There was domestic manufacture by the patentee and importation by existing licensees in *Smith & Nephew's Patent 1280631* (BL O/126/87), and in the circumstances of that case the hearing officer allowed importation under the licence of right. In the carboplatin case, the invention was worked in this country not by the patentee, but by a licensee and sub-contractor. This situation was held by the Patents Court not to alter the fact that the invention was being worked in the UK, and the hearing officer was therefore supported in banning imports from outside the then EC. However, the court gave leave to appeal on aspects of the question.

46.55.1 The Court of Appeal in the cimetidine case supported the Patents Court in its judgment that where a patent contains, in addition to the main product and process claims, a claim to pharmaceutical formulations containing the product, the mere formulation in the UK of the active ingredient manufactured in and imported from another country did not amount to commercial working of the patented invention to the fullest extent practicable for the purposes of section 48(3)(a) of the Patents Act 1977 at the time. However, the patentees' investment in the UK devoted to making up formulations from the imported active ingredient was a relevant matter to be taken into account under section 50(1)(c) and should not be unfairly prejudiced. Importation from non-EU countries should therefore be limited to the

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active ingredient.

46.55.2 The Court of Appeal in the cimetidine case rejected an argument that importation should be banned even where the invention is not being worked in the UK, with the object of thereby encouraging the initiation of such working. This follows the rejection of a similar argument in *Hoffmann-La Roche & Co AG's Patent* [1969] RPC 504.

Exportation

46.56 Following the Patents Court decision in the salbutamol case, it has been consistent practice to include no ban on exports other than to countries where parallel patents are in force. In the cimetidine case, Falconer, J. rejected an argument that exports should be banned to any country from which imports were permitted. Furthermore, he was not persuaded that a broader export ban was needed because of the patentees' apprehension that they might lose export sales. In that case there was little manufacture in the UK by the patentees. In the fenbufen case, the patentees manufactured exclusively in the UK and argued for a broader export ban to protect their UK manufacture. However, the hearing officer decided there was no evidence to suggest that UK manufacture by the patentees would be affected to any significant extent by exports on the part of the licensees to countries where the patentees had no patent protection.

46.57 The clause banning exportation to parallel patent countries which was settled in *Ciba-Geigy's Patent 1255258 (Agan/Alpha's Application)* (BL O/85/86) precluded supply of the licensed product to anyone whom the licensee believed would export it to such countries. Similar provision was made in the *Ciba-Geigy (Portman Agrochemicals' Application)* case (see 46.60), but in that case exports to other licensees in parallel patent countries were not precluded.

Sub-licensing and sub-contracting

46.58 From the salbutamol case and from Hilti AG's Patent [1988] RPC 51 it is clear that licences of right should only rarely give the licensees the right to grant sublicences. In the salbutamol case, the patent included claims to dosage forms as well as to the active ingredient, and the Patents Court and the Court of Appeal held that subcontracting of the manufacture of the dosage forms amounted to sub-licensing and should not be allowed under the licence. The sub-contractor, who would be infringing monopoly rights under the patent, should have been joined in the application and detailed proposals, including the intended form of sub-contract, should have been put before the comptroller. In the Hilti case, Falconer, J. confirmed that the comptroller has the jurisdiction to grant sublicensing rights, although in the circumstances of that case he refused to grant the right to sub-licence the licensees' subsidiary companies. Following that case, sub-licensing rights have rarely been given except where the parties were agreed. In Bergwerksverband Gmbh's Patent 1364674 (BL O/58/89), the applicants were a parent company and the patentees agreed that the applicants could sub-licence the one company in the group that would actually be working the patent. However, the hearing officer refused the right to sub-licence other companies in the group. In the Holywell Mining Group case (see 46.49), the hearing officer gave the licensees the right to sub-licence tendering companies to manufacture the patented equipment. However, the equipment would not be sold by the licensees and would be for their use alone. In the Shiley case (see 46.50), the licensee was granted the power to appoint a UK distributor to handle the sales etc but not the importation of the licensed product which was the primary infringement.

46.58.1 In *Penn's Patent 1357961* (not reported), the patent related to pumps, but included no claims to pump components. It was agreed that in these circumstances section 60(2) of the Act does not prevent a licensee from sub-contracting manufacture of such components. However, because the situation is already covered by statute, the hearing officer declined to

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include a clause confirming the position.

Quality control

Although in the *Gist-Brocades*' case Lord Diplock mentioned quality control as one of the conditions that the comptroller may attach to a licence of right, particularly in respect of pharmaceuticals, it has since been decided in a number of cases that for pharmaceuticals quality control is a matter for the authority responsible for granting product licences, and no specific provisions are needed in licences of right to safeguard the interests of the public or the patentees. This is consistent with cases decided under section 41 of the 1949 Act.

In non-pharmaceutical cases, proposals for quality control provisions have been accepted where necessary to protect the interests of the public or the patentees. That has occurred in a number of agrochemical cases where only a voluntary code of practice applied, see eg *Ciba-Geigy's Patents 1255258 and 1407587 (Portman Agrochemical's Application*; BL O/159/86), and *Schering AG's Patent 1193998* (BL O/133/87). Quality control provisions were also included in respect of the nail gun cartridges of *Hilti's Patent* (see 46.58) and the sterility indicator of *PyMah Corporation's Patent* (BL O/68/95). Provisions were refused in the *Cabot Safety Corporation's case* (see 46.50.3), where it was not established that the applicants' earplugs were likely to constitute a health risk, and in the *Holywell Mining Group case* (see 46.49), where it was decided that the normal run of commercial and safety considerations provided sufficient assurance that the licensees would not buy inferior goods from their sub-licensees.

Passing-off

Patentees frequently propose that licences of right should include antipassing off provisions, notably to ensure that licensees' products are clearly distinguished from their own. Such provisions were considered unnecessary in the naproxen case and that view was upheld by the Patents Court ([1986] RPC 585). In *Hilti's Patent* (see 46.58), the Patents Court supported the rejection of a clause preventing the licensees from suggesting that their products were licensed or approved by the patentees. In general it seems that patentees must rely on their remedies at law to combat any passing off or misrepresentation by licensees.

Most favoured nation/licensee

Voluntary licences often contain a "most favoured nation/licensee" clause providing a licensee with the right to have the terms of his licence revised to bring them into line with more favourable terms granted subsequently to some third party. However, Whitford, J. in the salbutamol case thought it inappropriate to include such clauses in licences of right, and Office decisions have consistently refused them. In *Allen & Hanbury's Patent 1266058* (BL O/137/85) and in *DST SA's Patent 1195871* (BL O/152/85), the hearing officer indicated that if circumstances change to the extent that a licensee considers that different terms are justified, then a fresh application should be made under section 46(3). A most favoured licensee clause was rejected in the diltiazem case (see 46.47) and in *Interdibipack SPA & Quickpack (UK) Ltd v Francesco Torre* (BL O/146/95) even though not actually disputed by the patentees.

Security for royalty, and other royalty provisions

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- In the *Shiley* case, the applicants agreed to provide a bank guarantee as security for royalties and the licence included a term keeping the guarantee in being throughout the term of the licence. In Penn's Patent (see 46.58.1), the applicant company was newly formed and there was no evidence available on which to judge its creditworthiness. The applicants agreed that security for royalty should be provided, but the hearing officer rejected the patentees' request that the level of security should be reassessed during the term of the licence. Requests for security for royalties have been refused in other cases, see eg *Pfizer's Patent 1257180* (BL O/78/87) and *Hilti's Patent 1217908* (*Bauco's Application*; BL O/170/86).
- Requests by patentees for initial lump sum payments in addition to normal royalties have been consistently rejected, see eg the hearing officers' decisions in the *Smith & Nephew* case (see 46.50.1), in the *Holywell Mining Group* case (see 46.49), and in the *Bergwerksverband* case (see 46.58). Those decisions held initial lump sum payments to be appropriate only when exclusive licences are granted or where capital assets, eg know-how, are changing hands.
- Requests for guarantees of minimum total royalty payments have also been rejected. In the *Shiley* case (see 46.50), an initial downpayment to be credited against royalties due was sought. As well as refusing the downpayment, the hearing officer declined to insert an anti-dumping clause in the licence which would have provided for additional royalties if the licensee's price was reduced below a specified level. A fixed unit price royalty was settled in that case and was considered to be a sufficient deterrent to dumping.
- 46.66 Except where the parties have agreed otherwise, quarterly accounting periods have been the general rule, with royalty due 30 days after the end of each period, although a 90 day period was settled in the exceptional circumstances of the DST case (see 46.62). In the *Firma Carl Kurt Walther* case (see 46.49), the hearing officer rejected a proposal from the applicants that they should not pay royalties before they received payment from their customers.
- 46.66.1 In general royalty is payable in respect of sales or other disposals under a licence. However, in the *DST* case (see 46.62) the hearing officer decided that royalty should instead be payable in respect of manufacture, and in the *Hassle* case (see 46.75) the hearing officer approved a clause relating royalty liability to the first of any series of infringing acts.
- 46.66.2 Patentees have been held to be entitled to royalty on licensed materials in the possession of the licensee at the natural expiry of the patent, but the licensee's stocks stand to be destroyed upon termination of the licence for breach of the terms.
- 46.66.3 In the *Firma Carl Kurt Walther's Patent* (see 46.49), the hearing officer declined to provide for back payment of royalties in respect of possible infringing acts, on the basis that the patentees already had a suitable remedy in the provisions of section 46(3)(c). The hearing officer in *Book Protectors and Co.'s Patent* (BL O/23/96) also declined to include a clause relating (i) to royalties for sales made before the licence came into force or (ii) to a lump sum representative of damages for past infringements since his jurisdiction lay in the settlement of terms of a licence of right and not, except to the limited extent provided for in s.46(3)(c), in determining payments, whether characterised as damages or as backpayments, in respect of acts which took place earlier.
- 46.66.4 In *Grace's Patent 1307054* (not reported), apparatus claims in the patent related to a whole machine of which the applicants proposed to import and sell a component. In considering whether the invention resided in the machine or in the component and therefore on which of them the royalty should be calculated, the hearing officer decided that the nature of the invention should be assessed against the prior art at the priority date, and that the invention therefore lay in the whole machine.

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Termination

46.67 Falconer, J. decided in the *Hilti* case (see 46.58) that a period of 30 days for remedying a breach of the licence terms was reasonable, the period to run from receipt of notice of the breach. Except where the parties have agreed otherwise, the 30 day period has been adopted.

46.68 In the naproxen case (see 46.38.1), the hearing officer included a clause in the licence providing for termination if the licensee came under the direct or indirect direction or control of any other company operating in the field covered by the licence, such a clause being considered to complement the usual no-assignment provision of the licence. The decision was upheld by the Patents Court and has been followed since.

46.69 It has also been accepted that a patentee should be entitled to terminate a licence if the licensee becomes insolvent or has a receiver appointed over a substantial part of its assets or enters into liquidation otherwise than for the purpose of amalgamation or reconstruction (eg as in the *Ciba-Geigy (Portman Agrochemicals' Application)* case (see 46.60)).

46.69.1 The inclusion of a clause providing for termination by the patentee upon a challenge to the validity of the patent by the licensee was considered and approved by the *Patents Court in Schering's Patent 1193998 (ABM Chemical Ltd's Application)* (see 46.26) and *Du Pont de Nemour's Patent 1393011 (Enka BV and other's Application)* [1988] RPC 479,497.

46.69.2 In the fenbufen case, prospective sub-contractors who were not subsidiaries of the main applicant had been joined in the application. The Patents Court confirmed the decision of the hearing officer that if either of the sub-contractors was in breach of the licence terms or changed its status as in 46.69 above, then the patentees should be entitled to terminate the sub-contractors' rights under the licence, but that the licence should otherwise remain in force.

Verification

46.70 Licences usually include clauses authorising the inspection of the licensee's books and records on behalf of the patentee. This will usually be by an independent accountant, who will commonly be required to pass on to the patentee no more information than is necessary to verify the amount of royalties due. There may be provision for payment of verification costs by the licensee if an underpayment of more than a certain amount, say 1/2% or 1%, is found. More onerous verification clauses involving provision by the licensee of samples of imported materials to allow the patentee to check the licensee's decision that their quality was unsatisfactory or to check whether foreign patents had been infringed were rejected in the cimetidine and fenbufen cases, and also in the *Smith Kline & French* case referred to in 46.73 (which latter case also related to cimetidine). It appears that such clauses should only be included where there may be doubts about the applicants' trustworthiness.

Indemnity clauses

46.71 Clauses indemnifying the licensor from any action brought on account of licensed goods sold by the licensee are common, whether applying to such things as

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product liability, or to infringement of third parties intellectual property rights. In the *Penn* case (see 46.58.1), the hearing officer rejected a request that the licensee should be required to take out liability insurance, and in *Allen & Hanbury Ltd's Patent 1429184 (3M Health Care Ltd's Application*) the hearing officer rejected a general indemnity clause in respect of all activities undertaken by the licensees in relation to the licence.

Force majeure clauses

46.72 In the two cases referred to in 46.71, the hearing officer thought it unnecessary to include force majeure clauses, ie clauses which protect the licensee against termination of the licence for events beyond the control of the parties, eg fire and earthquake.

Territorial extent

46.72.1 In *Interdibipack SPA & Quickpack (UK) Ltd v Francesco Torre* (BL O/146/95) the hearing officer when considering a draft licence which was intended to apply to "the United Kingdom, Hong Kong and Singapore" decided that he could only settle the terms of a licence of right in the territory to which the Patents Act 1977 extends and that he had no locus to arbitrate between the parties as to the terms of licences in other territories.

Costs

It has become conventional in proceedings before the comptroller to make no award of costs in respect of substantive issues. An exception is *Smith Kline & French Laboratories Ltd's Patents 1338169 and 1397436 (Ivax Corporation and others' applications)* where an award was made to the applicants, in part because the patentees had refused to grant a licence in the same terms as earlier licences under the same patents to one of the same applicants, and which terms were confirmed by the hearing officer on the later case as still applicable. Awards were also made in two cases which were ultimately settled by agreement, ie *Bayer's Patent 1170188 (DDSA Pharmaceuticals Application*; BL O/139/85) and *Rhone-Poulenc's Patent 1164585* (BL O/46/85). Awards of costs are sometimes made in respect of preliminary issues, eg in the *Smith & Nephew* case (see 46.50.1), and are often made to the patentees when an application has been withdrawn.

Miscellaneous

In *Frosst's Patent 1253709* (BL O/84/87), the hearing officer rejected a clause requiring the licensees to notify the patentees of any adverse reactions affecting the safety or efficacy claims of the product, since such matters were dealt with under the Medicines Act. He also rejected a clause restricting the licensees to promoting only the indications set out in the patentees' Data Sheet for the product and to making only representations approved by the patentees.

46.75 It was considered reasonable in *AB Hassle's Patent 1308106* (BL O/79/87) to require the licensees to notify the patentees of any apparent or threatened infringement, but in the *Frosst* case (see 46.74) a clause was rejected which would have had the effect that the licensees could be drawn against their will into the patentees' defence of their patent. A clause considered to derogate from the licensees' rights under section 46(4) was rejected in the *Eli Lilly* case (see 46.43).

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46.76 A limitation on the licensees' right to denigrate the patentees' own product was considered appropriate in the *Shiley* case (see 46.50), notwithstanding the possible availability of a trade libel remedy.

46.76.1 In cases where the applicant has asked for a licence to cover anything which would otherwise be an infringement of the patent in suit, yet appears from the statement and evidence not to be concerned to work the invention across its full range, the licence has been restricted to cover only those acts which have been specified and for which royalty and other terms can be settled on the evidence, eg as in *Bayer's Patent 1173862 (Generics' Application*; BL O/49/86). In *Rhone Poulenc's (Ketoprofen) Patent* [1989] RPC 561 where the need to obtain a Product Licence stood in the way of practical working of a licence of right, Falconer J approved the hearing officer's view that an application for a licence of right could be rejected if the licensee would as a practical matter be unable to use the licence. However, in *Coflexip Stena Offshore Ltd's Patent* (BL O/67/96) where the applicants had already converted a ship to a pipe laying vessel in accordance with the invention but it would be impossible for them to convert another in what remained of the patent term, the hearing officer nevertheless included manufacture in the acts permitted under the licence because s.46(3A) effectively contemplates retrospective capping of damages in infringement proceedings when an undertaking has been given under s.46(3)(c).

46.76.2 A clause requiring annual renewal of the licence was rejected in the *Hassle* case (see 46.75). This is consistent with the decision in *Cassou's* case (see 46.11).

46.76.3 A request by the patentees that the licence terms should remain confidential was rejected in the *Smith & Nephew* case (see 46.50.1).

Section 46(3)

(b) the comptroller may, on the application of the holder of any licence granted under the patent before the entry was made, order the licence to be exchanged for a licence of right on terms so settled.

APPLICATION BY EXISTING LICENSEE

An existing licensee may apply for his licence to be exchanged for a licence of right on terms which may be settled by the comptroller. The procedure for such applications is the same as that described in 46.14 et seq, except that the existing licensee should file not only Form 2 in duplicate together with two copies of the draft of a licence he seeks but also two copies of the licence he seeks to exchange. The considerations applying to the settlement of terms of such licences are generally the same as for any other licence of right. The terms of the existing licence, and the circumstances surrounding that licence, may also need to be taken into account.

Section 46(3)

(c) if in proceedings for infringement of the patent (otherwise than by the importation of any article from a country which is not a member State of the European Economic Community) the defendant or defender undertakes to take a licence on such terms, no injunction or interdict shall be granted against him and the amount (if any) recoverable against him by way of damages shall not exceed double the amount which would have been payable by him as licensee if such a licence on those terms had been granted before the earliest infringement;

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INFRINGEMENT BY PERSON WILLING TO TAKE A LICENCE

46.78 Restrictions are imposed by s.46(3)(c) on the penalties which may be imposed on an infringer who agrees to take out a licence on terms which may be settled by the comptroller.

46.78.1 The words "from a country which is not a member State of the European Economic Community" qualifying the exception of infringement by importation were added to s.46(3)(c) by paragraph 12 of Schedule 5 to the CDP Act. This amendment follows the 3 March 1988 decision of the European Court of Justice in *Allen and Hanbury v Generics* [1988] FSR 312 that the exclusion of importation from the then European Community from the benefits of the concession in s.46(3)(c) was contrary to the Treaty establishing the European Economic Community. The amendment came into force on 1 August 1989. Subsequently the European Economic Area Act 1993 has automatically modified the reference in this subsection to 'European Economic Community' to a reference to the "European Economic Area" (EEA). Thus, importation from elsewhere in the EEA is now on par with domestic production; the concession applies to both.

Section 46(3)

(d) if the expiry date in relation to a renewal fee falls after the date of that entry, that fee shall be half the fee which would be payable had the entry not been made.

46.78.2 A patent must be available for licences of right before the anniversary of the filing date (also see subsection (3B) below) if a patent proprietor is to take advantage of the reduction by one half in the renewal fee payable for the following year. For example, if the anniversary date is 18 June, the proprietor will have to make licences of right available prior to this date if the renewal fee for the following year (payable by 30 June) is to be halved.

Section 46(3A)

An undertaking under subsection (3)(c) above may be given at any time before final order in the proceedings, without any admission of liability.

46.78.3 Subsection (3A) clarifies that a person who wishes to give an undertaking to take out a licence (under s.46(3)(c)) is not prevented from contesting an infringement action.

Section 46(3B)

For the purposes of subsection (3)(d) above the expiry date in relation to a renewal fee is the day at the end of which, by virtue of section 25(3) above, the patent in question ceases to have effect if that fee is not paid.

Section 46(4)

The licensee under a licence of right may (unless, in the case of a licence the terms of which are settled by agreement, the licence otherwise expressly provides) request the proprietor of the patent to take proceedings to prevent any infringement of the patent; and if the proprietor refuses or neglects to do so within two months after being so requested, the licensee may institute proceedings for the infringement in his own name as if he were proprietor, making

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the proprietor a defendant or defender.

Section 46(5)

A proprietor so added as defendant or defender shall not be liable for any costs or expenses unless he enters an appearance and takes part in the proceedings.

RIGHT OF LICENSEE TO SUE FOR INFRINGEMENT

46.79 Unless otherwise provided by the terms of a licence of right which were settled by agreement, the licensee may request the patentee to take proceedings to prevent infringement. If the patentee fails to do so within two months of such request, the licensee may take action in his own name, making the patentee a defendant. A clause considered to derogate from this right of the licensee has been rejected by a hearing officer when settling the terms of a licence of right, see 46.75.

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Section 47: Cancellation of entry made under s.46

r.43(3)

47.01 This section provides for the cancellation of an entry made in the register under s.46, ie that licences under a patent are to be available as of right. It also provides for opposition to the cancellation. Relevant procedures are prescribed by rule r.43(3). A WTO proprietor of a patent for which an entry has been made under section 48 (compulsory licences) that licences are available as of right may apply to have the entry cancelled under section 52(2) on the grounds provided in that section (see 52.07)

47.02 See 46.01-07 for general discussion of the licence of right provisions (ss.46 and 47) including the relationship thereof with the compulsory licence provisions (ss.48 to 54).

Section 47(1)

At any time after an entry has been made under section 46 above in respect of a patent, the proprietor of the patent may apply to the comptroller for cancellation of the entry.

Application by proprietor

r.43(3) s.46(3)(d) 47.03 The proprietor of the patent may apply for cancellation of the "licences of right" entry at any time after it is made. The application should be made on Patents Form 30 and should be accompanied by fees to the amount of the balance of all renewal fees which would have been payable if the entry had not been made (only half fees having been payable while the entry is present).

r.75 47.04 The application is advertised in the Journal, to give an opportunity for opposition to the cancellation under s.47(6), see 47.11-13.

Section 47(2)

Where such an application is made and the balance paid of all renewal fees which would have been payable if the entry had not been made, the comptroller may cancel the entry, if satisfied that there is no existing licence under the patent or that all licensees under the patent consent to the application.

47.05 Form 30 includes a declaration that there is no existing licence under the patent or that all licensees consent to the application. If satisfied that this is so, the balance of renewal fees having been paid and any opposition to cancellation having been disposed of, the comptroller may cancel the entry in the register. The applicant will be informed by letter once the entry has been cancelled.

47.06 In *Cassou's Patent* [1971] RPC 91, in which cancellation of a "licences of right" endorsement was applied for during the course of proceedings to settle the terms of such a licence, cancellation was not permitted before the grant of the licence.

Section 47(3)

Within the prescribed period after an entry has been made under section 46 above in respect of a patent, any person who claims that the proprietor of the patent is, and was at the time of the entry, precluded by a contract in which the claimant is interested from

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granting licences under the patent may apply to the comptroller for cancellation of the entry.

Application by other persons

s.46(2) r.43(4) r.108(1) PR part 7 47.07 The comptroller makes a "licences of right" entry only if satisfied that the proprietor of the patent is not precluded by contract from granting licences under the patent. Nevertheless there is an opportunity after the entry is made for cancellation to be applied for by any person who claims that the proprietor is, and was at the time of the entry, precluded by a contract in which the claimant is interested from granting licences. An application by such a person should be made within two months after the making of the entry; this period cannot be extended. The application should be made by filing Form 2 with a copy thereof and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.13.

r.77 r.75 47.08 The Office sends a copy of the application and statement to the proprietor of the patent. The application is also advertised in the Journal.

Section 47(4)

Where the comptroller is satisfied, on an application under subsection (3) above, that the proprietor of the patent is and was so precluded, he shall cancel the entry; and the proprietor shall then be liable to pay, within a period specified by the comptroller, a sum equal to the balance of all renewal fees which would have been payable if the entry had not been made, and the patent shall cease to have effect at the expiration of that period if that sum is not so paid.

Where the comptroller is satisfied that the proprietor is and was precluded as indicated in 47.07, any opposition by the proprietor under s.47(6) having been disposed of (see 47.11-13), the entry is cancelled.

s.46(3)(d)

47.10 The Office informs the proprietor of the cancellation. Within such period as the comptroller specifies, the proprietor should pay fees to the amount of the balance of all renewal fees which would have been payable if the entry had not been made (only half fees having been payable while the entry was present). The patent ceases to have effect at the expiration of the specified period if the necessary sum is not so paid.

Section 47(5)

Where an entry is cancelled under this section, the rights and liabilities of the proprietor of the patent shall afterwards be the same as if the entry had not been made.

Section 47(6)

Where an application has been made under this section, then -

- (a) in the case of an application under subsection (1) above, any person, and
- (b) in the case of an application under subsection (3) above, the proprietor of the patent,

may within the prescribed period give notice to the comptroller of opposition to the

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cancellation; and the comptroller shall, in considering the application, determine whether the opposition is justified.

Opposition to cancellation

47.11 Applications under s.47(1) or (3) for cancellation of a "licences of right" entry may be opposed. Where the application is by the proprietor of the patent under s.47(1), any person may make such an opposition. Where the application is under s.47(3), only the proprietor of the patent in question may oppose the cancellation.

PR part 7 r.75 r.76(2) r.77(10) r.108(1) Every application under s.47(1) or (3) is advertised in the Journal. Notice of opposition to the cancellation of an entry should be given within four weeks after the advertisement; this period cannot be extended. Opposition to an application under section 47(1) should be made by filing Patents Form 15 accompanied by a copy of the form and by a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.13; a defendant should therefore file a counter-statement in accordance with rr.77(5)-(6) (see 123.05.3 and 123.05.5). In the case of an application under section 47(3), the applicant has already started proceedings by filing Form 2 and a statement of grounds (see 47.07), and the opposition should therefore be made by filing a counter-statement in accordance with rr.77(7)-(8) (see 123.05.3 and123.05.6).

47.13 [deleted]

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Section 48: Compulsory licences: general

s.52(2) 48.01 Under section 48, applications may be made to the comptroller for him to order the grant of a licence under a patent or make an entry in the register making licences under a patent available as of right. The grounds on which such an application may be made are set out in s.48A(1) if the patent's proprietor is a WTO proprietor (as defined in s.48(5)), or s.48B(1) if the proprietor is not a WTO proprietor. Those grounds are basically concerned with whether the monopoly conferred by the patent in question is operating against the public interest. A WTO proprietor may apply to have a compulsory licence or register entry cancelled if the circumstances leading to the order or entry have ceased to exist and are unlikely to recur.

The Patents and Trade Marks (World Trade Organisation) Regulations 1999 replaced previous section 48 with current sections 48, 48A and 48B with effect from 29 July 1999. The amendments bring the section more clearly into line with Articles 30 and 31 of the GATT Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1994) and the Treaty establishing the European Economic Community (Treaty of Rome), instead of relying on the limitation of section 53(5), which requires that no such licence should be granted which would be at variance with any treaty or convention to which the UK is a party. These amendments came into effect in the Isle of Man by virtue of the Patents Act 1977 (Isle of Man) Order 2003 (SI 2003 No. 1249).

48.03 Further provisions regarding applications for compulsory licences or for licences to be available as of right and resultant licences are contained in ss.49 to 54. Section 46 is also relevant to "licences of right" entries made under s.48 to 51 (see 48.16 and 49.07).

48.04 See 46.02-07 for general discussion of the licence of right and compulsory licence provisions, including the relationship of the voluntary "licences of right" provisions (ss.46 and 47) with the compulsory licence and "licences of right" provisions (ss.48 to 54).

Section 48(1)

At any time after the expiration of three years, or of such other period as may be prescribed, from the date of the grant of a patent, any person may apply to the comptroller on one or more of the relevant grounds-

- (a) for a licence under the patent;
- (b) for an entry to be made in the register to the effect that licences under the patent are to be available as of right; or
- (c) where the applicant is a government department, for the grant to any person specified in the application of a licence under the patent.

Making an application

- s.48(6) 48.05 Applications under s.48 are not entertained for a period of three years from the date when the notice of the grant of a patent appears in the Journal (see 25.02) in order to give some time for the invention to be worked. This period can be altered by a rule approved by Parliament, see 48.23.
- s.48(3) 48.06 Such an application may be made at any time after this period expires and may be made by any person (including an existing licensee).

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- s.48B(4) 48.07 The application may be for a "licences of right" entry to be made in the register or for the grant of a licence to the applicant. Such an entry is not available where the grounds for application are that a market for the export of any patented product made in the UK is not being supplied (only relevant where the proprietor is not a WTO proprietor).
- PR part 7 48.08 Any application under s.48(1) should be made by filing Patents Form 2 accompanied by a copy thereof and a statement of grounds in duplicate; it is not necessary (as was the case under r.68 of the Patents Rules 1995) to file evidence verifying the statement with the application. The statement should set out the grounds on which the application is made; these should be one or more of those specified in s.48A(1) (see 48A.02 et seq) if the proprietor is a WTO proprietor or 48B(1) otherwise (see 48B.03 et seq). The filing of Form 2 starts proceedings before the comptroller, the procedure for which (including the filing of evidence) is discussed at 123.05 123.05.13.

Section 48(2)

Subject to sections 48A and 48B below, if he is satisfied that any of the relevant grounds are established, the comptroller may-

- (a) where the application is under subsection (1)(a) above, order the grant of a licence to the applicant on such terms as the comptroller thinks fit;
- (b) where the application is under subsection (1)(b) above, make such an entry as is there mentioned;
- (c) where the application is under subsection (1)(c) above, order the grant of a licence to the person specified in the application on such terms as the comptroller thinks fit.

Considering the application

48.09 In considering the application, not only the provisions of ss.48-48B but also those of ss.49 and 50 should be borne in mind. Section 49 is concerned with the grant of licences on an application under s.48, while s.50 concerns the general purposes to be secured and matters to be taken into account by the comptroller when exercising his powers under s.48. Sections 52 to 54 are also relevant. Consideration of the application is essentially a two-stage process, namely determination of whether the grounds of s.48A(1) or 48B(1) as appropriate are established, followed by exercise of the discretion afforded by s.48(2) so as to determine whether to order the grant of a licence (or the making of a "licences of right" entry) taking s.50 into account (*Monsanto's CCP Patent* [1990] FSR 93).

- 48.10 [deleted]
- 48.11 [deleted]
- r.75 48.12 The application is advertised in the Journal. A copy of the application and the statement of grounds is sent to the proprietor of the patent and any other person shown on the register as having any right in or under the patent. These measures give an opportunity for opposition under s.52(1), see 52.03-06, 123.05.3 and 123.05.6.
 - 48.13 The proprietor of the patent cannot be heard on the terms of any licence ordered unless he opposes under s.52(1), although he can make written submissions for consideration by the comptroller (*Ultimatte Corp's Patent* (BL O/1/84)).
- s.49(2) 48.14 Where the applicant under s.48 already holds a licence under the patent in question, the comptroller may, if he orders the grant of a licence to the applicant, order the

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existing licence to be cancelled or may, instead of ordering such a new licence, order amendment of the existing licence.

- 48.15 A failure to discharge the onus on the applicant to show in his evidence that one or more of the grounds in s.48A(1) or 48B(1) is met cannot be remedied by seeking discovery from the patent proprietor to supplement that evidence (*Richco Plastic Co's Patent* [1989] RPC 722). However, if the evidence submitted by the applicant is sufficient to establish his grounds, on the usual principle of the balance of probabilities, then it is immaterial whether it is technically the "best" evidence (*Monsanto's CCP Patent* [1990] FSR 93).
- s.53(3) 48.16 The comptroller may make a "licences of right" entry under s.48 s.53(4) notwithstanding any contract precluding a voluntary entry under s.46. An entry made under s.52(3) s.48 has for all purposes the same effect as an entry made under s.46, except that a WTO proprietor may apply to have the entry cancelled and any licenses granted under the entry terminated if the circumstances leading to the order or entry have ceased to exist and are unlikely to recur.
- s.53(5) 48.17 No order or entry is made which would be at variance with any treaty or international convention to which the UK is a party (see 53.06). If any Order in Council is made under s.54, this will also restrict the making of orders or entries where the invention concerned is being commercially worked in a country with which the UK has reciprocal arrangements, see 54.01.
 - 48.18 In settling the terms of any licence ordered, particular notice is taken of the provisions of ss. 50 and 48A or 48B as appropriate. The royalty for a compulsory licence under s.48 should be one which would be negotiated between a willing licensor and a willing licensee; even though s.50(1)(b) requires the patentee to receive "reasonable remuneration", the royalty should not be such that the applicants could not bear it and were thus put out of the market (*Montgomerie Reid's Application* (BL O/145/83)).
- s.108 48.19 The effective date of a licence is the date on which all the terms of the licence are fixed and not merely the date on which it was decided to grant a compulsory licence (*Geigy S.A.'s Patent* [1966] RPC 250). Without prejudice to any other method of enforcement, an order for the grant of a licence has effect as if it were a deed, executed by the proprietor of the patent and all other necessary parties, granting a licence in accordance with the order.
 - 48.20 Sometimes where attempts to negotiate a licence voluntarily have broken down, not only is there an application for a compulsory licence by the party seeking a licence, but also proceedings against that party for infringement of the patent in question are commenced by the patentee. The question may then arise of whether there should be a stay in the s.48 proceedings rather than letting them proceed in parallel with a High Court infringement action. This is a matter of convenience having regard to all the circumstances, and of how the comptroller should exercise his discretion in the light of those circumstances. In a preliminary decision in *Halcon SD Group Inc's Patents* [1989] RPC 1, the hearing officer ordered a stay in the s.48 proceedings until the decision from the High Court was handed down. The main factors influencing this decision were that further evidence and discovery were still required before the substantive hearing could be held in the s.48 proceedings, a decision on infringement was necessary before the licence application could be satisfactorily resolved, the High Court action was set down to commence very shortly and the s.48 proceedings before the comptroller were liable to be rather lengthy and costly.
- s.97(1) 48.21 An appeal lies to the Patents Court from any decision of the comptroller under s.48. Section 52(4) makes special provision for the Attorney General or his representative to be heard in any such appeal.

Section 48(3)

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An application may be made under this section in respect of a patent even though the applicant is already the holder of a licence under the patent; and no person shall be estopped or barred from alleging any of the matters specified in the relevant grounds by reason of any admission made by him, whether in such a licence or otherwise, or by reason of his having accepted a licence.

Section 48(4)

In this section "the relevant grounds" means-

- (a) in the case of an application made in respect of a patent whose proprietor is a WTO proprietor, the grounds set out in section 48A(1) below;
- (b) in any other case, the grounds set out in section 48B(1) below.

Section 48(5)

A proprietor is a WTO proprietor for the purposes of this section and sections 48A, 48B, 50 and 52 below if-

- (a) he is a national of, or is domiciled in, a country which is a member of the World Trade Organisation; or
- (b) he has a real and effective industrial or commercial establishment in such a country.
- 48.22 The TRIPS Agreement limits the circumstances and manner in which use may be made of the subject matter of a patent without the authorisation of the patent holder if he is a "national" of another Member of the WTO as defined in note 1 of that agreement. For non-WTO proprietors, the provisions are equivalent to those provided by the original section 48.

Section 48(6)

A rule prescribing any such other period under subsection (1) above shall not be made unless a draft of the rule has been laid before, and approved by resolution of, each House of Parliament.

48.23 Sections 48(1) and 48(6) provide for the three-year period before compulsory licences or "licences of right" endorsements could be applied for to be varied by means of a rule approved by Parliament.

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Section 48A: Compulsory licences: WTO proprietors

s.52(2) 48A.01 This section provides the grounds for application under section 48 when the proprietor of the patent is a WTO proprietor and conditions specific to such applications. Section 48A was introduced by The Patents and Trade Marks (World Trade Organisation) Regulations 1999 regulation 5 with effect from 29 July 1999. A WTO proprietor may, if an order or entry is made, later apply to have that order or entry revoked or cancelled if the circumstances which led to the making of the order or entry have ceased to exist and are unlikely to recur (see 52.07).

Section 48A(1)(a)

In the case of an application made under section 48 above in respect of a patent whose proprietor is a WTO proprietor, the relevant grounds are-

(a) where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms;

Grounds for application (WTO proprietor)

48A.02 This ground applies where the patented invention is a "product", which in this context apparently does not include a product obtained by means of a patented process or to which a patented process has been applied. The ground is concerned with meeting a demand for the product in the UK. The demand must be an actual one and not merely one which an applicant hopes and expects to create if and when he has obtained a licence and commenced business (*Cathro's Applications* 51 RPC 75). Contrary to the situation where the proprietor is a non-WTO proprietor, it is immaterial whether the demand is met by production in the UK or by importation.

48A.03 The applicant needs to show that such a demand is not being met on reasonable terms. What constitutes "reasonable terms" depends on a careful consideration of all the surrounding circumstances in each case, eg the nature of the invention, the terms of any licences under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be a bona fide one and not one adopted to suppress or depress demand.

Section 48A(1)(b)

that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms-

- (i) the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or
- (ii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;

48A.04 This ground concerns various consequences of the refusal of the proprietor of the patent to grant a licence on "reasonable terms". This may be a refusal to grant a licence at all or an offer to grant a licence but on terms which are unreasonable despite discussion in an effort to agree terms (Loewe Radio Co Ltd's Applications 46 RPC 479). Under the

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provisions of the 1949 Act a similar ground was held not applicable to the refusal of an existing exclusive licensee to grant a licence on such terms (*Colbourne Engineering Co Ltd's Application* 72 RPC 169).

48A.05 With regard to the meaning of "reasonable terms", see 48.18 and 48A.03. In Brownie Wireless Co Ltd's Applications 46 RPC 457, the court considered the best test of whether a royalty is reasonable is: How much are manufacturers who are anxious to make and deal with the patented article on commercial lines ready and willing to pay? The court also held that it can in certain circumstances be reasonable to require licensees to take a licence under all patents belonging to a group rather than under an individual patent from the group, or to include terms requiring royalties to be paid on certain non-patented articles. In Monsanto's CCP Patent [1990] FSR 93, it was held that an offer of a licence covering a number of countries worldwide in return for a fully paid-up royalty of 1 million US dollars did not constitute a refusal to grant a licence on reasonable terms.

s.48A(4) 48A.06 The applicant must show that the refusal of the proprietor to grant a licence on reasonable terms has caused one or other of two situations. The first is that the working or efficient working in the UK of any other patented invention which "involves an important technical advance of considerable economic significance" is prevented or hindered. However, the patentee of the other invention must be able and willing to grant to the patentee and his licensees a licence in respect of the other invention on reasonable terms.

48A.07 The alternative situation under s.48A(1)(b) is that the establishment or development of commercial or industrial activities in the UK is unfairly prejudiced. An increase in the size of a business is regarded as sufficient to constitute such development (*Kamborian's Patent* [1961] RPC 403).

Section 48A(1)(c)

that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.

s.49(1) 48A.08 This last ground concerns conditions imposed by the patentee which unfairly prejudice (a) the manufacture, use or disposal of materials not protected by the patent, or (b) the establishment or development of commercial or industrial activities in the UK (see 48A.22 re the latter). Where (a) is held to be unfairly prejudiced, the comptroller may order the grant of licences to customers of the applicant as well as to the applicant.

Section 48A(2)

No order or entry shall be made under section 48 above in respect of a patent whose proprietor is a WTO proprietor unless-

- (a) the applicant has made efforts to obtain a licence from the proprietor on reasonable commercial terms and conditions; and
- (b) his efforts have not been successful within a reasonable period.

Section 48A(3)

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No order or entry shall be so made if the patented invention is in the field of semi-conductor technology.

48A.09 Article 31(c) of the TRIPS Agreement requires that use of the subject matter of a patent should not be allowed without the authorization of the right-holder in the case of semi-conductor technology other than for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive. While no order may be made for a compulsory licence or register entry in an application under section 48 where the invention is in this field and the proprietor is a WTO proprietor, a register entry that licences are available as of right may be made on application by the appropriate Minister under section 51 following a report of the Monopolies and Mergers Commission.

Section 48A(4)

No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(b)(i) above unless the comptroller is satisfied that the proprietor of the patent for the other invention is able and willing to grant the proprietor of the patent concerned and his licensees a licence under the patent for the other invention on reasonable terms.

Section 48A(5)

A licence granted in pursuance of an order or entry so made shall not be assigned except to a person to whom the patent for the other invention is also assigned.

Section 48A(6)

A licence granted in pursuance of an order or entry made under section 48 above in respect of a patent whose proprietor is a WTO proprietor-

- (a) shall not be exclusive;
- (b) shall not be assigned except to a person to whom there is also assigned the part of the enterprise that enjoys the use of the patented invention, or the part of the goodwill that belongs to that part;
- (c) shall be predominantly for the supply of the market in the United Kingdom;
- (d) shall include conditions entitling the proprietor of the patent concerned to remuneration adequate in the circumstances of the case, taking into account the economic value of the licence; and
- (e) shall be limited in scope and in duration to the purpose for which the licence was granted.

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Section 48B: Compulsory licences: other cases

s.48B(3)

48B.01 This section provides the grounds for application under section 48 when the proprietor of the patent is a non-WTO proprietor and conditions specific to such applications. Section 48B was introduced by The Patents and Trade Marks (World Trade Organisation) Regulations 1999 regulation 5 with effect from 29 July 1999. The provisions for the non-WTO proprietor case are substantially unchanged from those in the original Act, save that there are now explicit provisions to the effect that licences or register entries are not available because UK demand is being met by importation from a member State of the EEA, rather than production in the UK. Previously section 53(5) would have required that the comptroller should not make any order or entry in that case.

48B.02 In this section, as with the remainder of the Act, the term "member State" is deemed, under the European Economic Area Act 1993, to refer to a member State of the European Economic Area.

Section 48B(1)

In the case of an application made under section 48 above in respect of a patent whose proprietor is not a WTO proprietor, the relevant grounds are-

(a) where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;

Grounds for application (non-WTO proprietor)

s.130(1) s.48B(3) 48B.03 The first ground on which an application may be made applies where a patented invention is capable of being commercially worked in the UK. By "patented invention" is meant an invention for which a patent is granted. The hearing officer in *Enviro-Spray Systems Inc's Patents* [1986] RPC 147 declined to attempt a formal definition of "commercial working" but could "see no reason for departing from its plain and ordinary meaning. Thus, as far as manufactures are concerned, the expression is ... clearly satisfied by the straightforward manufacture of goods for the purposes of trade". He also observed that the wording of the then s.48(3)(a), equivalent to present s.48B(1)(a), "seems to recognise that working can be commercial and yet not be exploiting the invention to the full" so that manufacture which is on a scale too small to fully meet demand can still constitute commercial working. An invention which is being commercially worked abroad is normally regarded as capable of being commercially worked in the UK. However, no order or entry may be made if demand is being met by importation from a member State of the EEA where the invention is being worked.

48B.04 The onus is on the applicant to show that the invention is not being commercially worked in the UK or is not being so worked to the fullest extent that is reasonably practicable. In *Kamborian's Patent* [1961] RPC 403, the hearing officer considered that the fullest extent to which an invention may be worked may be expressed as "the highest rate of production which is practicable and necessary substantially to meet the demand". In order to be successful, the applicant must "bring evidence to show what the demand for the invention might reasonably be expected to be, and how far short, if at all, production under the patent falls, as far as is practicable to supply it". Demand for a product which merely includes the patented invention does not necessarily equate with demand for the patented invention per se; the contribution which the invention makes to the value of, or demand for, the product may need to be considered (*Quantel's Patents*, BL O/128/90).

48B.05 A previous and discontinued commercial working of the invention is no defence

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against an application on this ground (*Cathro's Application* 51 RPC 475; *Gebhardt's Patent*, see 48B.17). Unlikelihood of making a profit or lack of demand are also insufficient defences. If in fact there is a demand and manufacture in foreign countries, the patentee must make an effort to create a demand in this country.

s.48B(2) 48B.06 The comptroller may by order adjourn an application on this ground if it appears to him that the time since grant of the patent has for any reason been insufficient to allow the invention to be commercially worked, see 48B.17. The adjournment is for such period as will in his opinion allow such working.

Section 48B(1)(b)

where the patented invention is a product, that a demand for the product in the United Kingdom-

- (i) is not being met on reasonable terms, or
- (ii) is being met to a substantial extent by importation from a country which is not a member State:

48B.07 This ground applies where the patented invention is a "product", which in this context apparently does not include a product obtained by means of a patented process or to which a patented process has been applied. The ground is concerned with meeting a demand for the product in the UK. The demand must be an actual one and not merely one which an applicant hopes and expects to create if and when he has obtained a licence and commenced business (*Cathro's Applications* 51 RPC 75).

48B.08 The applicant needs to show that such a demand is not being met on reasonable terms or is being met to a substantial extent by importation. What constitutes "reasonable terms" depends on a careful consideration of all the surrounding circumstances in each case, eg the nature of the invention, the terms of any licences under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be a bona fide one and not one adopted to suppress or depress demand.

Section 48B(1)(c)

where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked-

- (i) where the invention is a product, by the importation of the product from a country which is not a member State,
- (ii) where the invention is a process, by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied;

48B.09 Like that of s.48B(1)(a), this ground applies where the patented invention is capable of being commercially worked in the UK (as discussed in 48B.03). The applicant needs to show that such working is being prevented or hindered by importation of the patented product from a country outside the EEA. This applies both where the invention is the product and where the invention is a process by which the product is directly obtained or which has been applied to the product.

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Section 48B(1)(d)

that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms-

- (i) a market for the export of any patented product made in the United Kingdom is not being supplied, or
- (ii) the working or efficient working in the United Kingdom of any other patented invention which makes a substantial contribution to the art is prevented or hindered,
- (iii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
- 48B.10 This ground concerns various consequences of the refusal of the proprietor of the patent to grant a licence on "reasonable terms". This may be a refusal to grant a licence at all or an offer to grant a licence but on terms which are unreasonable despite discussion in an effort to agree terms (Loewe Radio Co Ltd's Applications 46 RPC 479). This ground is not applicable to the refusal of an existing exclusive licensee to grant a licence on such terms (Colbourne Engineering Co Ltd's Application 72 RPC 169).
- 48B.11 With regard to the meaning of "reasonable terms", see 48.18 and 48B.08. In Brownie Wireless Co Ltd's Applications 46 RPC 457, the court considered the best test of whether a royalty is reasonable is: How much are manufacturers who are anxious to make and deal with the patented article on commercial lines ready and willing to pay? The court also held that it can in certain circumstances be reasonable to require licensees to take a licence under all patents belonging to a group rather than under an individual patent from the group, or to include terms requiring royalties to be paid on certain non-patented articles. In Monsanto's CCP Patent [1990] FSR 93, it was held that an offer of a licence covering a number of countries worldwide in return for a fully paid-up royalty of 1 million US dollars did not constitute a refusal to grant a licence on reasonable terms.
- 48B.12 The applicant here needs to show any of three things, firstly that a market for the export of any patented product made in the UK is not being supplied. (A "patented product" means a product which is a patented invention or, in relation to a patented process, a product obtained directly by means of the process or to which the process has been applied. It may not be appropriate to regard a system which merely includes the subject matter of a patent as a "patented product" (Quantel's Patents, see also the last sentence of 48B.04).) This condition can only be met if there is actual manufacture in being in the UK. If the patentee is manufacturing in the UK and exporting to certain foreign countries, it might well be reasonable for him to ask that any compulsory licence granted should be restricted so as to prevent export by the licensee to those countries (Penn Engineering & Manufacturing Corp's Patent [1973] RPC 233).
- s.48B(4) 48B.13 Further to the preceding paragraph, the Act in fact specifically provides that any licence granted on the unsupplied export market ground should, at the discretion of the comptroller, restrict the countries in which the product in question may be disposed of or used by the licensee. In addition, "licences of right" entries cannot be made on that ground.
- s.48B(5)48B.14 The second condition is that the working or efficient working in the UK of any other patented invention which makes a "substantial contribution to the art" is prevented or hindered. However, the patentee of the other invention must be able and willing to grant to the patentee and his licensees a licence in respect of the other invention on reasonable terms.
 - 48B.15 The final condition under s.48B(1)(d) is that the establishment or development of

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s.130(1)

commercial or industrial activities in the UK is unfairly prejudiced. An increase in the size of a business is regarded as sufficient to constitute such development (*Kamborian's Patent* [1961] RPC 403).

Section 48B(1)(e)

that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.

s.49(1) 48B.16 This last ground concerns conditions imposed by the patentee which unfairly prejudice (a) the manufacture, use or disposal of materials not protected by the patent, or (b) the establishment or development of commercial or industrial activities in the UK (see 48B.15 re the latter). Where (a) is held to be unfairly prejudiced, the comptroller may order the grant of licences to customers of the applicant as well as to the applicant.

Section 48B(2)

Where-

- (a) an application is made on the ground that the patented invention is not being commercially worked in the United Kingdom or is not being so worked to the fullest extent that is reasonably practicable; and
- (b) it appears to the comptroller that the time which has elapsed since the publication in the journal of a notice of the grant of the patent has for any reason been insufficient to enable the invention to be so worked,

he may by order adjourn the application for such period as will in his opinion give sufficient time for the invention to be so worked.

48B.17 Section 48B(2) provides for an application on the ground mentioned in s.48B(1)(a) to be stayed in order to give sufficient time for the invention to be commercially worked in the UK or so worked to the fullest extent that is reasonably practical. In *Gebhardt's Patent* [1992] RPC 1 the hearing officer (upheld on appeal) considered that the then s.48(5), equivalent to the present s.48B(2), was intended primarily, though not exclusively, for the situation where relatively little time had elapsed since the grant of the patent. He declined to stay the proceedings, having in mind the age of the patent (eleven years since grant), the length of the hiatus in exploitation (some five years) since earlier exploitation ceased and the absence of clear evidence of sales in the period (seventeen months) since a new UK distributor was appointed.

Section 48B(3)

No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(a) above if-

- (a) the patented invention is being commercially worked in a country which is a member State: and
- (b) demand in the United Kingdom is being met by importation from that country.

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Section 48B(4)

No entry shall be made in the register under section 48 above on the ground mentioned in subsection (1)(d)(i) above, and any licence granted under section 48 above on that ground shall contain such provisions as appear to the comptroller to be expedient for restricting the countries in which any product concerned may be disposed of or used by the licensee.

Section 48B(5)

No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(d)(ii) above unless the comptroller is satisfied that the proprietor of the patent for the other invention is able and willing to grant to the proprietor of the patent concerned and his licensees a licence under the patent for the other invention on reasonable terms.

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Section 49: Provisions about licences under s.48

- 49.01 Section 48 provides for the making of an application to the comptroller, by any person, for the grant of a compulsory licence under a patent or the making of a "licences of right" entry in the register in respect of the patent. Section 49 is a supplementary provision concerning licences granted by order of the comptroller, or by virtue of such an entry, as a result of such applications.
- 49.02 These sections are members of a group, 46 to 54, relating to "licences of right" entries and compulsory licences. See 46.02-07 for general discussion of this group.
- 49.03 The discussion in 48.17-21 concerning s.48 and orders for the grant of licences thereunder also applies in relation to s.49.

Section 49(1)

Where the comptroller is satisfied, on an application made under section 48 above in respect of a patent, that the manufacture, use or disposal of materials not protected by the patent is unfairly prejudiced by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or the use of the patented process, he may (subject to the provisions of that section) order the grant of licences under the patent to such customers of the applicant as he thinks fit as well as to the applicant.

Subsection (1) empowers the comptroller to order the grant of licences to customers of the applicant under s.48 where the ground set out in the first part of s.48A(1)(c) (WTO proprietor - see 48A.23) or s.48B(1)(e) (non-WTO proprietor - see 48B.16) is established. (The terms "patented product" and "patented process" used in the subsection are defined in s.130(1)).

Section 49(2)

Where an application under section 48 above is made in respect of a patent by a person who holds a licence under the patent, the comptroller -

- (a) may, if he orders the grant of a licence to the applicant, order the existing licence to be cancelled, or
- (b) may, instead of ordering the grant of a licence to the applicant, order the existing licence to be amended.

49.05 Section 48(3) allows an application under s.48 to be made by an existing licensee under the patent in question. Section 49(2) makes special provision regarding the grant, amendment or cancellation of licences by order of the comptroller on such applications.

[Section 49(3) Repealed]

49.06 Prior to the CDP Act, a licence ordered under s.48 could deprive the patentee of his rights under the patent in question, or revoke all existing licences. However, the comptroller did not in practice use this power and it was removed by the CDP Act with effect from 1 August 1989.

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Section 49(4)

Section 46(4) and (5) above shall apply to a licence granted in pursuance of an order under section 48 above and to a licence granted by virtue of an entry under that section as it applies to a licence granted by virtue of an entry under section 46 above.

49.07 The holder of a compulsory licence ordered under s.48 or of a licence granted by virtue of a "licences of right" entry made under s.48 has the same rights of suing for infringement as are conferred by s.46(4) and (5), see 46.79.

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Section 50: Exercise of powers on applications under s.48

50.01 This section sets out purposes and other matters to be borne in mind by the comptroller when dealing with applications under s.48, see 48.01.

50.02 Sections 48 to 54 relate to compulsory licences and "licences of right" entries in the register made in response to applications to the comptroller; sections 46 and 47 relate to voluntary "licences of right" entries. See 46.02-07 for general discussion of ss.46 to 54.

Section 50(1)

The powers of the comptroller on an application under section 48 above in respect of a patent whose proprietor is not a WTO proprietor shall be exercised with a view to securing the following general purposes -

- (a) that inventions which can be worked on a commercial scale in the United Kingdom and which should in the public interest be so worked shall be worked there without undue delay and to the fullest extent that is reasonably practicable;
- (b) that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention;
- (c) that the interests of any person for the time being working or developing an invention in the United Kingdom under the protection of a patent shall not be unfairly prejudiced.

Purposes to be secured (non-WTO proprietors)

Subsection (1) sets out purposes to which exercise of the comptroller's powers under s.48 should be directed, which are relevant only when the application under section 48 is in respect of a patent whose proprietor is a non-WTO proprietor (in the case of a WTO proprietor, the requirements of section 48A(6) should be considered). The first of the general purposes concerns inventions which can be worked on a commercial scale in the UK. If such working is in the public interest, it should occur quickly and "to the fullest extent that is reasonably practicable". The quoted expression is also used in s.48B(1)(a) which sets out a ground for applications under s.48 having a strong affinity with the purpose in s.50(1)(a), see 48B.03-05.

The second general purpose is for the inventor (or other person entitled) to receive reasonable remuneration, it being recognised that what is "reasonable" may vary from one invention to another. However, this purpose must be balanced against other considerations when settling the terms of a licence, see 48.33.

The final general purpose is that the interests of persons working or developing patented inventions in the UK should not be unfairly prejudiced. This has some affinity with the ground set out in s.48A(1)(b)(i), see 48A.17-21, and s.48B(1)(d)(ii), see 48B.14. In *Therma-Tru Corporation's Patent* (BL O/92/96) the hearing officer decided that the inherent risk that the applicants would take some market share from the proprietors and their licensees could not of itself be said unfairly to prejudice the proprietors and their licensees. In considering this purpose it should be recognised that section 48B does not allow for discrimination between working an invention in the UK and working in other EEA states as long as UK demand is met from within the EEA. This takes account of the ruling of the ECJ in *European Commission v United Kingdom* [1992] 2 CMLR 709, in a case relating to the original section 48, that to treat the case where domestic demand for a patented

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product is satisfied by imports from other member states differently from that where the product is produced domestically was contrary to Article 30 of the Treaty establishing the European Economic Community.

Section 50(2)

Subject to subsection (1) above, the comptroller shall, in determining whether to make an order or entry in pursuance of any application under section 48 above, take account of the following matters, that is to say -

- (a) the nature of the invention, the time which has elapsed since the publication in the journal of a notice of the grant of the patent and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention;
- (b) the ability of any person to whom a licence would be granted under the order concerned to work the invention to the public advantage; and
- (c) the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted,

but shall not be required to take account of matters subsequent to the making of the application.

Matters to be taken account of (all cases)

In determining whether to order the grant of a licence or make an entry in the register, the comptroller also takes account of the considerations (a) to (c) immediately above. Consideration (a) concerning the nature of the invention, the time since grant of the patent and the measures already taken to make full use of the invention appears to recognise that some inventions require longer than others to establish adequate working. This is also reflected by the power under s.48B(2) to adjourn an application to allow sufficient time for working, where the application is made on the ground in s.48B(1)(a) (see 48B.03-06).

50.07 Considerations (b) and (c) concern the ability of a potential licensee to work the invention to the public advantage and the risks to be undertaken by the potential licensee. The question of this ability of the potential licensee was considered by the hearing officer in *Enviro-Spray Systems Inc's Patents* [1986] RPC 147

"It would clearly be unreasonable, before the grant of a licence, to require any applicant to show contracts or firm agreements with anyone for either finance or for the other forms of assistance which would be required to operate a licence. On the other hand, if I am to take account of Section 50(2)(b) I have to be able to form some estimate of the ability of the applicants to work the inventions, at least to the extent of satisfying myself that the applicants are likely to have available to them the various resources, including technical expertise and know-how, which would be necessary to put the inventions into practice in a way which would benefit the public. It is in turn the responsibility of the applicants to explain as far as is reasonable what they expect to do, and also to put me in a position in which I can form some estimate of their likelihood of achieving it."

50.08 In *Therma-Tru Corporation's Patent* (BL O/92/96) although there was no specific evidence expressly showing that the applicants had the necessary technical expertise, evidence showed that they had gone to some lengths to obtain supplies of the necessary materials, equipment and advice. This, together with an offer by them to include quality control provisions, which would lead to the termination of the licence if breached, led the hearing officer to take the view that, so far as the applicants' technical expertise was

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concerned, there was no reason why he should not grant a licence.

50.09 The comptroller is not required to take account of matters subsequent to the making of the application under s.48(1), but he apparently may do so if he thinks fit.

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Section 50A: Powers exercisable following merger and market investigations

50A.01 Section 50A was introduced by the Enterprise Act 2002, which came into force on 20 June 2003. This replaced the provisions in section 51 for Ministers to apply to the comptroller in response to reports of the Competition and Markets Authority (previously known as the Competition Commission) in relation to monopoly or merger situations operating against the public interest. In April 2014, this section was amended by the Enterprise and Regulatory Reform Act 2013 (Competition) (Consequential, Transitional and Saving Provisions) Order 2014 to reflect the change in name and responsibilities from the Competition Commission to the Competition and Markets Authority.

50A.02 Section 50A allows the Competition and Markets Authority or the Secretary of State to apply to the comptroller to take action following a merger or market investigation to remedy, mitigate or prevent a competition matter that cannot be dealt with in any other way under the Enterprise Act. This application must involve conditions in licences granted under a patent by its proprietor restricting the use of invention by the licensee or the right of the proprietor to grant other licences, or a refusal by the proprietor to grant licences on reasonable terms.

50A.03 The Competition and Markets Authority must publish a notice describing the nature of the proposed application, and must consider any representations made within thirty days by persons likely to be affected.

50A.04 If, following the public consultation, the Competition and Markets Authority considers that the application should go ahead, section 50A(4) enables the comptroller to cancel or amend any licence conditions, and make an entry in the register to the effect that licences under the patent are available as of right.

Section 50A(1)

Subsection (2) below applies where -

- (a) section 41(2), 55(2), 66(6), 75(2), 83(2), 138(2), 147(2), 147A(2) or 160(2) of, or paragraph 5(2) or 10(2) of Schedule 7 to, the Enterprise Act 2002 (powers to take remedial action following merger or market investigations) applies;
- (b) the Competition and Markets Authority or (as the case may be) the Secretary of State considers that it would be appropriate to make an application under this section for the purpose of remedying, mitigating or preventing a matter which cannot be dealt with under the enactment concerned; and
- (c) the matter concerned involves-
 - (i) conditions in licences granted under a patent by its proprietor restricting the use of the invention by the licensee or the right of the proprietor to grant other licences; or
 - (ii) a refusal by the proprietor of a patent to grant licences on reasonable terms.

Section 50A(2)

The Competition and Markets Authority or (as the case may be) the Secretary of State may apply to the comptroller to take action under this section.

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PR part 7 50A.05 The application should be made by filing (in duplicate) Form 2 and a statement of grounds. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.13.

Section 50A(3)

Before making an application the Competition and Markets Authority or (as the case may be) the Secretary of State shall publish, in such manner as it or he thinks appropriate, a notice describing the nature of the proposed application and shall consider any representations which may be made within 30 days of such publication by persons whose interests appear to it or him to be affected.

Section 50A(4)

The comptroller may, if it appears to him on an application under this section that the application is made in accordance with this section, by order cancel or modify any condition concerned of the kind mentioned in subsection (1)(c)(i) above or may, instead or in addition, make an entry in the register to the effect that licences under the patent are to be available as of right.

Section 50A(5)

References in this section to the Competition and Markets Authority are references to a CMA group except where –

- (a) section 75(2) of the Enterprise Act 2002 applies; or
- (b) any other enactment mentioned in subsection (1)(a) above applies and the functions of the Competition and Markets Authority under that enactment are being performed by the CMA Board by virtue of section 34C(3) or 133A(2) of the Enterprise Act 2002.

Section 50A(6)

References in section 35, 36, 47, 63, 134, 141 or 141A of the Enterprise Act 2002 (questions to be decided by the Competition and Markets Authority in its reports) to taking action under section 41(2), 55, 66, 138, 147 or 147A shall include references to taking action under subsection (2) above.

Section 50A(7)

Action taken by virtue of subsection (4) above in consequence of an application under subsection (2) above where an enactment mentioned in subsection (1)(a) above applies shall be treated, for the purposes of sections 91(3), 92(1)(a), 162(1) and 166(3) of the Enterprise Act 2002 (duties to register and keep under review enforcement orders etc.), as if it were the making of an enforcement order (within the meaning of the Part concerned) under the relevant power in Part 3 or (as the case may be) 4 of that Act.

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Section 51: Powers exercisable in consequence of report of Competition and Markets Authority

- This section makes provision for Ministers to apply to the comptroller in response to reports by the Competition and Markets Authority (previously known as the Competition Commission of situations operating against the public interest. Such an application may lead to cancellation or modification of conditions in existing licences, and/or a "licences of right" entry in the register, in respect of a patent. In April 2014, this section was amended by the Enterprise and Regulatory Reform Act 2013 (Competition) (Consequential, Transitional and Saving Provisions) Order 2014 to reflect the change in name and responsibilities from the Competition Commission to the Competition and Markets Authority.
- 51.02 The application may be made in any of the circumstances set out in subsection (1), the relief available being as set out in subsection (3).
- s.51(2) PR part 7 r.75
- Before making the application, the Minister should publish notice of it and consider any representations made within thirty days by persons likely to be affected. The application should be made on Patents Form 2 accompanied by a copy thereof and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 123.05.13. The application is advertised in the journal; this gives an opportunity for opposition under section 52(1) (see 52.03-06, 123.05.3 and 123.05.6).
- 51.04 Applications under s.51 are subject to ss.52 to 54.
- For the comptroller to take action under s.51, the report of the Competition and Markets Authority must indicate that factors operating against the public interest include the terms or conditions in patent licences or a refusal to grant such licences on reasonable terms. Paragraphs (a) and (b) of section 51(1) which covered reports of the Competition and Markets Authority following monopoly and merger references, respectively, were repealed by the Enterprise Act 2002, which inserted section 50A into the 1977 Act to provide powers exercisable by the comptroller following merger and market investigations (see 50A.01-04).
- 51.06 Statements in reports of the Competition and Markets Authority are also treated as prima facie evidence in s.48 proceedings, see 53.04.

Section 51(1)

Where a report of the Competition and Markets Authority has been laid before Parliament containing conclusions to the effect -

- (a) and (b) [Repealed]
- (c) on a competition reference, that a person was engaged in an anticompetitive practice which operated or may be expected to operate against the public interest, or
- (d) on a reference under section 11 of the Competition Act 1980 (reference of public bodies and certain other persons), that a person is pursuing a course of conduct which operates against the public interest,

the appropriate Minister or Ministers may apply to the comptroller to take action under this section.

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Section 51(2)

Before making an application the appropriate Minister or Ministers shall publish, in such manner as he or they think appropriate, a notice describing the nature of the proposed application and shall consider any representations which may be made within 30 days of such publication by persons whose interests appear to him or them to be affected.

Section 51(3)

If on an application under this section it appears to the comptroller that the matters specified in the Competition and Markets Authority report as being those which in the opinion of the Competition and Markets Authority operate, or operated or may be expected to operate, against the public interest include -

- (a) conditions in licences granted under a patent by its proprietor restricting the use of the invention by the licensee or the right of the proprietor to grant other licences, or
- (b) a refusal by the proprietor of a patent to grant licences on reasonable terms

he may by order cancel or modify any such condition or may, instead or in addition, make an entry in the register to the effect that licences under the patent are to be available as of right.

Section 51(4)

In this section "the appropriate Minister or Ministers" means the Minister or Ministers to whom the report of the Competition and Markets Authority was made.

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Section 52: Opposition, appeal and arbitration

The Patents and Trade Marks (World Trade Organisation) Regulations 1999 replaced the original section 52 with effect from 29 July 1999. This section provides as before for opposition to applications under ss. 48 to 51, and for matters arising in such opposition proceedings to be referred to an arbitrator by the comptroller. In addition, WTO proprietors (see 48.22) may apply to have a compulsory licence or register entry cancelled if the circumstances leading to the order or entry have ceased to exist and are unlikely to recur. The section also makes special provision with regard to appeals from decisions made by the comptroller on applications under ss.48 to 51 or 52(2). Such applications may be for compulsory licences or "licences of right" entries or modification of licences, as outlined in 48.01 and 51.01 or cancellation of orders or register entries as outlined below.

52.02 These sections are members of a group (46 to 54) relating to licences of right, compulsory licences etc. For general discussion of this group see 46.02-07.

Section 52(1)

The proprietor of the patent concerned or any other person wishing to oppose an application under sections 48 to 51 above may, in accordance with rules, give to the comptroller notice of opposition; and the comptroller shall consider any opposition in deciding whether to grant the application.

Opposition

Any person, including the patentee, may oppose an application under ss.48 to 51. For example, the opponent was the exclusive licensee in *Montgomerie Reid's Application*, see 48.18. (However, if the patentee does not lodge an opposition under s.52(1), he is not entitled to be heard in proceedings to settle the terms of any licence, see 48.13.)

r.108(1) 52.04 Notice of opposition under s.52(1) must be given within four weeks (which cannot be extended) after the advertisement of the application in the Journal as described in 48.12. The notice is given by filing a counter-statement in the proceedings in accordance with rr.77(7)-(8).

52.05 [deleted]

s.52(5) 52.06 The comptroller may refer matters to an arbitrator, see 52.10.

Section 52(2)

Where an order or entry has been made under section 48 above in respect of a patent whose proprietor is a WTO proprietor-

- (a) the proprietor or any other person may, in accordance with rules, apply to the comptroller to have the order revoked or the entry cancelled on the grounds that the circumstances which led to the making of the order or entry have ceased to exist and are unlikely to recur;
- (b) any person wishing to oppose an application under paragraph (a) above may, in accordance with rules, give to the comptroller notice of opposition; and

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(c) the comptroller shall consider any opposition in deciding whether to grant the application.

Section 52(3)

If it appears to the comptroller on an application under subsection (2)(a) above that the circumstances which led to the making of the order or entry have ceased to exist and are unlikely to recur, he may -

- (a) revoke the order or cancel the entry; and
- (b) terminate any licence granted to a person in pursuance of the order or entry subject to such terms and conditions as he thinks necessary for the protection of the legitimate interests of that person.

Revocation or cancellation of order or entry

PR part 7 52.07 If the proprietor of the patent is a WTO proprietor, he or any other person may apply to have an order or entry made under section 48 revoked or cancelled on the grounds that the circumstances which led to the making of the order or entry have ceased to exist and are unlikely to recur. An application under s.52(2)(a) should be made on Form 2 accompanied by a copy thereof and a statement of grounds in duplicate. This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.13. It follows the same stages an application for an order or entry - see 48.12-48.13 mutatis mutandis.

52.08 Under section 52(2)(b), and like an application under section 48, an application under section 52(2)(a) may be opposed by anyone. The procedure for opposition is the same as for an opposition under section 52(1) - see 48.12 and 52.04.

Section 52(4)

Where an appeal is brought -

- (a) from an order made by the comptroller in pursuance of an application under sections 48 to 51 above;
- (b) from a decision of his to make an entry in the register in pursuance of such an application;
- (c) from a revocation or cancellation made by him under subsection (3) above; or
- (d) from a refusal of his to make such an order, entry, revocation or cancellation,

the Attorney General, the appropriate Law Officer within the meaning of section 4A of the Crown Suits (Scotland) Act 1857 or the Attorney General for Northern Ireland, or such other person who has a right of audience as any of them may appoint, shall be entitled to appear and be heard.

Appeal

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s.97(1) 52.09 An appeal lies to the Patents Court from any decision of the comptroller on an application under ss.48 to 51 or 52(2). Where such an appeal is brought, the Attorney General (or the equivalent of that officer in different parts of the UK) or such other person who has a right of audience as he may appoint is entitled to appear and be heard.

Section 52(5)

Where an application under sections 48 to 51 above or subsection (2) above is opposed, and either -

- (a) the parties consent, or
- (b) the proceedings require a prolonged examination of documents or any scientific or local investigation which cannot in the opinion of the comptroller conveniently be made before him,

the comptroller may at any time order the whole proceedings, or any question or issue of fact arising in them, to be referred to an arbitrator or arbiter agreed on by the parties or, in default of agreement, appointed by the comptroller.

Section 52(6)

Where the whole proceedings are so referred, unless the parties otherwise agree before the award of the arbitrator or arbiter is made, an appeal shall lie from the award to the court.

Section 52(7)

Where a question or issue of fact is so referred, the arbitrator shall report his findings to the comptroller.

Arbitration

Subsections (5) to (7) provide for reference to an arbitrator (arbiter in Scotland) where an application under ss.48 to 51 or 52(2) is opposed. Such a reference may be of the whole proceedings or of any question or issue of fact arising therein, and may be made by the comptroller at any time where the parties consent or the proceedings require examination or investigation as detailed in subsection (5)(b). Unless the parties previously agreed otherwise, an appeal lies from the award of the arbitrator to the court. Where only a question or issue of fact is referred, proceedings before the comptroller continue after he receives the arbitrator's findings.

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Section 53: Compulsory licences; supplementary provisions

This section comprises various supplementary provisions relating to ss.48 to 51 and applications thereunder. Such applications may be for compulsory licences or "licences of right" entries or modification of licences, as outlined in 48.01 and 51.01.

These sections are members of a group (46 to 54) relating to licences of right, compulsory licences etc. In April 2014, sections 50A, 51 and this section were amended by the Enterprise and Regulatory Reform Act 2013 (Competition) (Consequential, Transitional and Saving Provisions) Order 2014 to reflect the change in name and responsibilities from the Competition Commission to the Competition and Markets Authority.

[Section 53(1) Repealed]

53.03 Section 53(1) was repealed by the Patents Act 2004. This subsection was concerned with provisions under the Community Patent Convention, which never came into force.

Section 53(2)

In any proceedings on an application made under section 48 above in respect of a patent, any statement with respect to any activity in relation to the patented invention, or with respect to the grant or refusal of licences under the patent, contained in a report of the Competition and Markets Authority laid before Parliament under Part VII of the Fair Trading Act 1973 or section 17 of the Competition Act 1980 or published under Part 3 or 4 of the Enterprise Act 2002 shall be prima facie evidence of the matters stated, and in Scotland shall be sufficient evidence of those matters.

Effect of statements by Monopolies and Mergers Commission

The status as evidence, in proceedings under s.48, of statements in reports of the Competition Commission is set out in subsection (2). The scope of this provision was adjusted by the CDP Act, including introduction of the reference to the Competition Act 1980, and the reference to the Enterprise Act 2002 was added by Paragraph 8 of Schedule 25 of this Act, which came into force on 20 June 2003.

Section 53(3)

The comptroller may make an entry in the register under sections 48 to 51 above notwithstanding any contract which would have precluded the entry on the application of the proprietor of the patent under section 46 above.

Section 53(4)

An entry made in the register under sections 48 to 51 above shall for all purposes have the same effect as an entry made under section 46 above.

Relationship with entries made under s.46

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53.05 Section 46 provides for "licences of right" entries in the register to be made voluntarily, i.e. at the request of the proprietor of the patent in question. Section 53(3) and (4) give relationships between such entries and those made compulsorily under ss.48 to 51.

Section 53(5)

No order or entry shall be made in pursuance of an application under sections 48 to 51 above which would be at variance with any treaty or international convention to which the United Kingdom is a party.

Effect of treaties and international conventions

Register entries or orders regarding licences are not made under ss.48 to 51 if contrary to a treaty or convention, eg TRIPS or the Treaty establishing the European Community. Section 54 makes similar provision with regard to reciprocal arrangements with any country specified in an Order in Council, see 54.01.

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Section 54: Special provisions where patented invention is being worked abroad

s.54(2) 54.01 This section provides for Orders in Council to preclude orders regarding licences and "licences of right" entries in the register on applications under ss. 48 to 51. Any such Order in Council would specify one or more non-EU countries having reciprocal arrangements with the UK and would preclude such orders or entries if the invention concerned is being commercially worked in any such country and demand in the UK is being met by importation from that country. Orders or entries can however be made for purposes of the public interest. No Order in Council under s.54 has yet been made. Subsection (2) was amended by the Patents and Trade Marks (World Trade Organisation) Regulations 1999 to include the words "or a member of the World Trade Organisation".

54.02 Similar provision in respect of EU countries is made by s.53(1), see 53.03.

54.03 Section 54 is the last of a group of sections (46 to 54) relating to licences of right, compulsory licences etc. See 46.02-07 for general discussion of this group.

Section 54 is one of the sections mentioned in s.130(7) as being so framed as to have, as nearly as practicable, the same effects as the corresponding provisions of the EPC, CPC and PCT. Articles 47 and 82 of the CPC (renumbered as Articles 46 and 77 [1989]) correspond except that they apply to CPC contracting states see 53.03.

Section 54(1)

Her Majesty may by Order in Council provide that the comptroller may not (otherwise than for purposes of the public interest) make an order or entry in respect of a patent in pursuance of an application under sections 48 to 51 above if the invention concerned is being commercially worked in any relevant country specified in the Order and demand in the United Kingdom for any patented product resulting from that working is being met by importation from that country.

Section 54(2)

In subsection (1) above "relevant country" means a country other than a member state or a member of the World Trade Organisation whose law in the opinion of Her Majesty in Council incorporates or will incorporate provisions treating the working of an invention in, and importation from, the United Kingdom in a similar way to that in which the Order in Council would (if made) treat the working of an invention in, and importation from, that country.

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USE OF PATENTED INVENTIONS FOR SERVICES OF THE CROWN

Section 55: Use of patented inventions for services of the Crown

s.55(4)55.01 This is the first of a group of sections (55 to 59) relating to Crown use of Section 55 provides for any government department or person authorised thereby to do certain acts for the services of the Crown. It applies at all times but is supplemented by s.59 during periods of emergency. Section 56 lays down how various features in s.55 are to be interpreted. Section 57 provides for the effects of such Crown use on third parties such as licensees and assignees. Compensation for Crown use may be agreed between the parties; disputes may be referred to the court under s.58 (but Crown use may occur without any compensation of the proprietor of the patent in the circumstances of s.55(3)). Section 57A was added to the 1977 Act by the CDP Act to provide an additional form of compensation for loss of certain forms of profit as a result of Crown use. The comptroller is not normally involved in such matters and detailed discussion is therefore beyond the scope of this Manual.

> 55.02 [deleted]

s.55(1)55.03 Sections 55 to 59 relate to Crown use of "a patented invention", ie an invention for which a patent has been or is subsequently granted. The patent in question s.56(1)may be one granted under the 1977 Act or a European Patent (UK). In the case of s.78(2)subsequent grant, an application for a European patent (UK) or 1977 Act patent may be in question. There are special provisions concerning Crown use in relation to European patents or applications in s.77(3) and (5) (see 77.10 and 77.12), s.78(6) and (7) (see 78.10-11), s.79(3) (see 79.04) and s.80(3) and (4) (see 80.03-04).

Section 55(1)

Notwithstanding anything in this Act, any government department and any person authorised in writing by a government department may, for the services of the Crown and in accordance with this section, do any of the following acts in the United Kingdom in relation to a patented invention without the consent of the proprietor of the patent, that is to say -

- (a) where the invention is a product, may
 - make, use, import or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing or keeping it; or
 - in any event, sell or offer to sell it for foreign defence purposes or for the production or supply of specified drugs and medicines, or dispose or offer to dispose of it (otherwise than by selling it) for any purpose whatever;
- where the invention is a process, may use it or do in relation to any product obtained directly by means of the process anything mentioned in paragraph (a) above:
- without prejudice to the foregoing, where the invention or any product (c) obtained directly by means of the invention is a specified drug or medicine, may sell or offer to sell the drug or medicine;
- (d) may supply or offer to supply to any person any of the means, relating to an essential element of the invention, for putting the invention into effect;

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s.77(1)

(e) may dispose or offer to dispose of anything which was made, used, imported or kept in the exercise of the powers conferred by this section and which is no longer required for the purpose for which it was made, used, imported or kept (as the case may be),

and anything done by virtue of this subsection shall not amount to an infringement of the patent concerned.

The acts set out in subsection (1)(a) to (e) may be done in the UK, for the services of the Crown, without the consent of the proprietor of the patent for the invention in question and without amounting to infringement of that patent. The persons thus empowered are any government department or person authorised in writing thereby. Although the Act does not define "government department", judgments under previous legislation relating to its meaning (eg *Pfizer Corp. v. Ministry of Health* [1965] RPC 261) apparently remain relevant. The relevance of such judgments to construction of "for the services of the Crown" in the Act is less clear since the definition of the term "the services of the Crown" has changed somewhat. It is now stated to include certain things listed in s.56(2), although that list is clearly not exhaustive (see 56.03). Subsection (1)(a) and (c) are interpreted in accordance with s.56(3) and (4).

The power conferred by s.55(1) has been extended to include the use of patented inventions for the purposes of a visiting force or headquarters, to the extent that the use would have been permitted if the visiting force or headquarters were a part of the home forces. However, this extension does not apply to acts which fall within s.55(1)(a)(ii) or s.55(1)(c), nor to acts done for a purpose relating to the production or use of atomic energy or research into related matters. See the Visiting Forces and International Headquarters (Application of Law) Order 1999 (SI 1999 No. 1736).

Section 55(2)

Any act done in relation to an invention by virtue of this section is in the following provisions of this section referred to as use of the invention; and "use", in relation to an invention, in sections 56 to 58 below shall be construed accordingly.

Section 55(3)

So far as the invention has before its priority date been duly recorded by or tried by or on behalf of a government department or the United Kingdom Atomic Energy Authority otherwise than in consequence of a relevant communication made in confidence, any use of the invention by virtue of this section may be made free of any royalty or other payment to the proprietor.

Section 55(4)

So far as the invention has not been so recorded or tried, any use of it made by virtue of this section at any time either -

- (a) after the publication of the application for the patent for the invention; or
- (b) without prejudice to paragraph (a) above, in consequence of a relevant communication made after the priority date of the invention otherwise than in confidence;

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shall be made on such terms as may be agreed either before or after the use by the government department and the proprietor of the patent with the approval of the Treasury or as may in default of agreement be determined by the court on a reference under section 58 below.

55.06 S.55(4) is modified by the Atomic Energy (Weapons Group) Act 1973 (as amended by the Patents Act 1977 s.132(5), sch.5 para.6)

55.07 Terms for Crown use may thus be agreed with the proprietor of the patent or determined by the court under s.58, unless s.55(3) applies. Where rights have been assigned or a licence granted in relation to the patent, s.57(3) to (9) apply to the operation of s.55(4).

Section 55(5)

Where an invention is used by virtue of this section at any time after publication of an application for a patent for the invention but before such a patent is granted, and the terms for its use agreed or determined as mentioned in subsection (4) above include terms as to payment for the use, then (notwithstanding anything in those terms) any such payment shall be recoverable only -

- (a) after such a patent is granted; and
- (b) if (apart from this section) the use would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent but also the claims (as interpreted by the description and any drawings referred to in the description or claims) in the form in which they were contained in the application immediately before the preparations for its publication were completed by the Patent Office.

Where Crown use occurs after publication of an application but before grant, compensation is recoverable only after grant and if the conditions of subsection (5)(b) regarding infringement are met. The terms of subsection (5) are closely similar to those of s.69(2) and place the Crown in a position equivalent to that of an infringer under s.69, see 69.07.

Section 55(6)

The authority of a government department in respect of an invention may be given under this section either before or after the patent is granted and either before or after the use in respect of which the authority is given is made, and may be given to any person whether or not he is authorised directly or indirectly by the proprietor of the patent to do anything in relation to the invention.

Section 55(7)

Where any use of an invention is made by or with the authority of a government department under this section, then, unless it appears to the department that it would be contrary to the public interest to do so, the department shall notify the proprietor of the patent as soon as practicable after the second of the following events, that is to say, the use is begun and the patent is granted, and furnish him with such information as to the extent of the use as he may from time to time require.

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Section 55(8)

A person acquiring anything disposed of in the exercise of powers conferred by this section, and any person claiming through him, may deal with it in the same manner as if the patent were held on behalf of the Crown.

Section 55(9)

In this section "relevant communication", in relation to an invention, means a communication of the invention directly or indirectly by the proprietor of the patent or any person from whom he derives title.

Section 55(10)

Subsection (4) above is without prejudice to any rule of law relating to the confidentiality of information.

Section 55(11)

In the application of this section to Northern Ireland, the reference in subsection (4) above to the Treasury shall, where the government department referred to in that subsection is a department of the Government of Northern Ireland, be construed as a reference to the Department of Finance for Northern Ireland.

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Section 56: Interpretation, etc., of provisions about Crown use

This is the second of the group of sections relating to Crown use of patented inventions. It concerns the interpretation of certain terms used in the provisions of the Act relevant to Crown use, especially s.55. With regard to ss.55 to 59 in general, see 55.01-03.

Section 56(1)

Any reference in section 55 above to a patented invention, in relation to any time, is a reference to an invention for which a patent has before that time been, or is subsequently, granted.

In including an invention for which a patent is yet to be granted, the meaning of "patented invention" in s.55 is an exception to the definition in s.130(1). See also 55.03.

Section 56(2)

In this Act, except so far as the context otherwise requires, "the services of the Crown" includes -

- (a) the supply of anything for foreign defence purposes;
- (b) the production or supply of specified drugs and medicines; and
- such purposes relating to the production or use of atomic energy or research into matters connected therewith as the Secretary of State thinks necessary or expedient;

and "use for the services of the Crown" shall be construed accordingly.

s.130(156.03 Except so far as the context otherwise requires, "services of the Crown" and "use for the services of the Crown" in the Act have the meanings assigned to them by s.56(2) including, as respects any period of emergency within the meaning of s.59, the meanings assigned to them by s.59. The services of the Crown thus includes inter alia those things listed in s.56(2)(a) to (c), subsections (2)(a) and (b) being interpreted in accordance with subsections (3) and (4) respectively. See also 55.04.

Section 56(3)

In section 55(1)(a) above and subsection (2)(a) above, references to a sale or supply of anything for foreign defence purposes are references to a sale or supply of the thing -

- to the government of any country outside the United Kingdom, in pursuance of an agreement or arrangement between Her Majesty's Government in the United Kingdom and the government of that country, where the thing is required for the defence of that country or of any other country whose government is party to any agreement or arrangement with Her Majesty's Government in respect of defence matters; or
- to the United Nations, or to the government of any country belonging to that organisation, in pursuance of an agreement or arrangement between Her Majesty's Government and that organisation or government, where the thing is required for any armed forces operating in pursuance of a resolution of that organisation or any

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Section 56(4)

For the purposes of section 55(1)(a) and (c) above and subsection (2)(b) above, specified drugs and medicines are drugs and medicines which are both -

(a) required for the provision of -

- (ai) primary medical services under part 1 of the National Health Service Act 1977, part I of the National Health Service (Scotland) Act 1978 or any corresponding provisions of the law in force in Northern Ireland or the Isle of Man or primary dental services under part 1 of the National Health Service Act 1977, or any corresponding provisions of the law in force in Northern Ireland or the Isle of Man, or
- (i) pharmaceutical services, general medical services or general dental services under Part II of the National Health Service Act 1977 (in the case of pharmaceutical services), Part II of the National Health Service (Scotland) Act 1978 (in the case of pharmaceutical services or general dental services), or the corresponding provisions of the law in force in Northern Ireland or the Isle of Man. or
- (ii) personal medical services or personal dental services provided in accordance with arrangements made under section 17C of the 1978 Act (in the case of personal dental services), or the corresponding provisions of the law in force in Northern Ireland or the Isle of Man, or
- (iii) local pharmaceutical services provided under a pilot scheme established under section 28 of the Health and Social Care Act 2001 or an LPS scheme established under Schedule 8A to the National Health Service Act 1977, or under any corresponding provision of the law in force in the Isle of Man, and
- (b) specified for the purposes of this subsection in regulations made by the Secretary of State.

56.04 Paragraph (4)(a) was last amended by the Health and Social Care (Community Health and Standards) Act 2003, which inserted subparagraph (4)(a)(ai) and made consequential amendments to subparagraphs (4)(a)(i) and (ii). This came into force in relation to primary medical service in England and Wales on 1 April 2004 (The Health and Social Care (Community Health and Standards) Act 2003 Commencement (No. 2) Order 2004 SI 2004 No. 288 and The Health and Social Care (Community Health and Standards) Act 2003 Commencement (No.1) (Wales) Order 2004 SI 2004 No. 480). The reference in subparagraph 4(a)(ai) to the National Health Service (Scotland) Act 1978, and the consequential amendments to subparagraphs 4(a)(i) and (ii) were made by the Primary Medical Services (Scotland) Act 2004 (Consequential Modifications) Order (SI 2004 No. 957), which also came into force on 1 April 2004. Subparagraph (4)(a)(ai) came into force for primary dental services in England on 1 January 2006 (The Health and Social Care (Community Health and Standards) Act 2003 Commencement (No. 8) Order 2005 SI 2005 No. 2925) and in Wales on 15 February 2006 (The Health and Social Care (Community Health and Standards) Act 2003 Commencement (No. 8) Order 2005 SI 2006 No. 345). Subparagraph (4)(a)(iii) was inserted by the Health and Social Care Act 2001, and came into force in Wales on 1 July 2002 (The Health and Social Care Act 2001 (Commencement No. 2) (Wales) Order 2002 SI 2002 No. 1475), and in England on 1 January 2003 (The Health and Social Care Act 2001 (Commencement No. 11) (England) Order 2002 SI 2003 No. 53).

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Section 57: Rights of third parties in respect of Crown use

57.01 This is the third of the group of sections relating to use of patented inventions for the services of the Crown. It concerns the rights of third parties, particularly licensees and parties to assignments (assignations in Scotland). With regard to ss.55 to 59 in general, see 55.01-03.

Subsections (1) and (2) render ineffective any provisions of a licence, assignment or agreement which would otherwise inhibit Crown use; the use of models, documents or information relating to an invention affected by a licence, assignment or agreement is also subject to subsections (9) and (10). Exclusive licences not providing for royalties or other benefits determined by reference to the working of the invention are dealt with by subsection (3); other exclusive licences by subsections (5) to (8). Where patent rights were assigned to the proprietor of the patent or application, subsection (4) is applicable. Subsection (1) also renders ineffective copyright or Design Right which would otherwise inhibit Crown use, the reference to Design Right having been added by paragraph 20 of Schedule 7 to the CDP Act.

Section 57(1)

In relation to -

- (a) any use made for the services of the Crown of an invention by a government department, or a person authorised by a government department, by virtue of section 55 above, or
- (b) anything done for the services of the Crown to the order of a government department by the proprietor of a patent in respect of a patented invention or by the proprietor of an application in respect of an invention for which an application for a patent has been filed and is still pending,

the provisions of any licence, assignment, assignation or agreement to which this subsection applies shall be of no effect so far as those provisions restrict or regulate the working of the invention, or the use of any model, document or information relating to it, or provide for the making of payments in respect of, or calculated by reference to, such working or use; and the reproduction or publication of any model or document in connection with the said working or use shall not be deemed to be an infringement of any copyright or design right subsisting in the model or document.

Section 57(2)

Subsection (1) above applies to a licence, assignment, assignation or agreement which is made, whether before or after the appointed day, between (on the one hand) any person who is a proprietor of or an applicant for the patent, or anyone who derives title from any such person or from whom such person derives title, and (on the other hand) any person whatever other than a government department.

Section 57(3)

Where an exclusive licence granted otherwise than for royalties or other benefits determined by reference to the working of the invention is in force under the patent or application concerned, then -

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- (a) in relation to anything done in respect of the invention which, but for the provisions of this section and section 55 above, would constitute an infringement of the rights of the licensee, subsection (4) of that section shall have effect as if for the reference to the proprietor of the patent there were substituted a reference to the licensee; and
- (b) in relation to anything done in respect of the invention by virtue of an authority given under that section, that section shall have effect as if the said subsection (4) were omitted.

Section 57(4)

Subject to the provisions of subsection (3) above, where the patent, or the right to the grant of the patent, has been assigned to the proprietor of the patent or application in consideration of royalties or other benefits determined by reference to the working of the invention, then -

- (a) in relation to any use of the invention by virtue of section 55 above, subsection (4) of that section shall have effect as if the reference to the proprietor of the patent included a reference to the assignor, and any sum payable by virtue of that subsection shall be divided between the proprietor of the patent or application and the assignor in such proportion as may be agreed on by them or as may in default of agreement be determined by the court on a reference under section 58 below; and
- (b) in relation to any act done in respect of the invention for the services of the Crown by the proprietor of the patent or application to the order of a government department, section 55(4) above shall have effect as if that act were use made by virtue of an authority given under that section.

Section 57(5)

Where section 55(4) above applies to any use of an invention and a person holds an exclusive licence under the patent or application concerned (other than such a licence as is mentioned in subsection (3) above) authorising him to work the invention, then subsections (7) and (8) below shall apply.

Section 57(6)

In those subsections "the section 55(4)" payment means such payment (if any) as the proprietor of the patent or application and the department agree under section 55 above, or the court determines under section 58 below, should be made by the department to the proprietor in respect of the use of the invention.

Section 57(7)

The licensee shall be entitled to recover from the proprietor of the patent or application such part (if any) of the section 55(4) payment as may be agreed on by them or as may in default of agreement be determined by the court under section 58 below to be just having regard to any expenditure incurred by the licensee -

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- (a) in developing the invention, or
- (b) in making payments to the proprietor in consideration of the licence, other than royalties or other payments determined by reference to the use of the invention.

Section 57(8)

Any agreement by the proprietor of the patent or application and the department under section 55(4) above as to the amount of the section 55(4) payment shall be of no effect unless the licensee consents to the agreement; and any determination by the court under section 55(4) above as to the amount of that payment shall be of no effect unless the licensee has been informed of the reference to the court and is given an opportunity to be heard.

Section 57(9)

Where any models, documents or information relating to an invention are used in connection with any use of the invention which falls within subsection (1)(a) above, or with anything done in respect of the invention which falls within subsection (1)(b) above, subsection (4) of section 55 above shall (whether or not it applies to any such use of the invention) apply to the use of the models, documents or information as if for the reference in it to the proprietor of the patent there were substituted a reference to the person entitled to the benefit of any provision of an agreement which is rendered inoperative by this section in relation to that use; and in section 58 below the references to terms for the use of an invention shall be construed accordingly.

Section 57(10)

Nothing in this section shall be construed as authorising the disclosure to a government department or any other person of any model, document or information to the use of which this section applies in contravention of any such licence, assignment, assignation or agreement as is mentioned in this section.

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Section 57A: Compensation for loss of profit

57A.01 Section 57A was added by the CDP Act to make available an additional form of compensation for Crown use of a patented invention, which made consequential amendments to s.58. This supplements the provisions of sections 55 to 59 regarding Crown use.

57A.02 Section 57A is effective for any Crown use after commencement (1 August 1989) even if terms for such use had been settled previously.

Section 57A(1)

Where use is made of an invention for the services of the Crown, the government department concerned shall pay -

- (a) to the proprietor of the patent, or
- (b) if there is an exclusive licence in force in respect of the patent, to the exclusive licensee.

compensation for any loss resulting from his not being awarded a contract to supply the patented product or, as the case may be, to perform the patented process or supply a thing made by means of the patented process.

Section 57A(2)

Compensation is payable only to the extent that such a contract could have been fulfilled from his existing manufacturing or other capacity; but is payable notwithstanding the existence of circumstances rendering him ineligible for the award of such a contract.

Section 57A(3)

In determining the loss, regard shall be had to the profit which would have been made on such a contract and to the extent to which any manufacturing or other capacity was underused.

Section 57A(4)

No compensation is payable in respect of any failure to secure contracts to supply the patented product or, as the case may be, to perform the patented process or supply a thing made by means of the patented process, otherwise than for the services of the Crown.

Section 57A(5)

The amount payable shall, if not agreed between the proprietor or licensee and the government department concerned with the approval of the Treasury, be determined by the court on a reference under section 58, and is in addition to any amount payable under section 55 or 57.

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Section 57A(6)

In this section 'the government department concerned', in relation to any use of an invention for the services of the Crown, means the government department by whom or on whose authority the use was made.

Section 57A(7)

In the application of this section to Northern Ireland, the reference in subsection (5) above to the Treasury shall, where the government department concerned is a department of the Government of Northern Ireland, be construed as a reference to the Department of Finance and Personnel.

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Section 58: References of disputes as to Crown use

This is the fifth of the group of sections relating to use of patented inventions for the services of the Crown. It provides for the resolution by the court of disputes concerning Crown use, including the settlement of terms whereby the proprietor of a patent may be compensated for Crown use. With regard to ss.55 to 59 in general, see 55.01-03.

Section 58(1)

Any dispute as to -

- (a) the exercise by a government department, or a person authorised by a government department, of the powers conferred by section 55 above,
- (b) terms for the use of an invention for the services of the Crown under that section.
- (c) the right of any person to receive any part of a payment made in pursuance of subsection (4) of that section, or
- (d) the right of any person to receive a payment under section 57A,

may be referred to the court by either party to the dispute after a patent has been granted for the invention.

- s.57A(5) 58.02 Section 55 permits any government department or person authorised in writing thereby to do certain acts for the services of the Crown, see 55.04-05. Section 55(4) provides that if terms for such use cannot be agreed, they may be determined by the court on a reference under s.58, see 55.06-07. All disputes concerning Crown use, as detailed in s.58(1), may be referred to the court by either of the parties but the reference cannot be made until after the grant of the relevant patent. Section 58(1) was amended by the CDP Act to make disputes referable to the court regarding the right to compensation under section 57A (see 57A.01-02). The amount of such compensation may also be determined on such a reference and is in addition to any other amount payable under s.55 or 57.
- CPR 63.5
 s.130(1)
 s.58(12)
 Such a reference to the Patents Court should be made by issue of a claim form, the procedure being prescribed by the Civil Procedure Rules. In England and Wales, a reference may alternatively be made to the Patents County Court. In parts of the UK other than England or Wales, the reference may be made to the High Court of that part or, in Scotland, the Court of Session. Any such court may refer matters to a Circuit judge or arbiter.

Section 58(2)

If in such proceedings any question arises whether an invention has been recorded or tried as mentioned in section 55 above, and the disclosure of any document recording the invention, or of any evidence of the trial thereof, would in the opinion of the department be prejudicial to the public interest, the disclosure may be made confidentially to the other party's legal representative or to an independent expert mutually agreed upon.

58.04 Crown use may be made free of any royalty or other payment to the proprietor of the patent if the invention in question was before its priority date recorded or

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tried as set out in s.55(3). Documents or evidence establishing such record or trial may be disclosed confidentially to the other party's legal representative or an independent expert if general disclosure would be prejudicial to the public interest.

Section 58(3)

In determining under this section any dispute between a government department and any person as to the terms for the use of an invention for the services of the Crown, the court shall have regard -

- (a) to any benefit or compensation which that person or any person from whom he derives title may have received or may be entitled to receive directly or indirectly from any government department in respect of the invention in question;
- (b) to whether that person or any person from whom he derives title has in the court's opinion without reasonable cause failed to comply with a request of the department to use the invention for the services of the Crown on reasonable terms.

58.05 In settling terms for Crown use, the court has regard to the matters in subsection (3)(a) and (b).

Section 58(4)

In determining whether or not to grant any relief under subsection (1)(a), (b) or (c) above and the nature and extent of the relief granted the court shall, subject to the following provisions of this section, apply the principles applied by the court immediately before the appointed day to the granting of relief under section 48 of the 1949 Act.

Section 48 of the 1949 Act provided for the reference of Crown use disputes to the court and thus corresponded to the present s.58. The same principles are applied to the grant of relief under s.58 now as were applied immediately before 1 June 1978 under the old s.48. The provisions of s.58(4) with regard to Crown use correspond to those of s.61(6) with regard to infringement. The CDP Act made a minor change in the wording of s.58(4); this was consequential on amendment of s.58(1) and did not alter the effect of s.58(4). Section 58(1)(d) is excluded from comparability because there was no corresponding provision under the 1949 Act.

Section 58(5)

On a reference under this section the court may refuse to grant relief by way of compensation in respect of the use of an invention for the services of the Crown during any further period specified under section 25(4) above, but before the payment of the renewal fee and any additional fee prescribed for the purposes of that section.

58.07 The provisions of s.58(5) with regard to Crown use correspond to those of s.62(2) with regard to infringement, see 62.05.

Section 58(6)

Where an amendment of the specification of a patent has been allowed under any of the provisions of this Act, the court shall not grant relief by way of compensation under this

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section in respect of any such use before the decision to allow the amendment unless the court is satisfied that

- (a) the specification of the patent as published was framed in good faith and with reasonable skill and knowledge; and
- (b) the relief is sought in good faith.

58.08 The provisions of s.58(6) with regard to Crown use correspond to those of s.62(3) with regard to infringement, see 62.06.

Section 58(7)

If the validity of a patent is put in issue in proceedings under this section and it is found that the patent is only partially valid, the court may, subject to subsection (8) below, grant relief to the proprietor of the patent in respect of that part of the patent which is found to be valid and to have been used for the services of the Crown.

s.74(1) 58.09 The validity of a patent may be put in issue in proceedings under s.58, see 74.03. The provisions of s.58(7) with regard to Crown use correspond to those of s.63(1) with regard to infringement, see 63.03.

Section 58(8)

Where in any such proceedings it is found that a patent is only partially valid the Court shall not grant relief by way of compensation, costs or expenses except where the proprietor of the patent proves that

- (a) the specification of the patent was framed in good faith and with reasonable skill and knowledge, and
- (b) the relief is sought in good faith,

and in that event the court may grant relief in respect of the part of the patent which is valid and has been so used, subject to the discretion of the court as to costs and expenses and as to the date from which compensation should be awarded.

58.10 The provisions of s.58(8) with regard to Crown use correspond to those of s.63(2) with regard to infringement, see 63.04.

Section 58(9)

As a condition of any such relief the court may direct that the specification of the patent shall be amended to its satisfaction upon an application made for that purpose under section 75 below, and an application may be so made accordingly, whether or not all other issues in the proceedings have been determined.

58.11 The provisions of s.58(9) with regard to Crown use correspond to those of s.63(3) with regard to infringement, see 63.05.

Section 58(9A)

The court may also grant such relief in the case of a European patent (UK) on condition that the claims of the patent are limited to its satisfaction by The European Patent Office at the

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request of the proprietor.

Article 138(3) EPC provides a central amendment process for European Patents. This is an alternative to the existing possibility of the proprietor amending the patent under the 1977 Act. In the former case, the amendments are effective in each Contracting State designated by the patent whereas the latter would only affect the European patent (UK). This section provides that relief may be granted on the condition that the proprietor of a European patent (UK) limits the patent at the EPO. The limitation would have to be done to the satisfaction of the court for relief to be granted.

Section 58(10)

In considering the amount of any compensation for the use of an invention for the services of the Crown after publication of an application for a patent for the invention and before such a patent is granted, the court shall consider whether or not it would have been reasonable to expect, from a consideration of the application as published under section 16 above, that a patent would be granted conferring on the proprietor of the patent protection for an act of the same description as that found to constitute that use, and if the court finds that it would not have been reasonable, it shall reduce the compensation to such amount as it thinks just.

58.12 The provisions of s.58(10) with regard to Crown use correspond to those of s.69(3) with regard to infringement, see 69.08.

Section 58(11)

Where by virtue of a transaction, instrument or event to which section 33 above applies a person becomes the proprietor or one of the proprietors or an exclusive licensee of a patent (the new proprietor or licensee) and a government department or a person authorised by a government department subsequently makes use under section 55 above of the patented invention, the new proprietor or licensee shall not be entitled to any compensation under section 55(4) above (as it stands or as modified by section 57(3) above), or to any compensation under section 57A above, in respect of a subsequent use of the invention before the transaction, instrument or event is registered unless -

- (a) the transaction, instrument or event is registered within the period of six months beginning with its date; or
- (b) the court is satisfied that it was not practicable to register the transaction, instrument or event before the end of that period and that it was registered as soon as practicable thereafter.
- The provisions of s.58(11) with regard to Crown use correspond to those of s.68 with regard to infringement, see 68.04-05. The reference to compensation under s.57A was added the CDP Act, see 57A.01-02.

Section 58(12)

In any proceedings under this section the court may at any time order the whole proceedings or any question or issue of fact arising in them to be referred, on such terms as the court may direct, to a Circuit judge discharging the functions of an official referee or an arbitrator in England and Wales, the Isle of Man or Northern Ireland, or to an arbiter in Scotland; and references to the court in the foregoing provisions of this section shall be construed accordingly.

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58.14 The reference to the Isle of Man was added to s.58(12) by S.I. 1978 No. 621, which has since been replaced by S.I. 2003 No. 1249.

Section 58(13)

One of two or more joint proprietors of a patent or application for a patent may without the concurrence of the others refer a dispute to the court under this section, but shall not do so unless the others are made parties to the proceedings; but any of the others made a defendant or defender shall not be liable for any costs or expenses unless he enters an appearance and takes part in the proceedings.

58.15 The provisions of s.58(13) with regard to Crown use correspond to those of s.66(2) with regard to infringement.

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Section 59: Special provisions as to Crown use during emergency

This is the sixth and last of the group of sections relating to use of patented inventions for the services of the Crown. The powers for Crown use under s.55 (see 55.04) are extended by s.59 during any period of emergency as defined by s.59(3). The meanings of "the services of the Crown" and "use for the services of the Crown" are extended beyond their normal meanings (see 56.03) by s.59(1) and (2). With regard to ss.55 to 59 in general, see 55.01-03.

Section 59(1)

During any period of emergency within the meaning of this section the powers exercisable in relation to an invention by a government department or a person authorised by a government department under section 55 above shall include power to use the invention for any purpose which appears to the department necessary or expedient -

- (a) for the efficient prosecution of any war in which Her Majesty may be engaged;
- (b) for the maintenance of supplies and services essential to the life of the community;
- (c) for securing a sufficiency of supplies and services essential to the well-being of the community;
- (d) for promoting the productivity of industry, commerce and agriculture;
- (e) for fostering and directing exports and reducing imports, or imports of any classes, from all or any countries and for redressing the balance of trade;
- (f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community: or
- (g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory outside the United Kingdom which is in grave distress as the result of war;

and any reference in this Act to the services of the Crown shall, as respects any period of emergency, include a reference to those purposes.

Section 59(2)

In this section the use of an invention includes, in addition to any act constituting such use by virtue of section 55 above, any act which would, apart from that section and this section, amount to an infringement of the patent concerned or, as the case may be, give rise to a right under section 69 below to bring proceedings in respect of the application concerned, and any reference in this Act to "use for the services of the Crown" shall, as respects any period of emergency, be construed accordingly.

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Section 59(3)

In this section "period of emergency" means any period beginning with such date as may be declared by Order in Council to be the commencement, and ending with such date as may be so declared to be the termination, of a period of emergency for the purposes of this section.

Section 59(4)

A draft of an Order under this section shall not be submitted to Her Majesty unless it has been laid before, and approved by resolution of, each House of Parliament.

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INFRINGEMENT

Section 60: Meaning of infringement

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EXEMPTED ACTS

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SECTION 60(7)

s.67 60.01

This section is the first of a group (ss.60 to 71) relating to infringement. Section 60 governs what constitutes infringement of a patent for an invention under the Act while the patent is in force. Its provisions also apply, to the extent defined by section 69, in relation to a patent application under the Act which has been published but not granted. References to the proprietor of a patent are therefore to be construed as including references to the applicant. References to the proprietor are also to be construed as including references to an exclusive licensee and, in the case of two or more joint proprietors, are to be construed as set out in section 66.

s.77(1) 60.02 Sections 60 to 71 also apply in relation to European patents (UK) and s.78(2) sections 60 to 70F also apply in relation to applications for European patents (UK).

s.80(1) 60.03 In proceedings before the comptroller or the court the authentic text of a European patent is the text of the patent in the language used to prosecute the patent before

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- s.80(2) the EPO, unless section 80(2) applies (see 80.02). The translated claims of a European patent published in French or German which are filed under Article 14(6) are for information only. See 80.01-80.02 for more detail.
- s.130(7) Section 60 is so framed as to have, as nearly as practicable, the same effect in the UK as the corresponding provisions of the EPC, CPC and PCT. Articles 29 to 31 of the CPC (renumbered in December 1989 as Articles 25 to 27 [1989]) and Article 64 of the EPC are in question and are commented on below, see 60.11 to 60.14, 60.16, 60.17, 60.20, 60.21, 60.23, 60.24 and 60.30.

60.05 Prior to the Patents Act 1977, the meaning of infringement was a matter of common law.

Extent of protection

Whether or not a patent is infringed depends on the construction placed on the extent of the protection afforded by the patent. That protection is determined in accordance with the s.125(1) definition of an invention as that specified in a claim as interpreted by the description and any drawings. See 2.11 to 2.17, 14.111 to 14.120 and 125 with regard to construction in this respect. For biotechnological inventions, see paragraphs 76A.07 to 76A.09; which make clear that s.60 must be read in the light of paragraphs 7-10 of Schedule A2.

Matter which falls in some material respect outside the scope of the claims, when they have been interpreted in the light of s.125(1), is not protected. The following observation of Viscount Radcliffe in the House of Lords in *Van der Lely N V v Bamfords Ltd* [1963] RPC 61 at page 78 states: "one must be very careful to see that the inventor has not by the actual form of his claim left open to the world the appropriation of just that property that he says has been filched from him by piracy or theft. After all, it is he who has committed himself to the unequivocal description of what he claims to have invented, and he must submit in the first place to be judged by his own action and words".

60.08 [deleted]

Something which differs in an unessential respect from a patented invention may still infringe the patent; it is a question of considering substance rather than mere form. In the House of Lords in *Rodi & Wienenberger AG v Henry Showell Ltd* [1969] RPC 367 at page 380, Lord Morris of Borth-y-Gest endorsed the observations made in *Marconi v British Radio Telegraph and Telephone Co Ltd* (1911) 28 RPC 181 to the effect that no one who borrows the substance of a patented invention can escape the consequences of infringement by making immaterial variations, and that everyone who produces the same results by using the essential parts of the combination or process is an infringer, even though he has replaced some unessential part by an equivalent part.

Section 60(1)

Subject to the provision of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say -

- (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
- (b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an

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infringement of the patent;

(c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

ACTS CONSTITUTING INFRINGEMENT

Direct use of the invention (substantive infringement)

- A person infringes if he performs any of certain acts in the UK without the consent of the proprietor of the patent or, by virtue of s.69 in the case of a published application, the consent of the applicant. The acts in question are as set out in s.60(1)(a) where the invention is a product and as set out in s.60(1)(b) and (c) where the invention is a process.
- 60.11 CPC Article 29 (renumbered as Article 25 [1989]) corresponds to s.60(1) although its wording is somewhat different. The Article is headed "Prohibition of direct use of the invention".
- Where the invention is a product, the infringing acts according to s.60(1)(a) are to make, dispose of, offer to dispose of, use or import the product or keep it whether for disposal or otherwise; whereas according to CPC a.29(a) (renumbered as a.25(a) [1989]) they are to make, offer, put on the market or use the product, or import or stock the product for these purposes. Comparison of these corresponding provisions may serve as an aid in construction since they should have the same effect, see 60.04.
- 60.12.1 In <u>United Wire Ltd v Screen Repair Services (Scotland) Ltd ([2001] RPC 24)</u> the view of the Court of Appeal (subsequently endorsed by the House of Lords) was that "genuine repair" of a patented product does not amount to making that product and so does not constitute an infringing act. However, Aldous LJ observed that acts prohibited by s.60 are infringing acts whether or not they can be categorised as 'repairs' and stated:

"It is therefore better to consider whether the acts of a defendant amount to manufacture of the product rather than whether they can be called repair, particularly as what could be said to be repair can depend upon the perception of the person answering the question. Even so, when deciding whether there has been manufacture of the product of the invention, it will be necessary to take into account the nature of the invention as claimed and what was done by the defendant."

The case in question centred around mesh screen assemblies used in vibratory sifting or filtering machines, comprising two tensioned filter meshes bound to a frame. The defendants 'repair' of the screen involved stripping the frame, re-coating with adhesive and applying new meshes, followed by tensioning and heating to cure the adhesive. This process was found to be equivalent to purchasing the frames on the open market and then using them to produce an assembly, and thus constituting an infringing act.

60.12.2 The Supreme Court in <u>Schütz (UK) Ltd v Werit UK Ltd [2013] UKSC 16</u> considered whether the alleged infringing act constituted "making" the claimed product. In this case, the claimed invention was a liquid container comprising a bottle and protective cage. The new and inventive component of the container was the cage, and the alleged infringing act was replacement of the bottle within a re-used Schütz cage. The Supreme Court held that (as set out in <u>United Wire Ltd v Screen Repair Services (Scotland) Ltd</u> ([2001] RPC 24)) the critical question is whether replacing a component of an article

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constitutes "making" that article, and that the Court of Appeal ([2011] EWCA Civ 303) had failed to recognise that this question is a matter of fact and degree. In this case given that the bottle (i) was a freestanding, replaceable component of the patented article, (ii) had no connection with the claimed inventive concept, (iii) had a much shorter life expectancy than the other, inventive, component and (iv) could not be described as the main component of the article, and given that no additional work was done to the article beyond routine repairs, replacing the bottle did not constitute "making" the claimed invention. The patent was therefore not infringed.

60.12.3 In <u>Nestec SA & Ors v Dualit Ltd & Ors [2013] EWHC 923 (Pat)</u> the claimed invention was a system consisting of a coffee machine and a capsule adapted for use in that machine. With reference to both <u>Schütz (UK) Ltd v Werit UK Ltd [2013] UKSC 16</u> and <u>United Wire Ltd v Screen Repair Services (Scotland) Ltd ([2001] RPC 24)</u>, the Judge held that owners of the relevant coffee machine do not "make" the claimed system when they purchase capsules for use in said machine.

In *Smith, Kline and French Laboratories Ltd v R D Harbottle (Mercantile) Ltd and Others* [1980] RPC 363, the corresponding wording of CPC a.29 (renumbered as a.25 [1989]) was one of the reasons for the conclusion of the Patents Court that "keeps" in s.60(1)(a) connotes a keeping in some capacity and for a purpose other than that of a mere custodian or warehouseman; it was held that what the draftsman had in mind was "keeping" in the sense of "keeping in stock" so as to give effect to the words of the Convention "stocking the product for these purposes". A further reason for that conclusion was the lack of evidence of any intention to effect a revolutionary change from the situation before 1977 that a carrier or warehouseman who did no more than innocently carry or store infringing goods for a consignor or consignee was not liable as an infringer.

In Kalman and another v PCL Packaging (UK) Ltd and another [1982] FSR 406, the Patents Court considered the meaning to be given to the phrase "dispose of" in s.60(1)(a) and the equivalent expression "putting on the market" in CPC a.29(a) (renumbered as a.25(a) [1989]), and concluded that "dispose of" must at least include selling. In endorsing the conclusions reached in the Smith, Kline and French case (see 60.13) the Court held that mere carriers did not themselves "dispose of" the goods which they carried. The Court further held that "offers to dispose of" in s.60(1)(a) means "offers in the United Kingdom to dispose of the product in the United Kingdom".

According to s.60(1)(a), importing a patented product is an infringing act. 60.15 Article 28 of the Treaty establishing the European Community prohibits quantitative restrictions on imports and all measures having equivalent effect between Member States, but Article 30 of that Treaty provides that Article 28 shall not preclude prohibitions or restrictions on imports or goods in transit justified on grounds of inter alia the protection of industrial and commercial property. When considering Articles 28 and 30 of the Treaty (then Articles 30 and 36, respectively) in the case of Allen and Hanburys' Salbutamol Patent [1988] FSR 312, the European Court of Justice held that a person importing from another Member State of the then European Economic Community should be treated the same as one manufacturing in the UK: such importation can only be banned by injunction or by the terms of a licence if such manufacture would also be banned. This applies even if the product being imported is not patentable in the Member State in which it was manufactured (see 46.53). In SABAF SpA v Meneghetti SpA [2003] RPC 14 one defendant had sold some goods and then arranged carriage and importation of those goods into the UK for the owner. The Court of Appeal held that the seller had no title to those goods and so was not an infringer. It was artificial to regard someone as an importer within the meaning of s.60(1)(a) if they had no legal or beneficial interest in the goods. It was the owner of the goods who would be regarded as the importer in these circumstances. On appeal to the House of Lords, reported as SABAF SpA v MFI Furniture Centres Ltd [2005] RPC 10, the argument that the seller was the sole importer was rejected since the owner was the importer and it was accepted they were not jointly liable.

60.16 Where the invention is a process, the infringing acts in respect of any product obtained directly by means of that process are given in s.60(1)(c) and are the same

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(except for the omission of making the product) as those given in s.60(1)(a) and discussed above. The corresponding CPC provision is Article 29(c) (renumbered as Article 25(c) [1989]) which likewise refers to the same acts (except for making the product) as those in Article 29(a) (renumbered as Article 25(a) [1989]), see 60.12. EPC Article 64(2) provides that the protection conferred extends to products directly obtained by such process. After considering the French and German texts of the corresponding EPC provision Aldous J in *Pioneer Electronics Capital Inc and anr. v Warner Music Manufacturing Europe GmbH and anr.* [1995] RPC 487 considered it appropriate to assign to the word "directly" the meaning "without intermediary", and the Court of Appeal [1997] RPC 757 agreed with and adopted this interpretation in this case. Thus to infringe, a product must be the direct product of the claimed process and not a product resulting from further material and important steps. The Patents Court in *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] RPC 2 held that section 60(1)(c) should be given an interpretation that went as far as a product by process claim might go, but no further (see 2.15 and 14.121-14.122).

60.16.1 "Swiss-type" second medical use claims (see 4A.26-31) are considered to be a special form of "purpose-limited" process claims, and so the relevant sections for direct infringement are 60(1)(b) and (c). In Generics (UK) Ltd (t/a Mylan) v Warner-Lambert Company LLC [2015] EWHC 2548, the patents court considered whether there was infringement under s.60(1)(c) of a Swiss-type claim to the use of a drug (pregabalin) in the manufacture of a medicament for the treatment of pain. The alleged infringer manufactured a drug with a so-called "skinny label" which listed the non-protected uses of the drug and did not refer to treatment of pain. Nevertheless it was alleged that the manufacturer would know that its drug would in fact be prescribed for the treatment of pain (NB s.60(1)(b) did not apply as the drug was manufactured overseas). It was held that "for treatment of pain" meant "suitable and intended for treatment of pain", and in an interim decision, the Court of Appeal in Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Ors [2015] EWCA Civ 556 held that "intended for" meant that the manufacturer would know or could reasonably foresee that the product would be used for the claimed therapeutic method. In applying this test at the full trial, Arnold J held that this meant the manufacturer would know or could reasonably foresee that a doctor or pharmacist would intentionally prescribe or administer the manufacturer's drug (as opposed to the branded drug of the patent proprietor) for the claimed purpose. On the facts of the case the judge found that there was no infringement. However, on appeal from this decision, the Court of Appeal (Warner-Lambert Company v Generics (UK) Ltd (t/a Mylan) & Ors [2016] EWCA Civ 1006) held that Arnold J's interpretation was too restrictive - instead, all that is required for infringement is that the manufacturer could reasonably foresee that there would be intentional use of the drug for the claimed medical use. Nevertheless, the decision was upheld. It should be emphasised that these decisions relate to "Swiss-type" second medical use claims only, and the scope (for the purposes of infringement) of the "new form" second medical use claims of the form "Substance X for use in the treatment of disease Y" has not yet been tested (see 4A.26-31).

s.60(1)(b)

lt is also an infringing act, where the invention is a process, for a person to use that process or, subject to certain conditions, to offer it for use in the UK. Those conditions are that the person knows, or it is "obvious to a reasonable person in the circumstances" that the use of the process in the UK without the consent of the proprietor or applicant as the case may be would be an infringement. The corresponding CPC provision is Article 29(b) (renumbered as Article 25(b) [1989]) which is similar but uses the expression "obvious in the circumstances" without any reference to a "reasonable person".

Section 60(2)

Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are

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suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

Indirect use of the invention (contributory infringement)

60.18 [deleted]

60.19 Under section 60(2) a person may infringe if, without consent, he supplies or offers to supply in the UK a person not entitled to work the invention with means relating to an essential element of an invention for putting the invention into effect in the UK. A person does not infringe unless he knows, or it is "obvious to a reasonable person in the circumstances", that those means are suitable and intended for putting the invention into effect in the UK. The "intention" to use the means for putting the invention into effect is on the part of the end user, not the supplier of the product, as held by the Court of Appeal in *Grimme v Scott* [2010] EWCA Civ 1110. In this decision, Jacob LJ set out the following criteria for interpreting the requirements of s.60(2) for knowledge and intention:

"In short, the knowledge and intention requirements of ... section 60(2) are satisfied if, at the time of supply or offer of supply, the supplier knows, or it is obvious in the circumstances, that ultimate users will intend to put the invention into effect. That is to be proved on the usual standard of balance of probabilities. It is not enough merely that the means are suitable for putting the intention into effect (for that is a separate requirement), but it is likely to be the case where the supplier proposes or recommends or even indicates the possibility of such use in his promotional material."

Notwithstanding this final sentence, contributory infringement may still have taken place even without the supplier suggesting the possibility of an infringing use. In *KCI Licensing Inc & Ors v Smith & Nephew Plc & Ors* [2010] EWCA Civ 1260 the claimed invention was a canister for use in a wound treatment system, in which the inlet tube included "clamp means" for preventing escape of liquid. The alleged infringer supplied a canister which did not have any clamps on the inlet tube, and there was no suggestion from the supplier that any should be used. However, Jacob LJ observed that clamps were readily available in the hospital environment, and it would have been obvious to a reasonable person that medical staff would be highly likely to clamp the tube when using the device.

The supply must occur in the UK (judgment of the Patents Court in the *Kalman* case, see 60.14). The meaning of "putting the invention into effect in the UK" was considered in *Menashe Business Mercantile Ltd v William Hill Organization Ltd by the Court of Appeal* [2003] RPC 31. The patent in suit related to a host computer in communication with one or more terminal computers, and a program for operating the terminal computer. The alleged infringer provided a program in the UK which turned a user's computer into the terminal computer, but the host computer was located abroad. The court considered that locating the host computer abroad provided no defence to an allegation of infringement under s.60(2) and held that s.60(2) was concerned with "putting the invention into effect in the United Kingdom" and not something which merely has an effect in the UK. Aldous LJ determined that the invention had been put into effect in the United Kingdom as the terminal computer was being operated by the user in the UK, so the user could also be considered to be using the host computer in the UK; the actual location of the host computer was of no relevance to the functioning of the invention. See 60.29-31 with regard to persons entitled to work the invention for the purposes of s.60(2).

60.19.2 In Generics (UK) Ltd (t/a Mylan) v Warner-Lambert Company LLC [2015] EWHC 2548 the patents court considered whether the manufacture and supply of a drug with a so-called "skinny label" could be considered to be an indirect infringement under s.60(2) if the manufacturer knew or could foresee that the drug would be used for a protected purpose. The "skinny label" listed only non-protected uses of the drug. It did not refer to treatment of pain (which was protected by the patentees' "Swiss-type" second medical use claim). Arnold J held that there was no possibility of indirect infringement

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(despite an interim decision by the Court of Appeal which held that there was an arguable case - Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Ors [2015] EWCA Civ 556) as a "Swiss-type" claim was a claim to a method of manufacture, and the pharmacists and doctors were not doing anything which could be considered part of the manufacture of the drug. He therefore held that there was therefore no possibility of pharmacists or doctors supplying a "means... for putting the invention into effect". However, the Court of Appeal (Warner-Lambert Company v Generics (UK) Ltd (t/a Mylan) & Ors [2016] EWCA Civ 1006) held that the process of "manufacture" could include any labelling step performed by the pharmacist which ascribed the purpose to the drug, and so disagreed with this reasoning (though Arnold J's overall decision was upheld). Moreover, there could be indirect infringement if a doctor or pharmacist does anything which constitutes "manufacturing" the drug or composition, rather than simply administering or prescribing it. In Actavis UK Ltd & Ors v Eli Lilly & Company [2015] EWCA Civ 555, the Court of Appeal held that the supply of the potassium salt of a drug could constitute indirect infringement of a Swiss type claim to the use of the sodium salt, as the drug was supplied with instructions to reconstitute the dried salt in a saline (sodium chloride) solution, with the result that the sodium salt was made up in solution. It should be emphasised that these decisions relate to "Swiss-type" second medical use claims only, and the scope (for the purposes of infringement) of the "new form" second medical use claims of the form "Substance X for use in the treatment of disease Y" has not yet been tested (see 4A.26-31).

60.20 The corresponding provision of the CPC is paragraph 1 of Article 30 (renumbered as Article 26 [1989]), the wording of which is similar to that of s.60(2) although it does not mention a "reasonable person" (cf 60.17) and refers to a "party entitled to exploit the patented invention" instead of to a "licensee or other person entitled to work the invention". The Article is headed "Prohibition of indirect use of the invention".

Section 60(3)

Subsection (2) above shall not apply to the supply or offer of a staple commercial product unless the supply or the offer is made for the purpose of inducing the person supplied or, as the case may be, the person to whom the offer is made to do an act which constitutes an infringement of the patent by virtue of subsection (1) above.

The supply or offer of a staple commercial product does not constitute an infringing act under s.60(2) unless it is for the purpose of inducing the recipient to do an infringing act under s.60(1). CPC Article 30 (renumbered as Article 26 [1989]), paragraph 2, corresponds to s.60(3).

[Section 60(4) Repealed]

Section 60(4) was repealed by the Patents Act 2004. This subsection was concerned with the application of exhaustion of rights provisions of the Community Patent Convention, which has never come into force.

Section 60(5)

An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if -

- (a) it is done privately and for purposes which are not commercial;
- (b) it is done for experimental purposes relating to the subject-matter of the invention:

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- (c) it consists of the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;
- (d) it consists of the use, exclusively for the needs of a relevant ship, of a product or process in the body of such a ship or in its machinery, tackle, apparatus or other accessories, in a case where the ship has temporarily or accidentally entered the internal or territorial waters of the United Kingdom;
- (e) it consists of the use of a product or process in the body or operation of a relevant aircraft, hovercraft or vehicle which has temporarily or accidentally entered or is crossing the United Kingdom (including the air space above it and its territorial waters) or the use of accessories for such a relevant aircraft, hovercraft or vehicle;
- (f) it consists of the use of an exempted aircraft which has lawfully entered or is lawfully crossing the United Kingdom as aforesaid or of the importation into the United Kingdom, or the use or storage there, of any part or accessory for such an aircraft:
- (g) it consists of the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where there has been a sale of plant propagating material to the farmer by the proprietor of the patent or with his consent for agricultural use;
- (h) it consists of the use of an animal or animal reproductive material by a farmer for an agricultural purpose following a sale to the farmer, by the proprietor of the patent or with his consent, of breeding stock or other animal reproductive material which constitutes or contains the patented invention.
- (i) it consists of -
 - (i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or
 - (ii) any other act which is required for the purpose of the application of those paragraphs.

Section 60(6)

For the purposes of subsection (2) above a person who does an act in relation to an invention which is prevented only by virtue of paragraph (a), (b) or (c) of subsection (5) above from constituting an infringement of a patent for the invention shall not be treated as a person entitled to work the invention, but -

- (a) the reference in that subsection to a person entitled to work an invention includes a reference to a person so entitled by virtue of section 55 above, and
- (b) a person who by virtue of section 20B(4) or (5) above or section 28A(4) or (5) above or section 64 below or section 117A(4) or (5) below is entitled to do an act in relation to the invention without it constituting such an infringement shall, so far as concerns that act, be treated as a person entitled to work the invention.

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Section 60(6A)

Schedule A1 contains -

- (a) provisions restricting the circumstances in which subsection (5)(g) applies; and
- (b) provisions which apply where an act would constitute an infringement of a patent but for subsection (5)(g).

Section 60(6B)

For the purposes of subsection (5)(h), use for an agricultural purpose -

- (a) includes making an animal or animal reproductive material available for the purposes of pursuing the farmer's agricultural activity; but
- (b) does not include sale within the framework, or for the purposes, of a commercial reproduction activity.

Section 60(6C)

In paragraphs (g) and (h) of subsection (5) "sale" includes any other form of commercialisation.

Section 60(6D)

For the purposes of subsection (5)(b), anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention.

Section 60(6E)

In subsection (6D), "medicinal product assessment" means any testing, course of testing or other activity undertaken with a view to providing data for any of the following purposes—

- a) obtaining or varying an authorisation to sell or supply, or offer to sell or supply, a medicinal product (whether in the United Kingdom or elsewhere);
- b) complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation;
- enabling a government or public authority (whether in the United Kingdom or elsewhere), or a person (whether in the United Kingdom or elsewhere) with functions of—
 - (i) providing health care on behalf of such a government or public authority, or
 - (ii) providing advice to, or on behalf of, such a government or public authority about the provision of health care,

to carry out an assessment of suitability of a medicinal product for human use for the

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purpose of determining whether to use it, or recommend its use, in the provision of health care.

Section 60(6F)

In subsection (6E) and this subsection—

"medicinal product" means a medicinal product for human use or a veterinary medicinal product;

"medicinal product for human use" has the meaning given by article 1 of Directive 2001/83/EC(a);

"veterinary medicinal product" has the meaning given by article 1 of Directive 2001/82/EC(**b**).

Section 60 (6G)

Nothing in subsections (6D) to (6F) is to be read as affecting the application of subsection (5)(b) in relation to any act of a kind not falling within subsection (6D).

Exempted acts

60.23 Exempted from constituting infringement are certain acts done privately for non-commercial purposes (sub-section (5)(a)); for experimental purposes (sub-section (5)(b)); in preparing or dealing with a prescribed medicine (sub-section (5)(c)); in connection with a temporary or accidental incursion into or crossing of UK territory or air space by a ship, aircraft, hovercraft or vehicle as defined in s.60(7) (sub-sections (5)(d), (e) and (f)); by farmers in connection with certain harvested products, animals or animal reproductive material (sub-sections (5)(g) and (h)), or conducting studies, tests and trials on certain medicinal products (sub-section 5(i)). Sub-sections (5)(g) and (h) were added by the Patents Regulations 2000 (SI 2000 No.2037), along with ss.60(6A), 60(6B) and 60(6C). These subsections have effect in the Isle of Man by virtue of the Patents Act 1977 (Isle of Man) Order 2003 (SI 2003 No. 1249). Article 31 of the CPC (renumbered as Article 27 [1989]) corresponds to s.60(5)(a) to (f). Sub-section (5)(i) was added by the Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (SI 2005 No. 2759), and came into force on 30 October 2005. Sub-sections 6D to 6G were added by the Legislative Reform (Patents) Order 2014 (SI 2014/1997) and came into force on 1st October 2014. The exception set out in sub-sections 6D to 6G does not apply to acts committed before 1st October 2014.

s.130(7)

In *Monsanto Co v Stauffer Chemical Co and another* [1985] RPC 515, the Court of Appeal considered the meaning and effect of the words "for experimental purposes relating to the subject-matter of the invention" in s.60(5)(b). It was held that earlier decisions on phrases such as "reasonable trial" or "reasonable trial or experiment" were not of any assistance; there was no reason to suppose that the signatories of the CPC were concerning themselves with the minutiae of earlier UK patent law when deciding the wording of Article 31(b) (renumbered as Article 27(b) [1989]) to which s.60(5)(b) corresponds. Moreover, the word "experiment" is an ordinary word in the English language and has never been a term of art in UK patent law. Further, the presence of a reference to "purposes which are not commercial" in sub-section 5(a) but the absence of any such reference in subsection 5(b) indicates that experimental purposes in the latter may yet have a commercial end in view. Trials carried out in order to discover something unknown or to test a hypothesis or even in order to find out whether something which is known to work in specific conditions will work in different conditions can fairly, it was held, be regarded as

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experiments.

- Sub-section 6D sets out that for the purposes of subsection (5)(b), anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention. Use of a patented product, is permitted when carrying out work to provide information to the regulatory authorities who decide whether a drug should be given a marketing authorisation. It is also possible to use a patented product in work done to supply information for health technology assessments. Only products which fall within the scope of Directive on the on the Community code relating to medicinal products for human use (2001/83/EC) or the Directive on the Community code relating to veterinary medicinal products (2001/82/EC) are covered by this exception.
- Sub-section 6E defines what is meant by "medicinal product assessment". The definition covers activities carried out to provide information required by regulatory authorities e.g. clinical trials; or activities carried out to enable a government or public body to assess if a medicine should be used in the provision of healthcare e.g. health technology assessments. Examples of regulatory bodies include the Medicines and Healthcare Products Regulatory Authority (MHRA) and European Medicines Agency (EMA). An example of a body which assesses if a new drug should be used in the provision of healthcare is the National Institute for Health and Care Excellence (NICE). Provided the purpose of the work is medicinal product assessment, as defined in sub-section 6E, it will fall within the exemption even where the work is performed for drug approval abroad. The "medicinal product assessment" exception does not extend to commercial activities but does cover assessments of combinations where the patented drug is part of the combination.
- 60.24.3 It remains to be seen how the courts will interpret the exception set out in sub-sections 6D to 6F however the following activities would appear to fall within its scope:
 - a) Activities carried out to provide data to regulatory authorities.
 - Activities carried out to provide data to bodies carrying out health technology assessments.
 - c) Post approval studies to comply with regulatory requirements.
 - d) Activities carried out to amend an authorisation for a medicine.
 - e) Activities done to obtain an authorisation for a new indication of an existing drug
 - f) Any tests or studies required by regulatory bodies.
 - g) Activities carried out for the purposes of obtaining full authorisation of a generic drug or biosimilar e.g. where the abridged procedure exempted by the Bolar exception (see 60.28) is not used.
 - h) Activities related to health technology assessment of a generic or biosimilar product.
 - i) Activities carried out to provide data for obtaining regulatory approval for a generic or biosimilar product in another country.
- 60.25 In Smith, Kline & French Laboratories Ltd v Evans Medical Ltd [1989] FSR 513, Aldous J said that s.60(5) sets out the exceptions from s.60(1) and rejected the submission that, in addition, all patentees must be taken to have impliedly consented to the carrying out of experiments with a view to challenging the validity of the patent. He also considered that the word "privately" in s.60(5)(a) includes commercial and non-commercial situations; is not synonymous with "secret" or "confidential"; and is used as the opposite of "publicly", denoting an act done for the person's own use. With regard to the reference to "purposes which are not commercial" in s.60(5)(a), the purposes of acts had to be considered: there would be infringement if the purposes included any commercial ones in addition to the non-commercial ones. Experiments done for legal proceedings in the High Court or the Office were not done for a commercial purpose. Aldous J also considered that if an act is to fall within s.60(5)(b) it must be done for purposes relating to the subject matter of the invention found in the claims of the patent alleged to be infringed. The purposes must relate to the claimed subject matter in the sense of having a real and direct connection with it

60.26 In Stena Rederi Aktiebolag v Irish Ferries Ltd [2002] RPC 50, the Patents

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Court considered the meaning and effect of the defence in s.60(5)(d), which relates to ships which have "temporarily or accidentally entered the internal or territorial waters of the United Kingdom". The judgment of the Patents Court was upheld by the Court of Appeal [2003] RPC 36. The case concerned a high-speed catamaran used to provide a regular ferry service between Eire and the UK, with three or four crossings being made each day. The vessel's home port was in Dublin, but it spent around three hours in UK territorial waters on each crossing. The vessel's superstructure was found to fall within the scope of the claimant's patent, and the claimant argued that the vessel's regular and frequent crossings took it outside the ambit of s.60(5)(d) because "temporarily" should be interpreted as "on isolated occasions or casually". The court rejected this argument, stating that the primary purpose of the word "temporarily" was to distinguish between vessels which were engaged in essentially internal operations, and those which travelled between countries. Regard was to be had for the intention of the vessel's operator; on each crossing, the intention was for the vessel to enter and then leave UK territorial waters, and the fact that each crossing was repeated frequently did not alter the fact that each entry into UK waters was designed to be short-lived. The court therefore held that s.60(5)(d) applied and so infringement had not occurred. The court also rejected an argument that the defence in s.60(5)(d) applied only to "machinery, tackle, apparatus or other accessories" associated with the vessels. A purposive construction made clear that s.60(5)(d) applied as much to vessels as a whole as to any parts used on them.

Sch. A1 paras 3-4 Sch. A1 paras 5-8

Sub-section (5)(g) relates to the product of plant propagating material (incorporating patented material), where the material has been sold to a farmer by the proprietor of the patent, or with the proprietor's consent, for agricultural use. A farmer may subsequently use the product of his harvest from such material for further propagation or multiplication of the plant on his own land without infringing the patent in question. However, under s.60(6A) the infringement exemption provided by sub-section (5)(g) only applies in respect of certain varieties which are specified in paragraph 2 of Schedule A1 to the Act. Furthermore, the Schedule sets out the conditions which apply where an otherwise infringing act falls within the scope of sub-section (5)(g). These include (i) the requirement that a farmer (other than a "small farmer") must pay equitable remuneration to the proprietor (which must, however, be less than the farmer would have paid for buying more plant propagating material from the proprietor); and (ii) certain specified information must be supplied by the farmer and by the proprietor, on request from the other.

60.27.1 Sub-section (5)(h) similarly relates to breeding stock or other animal reproductive material which constitutes or contains a patented invention and which has been sold to a farmer by the proprietor of the patent, or with the proprietor's consent. A farmer may subsequently use the animal or animal reproductive material for an agricultural purpose without infringing the patent in question. There is no equivalent to Schedule A1 for this subsection and thus no restriction of the infringement exemption to certain varieties of animal. However, s.60(6B) makes clear that the farmer is not allowed subsequently to sell any animals or animal reproductive material derived from his "agricultural use" of the original animal or material as part of a commercial reproduction activity.

Sub-section (5)(i) relates to clinical trials on patented medicinal products, and implements the so-called "Bolar" exemption proposed in article 13 paragraph 6 of Directive 2001/82/EC on veterinary medicinal products and in article 10 paragraph 5 of Directive 2001/83/EC on medicinal products for human use (see also 60.32). This exempts from patent infringement studies, tests and trials on generic medicines required to show that the generic product is bioequivalent to an approved patented product where these acts are required to obtain marketing authorisation.

Persons entitled to work the invention

60.29 Section 60(2), concerning indirect or contributory infringement, refers to a person entitled to work the invention (see 60.19). A person authorised under s.55 to use the invention for the services of the Crown is regarded as a person so entitled. In addition, a

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person who has acquired rights during the period between termination of an application and publication of the notice to request reinstatement (under s.20B(4) or (5)), during the interim period prior to the publication of the notice of the application for restoration of a patent (under s.28A(4) or (5)), before the priority date of the invention (under s.64), or between withdrawal of a patent application and publication of notice under s. 117(3) of a request to correct an error or mistake in a withdrawal of a patent (under s. 117A(4) or (5)) to do an act without it constituting infringement is treated as a person entitled to work the invention but only so far as concerns that act. The reference to s.28A in s.60(6)(b) replaced the corresponding previous reference to s.28 as a result of paragraphs 6 to 8 of Schedule 5 to the CDP Act. The references to s.20B and s.117A in s.60(6)(b) were inserted by the Regulatory Reform (Patents) Order 2004.

A person who does something which, but for exemption under s.60(5)(a)(b) or (c), would be an infringing act is not treated as entitled to work the invention for the purposes of s.60(2). Paragraph 3 of CPC Article 30 (renumbered as Article 26 [1989]) corresponds to this provision.

As a consequence of s.60(5)(b) and (6), a person doing an act for experimental purposes does not thereby become entitled to work the invention. It may therefore be an infringing act under s.60(2) to supply that person with the material for carrying out that experimental act. In *Monsanto Co v Stauffer Chemical Co and another* [1985] RPC 515 (see 60.24) where the material was a herbicide and the person carrying out tests would benefit by eradication of weeds on his land, it was observed that there was at least force in the argument that such supply would constitute infringement.

Section 60(7)

In this section -

"relevant ship" and "relevant aircraft, hovercraft or vehicle" mean respectively a ship and an aircraft, hovercraft or vehicle registered in, or belonging to, any country, other than the United Kingdom, which is a party to the Convention for the Protection of Industrial Property signed at Paris on 20 March 1883 or which is a member of the World Trade Organisation; and

"exempted aircraft" means an aircraft to which section 89 of the Civil Aviation Act 1982 (aircraft exempted from seizure in respect of patent claims) applies.

"Directive 2001/82/EC" means Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products as amended by Directive 2004/28/EC of the European Parliament and of the Council;

"Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended by Directive 2002/98/EC of the European Parliament and of the Council, by Commission Directive 2003/63/EC, and by Directives 2004/24/EC and 2004/27/EC of the European Parliament and of the Council.

As a result of the Civil Aviation Act 1982, the original reference to the Civil Aviation Act 1949 in section 60(7) was replaced by the reference to the 1982 Act. The words "or which is a member of the World Trade Organisation" were inserted by the Patents and Trade Marks (World Trade Organisation) Regulations 1999. The references to Directives 2001/82/EC and 2001/83/EC were inserted by the Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (SI 2005 No. 2759).

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Section 61: Proceedings for infringement of patent

- s.69 61.01 This section provides for proceedings to be brought by the proprietor of a patent in relation to allegedly infringing acts and lays down some of the powers of the court and of the comptroller in such proceedings before each. It covers acts which are infringements of patents granted under the 1977 Act and, in respect of patent applications which have been published but not yet granted, acts which would have been infringements if a patent had already been granted under the Act. Proceedings cannot be commenced until notice of grant of the patent has been officially published, see 25.02. In *Hartington Conway Ltd's Patent Applications* [2004] RPC 7, the term "proprietor" was held not to mean "registered proprietor"; the statutory right of action was conferred on the person who could trace his title as set out in s.7.
 - 61.02 For the applicability of s.61 in relation to European patents, see 60.02.
- s.74(1) 61.03 In order to refute an accusation of infringement, the validity of the patent in question is often challenged. The validity of a patent may be put in issue by way of defence in s.61 proceedings on any of the grounds on which the patent may be revoked under s.72. These grounds are set out in s.72(1), see 72.03.
- s.61(6) 61.04 In s.61 proceedings, when determining whether to grant the relief claimed and the extent thereof, the court and the comptroller should each apply the principles applied by the court in relation to the same kind of relief immediately before the appointed day (1 June 1978), subject to other provisions in this Part of the Act.

Section 61(1)

Subject to the following provisions of this Part of this Act, civil proceedings may be brought in the court by the proprietor of a patent in respect of any act alleged to infringe the patent and (without prejudice to any other jurisdiction of the court) in those proceedings a claim may be made -

- (a) for an injunction or interdict restraining the defendant or defender from any apprehended act of infringement;
- (b) for an order for him to deliver up or destroy any patented product in relation to which the patent is infringed or any article in which that product is inextricably comprised;
- (c) for damages in respect of the infringement;
- (d) for an account of the profits derived by him from the infringement;
- (e) for a declaration or declarator that the patent is valid and has been infringed by him.

61.04.1 In the assessment of damages in an action for infringement where the defendant knew, or had reasonable grounds to know, that he had engaged in the infringing activity, the factors set out in regulation 3 of The Intellectual Property (Enforcement, etc.) Regulations 2006 (SI 2006 No. 1028) should be taken into account. This implements article 13 of Directive 2004/48/EC on the enforcement of intellectual property rights, and requires the damages awarded to the claimant to be appropriate to the actual prejudice he suffered as a result of the infringement. When awarding such damages, all appropriate aspects shall be taken into account, including in particular, negative economic consequences (e.g. any lost profits which the claimant has suffered and any unfair profits made by the defendant), and elements other than economic factors (e.g. the moral prejudice caused to the claimant by the defendant). Alternatively, where appropriate, the damages may be set on the basis of

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royalties or fees which would have been due had the defendant obtained a licence.

61.04.2 Following the Supreme Court judgment in Virgin Atlantic Airways Limited v Zodiac Seats UK Limited [2013] UKSC 46, revocation or amendment of the infringed patent can affect any damages payable by the infringer. The Supreme Court judgment overturns that of the Court of Appeal in Unilin Beheer BV v Berry Floor NV and Others [2007] EWCA Civ 364.

61.04.3 In Les Laboratoires Servier & Anor v Apotex Inc & Ors (Rev 1) [2014] UKSC 55, Apotex sought damages on the basis that Servier's EP(UK), under which Apotex had been subject to an interim injunction, had subsequently been found to be invalid. Because Apotex had separately been found to infringe Servier's Canadian patent, Servier argued that Apotex could not recover the damages sought in the UK, relying upon the principle that a party cannot benefit from their own illegal conduct (ex turpi causa). However, Lord Sumption JSC concluded that the illegality ("turpitude") must be one that "engage[s ...] the public interest" and that patent infringement was a breach of private rights which only affected the patentee's interests. Thus the ex turpi causa principle did not apply, and did not prevent damages from being sought in those circumstances.

Proceedings before the court

s.61(2) 61.05 In proceedings for infringement of a patent before the court, the proprietor may claim an injunction (or interdict) restraining infringement, an order to deliver up or destroy infringing articles, damages (see 61.11), an account of profits and a declaration (or declarator) that the patent is valid and infringed. However, the court cannot both award damages and order an account of profits in respect of the same infringement. (Interdict and declarator are the Scottish terms).

> The procedure in an action before the court is in general outside the scope of this Manual, and is governed by the Civil Procedure Rules.

> Court proceedings for infringement of a patent may be stayed pending the outcome of proceedings under ss.71 and 72 before the comptroller (Hawker Siddeley Dynamics Engineering Ltd v Real Time Developments Ltd [1983] RPC 395). In IPcom GmbH & Co Kg v HTC Europe Co Ltd & Ors [2013] EWCA Civ 1496 the Court of Appeal provided guidance on deciding whether to allow a stay of legal proceedings on the ground that there are parallel proceedings pending in the EPO contesting the validity of the patent (see 71.02).

The "court" means the High Court (or the Court of Session in Scotland) and, s.130(1)CPR 63.3 for England and Wales, the patents county court. However, all High Court s.61 proceedings in England and Wales are assigned to the Chancery Division of the High Court and taken by the Patents Court.

Section 61(2)

The court shall not, in respect of the same infringement, both award the proprietor of a patent damages and order that he shall be given an account of the profits.

Section 61(3)

The proprietor of a patent and any other person may by agreement with each other refer to the comptroller the question whether that other person has infringed the patent and on the reference the proprietor of the patent may make any claim mentioned in subsection (1)(c) or (e) above.

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Proceedings before the comptroller

- s.61(5) 61.09 If the proprietor and an alleged infringer agree to do so, they may refer the question of infringement to the comptroller. Unless he declines to do so (see 61.24) the comptroller will determine whether the alleged infringer has in fact infringed the patent. However, the powers of the comptroller are more limited than those of the court, and the proprietor can claim only the reliefs mentioned in s.61(1)(c) (damages in respect of the infringement) and (e) (a declaration that the patent is valid and infringed).
 - 61.10 It is customary to seek, in the first instance, a finding with regard to validity and infringement and an order for an enquiry as to damages; the amount of damages is then determined in separate proceedings.
 - 61.11 The Intellectual Property (Enforcement, etc.) Regulations 2006 (S.I. 2006 No. 1028) provides some guidance on the assessment of damages in an action for infringement (see 61.04.1).
- s.74(7) 61.12 Where proceedings are pending in the court under any of sections 58, 61, 69, 70-70F, 71 and 72, no proceedings may be instituted before the comptroller under s.61(3) without the leave of the court (see also 61.07 and 74.07).

Procedure

PR part 7 61.13 A reference to the comptroller under s.61(3) is made jointly by the parties thereto on Patents Form 2, accompanied by a joint statement giving full particulars of the matters which are in dispute and of those on which they are in agreement, and the capacity in which each is a party to the reference. The application should be accompanied by a statement of grounds in duplicate (see 61.14 and 61.22). This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.

Where validity is not the only matter in dispute

r.73(3) 61.14 The proprietor of the patent or an exclusive licensee should file the statement of grounds, thus becoming the claimant in the proceedings.

61.15 [deleted]

r.73(3) 61.16 The other party (the defendant in the proceedings before the comptroller) r.82(1) may in his counterstatement challenge the validity of the patent or part thereof (see 61.03). If he does, the claimant may be allowed to file a further statement setting out the grounds on which he contests the allegation of invalidity. The further statement may also include an application to amend the specification under s.75 (see 75.04 to 75.08).

61.17 [deleted]61.18 [deleted]61.19 [deleted]

- s.65 61.20 If the validity of the patent in question is contested to any extent and the patent is found to be wholly or partially valid, the hearing officer acting for the comptroller may certify the finding and the fact that its validity was so contested.
 - 61.21 In determining whether or not infringement has occurred, regard is had to the provisions of ss.60 and 64 as to what constitutes infringement. Regard is also had to the

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provisions of ss.46(3)(c), 62, 63 and 68 which inhibit the award of damages in various respects.

Where only validity is in dispute

- r.73(3) 61.22 The procedure where only validity is in dispute is generally similar to that in 61.14 to 61.20 except that the other party should file the initial statement of grounds (including full particulars of the grounds on which invalidity is alleged) to become the claimant in the proceedings. The proprietor's counter-statement may include an application to amend the specification under s.75.
- s.72(5) 61.23 A decision of the comptroller (or on appeal from the comptroller) does not estop any party to civil proceedings in which infringement of a patent is in issue from alleging invalidity of the patent on any of the grounds referred to in s.72(1), whether or not any of the issues involved were decided in that decision.

Section 61(4)

Except so far as the context requires, in the following provisions of this Act -

- (a) any reference to proceedings for infringement and the bringing of such proceedings includes a reference to a reference under subsection (3) above and the making of such a reference;
- (b) any reference to a claimant or pursuer includes a reference to the proprietor of the patent; and
- (c) any reference to a defendant or defender includes a reference to any other party to the reference.

Section 61(5)

If it appears to the comptroller on a reference under subsection (3) above that the question referred to him would more properly be determined by the court, he may decline to deal with it and the court shall have jurisdiction to determine the question as if the reference were proceedings brought in the court.

Comptroller declines to deal with question

CPR 63.11 61.24 The comptroller may consider that a question referred to him under s.61(3) would more properly be determined by the court and decline to deal with it. In such a case any person entitled to do must, within 14 days of the comptroller's decision, issue a claim form to the court to determine the question. The court then determines the question as if the reference to the comptroller were proceedings brought in the court.

Section 61(6)

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Subject to the following provisions of this Part of this Act, in determining whether or not to grant any kind of relief claimed under this section and the extent of the relief granted the court or the comptroller shall apply the principles applied by the court in relation to that kind of relief immediately before the appointed day.

Section 61(7)

If the comptroller awards any sum by way of damages on a reference under subsection (3) above, then -

- (a) in England and Wales, the sum shall be recoverable, if a county court so orders, by execution issued from the county court or otherwise as if it were payable under an order of that court:
- (b) in Scotland, payment of the sum may be enforced in like manner as an extract registered decree arbitral bearing a warrant for execution issued by the sheriff court of any sheriffdom in Scotland;
- (c) in Northern Ireland, payment of the sum may be enforced as if it were a money judgment.
- Section 61(7) was added by the Patents Act 2004 and came into force on 1 January 2005. This subsection enables any award of damages by the comptroller in infringement proceedings to be recovered through the enforcement mechanism of the county court in England and Wales (or the equivalent mechanisms in Scotland and Northern Ireland) without the need to bring fresh proceedings to enforce the award.

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Section 62: Restrictions on recovery of damages for infringement

This section relates to certain circumstances in which the remedies for infringement of damages and of an account of profits are not available or may be refused by the court or comptroller, in proceedings under s.61 (or s.69).

s.69(3)Section 62(2) and (3) do not apply to infringement of the rights conferred by s.69 in respect of published applications under the 1977 Act. For the applicability of s.62 in relation to European patents, see 60.02.

Section 62(1)

In proceedings for infringement of a patent damages shall not be awarded, and no order shall be made for an account of profits, against a defendant or defender who proves that at the date of the infringement he was not aware, and had no reasonable grounds for supposing, that the patent existed; and a person shall not be taken to have been so aware or to have had reasonable grounds for so supposing by reason only of the application to a product of the word "patent" or "patented", or any word or words expressing or implying that a patent has been obtained for the product, unless the number of the patent or a relevant internet link accompanied the word or words in question.

Section 62(1A)

The reference in subsection (1) to a relevant internet link is a reference to an address of a posting on the internet-

- (a) which is accessible to the public free of charge, and
- (b) which clearly associates the product with the number of the patent.

Ignorance of existence of patent

s.69 62.03 The court or the comptroller cannot award damages or make an order for an account of profits against an innocent infringer. However, the onus is on the infringer to prove his innocence, i.e. that at the date of the infringing act he was not aware, and had no reasonable grounds for supposing, that the patent (or published application for a patent) existed. The test thus concerns only ignorance of the existence of the patent and not failure to appreciate that an act committed by him might constitute an infringement. If the infringer had no actual knowledge, the existence of reasonable grounds must be judged in the light of all the circumstances at the time of the infringement; the test is objective (Lancer Boss v Henley Forklift [1975] RPC 307). In Texas Iron Works v Nodeco [2000] RPC 207 for example, the applicant was held not to be deemed to be aware of the patent until it had been sent a warning letter. The infringing act in question may have been committed either after grant of the patent or between publication of the application and grant.

> The fact that a product is marked with wording to the effect that it is patented is insufficient to establish that other persons should be taken to be aware of the patent, unless either the patent number is quoted in the marking, or (from 1st October 2014) a relevant web address is quoted in the marking. Marking a patented product in either of these ways is sufficient to establish that other persons should be taken to be aware of the patent. The web address must be of a webpage that is freely accessible to the public and clearly associates the patent number with that product. The product must be clearly identified on the webpage, e.g. by including any relevant model numbers and variants that exist. Where a dispute arises, it will be for the courts to decide whether sufficient notice had

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s.110

been provided. It is an offence to dispose of for value a product marked with wording claiming that it is patented if the claim is false.

Section 62(2)

In proceedings for infringement of a patent the court or the comptroller may, if it or he thinks fit, refuse to award any damages or make any such order in respect of an infringement committed during the further period specified in section 25(4) above, but before the payment of the renewal fee and any additional fee prescribed for the purposes of that subsection.

Late renewal of patent

62.05 Under s.25(4), if a patent lapses due to non-payment of a renewal fee by the renewal date but that fee together with an additional fee is paid by the end of the sixth month after that date, the patent is treated as if it had never lapsed (see 25.12 to 25.14). However, the court or comptroller has discretion to refuse to award damages or to order an account of profits in respect of an infringing act committed in the intervening period.

Section 62(3)

Where an amendment of the specification of a patent has been allowed under any of the provisions of this Act, the court or the comptroller shall, when awarding damages or making an order for an account of profits in proceedings for an infringement of the patent committed before the decision to allow the amendment, take into account the following -

- (a) whether at the date of infringement the defendant or defender knew, or had reasonable grounds to know, that he was infringing the patent;
- (b) whether the specification of the patent as published was framed in good faith and with reasonable skill and knowledge;
- (c) whether the proceedings are brought in good faith.

Pre-amendment infringement

Section 62(3) applies where the infringing act is committed before a decision to allow amendment of the specification of the patent in question. When awarding damages or making an order for an account of profits in such circumstances, the court or comptroller is required to take into account the various factors set out in paragraphs (a) to (c) of that provision. These factors were modified and expanded upon by the Intellectual Property (Enforcement, etc.) Regulations 2006 (S.I. 2006 No. 1028), which came into force on 29 April 2006, in order to implement Directive 2004/48/EC on the enforcement of intellectual property rights. (See also paragraphs 63.04 to 63.06).

Paragraph (a) requires the court or comptroller to take account of the defendant's actual or constructive knowledge that he was infringing the patent. This reflects the requirement in article 13.1 of the Directive that, in such circumstances, the proprietor is entitled to damages appropriate to the actual prejudice suffered. For this reason, the absolute bar on damages that was imposed in section 62(3) previously, in the circumstances

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where the specification was not framed in good faith and with reasonable skill and knowledge, was not compatible with the Directive. Thus no absolute bar on damages is maintained, but paragraph (b) requires account to be taken of the framing of the specification when determining what level of award is appropriate.

Paragraph (c) requires the court or comptroller to take into account whether the infringement proceedings are brought in good faith. Where it is shown that the proprietor knew that the infringed claim, before amendment, was invalid, the court or comptroller can take that matter into account when determining the appropriate level of damages.

Good faith; reasonable skill and knowledge

- 62.09 Aldous J considered in *Hallen Co v Brabantia (UK) Ltd* [1990] FSR 134 that good faith meant that the specification was framed honestly with a view to obtaining a monopoly to which, on the material known to the draftsman, he believed the applicant was entitled. The words "skill and knowledge" were observed to be a composite phrase relating to the competence employed in framing the specification, which should be in the form which a person with reasonable skill in drafting patent specifications and a knowledge of the law and practice relating thereto would produce.
- In Ronson Products Ltd v A Lewis & Co (Westminster) Ltd [1963] RPC 103 at page 138, it was observed that where the drafting of the specification departs in a material respect from the intention of the applicant, and this despite the transmission by the applicant to his patent agent of all relevant information, an acknowledgement by such agent that the way he expressed himself in the passage in question was wrong in view of the information he had received must establish an absence of reasonable skill and knowledge. On the other hand in Molnlycke AB v Procter & Gamble Ltd [1994] RPC 49 Morritt J observed (at p.106) that even if the reasonable knowledge required includes details of the invention, it is irrelevant that the draftsman was unaware of the best or optimum method for its performance so long as the description is sufficient.
- 62.11 In Page v Brent Toy Products Ltd (1950) 67 RPC 4 at page 21, the agent who drafted the specification in suit said that he had initially put in a "fairly broad claim" to "draw the Patent Office search report" and had modified the claim in accordance with what the report disclosed; and that this was the practice usually adopted by agents. The claim in question was held (although invalid) to have been framed in good faith and with reasonable skill and knowledge.
- 62.12 The patent in *Nutrinova Nutrition v Scanchem UK (No.2)* [2001] FSR 43 concerned a process for making a particular compound, but also included claims to the production of an intermediate compound. It was held that it was not bad faith to file the specification knowing of an arguable case of obviousness in respect of the claims to the intermediate compound. Although these claims were subsequently found to be obvious, the patent agents would have been failing in their duty had they not tried to cover what was a novel intermediate compound.
- 62.13 The Court of Appeal held, in *Kirin-Amgen Inc. v Transkaryotic Therapies Inc.* [2003] RPC 3, that any mistake in the specification on the part of the draftsman must be considered in the context of the whole specification, making due allowance for any difficulty that the draftsman had and for the importance of the passage said to be mistaken. If a specific passage has no importance, then, as held by the Court of Appeal in *Unilin Beheer BV v Berry Floor NV (No. 2)* [2006] FSR 26, even if it is negligently wrong, the specification is still drafted with reasonable skill and knowledge. Certain passages of the description not amended in conformity with amended claims could not in this case mislead the skilled reader and did not make the claims unclear; and if a specification retains such irrelevant and

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harmless material, however much there may be, it is still drafted with the relevant skill and knowledge for complying with the law and providing accurate technical information. That would not be the case where the unamended passages of the description made it difficult to decide on the meaning of the claim and had been left in through negligence.

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Section 63: Relief for infringement of partially valid patent

63.01 This section allows the court or the comptroller to grant relief for infringement of a patent found to be partially valid, but restricts the circumstances in which certain kinds of relief may be granted for such infringement. It also provides that amendment under s.75 may be made a condition of relief.

63.02 Section 63 is applicable only in relation to granted patents and not to applications for patents. For its applicability in relation to European patents, see 60.02.

Section 63(1)

If the validity of a patent is put in issue in proceedings for infringement of the patent and it is found that the patent is only partially valid, the court or the comptroller may, subject to subsection (2) below, grant relief in respect of that part of the patent which is found to be valid and infringed.

The court or the comptroller may find in infringement proceedings where the validity of a patent is questioned that the patent is partially invalid but partially valid and infringed. In other words, although some claims may be invalid, the remaining claims can nevertheless be found to be valid and infringed. Relief may be granted in respect of these valid claims, taking into account the factors in s.63(2) (see 63.04).

Section 63(2)

Where in any such proceedings it is found that a patent is only partially valid, the court or the comptroller shall, when awarding damages, costs or expenses or making an order for an account of profits, take into account the following -

- (a) whether at the date of the infringement the defendant or defender knew, or had reasonable grounds to know, that he was infringing the patent;
- (b) whether the specification of the patent was framed in good faith and with reasonable skill and knowledge;
- (c) whether the proceedings are brought in good faith;

and any relief granted shall be subject to the discretion of the court or the comptroller as to costs or expenses and as to the date from which damages or an account should be reckoned.

Section 63(2) therefore applies to infringement proceedings where the patent is found to be partially valid and infringed. When awarding damages, costs or expenses or making an order for an account of profits in such circumstances, the court or comptroller is required to take into account the various factors set out in paragraphs (a) to (c) of that provision. These factors were modified and expanded upon by the Intellectual Property (Enforcement, etc.) Regulations 2006 (S.I. 2006 No. 1028), which came into force on 29 April 2006, in order to implement Directive 2004/48/EC on the enforcement of intellectual property rights. (See also paragraphs 62.06 to 62.08). In SmithKline Beecham Plc v Apotex Europe Ltd (No.2) [2005] FSR 24, the Court of Appeal held that s.63(2) only applied when a finding had been made in proceedings that the patent was partially invalid; this involved determination of a dispute about the point. If the court acts on a concession by the patentee, e.g. that certain claims are invalid and should be deleted, that is not making a finding and s.63(2) should not apply.

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Paragraph (a) requires the court or comptroller to take account of the defendant's actual or constructive knowledge that he was infringing the patent. This reflects the requirement in article 13.1 of the Directive that, in such circumstances, the proprietor is entitled to damages appropriate to the actual prejudice suffered. For this reason, the absolute bar on damages, costs or expenses that was imposed in section 63(2) previously, in the circumstances where the specification was not framed in good faith and with reasonable skill and knowledge, was not compatible with the Directive. Thus no absolute bar on damages, costs or expenses is maintained, but paragraph (b) requires account to be taken of the framing of the specification when determining what level of award is appropriate. (See 62.08 to 62.13 for guidance on interpretation of the phrase "framed in good faith and with reasonable skill and knowledge").

Paragraph (c) requires the court or comptroller to take into account whether the infringement proceedings are brought in good faith. Therefore, where it is shown that the proprietor knew that the infringed patent was only partially valid, the court or comptroller can take that matter into account when determining the appropriate level of damages, costs or expenses.

Section 63(3)

As a condition of relief under this section the court or the comptroller may direct that the specification of the patent shall be amended to its or his satisfaction upon an application made for that purpose under section 75 below, and an application may be so made accordingly, whether or not all other issues in the proceedings have been determined.

63.07 The grant of relief may be made subject to the condition that the specification of the partially valid patent should be amended under s.75 to the satisfaction of the court or the comptroller. An application under s.75 for that purpose in response to a direction of the court or the comptroller imposing such a condition may be made regardless of whether or not other issues remain to be determined. The procedure followed should be generally similar to that for amendment of a patent found to be partially invalid in a revocation action, where a similar condition can be imposed under s.72(4) (see 72.43, 72.44 and the chapter on s.75).

Section 63(4)

The court or the comptroller may also grant relief under this section in the case of a European patent (UK) on condition that the claims of the patent are limited to its or his satisfaction by the European Patent Office at the request of the proprietor.

Article 138(3) EPC provides a central amendment process for European Patents. This is an alternative to the existing possibility of the proprietor amending the patent under the 1977 Act. In the former case, the amendments are effective in each Contracting State designated by the patent whereas the latter would only affect the European patent (UK). This section provides that relief may be granted on the condition that the proprietor of a European patent (UK) limits the patent at the EPO. The limitation would have to be done to the satisfaction of the court or comptroller for relief to be granted.

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Section 64: Right to continue use begun before priority date

Under this section, a person has rights to continue an act which he did or prepared to do before the priority date of an invention and which would otherwise be an infringement of a patent for the invention. The recipients of products disposed of in exercise of such rights are protected by subsection (3).

64.02 For the applicability of s.64 in relation to European patents, see 60.02.

64.03 The wording of section 64 generally corresponds to that of subsections (4) to (6) of section 28A, both being concerned with protecting the rights of third parties who take steps which would have constituted infringement of a patent if that patent had been in force at the time.

Section 64(1)

Where a patent is granted for an invention, a person who in the United Kingdom before the priority date of the invention -

- (a) does in good faith an act which would constitute an infringement of the patent if it were in force, or
- (b) makes in good faith effective and serious preparations to do such an act,

has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the grant of the patent; but this right does not extend to granting a licence to another person to do the act.

Section 64(2)

If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (1) may -

- (a) authorise the doing of that act by any partners of his for the time being in that business, and
- (b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.

The way in which a person acquires rights under this section is to perform a potentially infringing act or make "effective and serious preparations" to do so, before the priority date of the invention. The priority date is determined for each individual invention in accordance with s.5 and may differ for different matter in the same patent, see 5.20 to 5.25. The performance or preparations must be in the UK and "in good faith". In *Lubrizol Corporation v Esso Petroleum Co. Ltd.* [1998] RPC 727 the Court of Appeal affirmed (at page 770) that the protection afforded by the section to the prior user is not strictly limited to acts identical to those which were performed before the priority date but "cannot be a right to manufacture any product, nor a right to expand into other products". Jacob J's statement in the Patents Court was upheld that "if the protected act has to be exactly the same (whatever that may mean) as the prior art then the protection given by the section would be illusory. The section is intended to give practical protection to enable a man to continue in substance what he was doing before." In the event, two customer trials by the defendant in the UK of small samples imported from the US with a view to possible later manufacture in the UK but with no decision yet made, were held, although serious, not to be "effective" preparations to

do an infringing act. Brooke LJ (at page 785) amplified that it is not "sufficient to show that the serious preparations, if pursued to finality, will have the requisite effect." In the Patents Court ([1997] RPC 195), Jacob J also pointed out that in deciding whether an activity is substantially the same as the prior act, both technical and commercial matters must be taken into account, but there should be no account taken of how the patentee may have chosen to cast his monopoly. Furthermore, it was noted obiter that although the decision was governed by Section 64 as it stood prior to amendment by the CDP 1988, the amendment would not make any difference if it were applicable.

Although this section makes no distinction between public and secret acts, if the act was public it might constitute prior disclosure of the invention whereby it became part of the state of the art under s.2(2), thus depriving the invention of novelty and impugning the validity of the patent (see 2.27 to 2.29). If the patent was thus invalid, infringement would not arise and a user would not need the protection of s.64.

The rights resulting from such an act, or preparations therefor, prior to the priority date are that the person can continue to do, or do, that act without infringing the patent in question. He cannot grant a licence to any other person to do that act but, if the prior act or preparations occurred in the course of a business, he can assign or transmit the right to do it or authorise it to be done by a partner as set out in subsection (2).

Section 64(3)

Where a product is disposed of to another in exercise of the rights conferred by subsection (1) or (2), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent.

Section 65: Certificate of contested validity of patent

65.01 Both the court and the comptroller are empowered by this section to grant a certificate of contested validity. A party successfully relying on such a certificate in subsequent infringement or revocation proceedings is, unless the court or comptroller otherwise directs, entitled to his costs (expenses in Scotland) as detailed in s.65(2).

65.02 For the applicability of s.65 in relation to European patents, see 60.02.

Section 65(1)

If in any proceedings before the court or the comptroller the validity of a patent to any extent is contested and that patent is found by the court or the comptroller to be wholly or partially valid, the court or the comptroller may certify the finding and the fact that the validity of the patent was so contested.

The conditions in which a certificate may be issued are thus that the validity of the patent in question is contested, at least in part, and it is found to be valid, at least in part. This must occur in proceedings before the court or the comptroller each of which then has discretion to issue such a certificate certifying that validity was so contested and the resultant finding. Validity may be put in issue in any of the proceedings listed in s.74(1), see 74.03.

65.04 [deleted]

In *Brupat Ltd v Smith* [1985] FSR 156, the proprietors of a patent sought a certificate of contested validity in respect of two claims, the validity of both of which had been unsuccessfully challenged. Even though the other party had conceded the validity of one of those claims during the course of the hearing, the court held that since issue had been fully joined on the matter of that claim, the certificate should cover both claims.

Section 65(2)

Where a certificate is granted under this section, then, if in any subsequent proceedings before the court or the comptroller for infringement of the patent concerned or for revocation of the patent a final order or judgment or interlocutor is made or given in favour of the party relying on the validity of the patent as found in the earlier proceedings, that party shall, unless the court or the comptroller otherwise directs, be entitled to his costs or expenses as between solicitor and own client (other than the costs or expenses of any appeal in the subsequent proceedings).

In SmithKline Beecham Plc v Apotex Europe Ltd (No.2) [2005] FSR 24, the Court of Appeal held that the reference to "costs as between solicitor and own client" should be taken to mean "costs on an indemnity basis" within the meaning of r.44.4 of the Civil Procedure Rules. Where the patentee is issued with a certificate of validity from earlier proceedings, and the patentee is again victorious in a subsequent action on the validity of the patent, he can have his costs of the victory on an indemnity basis, but only at first instance. Jacob LJ held that the words "(other than the costs or expenses of any appeal in the subsequent proceedings)" had the effect that the provision did not apply to appeals because "subsequent proceedings" could not mean anything other than the second proceedings vexing the patentee.

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Section 66: Proceedings for infringement by a co-owner

66.01 This section lays down the way in which references to the proprietor of a patent should be construed in applying s.60 where there are two or more joint proprietors. It also provides, in subsection (2), for the bringing of infringement proceedings by one of the joint proprietors.

66.02 In accordance with s.69, references in inter alia ss.60 and 66 to a patent and the proprietor of a patent are to be respectively construed as including references to an application which has been published but not yet granted and the applicant. Section 66 thus also relates mutatis mutandis to the position of joint applicants with regard to infringement.

For the applicability of s.66 in relation to European patents, see 60.02.

Section 66(1)

In the application of section 60 above to a patent of which there are two or more joint proprietors the reference to the proprietor shall be construed -

- (a) in relation to any act, as a reference to that proprietor or those proprietors who, by virtue of section 36 above or any agreement referred to in that section, is or are entitled to do that act without its amounting to an infringement; and
- (b) in relation to any consent, as a reference to that proprietor or those proprietors who, by virtue of section 36 above or any such agreement, is or are the proper person or persons to give the requisite consent.
- s.36(1) Section 36 provides that joint proprietors of a patent are each (subject to any s.36(2) agreement to the contrary) entitled to an equal undivided share in the patent and also entitled to independently do an act which would otherwise amount to an infringement, but not to grant a licence or assignment etc without the consent of the others. In applying s.60, the proprietor means that proprietor or those proprietors entitled under s.36 or under any such agreement to do such an act or give such a consent, as the case may be.

Section 66(2)

One of two or more joint proprietors of a patent may without the concurrence of the others bring proceedings in respect of an act alleged to infringe the patent, but shall not do so unless the others are made parties to the proceedings; but any of the others made a defendant or defender shall not be liable for any costs or expenses unless he enters an appearance and takes part in the proceedings.

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Section 67: Proceedings for infringement by exclusive licensee

This section lays down the position of an exclusive licensee under a patent with regard to infringement of that patent. The exclusive licensee has the same right as the proprietor of the patent to bring infringement proceedings in respect of acts committed after the date of the licence (subsection (1)) and may be awarded damages or other relief by the court or the comptroller in respect of infringement of his rights as exclusive licensee (subsection (2)). The proprietor must be made a party to any such proceedings (subsection (3)).

67.02 In accordance with s.69, references in this section to a patent and the proprietor of a patent are to be respectively construed as including references to an application which has been published but not yet granted and the applicant.

67.03 For the applicability of s.67 in relation to European patents, see 60.02.

Section 67(1)

Subject to the provisions of this section, the holder of an exclusive licence under a patent shall have the same right as the proprietor of the patent to bring proceedings in respect of any infringement of the patent committed after the date of the licence; and references to the proprietor of the patent in the provisions of this Act relating to infringement shall be construed accordingly.

s.130(1) An exclusive licence is a licence from the proprietor of or applicant for a patent conferring on the licensee, or on him and persons authorised by him, to the exclusion of all other persons (including the proprietor or applicant), any right in respect of the invention to which the patent or application relates. Multiple exclusive licences may be granted under a single patent or application if those licences relate to distinct rights in respect of the invention (this fact was acknowledged in *Courtauld's Application* [1956] RPC 208). For example, separate exclusive licences could be granted to different parties for the respective rights of manufacturing the invention and using the invention, or to confer the rights in different geographical areas.

In Morton-Norwich Products Inc and others v Intercen Ltd [1981] FSR 337 the Patents Court held that the corresponding provisions of the 1949 Act were to be intended to give a licensee, who has stepped into the shoes of the patentee so as to be able to exercise any right in respect of the invention for his own benefit to the exclusion of all others including the patentee, exactly the same right as the patentee would have had. It was held that there was no requirement for any particular document or form of grant as being necessary to constitute an exclusive licence and that the position was a mixed question of law and fact.

67.06 The consequences of non-registration of the licence on infringement proceedings are laid down by s.68.

Section 67(2)

In awarding damages or granting any other relief in any such proceedings the court or the comptroller shall take into consideration any loss suffered or likely to be suffered by the exclusive licensee as such as a result of the infringement, or, as the case may be, the profits derived from the infringement, so far as it constitutes an infringement of the rights of the exclusive licensee as such.

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Section 67(3)

In any proceedings taken by an exclusive licensee by virtue of this section the proprietor of the patent shall be made a party to the proceedings, but if made a defendant or defender shall not be liable for any costs or expenses unless he enters an appearance and takes part in the proceedings.

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Section 68: Effect of non-registration on infringement proceedings

This section inhibits the award of costs or expenses by the court or the comptroller, in respect of infringement of a patent, to a person who has become a proprietor or exclusive licensee of the patent by virtue of a transaction, instrument or event which was not, or not sufficiently promptly, registered in the register of patents. The transactions, instruments or events in question are those to which s.33 applies; these are listed in s.33(3). This section was amended by The Intellectual Property (Enforcement, etc.) Regulations 2006 (SI 2006 No. 1028) which came into force on 29 April 2006. This removed the restriction on grant of damages or an account of profits to a proprietor or exclusive licensee who had not sufficiently promptly registered a transaction, instrument or event. Such a restriction was not compatible with article 13.1 of Directive 2004/48/EC on the enforcement of intellectual property rights.

In accordance with s.69, references in this section to a patent and the proprietor of a patent are to be respectively construed as including references to an application which has been published but not yet granted and the applicant. By an exclusive licensee is meant the holder of an exclusive licence as defined in 67.04.

For the applicability of s.68 in relation to European patents, see 60.02. With regard to applications for European patents, see also 68.05.

Section 68

Where by virtue of a transaction, instrument or event to which section 33 above applies a person becomes the proprietor or one of the proprietors or an exclusive licensee of a patent and the patent is subsequently infringed before the transaction, instrument or event is registered, in proceedings for such an infringement, the court or comptroller shall not award him costs or expenses unless -

- (a) the transaction, instrument or event is registered within the period of six months beginning with its date; or
- (b) the court or the comptroller is satisfied that it was not practicable to register the transaction, instrument or event before the end of that period and that it was registered as soon as practicable thereafter.

68.04 If a person became a proprietor or exclusive licensee before a particular infringement occurred, he cannot be awarded costs or expenses if the relevant transaction, instrument or event was not registered before the date of the infringement, unless either of the two conditions in section 68 is met. The conditions are that registration occurs within a period of six months of the date of the transaction, instrument or event, or it is established that registration within that period was not practicable but occurred as soon as practicable thereafter.

The appropriate registration procedure is prescribed by r.47 (see 32.07 to 32.09), except in the case of applications for European patents (UK) which have not yet been granted (see 32.06, 78.06 and 78.07).

The defendant argued in <u>H.Lundbeck A/S v Norpharma SpA [2011] EWHC 907 (Pat), [2011] RPC 23</u>, which related to a granted European patent (UK), that registration of an assignment at the EPO counts as registration for the purposes of s.68. However, this argument was rejected by the court. There is no provision which deems registration of a transaction, instrument or event on a granted European patent (UK) at the EPO to be registration under the Act (unlike section 78(3)(f) which allows the registration of an assignment of an application for a European patent (UK) at the EPO to be treated as a registration under the Act). The transaction, instrument or event therefore has to be

registered in the UK to be considered for the purposes of s.68.

In considering whether it was not practicable to register the transaction within six months of the date of the transaction, the actions of both the applicant and their agent should be considered. In <u>H.Lundbeck A/S v Norpharma SpA [2011] EWHC 907 (Pat)</u>, [2011] RPC 23 the applicant instructed their agent to register the assignment, but the agent subsequently failed to do so. The court held that these actions were not sufficient to show that it was not practicable to register the assignment. Considerations under section 68(b) should take account of what was done by the applicant and his agent and not just the applicant alone.

In <u>Schütz (UK) Ltd v Werit UK Ltd & Anr [2011] EWCA Civ 927</u>, Sir Robin Jacob explained that this provision was not intended to say that "once a party had failed to register a document in time it could never recover costs even if all the infringements complained of only occurred after registration." He explained that "if and in so far as a claim covers a period for which a relevant transaction was not registered when it should have been (a "non-registration period") then any costs incurred during that period cannot be recovered. Costs for periods outside a non-registration period are recoverable in the usual way".

Section 69: Infringement of rights conferred by publication of application

s.69(2)(a) 69.01 This section provides that the publication of an application before grant may give rise to a right to bring proceedings for infringement though that right cannot be enforced until after grant. For the purposes of s.69, grant occurs when notice of grant is officially published, see 25.02.

s.74(7) 69.02 Infringement proceedings under s.69 may be before the court or before the comptroller and should follow the same procedure as for infringement after grant, see the chapter on s.61. Where proceedings are pending in the court under any of sections 58, 61, 69, 70-70F, 71 and 72, no proceedings may be instituted before the comptroller under s.69 without the leave of the court (see 74.07).

In s.69, an application means one for a patent granted under the 1977 Act or one that is so treated, i.e. by virtue of s.78(1), s.79 or s.89(1) in the case of applications for a European patent (UK), international applications for a European patent (UK) and international applications for a patent (UK) respectively. Similarly publication is under s.16 or under the relevant provision of the EPC or PCT so that it is treated under s.78(3)(d), s.79 or s.89B(2) as publication under s.16, subject to the language requirements of s.78(7) (if in force), s.79(3) and s.89B(3).

69.04 [deleted]

s.130(7) Section 69 is one of the sections so framed as to have, as nearly as practicable, the same effect in the UK as the corresponding provisions of the EPC, CPC and PCT. The provisions in question are EPC Article 67, CPC Article 34 (renumbered as Article 32 [1989]) and PCT Article 29.

Section 69(1)

Where an application for a patent for an invention is published, then, subject to subsections (2) and (3) below, the applicant shall have, as from the publication and until the grant of the patent, the same right as he would have had, if the patent had been granted on the date of the publication of the application, to bring proceedings in the court or before the comptroller for damages in respect of any act which would have infringed the patent; and (subject to subsections (2) and (3) below) references in sections 60 to 62 and 66 to 68 above to a patent and the proprietor of a patent shall be respectively construed as including references to any such application and the applicant, and references to a patent being in force, being granted, being valid or existing shall be construed accordingly.

s.69(2)(a) From publication of the application until grant, the applicant has the same right as he would have had, if the patent had been granted on the day of publication, to sue for damages in respect of any act which would have infringed the patent. This allows proceedings to be brought (after grant) to recover damages in respect of such pre-grant infringements, subject to certain restrictions (see 69.07 and 69.08). In such proceedings, ss.60 to 62 and 66 to 68 apply to applications as if they were patents. In Spring Form Inc v Toy Brokers Ltd [2002] FSR 17 the court confirmed that, despite the explicit reference only to damages, in principle an account of profits is available as a remedy in respect of infringing actions under s.69.

Section 69(2)

The applicant shall be entitled to bring proceedings by virtue of this section in respect of any act only -

- (a) after the patent has been granted; and
- (b) if the act would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent, but also the claims (as interpreted by the description and any drawings referred to in the description or claims) in the form in which they were contained in the application immediately before the preparations for its publication were completed by the Patent Office.

The applicant is entitled to bring such proceedings only if the act in question would have infringed not only the granted patent (if grant had been on the day of publication of the application) but also the claims in the form extant immediately before preparations for publication were completed. For that purpose, those claims are to be construed as interpreted by the description etc, ie in the same way as under s.125(1), see 125.

Section 69(3)

Section 62(2) and (3) above shall not apply to an infringement of the rights conferred by this section, but in considering the amount of any damages for such an infringement the court or the comptroller shall consider whether or not it would have been reasonable to expect from a consideration of the application as published under section 16 above, that a patent would be granted conferring on the proprietor of the patent protection from an act of the same description as that found to infringe those rights, and if the court or the comptroller finds that it would not have been reasonable, it or he shall reduce the damages to such an amount as it or he thinks just.

69.08 Section 62(2) and (3) impose restrictions on the recovery of damages for infringement where there is late renewal of the patent or amendment of the specification of the patent, and are not applicable here. However, damages are reduced by the court or the comptroller if it is considered that it would not have been reasonable to expect from the application as published that a patent conferring protection against the infringing act would be granted.

UNJUSTIFIED THREATS

Section 70 of the Patents Act 1977 was replaced on 1 October 2017 by the Intellectual Property (Unjustified Threats) Act 2017 with new sections 70-70F. Sections 70-70F apply to alleged threats made from 1 October 2017 onwards. Any alleged threats made before 1 October 2017 are subject to the law as it was before the changes made by the 2017 Act.

Section 70: Threats of infringement proceedings

70.01 This section sets out the test for determining whether a communication contains a threat of infringement proceedings.

70.02 For the applicability of sections 70-70F in relation to European patents, see 60.02.

Section 70(1)

A communication contains a "threat of infringement proceedings" if a reasonable person in the position of a recipient would understand from the communication that—

- (a) a patent exists, and
- (b) a person intends to bring proceedings (whether in a court in the United Kingdom or elsewhere) against another person for infringement of the patent by—
 - (i) an act done in the United Kingdom, or
 - (ii) an act which, if done, would be done in the United Kingdom.

Section 70 defines what amounts to a "threat of infringement proceedings". In applying the two-part test, the contents of the communication are considered from the perspective of a reasonable person in the position of the recipient of a communication. The first part is whether the communication would be understood by a reasonable person in the position of a recipient to mean that a patent (or application for a patent) exists. The second part is whether the communication would be understood by such a person to mean that someone intends to bring infringement proceedings in respect of that patent (or application for a patent) for an act done (or which would be done) in the UK. If both parts of the test are satisfied, the communication contains a threat of infringement proceedings. It is worth noting that the second part of the test specifically covers an act which, if done, would be done in the UK; this provides for threats made in relation to acts which have not taken place yet. Threats can be in any form, for example written, oral, implied or express. The intention of the person making the threat is not important; it is only important whether a communication would be considered to contain a threat from the point of view of a reasonable person in the position of the recipient.

In *FH Brundle v Perry* [2014] EWHC 475 (IPEC) (a case decided under the previous threats provisions) the defendant, Mr Perry, submitted that the letter containing the alleged threat was addressed to the "Chief Executive/Chairman" of Brundle, and went on to claim that the CEO or Chairman of such a company would not take such letters seriously. The IPEC judge held that: "If a reasonable person in the shoes of a CEO or Chairman would understand the words of a communication as containing a threat of infringement proceedings, the extent to which he or she goes on to treat the threat seriously is irrelevant. The threat has still been made."

Section 70(2)

References in this section and in section 70C to a "recipient" include, in the case of a communication directed to the public or a section of the public, references to a person to whom the communication is directed.

Threats need not be made directly to an identified individual; a threat can be made more generally. However, it must be more than a general warning. Section 70(2) ensures that the threats provisions are engaged when a threat is made in a mass communication. It provides that, in such cases, the understanding of the reasonable person will be that of a recipient who is a member of the public, or a member of the section of the public to which the communication was directed.

Section 70A: Actionable threats

70A.01 A communication that satisfies the test at section 70 will be a threat to sue for infringement, and the threats provisions may be engaged in respect of it. However, not all threats to sue for infringement will give rise to a right to sue under these provisions. Section 70A sets out which types of threats are actionable by a person aggrieved, i.e. those threats where the person aggrieved can sue the person who made the threat.

Section 70A(1)

Subject to subsections (2) to (5), a threat of infringement proceedings made by any person is actionable by any person aggrieved by the threat.

The person making the threat need not have any right in a patent, nor need the threat have been made to the claimant for the threat to be actionable. However, the claimant is required to satisfy the court that such threats were made and that he is a person aggrieved by them, in order that the threat is actionable.

Anyone whose commercial interests have, or might be, affected by the threat in a real rather than fanciful way may sue as a person aggrieved by the threat. See *Brain v Ingledew Brown Bennison and Garrett* (No 3) [1997-98] Info TLR 329, [1997] FSR 511 at 520 (decided under the previous threats provisions). There are some exceptions which prevent a person aggrieved from suing the person who made the threat (see 70A.04-70A.08).

Section 70A(2)

A threat of infringement proceedings is not actionable if the infringement is alleged to consist of—

- (a) where the invention is a product, making a product for disposal or importing a product for disposal, or
- (b) where the invention is a process, using a process.

70A.04 Section 70A(2) sets out a "primary act" exception. A threat will not be actionable if it is a threat to bring proceedings for an infringement alleged to consist of an act of primary infringement. Thus a threats action cannot be brought against the person who made such a threat. A primary act is the making or importing of a patented product for disposal or the use of a patented process.

Section 70A(3)

A threat of infringement proceedings is not actionable if the infringement is alleged to consist of an act which, if done, would constitute an infringement of a kind mentioned in subsection (2)(a) or (b).

70A.05 Since a threat can be made in respect of an intended or future act (see 70.03), section 70A(3) makes clear that the "primary act" exception also applies to such acts – that is, to acts of primary infringement which have not yet been done. Thus a threat alleging that an act, if done, would constitute infringement is not actionable if the act referred to is a primary act.

Section 70A(4)

A threat of infringement proceedings is not actionable if the threat—

- (a) is made to a person who has done, or intends to do, an act mentioned in subsection (2)(a) or (b) in relation to a product or process, and
- (b) is a threat of proceedings for an infringement alleged to consist of doing anything else in relation to that product or process.

A threat made to a primary actor is not actionable. A person who has done or intends to do a primary act (see 70A.04) in relation to a product (or process) to which the threat relates cannot bring a threats action even if the threat refers to other acts which are not primary acts. This allows threats made to primary actors to extend to refer to secondary acts (such as selling the product in question) done by that primary actor. So, for example, a threat to sue a manufacturer for making an allegedly-infringing product may also extend to threatening in relation to acts of selling the product they have manufactured. This is an exception to the general principle that threats made to secondary actors are actionable.

70A.07 Importantly, this exception only applies where the mentioned secondary act is in relation to the same product or process as the primary act. So if a person produces and sells a product, a threat to sue for infringement for both producing and selling the product will not be actionable. But if the same person also sells an equivalent product produced by someone else, a threat to sue for infringement for selling that equivalent product will be actionable since, in this respect, the person being threatened is a pure secondary actor.

Section 70A(5)

A threat of infringement proceedings which is not an express threat is not actionable if it is contained in a permitted communication.

70A.08 A threat, as determined by the test of section 70(1) (see 70.03-70.04), is not actionable if it is contained in a "permitted communication", provided that it is not an express threat to sue. Section 70B defines what is meant by a permitted communication (see 70B.02-70B.03).

Section 70A(6)

In sections 70C and 70D "an actionable threat" means a threat of infringement proceedings that is actionable in accordance with this section.

Section 70B: Permitted communications

70B.01 This section defines "permitted communications". Threats contained in a permitted communication are not actionable, as defined by section 70A(5). Permitted communications allow parties to exchange information without triggering a threats action in situations where a person aggrieved may otherwise be entitled to bring such an action.

Section 70B(1)

For the purposes of section 70A(5), a communication containing a threat of infringement proceedings is a "permitted communication" if—

- (a) the communication, so far as it contains information that relates to the threat, is made for a permitted purpose;
- (b) all of the information that relates to the threat is information that—
- (i) is necessary for that purpose (see subsection (5)(a) to (c) for some examples of necessary information), and
 - (ii) the person making the communication reasonably believes is true.
- 70B.02 A communication which contains an implied threat of infringement proceedings is a permitted communication if it satisfies certain conditions. (A communication containing an express threat of infringement proceedings cannot be a permitted communication see 70A.08.) To be a "permitted communication", the information relating to the threat must be made for a "permitted purpose" (see 70B.04-70B.05). Furthermore, the information that relates to the threat must be necessary for the permitted purpose and reasonably believed to be true by the person making the communication.
- 70B.03 The conditions of section 70B(1) for a communication containing a threat of infringement proceedings to be a "permitted communication" only apply to the part of the communication that constitutes a threat within the section 70 test (see 70.03-70.04). Other material in the communication is separately subject to the test for a threat under section 70. If that material does not satisfy the test for a threat, then the "permitted communication" provisions are not engaged in respect of that material.

Section 70B(2)

Each of the following is a "permitted purpose"—

- (a) giving notice that a patent exists;
- (b) discovering whether, or by whom, a patent has been infringed by an act mentioned in section 70A(2)(a) or (b);
- (c) giving notice that a person has a right in or under a patent, where another person's awareness of the right is relevant to any proceedings that may be brought in respect of the patent.

Section 70B(3)

The court may, having regard to the nature of the purposes listed in subsection (2)(a) to (c), treat any other purpose as a "permitted purpose" if it considers that it is in the interests of justice to do so.

Section 70B(4)

But the following may not be treated as a "permitted purpose"—

- (a) requesting a person to cease doing, for commercial purposes, anything in relation to a product or process,
- (b) requesting a person to deliver up or destroy a product, or
- (c) requesting a person to give an undertaking relating to a product or process.

70B.04 Examples of permitted purposes are listed by section 70B(2). These, among other things, allow a patentee to use the permitted communications to contact a secondary infringer (e.g. a retailer) in order to identify a manufacturer or importer of an allegedly infringing product.

70B.05 The list of permitted purposes is not exhaustive and gives examples of purposes which will be considered to be permitted purposes. While having regard to the nature of that list, the court has discretion to treat any other purpose as permitted, if it is in the interests of justice to do so. However, section 70B(4) makes clear that certain purposes can never be a "permitted purpose". These are: requesting that a person stops doing something in relation to a product or process, or requesting that a person delivers up or destroys a product, or seeking an undertaking from a person in relation to a product or process.

Section 70B(5)

If any of the following information is included in a communication made for a permitted purpose, it is information that is "necessary for that purpose" (see subsection (1)(b)(i))—

- (a) a statement that a patent exists and is in force or that an application for a patent has been made;
- (b) details of the patent, or of a right in or under the patent, which-
 - (i) are accurate in all material respects, and
 - (ii) are not misleading in any material respect; and
- (c) information enabling the identification of the products or processes in respect of which it is alleged that acts infringing the patent have been carried out.

70B.06 Section 70B(5) sets out examples of information that will fulfil the condition of being necessary for a permitted purpose. These include: a statement that a patent exists, accurate and not misleading details of the patent and enough information to identify the product or process that is allegedly being infringed. The inclusion of this information in a permitted communication satisfying the other conditions of this section will not give rise to an actionable threat.

Section 70C: Remedies and defences

Section 70C(1)

Proceedings in respect of an actionable threat may be brought against the person who made the threat for—

- (a) a declaration that the threat is unjustified;
- (b) an injunction against the continuance of the threat;
- (c) damages in respect of any loss sustained by the aggrieved person by reason of the threat.

Section 70C(2)

In the application of subsection (1) to Scotland—

- (a) "declaration" means "declarator", and
- (b) "injunction" means "interdict".

70C.01 Section 70C(1) sets out the remedies that a person aggrieved by the threat can obtain when bringing legal action against a person who has made the threat. An injunction can be obtained as an interim or final remedy. The damages that can be awarded must relate to a loss caused by the threat that is a natural and reasonable consequence of the threat being made.

Section 70C(3)

It is a defence for the person who made the threat to show that the act in respect of which proceedings were threatened constitutes (or if done would constitute) an infringement of the patent.

Section 70C(3) sets out that, if the person who has made the threat can show the act in question is an infringing act, or if done would be an infringing act, then they have a defence in any threats proceedings. However, the validity of the patent can be put in issue in proceedings under the unjustified threats provisions (see 74.03). Therefore, even if the act in question was found to fall within the scope of the patent claims, if the person aggrieved by the threat successfully shows that the patent is invalid, then no infringement can have occurred. In this case, the section 70C(3) defence that infringement occurred must fail.

Section 70C(4)

It is a defence for the person who made the threat to show—

- (a) that, despite having taken reasonable steps, the person has not identified anyone who has done an act mentioned in section 70A(2)(a) or (b) in relation to the product or the use of a process which is the subject of the threat, and
- (b) that the person notified the recipient, before or at the time of making the threat, of the steps taken.

70C.03 Section 70C(4) provides a defence which allows alleged secondary infringers to be threatened in the circumstances where a primary actor cannot be found. This defence applies the principle that a patent holder must first try to direct any threats towards an alleged primary actor. If the steps taken identify a primary actor, then this defence cannot be relied upon even if it appears likely that there are multiple primary actors, not all of whom have been found.

70C.04 Whether the requirement of "reasonable steps" is satisfied depends on the facts of the case. A reasonable step can include the use of the permitted communications exception (see 70B.02-70B.03) to determine whether a primary act has been committed and by whom. In some circumstances, it is reasonable to pursue all possible lines of enquiry, however in other circumstances it may be reasonable to do less.

Section 70D: Professional advisers

Section 70D(1)

Proceedings in respect of an actionable threat may not be brought against a professional adviser (or any person vicariously liable for the actions of that professional adviser) if the conditions in subsection (3) are met.

70D.01 Section 70D(1) sets out that a professional adviser cannot be sued for a threat made on behalf of a client if certain conditions are met (see 70D.03)

Section 70D(2)

In this section "professional adviser" means a person who, in relation to the making of the communication containing the threat—

- (a) is acting in a professional capacity in providing legal services or the services of a trade mark attorney or a patent attorney, and
- (b) is regulated in the provision of legal services, or the services of a trade mark attorney or a patent attorney, by one or more regulatory bodies (whether through membership of a regulatory body, the issue of a licence to practise or any other means).

70D.02 Section 70D(2) defines a "professional adviser" as someone who is providing legal services and is regulated by one or more regulatory bodies, such as the Intellectual Property Regulation Board (IPReg). This provision does not affect the principle that anyone, not just the patent holder, may be liable for making a threat.

Section 70D(3)

The conditions are that-

- (a) in making the communication the professional adviser is acting on the instructions of another person, and
- (b) when the communication is made the professional adviser identifies the person on whose instructions the adviser is acting.

70D.03 Section 70D(3) sets out the conditions that must be met for the professional adviser to be protected by section 70D. These conditions apply to both a single instruction to send a specific communication given to a professional adviser and an in-house adviser with a general instruction to protect the intellectual property rights of a specific company. In both cases, the professional adviser is acting on the instructions of another and not of their own volition. This protection applies equally to non-UK advisers if the above conditions are met.

Section 70D(4)

This section does not affect any liability of the person on whose instructions the professional adviser is acting.

70D.04 Section 70D(4) states that this protection only relates to the professional adviser. Any liability incurred by the client (patent holder) for making threats is unaffected and a threats action may be brought against the client.

Section 70D(5)

It is for a person asserting that subsection (1) applies to prove (if required) that at the material time—

- (a) the person concerned was acting as a professional adviser, and
- (b) the conditions in subsection (3) were met.

70D.05 The onus is on the professional adviser to prove that they were acting as a professional adviser and that the conditions set out in section 70D(3) (see 70D.03) were met at the time the threat was sent.

Section 70E: Supplementary: pending registration

Section 70E(1)

In sections 70 and 70B references to a patent include references to an application for a patent that has been published under section 16.

70E.01 Section 70E(1) ensures that a threat made in relation to a published patent application is subject to the threats regime set out in section 70 onwards. Threats proceedings can take place before (as well as after) the patent is granted. Infringement proceedings cannot be brought until after grant; however the alleged infringer may be liable from the publication date (see 69.06).

Section 70E(2)

Where the threat of infringement proceedings is made after an application has been published (but before grant) the reference in section 70C(3) to "the patent" is to be treated as a reference to the patent as granted in pursuance of that application.

70E.02 Section 70E(2) sets out that, when the infringement defence (see 70C.02) is relied upon, it relates to the scope of the patent as granted rather than the scope of the patent application when published under section 16.

Section 70F: Supplementary: proceedings for delivery up etc.

Section 70F

In section 70(1)(b) the reference to proceedings for infringement of a patent includes a reference to proceedings for an order under section 61(1)(b) (order to deliver up or destroy patented products etc.)

70F.01 Section 70F confirms that a threat of infringement proceedings within the definition in section 70 includes a threat to bring proceedings for an order to deliver up or destroy a patented product. See also section 61.

DECLARATION OR DECLARATOR AS TO NON-INFRINGEMENT

Section 71: Declaration or declarator as to non-infringement

71.01 This section provides for the making of a declaration or declarator that an act does not, or a proposed act would not, constitute an infringement of a patent. Hereinafter the word 'declaration' will generally just be used, the word 'declarator' being the Scottish term. The procedure within the Office is prescribed by Part 7 of the Patents Rules 2007.

Section 71(1)

Without prejudice to the court's jurisdiction to make a declaration or declarator apart from this section, a declaration or declarator that an act does not, or a proposed act would not, constitute an infringement of a patent may be made by the court or the comptroller in proceedings between the person doing or proposing to do the act and the proprietor of the patent, notwithstanding that no assertion to the contrary has been made by the proprietor. if it is shown -

- that that person has applied in writing to the proprietor for a written (a) acknowledgment to the effect of the declaration or declarator claimed, and has furnished him with full particulars in writing of the act in question; and
- that the proprietor has refused or failed to give any such acknowledgment. (b)
- s.60(5)Section 71 provides for the court or the comptroller to make a declaration that an act or proposed act does not constitute an infringement of the patent. The validity of the patent may be put in issue in s.71 proceedings by virtue of s.74(1)(c), but this should be specifically pleaded in the statement (see 71.05). However, in Johnson Matthey PLC v Sumitomo Special Metals Co Ltd (BL O/168/92 and O/145/94) s.71 proceedings were stayed at the applicant's request pending the outcome of opposition proceedings under the EPC where the validity of the patent was at issue. In Glaxo Group Ltd v Genentech Inc [2008] EWCA Civ 23, [2008] FSR 18, the Court of Appeal set out various factors (which were updated in IPcom GmbH & Co Kg v HTC Europe Co Ltd & Ors [2013] EWCA Civ 1496 and applied in Actavis Group PTC EHF v Pharmacia LLC [2014] EWHC 2265 (Pat)) which might be useful to consider in deciding whether to stay legal proceedings on the ground that there are parallel proceedings pending in the EPO contesting the validity of the patent. For further discussion of staying proceedings, see the Patents Hearings Manual (paragraphs 2.73-2.76). A declaration can only be granted if the act or proposed act (i) falls outside the scope of the claim, (ii) only falls within the scope of claims held to be invalid (since an invalid claim cannot be infringed), or (iii) is exempted from being an infringement under s. 60(5) (see 60.23-60.28). Such a declaration is the only form of relief available under s.71; a finding of invalidity in such proceedings does not itself cause revocation (Zeigler's Patent (BL O/64/87)).
- s.74(7)71.03 Where proceedings are pending in the court under any of sections 58, 61, 69, 70-70F, 71 and 72, no proceedings may be instituted before the comptroller under s.71 without the leave of the court (see also 71.10 and 74.07).
 - 71.04 Before an application can be properly launched under s.71, the person seeking the declaration must apply in writing to the proprietor for a written acknowledgement to the effect of the declaration claimed and must furnish him with full particulars in writing of the act in question. Scarman L J, when considering the need for full particulars in Mallory Metallurgical Products Limited v Black Sivalls and Bryson Incorporated [1977] RPC 321, stated at page 345 that, ".... the description must be sufficiently clear and precise to enable the court to declare that an article corresponding with the description would not constitute an infringement. The burden of proving the

absence of infringement rests, in my judgment, upon the plaintiff. If there be lack of clarity or precision, the court is not in a position to grant the declaration sought". As pointed out in *British Railways Board's Patent* (BL O/41/85), it is also essential for any difference between the act and the invention claimed in the patent to be brought out whether the difference relates to the absence, or to the replacement, of a feature claimed. In *Minnesota Mining and Manufacturing Co's (Suspension Aerosol Formulation) Patent* [1999] RPC 135, Pumfrey J suggested that it would always be desirable to provide the patentee with a sample or drawings to aid the description.

71.04.1 In MMD Design & Consultancy Ltd's Patent [1989] RPC 131, a written description which was inadequate under s.71(1) by itself was held to suffice when taken together with a drawing. Although the drawing was only made available to the patentees on, rather than before, the day the application under s.71 was filed, the hearing officer refused to dismiss the application as not properly launched, since the practical consequence of doing so would simply have been the filing of another application. Following this, in Johnson Matthey PLC v Sumitomo Special Metals Co Ltd (BL O/168/92) the hearing officer decided that s.71 proceedings had not been properly launched because the claimant had provided insufficient particulars of a range of alloys, on which a declaration of non-infringement was sought, for the proprietors to argue against the declaration and also for the comptroller to determine whether or not the alloys fell within the scope of the patent. However, an opportunity was given to clarify the act on which a declaration was sought. These decisions should now be viewed in the light of Melkris Ltd v Denman (BL O/369/01), in which the applicant provided particulars to the proprietors as required, but then filed an application for declaration of non-infringement the next working day. The hearing officer made clear that "this approach is completely at odds with one of the key elements of the reform of civil justice initiated by the Woolf report....under which parties are expected to try and settle their disputes first before resorting to litigation". Because the MMD Design decision (and, on that basis, Office publications and other guidance) had encouraged parties to believe that it was perfectly acceptable to defer seeking an acknowledgement from the proprietor until an application under s.71 was made, the hearing officer declined to dismiss the application in this case. However, he indicated that the comptroller may well in the future dismiss with an appropriate award of costs any application where the applicant's actions had failed to give adequate opportunity for the proprietor to give the requested acknowledgement.

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71.05 If the proprietor refuses or does not give the acknowledgement sought, then an application for a declaration may be made to the comptroller (after grant of the patent) on Patents Form 2 accompanied by a copy thereof and by a statement of grounds (in duplicate). This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 – 123.05.13.

r.77(5) r.77(6) r.78 71.06 The counter-statement in the proceedings may include an application to amend the specification under s.75 (see 75.04-75.08).

71.07 In determining whether an act does not constitute or would not constitute infringement of the patent regard is had to the provisions of s.60 and s.64 as to what constitutes infringement. Because s.60 makes clear that infringement has only occurred if a person has done an act within the United Kingdom without the consent of the patent proprietor, the power to make a declaration under s.71 is confined to acts within the United Kingdom (*Plastus Kreativ AB v Minnesota Mining and Manufacturing Co and anr.* [1995] RPC 438). In determining whether there would be infringement in MMD (see 71.04), the hearing officer took into account a point which was not raised by the applicants but which emerged directly out of and could be decided solely upon the evidence.

s.77(1) 71.08 It is also possible for a declaration to be made under s.71 in respect of a European patent (UK).

Section 71(2)

Subject to section 72(5) below, a declaration made by the comptroller under this section shall have the same effect as a declaration or declarator by the court.

- 71.09 S.72(5) provides that a decision of the comptroller or on appeal from the comptroller shall not estop any party to civil proceedings in which infringement of a patent is in issue from alleging invalidity of the patent on any of the grounds referred to in s.72(1), whether or not any of the issues involved were decided in the said decision.
- 71.10 However court proceedings for infringement of a patent may be stayed pending the outcome of proceedings under sections 71 and 72 before the comptroller (Hawker Siddeley Dynamics Engineering Ltd v Real Time Developments Ltd [1983] RPC 395).

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REVOCATION OF PATENTS

Section 72: Power to revoke patents on application

s.77(1) s.130(7) 72.01 This section provides for the revocation of patents granted under the 1977 Act, including European patents (UK). Section 72(1) and (2) are so framed as to have, as nearly as practicable, the same effects as the corresponding provisions of the EPC and CPC. These are Articles 100 and 138(1) of the EPC and Article 57(1) (renumbered in December 1989 as Article 56(1) [1989]) of the CPC.

72.02 The following discussion is largely concerned with revocation proceedings brought before the comptroller. Procedure in applications to the Patents Court and Patents County Court, which is outside the scope of this Manual, is governed by Part 63 of the Civil Procedure Rules and the Practice Direction supplementing Part 63.

Section 72(1)

Subject to the following provisions of this Act, the court or the comptroller may by order revoke a patent for an invention on the application of any person (including the proprietor of the patent) on (but only on) any of the following grounds, that is to say -

- (a) the invention is not a patentable invention;
- (b) that the patent was granted to a person who was not entitled to be granted that patent;
- (c) the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art;
- (d) the matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent, as filed, or, if the patent was granted on a new application filed under section 8(3), 12 or 37(4) above or as mentioned in section 15(9) above, in the earlier application, as filed;
- (e) the protection conferred by the patent has been extended by an amendment which should not have been allowed.

72.03 Revocation has effect ex tunc and the patent is therefore deemed never to have been granted. The matters which are specified as grounds for revocation in s.72(1) (a) to (e) are discussed more fully in (a) paragraphs 1.01 to 1.39, 2.01 to 2.56, 3.01 to 3.99 and 4.01 to 4.24, (b) paragraphs 7.06 to 7.11, (c) paragraphs 14.58-14.105, (d) paragraphs 76.01 to 76.23, and (e) paragraphs 76.24-76.27. (It has been confirmed by the Patents Court in Liversidge v British Telecommunications plc [1991] RPC 229 that s.72(1)(e) relates only to amendment of the patent which occurred after it had been granted.) Although the grounds listed for revocation do not, as such, include non-compliance with section 14(5), Lord Hoffmann in Biogen v Medeva [1997] RPC 1 held (at page 47) that "the substantive effect of section 14(5)(c), namely that the description should, together with the rest of the specification, constitute an enabling disclosure, is given effect by section 72(1)(c)". That said, in Kirin-Amgen Inc. v Transkaryotic Therapies Inc. [2003] RPC 3, the Court of Appeal stated that "Section 72 which contains the grounds of revocation has no equivalent to s.14(5). Thus clarity, conciseness and support are matters to be considered by the Patent Office granting the patent, but lack of clarity, conciseness and support are not grounds for revocation".

The list of grounds for revocation in s.72(1) is an exhaustive one. In <u>Virgin Atlantic Airways</u> <u>Ltd v Jet Airways (India) Ltd & Ors [2013] EWCA Civ 1713</u> the defendants challenged the

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validity of Virgin's European Patent (UK) based on the allegation that the EPO had applied the UK designation to the application in error. The defendants sought to engage Article 6 of the European Convention on Human Rights (ECHR) claiming their inability, as a third party, to challenge the patent on the basis of the actions of the EPO pre-grant breached their Article 6 rights by denying them a fair hearing. The Court of Appeal held that Article 6 does not extend to creating substantive rights to challenge the validity of a patent where none already exist. The only grounds available to challenge the grant of a patent are therefore those under s.72 and s.74 (see also 77.03.1)

72.03.1 The provision in subsection (b) allows revocation if the patent was granted to one person when it should have been granted to another. It also allows revocation if the patent was granted to two people when it should have been granted only to one of them. In *Henry Brothers (Magherafelt) Ltd. v The Ministry of Defence and the Northern Ireland Office* [1999] RPC 442, the Court of Appeal considered the situation where a patent was granted to one person when it should have been granted jointly to that person and another person and concluded that, although the question of co-ownership called for clarification in the law, revocation did not appear to be possible in these circumstances. Section 37(2)(a) of the 1977 Act allows the second person to be included as one of the proprietors of the patent, and this is an adequate remedy.

s.36(3)

Any person may apply for revocation, including the proprietor of the patent. However, where there are co-owners, unless all co-owners agree that it should be possible, one co-owner may not seek revocation of the patent against the wishes of the others. More generally, there is no need for the applicant for revocation to establish locus standi (except in the circumstances set out in 72.40) nor is there any limit as to the time within which an action may be brought. Thus in Cairnstores Ltd v Aktiebolaget Hassle [2002] FSR 35 the court refused to strike out an application for revocation made by a company with no assets, which did not trade and which was unrelated to the technology of the patent in question. The court also refused to order the applicant to disclose the name of any party on behalf of whom it was acting. Similarly, in Oystertec Plc's Patent [2003] RPC 29, the Patents Court upheld a hearing officer's decision (BL O/0298/02) to refuse an application for an order for a firm of patent agents applying for revocation of a patent to disclose the identity of the principal they were assumed to be acting for. However, in British Numberplate Manufacturers Association v Hills Numberplates Limited (BL O/066/05), the hearing officer held that an unincorporated association was not entitled to bring revocation proceedings in its own name in light of general case law which prevents an unincorporated body launching proceedings. In Buehler AG v Chronos Richardson Ltd [1998] RPC 609, it was held that both cause-of-action estoppel and issue estoppel may apply to proceedings concerning the validity of a patent where there had been a final judicial decision, but that the decision of the Opposition Division of the EPO is not a final judicial decision as to the validity of a European Patent. It was also noted that cause-of-action estoppel would not be applicable in any case since the grounds of revocation under section 72 are not the same as those in Article 100. Please refer to 1.94-1.106 of the Patent Hearings Manual for detailed discussion of the different types of estoppel.

72.04.1 In Axis Genetics PLC's (In Administration) Patent [2000] FSR 448 it was held that a revocation action falls within the wording of section 11(3)(d) of the Insolvency Act 1986. This means that proceedings for the revocation of a patent held by a company in administration requires either the consent of the administrators or the leave of the court. The Enterprise Act 2002 replaced section 11 and inserted Schedule B1 into the Insolvency Act 1986; the equivalent provision to section 11(3)(d) is now in paragraph 43(6) of this Schedule.

PRELIMINARY PROCEDURE

The Application, Statement and Counterstatement

PR part 7

72.05 An application for revocation should be made by filing Form 2 accompanied by a copy thereof and by a statement of grounds in duplicate. This starts proceedings

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before the comptroller, the procedures for which are discussed at 123.05 – 123.05.13. Where the patent is co-owned, and an applicant for revocation is one of the proprietors of the patent, references to the proprietor of the patent in r.77 (and in 72.05-72.23) should be taken as a referring to the proprietors who do not make the application. However, rr.75(2)-(8) do not apply where all the proprietors have made the application, and instead, the comptroller shall give directions as he may think fit with regard to the procedure for determining the application.

The statement should be sufficiently explicit to allow the proprietor of the patent to be aware of the specific allegations which he will have to answer if he wishes to defend his patent. Thus while normally it will not be necessary to provide elaborations of technical fact, nevertheless where prior disclosure or prior use of the invention are alleged, or an argument of obviousness is based thereon, the disclosure or use must be sufficiently identified to allow the proprietor to appreciate the scope of the allegation he is required to meet. While there are no prescribed requirements as to the particular facts which need to be pleaded in the statement in proceedings before the comptroller, guidance as to what is required under s.72(1)(a) may be obtained from paragraph 4.4 of the Practice Direction supplementing Part 63 of the Civil Procedure Rules. The details required from this paragraph are as follows:

- "(1) in the case of matter made available to the public by written description the date on which and the means by which it was so made available, unless this is clear from the face of the matter; and
- (2) in the case of matter made available to the public by use -
 - (a) the date or dates of such use;
 - (b) the name of all persons making such use;
 - (c) any written material which identifies such use;
 - (d) the existence and location of any apparatus employed in such use;and
 - (e) all facts and matters relied on to establish that such matter was made available to the public."

Contesting an application for revocation

r.77(5) 72.07 If the proprietor wishes to contest the application, he must file a counterr.77(6) statement in the proceedings.

72.08 The contents of the counter-statement are prescribed by r.78. Provided that a ground is replied to, the proprietor is not required to argue with every point of detail advanced by the applicant (*Marshall's Application*, [1969] RPC 83).

Failure to file counterstatement

Failure to file a counterstatement (except where the applicant has withdrawn unconditionally) will lead to the proprietor's case being treated as undefended, and he will forfeit the right to take any further part in the proceedings. However, the proceedings remain strictly inter parties. The application will be considered by the comptroller as if each specific fact set out in the statement were conceded, except insofar as it is contradicted by other documents available to the comptroller. If on this basis it is determined that a ground has been made out, then the patent will be revoked. However, if it is the preliminary opinion of the Office that no ground has been made out then the applicant should be informed by Tribunal Section of this preliminary opinion and offered a hearing before the application is dismissed. The application will be considered in a similar way by the comptroller if the

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patentee decides not to defend the application at a later stage in the proceedings.

Offer to amend under s.75

A counterstatement is still required even if, before it is due to be filed, the applicant has indicated that he is willing to withdraw on the condition that certain amendments are made to the specification and the proprietor is agreeable to these amendments. In such a case however it will be sufficient for the counterstatement merely to offer the proposed amendments, stating that the offer is unconditional (see 72.11).

s.76(2) 72.11 If the proprietor offers in his counterstatement to amend the specification it should be made clear on what basis the offer is made, that is, whether the offer is firm or is conditional upon an adverse finding on the unamended specification. Unless the amendments are very minor, they should preferably be identified on a copy of the published specification showing the amendments, referred to in the counterstatement, in red. Any such amendments are made under s.75 and are subject to r.35 procedure (see 75.04-07 and 75.15-17). The proposed amendments should be considered by the examiner to report on whether in his opinion they are prima facie allowable. At this stage the only questions which need to be considered by the examiner are whether the amendments would add matter or extend the protection conferred by the patent; no attempt should be made to consider whether they meet the alleged ground of invalidity.

[Once the action officer has checked that the nature of the proposed amendments and the basis upon which they are offered has been properly indicated the case should be referred to the Deputy Director in charge of the subject matter concerned for a preliminary report on the amendments. In making his assessment the Deputy Director should make no attempt to review the whole case; in most cases it should not be necessary to look beyond the copy of the specification on which the proposed amendments are shown. He should bring the case to the attention of the hearing officer at this stage of the proceedings. Reporting on an offer to amend should be regarded as urgent and if the Deputy Director is absent for more than a few days the Senior Examiner acting for him should consult the hearing officer as to the course to follow.]

Any objection arising out of this preliminary scrutiny of the amendments should be communicated in an official letter to the proprietor allowing a specified period for reply (normally one month). If the proprietor maintains that the amendments are allowable, both parties should be informed that this has been noted and that the matter will be determined at the substantive hearing. If no reply is received within the specified period, the proposed amendments should be treated as if the proprietor maintains that they are allowable and the parties should be informed accordingly. If new or modified amendments are proposed in reply, the above procedures should be repeated. Although such amendments may initially be proposed in correspondence, in order to be brought formally into the proceedings, they must be incorporated into or referred to in an amended counterstatement.

[If the Deputy Director is satisfied that there is a clear major objection under s.76, he should report in a form suitable for incorporation in a letter expressing the objection as a prima facie view. To this end such a letter (issued by the tribunal manager) should open with, 'The amendments have been referred to an examiner who has expressed the following prima facie view:-' If, however, there are no or only minor objections or there is a reasonable element of doubt, the Deputy Director should report accordingly in a minute and inform Tribunal Section that in the circumstances no action on the amendments is necessary at this stage; he should not expressly state or imply that the amendments are allowable. It must be remembered that it is for the hearing officer to pronounce on the allowability of the amendments and nothing that the Deputy Director reports to the applicant should purport to derogate from the hearing officer's authority. The Deputy Director must accordingly communicate nothing which could be interpreted as a decision or as a

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72.12.1 When amendments have been submitted in a counterstatement they should be advertised in the form subsisting as soon as the procedure described in paragraphs 72.11-72.12 has been completed unless they are clearly minor and of no substance.

- s.75(2)

 72.13 The revocation proceedings should usually proceed in parallel with the consideration of the amendments under s.75. Thus the applicant should be allowed (a) a specified period (normally one month) in which, if he wishes, to amend his statement or file a supplementary statement in respect of the amendments (*Dust Suppression Ltd's Application* [1976] FSR 438) and (b) a period in which to file evidence in chief (see 123.05.9-123.05.11). The comptroller may however stay the revocation proceedings at the request of the applicant pending consideration of the amendments. Similarly, if the amendments are opposed the comptroller may stay the revocation proceedings pending a resolution of the opposition or may leave the opposition to be decided in the revocation proceedings. Note that the proprietor also has the opportunity of amending a European patent (UK) before the EPO (see 72.44.1 below).
- r.82(1) Amendment of the application for revocation, the statement or the counterstatement is allowable with the leave of the comptroller; for example a new applicant for revocation may be added or substituted or a new ground or further facts may be introduced. In a preliminary decision, (GEC Avery Service Ltd v Derwent Measurement and Control Ltd, BL O/62/94) the hearing officer acting for the comptroller held that, in exercising discretion as to admit new or amended grounds, he should follow the principles established in Owens-Corning Fibreglas Corporation's Patent [1972] RPC 684 for cases decided under the 1949 Act, namely (a) whether the applicant had used due diligence in preparing his case; (b) the relevance of new art sought to be introduced; (c) the time that had elapsed since the filing of the application; and (d) whether delay will be caused which might be unjust to the patentee or against the public interest. Evidence in the form of statutory declaration or affidavit may be necessary to explain the lateness of the amendment. The fact that evidence may be necessary in support of a new ground does not of itself justify a refusal to allow the introduction of that ground (Allmanna Svenska Electriska Aktiebolaget's Application, [1976] RPC 464).

Admission of new grounds

- Where the comptroller decides to admit a new ground, a supplementary or amended statement should be filed. The proprietor should then be given the opportunity to file a supplementary or amended counterstatement in reply. Unless the new ground is not contested or evidence relevant to the new ground has already been filed, each party should be given a specified period (which may run concurrently with any other period set) in which to file further evidence in support of or in response to this new ground.
- 72.16 Matters not included in the statement or counterstatement as originally filed cannot be raised at the hearing (*Bradford Dyers Association Ltd's Application*, [1966] FSR 79 and *Roussel-Uclaf (Joly and Warmant's) Patent*, [1971] RPC 304), unless they have been allowed to be introduced into the statement or counterstatement by way of amendment (see 75.14).

Evidence

72.17	[deleted]
72.18	[deleted]

72.19 The applicant for revocation should not wait until the reply stage to complete the evidence necessary to make out his case. Further evidence filed at this stage must be strictly in reply to the proprietor's evidence. In *Scragg (Ernest) Ltd's Application*, [1972] RPC 679, which was an opposition under the 1949 Act, Graham J quoted Halsbury's Laws of England as authority for the principle that the party on which the onus of proof falls (which in

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the present case is the applicant for revocation) must adduce all his primary evidence when presenting his case and not seek thereafter to adduce additional evidence to strengthen his case. He stated (at page 682) "to my mind it is quite wrong in these cases that there should be any sort of skirmishing in regard to evidence, and if an opponent has a case he should straight away state what his case is and should put in declarations dealing with any evidence which he thinks may be relevant to his case". In *Peckitt's Application* [1999] RPC 337 some further evidence was allowed to stand which was little more than repetition of elements of the case put in chief with some minor clarification and comment. The important factor was said to be that it did not either alter or strengthen the party's case or be such as to prolong the pre-hearing procedure by justifying another round of evidence from the other party.

72.20 For the form of evidence, see 123.17-18 and Chapter 3 of the Patent Hearings Manual.

Documents referred to

r.87

72.21 The provision of copies of documents referred to in statements and evidence is governed by r.79 - see 123.18

Extension of periods

72.22 [deleted]

SUBSEQUENT PROCEDURE

After completion of the stages referred to above the matter will normally proceed to a hearing unless either the applicant withdraws or abandons by failure to give security for costs (see 72.24-72.35 and 123.05.10-123.05.12) or the proprietor offers to surrender his patent (see 72.36-72.39). Following the hearing a decision will be issued (see 72.42-72.44 and 123.05.13). In some cases a preliminary hearing may be necessary to decide a dispute between the parties or between the Office and either or both of the parties.

WITHDRAWAL OF APPLICANT

Conditions of withdrawal

A withdrawal by the applicant may be unconditional, or it may be conditional on amendments which have been submitted by the proprietor being allowed. The applicant's willingness to withdraw on the basis of the proposed amendments may be indicated in a letter or by counter-signature on a copy of the specification showing the amendments. If it is not clear whether an offer to withdraw is conditional or unconditional, or what the conditions for withdrawal are, Tribunal Section should seek clarification from the applicant.

In Flude (H) & Co (Hinckley) Ltd's Patent [1993] RPC 197 in which the applicant sought to amend the statement of case under rule 75(1) by a conditional withdrawal of certain grounds of revocation and some of the evidence while leaving open the possibility of relying on them subsequently once a decision had been made on the remaining issues, the applicant was required to choose whether to proceed on the original pleadings or to withdraw certain grounds of invalidity with an order that they should not be raised again in any proceedings between the parties before the comptroller or in the court without leave of the court.

Public interest

72.26 Where an applicant serves notice of withdrawal from revocation proceedings before the comptroller which have been properly launched, an examiner considers whether the comptroller should accept the notice of withdrawal without

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qualification or whether there are questions remaining that the comptroller should further consider in the public interest (*Abbott Laboratories (Chu's) Patent* [1992] RPC 487, following *General Motors (Tunney & Barr's Application)* [1976] RPC 659 decided under the 1949 Act). The proceedings are concluded by a formal decision of a hearing officer acting for the comptroller. This procedure, which differs from that in proceedings before the court because the comptroller has technical staff to investigate the matter, was endorsed in *R v Comptroller-General of Patents*, ex parte Ash & Lacey Building Products Ltd [2002] RPC 46. Prima facie, where an application is treated as abandoned under s.107(4) in default of security for costs or expenses, the same public interest considerations apply as in the case of unconditional withdrawal of the application.

72.27 The specification, including any amendments submitted by the proprietor, should be considered in order to ascertain whether a case for revocation is made out on the evidence of the documents so far filed. The allowability of amendments is subject to the principles referred to in 75.04-75.05.1. Normally only clear cases of lack of novelty or inventive step based on prior documentary disclosure should be pursued by the comptroller. Only exceptionally should some other ground of revocation be continued with after withdrawal of the applicant. In *R v Comptroller-General of Patents, ex parte Ash & Lacey Building Products* (above), it was held that it was allowable for the hearing officer to first come to a view on construction of the claims before determining whether a clear case of lack of novelty or inventive step had been made out.

[If the applicant for revocation seeks to withdraw, the action officer in Tribunal Section should refer the file to the hearing officer's assistant, if one has been appointed, or otherwise to the Deputy Director in charge of the subject-matter, to determine whether any action is necessary in the public interest. If the Deputy Director considers that revocation is justified on some ground other than lack of novelty or of inventive step, then he should consult the hearing officer concerned before issuing a report. The Deputy Director concerned may deal with the case himself or call on a Senior Examiner to make a report but in either case the Deputy Director remains responsible for any decision made and only he (or a hearing officer in his absence) may sign the decision. When a Senior Examiner is asked to report on a withdrawn revocation, no more than a brief report on the issues which he is required to consider is called for, and this should be minuted. Any points to be raised with the proprietor should be the subject of an appendix drafted in terms suitable for incorporation in a letter which will be issued by the action officer in Tribunal Section. All action taken should be recorded in a minute added to the the dossier (PDAX cases) or on the proceedings sheets in the revocation shell (Paper cases).]

Procedure when no ground for revocation remains

Where the applicant has requested conditionally or unconditionally to withdraw and the proprietor has submitted amendments which appear to be allowable and to remove the ground for revocation, or where the applicant has withdrawn unconditionally and no amendments have been offered and the Office is satisfied that no ground for revocation has been made out, the proceedings should be dealt with as described in 72.42 except that since the decision does not involve determination of an issue in dispute between the parties it may be issued by the Deputy Director rather than the hearing officer.

Procedure when grounds for revocation remain

Unconditional withdrawal of applicant

72.29 Where the applicant has requested unconditionally to withdraw and the examiner determines that the action should be continued in the public interest by the comptroller, a letter should be sent to the proprietor including a statement that whilst the request for withdrawal has been noted the revocation proceedings are regarded as still in being and the comptroller cannot yet decide the matter. The letter should set out clearly the grounds which are being pursued in the public interest. This letter from the Office must be

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worded in such a way that there is no danger of it being construed as a decision.

[The following is a specimen letter:-

'The applicant's desire to withdraw from these proceedings, expressed in his letter dated, has been noted. However, the application has been referred to an examiner, who feels that the issue(s) of should be pursued in the public interest for the following reasons:-

'Accordingly the revocation proceedings are still regarded as in being and the comptroller cannot yet decide the case.

'This letter has been copied to the applicant for information. However since he is not actively pursuing these proceedings, further correspondence need be sent to the comptroller only.'

[The letter should also indicate the action required, such as the filing of a counterstatement, comments, evidence, amendments or further amendments. A period for reply (normally one month) should be specified and the proprietor should be informed of his right to be heard. The letter should be issued by the action officer in Tribunal Section on the instruction of the Deputy Director. A copy should be sent to the applicant.]

- 72.30 The proprietor should be advised that any further proposals for amendment should be filed with the Office within the period allowed for reply to the letter. The proprietor should also be advised that such proposals should be shown clearly on a copy of the published specification. Since the applicant is no longer actively pursuing the proceedings, the proposals need be sent to the Office only. Once a form of amendment which is allowable is arrived at, the procedure in paragraph 72.42 should be followed.
- 72.31 The applicant should be sent a copy of the initial letter to the proprietor and warned that thereafter, unless he requests otherwise, no further correspondence will be copied to him except that, for information, he will be sent a copy of any decision revoking the patent or dismissing the application or an advertisement of amendments to be published in the Journal.

Conditional withdrawal of applicant

- 72.32 Where the applicant has requested to withdraw conditionally on amendments being allowed and the examiner determines that further action would be required in the public interest by the comptroller, the applicant remains an active party to the proceedings since his conditions for withdrawal have not been met. The hearing officer should then determine the most efficient course of action in the circumstances.
- Since the applicant had offered to withdraw subject to the amendments being allowed, he presumably has no objections to them; the examiner will therefore normally pursue any objections directly with the proprietor until he is satisfied that the amendments are acceptable, the correspondence being copied to the applicant for comment. The action under section 72 will then usually be stayed pending the outcome of the application to amend under section 75. In any case, the examiner will write to the proprietor setting out the objections which would be pursued. As in the case discussed in 72.29 above, this should not be in terms that could be construed as a decision.

[The following is a specimen letter:-

'The applicant's desire, expressed in his letter dated, to withdraw from the revocation proceedings subject to acceptance of the proposed amendments submitted with your letter dated has been noted. However, the amendments have been referred to an examiner, who feels that the amendments do not meet the

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s.101

issue(s) of for the following reasons:-

'Accordingly the revocation proceedings are still regarded as in being and the comptroller cannot yet decide the case.

'This letter has been copied to the applicant for information.'

[The letter should also indicate the action required, such as the filing of a counterstatement, comments, evidence, amendments or further amendments. A period for reply (normally one month) should be specified and the proprietor should be informed of his right to be heard. The letter should be issued by the action officer in Tribunal Section on the instruction of the Deputy Director. A copy should be sent to the applicant.]

Once amendments acceptable to the examiner have been reached, it should be determined whether the applicant still wishes to withdraw the application under section 72 on the basis of these amendments being accepted; if not then the applicant should be given an opportunity to amend his statement or file a supplementary statement as described in 72.13. If there is no likelihood of agreement being reached or if further amendments are not acceptable to the examiner a hearing may be necessary.

Costs

72.35 In any case involving withdrawal following agreement between the parties the question of costs should normally have been dealt with as part of the agreement, and in such a case the hearing officer will not normally concern himself with costs, and his decision will not refer to them. If however an order for costs is sought, other than merely in the statement or counterstatement, before the decision issues, then such an order can be included in the decision. Where, after the issue of the decision, one party asks for costs, the request should be referred to the hearing officer for consideration of an award of costs.

[The Deputy Director is empowered to award costs in withdrawn revocation proceedings. For further details on awarding costs, see Chapter 5 of the Patents Hearings Manual.]

SURRENDER

s.29(1) 72.36 The proprietor may at any time offer to surrender his patent (see 29.01-s.29(3) 29.07). Unlike revocation, however, the surrender only takes effect from the date when notice of acceptance of the surrender is published in the Journal. There will therefore have been some time during which the patent was in force. It follows that an offer to surrender during revocation proceedings will not automatically terminate those proceedings. No suggestion should therefore be made that a proprietor (or patentee) who does not wish to oppose an application for revocation should offer to surrender his patent.

72.37 The offer to surrender must be advertised and the parties informed of the date of the advertisement. The four week period for opposition to the surrender runs from that date.

[As soon as arrangements for the advertisement have been made and letters sent to the proprietor and applicant for revocation notifying them of the date of the advertisement the case should be referred to the hearing officer to decide on the future action. Normally the hearing officer should arrange for a member of his division, usually a Deputy Director, to write a report on the revocation action.]

72.38 The matter should be considered as though no counterstatement had been filed, that is, as if each specific fact set out in the statement had been conceded except insofar as it is contradicted by other documents before the Office. If on this basis it is determined that at least one ground for revocation has been made out (and provided that the

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s.101

0...

r.42

r.75

r.76(2)

two month period has expired without an opposition being lodged), the parties should be informed that it is proposed to issue a formal decision revoking the patent, and consequently not to accept the offer to surrender, unless within one month either party opposes this course of action.

[If it is determined that at least one ground for revocation has been made out, the examiner should draft a letter for issue by Tribunal Section. The case should be referred to Tribunal Section via the hearing officer. If either party opposes the decision to revoke instead of allowing surrender, or in the very rare cases when no ground for revocation is found, the matter should be referred to the hearing officer for direction as to future proceedings.

[The hearing officer may change the procedure outlined above in exceptional cases, for example if (a) the offer to surrender is made after both sides have filed evidence in the revocation action, (b) the applicant for revocation is a private applicant who gives no substantial grounds for revocation, or (c) an opposition to the advertised offer has been entered.]

72.39 If, in revocation proceedings before the comptroller under this section, the proprietor offers to surrender the patent, the comptroller shall, in deciding whether costs should be awarded to the applicant for revocation, consider whether proceedings might have been avoided if the applicant had given reasonable notice to the proprietor before the application was filed.

Section 72(2)

An application for the revocation of a patent on the ground mentioned in subsection (1)(b) above -

- (a) may only be made by a person found by the court in an action for a declaration or declarator, or found by the court or the comptroller on a reference under section 37 above, to be entitled to be granted that patent or to be granted a patent for part of the matter comprised in the specification of the patent sought to be revoked; and
- (b) may not be made if that action was commenced or that reference was made after the second anniversary of the date of the grant of the patent sought to be revoked, unless it is shown that any person registered as a proprietor of the patent knew at the time of the grant or of the transfer of the patent to him that he was not entitled to the patent.
- Thus revocation of a patent on the ground that the patent was granted to a person who was not entitled to be granted that patent may only be sought by a person who has already satisfied the court or the comptroller that he himself should have been the or a proprietor. (See also 37.05 and 37.15). No one else may apply for revocation on this ground. Nor may any application be made on this ground unless proceedings to contest the proprietor's right to the patent had been started by, at the latest, the second anniversary of the date of grant, unless the applicant can show bad faith on the part of the proprietor.

[Section 72(3) Repealed]

72.41 Section 72(3) was concerned with patents for inventions requiring microorganisms for their performance. This was repealed by the CDP Act, and the equivalent provision is now in section 125A.

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Section 72(4)

r.75

An order under this section may be an order for the unconditional revocation of the patent or, where the court or the comptroller determines that one of the grounds mentioned in subsection (1) above has been established, but only so as to invalidate the patent to a limited extent, an order that the patent should be revoked unless within a specified time the specification is amended to the satisfaction of the court or the comptroller, as the case may be.

If the case for revocation has not been made out, and amendments have been proposed by the proprietor during the hearing, the hearing officer must ensure that the amendments are advertised (see <u>Tribunal Patents Manual</u> paragraph 14.30, and chapter 23) unless they are clearly not allowable or would not cure invalidity. If the amendments are to be advertised the issue of a final decision should be deferred until the procedure described in 75.05 has been followed. If the amendments are not to be advertised, or if the specification had already been amended before the hearing (see 72.11-72.13), or if no amendments have been offered, a final decision should be issued dismissing the application for revocation.

[In the case of revocation proceedings where the applicant has withdrawn, when a decision is due to issue, Tribunal Section should be instructed to prepare a Decisions Form; Form B should be used where the applicant has withdrawn unconditionally and there have been no amendments, Form D' where the applicant has withdrawn conditionally (see 72.32-72.34) and Form G' where the specification has been amended following an unconditional withdrawal (see 72.29-72.31). The Deputy Director should sign but not date the decision. Tribunal Section should apply the appropriate electronic signature, prepare copies of the signed decision, date them and send them to each of the parties.

[When a decision authorises amendment of a specification, the amendments are shown in a copy of the specification attached to the decision. After issue of the decision, the amendments should be incorporated into the original specification by Tribunal Section and upon receipt of confirmation from the hearing officer a certificate with the appropriate electronic signature is placed on the dossier. If the amendments are extensive, Tribunal Section should request retyped pages in accordance with r.35(6) if these have not already been filed. The file should then be referred to the hearing officer (or Deputy Director where the applicant has withdrawn). Where there is an assistant he should check the amendments and the certificate with the appropriate electronic signature is then placed on the dossier.]

72.43 When the hearing officer decides that one or more of the grounds for revocation has been made out but that the defects of the patent might be cured by amendment of the specification he may if he sees fit issue an interim decision giving the proprietor a specified period, normally two months, in which to amend to meet the findings and thereby avoid revocation (see also 72.44.1). A factor in deciding whether to give an opportunity to amend (see 75.04) is the necessity for further proceedings to determine validity of any amendments. In Nikken Kosakusho Works v Pioneer Trading Co. [2006] FSR 4, the Court of Appeal drew a distinction between post-trial amendments only involving deletion of invalid claims or re-writing claims to exclude various dependencies, and those where the patentee sought to introduce a different claim which had not been under attack at the trial, where there was bound to be a further battle in proceedings over the proposed amendments to determine their validity. Considering the overriding objective of the Civil Procedure Rules that in any given litigation the parties are required to bring forward their whole case and the specific requirements of Part 1.1.2 of the CPR that the court should deal with cases justly by saving expense and ensuring that they were dealt with expeditiously and fairly, the court held that the latter sort of post-trial amendment should not be allowed if it would involve a second trial on validity.

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Monkey Tower Ltd v Ability International Ltd [2013] EWHC 18 (Pat) provided more details about the factors to be considered when deciding whether to exercise discretion to allow an opportunity to amend. Henry Carr QC, sitting as a Deputy Judge, explained that it is necessary for the comptroller to have regard to all circumstances which are relevant to the question of procedural fairness to the parties. These circumstances might include:

- a) The resources already devoted by the parties to the proceedings.
- b) The extent of any re-litigation as a result of the amendment.
- c) The likelihood that a valid amendment can be proposed.
- d) Whether there is evidence that prejudice will be caused to the applicant for revocation by the delay caused by an application to amend.

Where the hearing officer does not see fit to allow such an opportunity to amend, or it appears that no saving amendment is possible, a final decision should be issued revoking the patent without allowing an opportunity to amend.

[Any request for extension of the specified period should be referred by the action officer to the hearing officer.]

When amendments are submitted following an interim decision the applicant should be invited to comment within a period specified in the decision, usually one month. If a dispute is apparent the proprietor should be allowed a similar period in which to reply. A further hearing may be necessary if no agreement is reached. A further interim decision may be issued with or without a further hearing. If the amendments are allowable and meet the terms of the interim decision the matter should proceed as described in 72.42.

Section 72(4A)

The reference in subsection (4) above to the specification being amended is to its being amended under section 75 below and also, in the case of a European Patent (UK), to its being amended under any provision of the European Patent Convention under which the claims of the patent may be limited by amendment at the request of the proprietor.

72.44.1 Article 138(3) EPC provides a central amendment process for European Patents. This is an alternative to the existing possibility of the proprietor amending the patent under the 1977 Act. In the former case, the amendments are effective in each Contracting State designated by the patent whereas the latter would only affect the European patent (UK). This subsection makes it clear that references to the patent being amended take account of the central limitation process at the EPO.

Section 72(5)

A decision of the comptroller or on appeal from the comptroller shall not estop any party to civil proceedings in which infringement of a patent is in issue from alleging invalidity of the patent on any of the grounds referred to in subsection (1) above, whether or not any of the issues involved were decided in the said decision.

Section 72(6)

Where the comptroller refuses to grant an application made to him by any person under this section, no application (otherwise than by way of appeal or by way of putting validity in issue in proceedings for infringement) may be made to the court by that person under this section

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in relation to the patent concerned, without the leave of the court.

Section 72(7)

Where the comptroller has not disposed of an application made to him under this section, the applicant may not apply to the court under this section in respect of the patent concerned unless either -

- (a) the proprietor of the patent agrees that the applicant may so apply, or
- (b) the comptroller certifies in writing that it appears to him that the question whether the patent should be revoked is one which would more properly be determined by the court.
- CPR 63.11 72.45 The comptroller may decide that it appears to him that the question whether the patent should be revoked should be more properly determined by the court. In such a case any person seeking the court's determination of that question must issue a claim form within 14 days of the comptroller's decision.

[Further guidance on certification that revocation would more properly be determined by the court is given in Chapter 2 of the Patent Hearings Manual]

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Section 73: Comptroller's power to revoke patents on his own initiative

This section specifies the only grounds on which a patent may be revoked other than at the request of a third party.

Section 73(1)

If it appears to the comptroller that an invention for which a patent has been granted formed part of the state of the art by virtue only of section 2(3) above, he may on his own initiative by order revoke the patent, but shall not do so without giving the proprietor of the patent an opportunity of making any observations and of amending the specification of the patent so as to exclude any matter which formed part of the state of the art as aforesaid without contravening section 76 below.

73.02 Proceedings under s.73(1) will be initiated after the grant of a patent where a relevant document has been brought to the attention of the examiner (either because of actions within the Office or as a result of observations from a third party - see 21.17) after the date of issue of the letter informing the applicant that the application is in order (see 18.88). Unless the examiner is not satisfied that the pre-grant search was complete for art in the s.2(3) field (see 17.118), no search is done after grant as a matter of course for such documents. Action may also be taken under s.73(1) in the exceptional case where it has not been possible before the end of the s.20 period to obtain a copy of the priority document of a cited European application (UK) in order to determine whether or not it has an earlier priority date than the invention (see 18.18). Proceedings under s.73(1) may also be initiated in the event that an opinion is issued which concludes that a granted UK patent or European patent (UK) lacks novelty over a patent application which forms part of the state of the art under section 2(3) (see 74A.11.1)

73.02.1 Where the patent is a European patent (UK), the examiner should ensure that they are referring to the latest version of the patent, which could have been amended under the central limitation procedure at the EPO.

A UK or European patent application which was withdrawn prior to 73.02.2 publication, but too late to prevent publication, is not considered to form part of the state of the art under s.2(3) (Woolard's Application [2002] RPC 39 - see 2.32). The examiner should therefore check the status of the potential s.2(3) citation, and if it is withdrawn, the date on which it was withdrawn.

[The status of a UK application, including the date of any withdrawal, can be checked using the DISPLAY FULL REGISTER function on the Common Enquiries Menu of COPS. The status of an EP application, including the date of any withdrawal, can be checked using the European Patent Register.]

When action appears necessary the proprietor must be informed and must be given a period within which to submit observations and/or amendments. A suitable r.109 period is normally three months, although a shorter period may be specified at the comptroller's discretion, and this period may be extended under r.109. (The amendments must comply with s.76. They are not advertised since s.73 proceedings are ex parte and so third parties cannot intervene.) If leave to amend is given, the applicant may be required to file a new specification as amended, prepared in accordance with rules 12 and 14, before

the amendment is effected. Any offer to amend and its outcome should be specifically recorded on the Register.

73.03.1 Proceedings under s.73(1) should normally be initiated using Letter Clause PL2. However where the document was a European application cited before grant but action was deferred because of non-availability of priority documents (see 73.02, 18.18), Letter Clause PL1 should be used.

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r.35(6)

[(a) A report should be made by the examiner in a minute and the case referred to Restoration and Post Grant Section (RAPS) who will arrange for the action to be noted in the Register, for the appropriate letter to be issued, and for the case to be referred back to the examiner on receipt of any amendments and/or observations.]

[The examiner should add the minute to the dossier, addressing the minute to RAPS, and a PDAX message should be sent to the RAPS mailbox.]

[(b) If the examiner is satisfied after consideration of any amendments and/or observations submitted by the proprietor that revocation is not necessary, he should report this in a minute and the case should be referred to RAPS. RAPS will create a minute and send a message to the Deputy Director in charge of the group of the examiner considering the amendment. The Deputy Director will confirm whether the amendments are allowable and that Decision Form 1, 1a or 2a can be prepared. Where amendments have been allowed, RAPS should effect them in the specification and prepare a certificate for signature by the Deputy Director. The case should be referred to Publishing Section for the issue of a 'C' publication as described in 27.20. Unless the amendments can be dealt with in the 'C' publication by means of a schedule, RAPS should firstly obtain a retyped specification from the patentee under r.35(6).]

[The examiner should add the minute to the dossier, addressing the minute to RAPS, and a PDAX message should be sent to the RAPS mailbox]

[(c) If amendments and/or observations are received but the examiner cannot be satisfied that the objection is overcome, and further amendments appear possible, a further period may be specified in order to allow such amendments to be filed. The time periods specified may be extended if appropriate under s.117B and rule 109. If no agreement can be reached, a hearing should be offered to be taken by the Deputy Director. The examiner should report to the Deputy Director before the hearing. If the Deputy Director decides, as a result of the hearing, that the patent should be revoked, he should issue a reasoned decision to that effect.]

[The examiner should record his objection(s) in a minute which should be added to the dossier and addressed to RAPS and a PDAX message should be sent to the RAPS mailbox. The objection(s) should be stated in a form which is suitable for inclusion in an official letter, which will be sent over the signature of a member of RAPS but will give the name and telephone number of the examiner. RAPS will inform the applicant of the latest date for response and will deal with requests for extensions of time periods.]

- [(d) Where the proprietor responds but raises no objection to revocation of the patent or leaves the question of revocation to be decided by the comptroller, RAPS should prepare Decision Form 3a and refer the case along with the Decision Form to the group Deputy Director for his signature.]
- [(e) If the proprietor fails to reply to Letter Clause PL1 or PL2, RAPS should offer a hearing by issuing Letter Clause PL4. If there is still no response from the proprietor, RAPS should prepare Decision Form 5 and refer the case along with the Decision Form to the group Deputy Director for his signature.]
- Article 54(3) of the EPC specifies that the only document published on or after the filing date of an application for a European patent which forms part of the state of the art for that application is another European application. If follows therefore that a European patent (UK) may be validly granted by the EPO even though the invention is disclosed in a published UK patent application having an earlier priority date. Such a patent could however then be revoked by the comptroller under s.73(1). An examiner who becomes aware of such a situation should proceed as described in paragraph 73.03. Such action should also be taken where a European patent (UK) is clearly anticipated by another European patent application (UK) which form part of the state of the art by virtue of s.2(3)

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and EPC a.54(3) but which was not cited by the EPO.

[Action under s.73(1) against a European patent (UK) should be initiated using Letter Clause PL2.

[Action to cite a prior European application against a European patent (UK) under s.73(1) should be taken only in the clearest cases, and in any case should not be taken if the application had been indicated on the printed European patent specification as having been cited by the EPO.]

Section 73(1A)

Where the comptroller issues an opinion under section 74A that section 1(1)(a) or (b) is not satisfied in relation to an invention for which there is a patent, the comptroller may revoke the patent.

Section 73(1B)

The power under subsection (1A) may not be exercised before—

- (a) the end of the period in which the proprietor of the patent may apply under the rules (by virtue of section 74B) for a review of the opinion, or
- (b) if the proprietor applies for a review, the decision on the review is made (or, if there is an appeal against that decision, the appeal is determined).

Section 73(1C)

The comptroller shall not exercise the power under subsection (1A) without giving the proprietor of the patent an opportunity to make any observations and to amend the specification of the patent without contravening section 76.

73.04.1 Proceedings under s.73(1A) will be considered where an opinion issued under section 74A has concluded that the invention in a granted patent is not new or does not involve an inventive step. The patent cannot be revoked until EITHER the period for requesting a review of the opinion (which is three months from the date of issue of the opinion) has expired and no review has been requested OR, where a review has been requested, until after a decision has been made on the review (and if there is an appeal against that decision, the appeal has been determined) and that decision and any appeal has upheld the opinion. However, action under section 73(1A) may be initiated during the period for requesting a review. Action should not be initiated if a review has already been requested.

[Once the opinion has been issued, Tribunal Section should send a message to the group head (who handles the relevant subject matter), who should consider whether action under section 73(1A) is necessary. Action under this section should only be initiated if the group head considers that the patent is clearly invalid due to lack of novelty or inventive step. The opinion should be considered but the group head is in no way bound by it.]

- 73.04.2 Where the patent is a European patent (UK), the group head should ensure that they are referring to the latest version of the patent, which could have been amended under the central limitation procedure at the EPO.
- 73.04.3 If action under s.73(1A) appears necessary, the procedure described below should be followed.
 - [(a) The group head should report in a minute whether or not action is justified under s.73(1A) and refer the case to Tribunal Section who will arrange for an appropriate entry in the Register, for the appropriate letter to be issued, and for the case to be referred back to the group head on receipt of any amendments and/or

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observations.]

[The group head should add the minute to the dossier, addressing the minute to Litigation Section, and a PDAX message should be sent to the Litigation mailbox. The minute should also confirm that the group head is content for the case not to be referred back to them in the event that the proprietor fails to reply (see point (e) below).]

- [(b) If the group head is satisfied after consideration of any amendments and/or observations submitted by the proprietor that revocation is not necessary, they should report this in a minute and the case should be referred to Tribunal Section. The group head should confirm that any amendments are allowable and that Decision Form 1A or 2A can be prepared. Where amendments have been allowed, Tribunal Section should effect them in the specification and prepare a certificate for signature by the group head. The case should be referred to Publishing Section for the issue of a 'C' publication as described in 27.20. Unless the amendments can be dealt with in the 'C' publication by means of a schedule, Tribunal Section should firstly obtain a retyped specification from the patentee under r.35(6).
- [The group head should add the minute to the dossier, addressing the minute to Litigation Section, and a PDAX message should be sent to the Litigation mailbox]
- [(c) If amendments and/or observations are received but the group head cannot be satisfied that the objection is overcome, and further amendments appear possible, a further period may be specified in order to allow such amendments to be filed. The time periods specified may be extended if appropriate under s.117B and rule 109. If no agreement can be reached, a hearing should be offered to be taken by a Deputy Director (DD). If the DD decides, as a result of the hearing, that the patent should be revoked, they should issue a reasoned decision to that effect.]

[The group head should record their objection(s) in a minute which should be added to the dossier and addressed to Litigation Section, and a PDAX message should be sent to the Litigation mailbox. The objection(s) should be stated in a form which is suitable for inclusion in an official letter, which will be sent over the signature of a member of Tribunal Section but will give the name and telephone number of the group head. Tribunal Section will inform the proprietor of the latest date for response and will deal with requests for extensions of time periods.]

- [(d) Where the proprietor responds but raises no objection to revocation of the patent or leaves the question of revocation to be decided by the comptroller, Tribunal Section should prepare Decision Form 3A and refer the case along with the Decision Form to the group head for their signature.]
- [(e) If the proprietor fails to reply Tribunal Section should issue Decision Form 5A on behalf of the group head.]

Section 73(2)

If it appears to the comptroller that a patent under this Act and a European patent (UK) have been granted for the same invention having the same priority date, and that the applications for the patents were filed by the same applicant or his successor in title, he shall give the proprietor of the patent under this Act an opportunity of making observations and of amending the specification of the patent, and if the proprietor fails to satisfy the comptroller that there are not two patents in respect of the same invention, or to amend the specification so as to prevent there being two patents in respect of the same invention, the comptroller shall revoke the patent.

Section 73(3)

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The comptroller shall not take action under subsection (2) above before -

- (a) the end of the period for filing an opposition to the European patent (UK) under the European Patent Convention, or
- (b) if later, the date on which opposition proceedings are finally disposed of;

and he shall not then take any action if the decision is not to maintain the European patent or if it is amended so that there are not two patents in respect of the same invention.

73.05 Subsections (2) to (4) empower the comptroller to revoke a 1977 Act patent which is for the same invention as a European patent (UK), in certain circumstances, in order to avoid having two patents in force in the UK for that invention. However, conflict with a granted European patent (UK) does not constitute a reason for the comptroller to refuse to grant a patent in the UK.

73.06 The tests for determining whether the two patents relate to the same invention are the same as for deciding whether two UK applications are in conflict (see 18.91-18.97.1).

If an examiner becomes aware of a European application or patent (UK), or an international application designating GB (European Patent), which apparently relates to the same invention as an application with which he is dealing, both applications being filed by the same applicant and having the same priority date, he should warn the applicant that if this application proceeds to grant (after entering the regional phase in the case of an international application), revocation under s.73(2) may subsequently need to be considered. If the application is due to be sent for grant, or if a patent has already been granted on it, then the examiner should decide whether or not to issue a warning letter if no other matters arise. It will be appropriate to issue a letter if it is considered that the agent/applicant may not be aware of the consequences of s.73(2) (e.g. for private applicant cases); alternatively, a telephone call to the agent to alert them to the possible conflict may suffice. An opportunity to withdraw the UK application should not be offered if the application has already been marked in order for grant. For the case when the conflicting application is an international application designating the UK (i.e. not a European patent (UK)), see 18.91.

[The examiner should ensure that they are referring to the latest version of the European patent (UK), as it could have been amended under the central limitation procedure at the EPO.]

[A warning to the applicant should be given by adding clause RC31 to the examination report under s.18(3) or to EL3 in the appropriate circumstances regardless of whether the corresponding EP(UK) patent has already been granted. If the potential conflict is with an international application designating EP(UK) which has not yet entered the regional phase, RC31 will be used with the WO publication number]

[If the application is in order and an intention to grant letter will be issued by the examiner assistants. The examiner should write a minute and send a PSM message to the examiner assistants to ask them to include the RC31 clause in the intention to grant letter. This ensures the applicant is notified about possible conflict (see 18.81 and 18.86.2 for detail on the intention to grant process).]

[Examiners can determine whether an international application has entered the regional phase by checking on the European Register, e.g. using the European Patent Register (the COPS function DIS EQU cannot be used to obtain this information). An international application will normally be recorded on the European Patent Register as having entered the regional phase within 40 months from the priority date. The COPS function DIS FUL will give information about an EP(UK) once granted, including about the filing of any opposition proceedings. If there is reason to suspect that the relevant record is inaccurate or incomplete, the matter

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should be referred to Patents IT BAU Team.]

[Restoration and Post-grant section (RAPS) will identify all granted GB patents that have granted EP(UK) equivalents and maintain an active electronic report of these cases showing the status of each. For those GB patents where an assessment of conflict has been made, this RAPS report will indicate the action taken (for example: "no action", "PL3 issued", "revoked", etc.). The report will be periodically updated by cross-referencing IPO records with data received from the EPO to identify GB patents with potential s.73(2) conflict. For each newly identified GB patent, RAPS will first determine if the EP equivalent is in the opposition period. If so, no further action can be taken under s.73(3)(a), and RAPS will therefore indicate the earliest date on which the case should be re-inspected. Where opposition proceedings are ongoing, further action will again be deferred until such proceedings are disposed of under s.73(3)(b). If the opposition period for the EP equivalent has ended (or opposition proceedings have been disposed of), RAPS will then determine whether the EP equivalent no longer designates UK, or has been refused, revoked or ceased. In these circumstances action under s.73(2) does not need to be initiated. It is possible to ascertain whether the European patent application has been refused, withdrawn or treated as withdrawn or the UK designation has been withdrawn (thus removing the possibility of section 73(2) action) from the same COPS function. Furthermore, the European patent may have been centrally revoked at the EPO. It can be determined if this is the case by checking on the European Register, e.g. using the European Patent Register All enquiries as to register status should be recorded in a minute.]

[RAPS will determine if an application to surrender the EP(UK) has been made before its date of grant (see 73.11-12 for where an offer to surrender the EP(UK) patent has been made). If no application to surrender has been made prior to grant, RAPS will then determine if the EP patent designates UK; if no UK designation is present, no action is required and RAPS will record this accordingly in their report. If the EP patent designates UK, an assessment of conflict will be necessary.]

[The above procedure will be used even where either or both of the GB or EP(UK) patents have ceased due to non-payment of renewal fees. Under these circumstances there will have been a period of time where both patents will have been in force at the same time (and therefore potentially in conflict), which the applicant retains legal rights to even though the patent has ceased. See 73.10.]

EPC a.99 73.08 In accordance with subsection (3), action to revoke a patent under s.73(2) cannot be taken until after either the date of expiry of the period within which an opposition to the European patent may be filed, i.e., nine months from the publication of the mention of the grant in the European Patent Bulletin, or the date when any opposition proceedings are disposed of by a decision to maintain the European patent, or, if later than either of these dates, the date when notice of grant of the UK patent is published in the Journal. The amended section removes any doubt which there might previously have been as to what should happen if the European patent (UK) failed as a result of opposition proceedings: it is now made clear that revocation action should not be taken. The "decision" in question in s.73(3) is that of the EPO in determining opposition proceedings (*Citizen Watch Ltd's Patent* [1993] RPC 1).

[The date of publication of the mention of the grant in the European Patent Bulletin is the same as the date of publication by the EPO of the specification as granted, this date being given on COPS (see 73.07).]

73.09 If, after the relevant date (see 73.08), action under s.73(2) appears necessary, this should be taken as described below in paragraph 73.09.1. Although under previous practice it would have been considered unnecessary to take action under s.73(2) if a UK patent had been surrendered or have lapsed, action under s.73(2) should be taken for

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all granted UK patents, even if they have been surrendered or have lapsed. Similarly, it would have previously been considered unnecessary work if an offer to surrender the UK patent had been made, unless the offer was withdrawn or refused; however s.73(2) action should be taken on these UK patents too.

73.09.1 Action should be initiated by the issue of Letter Clause PL3. This gives a period of two months (reducible at the comptroller's discretion) for the proprietor to submit amendments and/or observations.

- [(a) RAPS will create a "Section 73(2)" PAFS action and forward the case via PDAX to an examiner assistant for a preliminary assessment of conflict. If the examiner assistant identifies any identically worded claims or combinations of claims, they will report this in PROSE form GBEPCONF and send the associated checklist via a PDAX message to the RAPS mailbox. RAPS will then complete the PAFS action, and arrange for the action to be noted in the Register and for the Letter Clause PL3 to be issued. The claims of the EP(UK) may be centrally amended before the EPO, and care should be taken to ensure that the latest version of the claims is considered when assessing the requirement for revocation action under section 73(2).
- If the examiner assistant cannot identify any identically worded claims or combinations of claims, they will report this to RAPS and the PAFS action will be transferred to the examiner, who will make their assessment of conflict and report their findings in PROSE form GBEPCONF, sending the associated checklist to RAPS once complete. Where conflict is present, the PROSE form should indicate that revocation action should commence in respect of the patent, outlining the reasons why claim conflict exists. The content of PROSE form GBEPCONF should be recorded in a form which is suitable for inclusion in the official PL3 letter, which will be sent with the signature of a member of RAPS but will give the name and telephone number of the examiner. Note that only examiners can report a status of "no conflict". If amendments or observations are made in a response to the PL3 letter, RAPS will refer them to the examiner and create a new PAFS action.]
- [(b) If amendments and/or observations are submitted by the proprietor and the examiner is satisfied that the UK patent and the European patent (UK) are no longer in conflict, he should report this in PROSE form GBEPCONF and the case should be referred to RAPS. RAPS will create a minute and send a message to the Deputy Director or group head in charge of the group of the examiner considering the amendment. The Deputy Director or group head will confirm whether the amendment is acceptable and that Decision Form 1B, 1C or 2 can be prepared. Where amendments have been allowed, RAPS should effect them in the specification and prepare a certificate for signature by the Deputy Director or group head. The case should be referred to Publishing Section for the issue of a 'C' publication as described in 27.19.]
- [(c) If the proprietor offers amendments and/or observations but fails to satisfy the examiner that the UK patent and the European patent (UK) are no longer in conflict, but further amendments appear possible, a further period may be specified in order to allow such amendments to be filed. The time periods specified may be extended if appropriate under s.117B and rule 109. If no agreement can be reached, a hearing should be appointed (see 73.03.1) to be taken by the Deputy Director or group head. A report should be made to the Deputy Director or group head before the hearing. If the Deputy Director or group head decides, as a result of the hearing, that the patent should be revoked, they should issue a reasoned decision to that effect.]

[The examiner should record his objection(s) in PROSE form GBEPCONF and a PDAX checklist message should be sent to the RAPS mailbox. The objection(s) should be stated in a form which is suitable for inclusion in an official letter, which will be sent over the signature of a member of RAPS but will give the name and

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telephone number of the examiner. RAPS will inform the applicant of the latest date for response and will deal with requests for extensions of time periods.]

- [(d) Where the proprietor responds but raises no objection to revocation of the patent or leaves the question of revocation to be decided by the comptroller, RAPS should prepare Decision Form 3 and refer the case along with the Decision form to the group Deputy Director or group head for their signature.]
- [(e) If the proprietor does not respond to Letter Clause PL3, RAPS should issue Letter Clause PL5 offering a hearing and, if there is still no response from the proprietor, RAPS should prepare Decision Form 6 and refer the case along with the Decision Form to the Deputy Director or group head for their signature.]

EPC r.39, a.105a s.27(3) 73.10 It is not possible to withdraw the UK designation after grant of the European patent. Nor does s.73(2) allow the comptroller discretion instead to revoke the European patent (UK). One way envisaged by s.73(2) to avoid revocation of the UK patent is to amend the specification of the UK patent to remove the conflict. Such amendment is deemed to take effect from the date of grant, so that any double grant that may have taken place will be nullified. Any amendments offered under s.73(2) are not advertised since s.73 proceedings are ex parte and so third parties cannot intervene. A further alternative available to the proprietor may be to request central revocation of the European patent before the EPO under EPC Article 105a. This allows the proprietor to request that their patent is revoked in all Contracting States in which the patent is in force. If the request is allowed, the revocation takes place ab initio having the effect of nullifying any double grant. Another course open to the patentee seeking to avoid revocation under s.73(2) is to make observations. In Henry Reed v Sir James Laing & Sons Ltd (BL C/74/96) Laddie J allowed amendment of the European patent (UK) under s.27 to avoid s.73(2) conflict even though the patent had lapsed. In this case Laddie J did not view a delay of 2½ years in seeking amendment enough to justify refusing leave to amend since the question whether or not the patent protection should proceed under the UK patent or the European patent (UK) or whether both could survive side by side was much more a matter of patent formality than substance.

Another option available to the proprietor may be to amend the European patent (UK) under s.27 to remove the conflict (see 27.03-27.06 and 27.12-27.17 for further details of this process). In such circumstances, the s.27 proceedings should have a clear timetable in order to expedite the s.73(2) proceedings. The procedure for advertising the notice of such amendments in the Journal is the same as that of other requests to amend under s.27 (see 27.20) The patent proprietor also has the option of amending his patent centrally before the EPO. If this course of action is taken then the time periods specified by the comptroller will still apply (see 73.09.1). If the patent in question has lapsed; the effect of the patent would be altered for the time it was in force as well as if it were to be restored. If s.28 proceedings are commenced for restoration of a lapsed European patent (UK) in case the corresponding UK patent gets revoked, but are not pursued following successful disposal of the s.73(2) proceedings, refund of the s.28 proceedings fee is not normally appropriate. See 73.11-12 for a further option open to the patentee.

Section 73(4)

The comptroller shall not take action under subsection (2) above if the European patent (UK) has been surrendered under section 29(1) above before the date on which by virtue of section 25(1) above the patent under this Act is to be treated as having been granted or, if proceedings for the surrender of the European patent (UK) have been begun before that date, until those proceedings are finally disposed of; and he shall not then take any action if the decision is to accept the surrender of the European patent.

73.11 Section 73(4) gives an opportunity to avoid revocation of the UK patent by, before grant of the UK patent, offering to surrender the corresponding European patent (UK). Surrender differs from revocation in that it is not fully retrospective in effect. There

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may, therefore, be a period in which two patents are in force for the same invention, but as one of those patents will be under notice of surrender throughout that period, nobody will be misled. However, once objection under s.73(2) has been made, revocation of the UK patent cannot be avoided by allowing the EP(UK) patent to lapse by non-payment of renewal fees, irrespective of whether the EP(UK) lapsed before or after the grant of the corresponding UK patent (*Albright & Wilson Ltd's Patent* (BL O/190/92) and *Citizen Watch Ltd's Patent* [1993] RPC 1).

- 73.11.1 For the avoidance of doubt, s.73(4) makes it clear that the date at which the UK patent is to be treated as granted for this purpose is governed by s.25(1). In other words, for the purpose of the s.73(4), as with all provisions of the Act following s.25(1), the effective date of grant is the date on which the notice of grant appears in the Journal. The grant letter informing the applicant under s.18(4) that the UK application complies with the requirements of the Act and Rules and that a patent is therefore granted is issued several weeks before this date. This letter also informs the applicant of the date on which notice of the grant will be published in the Journal. Receipt of this letter therefore potentially gives the applicant a short window of time in which they can offer to surrender the European patent (UK) under s.29, secure in the knowledge that the UK patent will shortly come into force.
- Revocation action should not be initiated if an offer to surrender the European patent (UK) under s.29 has been made and either been accepted or is still pending when the UK patent is granted. Such an offer should follow the procedure in 29.02-06. If however the offer is refused, action under s.73(2) should then be taken in the usual way. Where there are ongoing court proceedings which could result in an EP(UK) being revoked, this does not prevent revocation action being initiated under s.73(2) against a conflicting UK patent.

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PUTTING VALIDITY IN ISSUE

Section 74: Proceedings in which validity of patent may be put in issue

74.01 This section is concerned with putting the validity of a patent in issue, including the proceedings in which it can be done (s.74(1)-(2)), the grounds on which it can be done (s.74(3)), the relationship of the determination of validity with the determination of entitlement (s.74(4)-(6)) and the effect of pending court proceedings on the institution of proceedings before the comptroller (s.74(7)).

s.77(1) 74.02 It also applies in relation to applications for a European patent (UK) to the extent indicated in s.78(2), and in relation to granted European patents (UK).

Section 74(1)

Subject to the following provisions of this section, the validity of a patent may be put in issue -

- (a) by way of defence, in proceedings for infringement of the patent under section 61 above or proceedings under section 69 above for infringement of rights conferred by the publication of an application;
- (b) in proceedings in respect of an actionable threat under section 70A above;
- (c) in proceedings in which a declaration in relation to the patent is sought under section 71 above;
- (d) in proceedings before the court or the comptroller under section 72 above for the revocation of the patent;
- (e) in proceedings under section 58 above.

Section 74(2)

The validity of a patent may not be put in issue in any other proceedings and, in particular, no proceedings may be instituted (whether under this Act or otherwise) seeking only a declaration as to the validity or invalidity of a patent.

Proceedings in which validity may be questioned

s.74(8)

74.03

Validity cannot be put in issue except in proceedings under the Act as above defined, i.e. ss.58 (disputes as to Crown use), 61 (infringement of patent), 69 (infringement of rights conferred by publication of application), 70A (unjustified threats of infringement proceedings), 71 (declaration as to non-infringement) and 72 (revocation of patents on application). Section 73 is specifically excluded by a declaration that the validity of a patent is not put in issue merely because the comptroller is considering its validity in order to decide whether to revoke it under s.73. There are no other proceedings in which validity may be put in issue, proceedings directed solely to the question of validity being specifically prohibited. This includes a non-statutory claim for a declaration of non-infringement pursuant to the inherent jurisdiction of the court (*Organon Teknika Ltd v F. Hoffmann-La Roche AG* [1996] FSR 383).

74.03.1 S.74(2) does not exclude oppositions in the European Patent Office since s.77(2) specifically preserves the jurisdiction of the European Patent Office to revoke a European

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patent (UK) (see 77.08) (Organon Teknika Ltd v F. Hoffmann-La Roche AG [1996] FSR 383).

74.03.2 Although section 74 does not allow validity to be put in issue in inventorship or entitlement disputes, the Court of Appeal in *Markem Corp v Zipher Ltd* [2005] RPC 31 held that if a clear and unarguable attack on validity is raised, there is no reason why the Comptroller should not take it into account as part of his wide discretion in determining such disputes (see 8.09).

74.03.3 Section 74(1)(b) was amended by the Intellectual Property (Unjustified Threats) Act 2017 to refer to the relevant part of the threats provisions as reformed by that Act, namely to an actionable threat under section 70A.

Section 74(3)

The only grounds on which the validity of a patent may be put in issue (whether in proceedings for revocation under section 72 above or otherwise) are the grounds on which the patent may be revoked under that section.

Grounds on which validity may be questioned

74.04 Validity cannot be put in issue except on one or more of the grounds set out in s.72(1) (see 72.03).

Section 74(4)

No determination shall be made in any proceedings mentioned in subsection (1) above on the validity of a patent which any person puts in issue on the ground mentioned in section 72(1)(b) above unless -

- (a) it has been determined in entitlement proceedings commenced by that person or in the proceedings in which the validity of the patent is in issue that the patent should have been granted to him and not some other person; and
- (b) except where it has been so determined in entitlement proceedings, the proceedings in which the validity of the patent is in issue are commenced on or before the second anniversary of the date of the grant of the patent or it is shown that any person registered as a proprietor of the patent knew at the time of the grant or of the transfer of the patent to him that he was not entitled to the patent.

Section 74(5)

Where the validity of a patent is put in issue by way of defence or counterclaim the court or the comptroller shall, if it or he thinks it just to do so, give the defendant an opportunity to comply with the condition in subsection (4)(a) above.

Section 74(6)

In subsection (4) above "entitlement proceedings", in relation to a patent, means a reference under section 37(1) above on the ground that the patent was granted to a person not entitled to it or proceedings for a declaration or declarator that it was so granted.

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Determination of validity on entitlement ground

s.130(7) 74.05 Sub-sections (4) to (6) are concerned only with proceedings in which validity is put in issue on the entitlement ground set out in s.72(1)(b). Sub-section (4) is so framed as to have, as nearly as practicable, the same effects as the corresponding provisions of the EPC, CPC and PCT. Articles 27 and 56(1) of the CPC (renumbered as Articles 23 and 55(1) [1989]) appear to be in question.

74.06 Validity cannot be determined on that ground unless it has first been determined that the patent should have been granted to the person who has put validity in issue and not some other person. The proceedings in which such determinations can be made are defined in s.74(4)-(6).

Section 74(7)

Where proceedings with respect to a patent are pending in the court under any provision of this Act mentioned in sub-section (1) above, no proceedings may be instituted without the leave of the court before the comptroller with respect to that patent under section 61(3), 69, 71 or 72 above.

Proceedings pending in the court in which validity may be put in issue preclude the institution of certain proceedings before the comptroller unless the court gives leave, as detailed in subsection (7). However, court proceedings for infringement may be stayed pending the outcome of proceedings under ss.71 and 72 before the comptroller (Hawker Siddeley Dynamics Engineering Ltd v Real Time Developments Ltd [1983] RPC 395). In Cayless & Sci-Sport Limited v Barton & Cullis (BL O/073/98), an application under s.71(1) for a declaration of non-infringement was seriously defective and the proprietors of the patent then launched a High Court infringement action. The hearing officer subsequently refused to allow amendment of the s.71(1) application, holding that the application had not properly been launched and that the amendment would have effectively been the institution of the proceedings in the meaning of s.74(7).

Section 74(8)

It is hereby declared that for the purposes of this Act the validity of a patent is not put in issue merely because -

- (a) the comptroller is considering its validity in order to decide whether to revoke it under section 73 above, or
- (b) its validity is being considered in connection with an opinion under section 74A below or a review of such an opinion.

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OPINIONS BY INTELLECTUAL PROPERTY OFFICE

Section 74A: Opinions on matters prescribed in the rules

74A.01 Section 74A was introduced by the Patents Act 2004 and came into force on 1 October 2005. The section provides for a procedure where the comptroller can issue, on request, non-binding opinions. Initially such opinions were restricted to questions of validity relating to novelty or inventive step, and questions of infringement. On 1 October 2014, section 74A was amended by the Intellectual Property Act 2014, such that from this date onwards the matters on which an opinion can be requested are set out in rule 93(6).

[The Patents Opinions Service Procedures Manual should be consulted for full details of practice concerning opinions under section 74A and reviews of opinions under section 74B.]

Section 74A(1)

The proprietor of a patent or any other person may request the comptroller to issue an opinion on a prescribed matter in relation to the patent.

Section 74A(2)

Subsection (1) above applies even if the patent has expired or has been surrendered.

Making a request for an opinion

r.92 r.93 sch 4A, para 1(2)

r.93

74A.02 Anyone may ask the comptroller for an opinion on infringement or validity in relation to a UK patent, European patent (UK), or supplementary protection certificate (SPC), whether in force or not, except when the patent has been revoked or the SPC declared invalid. However, opinions on infringement or validity are limited to the matters set out in rule 93(6):

- (a) whether a particular act constitutes, or (if done) would constitute, an infringement of the patent;
- (b) whether, or to what extent, an invention for which the patent has been granted is not a patentable invention (as set out in s.1(1));
- (c) whether the specification of the patent discloses the invention clearly enough and completely enough for it to be performed by a person skilled in the art;
- (d) whether the matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent as filed or, if the patent was granted on a a divisional application under s.15(9) or a new application filed under s.8(3), s.12(6) or s.37(4), in the earlier application as filed;
- (e) whether the protection conferred by the patent has been extended by an amendment which should not have been allowed;
- (f) whether a supplementary protection certificate is invalid under Article 15 of the Medicinal Products Regulation; and
- (g) whether a supplementary protection certificate is invalid under Article 15 of the Plant Protection Products Regulation.

In the following paragraphs, the term "patent holder" means the proprietor of the patent and any exclusive licensee.

74A.03 A request for an opinion should be made on Patents Form 17 filed in duplicate. This

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r.53(2)(b) r.51 shall be accompanied by a statement setting out the question upon which an opinion is sought, submissions from the requester on that question, and any matters of fact which are requested to be taken into account. The statement shall be accompanied by the name and address of anyone, of whom the requester is aware, having an interest in that question, particulars of any proceedings of which the requester is aware which relate to the patent and which may be relevant to that question, and a copy of any evidence or other document which is referred to in the statement, but there is no need to provide copies of published UK granted patents or applications. However, when the requester is acting as an agent in making the request, there is no requirement for the agent to disclose the person for whom he is acting. The statement, evidence and any other documents must be provided in duplicate. Any document filed in connection with a request for an opinion cannot be kept confidential (see 118.10).

Section 74A(3)

The comptroller shall issue an opinion if requested to do so under subsection (1) above, but shall not do so -

- (a) in such circumstances as may be prescribed, or
- (b) if for any reason he considers it inappropriate in all the circumstances to do so.

Refusal or withdrawal of request

r.94 r.106(3) r.106(4) 74A.04 An opinion will not be issued if the request for an opinion appears to the comptroller to be frivolous or vexatious, or the question upon which an opinion is sought appears to have been sufficiently considered in any proceedings. In addition, an opinion is not issued if the requester withdraws the request by giving notice to the comptroller in writing. In this situation, the comptroller may remit the whole or part of the fee paid to request the opinion. The requester is notified by the comptroller where a request for an opinion is refused, and has a right to be heard (see 74A.10). Where the request is refused, the comptroller has discretion to remit the whole or part of the fee paid to request the opinion. Under the Patents Rules 2007 there is no longer a requirement to apply in writing for remission of the whole or part of the fee.

Notification and advertisement of request

r.95(1) r.95(2) r.92 r.54(1)

r.54(6)(a)

74A.05 Various parties are notified of the request for an opinion by being sent a copy of the statement and Patents Form 17 filed by the requester, along with any other documents filed by the requester that the comptroller sees fit to send. The parties notified are (unless they are also the requester for an opinion): the patent holder (i.e. the patent proprietor and any exclusive licensee of the patent), any holder of a licence or sub-licence which has been registered under r.47, any person who has made a request for information as to when an opinion has been filed on a patent, any person who is specified in the statement filed by the requester as having an interest in the question, and any other person who the comptroller considers to have an interest in the question upon which the opinion is sought.

- r.95(4) 74A.06 The request for an opinion is advertised on the Office website. The URL index for opinions is http://www.ipo.gov.uk/pro-p-opinion-advert.htm.
- r.95(5) 74A.07 If a request is refused or withdrawn before parties are notified that the request for an opinion has been filed, only the patent holder is notified of the request (if he is not also the requester). In this event, the request for an opinion is not advertised.

Submission of observations and observations in reply

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- r.96(1)-(3)
 74A.08 Unless the request for an opinion has been refused or withdrawn, any person may submit written observations within four weeks from the date of advertisement of the request on the Office website. This time period is extendable at the comptroller's discretion under rule 108(1). Within this period, the person submitting the observations is required to supply a copy of these observations to the patent holder (except where the patent holder is the person submitting the observations) and the requester of the opinion. The observations must be confined to the issues raised in the request for an opinion, but may include reasons why the comptroller should refuse the request for an opinion.
- r.96(4)-(5)

 74A.09 Once the period for submitting observations has expired, the requester and the patent holder (if he is not the person submitting the observations in question) have two weeks to submit observations in reply. This period is extendable at the comptroller's discretion under rule 108(1). This response must be strictly confined to issues raised in the observations. Within this period, any observations in reply from the requester must be sent by him to the patent holder. Similarly, the patent holder must send any observations in reply to the requester.

[Any request for an extension of time to submit observations or observations in reply should be referred to a Deputy Director with responsibility for the opinions procedure. As the procedure of issuing an opinion is intended to be quick, only very short extensions will normally be granted, and only with very good reasons]

r.96(6) 74A.10 If it is reasonably possible, the observations filed and copies of such observations should be delivered only in electronic form or using electronic communications. Directions made under section 124A prescribing the form and manner for making these observations using electronic media were published in PDJ No. 6071 on 28 September 2005 and are reprinted in full in the "Relevant Official Notices and Directions" section of this Manual. The Directions require observations to be sent by email to address opinions@ipo.gov.uk or to be delivered on digital media.

Section 74A(4)

Any opinion under this section shall not be binding for any purposes.

74A.11 The opinion does not have binding legal effect on the requester, observers or anyone else. However, that does not prevent the fact that an opinion has been given from being referred to in subsequent proceedings.

74A.11.1 See 73.02 and 73.04.1 for details of when action may be taken to commence revocation proceedings under s.73 after an opinion concludes that a granted UK patent or European patent (UK) lacks novelty or an inventive step.

Section 74A(5)

An opinion under this section shall be prepared by an examiner.

Issue of the opinion

r.97 74A.12 After the end of the procedure for submission of observations, the request is referred to an examiner for preparation of the opinion. A copy of the opinion is sent to the requester, the patent holder, and any other person who filed observations. The opinion is also made available on the Office website (see http://www.ipo.gov.uk/pro-p-opinion-advert.htm).

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[A senior patent examiner should consider the observations and prepare the written opinion. The examiner will first see the file about 2 weeks after the request for an opinion is received and may study the patent and any observations during the submission period. Further details on preparing the opinion are given in chapter 5 of the Patents Opinions Service Procedures Manual.]

Section 74A(6)

In relation to a decision of the comptroller whether to issue an opinion under this section -

- (a) for the purposes of section 101 below, only the person making the request under subsection (1) above shall be regarded as a party to a proceeding before the comptroller; and
- (b) no appeal shall lie at the instance of any other person.

74A.13 The requester of an opinion has the right to be heard before the request is refused by the comptroller. No other person has the right to be heard on the question whether the request should be granted. Similarly, no person other than the requester has the right to appeal to the courts against that decision (under the general right of appeal given by section 97).

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Section 74B: Reviews of opinions under section 74A

74B.01 Section 74B was introduced by the Patents Act 2004 and came into force on 1 October 2005. The section enables provision to be made for a review of opinions made under section 74A.

[The Patents Opinions Service Procedures Manual should be consulted for full details of practice concerning opinions under section 74A and reviews of opinions under section 74B.]

Section 74B(1)

Rules may make provision for a review before the comptroller, on an application by the proprietor or an exclusive licensee of the patent in question, or an opinion under section 74A above.

74B.02 The comptroller may undertake a review of an opinion made under section 74A. Only the patent proprietor or exclusive licensee ("the patent holder") may apply for a review, which is considered in full proceedings before the comptroller.

Section 74B(2)

r.92

The rules may, in particular -

- (a) prescribe the circumstances in which, and the period within which, an application may be made;
- (b) provide that, in prescribed circumstances, proceedings for a review may not be brought or continued where other proceedings have been brought;
- (c) [Repealed]
- (d) provide for there to be a right of appeal against a decision made on a review only in prescribed cases.

Applying for a review of an opinion

- r.98(1)-(4) 74B.03 The patent proprietor or exclusive licensee may apply to the comptroller for a review of an opinion within three months of the date of issue of the opinion (extendable under rule 108(1)). The application should be made on Patents Form 2 filed in duplicate. The form should be accompanied by a statement in duplicate setting out fully the grounds on which the review is sought. This statement should contain details of any proceedings of which the applicant is aware which may be relevant to the question whether the review proceedings can be brought or continued. Proceedings for a review may not be brought or continued if the issue raised by the review has been decided in other proceedings.
- r.98(5)

 74B.04 The application for a review of an opinion may only be brought on two grounds. Firstly, the patent proprietor or exclusive licensee may apply to have an opinion set aside on the grounds that the opinion wrongly concluded that the patent was invalid, or was invalid to a limited extent. Secondly, he may apply for a review of an opinion which concluded that a particular act did not or would not constitute an infringement of the patent. In this case, an application for a review can only be made where this conclusion was reached by what is believed to be an erroneous construction of the patent specification.

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Procedure on review

- r.99(1) 74B.05 Upon receipt of the application, a copy of the form and statement is sent to the original requester of the opinion (if different from the applicant for the review) and to anyone who submitted observations during the original opinions procedure (see 74A.08).
- r.99(2) 74B.06 An application for a review of an opinion is advertised on the Office website (see www.ipo.gov.uk/pro-p-review-advert).
- r.99(3)-(6) 74B.07 Following advertisement of the review, any person may file a statement in support of the application for review, or a counter-statement contesting the application. In doing so, the person becomes party to the proceedings. Any statement or counter-statement must be filed within four weeks from publication of the advertisement of the review, or within two months of the date of issue of the opinion under s.74A, whichever period is the later to expire. Copies of statements or counter-statements are sent to the other parties in the review. The comptroller may give directions as he thinks fit with regard to subsequent procedure.

Outcome of review

r.100(1)-(2) 74B.08 As with other proceedings before the comptroller, the parties to the proceedings have a right to be heard before the comptroller issues a decision upon completion of the review. The decision shall either set aside the opinion in whole or in part, or decide that no reason has been shown for the opinion to be set aside. The decision does not estop any of the parties from raising an issue regarding the validity or the infringement of the patent.

Appeals against a decision on review

r.100 74B.09 There is no appeal to the courts against a decision by the comptroller to set aside an opinion, except where the appeal relates to a part of the opinion that is not set aside. Therefore, it is not possible for the courts to consider the issue of whether to reinstate a non-binding opinion.

Revocation action following a review

74B.10 See 73.02 and 73.04.1 for details of when action may be taken to commence revocation proceedings under s.73 after an opinion concludes that a granted UK patent or European patent (UK) lacks novelty or an inventive step, and a decision has been issued that no reason has been shown for the opinion to be set aside.

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GENERAL PROVISIONS AS TO AMENDMENT OF PATENTS AND APPLICATIONS

Section 75: Amendment of patent in infringement or revocation proceedings

s.74(8)

This section is concerned with the amendment of the specification of a granted patent, including a European patent (UK), during proceedings in which the validity of the patent may be put in issue. Such proceedings are defined in s.74(1), and the definition is somewhat broader than the title of s.75 might appear to imply. It does not include revocation proceedings initiated by the comptroller under s.73. The Patents Act 2004 amended s.75(1) to remove the necessity for validity to have been put in issue before a proprietor can apply to amend under s.75. For proceedings brought on or after 1 January 2005, a patent proprietor can propose amendments during the course of any proceedings in which it is possible for the validity of the patent to be put in issue, whether or not validity has actually been raised.

75.01.1 In *Chiron Corp v Organon Teknika Ltd* [1994] FSR 258 Aldous J held that s.74 does not bar an opponent from raising lack of support under s.14(5)(c) in amendment proceedings. He was also upheld on appeal ([1995] FSR 559) in finding that a proposal to delete claims, which had been found to be invalid, should not open the door to an allegation that other valid claims lacked support, when the proposed amendment did not impinge on the invention claimed in the valid claims. In particular, Aldous J concluded that there was no justification for requiring amendment of the valid claims to disclaim the matter of the claims to be deleted.

There are two distinct procedures, depending on whether the proceedings are taking place before the comptroller or the court. In the former case the procedure is governed by Part 7 of the Patents Rules 2007, while in the latter case it is subject to rule 63.10 of Part 63 of the Civil Procedure Rules 1998 (CPR 63) and section 12 of the Practice Direction supplementing CPR 63 (CPR 63PD). Further information concerning procedures before the court is provided in The Patents Court Guide available through the website of the Court Service (www.justice.gov.uk). It should also be noted that slightly different procedures again apply where the proceedings are before the Court of Session. These are not detailed below, but are governed by paragraph 55.5 of the Rules of the Court of Session.

s.74(8) CPR 63.10(3) 75.02.1 Rule 35(2) requires a proposed amendment to a specification of a patent to be delivered in electronic form or using electronic communications if reasonably possible. Similarly, CPR 63 requires the application notice for permission to amend under s.75 before the court to be served on the comptroller electronically if reasonably possible. Directions prescribing the form and manner for electronic delivery of applications to amend under s.75 were published in the PDJ No. 5938 on 12 March 2003, and came into force with the Patents Act 1977 (Electronic Communications Order) 2003 (S.I. 2003 No. 512) on 1 April 2003. Electronic delivery should be made either by email to litigationamend@ipo.gov.uk entitled "Proposal to amend under s.75 before the comptroller [or the courts]" as appropriate, or on an electronic carrier delivered to the Office accompanied by an identifying letter (see 27.03.1 and the Directions for further information on the formats for electronic submission).

75.03 [deleted]

Section 75(1)

In any proceedings before the court or the comptroller in which the validity of a patent may be put in issue the court or, as the case may be, the comptroller may, subject to section 76 below, allow the proprietor of the patent to amend the specification of the patent in such manner, and subject to such terms as to advertising the proposed amendment and as to costs, expenses or otherwise, as the court or comptroller thinks fit.

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EXERCISING DISCRETION

The allowance of amendments is a matter of discretion and similar considerations apply as under s.27 (see 27.07-27.11.1 and 27.32). However, section 75(5) was added on 13 December 2007 and provides that in considering whether to allow a proposed amendment the court or comptroller shall have regard to relevant principles under the European Patent Convention (EPC) (see 75.21 and 75.21.1). Various judgments provide discussion of the exercise of discretion prior to the introduction of s.75(5). The extent to which these cases are now relevant is set out below.

In Smith Kline & French Laboratories Ltd v Evans Medical Ltd [1989] FSR 561, Aldous J identified the following principles concerning discretion as to whether or not to allow amendment -

- (i) the onus to establish that amendment should be allowed is upon the patentee and full disclosure must be made of all relevant matters:
- (ii) amendment will be allowed provided the amendments are permitted under the Act and no circumstances arise which would lead the court to refuse the amendment:
- (iii) it is in the public interest that amendment is sought promptly, so a patentee who delays for an unreasonable period before seeking amendment must show reasonable grounds for his delay; This principle is no longer relevant in light of s.75(5).
- (iv) a patentee who seeks to obtain an unfair advantage from a patent, which he knows or should have known should be amended, will not be allowed to amend;
- (v) the court is concerned with the conduct of the patentee and not with the merit of the invention. This principle is no longer relevant in light of s.75(5).

The exercise of discretion was also discussed by the Court of Appeal in *Kimberly-Clark Worldwide Inc v Procter & Gamble Ltd* ([2000] RPC 422). However, the intended effect of s.75(5) is that the old law relating to covetousness and delay is swept away and these matters are no longer an issue in post-grant amendment (see 75.21 and 75.21.1). This effect was explicitly confirmed by Floyd J in *Zipher Ltd v Markem Systems Ltd & Anr* [2008] EWCH 1379 (Pat):

'It follows that if I am to have regard to the principles applicable under the EPC, the discretion which I have to refuse amendments which comply with the Act has been limited. Considerations such as those formerly considered relevant to the discretion, such as the conduct of the patentee, are no longer relevant.'

r.35(6)

It is considered that the above factors apply not only to the allowance of amendments but also to whether to give an opportunity to amend. In *ICI Plc v Ram Bathrooms Plc and Rohm GmbH* ([1994] FSR 181) Aldous J held that, in actions where the parties have in effect settled their dispute, he would only allow patents to be amended where (a) the amendments are not substantial in amount or effect; (b) there is no apparent matter of controversy; and (c) no matter of public interest arises. It follows that if any of these matters exist the patentee should apply to the comptroller for amendment under s.27. Jacob J allowed amendment in *Mabuchi Motor KK's Patents* [1996] RPC 387 despite a patent in question not having been framed with reasonable skill and knowledge and despite the proprietors being dilatory in pursuing the matter of amendment after having started proceedings, because no actual or likely prejudice to the public had been shown and interested parties could have learnt of the existence of the amendment proceedings from the register. It may also be made a condition for allowing the amendments that a new specification or replacement pages be provided, in the same way as described in 27.18. However, when comparing ss.27 and 75, the hearing officer in *Osterman's Patent* [1985]

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RPC 579 held that where the application to amend is under s.75 there is a difference; the Act and the Rules make no specific provision for the giving of reasons, because there is a presumption (in proceedings under s.72) that the amendments are offered with a view to meeting the grounds for revocation. (Note that the proprietor may amend his patent centrally before the EPO to meet the grounds for revocation (see 72.44.1)). He declined to direct that the patentees should give evidence directed towards the proposed amendments, and in particular the reasons for them, prior to the applicants for revocation giving their evidence in chief on those amendments and on the revocation issue. The Patents Court held that the hearing officer had not wrongly exercised his discretion.

75.05.1 In Koninklijke Philips Electronics n.v. v Nintendo of Europe GmbH [2014] EWHC 1959 (Pat) the Patents Court found that a double patenting objection taken as a ground for refusing a post-grant amendment to a claim can be taken but should only be made in the following circumstances:

- i) The two patents must have the same priority dates and be held by the same applicant (or its successor in title);
- ii) The two claims must be for the same invention, that is to say they must be for the same subject matter and have the same scope. The scope is considered as a matter of substance. Trivial differences in wording will not avoid the objection but if one claim covers embodiments which the other claim does not, then the objection does not arise.
- iii) The two claims must be independent claims. If two independent claims have different scope then there is no reason to object even if the patents contain dependent claims with the same scope.

If the objection arises, and both patents are before the comptroller or court, then it can be cured by an amendment or amendments to either patent. Even if the objection properly arises in the sense that two relevant claims have the same scope, if the patentee has a legitimate interest in maintaining both claims then the amendment should not be refused (see paragraphs 296-309 of the judgment).

AMENDMENT DURING PROCEEDINGS BEFORE THE COMPTROLLER

75.06 Much of what follows in paragraph 75.07 relates specifically to amendment during revocation proceedings under s.72, but is applicable mutatis mutandis to other proceedings in which validity is put in issue. The outcome of any offer to amend the patent is recorded in the Register.

75.07 When amendments have been proposed during a hearing (see 72.42) or following an interim decision (see 72.44) the comptroller has discretion as to whether or not to advertise them in the Journal as open to opposition. In exercising this discretion, the comptroller will consider how significant the amendments are and the likelihood of another party wishing to object. Where the amendments are being proposed to avoid revocation it is likely they will be significant amendments to which another party may wish to object. If however the amendments are clearly not allowable, or would not cure invalidity, or are clearly minor, then the comptroller may consider that advertisement is not necessary. Where an amendment is advertised in the Journal, copies of the amendment are available through Tribunal Section, and, if the amendment has been filed electronically, through the website. The amendments will be available in the form subsisting after the proprietor has considered any objection to them by the Office or by the other party. The hearing officer will normally defer issuing a final decision terminating the proceedings until the period allowed for opposing the amendments (see 75.15) has expired or until any opposition has been resolved.

[If it is decided that the amendments should be advertised as open to opposition, Tribunal Section is responsible for seeing that this is done.]

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r.75

AMENDMENT DURING PROCEEDINGS BEFORE THE COURT

CPR 63.10(1)

75.09 An application to the court under section 75 of the 1977 Act for permission to amend the specification of a patent by the proprietor of the patent must be made by application notice.

CPR 63.10(2)

75.09.1 The application notice must -

- (a) give particulars of -
 - (i) the proposed amendment sought; and
 - (ii) the grounds upon which the amendment is sought;
- (b) state whether the applicant will contend that the claims prior to amendment are valid;
- (c) be served by the applicant on all parties and the comptroller within 7 days of its issue.

General rules about applications for court orders are governed by Part 23 of the Civil Procedure Rules.

CPR 63.10(3) CPR 63PD

para 12.2

75.09.2 The application notice must, if it is reasonably possible, be served on the comptroller electronically. When served electronically, the application notice must comply with any requirements for the sending of electronic communications to the comptroller (see <u>Directions under section 124A</u>, <u>Submitting post-grant amendments by e-mail</u>, and also 27.03.1 and 75.02.1).

CPR 63.10(4)

75.10 Unless the Court otherwise orders, the comptroller will forthwith advertise the application to amend in the Journal.

CPR 63.10(5)

75.10.1 The advertisement will contain an electronic copy of the amendments or will state that any person may apply to the comptroller for a copy of the application notice.

CPR 63.10(6)

75.11 Within 14 days of the first appearance of the advertisement any person who wishes to oppose the application must file and serve on all parties and the comptroller a notice opposing the application which must include the grounds relied on.

[Any notice opposing the application should be forwarded to the Deputy Director responsible for preparing the comptroller's comments on the proposed amendments (see 75.12).]

CPR 63.10(7)

75.11.1 Within 28 days of the first appearance of the advertisement the applicant must apply to the Court for directions.

A report should be prepared in the Office for the benefit of the Court on the question as to whether the proposals are considered by the Office to be prima facie allowable. In general, the Office need only consider whether the amendments meet the requirements of ss.14(5) and 76: there is no point in considering whether they meet any objection that has been raised as to, e.g. lack of novelty, obviousness or insufficiency, because these are likely to be considered by the court with the benefit of material to which the comptroller does not have access. In order to avoid any misunderstanding that the Office has considered all aspects relevant to allowance of the amendment, the report should make clear that the Office's consideration has only extended to ss.14(5) and 76. In addition,

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if the amendments appear prima facie allowable the report should say that the comptroller considers that the amendments meet the requirements of these sections, but if they are not prima facie allowable the reason for this should be explained in the report. All parties to the proceedings before the court should be informed of the Office views on the amendments and whether the comptroller has decided to be represented in Court. The Office does not normally communicate the report direct to the Court but instead asks the applicant to pass it on (see 75.20). In paragraph 128 of <u>L'Oréal Ltd v RN Ventures Ltd [2018] EWHC 173 (Pat)</u>, Carr J discusses the report prepared in this case and agrees with it. Further judgments which discuss the report prepared by the Office include <u>Curt G Joan Inc v Fameccanica Data SpA [2017] EWHC 1251 (IPEC)</u> and <u>Cantel Medical et al v Arc Medical [2018] EWHC 345 (Pat)</u>.

[The application to amend should be referred for the report as soon as advertisement has been arranged, but the report generally should not be finalised or issued until the 14 day opposition period has passed (see 75.11), which will allow any notice opposing the application to be taken into account. The Deputy Director in charge of the subject-matter concerned is responsible for preparing the report or having it prepared. The report may take the form of a letter to the applicant informing him of the comptroller's views. It is for the Court to decide ultimately on the allowability of the amendments and the Office merely gives its views without becoming involved in the discussion.]

CPR 63PD 75.12.1 Not less than 2 days before the first hearing date, the applicant, the comptroller if he wishes to be heard, the parties to the proceedings and any other opponent, must file and serve a document stating the directions sought.

CPR 75.13 Unless the Court otherwise orders, the applicant must within 7 days serve on the comptroller any order of the Court on the application.

[Where the specification should be amended by Tribunal Section who will also prepare the appropriate certificate Court allows a specification to be amended, the original copy of the (s) for the signature of the Deputy Director. The Deputy Director is thus responsible for approving the wording of the certificate and certifying that the amendments comply with the Court order. It should be noted that the Deputy Director concerned is not acting for the comptroller in this particular situation since the allowability of the amendments has been decided by the Court.]

[A decision by the Court or comptroller to allow an amendment should be actioned immediately and not deferred if an appeal is entered, unless the decision has been stayed pending appeal. Accordingly appropriate Register/Journal entries should be made and the Office copy, ie the authentic version of the patent specification, should be amended. Notice of any appeal should be entered into the Register/Journal to advise the public of the potential transient nature of the decision. It is also desirable that the public should have a published version of the amended patent as soon as reasonably possible. Thus, unless the Office is aware that an early date for an appeal hearing has been fixed, a 'C' publication should be produced with a footnote that the decision to allow the amendment is under appeal as of a certain date. A 'C' publication of the amended patent without the footnote should not be produced once the final appeal has been disposed of unless the final appeal further amends the patent. The procedure for production of the 'C' publication is as described in 27.20. If a decision by the Court or comptroller has been stayed pending an appeal and an appeal has been lodged, the Office will note the Register and Journal that the decision is stayed pending appeal and that an appeal has been lodged on a certain date. 1

Section 75(2)

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A person may give notice to the court or the comptroller of his opposition to an amendment proposed by the proprietor of the patent under this section, and if he does so the court or the comptroller shall notify the proprietor and consider the opposition in deciding whether the amendment or any amendment should be allowed.

75.14 The considerations referred to in 27.24 and 27.28 also apply to an opposition under s.75.

OPPOSITION TO AMENDMENT BEFORE THE COMPTROLLER

PR part 7 75.15 Where in any proceedings before him, the comptroller requires an amendment proposed under s.75 to be advertised, notice of the amendment is advertised in r.75 the Journal, stating that details of the amendment are available through Tribunal Section, r.76(2)(a) and if the amendment has been filed electronically, through the website. Notice of r.108(1) opposition should be given on Form 15 which should be filed within two weeks of the date of the advertisement of the amendments sought; this period may not be extended. The form should be accompanied by a copy thereof and a statement of grounds (in duplicate). This starts opposition proceedings before the comptroller, the procedure for which is discussed at 123.05 - 123.05.13. However, if an applicant for revocation has opposed an amendment offered by the proprietor during revocation proceedings, the applicant for revocation does not subsequently need also to give notice of opposition to the amendment on Form 15 (Eickhoff Maschinenfabrik's Patent, BL O/031/87; Harding's Patent, BL O/094/90).

- 75.15.1 In <u>Ability International Ltd v Monkey Tower Ltd (BL O/484/14)</u>, the hearing officer decided that any opposition to amendment under s.75 must be limited to questioning whether the amendment overcomes the stated defects (that is, the defects which led to the amendment request), and whether the amendment meets the requirements of s.76. A similar limitation applies in opposition proceedings to amendments made under s.27 (see 27.28).
- r.77(1) 75.16 The Office will send a copy of the notice of opposition and the statement to the proprietor and to any other party to the proceedings before the comptroller.
 - 75.17 The comptroller may stay the other proceedings and decide the opposition, if necessary at a hearing, or may decide both actions together.

OPPOSITION TO AMENDMENT BEFORE THE COURT

75.18 See 75.11

Section 75(3)

An amendment of a specification of a patent under this section shall have effect and be deemed always to have had effect from the grant of the patent.

75.19 See 27.22.

Section 75(4)

Where an application for an order under this section is made to the court, the applicant shall notify the comptroller, who shall be entitled to appear and be heard and shall appear if so directed by the court.

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75.20 (See also 75.12). If, as is normally the case, the comptroller is not to be represented, the applicant should be asked to inform the Court of the comptroller's views. The Court may, however, decide that the comptroller should be represented.

Section 75(5)

In considering whether or not to allow an amendment proposed under this section, the court or the comptroller shall have regard to any relevant principles applicable under the European Patent Convention.

75.21 Section 75(5) confers on the comptroller or court discretion to allow or refuse an amendment to the patent. Articles 105a(1) and 123 EPC also confer on the EPO discretion to allow or refuse an amendment of the European patent. The comptroller or court continue to have discretion to allow or refuse an amendment, but in exercising that discretion, section 75(5) requires the comptroller or court to have regard to any relevant principles which are applicable to amendment or limitation proceedings under the EPC. These may include relevant regulations made under the EPC, any relevant guidelines produced by the EPO, and decisions of the Opposition Division and Boards of Appeal. This should ensure that, as far as possible, there is consistency in approach as regards postgrant amendment in national proceedings and before the EPO. The EPO do not consider the behaviour of the patent proprietor when exercising discretion in allowing amendments. The intended effect of section 75(5) is that the behaviour of the patent proprietor will no longer be an issue to be considered in the UK when deciding whether to allow an amendment to be made under section 75. This effect was confirmed by Floyd J in Zipher v Markem (see 75.04 and below).

75.21.1 In *Zipher Ltd v Markem Systems Ltd & Anr* [2008] EWCH 1379 (Pat), Justice Floyd summarised the position under the EPC as follows:

- in opposition proceedings, appropriateness of the amendments to the proceedings, their necessity and procedural fairness are the main, perhaps only, factors considered relevant to the discretion to allow amendment;
- ii) in central amendment proceedings, compliance with the procedural requirements gives rise to a right to have the patent limited in accordance with the request.

These are therefore the factors which should be taken into account when considering whether or not to allow an amendment under this section.

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Section 76: Amendments of applications and patents not to include added matter

This section, which bars the inclusion of additional matter in a patent application or specification, was rewritten by the CDP Act. The changes then made had little effect with regard to the prohibition on the introduction of new matter when amending an application or patent, but changed the consequences of the presence of such matter in a new application based on, and claiming the filing date of, an earlier application or patent. Section 76(1A) was added to this section by the Regulatory Reform (Patents) Order 2004 to prohibit the introduction of new matter in a description when the initial filing includes a reference under s.15(1)(c)(ii) to an earlier application.

Section 76(1)

An application for a patent which -

- (a) is made in respect of matter disclosed in an earlier application, or in the specification of a patent which has been granted, and
- (b) discloses additional matter, that is, matter extending beyond that disclosed in the earlier application, as filed, or the application for the patent, as filed,

may be filed under section 8(3), 12 or 37(4) above, or as mentioned in section 15(9) above, but shall not be allowed to proceed unless it is amended so as to exclude the additional matter.

Section 76(1A)

Where, in relation to an application for a patent -

- (a) a reference to an earlier relevant application has been filed as mentioned in section 15(1)(c)(ii) above; and
- (b) the description filed under section 15(10)(b)(i) above discloses additional matter, that is, matter extending beyond that disclosed in the earlier relevant application,,

the application shall not be allowed to proceed unless it is amended so as to exclude the additional matter.

Section 76(1) requires that an application which seeks divisional status under s.15(9) (or to be treated as a new application under s.8(3), 12 or 37(4) following entitlement proceedings) and which discloses matter extending beyond that disclosed in the relevant earlier application, shall not be allowed to proceed unless it is amended to exclude that matter (see procedure in 15.35 and 15.45). Once amended, it should be published (provided all requirements are met) under s.16(1) as filed (see 15.38-39 and 16.08). Similarly, where an application contains a reference to an earlier application under s.15(1)(c)(ii) and the description of the invention sought required under s.15(10)(b)(i) discloses matter extending beyond the earlier application, the application shall not be allowed to proceed unless it is amended to exclude that matter (see 15.06.3 to 15.06.5), but once amended, the description as first filed should be published under s.16(1).

76.03 The tests for deciding whether a later application discloses matter which extends beyond that disclosed in an earlier application are the same as the tests for

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determining whether amendment of an application adds matter (see 76.05-19).

Section 76(2)

No amendment of an application for a patent shall be allowed under section 15A(6), 18(3) or 19(1) if it results in the application disclosing matter extending beyond that disclosed in the application as filed.

BEFORE GRANT

76.04 Section 76(2) disallows amendment of an application which results in it disclosing matter extending beyond that which it disclosed when filed. Its strictures apply to amendment of an application made either in response to an objection made in the course of preliminary or substantive examination or at the applicant's own volition.

[RC9 may be used to object to a specification which contains added matter as a result of amendment under s.18(3), r.31(3) or r.31(4). It is not however appropriate for amendments requested under r.31(6) which would add matter. (See further 19.19, 19.21)]

In addition to the following UK precedents, Decisions of the EPO's Boards of Appeal are also relevant. In *Lowndes' Application* (BL O/019/93), the hearing officer noted that, although s.76 is not one of those specified in s.130(7) as having been framed to have the same effect as a corresponding provision of the EPC, there is an indirect link to the EPC through s.72(1)(d), which concerns added matter as a ground for revocation. This latter provision is worded in similar terms to s.76(1) and (2) and is covered by s.130(7) (see also 76.22 and 91.02). Moreover, in *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* (BL C/089/96) Jacob J came to the firm conclusion that s.76 is not intended to have a different effect from a.123 EPC.

The same general considerations arise under s.76(2), and s.72(1)(d), regardless of whether an amendment relates to the description (including any drawings) (see paras 76.06-14) or to the claims (see paras 76.15-22). Questions as to whether amendments disclose additional matter can arise both pre- and post-grant in the context of claim broadening. However, it is important to realise that the stricture against claim broadening in s.76(3)(b) and the sanction provided by s.72(1)(e) only apply to post-grant amendment (see 76.24-27), as was confirmed by the Court of Appeal in *Texas Iron Works v Nodeco* [2000] RPC 207. The only stricture governing pre-grant amendment is that no additional matter should be disclosed, and s.69(2) clearly contemplates allowability of claim broadening (or "lateral shifting") so that acts which did not infringe the claims of the published application could yet infringe those of the granted patent (see 76.16). The same possibility is contemplated by ss.17(8) and 18(1A).

76.06 When considering in *Bonzel and Schneider (Europe) AG v Intervention Ltd* [1991] RPC 553 whether an amendment to the description had the result that a patent as granted disclosed matter which extended beyond that disclosed in the application, Aldous J described his task as -

- (1) to ascertain through the eyes of the skilled addressee what is disclosed, both explicitly and implicitly in the application;
- (2) to do the same in respect of the patent as granted;
- (3) to compare the two disclosures and decide whether any subject matter relevant to the invention has been added whether by deletion or addition. The comparison is strict in the sense that subject matter will be added unless such matter is clearly and unambiguously disclosed in the application either explicitly or

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implicitly.

As summarised by Jacob J. in Richardson-Vicks Inc.'s Patent [1995] RPC 568, "the test of added matter is whether a skilled man would, upon looking at the amended specification, learn anything about the invention which he could not learn from the unamended specification."

(With regard to the narrowing of a claim to claim a sub-range not specified before, see 18.69-18.69.1 and 76.27).

76.07 In the Bonzel case, it was decided that additional matter was disclosed by an amendment resulting in a guide wire lumen of a dilatation catheter being described as "relatively short" (compared with the prior art), rather than as "about as long as the (catheter) balloon" (the original description of its length). The terms of the comparison at (3) above conform broadly with those of the test for novelty adopted in some EPO decisions as a basis for determining the allowability of amendments. (i.e. no (new) subject matter may be disclosed by amendment which is not derivable directly and unambiguously from the original application by a person skilled in the art; see, eg, Technical Board of Appeal Decision T201/83, OJEPO 10/84.) However, in A C Edwards Ltd v Acme Signs & Displays Ltd [1990] RPC 621 at p.644 whilst acknowledging that the novelty test could often prove useful, and would have given the same result in that case. Aldous J observed nonetheless that it should be applied with caution.

- 76.08 In order to determine the original teaching of an application, the whole of the r.15(2) description, any drawings and any claims which was or were present on the filing date may s.14(2)be considered (for later-filed original claims, see 14.145). When viewed as a source of disclosure, the claims of a patent specification are no different from any other source. The Court of Appeal so held in A C Edwards Ltd v Acme Signs & Displays Ltd [1992] RPC 131 at p.142, applying the decision of the House of Lords in Asahi Kasei Kogyo KK [1991] RPC 485 (see also 2.10.2).
 - 76.08.1 A priority document does not form part of the application, and matter disclosed in the priority document but omitted from the specification as filed may not be subsequently added (as confirmed in VEB Kombinat Walzlager [1987] RPC 405, see 15.08).
- 76.08.2 Matter that is only disclosed in the abstract cannot be added to the s.14(2)specification, regardless of whether the abstract was filed on or after the filing date. The abstract is part of the application, though not part of the specification, and so the hearing officer in ARMCO Inc's Application (BL O/84/85) accepted that matter present in an abstract filed on the date of filing could be considered to be part of the disclosure of the application when determining under s.76(2) whether an amendment adds matter. However, the Patents Court in Abbott Laboratories Ltd. v Medinol Ltd [2010] EWHC 2865 (Pat) held that the content of the abstract, filed on the date of filing of the application, could not be used to determine the content of the application as filed for the purpose of s.76 - see 14.171. Examiners should therefore disregard the content of the abstract in determining whether an amendment adds matter.
 - 76.09 It is allowable to add to the description or claims matter disclosed in a drawing provided it does not go beyond what a skilled person would judge to be disclosed in the drawing. If it is necessary to rely on the drawings for support and the formal drawings were filed later than the application date, then the informal drawings should be consulted. A drawing treated as omitted under s.15(2) or (3) (see 15.07-15.16) may be reinstated by amendment, or a new drawing may be added, provided that it shows nothing not originally disclosed in the application (including any other drawings) on the date of filling. A similar criterion applies to the amendment of a drawing.

Implicit Disclosure

76.10 Matter may be regarded as having been disclosed if the skilled reader would realise that it was implicit in the original document (cf 18.22) - see, for example, DSM NV's

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Patent [2001] RPC 35 at paragraphs 197-200. In this decision, Neuberger J gives the hypothetical illustration of a description which refers to carrying out experiments at a certain acidity, but which does not contain a reference to the fact that pH is a measure of acidity. Since the skilled person would take this for granted, it means that a claim which was amended to refer to this acidity in terms of pH would not amount to added matter.

- 76.11 Consider a further hypothetical example. If an applicant seeks to amend a disclosure of a rubber composition comprising several ingredients to specify that a further ingredient is present, this is prima facie not allowable. However, the amendment may be allowable if the applicant can show convincingly that the further ingredient is an additive normally used in rubber compositions of that kind and that its omission would be questioned by the skilled reader; such an amendment may be regarded as clarification and as introducing nothing not already known to such a reader, since the presence of the additive is implicit in the description of the composition. If however the additive is merely common but by no means universal, or if it is merely one additive selected from several which are generally used, then the reference to its presence constitutes added matter. A third example is an application originally disclosing "resilient means" without disclosing any particular form of such means. An amendment introducing the specific information that the resilient means is, or could be, a helical spring, will not normally be allowable. If however it can be convincingly argued that in the kind of apparatus in question use of a helical spring is universal (for example if the "resilient means" is for retracting the tip of a ball-point pen), then the amendment may be allowable.
- Matter which is not disclosed, but which the skilled reader would find it obvious to add, is not regarded as having been implicitly disclosed. The specification of Flexible Direction Indicators Ltd's Application [1994] RPC 207 concerned a traffic bollard characterised by its flexibility and originally indicated that the bollard was made from a compound of two polymers. The applicants produced evidence, suggesting that a skilled reader would immediately see that one of the polymers alone could provide the desired flexibility. They argued that removal of the reference to a second polymer would be no more than rendering explicit that which was already implicit. In refusing the amendment, Aldous, J observed that s.76 "is concerned with what is disclosed, not with that which the skilled reader might think could be substituted or what had been omitted".
- 76.13 If a generic term used in the document can be regarded as necessarily disclosing a relatively small number of particular alternatives, then restriction to one of these may be an allowable amendment. For example, if a pump or valve is disclosed as for use with "fluid" then it is reasonable to construe this as disclosing use with either liquid or gas, so that a statement that use with only one of these is contemplated can be regarded as a restriction of the disclosure rather than as added subject-matter. However, in *Noxell Ltd's Application* (BL O/137/92), the hearing officer refused to allow the applicants to specify that a layer of plastic film was non-peelable, rejecting their submission that the word "layer" disclosed two particular alternatives: peelable and non-peelable layers. The hearing officer also rejected the applicant's submission that s.76 does not apply to disclaiming amendments.
- 76.13.1 In *Protoned BV's Application*, [1983] FSR 110, the invention as originally described and claimed related to a mechanism for adjusting the seat and back of a chair which used the co-operation of a gas spring and a mechanical compression spring. The applicant sought to delete from the claims the word "compression", and argued that a skilled reader would at once realise that a tension spring could be used equally effectively. This was rejected by Whitford J, who stated that even if this were accepted to be the case, the amendment was not allowable, since it added notionally to the body of the specification a whole range of springs which were not originally in the application as filed. However, the claim could well have been allowed if the approach taken later in *A C Edwards Ltd v Acme Signs & Displays Ltd* and *Southco Inc v Dzus Fastener Europe Ltd* (see 76.15 and 76.20) had been applied.

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76.14 There may be no objection to an amendment introducing information regarding prior art, provided it does not alter the construction of the claims of the patent in suit (Cartonneries de Thulin SA v CTP White Knight Ltd [2001] RPC 6). For example, while the originally filed description of prior art may give the impression that the inventor has developed the invention from a certain point, cited documents may show that certain aspects of the alleged development were already known. The subsequent inclusion of a reference to or a brief summary of the relevant documents would not contravene s.76 (Merrell Dow Pharmaceutical Inc v N H Norton & Co Ltd BL C/089/96). Likewise an amendment may be allowable which sets out disadvantages of the prior art, and thus helps to put the invention in its proper perspective in the art. If, however, such an amendment implies an advantage of the invention, or if a statement of such an advantage is sought to be introduced, for example in order to distinguish the invention from the prior art, then this will be allowable only if the advantage would have been apparent to a skilled reader of the specification who was aware of the prior art (EPO Decision T344/89; [1993] EPOR 209). In Palmaz's European Patents (UK) ([1999] RPC 47, upheld on appeal [2000] RPC 631) Pumfrey J stated that the practice, allowed by Advanced Semiconductor Products OJEPO 8/94 & [1995] EPOR 97 (G 01/93) of adding an acknowledgement of prior art to the body of the specification and limiting the claim by reference to the prior art so acknowledged was too generally used in proceedings before the EPO to be challenged, but noted that caution must be exercised where the patentee himself described the prior art in terms which he proposes to use in the limitation of his claim.

Scope of the Claims vs. Disclosure

In the case of <u>A C Edwards Ltd v Acme Signs & Displays Ltd [1992] RPC 131</u> (see 76.08), the claim had been reduced in scope during examination by the introduction of further features in generalised terms which, the defendants contended, had the result that the claim covered, and therefore disclosed, certain variations not disclosed in the application as filed. The Court, in rejecting this argument, distinguished between the ambit of the protection which the claim identified and the matters which it disclosed. The Court decided that although the claim covered certain variations, it contained no disclosure of any of them; thus there was no added information and the disclosure had not been extended. The Court also held that, in any event, the variations in question had been implicitly disclosed to a person skilled in the art by the contents of the application as filed.

76.15.0 Similarly, <u>AP Racing Ltd v Alcon Components Ltd [2014] EWCA Civ 40</u> concerned an appeal of a Patents County Court decision to revoke AP Racing's patent due to added matter. The patent related to a disc brake calliper with the claimed feature of asymmetrical peripheral stiffening bands (PSBs); however the application as filed did not explicitly refer to the PSBs as being asymmetrical and contained instead disclosure of [...one particular geometry of PSB in a "hockey stick" shape...]. The Patents County Court judge recognised that the PSBs disclosed in the application were necessarily asymmetrical but said that a skilled addressee would not have derived from the application "a concept at the same level of generality as" the feature of claim 1. Thus he held matter had been added in claiming the general feature of asymmetrical PSBs. However, this was overturned by a decision of the Court of Appeal, in which Floyd LJ stated:

"Having correctly concluded that the description in the application of the hockey stick shaped PSBs was of something "necessarily asymmetrical" [the judge] should have gone on to ask himself whether there was any added disclosure in the granted specification. The description of the PSBs in claim 1 as "asymmetric" has to be read as part of the disclosure of the specification of the granted patent as a whole, taking account of the different function of the claims and the specification. When this is done the skilled person would understand that the patentee has drafted his claim so that it *covers* asymmetric PSBs generally. However I am not persuaded that the specification read as a whole discloses any configuration of PSB which is not disclosed in the application."

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It is therefore possible to broaden the scope of a claim without disclosing new information about an invention (also see 76.15). That is, although broadening the scope of a claim may result in the claim *covering* matter which was not previously disclosed, this does not necessarily mean that the claim itself (and the specification as a whole) actually discloses any additional matter. In contrast, Koninklijke Philips Electronics NV v Nintendo of Europe GmbH [2014] EWHC 1959 (Pat) illustrates that a granted claim may cover new matter and also disclose new matter over what was filed. A granted claim referring to "at least one room localisation beacon" was held to add matter over an application which disclosed only the use of plural beacons. The judge determined that the granted claim clearly covered a system with only one beacon, and also disclosed such a system, because that idea is conveyed by the language of the claim. He stated "The skilled addressee reading the granted patent would have the idea that one of the things they could build if they put the ideas in the document into practice was a system with a single beacon in it".

- 76.15.1 The addition of what, in essence, was specific new disclosure was considered in *Van der Lely's Application* [1987] RPC 61. In that case, a divisional application claimed a baling machine comprising "at least one swingable conveyor" whereas the main application only disclosed a machine having three such conveyors. In the absence of any suggestion in the main application that the baling machine could have less than three swingable conveyors, and because the claim of the divisional application embraced a machine with only one or only two conveyors of this type, the disclosure of the divisional application was considered to extend beyond that of the main application.
- As discussed in paragraph 4A.27.1, it does not add matter to amend a "Swisstype" second medical use claim (e.g. "The use of substance X in the manufacture of a medicament to treat disease Y"), or an unpatentable method of treatment claim (e.g. "A method of treating disease Y by administering substance X"), to the equivalent direct form of second medical use claim ("Substance X for use in the treatment of disease Y"). Although such a change in claim format does not add to the technical disclosure of a patent application, it would extend the scope of the claims and is therefore contrary to s.76(3)(b) if made post grant (see 4A.27.1 and 76.26).

Intermediate Generalisation

Amendments which limit the scope of a claim by the introduction of one or more features from the description or claims may in certain circumstances add matter through what is known as "intermediate generalisation". This concept was explained by Pumfrey J in *Palmaz's European Patents (UK)* ([1999] RPC 47, upheld on appeal [2000] RPC 631):

"If the specification discloses distinct sub-classes of the overall inventive concept, then it should be possible to amend down to one or other of those sub-classes, whether or not they are presented as inventively distinct in the specification before amendment. The difficulty comes when it is sought to take features which are only disclosed in a particular context and which are not disclosed as having any inventive significance and introduce them into the claim deprived of that context. This is a process sometimes called 'intermediate generalisation'."

- 76.15.4 This definition has been endorsed in subsequent decisions of the courts, such as *Vector Corp v Glatt Air Technologies Ltd* [2007] RPC 12. In particular, if a feature is taken from only one, or a subset, of the embodiments, stripped of the other related features of the embodiment(s), and claimed as a defining feature of the invention, then unless the application suggests that this feature has a particular significance this is likely to constitute an intermediate generalisation; as in *Datacard Corp. v Eagle Technologies Ltd.* [2011] EWHC 244 (Pat), [2011] RPC 17.
- 76.15.5 As discussed in <u>Nokia Corporation v IPCOM GMBH & Co KG (No. 3) [2013]</u> R.P.C. 5 it is not permissible to introduce into a claim a feature taken from a specific embodiment unless the skilled person would understand that the other features of the embodiment are not necessary to carry out the claimed invention. Put another way, it must

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be apparent to the skilled person that the selected feature is generally applicable to the claimed invention absent the other features of that embodiment. Teva UK Limited & Anor v AstraZeneca AB [2014] EWHC 2873 (Pat) relates to a patent for a therapy for asthma. In his decision Mr Justice Sales applied the teaching of Nokia Corporation v IPCOM and found that a specific example given in the patent specification could not be used to generate generalisable patent claims. He held that the skilled addressee would not be able to derive from the example that the dose amounts set out are capable of abstraction from the details of the factual scenario set out in that example. The proprietor was thus held to have added matter to the application in attempting to generate patent claims based on particular details from the example. In Starsight Telecast Inc & Anor v Virgin Media Ltd & Ors [2014] EWHC 828 (Pat) the invention presented in the application as filed was a detailed and specific method of using parental controls to restrict access to program schedule information displayed on a television. The judge however considered that the claim 1 in the granted patent was directed to a method of restricting access to program schedule information based on parental control options per se and was not restricted to the specific features set out in the specification as filed. The granted claim 1 therefore presented the skilled team with new information about the invention which was not directly and unambiguously apparent from the original disclosure. It was further held that claim 4, in combination with claims 1 and 2, generalised the invention in a way that omitted important parts of the disclosed method and thereby told the skilled team for the first time that those parts were inessential. Consequently claim 1 and the combination of claims 1, 2 and 4 were held to be intermediate generalisations and therefore invalid on the grounds of added matter.

76.15.6 It is worth noting that the disclosure of the application includes all the information that the skilled person may ascertain about the invention. An intermediate generalisation is considered to add matter (at least in part) because it results in the skilled addressee being presented with information which they could not have derived from the application as originally filed, concerning the importance of the newly claimed feature. This new understanding is the 'matter' which is added. In a similar vein, an amendment limiting the scope of a claim to a single pill comprising 70 mg of alendronate by deleting other tablet weights and dosage combinations was held by the Court of Appeal in *Merck & Co Inc's Patents* [2004] FSR 16 to add to the teaching of the patent by introducing the importance of the 70 mg dosage being in the form of a single pill. For discussion of amendments which restrict a claim to a sub-range of a range disclosed at filing see 18.69.1.

76.16 [see 76.20]

Omission of a feature

Thus the omission from an amended claim of a feature specified in the original claim may be allowable if it is apparent from the whole document that its inclusion as a characterising feature was arbitrary and unnecessary. On the other hand, if the specification gave the impression that a feature was regarded as an essential element of the invention then amendment to omit this feature is not allowable. In Raychem Ltd's Application [1986] RPC 547, the applicants sought to amend two divisional applications by omitting the final (cross-linking) step from a process for producing a heat-recoverable polymeric sleeve assembly. The hearing officer's refusal to allow the applications as so amended to proceed under s.15(4) was upheld in the Patents Court where it was held that the cross-linking feature was clearly disclosed as an essential feature of the invention described; claims relating to the "intermediate" product obtained without the final crosslinking were not supported by that disclosure and would offend against s.76 as disclosing matter extending beyond that disclosed in the applications (and parent) as filed. In Decision T122/90, not published, concerning corresponding European patent applications, the EPO Board of Appeal similarly supported objection to claims "which did not specify that the bonded parts could be cross-linked so that the sleeve assembly was presented out of its original context", but allowed claims to the intermediate product which required the relevant material to be cross-linkable so that the bonded parts could be cross-linked, thus preserving the cross-linking feature.

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- The same outcome would appear likely under the current law.
- 76.18.1 The Court of Appeal in <u>Nokia Corporation v IPCOM GMBH & Co KG (No. 3)</u> [2013] R.P.C. 5 considered whether matter had been added by omission with reference to the "Houdaille Test" set out by the EPO Board of Appeal in <u>T331/87 Houdaille/Removal of feature [1991] E.P.O.R. 194</u>. The test was summarised by Kitchin L J:

"The skilled person must be able to recognise directly and unambiguously that (1) the [omitted] feature is not explained as essential in the original disclosure, (2) it is not, as such, indispensible for the function of the invention in light of the technical problem it serves to solve, and (3) the replacement or removal requires no real modification of other features to compensate for the change."

Claim Broadening

- 76.19 If an invention has been claimed narrowly and the applicant subsequently realises that he could have claimed it more broadly, this will not generally be possible if the whole teaching of the original specification was that the invention related only to the narrow aspect. For example, *Glatt's Application* [1983] RPC 122 was for an article (suitable for conditioning fabrics in a laundry dryer) comprising a flexible woven or non-woven airpermeable web. It was held to be wrong to allow claims to go forward omitting the requirement of air-permeability "upon a description of the invention in the body of the specification which only supports an article in which the use of an air-permeable base fabric is an essential feature".
- Nevertheless, the fact that an amendment has the effect of broadening the scope of the claims does not necessarily mean that it will be regarded as adding matter (see 76.05). Aldous J said in *Southco Inc v Dzus Fastener Europe Ltd* ([1990] RPC 587; upheld on appeal see [1992] RPC 299) that "What the Act is seeking to prevent is a patentee altering his claims in such a way that they claim a different invention from that which is disclosed in the application. Thus, provided the invention in the amended claim is disclosed in the application when read as a whole, it will not offend against section 76", and that "section 76 is there to prevent the patentee disclosing either by deletion or addition any inventive concept which was not disclosed before but not to prevent a patentee claiming the same invention in a different way". From a consideration of ss.125 and 130(3) in that case, the judge concluded that although there was no definition of the word "matter" it was wide enough to cover structural features of the mechanism and inventive concepts, and that it was reasonable to look at the claims construed as part of the whole document to see what was the invention.
- 76.21 In many cases it will be possible to raise objection to unacceptable claim broadening under either s.76 or s.14(5)(c); if both are contravened, then in general objection should be raised under both. When objecting under s.14(5)(c), a warning should be given against an attempt to overcome the objection by amending the description in a way which would contravene s.76(2). (For divisional applications, see 15.30).

76.22 [See 76.15.1]

76.23 [deleted]

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Section 76(3)

No amendment of the specification of a patent shall be allowed under section 27(1), 73 or 75 if it -

- (a) results in the specification disclosing additional matter, or
- (b) extends the protection conferred by the patent.

AFTER GRANT

- 76.24 Post-grant amendments are barred not only if they add matter (see 76.04-76.23) but also if they extend the protection conferred by the patent. These strictures apply to amendment of a granted patent, whether in proceedings initiated by the proprietor of the patent for that purpose or in the course of either proceedings initiated by the comptroller to revoke the patent, or of other proceedings in which the validity of the patent is put in issue.
- s.125(1)76.25 There is no restriction in the form of a post grant amendment, provided that it neither (a) extends the disclosure of the granted patent over the application as filed - see 76.05-23, nor (b) extends the protection conferred by the patent. The protection conferred is determined by the scope of the claims interpreted by the description and any drawings, and the disclosure of the claims is similarly determined - see 76.16. The term "matter" was held by Jacob J in Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd (BL C/089/96) to be equivalent to "subject matter" in EPC a.123(2) and from the purposive construction applied in that case it is presumed that "additional" means compared to the application as filed, not as granted. This means that it could be possible to re-introduce matter deleted before grant, provided that it does not result in extending the protection conferred by the patent. When interpreting s.76(3), due account may be taken of relevant decisions of the EPO Boards of Appeal; see 76.04.1.
 - To determine whether an amendment extends the protection conferred by the patent, the question to be asked is, is it possible to conceive of any act or apparatus which would infringe the amended claim but would not infringe any claim of the patent as it stands, without the proposed amendment? If the answer is negative then no objection arises under s.76(3)(b). If the claims have already been amended post-grant, then the proposed amendment must not extend the scope of the patent as currently amended. So, for example, if the claims have already been limited by amendment post-grant, the limitation cannot be removed in a further amendment. In Siegfried Demel v C & H Jefferson [1999] FSR 204 it was held that an amendment was permissible which broadened the scope of an appendant claim on the grounds that any case covered by that claim as amended would already have been covered by the earlier broader independent claim. It would appear that it would also be permissible to broaden the scope of an independent claim which is within the scope of another independent claim, or to introduce a new claim, whether appendant or independent providing the overall scope of the protection conferred by the patent is not extended. However any such broadening or intermediate generalisation (see 76.15.2) must not be contrary to the provisions of Sections 76(3)(a) and 14(5)(c) - ie must not extend the matter disclosed and must be supported by the description (see also 27.11). In patents with second medical use claims, post-grant amendment to replace "Swiss-type" claims (e.g. "The use of substance X in the manufacture of a medicament to treat disease Y") with the direct form of second medical use claim ("Substance X for use in the treatment of disease Y") is considered to extend the scope of protection and thus is contrary to s.76(3)(b) - see 4A.27.1.
 - 76.27 If an amendment allowed pre-grant is determined post-grant to have disclosed additional matter, then s.76(3)(b) prevents amendment to remove the additional matter if removal would have the result of extending the protection conferred by the patent

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(see EPO Enlarged Board of Appeal Decision G 01/93 *Advanced Semiconductor Products*, OJEPO 8/94). This can have potentially fatal consequences for the validity of the patent post-grant; the Enlarged Board described this as an "inescapable trap".

Section 76(4)

In subsection (1A) above "relevant application" has the meaning given by section 5(5) above.

76.28 See 5.30.

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Section 76A: Biotechnological inventions

76A.01 This section was introduced by the Patents Regulations 2000 (SI 2000 No.2037), which implemented articles 1-11 of Directive 98/44/EC on the legal protection of biotechnological inventions. The Patents Act 1977 (Isle of Man) Order 2003 (SI 2003 No. 1249) brought this section into force in the Isle of Man.

[The <u>Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office</u> provide further details on practice in this field.]

Section 76A(1)

Any provision of, or made under, this Act is to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention, subject to the provisions of Schedule A2.

Patentability of biotechnological inventions

Sch. A2
paras 1& 3
par

However, it then sets out the following as not being patentable inventions:

- (a) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;
- (b) processes for cloning human beings;
- (c) processes for modifying the germ line genetic identity of human beings;
- (d) uses of human embryos for industrial or commercial purposes;
- (e) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes;
- (f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.

The list is not exhaustive, since other subject matter which does not fall within this list may still fall within the general exclusion of s.1(3) - see 1.41-1.46.

76A.02.1 In C-34/10 ("Brüstle"), the Court of Justice of the European Union (CJEU) ruled on the interpretation of Article 6(2)(c) of Directive 98/44/EC, which corresponds with paragraph 3(d) of Schedule A2 of the Act. The CJEU ruled that, for the purposes of Article 6(2)(c), the term "human embryo" must be interpreted broadly to include any organism that is "capable of commencing the process of development of a human being". In paragraphs 35-38 the

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CJEU held that the term "human embryo" included:

- any human ovum after fertilisation, if that fertilisation is such as to commence the process of development of a human being;
- a non-fertilised human ovum into which the cell nucleus from a mature human cell
 has been transplanted, insofar as it is capable of commencing the process of
 development of a human being;
- a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis, insofar as it is capable of commencing the process of development of a human being.

In <u>C-364/13</u> ("International Stem Cell Corporation"), the CJEU further clarified the definition of the term "embryo" for the purposes of Article 6(2)(c) of the Directive, by ruling that:

"an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a 'human embryo' within the meaning of that provision [i.e. Article 6(2)(c) of the Directive], if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being."

76A.02.2 In light of the aforementioned decisions, the examination practice for inventions involving human embryonic stem cells is set out below, with the term "human embryo" interpreted in accordance with those decisions:

(i) Processes for obtaining stem cells from human embryos

The Office will not grant patents for processes of obtaining stem cells from human embryos because they involve the use of human embryos for industrial or commercial purposes, as excluded under paragraph 3(d) of schedule 2 of the Act.

(ii) Human totipotent cells

Human totipotent cells have the potential to develop into an entire human body. In view of this potential, such cells are not patentable because the human body at the various stages of its formation and development is excluded from patentability by paragraph 3(a) of Schedule A2 to the Act. The Office will therefore not grant patents for human totipotent cells.

(iii) Inventions requiring the destruction of human embryos

In *Brüstle*, the CJEU ruled that use of human embryos within the meaning of Article 6(2)(c) of the Directive occurs if the implementation of the invention requires the destruction of human embryos, even if the claims of the patent do not refer to the use of human embryos. The CJEU also ruled that the destruction may occur at any stage, including long before the implementation of the invention. Thus, where the implementation of an invention requires the use of cells that originate from a process which requires the destruction of a human embryo, the invention is not patentable according to paragraph 3(d) of Schedule A2 to the Act. For example, where the implementation of the invention requires the use of a human embryonic stem cell line, the establishment of which originally required the destruction of a human embryo, the invention is not patentable.

(iv) Human stem cells not derived from human embryos

Patents for inventions concerning human stem cells that are not derived from human embryos, such as induced pluripotent cells and adult stem cells, will be granted, provided they satisfy the other requirements for patentability.

(v) Inventions for therapeutic or diagnostic purposes

The CJEU judgment in Brüstle confirmed that inventions that are for therapeutic or

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diagnostic purposes that are applied to and useful to the human embryo are not excluded from patentability. The Office will continue to grant patents for such inventions, provided they meet the other legal requirements.

Further details of examination practice in relation to inventions involving human embryonic stem cells can be found in the Practice Notice dated 25 March 2015.

76A.02.3 In the Harvard "oncomouse" case T 315/03 ([2006] 1 OJEPO 15, [2005] EPOR 31), the EPO Board of Appeal held that an assessment of an objection to patentability under r.23 (d) EPC [1973] (the corresponding provisions of subparagraphs (b) to (e)) is to be made as of the filing or priority date of the patent application; evidence arising after this date may be taken into account provided it is directed to the position at that date. The Board held that when assessing the factors in subparagraph (e), only three matters should be considered: animal suffering, medical benefit and the necessary correspondence between the two in terms of the animals in question. The level of proof required is the same for both animal suffering and substantial medical benefit, namely a likelihood. In this case, claims covering transgenic rodents were refused as there was no evidence of substantial medical benefit deriving from applying the claimed process to all rodents. However, the Board allowed claims restricted to "mice", considering that the likelihood of substantial medical benefit in relation to advances in cancer research was relevant to all members of the mouse family, and there was clear correspondence between the medical benefit and the animal suffering.

76A.03 The wording of subparagraph (f) closely follows that of the repealed s.1(3)(b) - see 1.46. Whether or not a (non-microbiological) process for the production of animals or plants is to be considered as "essentially biological" has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved. However, the necessity for human intervention alone is not a sufficient criterion for an invention not being "essentially biological". The EPO Enlarged Board of Appeal in two related decisions (G 02/07 and G 01/08) held that claims to any nonmicrobiological processes for the sexual crossing of the whole genomes of plants are excluded as being "essentially biological". Furthermore, claims to a breeding process do not escape the exclusion merely by the addition of a further technical step which serves to enable or assist the the steps of sexually crossing or subsequently selecting the offspring. This is because such steps do not move the process beyond what is considered to be "essentially biological" processes. Therefore, in order to be patentable at least one additional technical step must be performed within the steps of sexual crossing and selection, which "by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing".

76A.04 As subparagraph (f) makes clear, the exclusion does not apply to micro-biological or other technical processes or the products thereof, and patents may therefore be obtained not only for processes involving micro-organisms, but also for micro-organisms themselves (as well as inanimate products) when produced by a micro-biological process. "Micro-biological or other technical processes" should be construed widely as including selective culturing or cross-breeding of micro-organisms including sub micro-organisms and not be restricted to essentially chemical manufacturing processes in which micro-organisms are used. Thus a claim to micro-organisms per se may be allowed when they have been obtained by cross-selecting from known micro-organisms, by artificial mutation or by micro-biological reproduction processes in which normal conditions have been altered by human intervention.

Sch. A2
76A.05 Inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. The EPO Enlarged Board of Appeal in *Novartis/Transgenic plant* G1/98 ([2000] EPOR 303; [2000] 3 OJEPO 111) has stated that a claim in which specific varieties are not individually claimed is not excluded from patentability under a.53(b) EPC (equivalent to Sch A2 para 3(f)) even if the claim embraces within its scope plant varieties. (Certain plant varieties are capable of protection in the UK under the Plant Varieties and Seeds Act 1964, which is administered by

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the Plant Variety Rights Office, White House Lane, Huntingdon Road, Cambridge CB3 OLF). The scope of the exclusion of animal varieties was considered by the EPO in the Harvard "oncomouse" case T 315/03 ([2006] 1 OJEPO 15, [2005] EPOR 31). Here it was held that the principle enunciated in G1/98 concerning plant and plant varieties should be followed in the case of animals: a patent should not be granted for a single animal variety (or species or race, depending on which language text of the EPC is used) but can be granted if varieties may fall within the scope of its claims. The Board pointed out the inconsistency in taxonomical rank between variety, species and race, with the German term "Tierarten" (i.e. "animal species") having the highest taxonomical order, but it concluded that mice constituted a taxonomic classification broader than species, and therefore claims to transgenic mice were not excluded from patentability under a.53(b) EPC. (see also 1.43).

Sch. A2 paras 2, 5 Sch. A2 para 6 76A.06 Finding biological material, such as a micro-organism, occurring freely in nature is a mere discovery and is therefore unpatentable as such (see 1.27-1.28). However, biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention, even if the material previously occurred in nature. More specifically, following the *Relaxin* case (*Howard Florey Institute of Experimental Physiology* [1995] 6 OJEPO 388 (V 08/94), the Schedule states that an element isolated from the human body or otherwise produced by means of a technical process may be patentable even if the structure of that element is identical to that of the natural element. This includes the sequence or partial sequence of a gene. However, where the invention in a patent application resides in a whole or partial gene sequence, the industrial application of the sequence must be disclosed in the application as filed – see 4.07.1-2.

Construction of claims relating to biotechnological inventions

Sch. A2 para 7 Sch. A2 para 8 Sch. A2 para 9 Sch. A2 para 10 ss.60(5) &(6A)-(6C) 76A.07 Paragraphs 7 to 10 of Schedule A2 set out certain rules for the construction of claims which relate to biological material or to processes that enable biological material to be produced. In particular, a claim to a biological material which has certain specific characteristics as a result of the invention is construed as extending to protect biological material possessing the same specific characteristics which has been derived from the claimed material by propagation or multiplication. Similarly, a claim to a process for producing biological material which has certain specific characteristics as a result of the invention is construed as extending to protect the biological material itself and to biological material possessing the same specific characteristics which has been derived from that material by propagation or multiplication.

76A.08 Paragraph 9 of Schedule A2 (derived from Article 9 of Directive 98/44/EC) states that a claim to a product containing or consisting of genetic information is construed as extending to all material (except excluded material - see 76A.02) in which the product is incorporated and in which the genetic information is contained and performs its function. The interpretation of Article 9 of the Directive was considered by the European Court of Justice in *Monsanto Technology LLC v Cefetra BV et al* ECJ Case C-428/08. This was a reference from the Dutch courts on a case concerning the import of soy meal derived from genetically modified soybeans. The soy meal was found to contain a modified gene; this modified gene, and plants and plant cells containing it, were covered by a valid European patent held by Monsanto. The DNA in the soy meal was clearly not "performing its function", as the soy meal was dead, but it had performed its function (of protecting the plant against a herbicide) in the living plant from which the soy meal was derived, and could conceivably do so again if it was extracted and transferred to a living plant or cell.

76A.08.1 The ECJ held that patent protection for genetic material does not extend to circumstances where the genetic material has ceased to perform its function, even if it did perform this function in the past and could possibly do so in the future if isolated and transferred into a living cell. Moreover, Article 9 of the Directive precludes national patent law from offering absolute protection to the patented genetic material, regardless of whether it performs its function in the material containing it. This has implications for the

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interpretation of s.60 in the case of biotechnological inventions. Section 60(1)(a) states that where the invention is a product, it is an infringement to make, dispose of, offer to dispose of, use or import the product or keep it whether for disposal or otherwise (see 60.06-16). However, if the product contains or consists of genetic material, this is subject to the proviso that it performs its function in the material containing it. In other words, s.60 must be read in the light of paragraph 9 of Schedule A2 for inventions of this type, and it may be inferred that the same applies for all of paragraphs 7-10 of Schedule A2. In addition, the ECJ held that it was irrelevant whether the patent had been filed or granted before adoption of the Directive, and that the interpretation of Article 9 is not affected by the provisions of the TRIPS Agreement.

76A.09 Where biological material which is subject to patent protection is put on the market by the proprietor (or with his consent), and where propagation or multiplication of further biological material necessarily results, the protection conferred by the patent does not extend to this further biological material, provided that this further material is not then used for further propagation or multiplication. (Under certain limited circumstances, however, it is possible for farmers to use this further material for further propagation or multiplication without infringing - see 60.26-27).

Section 76A(2)

Nothing in this section or Schedule A2 is to be read as affecting the application of any provision in relation to any other kind of patent or application for a patent.

76A.10 Section 76A(2) makes clear that the provisions of this section and of Schedule A2 cannot be construed as having any effect on a patent or application which does not concern a biotechnological invention. The Patents Regulations 2000 added to s.130(1) a definition of what constitutes a 'biotechnological invention' - see 130.04.1.

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PART II: PROVISIONS ABOUT INTERNATIONAL CONVENTIONS

EUROPEAN PATENTS AND PATENT APPLICATIONS

Section 77: Effect of European patent (UK)

77.01 This section provides for a granted European patent (UK) to be treated like a granted domestic patent. It further relates to the effects on a European patent (UK) of certain proceedings under the EPC (involving amendment, revocation, restoration or determination of the validity of the patent).

s.130(1) 77.02 European patent (UK) means a patent granted under the EPC designating the United Kingdom as a country in which protection is sought for the invention which is the subject of the patent. The EPC is the European Patent Convention, ie the Convention on the Grant of European Patents.

Section 77(1)

Subject to the provisions of this Act, a European patent (UK) shall, as from the publication of the mention of its grant in the European Patent Bulletin, be treated for the purposes of Parts I and III of this Act as if it were a patent under this Act granted in pursuance of an application made under this Act and as if notice of the grant of the patent had, on the date of that publication, been published under section 24 above in the journal; and -

- (a) the proprietor of a European patent (UK) shall accordingly as respects the United Kingdom have the same rights and remedies, subject to the same conditions, as the proprietor of a patent under this Act;
- (b) references in Parts I and III of this Act to a patent shall be construed accordingly; and
- (c) any statement made and any certificate filed for the purposes of the provision of the convention corresponding to section 2(4)(c) above shall be respectively treated as a statement made and written evidence filed for the purposes of the said paragraph (c).
- 77.03 A European patent (UK) granted under the EPC is thus treated as if it were a patent granted under the Patents Act 1977, and the proprietors of the patent have the same rights and remedies as the proprietors of a domestic patent. The effective date of grant from which it is so treated is the date of mention of the grant in the Bulletin published under the EPC.
- In <u>Virgin Atlantic Airways Ltd v Jet Airways (India) Ltd & Ors [2013] EWCA Civ 1713 the Court of Appeal considered whether the UK had jurisdiction over the decisions of the EPO for the purposes of Article 1 of the European Convention on Human Rights (ECHR). The court held that the EPO is factually and legally independent of the IPO and since s.77(1) makes European patents directly effective in domestic law from the date of publication in the Bulletin the Comptroller's function in the process is purely administrative. It was considered that the recognition of the validity and effect of European patents by virtue of s.77 is not sufficient to create a jurisdictional link. Consequently the automatic recognition of grant of an EP(UK) is not subject to qualification by the ECHR, and the courts and the Comptroller do not have a general power to review the validity of patents granted by the EPO on grounds other than those specified in the EPC (in this case it was claimed that the EP(UK) was not valid as the UK designation was the result of a procedural error at the EPO</u>

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- see also 72.03). The court went on to say that to allow such a power would fatally undermine the whole system for the grant of European patents.

a.86 EPC r.37(4) r.38(1) 77.04 The term of a European patent (UK) is twenty years measured from the date of filing accorded to it under Rule 40 of the EPC. Fees to keep it in force in respect of years up to and including the year in which mention of grant is published are paid direct to the EPO. Annual renewal fees should be paid to the UK Office in order to maintain the patent after the end of the year of grant or, if it is granted before the end of the fourth year of its term, after the end of that fourth year (for procedure, see 25.06 and 25.08-25.11).

r.103 r.39

77.05 The proprietors of a European patent (UK) may provide an address for service within the United Kingdom, another EEA State or the Channel Islands. A convenient time for proprietors to notify the Office of this address is as soon as it becomes apparent that a European patent application is going to be granted, which will usually be on receipt of the notice issued by the EPO under EPC rule 71(3). If, however, the comptroller is not notified of an address for service for the proprietor of a European patent (UK), then the proprietor's address on the register will be treated as the address for service, even if that address is outside the EEA or the Channel Islands. Where no other address is provided, this address will be used for issuing any notice under rule 39(2) reminding the proprietor of overdue renewal fees (see 25.08) unless an address specifically for this purpose has been given on Form 12 at a previous renewal (see 25.12). Notification to the Office of an address for service can be made on Form 51 appointing an agent in the UK, or by letter. If this letter or form is filed in duplicate, receipt is acknowledged by returning the copy. The publication (serial) number of the European patent (UK) should be clearly stated in the notification.

r.103 r.104 PR Sch. 4 Parts 2 & 3 Any person, including the proprietor of a European patent (UK), who makes any application, reference or request relating to any proceeding under the Patents Act 1977 or Patents Rules 2007, or who gives any notice of opposition under the Patents Act 1977, or who opposes such an application, reference, request or notice must furnish the Office with an address for service in the UK, another EEA State or the Channel Islands. If a person fails to provide such an address for service, and there is sufficient information to contact the person, he should be contacted and be directed to file an acceptable address for service within 2 months (this period can be extended using rule 108(2) and 108(3) - see 123.36.5). If an acceptable address is not provided within this time period, or there is insufficient information to make contact with anyone to provide such an address, the person is taken either to have failed to initiate or to have withdrawn from proceedings as appropriate.

77.06 Where the invention to which a European patent (UK) relates was disclosed at an international exhibition within the six months preceding the filing of the European patent application, the statement and certificate filed under EPC Article 55 and EPC rule 25 are treated as the statement and evidence required under s.2(4)(c) and r.5, see 2.40.

r.31(1) EPC 77.07 In accordance with paragraphs 2 and 3 of Schedule 1 of the Patents Rules 2007, if the invention to which a European patent (UK) relates involves the use of or concerns biological material, the relevant disclosure is regarded as clear enough and complete enough for the invention to be performed by a person skilled in the art if the relevant provisions of the Implementing Regulations to the EPC have been complied with, and the biological material has been deposited, on or before the date of filing of the application, in a depositary institution which is able to furnish subsequently a sample of the biological material, and the specification of the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material. See also 125A.07.

Section 77(2)

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Subsection (1) above shall not affect the operation in relation to a European patent (UK) of any provisions of the European Patent Convention relating to the amendment or revocation of such a patent in proceedings before the European Patent Office.

a.99 EPC a.101 EPC 77.08 Even though a European patent (UK) is treated as if it were a patent under the 1977 Act, it is still subject to revocation, including amendment, proceedings before the EPO. Notice of opposition to a European patent may be given to the EPO within nine months of the mention of its grant, and the opposition applies in all the contracting states in which the patent has effect. This can lead to revocation of the patent or its maintenance in amended or unamended form, whichever is decided by the EPO.

[If proceedings before the comptroller are initiated in respect of a European patent (UK) which is the subject of opposition proceedings before the EPO, it is important to be aware of the progress of the opposition. This can be monitored through the online file and register inspection facilities available through the <u>European Patent Register</u>. Queries about using this inspection facility should be raised with the European Patent Filing Department on ext 4636.]

s.77(4) and(4A) 77.09 A European patent (UK) amended or revoked under the EPC is treated as if it had been amended or revoked under the Act.

Section 77(3)

Where in the case of a European patent (UK) -

- (a) proceedings for infringement, or proceedings under section 58 above, have been commenced before the court or the comptroller and have not been finally disposed of, and
- (b) it is established in proceedings before the European Patent Office that the patent is only partially valid,

the provisions of section 63 or, as the case may be, of subsections (7) to (9) of section 58 apply as they apply to proceedings in which the validity of a patent is put in issue and in which it is found that the patent is only partially valid.

77.10 In proceedings under the Act relating to infringement of, or Crown use of an invention protected by, a European patent (UK), the effect of a finding of partial validity before the EPO is the same as that of a finding of partial validity under the Act. The provisions of ss.58(7) to (9) (relief for Crown use of invention of patent found to be only partially valid) and 63 (relief for infringement of patent found to be only partially valid) thus apply regardless of which of these ways partial validity was found. Section 77(3) was amended by the CDP Act to make it clear that its provisions apply to Crown use proceedings under s.58 as well as to infringement proceedings.

Section 77(4)

Where a European patent (UK) is amended in accordance with the European Patent Convention, the amendment shall have effect for the purposes of Parts I and III of this Act as if the specification of the patent had been amended under this Act; but subject to subsection (6)(b) below.

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Section 77(4A)

Where a European patent (UK) is revoked in accordance with the European Patent Convention, the patent shall be treated for the purposes of Parts I and III of this Act as having been revoked under this Act.

77.11 See 77.08-09.

Section 77(5)

Where -

- under the European Patent Convention a European patent (UK) is revoked for failure to observe a time limit and is subsequently restored or is revoked by the Board of Appeal and is subsequently restored by the Enlarged Board of Appeal; and
- (b) between the revocation and publication of the fact that it has been restored a person begins in good faith to do an act which would, apart from section 55 above, constitute an infringement of the patent or makes in good faith effective and serious preparations to do such an act;

he shall have the rights conferred by section 28A(4) and (5) above, and subsections (6) and (7) of that section shall apply accordingly.

Where under the EPC a European patent (UK) is revoked for failure to observe a time limit and subsequently restored or is revoked by the Board of Appeal and is subsequently restored by the Enlarged Board of Appeal, the exemption of third parties from infringement proceedings provided by s.28A applies to acts or preparations in the intervening period. This includes acts of Crown use which, but for s.55, would constitute infringement.

Section 77(5A)

Where, under the European Patent Convention, a European patent (UK) is revoked and subsequently restored (including where it is revoked by the Board of Appeal and subsequently restored by the Enlarged Board of Appeal), any fee that would have been imposed in relation to the patent after the revocation but before the restoration is payable within the prescribed period following the restoration.

- r.41A This subsection was introduced on 1 October 2014 by the Intellectual Property Act 2014. It relates to the situation where a European patent (UK) has been r.36 revoked by the EPO Board of Appeal and is subsequently restored by the Enlarged Board of Appeal following a petition for review under Art.112a EPC. Unlike other forms of appeal, where a petition for review has been filed this does not have suspensive effect, meaning that the patent remains revoked whilst the petition for review is being considered. Renewal fees cannot be paid when a patent is revoked. Section 77(5A) and rule 41A introduce a clear requirement for any renewal fees which fell due whilst the patent was revoked to be paid within a two-month period following the restoration. As with any other renewal fees, Patents Form 12 should accompany any payment.
- See 25.12-15 for the actions taken should any outstanding renewal fees s.25(5)77.12.2 not be paid in the two-month period following the restoration, and for the consequences of r.39 non-payment.

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Section 77(6) (Not in force from 1 May 2008)

While this subsection is in force -

- subsection (1) above shall not apply to a European patent (UK) the specification of which was published in French or German, unless a translation of the specification into English is filed at the Patent Office and the prescribed fee is paid before the end of the prescribed period;
- subsection (4) above shall not apply to an amendment made in French or German unless a translation into English of the specification as amended is filed at the Patent Office and the prescribed fee is paid before the end of the prescribed period.

Section 77(7)

Where such a translation is not filed, the patent shall be treated as always having been void.

Section 77(8)

The comptroller shall publish any translation filed at the Patent Office under subsection (6) above.

Section 77(9)

Subsection (6) above shall come into force on a day appointed for the purpose by rules and shall cease to have effect on a day so appointed, without prejudice, however, to the power to bring it into force again.

Rule 56(10) sets out that the appointed day is the day of coming into force of r.56(10) 77.12.2 the Agreement on the Application of Article 65 of the convention on the grant of European patents made in London on 17 October 2000 ("the London Agreement"). The London Agreement came into force on 1 May 2008 from which date section 77(6) is no longer in force.

Translations of European patents (UK) in French or German

- 77.13 While s.77(6) was in force, European patents (UK) published or amended s.80(2)in French or German were treated in the UK as ineffective and always having been void unless an English translation of the specification or amended specification was filed. Any translation filed of such a specification or amended specification was published by the Office. Such a translation of a specification may in some circumstances be treated as the authentic text for the purposes of proceedings under the Act, see 80.02.
 - The Patents (Amendment) Rules 1987 (S.I. 1987 No. 288) appointed 1 September 1987 as the day on which s.77(6) came into force but only in respect of European patents (UK) granted on or after that day. The date of grant is that on which mention of the grant of the patent is published in the European Patent Bulletin. Rule 56(9) and (10) of the Patents Rules 2007 make provision for s. 77(6) and rule 56(1)(a) and (5) to

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(8) to cease to have effect on the date that the Agreement on the application of Article 65 of the Convention on the Grant of European Patents made in London on 17 October 2000 ("the London Agreement") comes into force. The coming into force date for the London Agreement was 1 May 2008 from which date translations are no longer required. Article 9 of the London Agreement sets out that that the agreement applies to European patents in respect of which the mention of grant is published in the European Patent Bulletin on or after the date the agreement comes into force. However, there are no similar transitional arrangements for rule 56 which has the effect that patent proprietors may take advantage of the three month period prescribed for filing a translation. European patents granted or amended from 1 February 2008 therefore do not require a translation to be filed in order for the patent or amendment to enter into force in the UK.

77.15 The prescribed period may be extended in accordance with r.108(2) or (3) and (4) to (6), see 123.34-41 and therefore patents granted or amended prior to 1 February 2008 may not require a translation to be filed.

77.16	[deleted]
77.17	[deleted]
77.18	[deleted]
77.19	[deleted]
77.20	[deleted]
77.21	[deleted]
77.22	[deleted]
77.23	[deleted]
77.24	[deleted]

77.25 Any renewal fees paid in respect of European patents (UK) which are ultimately declared void because of failure to file a necessary translation are not refunded.

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Section 78: Effect of filing an application for a European patent (UK)

78.01 EPC applications for European patents (UK), although searched, published and processed to grant by the EPO, are treated as applications under the 1977 Act in certain respects, as laid down in this section. The section also includes a provision whereby English translations of the claims of applications for European patents (UK) published in French or German are required in order to establish certain rights.

s.130(1)

78.02 An application for a European patent (UK) is an application which has been filed under the EPC and which, on its date of filing, designated the United Kingdom as a country in which protection is sought for the invention which is the subject of the application.

a.75 EPC s.23(1) s.23(1A) s.22(3)(b) a.77(5) EPC a.135 EPC a.76 EPC

A European patent application (other than a European divisional application) may be filed at the EPO (Munich or The Hague) or, if the law of a contracting state so permits, at the central industrial property office or other competent authority of that state. The UK Office is just such a central industrial property office and may thus receive any European patent application. However, in the case of applications which contain information relating to military technology or other information whose publication might be prejudicial to national security or the safety of the public by residents of the UK, they must be first filed with the UK Office unless either, written authority for filing elsewhere has been previously given by the comptroller, or an application for the same invention has been filed in the UK not less than six weeks earlier and no prohibition directions under s.22 are in force. While any such directions are in force with respect to a European patent application, it is not forwarded to the EPO. If this prevents it reaching the EPO before the end of the fourteenth month after filing or, if priority has been claimed, after the date of priority, it is deemed to be withdrawn. The applicant may then apply (under s.81) for the application to be converted to one for a patent under the Act. European divisional applications must be filed directly with the EPO.

78.04 Section 79 provides for the operation of s.78 in relation to applications for a European patent (UK) initiated by an international application under the PCT.

Section 78(1)

Subject to the provisions of this Act, an application for a European patent (UK) having a date of filing under the European Patent Convention shall be treated for the purposes of the provisions of this Act to which this section applies as an application for a patent under this Act having that date as its date of filing and having the other incidents listed in subsection (3) below, but subject to the modifications mentioned in the following provisions of this section.

Section 78(2)

This section applies to the following provisions of this Act -

section 2(3) and so much of section 14(7) as relates to section 2(3);

section 5;

section 6;

so much of section 13(3) as relates to an application for and issue of a certificate under that subsection:

sections 30 to 33;

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section 36;
sections 55 to 69;
sections 70 to 70F;
section 74, so far as relevant to any of the provisions mentioned above;
section 111; and
section 125.
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An application for a European patent (UK) made under the EPC is treated as an application under the Act for the purposes of the provisions set out in sub-section (2). These purposes relate to the extent of the prior art under s.2(3) (and exclusion of the abstract therefrom); priority dates under s.5; disclosure in earlier and later applications, under s.6; certificates under s.13(3) to the effect that a person ought not to have been mentioned as sole or joint inventor; transactions and property in patents and applications under ss.30 and 31; registration of patents and published applications and transactions etc under ss.32 and 33; co-ownership of patents and applications under s.36; Crown use and infringement under ss.55 to 69; proceedings relevant to any of the preceding sections where validity can be put in issue under s.74; unauthorised claims that a patent has been applied for, under s.111; and the extent of an invention under s.125.

78.05.1 Sections 70 to 70F were added to section 78(2) by the Intellectual Property (Unjustified Threats) Act 2017. This ensures that threats provisions apply to European Patent applications in the same way that they apply to UK patent applications.

Section 78(3)

The incidents referred to in subsection (1) above in relation to an application for a European patent (UK) are as follows -

- (a) any declaration of priority made in connection with the application under the European Patent Convention shall be treated for the purposes of this Act as a declaration made under section 5(2) above;
- (b) where a period of time relevant to priority is extended under that convention, the period of twelve months allowed under section 5(2A)(a) above shall be so treated as altered correspondingly;
- (c) where the date of filing an application is re-dated under that convention to a later date, that date shall be so treated as the date of filing the application;
- (d) the application, if published in accordance with that convention, shall, subject to subsection (7) and section 79 below, be so treated as published under section 16 above:
- (e) any designation of the inventor under that convention or any statement under it indicating the origin of the right to a European patent shall be treated for the purposes of section 13(3) above as a statement filed under section 13(2) above;
- (f) registration of the application in the register of European patents shall be treated as registration under this Act.

s.78(1) 78.06 The date of filing accorded to the application for a European patent (UK) under EPC Article 80 is taken as if it were the date of filing under the Act. Various other acts

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(concerning priority, filing, publication, indicating the name of the inventor or derivation of the right to apply, and registration all as set out in sub-section (3)) done under the EPC can be treated as having been done under the Act. Treatment of publication under the EPC as publication under s.16 of the Act is subject to compliance with the requirements as to the language of the published application set out in s.78(7) (since this sub-section was brought into force, see 78.11-12) and s.79(2) and (3) (if the European patent application was initiated by a PCT international application).

Section 78(4)

Rules under section 32 above may not impose any requirements as to the registration of applications for European patents (UK) but may provide for the registration of copies of entries relating to such applications in the European register of patents.

78.07 Rule 79 of the Patents Rules 1995 provided for keeping entries in the register relating to published applications for European patents (UK), but was revoked by the Patents (Amendments) Rules 1999. See 32.07.

Section 78(5)

Subsections (1) to (3) above shall cease to apply to an application for a European patent (UK), except as mentioned in subsection (5A) below, if -

- (a) the application is refused or withdrawn or deemed to be withdrawn, or
- (b) the designation of the United Kingdom in the application is withdrawn or deemed to be withdrawn,

but shall apply again if the rights of the applicant are re-established under the European Patent Convention, as from their re-establishment.

Section 78(5A)

The occurrence of any of the events mentioned in subsection (5)(a) or (b) shall not affect the continued operation of section 2(3) above in relation to matter contained in an application for a European patent (UK) which by virtue of that provision has become part of the state of the art as regards other inventions; and the occurrence of any event mentioned in subsection (5)(b) shall not prevent matter contained in an application for a European patent (UK) becoming part of the state of the art by virtue of section 2(3) above as regards other inventions where the event occurs before the publication of that application.

78.08 Under EPC, every European patent application will designate the UK on filing and will be treated as an application for a European patent (UK). Upon the refusal or the actual or deemed withdrawal of an application for a European patent (UK), or of its designation of the UK, it is no longer treated as an application under the Act except as provided for by subsection (5A). This subsection means that any document which forms part of the state of the art under s.2(3) will not cease to do so if the application is withdrawn or refused. Furthermore, under section 78(5A) removal of the designation prior to publication will not have an effect on the prior art status under section 2(3). Every European patent application will therefore have prior art effect under section 2(3) on publication regardless of whether the UK remains designated at the time of publication. If the rights of the applicant in relation to the application are subsequently re-established under the EPC, the application at the same time resumes its status under the Act as set out in s.78(1)-(3).

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However, the provisions of s.78(6) apply to infringers in the intervening period.

78.09 [deleted]

Section 78(6)

Where, between subsections (1) to (3) above ceasing to apply to an application for a European patent (UK) and the re-establishment of the rights of the applicant, a person –

- (a) begins in good faith to do an act which would constitute an infringement of the rights conferred by publication of the application if those subsections then applied, or
- (b) makes in good faith effective and serious preparations to do such an act,

he shall have the right to continue to do the act, or as the case may be, to do the act, notwithstanding subsections (1) to (3) applying again and notwithstanding the grant of the patent.

78.10 The exemption of third parties from infringement proceedings provided by s.28A(4) to (7) applies to acts or preparations in the period between cessation and reestablishment (see 78.08). This includes acts of Crown use which, but for s.55, would constitute infringements.

Section 78(6A)

Subsections (5) and (6) of section 20B above have effect for the purposes of subsection (6) above as they have effect for the purposes of that section and as if the references to subsection (4) of that section were references to subsection (6) above.

Section 78(6B)

Subject to subsection (6A) above, the right conferred by subsection (6) above does not extend to granting a licence to another person to do the act in question.

Section 78(6C)

Subsections (6) to (6B) above apply in relation to the use of a patented invention for the services of the Crown as they apply in relation to an infringement of the rights conferred by publication of the application (or, as the case may be, infringement of the patent).

"Patented invention" has the same meaning as in section 55 above.

78.10.1 Section 78(6) prior to implementation of the revised EPC on 13 December 2007 provided protection for third parties when a European patent application was terminated or refused. Sections 78(6) to 78 (6C) clarify the protection afforded to third parties when a European patent application has been refused and then reinstated. This includes reinstatement by the Enlarged Board of Appeal. The provision as amended is consistent with sections 20B and 177A on reinstatement and resuscitation of national patent applications.

Section 78(7)

While this subsection is in force, an application for a European patent (UK) published by the

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European Patent Office under the European Patent Convention in French or German shall be treated for the purposes of sections 55 and 69 above as published under section 16 above when a translation into English of the claims of the specification of the application has been filed at and published by the Patent Office and the prescribed fee has been paid, but an applicant -

- (a) may recover a payment by virtue of section 55(5) above in respect of the use of the invention in question before publication of that translation; or
- (b) may bring proceedings by virtue of section 69 above in respect of an act mentioned in that section which is done before publication of that translation;

if before that use or the doing of that act he has sent by post or delivered to the government department who made use or authorised the use of the invention, or, as the case may be, to the person alleged to have done the act, a translation into English of those claims.

Section 78(8)

Subsection (7) above shall come into force on a day appointed for the purpose by rules and shall cease to have effect on a day so appointed, without prejudice, however, to the power to bring it into force again.

Translation of claims from French or German

s.79(1) r.56(1)(b) s.80(2)

- 78.11 Since s.78(7) was brought into force, applications for European patents (UK) published by the EPO (and international applications for a European patent (UK) the subject of proceedings before the EPO under EPC a.150 and published under PCT a.21) in French or German are treated as published for Crown use or infringement purposes under the Act when an English language translation of the claims thereof has been filed at and published by the UK Office. Rights are also obtainable by the applicant in relation to use or acts done before publication of that translation from the date on which the applicant sends a translation to the government department or potential infringer in question under s.55 or 69 respectively. Such a translation may in some circumstances be treated as the authentic text for the purposes of proceedings under the Act, see 80.02.
- 78.12 The Patents (Amendment) Rules 1987 appointed 1 September 1987 as the day on which s.78(7) came into force but only in respect of applications for a European patent (UK) which were published by the EPO on or after that day.
- 78.13 It is not obligatory to file a translation of the claims; it is entirely at the option of the applicant to do so if he wishes to secure the rights referred to in 78.11. There is no time limit for filing it.

r.56 r.115 78.14 The translation should be filed in duplicate together with Patents Form 54 in duplicate and the appropriate fee. The translation should comply with certain formal requirements, as set out in Parts 1 to 3 of Schedule 2. These requirements are described in 14.27-30 and 14.33-36. There is no requirement for a translation to be verified. However, if there are reasonable doubts about the accuracy of the translation, the comptroller should notify the person of the reasons for his doubts and may require evidence to be filed to establish that the translation is accurate. The comptroller may, if he thinks fit, take no further action in relation to the document where the person fails to furnish evidence.

s.118(1)

78.15 If the requirements are met, the fact that the translation has been filed is recorded in the register and announced in the Journal. It is made available for sale and a copy is placed on file and thus open to public inspection at the Office. Requests for inspection of the file containing the translation should be accompanied by the prescribed fee, if any.

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Section 79: Operation of s.78 in relation to certain European patent applications

a.150 EPC

79.01 An international application made under the PCT in which the EPO acts as designated or elected Office (and will therefore conduct the substantive examination) is deemed to be a European patent application. This section provides for the operation of s.78 in relation to such an application which designates the UK as a country in which protection is sought.

Section 79(1)

Subject to the following provisions of this section, section 78 above, in its operation in relation to an international application for a patent (UK) which is treated by virtue of the European Patent Convention as an application for a European patent (UK), shall have effect as if any reference in that section to anything done in relation to the application under the European Patent Convention included a reference to the corresponding thing done under the Patent Co-operation Treaty.

s.79(1)-(3) s.78(7) An application for a European patent (UK) initiated by an international application is treated as an application under the 1977 Act to the extent specified in s.78, in the same way as any other application for a European patent (UK) except for requirements with regard to language and filing at the EPO (see 79.03-04) and the fact that acts done under the PCT are treated as if they were the corresponding acts done under the EPC. Publication by the International Bureau under PCT a.21 in French or German can be taken to be publication by the EPO for the purposes of s.78(7), see 78.11.

Section 79(2)

Any such international application which is published under that treaty shall be treated for the purposes of section 2(3) above as published only when a copy of the application has been supplied to the European Patent Office in English, French or German and the relevant fee has been paid under that convention.

79.03 The matter in such an international application published under the PCT becomes part of the state of the art under s.2(3) only if a copy of the application in English, French or German has been filed at the EPO.

Section 79(3)

Any such international application which is published under that treaty in a language other than English, French or German shall, subject to section 78(7) above, be treated for the purposes of sections 55 and 69 above as published only when it is re-published in English, French or German by the European Patent Office under that convention.

If the international application is published under the PCT in a language other than English, French or German, it is not treated as published for Crown use or infringement purposes under the Act until it is re-published in English, French or German by the EPO. However, under s.78(7), those re-published in French or German are not so treated until an English translation of the claims has been filed at and published by the UK Office, see 78.11.

Section 80: Authentic text of European patents and patent applications

Section 80(1)

Subject to subsection (2) below, the text of a European patent or application for such a patent in the language of the proceedings, that is to say, the language in which proceedings relating to the patent or the application are to be conducted before the European Patent Office, shall be the authentic text for the purposes of any domestic proceedings, that is to say, any proceedings relating to the patent or application before the comptroller or the court.

- r.114 80.01 The authentic text of a European patent or application therefor in proceedings before the comptroller or the court is the text in the language used in the EPO proceedings, except as provided for below (see 80.02-07). (Where proceedings are instituted before the comptroller in relation to a European patent (UK) the specification of which was published in French or German, the party who institutes those proceedings is normally required to furnish a verified translation into English of the specification unless such a translation has already been filed under s.77(6). This also applies to the making a request of an opinion under section 74A. A party given leave to amend the specification during such proceedings must furnish a verified translation of the amendment into the language in which the specification was published).
- a.70(1) 80.01.1 Since the authentic text of a European patent published in French or German is that in the language used in the EPO proceedings, the authentic text for the claims is the text of the claims in the language of the EPO proceedings. The translated claims of a European patent published in French or German which are filed under Article 14(6) are for information only.

Section 80(2)

Where the language of the proceedings is French or German, a translation into English of the specification of the patent under section 77 above or of the claims of the application under section 78 above shall be treated as the authentic text for the purpose of any domestic proceedings, other than proceedings for the revocation of the patent, if the patent or application as translated into English confers protection which is narrower than that conferred by it in French or German.

This sub-section became effective only when s.77(6) and s.78(7) were brought into force, see 77.13-14 and 78.11-12 respectively. Where the language of the EPO proceedings is French or German, an English translation of the specification under s.77(6) or of the claims under s.78(7) is treated as the authentic text if it confers protection narrower than that conferred by the French or German text. This provision does not apply to proceedings for the revocation of the patent.

Section 80(3)

If any such translation results in a European patent or application conferring the narrower protection, the proprietor of or applicant for the patent may file a corrected translation with the Office and, if he pays the prescribed fee within the prescribed period, the Office shall publish it, but -

(a) any payment for any use of the invention which (apart from section 55 above) would have infringed the patent as correctly translated, but not as originally translated, or in the case of an application would have infringed it as aforesaid if the patent had been granted,

shall not be recoverable under that section,

(b) the proprietor or applicant shall not be entitled to bring proceedings in respect of an act which infringed the patent as correctly translated, but not as originally translated, or in the case of an application would have infringed it as aforesaid if the patent had been granted,

unless before that use or the doing of the act the corrected translation has been published by the Office or the proprietor or applicant has sent the corrected translation by post or delivered it to the government department who made use or authorised the use of the invention or, as the case may be, to the person alleged to have done that act.

80.03 If a translation as referred to in 80.02 results in narrower protection being conferred by the European patent or application, the proprietor or applicant may file a corrected translation. In such a case it is the specific provisions of s.80(3) and r.57 that apply rather than the general provisions of s.117 (Rhône-Poulenc Santé's European Patent (UK) [1996] RPC 125). However, rights of the proprietor or applicant with regard to acts or use (including Crown use which, but for s.55, would constitute infringement) which would infringe in relation to the corrected translation but not in relation to the original translation apply only to such acts or use done after the date on which the corrected translation is published by the Office or sent to the potential infringer or government department in question by the proprietor or applicant.

- r.57(2) & 80.04
 (4) whole of requiremed 2007 (see in contents should be
- 80.04 The corrected translation should be a corrected version, in duplicate, of the whole of the specification or of the claims as the case may be. It should comply with the requirements as to presentation set out in Parts 1 to 3 of Schedule 2 of the Patents Rules 2007 (see 78.14). Where the translation includes drawings, they should correspond exactly in content and presentation to those published by the EPO except that any textual matter should be replaced by an English translation and each sheet of drawings should be numbered consecutively in arabic numerals, as a separate series from that used for the other sheets of the translation, if not so numbered when published by the EPO. Verification is necessary in the same way as referred to in 78.14.
 - r.57(4) & 80.05 Patents Form 54 in duplicate should accompany the corrected translation.

 The appropriate fee should be paid within fourteen days of the filing of the corrected translation. This period may be extended at the comptroller's discretion under rule 108(1).
 - s.118(1) 80.06 If the requirements are met, the fact that the corrected translation has been filed is recorded in the register and announced in the Journal. Copies of the translation are made available for public inspection or sale. Requests for inspection of such translations should be accompanied by the prescribed fee, if any.

Section 80(4)

Where a correction of a translation is published under subsection (3) above and before it is so published a person –

begins in good faith to do an act which would not constitute an infringement of the patent as originally translated, or of the rights conferred by publication of the application as originally translated, but would do so under the amended translation, or

makes in good faith effective and serious preparations to do such an act,

he shall have the right to continue to do the act or, as the case may be, to do the act, notwithstanding the publication of the corrected translation and notwithstanding the grant of the patent.

80.07 The exemption of third parties from infringement proceedings provided by s.28A(4) to (7) applies to acts or preparations for acts, which would infringe in relation to the

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corrected translation but not in relation to the original translation, done or made before the corrected translation is published by the Office. This includes acts of Crown use which, but for s.55, would constitute infringement.

Section 80(5)

Subsections (5) and (6) of section 28A above have effect for the purposes of subsection (4) above as they have effect for the purposes of that section and as if –

the references to subsection (4) of that section were references to subsection (4) above;

the reference to the registered proprietor of the patent included a reference to the applicant.

Section 80(6)

Subject to subsection (5) above, the right conferred by subsection (4) above does not extend to granting a licence to another person to do the act in question.

Section 80(7)

Subsections 4) to (6) above apply in relation to the use of a patented invention for the services of the Crown as they apply in relation to an infringement of the patent or of the rights conferred by the publication of the application.

"Patented invention" has the same meaning as in section 55 above.

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Section 81: Conversion of European patent applications

a.135 EPC

81.01 This section provides for the conversion of applications for European patents (UK) into applications under the Patents Act 1977, at the discretion of the comptroller in response to a request by the applicant and includes the circumstances in which conversion may be allowed and the effects of conversion.

[For applications resulting from EPC s.81 conversions the order of documents on a file is similar to that for PCT s.89 conversions (see 89.01).]

Section 81(1)

The comptroller may direct that on compliance with the relevant conditions mentioned in subsection (2) below an application for a European patent (UK) shall be treated as an application for a patent under this Act where the application is deemed to be withdrawn under the provisions of the European Patent Convention relating to the time for forwarding applications to the European Patent Office.

Section 81(2)

The relevant conditions referred to above are -

- [(a) repealed]
- (b) that -
 - (i) the applicant requests the comptroller within the relevant prescribed period (where the application was filed with the Patent Office) to give a direction under this section, or
 - (ii) the central industrial property office of a country which is party to the convention, other than the United Kingdom, with which the application was filed transmits within the relevant prescribed period a request that the application should be converted into an application under this Act, together with a copy of the application; and
- (c) that the applicant within the relevant prescribed period pays the application fee and if the application is in a language other than English, files a translation into English of the application and of any amendments previously made in accordance with the convention.

CIRCUMSTANCES FOR CONVERSION

81.02 [deleted]

Failure to transmit application to EPO

a.77(3) EPC 81.03 Sections 81(1) and 81(2)(b) provide for the situation where a European patent application is deemed to be withdrawn because it has not been received by the EPO within a period of fourteen months from its date of filing or, if priority is claimed, the declared priority date. The filing of the application may have been made at the UK Patent Office, see 81.05, or at the central industrial property office of another country which is party to the EPC, see 81.06.

a.77(4) EPC s.22(3)(b) 81.04 Failure to transmit a European application to the EPO arises as a result of a decision at a national office to make the subject of the application secret, eg prohibition directions under s.22 in the case of the UK. It could also arise accidentally.

r.58(1) r.58(3) PR Sch 4, Part 1 r.58(4) PR Sch 4, Parts 2 & 3 81.05 Where the application was filed with the UK Patent Office, a request for conversion should be made in writing by the applicant with the prescribed fee (if any), within three months (which cannot be extended) from the date on which the applicant is notified by the EPO that his application for a European patent (UK) has been deemed to be withdrawn. This notification should accompany the request. Within two months of the date of filing of that request, the applicant should file the application fee, an English language translation of the application, where necessary, Patents Form 9A with fee requesting search, and Patents Form 7 if appropriate (see 81.11). This period may be extended in periods of two months only in accordance with r.108(2) or (3) and (4) to (7) (see 123.34-41). According to r.108(7), no extension may be granted more than two months after the expiry of the period as prescribed (or previously extended). If the application fee is paid at the time of requesting conversion, no surcharge will be payable. However if the application fee is paid at a later date, a surcharge will be due.

r.58(2)

81.05.1 At the same time as making a request for conversion referred to in 81.05, the applicant may also request that a copy of the European patent application, together with a copy of the request, be sent by the comptroller in accordance with the relevant provisions of the EPC to the central industrial property office of any specified Contracting State designated in the application.

r.59 PR Sch 4 81.06 Where the application was filed with another national office, a request for conversion should be filed by the applicant at that office for transmission, together with a copy of the application, to the UK Patent Office within twenty months (which cannot be extended) from the declared priority date or, if no priority was claimed, the filing date of the application for a European patent (UK). The Office sends a notification of receipt of the request to the applicant who should, within four months of the date of the notification, file the application fee, an English language translation of the application, where necessary, Patents Form 9A with fee requesting search and Patents Form 7 if appropriate (see 81.11). The four month period may be extended in periods of two months only in accordance with r.108(2) or (3) and (4) to (7) (see 123.34-41). According to r.108(7), no extension may be granted more than two months after the expiry of the period as prescribed (or previously extended). If the application fee is paid at the time of requesting conversion, no surcharge will be payable. However if the application fee is paid at a later date, a surcharge will be due.

Section 81(3)(a)

Where an application for a European patent falls to be treated as an application for a patent under this Act by virtue of a direction under this section -

(a) the date which is the date of filing the application under the European Patent Convention shall be treated as its date of filing for the purposes of this Act, but if that date is re-dated under the convention to a later date, that later date shall be treated for those purposes as the date of filing the application;

EFFECTS OF CONVERSION

81.07 Where conversion is allowed, the application for a European patent (UK) is treated as an application under the Act. The filing date of the application under EPC Article 80 and EPC rule 40 is treated as its filing date under the Act, unless it is re-dated under the EPC to a later date in which case that later date is so treated.

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Section 81(3)(b)

if the application satisfies a requirement of the convention corresponding to any of the requirements of this Act or rules designated as formal requirements, it shall be treated as satisfying that formal requirement;

r.25 81.08 Those requirements of Patents Rules 12(1) and 14(1), (2) and (3) which are r.103 designated as formal requirements (see 15A.04) are treated as having been complied with provided that the corresponding provisions of the EPC Implementing Regulations have been fulfilled (see 15A.10). However, amendments filed after conversion are subject to the Patents Rules in the normal way. An address for service within the UK, another EEA state or the Channel Islands is also required in the same way as for any other application under

Section 81(3)(c)

the Act (see 14.04.13).

Any document filed with the European Patent Office under any provision of the convention corresponding to any of the following provisions of this Act, that is to say, sections 2(4)(c), 5, 13(2) and 14, or any rule made for the purposes of any of those provisions shall be treated as filed with the Patent Office under that provision or rule; and

- Where the invention to which the application relates was disclosed at an international exhibition within the six months preceding the filing of the European patent application, the statement and certificate filed under EPC Article 55 and EPC rule 25 are treated as filed under s.2(4)(c) and r.5, see 2.40.
- r.3 81.10 The date of filing of the earliest previous application mentioned in the declaration of priority filed by the applicant in respect of the application for a European patent (UK) under EPC Article 88(1) and EPC rule 53 (where the priority date claimed in the declaration has not been lost or abandoned and where the declaration has not been withdrawn before conversion is allowed) is treated as the declared priority date of the converted application. The declaration of priority and the file number and certified copy of the or each previous application mentioned therein, filed under EPC Article 88(1) and EPC rules 52 and 53, are treated as filed under s.5 and r.8(1) and (2).
- A statement of inventorship filed under EPC Article 81 and EPC rule 19 is treated as filed under s.13(2), see 13.12. (Otherwise, Form 7 should be filed within the and 59(3) same period as that specified for filing Form 9A in 81.05 or 81.06 as appropriate.)
 - The description of the invention, the claim(s), any drawings and the abstract filed under EPC Article 78 are treated as filed under s.14.
- PR Sch 1, 81.13 If the invention involves the use of or concerns biological material, information regarding the biological material and its deposit in a culture collection filed under para 3(4) EPC Article 83 and EPC rules 31-33 is treated as filed under the Act. The relevant disclosure is regarded as clear enough and complete enough if EPC rule 31 has been complied with, see 125A.07.

Section 81(3)(d)

the comptroller shall refer the application for only so much of the examination and search required by sections 15A, 17 and 18 above as he considers appropriate in view of any examination and search carried out under the convention, and those sections shall apply

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r.8

rr. 58(4)

with any necessary modifications accordingly.

Examination and search

- 81.14 Search should be requested by the filing of Patents Form 9A as mentioned in 81.05 and 81.06.
- 81.15 Preliminary examination under s.15A is modified in that many requirements are regarded as met if those of corresponding EPC provisions have been fulfilled, see 81.07 to 81.13.
- r.31(3) & (5)
- 81.16 No search will have been carried out under the EPC. A search under s.17 is therefore conducted in the normal way on the basis of the documents filed under the EPC and treated as filed under the Act but incorporating with the comptroller's consent any amendments filed since conversion.
- r.60 PR Sch 4, Parts 2 & 3 r.28(1)
- 81.17 A request for substantive examination of the converted application should be made on Patents Form 10 with fee, within two years (extensible under r.108 (2) or (3) and (4) to (7), however r.108(7) states that no extension may be granted after two months following the expiry of the period as prescribed or previously extended see 123.36.10-12) from the declared priority date, if any, or the date of filing of the application for a European patent (UK). Substantive examination under s.18 follows in due course.
- 81.18 [deleted]
- r.30 PR Sch 4A, Parts 2 & 3
- 81.19 The periods prescribed (including permissible extensions thereto) for the purposes of ss.18(4) and 20(1) as set out in 20.02 also apply to a converted application except that any reference to the date of filing is taken to refer to the date of filing of the application for the European patent (UK). These periods may be extended in tranches of two months in accordance with r.108(2) or (3) and (4) to (7) (see 123.34-41). According to r.108(7), no extension may be granted more than two months after the expiry of the period as prescribed (or previously extended).

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Section 82: Jurisdiction to determine questions as to right to a patent

- s.82(3) 82.01 Sections 82 and 83 relate to questions arising before the grant of a European patent whether a person has a right to be granted a European patent or a share therein. Section 82 lays down the jurisdiction of the court and the comptroller to determine such questions; section 83 concerns the effect in the UK of determinations of such questions by authorities of other states which are party to the EPC.
- s.130(7) 82.02 Both sections 82 and 83 are so framed as to have, as nearly as practicable, the same effects in the UK as the corresponding provisions of the EPC, CPC and PCT. CPC Article 69(4)(b) (renumbered in December 1989 as Article 67(b) [1989]) and EPC Article 60(1) correspond to s.82(5), see 82.04-05.1.

Section 82(1)

The court shall not have jurisdiction to determine a question to which this section applies except in accordance with the following provisions of this section.

Section 82(2)

Section 12 above shall not confer jurisdiction on the comptroller to determine a question to which this section applies except in accordance with the following provisions of this section.

s.12(3) 82.03 Sub-sections (1) and (2) thus limit the jurisdiction of the court and the s.82(8) comptroller, respectively, to determine such questions (see 82.01) by reference to the subsequent sub-sections. Section 12 relates to the determination of questions about entitlement to foreign and convention patents before grant. However, the powers of the comptroller under s.12 with regard to European patents and applications for such patents are limited by s.82(3) to (9) (s.12 itself also including a reference to its effect on European patents being subject to s.82). The determination of a question under s.82 includes the making of an order under s.12 in relation to that question.

Section 82(3)

This section applies to a question arising before the grant of a European patent whether a person has a right to be granted a European patent, or a share in any such patent, and in this section "employer-employee question" means any such question between an employer and an employee, or their successors in title, arising out of an application for a European patent for an invention made by the employee.

Section 82(4)

The court and the comptroller shall have jurisdiction to determine any question to which this section applies, other than an employer-employee question, if either of the following conditions is satisfied, that is to say -

- (a) the applicant has his residence or principal place of business in the United Kingdom; or
- (b) the other party claims that the patent should be granted to him and he has his residence or principal place of business in the United Kingdom and the applicant does

not have his residence or principal place of business in any of the relevant contracting states:

and also if in either of those cases there is no written evidence that the parties have agreed to submit to the jurisdiction of the competent authority of a relevant contracting state other than the United Kingdom.

Section 82(5)

The court and the comptroller shall have jurisdiction to determine an employer-employee question if either of the following conditions is satisfied, that is to say -

- (a) the employee is mainly employed in the United Kingdom; or
- (b) the employee is not mainly employed anywhere or his place of main employment cannot be determined, but the employer has a place of business in the United Kingdom to which the employee is attached (whether or not he is also attached elsewhere);

and also if in either of those cases there is no written evidence that the parties have agreed to submit to the jurisdiction of the competent authority of a relevant contracting state other than the United Kingdom or, where there is such evidence of such an agreement, if the law applicable to the contract of employment does not recognise the validity of the agreement.

- 82.04 The words "the law applicable to the contract of employment" were substituted for the words "the proper law of the contract of employment" by s.5, Sch 4 of the Contracts (Applicable Law) Act 1990.
- 82.04.1 The jurisdiction of the court and the comptroller depends on whether or not the question to be determined is an "employer-employee question", ie one between an employer and an employee, or their successors in title, arising out of an application for a European patent for an invention made by the employee. If it is an employer-employee question, the country of employment of the employee (at which he is mainly employed or, if no such country can be identified, to which he is attached) decides whether there is jurisdiction, as detailed in sub-section (5); if not, the country of residence or of the principal place of business of the parties so decides, as in sub-section (4) (but see 82.05.1). In most cases, there is jurisdiction if the country of employment, residence or business is the UK. Even though there was no dispute in respect of a reference under s.12 in respect of Oxford Instruments' Ltd's Application (BL O/068/93) for a European patent, before determining the substance of the reference the hearing officer first satisfied himself that the proceedings fell to be considered under s.82(4) and that, since the patent applicant's residence was in the UK, the comptroller had jurisdiction in accordance with s.82.

Section 82(6)

Without prejudice to subsections (2) to (5) above, the court and the comptroller shall have jurisdiction to determine any question to which this section applies if there is written evidence that the parties have agreed to submit to the jurisdiction of the court or the comptroller, as the case may be, and, in the case of an employer-employee question, the law applicable to the contract of employment recognises the validity of the agreement.

82.05 The words "the law applicable to the contract of employment" were substituted for the words "the proper law of the contract of employment" by s.5, Sch 4 of the Contracts (Applicable Law) Act 1990.

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s.82(9) 82.05.1 The considerations in 82.04.1 are over-ridden if there is written evidence that the parties (whether employer and employee or otherwise) have agreed to submit to a particular jurisdiction. In the case of an employer-employee question, the agreement must be one which the contract of employment properly recognises as valid. If the agreed jurisdiction is that of the competent authority of another state which is a party to the EPC, then the court and the comptroller do not have jurisdiction. (Determinations by such authorities may be recognised in the UK, see 83.03-04). The court and the comptroller do however have jurisdiction if so agreed by the parties.

Section 82(7)

If, after proceedings to determine a question to which this section applies have been brought before the competent authority of a relevant contracting state other than the United Kingdom, proceedings are begun before the court or a reference is made to the comptroller under section 12 above to determine that question, the court or the comptroller, as the case may be, shall stay or sist the proceedings before the court or the comptroller unless or until the competent authority of that other state either -

- (a) determines to decline jurisdiction and no appeal lies from the determination or the time for appealing expires, or
- (b) makes a determination which the court or the comptroller refuses to recognise under section 83 below.
- s.82(9) 82.06 Any proceedings begun before the court or references made to the comptroller under s.12 to determine a relevant question are stayed if proceedings before the competent authority of another state, which is a party to the EPC, are already in being. Proceedings before the court or the comptroller resume only if and when that competent authority either declines jurisdiction and its decision cannot be reversed, or makes a determination which the court or the comptroller refuses to recognise under s.83, see 83.05.

Section 82(8)

References in this section to the determination of a question include respectively references to -

- (a) the making of a declaration or the grant of a declarator with respect to that question (in the case of the court); and
- (b) the making of an order under section 12 above in relation to that question (in the case of the court or the comptroller).

Section 82(9)

In this section and section 83 below "relevant contracting state" means a country which is a party to the European Patent Convention and has not exercised its right under the convention to exclude the application of the protocol to the convention known as the Protocol on Recognition.

82.07 All contracting states are now bound by the Protocol on Recognition. Article 167 EPC [1973] which allowed contracting states to enter a reservation not to be bound by the Protocol, also limited the time that the reservation was available to ten years (or fifteen years with an extension) from the date that the Convention entered into force.

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Section 83: Effect of patent decisions of competent authorities of other states

- s.82(3) 83.01 Section 83 relates, like section 82, to questions arising before the grant of a European patent whether a person has a right to be granted a European patent or a share therein. Section 83 concerns the effect in the UK of determinations of such questions by authorities of states other than the UK which are party to the EPC, whereas section 82 lays down the jurisdiction of the court and the comptroller to determine such questions.
- s.130(7) 83.02 Both sections 82 and 83 are so framed as to have, as nearly as practicable, the same effects in the UK as the corresponding provisions of the EPC, CPC and PCT.

Section 83(1)

A determination of a question to which section 82 above applies by the competent authority of a relevant contracting state other than the United Kingdom shall, if no appeal lies from the determination or the time for appealing has expired, be recognised in the United Kingdom as if it had been made by the court or the comptroller unless the court or he refuses to recognise it under subsection (2) below.

- s.82(9) 83.03 A determination of such a question (see 83.01) by the competent authority of a state other than the UK (which state is a party to the EPC) is recognised in the UK as if the court or the comptroller had made it, unless recognition is refused by the comptroller or court, see 83.05. Recognition is subject to no appeal lying from the determination or the time for appealing having expired.
- r.61 83.04 Any person seeking recognition in proceedings before the comptroller of such a determination should furnish the comptroller with a copy thereof certified as a true copy by an official of the competent authority in question.

Section 83(2)

The court or the comptroller may refuse to recognise any such determination that the applicant for a European patent had no right to be granted the patent, or any share in it, if either -

- (a) the applicant did not contest the proceedings in question because he was not notified of them at all or in the proper manner or was not notified of them in time for him to contest the proceedings; or
- (b) the determination in the proceedings in question conflicts with the determination of the competent authority of any relevant contracting state in proceedings instituted earlier between the same parties as in the proceedings in question.
- 83.05 The court or the comptroller may in certain circumstances refuse recognition of a determination by such an authority that the applicant for a European patent had no right to be granted the patent, or any share in it. Those circumstances are that either the applicant was not given a proper opportunity to contest the proceedings, as detailed in sub-section (2)(a), or the determination conflicts with an earlier one by a competent authority, as detailed in sub-section (2)(b).

Section 84: Patent agents and other representatives [Repealed]

84.01 This section formerly determined who was permitted to practise in the UK as a representative of other persons in relation to European patents and patent applications. This included taking part in proceedings relevant thereto before the EPO or the comptroller as well as applying for or obtaining European patents.

84.02 Section 84, together with other provisions of the 1977 Act concerning patent agents, has been repealed by the CDP Act and replaced by Part V of the CDP Act (Patent Agents and Trade Mark Agents) (see sections 274 to 286).

Section 85: European patent attorneys [Repealed]

85.01 This section provided that a person on the European list (ie the list of professional representatives maintained by the EPO under the EPC) could describe himself as a European patent attorney, and could prepare documents (other than deeds) for use in proceedings before the comptroller under the Act in relation to a European patent or application therefor, without being guilty of an offence under certain enactments.

85.02 Section 85, together with other provisions of the 1977 Act concerning patent agents, has been repealed by the CDP Act and been replaced by Part V of the CDP Act (Patent Agents and Trade Mark Agents), in which s.277 relates particularly to European patent attorneys.

COMMUNITY PATENTS

Section 86: Implementation of Community Patent Convention [Repealed]

86.01 Sections 86 to 88 were concerned with the Community Patent Convention (CPC), which never came into force. Section 86 was repealed by the Patents Act 2004.

86.02-03 [deleted]

Section 87: Decisions on Community Patent Convention [Repealed]

87.01 Section 87 related to questions of construction of the Community Patent Convention, which has never come into force. This section was repealed by the Patents Act 2004.

87.02 [deleted]

Section 88: Jurisdiction in legal proceedings in connection with Community Patent Convention [Repealed]

88.01 The CDP Act repealed section 88 of the 1977 Act, as this section had been rendered otiose by the coming into force in respect of the UK of the "Judgments Convention" (the 1968 Convention on Jurisdiction and Enforcement of Judgments in Civil and Commercial Matters). Section 88 specified how to determine the residence of a party for the purposes of deciding which courts of the Member States of the then European Community had jurisdiction in proceedings relating to infringement of a patent granted under the Community Patent Convention. It was introduced as an interim measure because the Community Patent Convention was expected to enter into force before the Judgments Convention - which also specifies how this question is to be determined - became effective in the UK. In the event the Community Patent Convention has not entered into force, whereas the Judgments Convention is now effective.

UNIFIED PATENT COURT

Section 88A: Implementation of Agreement on a Unified Patent Court

88A.01 Section 88A was introduced by the Intellectual Property Act 2014 and came into force on 1 October 2014. The section provides a general power to amend any legislation, including the Act itself, in order to bring the Agreement on a Unified Patent Court into effect. It also allows any provisions of the Act to be aligned with any provisions in the Agreement.

Section 88A(1)

The Secretary of State may by order make provision for giving effect in the United Kingdom to the provisions of the Agreement on a Unified Patent Court made in Brussels on 19 February 2013.

Section 88A(2)

An order under this section may, in particular, make provision—

- (a) to confer jurisdiction on a court, remove jurisdiction from a court or vary the jurisdiction of a court;
- (b) to require the payment of fees.

Section 88A(3)

An order under this section may also make provision for varying the application of specified provisions of this Act so that they correspond to provision made by the Agreement.

Section 88A(4)

An order under this section may—

- (a) make provision which applies generally or in relation only to specified cases;
- (b) make different provision for different cases.

Section 88A(5)

An order under this section may amend this Act or any other enactment.

88A.02 Subsection (1) gives the Secretary of State a general power to amend legislation, including the Act, to allow the Unified Patent Court Agreement signed on 19 February 2013 to be brought into effect.

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88A.03 Subsections (2), (3), and (4) list the main areas which may be included in such an order, for example provisions relating to jurisdiction of the Unified Patent Court and for the payment of fees. There is also provision for the order to make different provisions in different cases and to align provisions in the Act with equivalent provisions in the Agreement on a Unified Patent Court. This would allow provisions in the Act relating to all types of patents to be aligned with those in the Agreement.

Section 88A(6)

An order under this section may not be made unless a draft of the order has been laid before, and approved by resolution of, each House of Parliament.

88A.04 Subsection (6) states that any statutory instruments made under this section must be approved by resolution of both Houses of Parliament before it can come into law (this is known as the 'affirmative procedure').

Section 88A(7)

The meaning of "court" in this section is not limited by the definition of that expression in section 130(1).

88A.05 The Unified Patent Court is not within the definition of court given in the Act, which is in section 130(1). The effect of subsection (7) is that the definition in section 130(1) does not apply to section 88A. This means that in section 88A the word court includes the Unified Patent Court.

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Section 88B: Designation as international organisation of which UK is member

88B.01 Section 88B was introduced by the Intellectual Property Act 2014 and came into force on 1 October 2014.

Section 88B

The Unified Patent Court is to be treated for the purposes of section 1 of the International Organisations Act 1968 (organisations of which the United Kingdom is a member) as an organisation to which that section applies.

This provides for the Unified Patent Court to be treated as an organisation to which section 1 of the International Organisations Act 1968 applies.

88B.03 This will allow an Order in Council to be made granting privileges and immunities to Unified Patent Court and its staff, in accordance with the usual arrangements for international organisations located in the UK.

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INTERNATIONAL APPLICATIONS FOR PATENTS

Section 89: Effect of international application for patent

s.130(1)

89.01 Sections 89, 89A and 89B make provision for an international application under the Patent Cooperation Treaty to be treated as an application for a patent under the Patents Act 1977. An international application for a patent (UK) is an application which has been filed under the PCT and which, on its date of filing, separately designated the United Kingdom as a country in which protection is sought. (See 89.08). In *Archibald Kenrick & Sons Ltd's International Application* [1994] RPC 635, which related to a postal delay affecting an international application filed at the UK Office as receiving Office, Aldous J described the PCT as "a complete code". This comment was re-iterated in *Abaco Machines (Australasia) Pty Ltd's Application* [2007] EWHC 347 (Pat) where Lewison J commented that a PCT application cannot be an application under the 1977 Act except to the extent that the Act says it is. This case concerned a request to make a late declaration of priority under section 5(2B) for a national application when the applicants intention had been to file a PCT application within the twelve month priority period. He said:

"In my judgment Mr Mitcheson's submission, if accepted, would amount to a major breach in the complete code of the PCT. The PCT undoubtedly has advantages to those who make international applications under it. As Mr Mitcheson said, these advantages include savings in cost and the flexibility given to applicants to decide whether to enter the national phase in all or only some of the territories designated in the international phase. But the PCT is a package. Part of the package is, for the moment, a rigid timetable. As Mr Birss submitted, having chosen to use the PCT route, Abaco must take the PCT system as they find it."

[Deleted]

89.02 The international application must be filed at a receiving office under the PCT. Rule 65 relates to the role of this Office as such a receiving office. The Office ceased to receive new demands for international preliminary examination after 28 May 1993 in accordance with the EPC Protocol on Centralisation.

The application is searched by an International Searching Authority (ISA), 89 03 such as the EPO in the case of applications received at the UK Office. The ISA also produces a written opinion on patentability based on the results of its search. Applicants also have the option of requesting one or more additional "supplementary international searches (SIS)" which are each carried out by an ISA other than the one that performed the main international search. A SIS usually covers the same claims as the main international search, but where plurality has been reported by the main ISA the applicant may choose which invention is to be the subject of the SIS. The international application is published by the International Bureau of WIPO, together with the main international search report (if completed); the written opinion and any supplementary international search reports are not included in the published specification. The procedures for search, issue of a written opinion and publication of international applications are governed by PCT Chapter I. After receipt of the international search report and written opinion, the applicant may then request international preliminary examination under PCT Chapter II. The International Bureau issue an international preliminary report on patentability (IPRP) on all international applications, regardless of whether international preliminary examination is requested under Chapter II. For applications undergoing Chapter I processing only, the IPRP is established on the basis of the written opinion of the ISA. Where the applicant elects to have international preliminary examination under Chapter II, the International Preliminary Examination Report (IPER) is issued as the IPRP. The IPRP provides a non-binding opinion on (i) unity of invention, (ii) whether each individual claim meets the criteria of novelty, inventive step and industrial applicability, (iii) any lack of clarity in the claims or description or lack of support for the claims in the description and

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(iv) whether any amendments add subject matter.

PCT a.30(1) PCT r.94.1

PCT r.17.2(c)

PCT a.38

89.03.1 In accordance with PCT Article 30(1), the international application is confidential prior to international publication and may not be accessed by any person or authority, unless requested or authorised by the applicant, except for the transmission of information specifically required under the PCT for the purposes of processing the application. After international publication, documents held in the International Bureau's files are made publicly available online via WIPO's <u>Patentscope</u> database. The available documents include the international application itself, any amendments under PCT Article 19, the international search report (these elements are included in the published pamphlet), the priority document(s) (unless the relevant priority claim was withdrawn or considered not to have been made prior to international publication), the written opinion of the ISA, any supplementary international search reports, the IPRP, once it has been established, and any third party observations submitted during the international phase. However, documents relating to international preliminary examination are not made available as PCT Article 38 prohibits access to these unless requested or authorised by the applicant.

s.89A(3) r.66(1) 89.03.2 The applicant has a period of 31 months from the (priority) date of the international application in which to enter the UK national phase in accordance with ss.89, 89A and 89B (see 89A.05). This period is not affected by whether the application is elected under PCT Chapter II.

89.04 [deleted]

[CODE OF PRACTICE FOR APPLICANTS AND AGENTS

International applications for patents

The legal requirements of the Patent Cooperation Treaty (PCT) differ from those of the Patents Act in important ways and those filing international applications with the UK Office as PCT Receiving Office need to take particular care to follow PCT requirements. It may not be possible to remedy some problems if they are not spotted in time. The more important points are summarised in a checklist below. The International Unit of the Patents Directorate can provide further guidance and queries may be made by email to pct@ipo.gov.uk or by telephone on +44 (0)1633 814586.

POINT 10: International applications

- a The provisions of the Patent Cooperation Treaty, eg as to forms and formalities, should be observed when filing international applications with the UK Office as PCT Receiving Office.
- A power of attorney and/or a copy of a previously-filed general power of attorney is needed: (i) for all withdrawal requests; and (ii) where it is unclear that an agent or common representative has power to act on behalf of the applicant.
- c **Withdrawals:** Notices of withdrawal should be sent to the International Bureau in Geneva, with a copy sent to the Intellectual Property Office (see also point b above).

PCT filing checklist

- **Claims** It is vital for claims to be included in the international application if it is to be awarded an international filing date.
- Timing If it is critical that an international application be filed within a certain time window such as the twelve months of the Paris Convention, the application should be filed with sufficient time remaining for any fatal defects to be detected

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and put right.

- Application form It is necessary to complete a Request Form (Form PCT/RO/101), and it is important that the current version be used. British nationality and residency should be shown as either "GB" or "United Kingdom". Applicants should be identified by family name followed by forename(s). It is possible to request correction of a PCT form; in some circumstances we may request a replacement form be provided.
- Fees and copies A fee sheet should be completed if fees are being paid.
 Details of fees payable for PCT applications can be found at www.ipo.gov.uk/p-pct-fees. If there is doubt over what fee is due the Receiving Office will clarify this by issuing a Form PCT/RO/102.
- Filing PCT applications electronically PCT applications can be filed electronically using EPO Online Services (www.ipo.gov.uk/p-apply-online-epoline) or PCT-Safe (www.ipo.gov.uk/p-apply-online-pctsafe). When using EPO Online Services, it is important that the latest version of the software is used to ensure that the request form and fees are current.]

Section 89(1)

An international application for a patent (UK) for which a date of filing has been accorded under the Patent Co-operation Treaty shall, subject to -

section 89A (international and national phases of application), and

section 89B (adaptation of provisions in relation to international application),

be treated for the purposes of Parts I and III of this Act as an application for a patent under this Act.

89.05 Section 89 provides for an international application for a patent (UK) filed under the PCT to be treated from the date of filing as an application under the 1977 Act, subject to sections 89A and 89B.

Section 89(2)

If the application, or the designation of the United Kingdom in it, is withdrawn or (except as mentioned in subsection (3)) deemed to be withdrawn under the Treaty, it shall be treated as withdrawn under this Act.

Section 89(3)

An application shall not be treated as withdrawn under this Act if it, or the designation of the United Kingdom in it, is deemed to be withdrawn under the Treaty -

- (a) because of an error or omission in an institution having functions under the Treaty, or
- (b) because, owing to circumstances outside the applicant's control, a copy of the application was not received by the International Bureau before the end of the time limited for that purpose under the Treaty,

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or in such other circumstances as may be prescribed.

r.71(2) r.71(7) PCT a.25(1) PCT r.51.1

Subsections (2) and (3) deal with the effects under the 1977 Act of actual or deemed withdrawal under the PCT. The application is treated as withdrawn under the Act unless it was deemed to be withdrawn under the PCT in circumstances referred to in subsection (3), in which case the applicant may apply in writing for the international application to be or continue to be treated as an application under the 1977 Act. This should be accompanied by a statement of facts on which the applicant relies. translation of any document which is not in the English or Welsh language should be filed in accordance with r.113(1) and (2). Where section 89(3) applies such that the application is not to be treated as withdrawn, the comptroller may amend any document kept at the Office in relation to the application and alter any period of time (whether it has already expired or not) specified in the Act or listed in Parts 1 to 3 of Schedule 4 to the Patents Rules 2007 subject to such conditions as the comptroller may direct (including payment of any appropriate prescribed fee (including extension fees) but not that under s.89A(3)). The time within which an application under s.89(3) can be made is not in itself limited by the Regulations under the PCT (Fletcher's Application BL O/235/98). However it will normally be necessary to request the International Bureau to send copies of the documents from the file to the Office and such a request must be made within two months of the notification sent to the applicant that his application has been treated as withdrawn.

[An application filed with the Office under s.89(3) should be referred to the appropriate legal adviser in PD/CL.]

r.72 PCT a.48(2)(a) 89.07 The comptroller's power to reinstate applications deemed to be withdrawn has been extended in subsection (3) to cover such circumstances as may be prescribed, in addition to the particular circumstances (a) and (b) above. The other circumstance prescribed for the purposes of section 89(3) by rule 72 is where the comptroller determines that, in comparable circumstances in relation to an application under the Act (other than an international application for a patent (UK)), he would have exercised his powers under rule 107 or 108 to prevent the application being treated as withdrawn.

The comptroller's powers to amend documents and alter periods of time in this context thus apply in the same way as for equivalent situations relating to a domestic application. This accords with the PCT requirement that any Contracting State shall, as far as that State is concerned, excuse, for reasons admitted under its national law, any delay in meeting any time limit.

[Section 89(4) repealed]

89.08 The Patents Act 2004 repealed subsection (4), which stated that an international application should not to be treated as an international application for a patent (UK) by virtue of designating EP(UK) and not separately designating the UK. This subsection was replaced by section 130(4A), which reworded this subsection to bring it into consistency with the PCT, where all contracting states and regions are automatically designated on filing (see 130.27.1). (Applications for a European patent (UK) initiated by an international application under the PCT are dealt with by s.79.)

Section 89(5)

If an international application for a patent which designates the United Kingdom is refused a filing date under the Treaty and the comptroller determines that the refusal was caused by an error or omission in an institution having functions under the Treaty, he may direct that the application shall be treated as an application under this Act, having such date of filing as he may direct.

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r.71 PCT a.25(2)(a) PCT r.51(3) PCT r.51(1) PCT r.51(2)

Subsection (5) provides for the comptroller to direct that an application is 89.09 to be treated as one under the 1977 Act (having such date of filing as the comptroller may direct) when it has been refused a filing date as an international one because of an error in an institution having functions under the PCT. A written request for such a direction should be accompanied by a statement of the reasons for the request and the fee prescribed for the purposes of section 89A(3). A translation of any document which is not in the English language should be filed in accordance with r.113(1) and (2). If the application is to be treated as one under the 1977 Act, the comptroller may amend any document kept at the Office in relation to the application and alter any period of time which is specified in the Act or listed in Parts 1 to 3 of Schedule 4 to the Patents Rules 2007 (whether it has already expired or not), subject to such conditions as the comptroller may direct. The time within which an application under s.89(5) can be made is not in itself limited by the Regulations under the PCT (cf Fletcher's Application BL O/235/98). However it will normally be necessary to request the International Bureau to send copies of the documents from the file to the Office and such a request must be made within two months of the notification sent to the applicant that his application has been refused a filing date.

[An application for directions under s.89(5) should be referred to the appropriate legal adviser in PD/CL.]

89.10 Following refusal of the United States Patent and Trademark Office (USPTO) to treat a purported international application deposited with them as an international application because the applicants had declared themselves as residents of a country which was not a PCT member country, an application was made under s.89(5) for a direction that the application shall be treated as an application under the Act. In refusing to treat the purported international application in this way, the hearing officer decided that the USPTO had not erred both in refusing a filing date under the PCT and failing that in not transmitting the application to the International Bureau under PCT Rule 19.4 (*Unique Products & Design Co Ltd's Application BL O/147/95*).

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Section 89A: International and national phases of application

89A.01 This is the second of the three sections concerned specifically with international applications for patents. Section 89 makes provision for an international application for a patent (UK) to be treated as an application under the 1977 Act, subject to sections 89A and 89B (see 89.01-05). Section 89A was introduced by the CDP Act and clarifies the relationship between the international phase, initiated by filing under the PCT, and the UK national phase. In particular, it relates to what is often known as "entry" into the latter phase.

Section 89A(1)

The provisions of the Patent Co-operation Treaty relating to publication, search, examination and amendment, and not those of this Act, apply to an international application for a patent (UK) during the international phase of the application.

89A.02 PCT provisions relating to publication, search, examination and amendment, rather than those of the 1977 Act, apply to the application during the international phase.

Section 89A(2)

The international phase of the application means the period from the filing of the application in accordance with the Treaty until the national phase of the application begins.

89A.03 The international phase runs from filing under the PCT until the national phase begins, the beginning of the national phase being defined in subsection (3).

Section 89A(3)

The national phase of the application begins -

- (a) when the prescribed period expires, provided any necessary translation of the application into English has been filed at the Patent Office and the prescribed fee has been paid by the applicant; or
- (b) on the applicant expressly requesting the comptroller to proceed earlier with the national phase of the application, filing at the Patent Office -
 - (i) a copy of the application, if none has yet been sent to the Patent Office in accordance with the Treaty, and
 - (ii) any necessary translation of the application into English,

and paying the prescribed fee.

PCT a.3(2) 89A.03.1 For this purpose a "copy of the application" includes a copy published in accordance with the Treaty in a language other than that in which it was originally filed. Where the application has not been published in accordance with the Treaty, the "copy of the application" must include a copy of the PCT request form (Form PCT/RO/101), the specification and the abstract.

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ENTERING THE NATIONAL PHASE

PCT r.49.4

89A.04 Applicants are strongly recommended to enter the national phase by filing Form NP1, which has spaces for details of the international application, details of the applicant and the required address for service. However, the use of this form is not obligatory.

89A.04.1 If, as in the vast majority of cases, there is no request for early entry into the national phase, the application enters the national phase at the expiry of the prescribed period in accordance with s.89A(3)(a) provided that the requirements of this sub-section are satisfied.

[On receipt, the application is allocated a UK application number and the appropriate label is applied to the cover of the PDAX dossier. A check is made as to whether early entry into the national phase under s.89A(3)(b) has been expressly requested (see also 89A.21). If it has, the procedure outlined in 89A.16-21 should be followed. If there is any uncertainty in the matter, the case should be referred to the appropriate legal adviser in PD/CL for instructions on the subsequent procedure.]

r.66(1) PCT a.22 89A.05 The prescribed period for entry into the national phase is (since 1 April 2002) thirty-one months from the priority date declared under the PCT or from the date of filing of the international application if there is no declared priority date. This period is extensible in two month tranches, but not after the expiry of the period as extended, in accordance with r.108(2) or (3) and (4) to (7) - see 123.34-41 and in particular see the discussion of *Meunier's International Application* (BL O/013/01) in 123.37.

Entry into the national phase at the expiry of the prescribed period

r.65(1) r.66(1) 89A.06 Where there is no express request for early entry into the national phase, the application is examined by a formalities examiner to determine whether it complies with the requirements of s.89A(3)(a). When the international application is in English or Welsh, the only requirement for entry into the national phase at the end of the prescribed period under s.89A(3)(a) is the payment of the prescribed fee before the expiry of the prescribed period. However, if the international application is not in English or Welsh, the applicant must also file any necessary translations (see 89A.08) before the expiry of the prescribed period. As noted in 89A.05 this period may be extended.

89A.06.1 Between 1 October 1998 and 3 May 1999 inclusive, the national fee prescribed under s.89A(3) was zero (The Patents (Fees) Rules 1998, amended by The Patents (Fees) (Amendment) Rules 1999). As a consequence, any international application in the English language which designated the UK whose s.89A(3)(a) prescribed period ended within these dates will have entered the national phase in the UK, and thus will form part of the state of the art for the purposes of s.2(3), without further action by the applicant, unless the application or the designation of the UK in it was withdrawn before the expiry of the prescribed period. The Office allotted application numbers to such applications only if the applicant filed Form NP1 (see 89A.04) or indicated in writing in some other way that he intended to enter the UK national phase.

PCT a.20 PCT a.36(3)(a) 89A.07 The applicant is not required to file a copy of the international application or of the International Search Report as these are communicated to designated Offices by making them available on WIPO's Patentscope database, normally in the form of a WO pamphlet. The documents made available on Patentscope will also include the International Preliminary Report on Patentability (IPRP) and annexes thereto; any amendments to the claims filed with WIPO under PCT a.19 and a copy of any statement under a.19 explaining the amendments and indicating any impact on the description and drawings (these documents are included in the WO pamphlet); any Supplementary International Search Reports; and any third party observations submitted in the international phase. If the WO pamphlet is not available when national processing is due to commence, Security Section

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will establish with WIPO when it can be expected.

r.69, r.70 PCT r.48.3 PCT r.47.1(c) PCT r.49.5(d) 89A.08 Where the international application has been filed in a foreign language other than Arabic, Chinese, French, German, Japanese, Korean, Portuguese, Russian or Spanish, and has been published by WIPO as a WO pamphlet in English translation and the WO pamphlet has been communicated to the Office under PCT a.20 before the expiry of the thirty-one month period for entry into the national phase, then no further translation of the application or of any amendments under PCT a.19 need be filed. A notice under PCT r.47 is sent by WIPO to the applicant indicating the designated Offices to which the communication under PCT a.20 has been sent and the date of the communication. This notice must be accepted as conclusive evidence that the communication was sent on the date specified. In other instances where the application is not published in English, or exceptionally the WO pamphlet has not been communicated, the applicant must provide a translation into English of the application as published under the PCT (including any textual matter in the drawings) and of any amendments before the expiry of the prescribed period in order to gain entry into the national phase, subject to the exceptions set out in 89A.09.

89A.09 Exceptions to the requirement to file a translation of the application as originally filed and of any amendments are:-

r.69(2), (3)

(a) the request for the international application on Form PCT/RO/101 and the abstract. A translation of these must be included when the applicant expressly requests the comptroller to proceed with the national phase before the end of the period prescribed by rule 66(1) but not where a copy of the application, as published in accordance with the PCT is available to the comptroller (since the request and abstract are always published in English in the WO pamphlet).

r.70(4)

(b) the original title if this has since been amended by the international searching authority; however, a translation of the amended title must be supplied instead.

r.70(5) PCT r.49.5(a-bis) (c) any sequence listing complying with the relevant requirements of the PCT (PCT r.12.1(d)), provided any free text in the sequence listing also appears in the main part of the description in accordance with PCT r.5.2(b).

r.69(5) r.66(2) 89A.09.1 Where the application has been amended and the applicant has filed a translation of the application as originally filed but not of the amendment, and the prescribed fee has been paid, notice is given to the applicant that a necessary translation is missing and requiring the necessary translation to be filed within three months of the date of such notice, in accordance with rule 66(2). (See also 89A.25)

[The formalities examiner should notify the applicant that the necessary translation should be filed whenever the application has been amended and the applicant has not filed a translation of the amendment.]

PR Sch.1, para 3(2) r.69(1) r.66(2) 89A.10 In addition, where information in a language other than English regarding the deposit of biological material has been provided and a translation thereof has not been filed within the period prescribed by rule 66(1), the comptroller must notify the applicant that this translation is missing and should be filed within three months of the date the notification is sent. The information in question is the name of the depositary institution and the accession number of the deposit, and (where the biological material has been deposited by a person other than the applicant) the name and address of the depositor and the statement referred to in paragraph 3(2)(b)(ii) of Schedule 1 to the Patents Rules 2007.

[When information concerning the deposit of biological material is filed after the international filing date, the date this information was received is published on the front page of the PCT pamphlet. The formalities examiner will check the PCT pamphlet to see whether such information has been received after the international filing date. If it has and this information is not in English, the formalities examiner will notify the applicant that a translation of that information must be filed, in

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accordance with rule 69(1), within three months of the date on which the notice is sent.

89A.11 If the formalities examiner is of the opinion that at the end of the prescribed period (including any extension under r.107 or r.108) the requirements of s.89A(3)(a) are not satisfied, the applicant should be notified accordingly and informed that, subject to any comments received within one month of the notification, it is proposed to treat the application as withdrawn.

89A.12 In order for the application to proceed, the following should be provided:-

r.68(3)

(i) a request for search on Patents Form 9A accompanied by the appropriate fee, including any excess claims fees, – these should be filed before the end of the period prescribed by rule 22(2) and (7) or, if it expires later, the period of two months after the national phase begins;

r.68(2)

(ii) a statement of inventorship on Patents Form 7 (no fee), if the name(s) and address(es) of the inventor(s) have not been disclosed in the request for international processing made in accordance with Article 4 of the PCT. The statement of inventorship should be filed before the end of the period prescribed by rule 10(3) or, if it expires later, the period of two months after the national phase begins (see 13.12);

These periods may be extended in two month tranches, but any extension is not available after the end of the period of two months beginning immediately after the expiry of the period to be extended, in accordance with r.108(2) or (3) and (4) to (7) - see 123.34-41.

r.5 r.67 89A.12.1 Where the invention has been displayed at an international exhibition within the period of six months immediately preceding the filing date of the application, a certificate and statement identifying the invention should be filed in accordance with rule 5. The certificate and statement should be filed within four months of the date of filing, except where the applicant, on filing the application, informed the receiving office under the PCT in writing of the display at an international exhibition, in which case the certificate and statement should be filed within two months of the date the national phase begins. This time period may be extended at the comptroller's discretion under r.108(1) - see 123.34-42.

r.9

89A.12.2 A translation of any priority document in a language other than English or Welsh may also be required within the normal period (see 5.11 to 5.13.2).

89A.13 [deleted]

- 89A.14 When the formalities examiner is satisfied that the requirements for entry into the national phase have been met and Patents Form 9A has been filed, the application is allocated to an examining group for CPC classification to be applied, the IPC to be checked and necessary data capture.
- 89A.14.1 The examiner should check Patentscope for the presence of an International Search Report and International Preliminary Report on Patentability (IPRP), where these have not already been received from the International Bureau and imported onto the PDAX dossier. A check should also be made for any Supplementary International Search Reports, third party observations and applicant comments in response to such observations. If such documents are found, the examiner should ask formalities to import these documents onto the dossier, in accordance with paragraph 13.124 of the Formalities Manual. The examiner should consider issuing an abbreviated examination report (AER) under s18(3) at this stage based on the international reports, however the examiner has discretion to choose whether this is issued at this stage or at substantive examination stage (see 18.47.1).
- 89A.14.2 The application is then forwarded for re-publication under a UK A-document publication number with the re-published document bearing relevant

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bibliographic information from the WO pamphlet including IPC (revised if necessary), field of search and citations as reported by the international searching authority. If the PCT application is in English and the national phase has started at the end of the prescribed period the re-published A-document consists of a front page only. If it is not in English, the A-document includes the translation of the specification together with any translation filed under s.89A(5) of amendments included in the WO pamphlet, the front page and the ISR in English. However, any amendments to the claims which are not included in the WO pamphlet (including claims filed at the Office in its capacity as designated office under PCT a.28 or elected office under PCT a.41) should not be included in the re-published document. This re-publication is an administrative act, ie it is not required by the 1977 Act or the Rules or the PCT. It thus does not constitute publication under s.16. Publication under s.16 is deemed to have occurred by virtue of publication of the WO pamphlet by WIPO and once the conditions for entering the national phase are met - see 89B.04.

[In general, applications should not be retained in an examining group longer than 2 weeks for classification. Classification and re-publication should not be delayed if priority documents or an International Preliminary Report on Patentability (IPRP) are not on file. Formalities should issue any necessary reminders to WIPO in respect of outstanding documents. On receipt the documents should be sent to Index & Scan to be scanned onto the dossier.]

[Where the WIPO specification is in the form of an 'A2' document (that is, published without a search report) then classification and re-publication should not be delayed to await the publication of the international search report as an 'A3' document ('A3' documents are not normally sent to examining groups). Nevertheless, the examiner should check on EPOQUE to see if the 'A3' document has become available, and if so should enter the data from it in PROSE. If it is not available, "Not yet advised" should be entered for 'Field of Search' and 'Citations' on PROSE. In such cases, it will be necessary to check for a search report at the examination stage and to enter the field of search and citation information into COPS as data for B-publication. The examiner should therefore create a minute reminding the substantive examiner to enter the necessary data.]

[If a "Declaration of Non-establishment of International Search Report" has been made by the International Search Authority, this should be reflected in the 'Field of search' entry on PROSE with reference to the relevant PCT Article indicated in the Declaration; e.g. "No search performed: PCT Article 17(2)(a)". For the 'citations' field, "None" should be entered.]

[If only a partial search has been performed by the International Search Authority (ISA) then details of the fields searched should still be recorded on PROSE. If the ISA has performed only a partial search or no search at all and the substantive examiner considers that the claims may relate to a patentable invention, then it is likely that a complete search will be required at the substantive examination stage.]

[Where there is a Supplementary International Search Report on file, the fields of search and citations indicated in that report should also be recorded on PROSE.]

[The abstract title will already have been input into COPS by New Applications Section, and should not be amended. If the title has been incorrectly input, the matter should be referred to Index & Scan for correction.]

[If any drawing accompanying the abstract on the front page of a WIPO specification includes text in a foreign language, the formalities examiner should (a) ensure that translated drawings are on file, (b) identify the translated drawing corresponding to that shown on the front page of the WIPO specification, (c) flag the relevant drawing and (d) minute the case examiner for confirmation that the flagged drawing is the one that should accompany the abstract for re-publication. The case examiner should confirm that the correct drawing has been identified or indicate which is the correct drawing. On return to the formalities examiner the

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application should be forwarded for re-publication with the correct drawing flagged for the attention of Publication Section.

[If the wrong abstract has been used on the front page of the WIPO specification (i.e. where the abstract does not relate to invention described in the specification), the examiner should notify formalities. The formalities examiner should contact WIPO to inform them of the error and to request that the correct abstract be made available on Patentscope (contact details for the relevant processing team at WIPO can be obtained from www.wipo.int/pctdb/en/iateamlookup.jsp). Once the correct abstract is available the formalities examiner should import a copy into the dossier from Patentscope, giving it a document code WIPOFP so that the correct abstract is used for republication. The examiner should be consulted if the formalities examiner is in any doubt about whether the abstract on Patentscope is the correct one.]

[The full data for COPS that has to be entered on PROSE to allow the case to proceed to republication in the national phase is:

- Field of Search
- Citations
- IPC classification
- Processing status

CPC classification should also be entered. ClassTool should be used to enter IPC and CPC classification data. Classification to the UKC is no longer required.

Field of search and citation data should be entered using the PROSE entry screens. Any IPC field of search information on the International Search Report (and any Supplementary International Search Reports) should be entered after selecting the IPC tab. All other field of search data including US classification terms and databases (but not search words used) should be entered under the Other tab. See 17.75 for the formats which should be used for different types of citation.

The examiner should ensure that the 5 data markers have been activated at the bottom right of the PROSE screen.

A REPUBP checklist should be created on PROSE and signed off to set the processing status for republication.]

[Although Form 9A has been filed, no search is made at this stage since the results of the international search (updated at the substantive examination stage) are utilised during substantive examination. Nevertheless, the examiner should record a search as having been done.]

[As the first action under s.18(3), the issue of an abbreviated examination report (AER) should be booked out as a completed examination. Where an AER is issued in the form of an EL1C prior to re-publication, there is no need to create a REPUBP checklist, because the checklist associated with the EL1C contains all the necessary information.]

89A.15 If the formalities examiner is of the opinion that any of the requirements listed in 89A.12 or 89A.12.1 have not been complied with, the applicant should be informed as soon as possible of the need for compliance within the prescribed period. Any request for extension under r.108(1) in respect of requirement to file an international exhibition certificate should be considered on its merits (see 123.36-123.39).

s.89A(3) Early entry into the national phase

89A.16 Where the applicant has expressly requested early entry into the national phase, the formalities examiner should establish whether the requirements prescribed in

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s.89A(3)(b) have been satisfied, namely whether

- -the prescribed fee has been paid
- -a copy of the application has either been communicated to the Office by WIPO (see 89A.07) or has been filed directly with the Office by the applicant; and
- -any necessary translation of the application into English has been filed at the Office.
- PCT a.3(2) The copy of the application may be a copy published in accordance with the PCT (ie a WO pamphlet) in a language other than that in which it was originally filed. Where the application has not been published in accordance with the Treaty, the "copy of the application" must include a copy of the PCT request form (Form PCT/RO/101), the specification and the abstract. A translation of the application into English is required where the application is in Arabic, Chinese, French, German, Japanese, Korean, Portuguese, Russian or Spanish or where the WO pamphlet containing the English translation referred to in 89A.08 has not been published or has not been communicated to the Office under PCT a.20 (see 89A.09-89A.10).

89A.17 Where any of these requirements have not been met, the applicant should be notified accordingly and informed that early entry into the national phase cannot occur until they are met. The applicant should also be informed that the application will be treated as withdrawn under s.89A(4) if the requirements are not met before the expiry of the prescribed period of Section 89A(3)(a), including any extension (see 89A.05).

- r.68(1)-(3) 89A.18 In order for the application to proceed once it has gained early entry into the national phase, it is also necessary for the relevant requirements listed in 89A.12 and 89A.12.1 to be satisfied. However, the periods for paying the application fee and filing Patents Form 7 and 9A are determined by r.68. Form 7 should be filed within the last to expire of the period prescribed by r.10(3) or two months from the date on which the national phase begins. Similarly, the application fee (currently set at zero for international applications) and Form 9A should be filed within the last to expire of the period prescribed by r.22(2) and (7) or two months from the date on which the national phase begins. These periods are extensible in two month tranches, but any extension is not available after the end of the period of two months beginning immediately after the expiry of the period to be extended, in accordance with r.108(2) or (3) and (4) to (7) - see 123.34-41.
- S.89A(1) 89A.19 If the international application has been published with an international search report by the International Bureau by the date of early entry into the national phase, the application is re-published in the normal way (see 89A.14-89A14.2). If however the international search report is not available, either from the International Bureau or from the applicant, and the applicant has not requested a full search under s.17, classification and re-publication should not be delayed to await publication of the international search report.

If the international search report is not available and the applicant has not requested a full search under s.17, "Not yet advised" should be entered for 'Field of Search' and 'Citations' on PROSE. In such cases, it will be necessary to check for a search report at the examination stage and to enter the field of search and citation information into COPS as data for B-publication. The examiner should therefore create a minute reminding the substantive examiner to enter the necessary data.]

Where the international search report is not available, the applicant has the option of requesting that a full search be done under s.17, as for a domestic UK application. The full search fee will be payable (see 89B.08). Re-publication of the whole WO specification together with the UK external search report will then take place. This practice remains the same even if the international search report has become available after the s.17 search was commenced but before preparations for publication are complete. However, a request for a full search under s.17 should not be accepted if the international

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search report is available; in such cases the examiner should arrange for the excess fee to be refunded. Similarly, if the international search report becomes available after the request for a full search under s.17, but before the examiner commences the search, the excess fee should be refunded - see 89B.08.

[In cases where a full UK search under s.17 is carried out on a PCT application without an ISR, the search, citation and classification data reported by the UK search examiner should be entered via PROSE in the usual way for inclusion on the front page of the specification.]

89A.20 If the international application has not been published by the International Bureau by the date of early entry into the national phase, then, in the absence of a request for accelerated publication, the usual re-publication of the application will have to wait until the WO pamphlet becomes available. On no account should it be assumed that accelerated publication is required unless an explicit request has been made. In accelerated cases where it is not clear whether earlier publication is desired in order to secure early grant, the applicant should be contacted by telephone to clarify his intentions.

Where the applicant does not wish to await publication by the International Bureau they may explicitly request accelerated publication of the application. If the international search report is available, then the application should have accelerated publication under s.16 in the same way as a domestic UK application, but including the international search report instead of a domestic external search report (even if the international search report has not yet been published by the International Bureau). No subsequent re-publication of the WO pamphlet is required. If the international search report has been established in a language other than English and no translation is available at the time that accelerated publication is requested, the applicant should be asked under rule 113(1) to provide such a translation for publication. Otherwise, publication must wait until the English translation is available from WIPO. If the international search report is not available, then accelerated publication cannot take place until the international search report becomes available, unless the applicant also makes a request for a full search under s.17. The full search fee will then be payable (see 89B.08), and the application will be published under s.16 in the usual way for domestic UK applications, including the UK external search report. Again, no subsequent re-publication of the WO pamphlet is required. However, see 89B.08 for the situation where the international search report becomes available before the examiner commences the search. Where the applicant has requested a full search, the application may be processed as a CS&E if Forms 9A and 10 have been filed on the same date or a specific request has been made when filing Form 10 (see 18.03). For restrictions on the earliest date a s.18(4) report may be issued, including allowing time for third party observations, see 18.07.2.

[In cases where accelerated publication of an unpublished PCT application is requested and the international search report is available, classification data (revised if necessary), field of search and citations as reported by the international search authority should be entered via PROSE and the abstract should be reframed if necessary (see 14.170-191). The examiner should create a minute to formalities to confirm that accelerated publication has been requested. If the international search report is not available and a full UK search under s.17 is carried out, the search, citation and classification data should be entered via PROSE in the normal way, and again the abstract should be reframed if necessary.]

89A.21 A specific request for accelerated examination made before the expiry of the prescribed period is considered to be an express request for early entry into the national phase. However, accelerated processing does not follow early entry into the national phase unless a specific request is made and allowed for accelerated search (see 17.05.1-2), accelerated publication (see 16.04) or accelerated examination (see 18.07-18.07.1). Where a request for accelerated examination has been accepted then the examination may be carried out at the same time as the search (or classification). For accelerated processing under the PCT(UK) Fast Track, see 89B.17. For restrictions on the earliest

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date a s.18(4) report may be issued, including allowing time for third party observations, see 18.07.2.

Section 89A(4)

If the prescribed period expires without the conditions mentioned in subsection (3)(a) being satisfied, the application shall be taken to be withdrawn.

89A.22 The application for a UK national patent is taken to be withdrawn if the conditions in subsection (3)(a) are not met within the prescribed period to which 89A.05 refers.

Section 89A(5)

Where during the international phase the application is amended in accordance with the Treaty, the amendment shall be treated as made under this Act if -

- (a) when the prescribed period expires, any necessary translation of the amendment into English has been filed at the Patent Office, or
- (b) where the applicant expressly requests the comptroller to proceed earlier with the national phase of the application, there is then filed at the Patent Office -
 - (i) a copy of the amendment, if none has yet been sent to the Patent Office in accordance with the Treaty, and
 - (ii) any necessary translation of the amendment into English;

otherwise the amendment shall be disregarded.

- PCT aa.19 & 89A.23 Any amendments made during the international phase should be taken into account during examination in the national phase, providing the amendments and any necessary translations have either been communicated to the Office by the International Bureau, or filed at the Office by the applicant. If the application has been amended during the international phase but the amendments and any necessary translations have neither been communicated to the Office by the International Bureau, nor filed at the Office by the applicant, the application is allowed to proceed in its unamended form into the national phase see 89A.25.
- r.66(2)

 89A.24 Where an applicant is required to file a translation into English both of an application as originally filed and of the amendment to it and where at the expiry of the 31 month period for entry into the national phase (see 89A.05) the prescribed fee has been paid and a translation of the application has been filed but a translation of the amendment has not been filed, the comptroller gives notice to the applicant requiring that the required translation be filed within three months of the date on which the notice is sent, and the 31 month period is treated in respect of that translation as not expiring until the end of the period specified in the notice. The period for filing a missing translation is extensible in two month tranches, but any extension is not available after the end of the period of two months beginning immediately after the expiry of the period to be extended, in accordance with r.108(2) or (3) and (4) to (7) see 123.34-41.
- r.69, 70 89A.25 The amendments are disregarded unless the requirements of subsection (5) are met; if they are met, such amendments are treated as if made under the 1977 Act. The requirements in question are set out under (a) or (b) in the subsection and are concerned in effect with the amendment and any necessary translation being available at the time of entry into the national phase. Amendments other than in English are marked "to be

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disregarded" if a translation has not been received in the Office when the national phase starts. If an amendment is to be disregarded the applicant should be notified accordingly and invited to re-submit it (in duplicate for applications filed before 26 June 2006), under s.19 and r.66A.

[Where a translation of an amendment is not filed by the end of the prescribed period, the application should be referred to the appropriate Formalities Manager who may decide to consult the appropriate heading examiner before marking the amendment as disregarded.]

89A.25.1 For details of when an international application may be amended upon entry to or during the national phase, see 19.15.1.

Section 89A(6)

The comptroller shall on payment of the prescribed fee publish any translation filed at the Patent Office under subsection (3) or (5) above.

89A.26 In order to secure certain rights as set out in subsection (3) of s.89B, the applicant may under subsection (6) of s.89A pay a prescribed fee for publication of a translation filed under section 89A(3) or (5). The Office automatically publishes translations supplied in accordance with s.89A(3) or (5) (see 89A.14.2 above) but, in order to obtain the protection to which s.89B(3) refers when the international application was not in English, the applicant should file a written request, accompanied by the appropriate fee, that publication for the purposes of s.89A(6) is sought.

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Section 89B: Adaptation of provisions in relation to international application

89B.01 This is the third and last section concerned specifically with international applications for patents (UK), and was introduced by the CDP Act. It modifies the requirements to be met by the application under the 1977 Act in view of its status as an international application. Section 89 makes provision for an international application for a patent (UK) to be treated as an application under the 1977 Act, subject to sections 89A and 89B (see 89.01-05).

Section 89B(1)

Where an international application for a patent (UK) is accorded a filing date under the Patent Co-operation Treaty -

- (a) that date, or if the application is re-dated under the Treaty to a later date that later date, shall be treated as the date of filing the application under this Act,
- (b) any declaration of priority made under the Treaty shall be treated as made under section 5(2) above, and where in accordance with the Treaty any extra days are allowed, the period of 12 months allowed under section 5(2A) above shall be treated as altered accordingly, and
- (c) any statement of the name of the inventor under the Treaty shall be treated as a statement filed under section 13(2) above.
- 89B.02 Subsection (1) provides for various acts (concerning filing, priority and naming of the inventor) done under the PCT to be treated as having been done under the 1977 Act. With regard to subsection (1)(b), the declaration of priority must have been made under Article 8 of the PCT, must not have been lost or abandoned and must fulfil certain requirements of the PCT Rules (see 5.10). With regard to whether, under subsection (1)(c), information concerning the inventor given under Article 4 of the PCT obviates the need for filing of Form 7, see 13.12, 89A.12 and 89A.18.
 - [See section 117 for the procedure for correcting an error made by the receiving office under the PCT whereby an international application for a patent (UK) has been accorded an incorrect date of filing, or where the declaration made under Article 8(1) of the PCT (ie claiming priority) has been considered not to have been made by the receiving office or by the International Bureau because of an error made by that office or Bureau. Alternatively, rule 108 may be applicable.]

89B.03 Certain of the UK national formal requirements concerning the form and manner of presentation of the drawings and other documents included in an international application, as well as the filing of a request for grant, are treated as having been complied with provided that the corresponding provisions of the PCT Regulations have been fulfilled (see 15A.10). However, any translations which are filed at this Office by the applicant and are to be included in the re-published application (see 89A.14.2) (including drawings re-executed because the originals contained textual matter in a foreign language) must comply with the UK national rules, especially rule 14. All amendments filed after entry into the national phase are subject to the UK national rules (see 19.15.1 for voluntary amendments filed after entry into the national phase and before issue of the first examination report).

Section 89B(2)

If the application, not having been published under this Act, is published in accordance with the Treaty it shall be treated, for purposes other than those mentioned in subsection (3), as

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r.3

r.25(3)

published under section 16 above when the national phase of the application begins or, if later, when published in accordance with the Treaty.

r.66(1) 89B.04 Subsection (2) provides for publication under the PCT to be treated for most purposes as publication under s.16 of the 1977 Act when the conditions for entering the national phase (as set out in subsection (3) of section 89A) are met. An international application published under the PCT thus becomes part of the state of the art under s.2(3) upon entering the national phase (whether this occurs on expiry of the prescribed 31 month period (see 89A.05) or occurs early at the applicant's request (see 89A.16 to 89A.21)). The file and register entry become open to public inspection at the same time. There is then no need for the specification to be republished in full in the UK, since publication under s.16 is deemed to have already taken place. Instead, the administrative act of re-publication takes place (see 89A.14.2). If an application has not been published under the PCT when it enters the national phase, the application is not treated as published under section 16 until it is either published under the PCT or published in full under s.16 following a request from the applicant for accelerated publication upon early entry to the national phase (see 89A.20.1).

Section 89B(3)

For the purposes of section 55 (use of invention for service of the Crown) and section 69 (infringement of rights conferred by publication) the application, not having been published under this Act, shall be treated as published under section 16 above -

- (a) if it is published in accordance with the Treaty in English, on its being so published; and
- (b) if it is so published in a language other than English -
 - (i) on the publication of a translation of the application in accordance with section 89A(6) above, or
 - (ii) on the service by the applicant of a translation into English of the specification of the application on the government department concerned or, as the case may be, on the person committing the infringing act.

The reference in paragraph (b)(ii) to the service of a translation on a government department or other person is to its being sent by post or delivered to that department or person.

89B.05 The purposes excepted under subsection (2) are those mentioned in subsection (3). The latter relates to the provision of the text of the application in English in order to secure certain rights regarding Crown use and infringement, and is substantially a continuation of the provisions of the old section 89(7). For the purposes of sections 55 and 69, the publication of the international application by the International Bureau is, if it is in English, considered to constitute publication under section 16. If in any other language, it is not treated as published under section 16 for the purposes of sections 55 and 69 until a translation of the application under section 89A(6) is published (see 89A.26). It is therefore necessary to file a written request with the prescribed fee that publication for the purposes of s.89A(6) is sought in order to obtain the rights in question in this way. These rights may also be obtained in relation to use or acts done before publication of that translation from the date on which the applicant sends a translation to the government department or potential infringer in question under section 55 or 69 respectively.

Section 89B(4)

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During the international phase of the application, section 8 above does not apply (determination of questions of entitlement in relation to application under this Act) and section 12 above (determination of entitlement in relation to foreign and convention patents) applies notwithstanding the application; but after the end of the international phase, section 8 applies and section 12 does not.

89B.06 Subsection (4) sets out which sections of the 1977 Act apply to any disputes about entitlement to the application during and after the international phase. Prior to entry into the national phase, questions about entitlement to the international application may be determined under s.12. Upon entry, s.12 ceases to be applicable and such questions become subject to ss.8 to 11.

Section 89B(5)

When the national phase begins the comptroller shall refer the application for so much of the examination and search under sections 15A, 17 and 18 above as he considers appropriate in view of any examination or search carried out under the Treaty.

89B.07 Subsection (5) provides for search and examination of the application after it enters the national phase.

89B.08 Filing of a Form 9A with the appropriate fee, including any excess claims fees, is required. There is a lower fee for a search under section 17(1) where the application has already been the subject of a search by the International Searching Authority before the request for search is made. If the International Search Authority has issued a declaration under article 17(2) of the PCT that no international search has been established, the application is considered to have been "subject of a search" and the lower fee applies. If neither an international search nor a declaration that no international search has been established has been issued by the date of request for search, the full fee is payable (see also 89A.19-20.1). If the lower fee has been paid apparently without justification, the applicant should be contacted to establish whether or not a search has been performed. If not, the full fee should be requested. In the event that an international search report becomes available before the examiner commences the search, then the examiner should use the information from the international search report and arrange for the excess fee to be refunded. Similarly, if in other circumstances the larger fee has been paid unnecessarily, the excess should be refunded before the application is forwarded to the examiner. These are the only situations in which rule 106(2)(a) can be used to provide a refund, under no circumstances can rule 106(2)(a) be used to refund the reduced search fee. If the application is withdrawn prior to substantive examination, the whole of the search fee may be refunded unless it has been necessary to perform a search within the Office. If an international search report has been established on the application, but the claims are amended so that a supplementary search is necessary under s.17(8), a full supplementary search fee in addition to the reduced search fee is payable - no refund of the latter can be

> [At the examination stage, where the examiner performs a search beyond the topup search (see 89B.12), whether or not a full search fee has been paid, there is no requirement to produce an external search report on the application. Any new citations found should be included in the substantive examination report issued to the applicant. For procedures to be followed when a full search is to be carried out, see 89A.18-21.1

89B.09 Patents Form 10 must be filed together with the appropriate fee, including any excess pages fees, within 33 months of the priority date or, if none, the filing date of the application, or within two months of the date on which the national phase begins, whichever expires the later. This period may be extended in two month tranches, but any extension is not available after the end of the period of two months beginning immediately after the

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r.106(2)(a)

r.68(4)

given.

expiry of the period to be extended, in accordance with r.108(2) or (3) and (4) to (7) - see 123.34-41.

SUBSTANTIVE EXAMINATION

PCT r.44bis.1(a)

89B.10 When Form 10 has been filed, and after re-publication or publication under s.16, the application is referred to the appropriate examining group, where it ranks with national applications of the same priority date, for its substantive examination. If the application is withdrawn prior to substantive examination, the examination fee may be refunded. The examination process is much like that for any other UK application (see section 18) except for the regard paid to the results of the International Search Report, any Supplementary International Search Reports and the International Preliminary Report on Patentability (IPRP). The examiner should check Patentscope for the presence of an International Search Report, any Supplementary International Search Reports and an International Preliminary Report on Patentability (IPRP), where these have not already been received from the International Bureau and imported onto the PDAX dossier. If such documents are found, a minute should be added to the PDAX dossier, with an appropriate title (e.g. EXR IPRP), detailing what the document is, along with when and where it was found. A Supplementary International Search Report will only be present if the applicant requested such a search in the international phase (see 89.03). It should be noted that the "written opinion" issued to the applicant on every PCT application has the same contents as the IPRP if the applicant has not requested international preliminary examination (IPE) under Chapter II of the PCT. If IPE has been requested, the written opinion will have been superseded by an IPRP issued under Chapter II. There should therefore be no need to check the contents of the written opinion as long as the IPRP has been referred to. If accelerated processing under the PCT(UK) Fast Track is requested, the procedure described in 89B.17 should be followed.

[The application should be checked to confirm that re-publication has in fact taken place. Applications not re-published should be referred to Publishing Section (although if examination is due or overdue, sending for re-publication may be deferred until after examination).

The examination document will comprise the documents in the TOC with the codes DESC, CLMS and DRWG, each annotated as the "WORKING COPY", which will have been assembled by Formalities.

[Deleted]

Care should be taken in the case of a translation that the translation of the application and not that of the priority document is examined. Serious errors discovered in PCT applications should be brought to the attention of the appropriate legal adviser in PD/CL, who will liaise with the International Bureau if necessary. Other errors should be ignored. Where the wrong abstract has been published in the international phase, see 89A.14.2.

r.113(5), (6)

89B.11 The International Search Report (and any Supplementary International Search Reports) should be inspected before examination becomes due and copies of cited documents ordered. If there are a large number of citations, the case may be referred to the examiner to confirm whether all of them are needed. A translation of the search report, when not in English, is available. Where a cited document is not in the English language, an equivalent which is in English should be obtained if available. Rule 113(5) allows the comptroller to request a translation of any document or part thereof which is in a language other than English and is referred to in an International Search Report or International Preliminary Report on Patentability, or cited in an International Preliminary Examination Report of the application. If the family of any document listed in the International Search Report as X or Y category does not include an English language equivalent, the application should be referred to the examiner prior to examination to determine whether he wishes to make such a request. The examiner should bear in mind that translation costs can be a

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significant burden to the applicant and should not request a translation unless he believes that he will not otherwise easily be able to determine the relevance of the document to the patentability of the invention. He may call for a partial translation, eg only of the claims, if that is felt likely to be sufficient. A fuller translation may be requested at a later stage if it is found to be necessary.

[Where the International Search Report includes a list of family members this can normally be relied on to identify any English language equivalents of cited documents. If there is no list of family members provided, they should be identified by using EPOQUE. In the case of recently published citations, the family listing by either of these routes may not be complete and it may be advisable to make a further inquiry when conducting the substantive examination if an English language equivalent was not identified earlier.]

[Letter EL6 should be used for requesting a translation.]

89B.12 The substantive examiner should consider the International Search Report (and any Supplementary International Search Reports) and should re-search the application only if he is reasonably sure that such a search will yield more pertinent art. Circumstances where re-searching might be needed include: if the examiner is already aware of documents that would be relevant (e.g. from an earlier case), or if a particularly relevant classification area has been created in the interim or otherwise missed in the international search. Such re-searching should not be done on a purely speculative basis – i.e. if the examiner is surprised that no relevant documents have been found. Otherwise, their searching will be restricted to the "top-up" search (if necessary in light of any top-up search performed in the international phase – see 89B.12.1) and any supplementary search under s.17(8) necessitated by allowable amendment of the claims, as with national applications (see 17.120-17.123).

89B.12.1 Where international preliminary examination under Chapter II of the PCT has been requested, and the request was made after 1 July 2014, a top-up search is normally performed as part of the international preliminary examination process. The International Preliminary Report on Patentability (IPRP) indicates whether a top-up search has been performed and includes any documents identified in this search that are relevant to patentability; a separate search report will not be issued by the International Preliminary Examining Authority. Where such a search has been performed, the examiner is not required to perform any further searching in the national phase, unless the top-up search was performed before 21 months from the priority date (in which case, a standard top-up search should be performed), or the circumstances in 89B.12 apply.

[All documents cited in the PCT top-up search should be recorded in PROSE by adding them to the Citations list, even if they are not relied upon in the examination report, as per 18.85.]

89B.12.2 Where the International Searching Authority (ISA) has issued a declaration under article 17(2) of the PCT that no International Search Report has been established, but the substantive examiner considers that the claims relate to a patentable invention, a full search should be performed but no additional fee may be requested from the applicant. If the substantive examiner disagrees with the ISA's assessment of plurality, and as a result determines that further searching is needed (bearing in mind 89B.12), this should be carried out without requiring an additional fee. Where amendments have been made during the international or national phase which necessitate a supplementary search under s.17(8), a full supplementary search fee – in addition to the reduced search fee payable on entry to the national phase for all international applications with an International Search Report (see 89B.08) – is payable under ss.17(8), 19(1) and 89A(5).

89B.12.3 If any searching has been performed, no search report should be issued to the applicant; if additional citations are found, these should be brought to the applicant's attention on the examination report. (This does not apply to a supplementary search under s.17(8), or to a UK application divided from an international application, for which the

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preparation and issue of a search report is necessary, see 15.38 and 17.121). Copies of additional documents cited by the UK examiner are issued to the applicant, but not copies of the documents cited in the international search report or the IPRP (see 17.104.1, 17.105.2).

[The examiner should record details of the top-up search in an internal search report. If no top-up searching is necessary, this should be recorded in the report instead. Otherwise, the report should include a search statement and details of subclasses searched additional to the international search report. Where only top-up searching is done then there are no "additional fields of search". However, where a full further search is conducted in areas not corresponding to areas covered by the international search then they should be recorded as "additional fields of search" for inclusion on the front page of the B document.]

PCT r.44bis.2 PCT r.94.2 89B.13 Where the UK has been elected under Chapter II of the PCT, a copy of the International Preliminary Report on Patentability (IPRP) issued under Chapter II together with any annexes (amendments) is communicated to the United Kingdom Office by the International Bureau. Similarly, where no election under Chapter II is made, a copy of the International Preliminary Report on Patentability (IPRP) issued under Chapter I is communicated to the United Kingdom Office by the International Bureau. The IPRP is either prepared in English or a translation into English is made available. If the report or translation into English is not on file, the examiner should check Patentscope for its presence. If such documents are found, a minute should be added to the PDAX dossier, with an appropriate title (e.g. EXR IPRP), detailing what the document is, along with when and where it was found. If the IPRP was issued under Chapter II, the examiner should check for the presence of amendments annexed to it and a minute should be sent to formalities asking them to import the IPRP (Chapter II) and any amendments into the dossier. If the document in question is not available via Patentscope, the examiner should ask Formalities to obtain it so that the report, and any amendments annexed to it, can be taken into account in the substantive examination (see 89B.15). (On the rare occasion that Formalities are unable to obtain the document, they should refer the request to Security Section so that the report can be ordered from WIPO). An EPO online file inspection could also be considered to view missing documents if the application has an equivalent going through the European regional phase. As a final resort, the agent for the applicant may be approached to obtain a missing report. In exceptional cases, the examiner may consider that it is necessary to see other documents, such as written opinions, kept on file at the international authority. Security Section should be asked to obtain a copy of the document(s) in question.

[The copy of the IPRP communicated by the International Bureau is added to the dossier and set as "open to public inspection". Any other documents obtained from the IPEA at the examiner's request are also added to the dossier and set as "open to public inspection".]

89B.14 Substantive examination of a PCT application after an IPRP is based on the PCT pamphlet as published (which may include new or amended claims) and as amended during the international phase and/or after entry into the national phase. Any amendments made during the international phase which have been taken into account in the IPRP will be attached as "annexes" to the IPRP. Under section 89A(5) amendments during the international phase are normally to be treated as if made under the Act provided that, if the amendments are not in English, the applicant has filed a translation (see 89A.25). If such a translation is not filed then those amendments, made under the PCT, should be "disregarded" as described in 89A.25 unless subsequently re-submitted under the Act. The first report under section 18 should indicate whether the international application examined has been amended since publication and if so which pages, so that the applicant can check whether the Office has the correct form of the specification.

[If the specification has been amended during the international phase, copies of replacement pages embodying these amendments in their latest form are incorporated in the examination document by the formalities examiner before the

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case is forwarded to the substantive examiner (see under 89B.10). The substantive examiner should check that they are examining the latest version of the application, taking into account any amendments made during the international phase. If the substantive examiner notices that amendments made during the international phase have not been incorporated into the specification, a minute should be sent to formalities asking them to do this (as long as the required translation has been filed if the amendments are not in English). RC8A, RC8B and RC8C respectively should be used to indicate that an international application has not been, or has been, amended since publication; where the amendments are annexed to the IPRP, the date of the letter for RC8B is that given in the report. If amendment has occurred the new pages with their filing dates should be listed.]

89B.14.1 Where a number of conflicting amendments are on file, the latest to be filed are considered unless they are to be disregarded (see 89A.25). The date of filing of any amendments is stated in the IPRP; if subsequently filed amendments or statements make the applicant's intentions appear uncertain, then the matter should be cleared up before examination begins.

89B.15 Since the question of patentability will have been considered by the international examiner in the light of the international search report, any amendments filed during the international phase are probably a response to one or more written opinions of the international phase examiner. The IPRP (see 89B.13) contains an explicit statement for each claim examined in respect of novelty, inventive step and industrial applicability, and may also include observations on plurality of invention, clarity, support, and whether any amendment adds matter. It should be noted that documents which appear to be included in the state of the art as defined in section 2(3) are not part of the art for the purposes of any international opinion or preliminary examination on patentability: however such documents can be listed in the IPRP under the heading 'CERTAIN PUBLISHED DOCUMENTS'. The IPRP is not binding, and the final responsibility for determining whether the application complies with the Act and Rules belongs to the UK examiner, who should, however, derive as much assistance as possible from the report to reduce the work of substantive examination and to avoid going over the same ground as the international phase examiner. For example, the claims should be considered first in the light of any citations and explanations in the IPRP and in the written opinions, if available. Similarly, other issues should be approached on the basis of any relevant observations in the IPRP. Where a report is issued under s.18(3) for the first time, the examiner should include a paragraph indicating that the IPRP has been considered. On no account, however, should an IPRP objection be repeated unless the examiner is satisfied it is proper under the UK law or practice.

89B.15.1 If the IPRP raises major objections, and the applicant has not responded to these either by amendment or argument, the examiner should consider whether to issue an abbreviated examination report (AER) as the first report under s.18(3), if it has not already been done at the classification stage (see 18.47.1 and 89A.14.1).

89B.15.2 Consideration should be given to observations or objections on unity of invention in the international search report or IPRP, but as for other substantive issues, the examiner should raise an objection under s.14(5)(d) if it is considered justified under UK practice. The need for search of a second or later invention should then be considered in accordance with 89B.12, and in the light of the claims actually covered by the international search report.

Third party observations

89B.16 Where third party observations have been filed in the international phase, the substantive examiner should consider them in the same way as they would third party observations filed on a domestic application (see 21.07). However, there is no need to acknowledge the third party observations or bring them to the attention of the applicant, since this will have been done in the international phase. Any comments filed by the applicant in the international phase in response to the observations should also be

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considered. Depending on when they were received, the observations may have been considered by the International Searching Authority (ISA) and/or the International Preliminary Examining Authority (IPEA). When checking the International Preliminary Report on Patentability (IPRP) as part of the routine examination procedure, the substantive examiner should consider any comments regarding the observations and related prior art, but ultimately should come to their own view on their relevance. Where a PCT application enters the national phase early, third party observations may be received by the International Bureau (IB) and appear on Patentscope later, after the application has been received by the examiner. In such cases the examiner should consider any such observations they discover as part of their usual checks of Patentscope during the examination process.

[Security Section should have imported any third party observations and response documents from the applicant into the PDAX dossier and ordered copies of any non-patent literature referred to in the observations. However, if the substantive examiner comes across any third party observations and/or related comments on Patentscope that are not present on the PDAX dossier, he/she should import them to the dossier or create a minute giving details of the documents.]

[Just as for domestic applications, third party observations filed in the international phase are made available on IPSUM along with any response documents from the applicant. The formalities examiner should skim all documents for any personal information and redact if necessary, adding the OLFI annotation to the redacted versions as usual. It should not be necessary to check for libellous or offensive material as the IB carries out such a check before publishing the observations on Patentscope. However, if the formalities or substantive examiner notices any such material that has been missed by the IB, it should be redacted as it would be for observations received under s.21 of the Act (see 21.03).]

Accelerated processing - PCT(UK) Fast Track

As set out in the Practice Notice issued on 8 June 2012, patent applicants can request accelerated examination in the UK national phase through the PCT(UK) Fast Track if their PCT application has received a positive International Preliminary Report on Patentability (IPRP) in respect of at least one claim, under either PCT Chapter I or Chapter II. If the IPRP has not yet been issued, a positive Written Opinion of the International Searching Authority (WO-ISA) is also acceptable, since the WO-ISA will later be re-issued as the IPRP under PCT Chapter I. In order to qualify for this service, all claims present in the application at the time of the request must sufficiently correspond to one or more claims that have been examined in the IPRP or WO-ISA and found to meet the requirements for novelty, inventive step and industrial applicability. The claim correspondence requirements are the same as those applied under the Office's Patent Prosecution Highway (PPH) agreements. Claims are considered to "sufficiently correspond" where, accounting for differences due to translations and claim format, the claims on file in the UK national phase are:

- (i) of the same or similar scope as the claims found acceptable in the IPRP or WO-ISA or
- (ii) narrower in scope than the claims found acceptable in the IPRP or WO-ISA.

With regard to (ii), a claim that is narrower in scope occurs when a claim found to be acceptable in the IPRP or WO-ISA is amended to be further limited by an additional feature that is supported in the specification (description and/or claims). A claim in the UK national phase which is in a new or different category from those claims indicated as acceptable in the IPRP or WO-ISA is not considered to "sufficiently correspond". For example, where the acceptable claims relate to a process of manufacturing a product, then the claims in the UK national phase are not considered to sufficiently correspond if they introduce product claims that are dependent on the corresponding process claims.

To request accelerated treatment, the applicant must make a request in writing before UK examination has commenced, indicating that the claims currently on file sufficiently correspond to one or more claims that were indicated as acceptable in the IPRP or WO-

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ISA; no further reasons for acceleration are needed. Though it should be noted that accelerated examination cannot take place until the international search has been performed or the applicant pays the additional search fee and a search is performed (see 89B.08). If the request for accelerated treatment is accepted, the usual procedure for accelerated examination is followed (see 18.07-18.07.2). As with all PCT applications, the examiner is not bound by the IPRP or WO-ISA and may come to his own conclusion in respect of novelty, inventive step or industrial applicability. Other matters will require full consideration, taking into account any observations which have been made in the IPRP or WO-ISA. For restrictions on the earliest date a s.18(4) report may be issued, see 18.07.2.

[The Formalities Examiner should check all requests for accelerated processing and on identifying a PCT(UK) Fast Track request should apply the "PCT(UK) FAST TRACK" label to the PDAX dossier cover, in addition to the appropriate Acceleration label(s).]

[Where the IPRP (and any associated amendments) or any other necessary documents are not already available on the dossier, the formalities examiner should obtain them using Patentscope and import them into the dossier. If there is no IPRP, but there is a Written Opinion, then this should be imported into the dossier. Where the documents are not available on Patentscope, the Formalities Examiner should ask Security Section to request the IPRP or Written Opinion and any amendments from the International Bureau. If the documents are still unavailable they should be requested from the applicant/attorney.]

[If the application has not been published in the international phase (i.e. because the application is entering the national phase early) and the applicant has requested accelerated publication, the practice set out in 89A.20.1 should be followed.]

The examiner should take a prima facie view as to whether all claims present in the application sufficiently correspond to one or more claims that have been examined and found to meet the requirements for novelty, inventive step and industrial applicability in the IPRP or WO-ISA. If Box III of the IPRP indicates that certain claims have not been examined, the request for acceleration may only be accepted if those claims have been deleted. However, where the ISA has made no attempt to assess the industrial applicability of certain claims because they consider them to relate to a method of treatment or diagnosis, but the IPRP or WO-ISA is positive in respect of the novelty and inventive step of those claims, this can be treated as an exception and the request for acceleration should be allowed if the claims in the application sufficiently correspond to those claims. If there are any objections in Box V to novelty, inventive step or industrial applicability, the request may only be accepted if those claims have been deleted or amended such that they sufficiently correspond to allowable claims. Where the claims have been narrowed in scope, there is no need for the examiner to check whether the limitations to the claims are supported by the specification when considering the request for acceleration; the request may be accepted as long as the examiner is satisfied that the claims are narrower that those found acceptable in the IPRP or However, a full assessment of support should be performed at substantive examination. If it is not clear from the request how the claims correspond to those indicated as acceptable in the IPRP or WO-ISA, the examiner may contact the applicant to request further clarification. Outstanding matters raised in the IPRP in relation to other issues, such as clarity, support or formal requirements, do not need to have been overcome for acceleration to be allowed.]

[If the application is in the publication or republication cycle an examination report can still issue – see 18.64 square brackets].

[If the request is refused, the examiner should write to the applicant explaining the reasons for the refusal (PROSE letter EL29 may be adjusted for this purpose) and remove the ACCELERATED EXAMINATION label from the PDAX dossier, but

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leave the PCT(UK) FAST TRACK label active]

Grant

r.30

89B.18 The process of examination and re-examination in response to the agent's or applicant's replies continues in the same way as for any other UK application until, if the examiner is satisfied that the application complies with all the requirements of the Act within the appropriate period, the grant of a patent follows. That period (and permissible extensions of the period) is as set out in 20.02 except that any reference to the priority date or date of filing is taken to refer to the priority date or date of filing of the PCT application (see 89B.02). For restrictions on the earliest date a s18(4) report may be issued, including allowing time for third party observations, see 18.07.2.

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CONVENTION COUNTRIES

Section 90: Orders in Council as to convention countries

Section 90(1)

Her Majesty may with a view to the fulfilment of a treaty or international convention, arrangement or engagement, by Order in Council declare that any country specified in the Order is a convention country for the purposes of section 5 above.

Section 90(2)

Her Majesty may by Order in Council direct that any of the Channel Islands, any colony shall be taken to be a convention country for those purposes.

Section 90(3)

For the purposes of subsection (1) above every colony, protectorate, and territory subject to the authority or under the suzerainty of another country, and every territory administered by another country under the trusteeship system of the United Nations shall be taken to be a country in the case of which a declaration may be made under that subsection.

90.01 Any country may be declared a convention country by Order in Council, with the effect that priority may be claimed from an application made in or for that country (see 5.30). The making of a new Order is advertised in the Journal.

90.02 The following is a list of the countries which have been declared to be a convention country under the Patents (Convention Countries) Order 2007 (SI 2007 No. 276), which revoked the Patents (Convention Countries) Order 2006, and the Patents (Convention Countries) (Amendment) Order 2009 (SI 2009 No. 2746).

Albania	Bahamas	Bosnia and Herzegovina	Cape Verde
Algeria	Bahrain	Botswana	Central African Republic
Andorra	Bangladesh		·
Angola	Barbados	Brazil	Chad
· ·		Brunei Darussalam	Chile
Antigua and Barbuda	Belarus	Bulgaria	China
Armontino	Belgium	Durking Face	Colombia
Argentina	Belize	Burkina Faso	Colombia
Armenia	Benin	Burundi	Comoros
Australia	Deriiri	Cambodia	Congo
Austria	Bhutan	Cameroon	Congo,
Austria	Bolivia	Cameroon	Democratic
Azerbaijan		Canada	Republic of the

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Costa Rica	Guinea	Lebanon	Netherlands
Côte d'Ivoire	Guinea - Bissau	Lesotho	Netherlands Antilles and Aruba
Croatia	Guyana	Liberia	
Cuba	Haiti	Libyan Arab Jamahiriya	New Zealand, including the Cook Islands, Niue and
Cyprus	Holy See	Liechtenstein	Tokelau
Czech Republic	Honduras	Lithuania	Nicaragua
Denmark	Hong Kong		Niger
Djibouti	Hungary	Luxembourg Macao	Nigeria
Dominica	Iceland	Macao	Norway
Dominican Republic	India	Macedonia, Former Yugoslav Republic of	Oman
·	Indonesia	·	Pakistan
Ecuador	Iran, Islamic	Madagascar	Panama
Egypt	Republic of	Malawi	Danua Naw Cuinas
El Salvador	Iraq	Malaysia	Papua New Guinea Paraguay
Equatorial Guinea	Ireland	Maldives	
Estonia	Israel	Mali	Peru
Faeroe Islands	Italy	Malta	Philippines
Fiji	Jamaica	Mauritania	Poland
•			Portugal
Finland	Japan	Mauritius	Qatar
France, including	Jordan	Mexico	Damania
all Overseas Departments and	Kazakhstan	Moldova, Republic	Romania
Territories	Vanua	of	Russian Federation
Gabon	Kenya	Monaco	Rwanda
Gambia	Korea, Democratic People's Republic of	Mongolia	Saint Kitts and Nevis
Georgia		Montenegro	Saint Lucia
Germany	Korea, Republic of	Morocco	Saint Vincent and the
•	Kuwait		Grenadines
Ghana	Kyrgyzstan	Mozambique	Samoa
Greece		Myanmar	l
Grenada	Lao People's Democratic	Namibia	San Marino
	Republic		Sao Tome and
Guatemala	Latvia	Nepal	Principe
			

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Saudi Arabia	Sudan	Tonga	Uruguay
Senegal	Suriname	Trinidad and	Uzbekistan
Serbia	Swaziland	Tobago Tunisia	Venezuela
Seychelles	Sweden		Vanuatu
Sierra Leone	Switzerland	Turkey	Vietnam
Singapore	Syrian Arab	Turkmenistan	Yemen
Slovakia	Republic	Uganda	Zambia
Slovenia	Taiwan	Ukraine	Zimbabwe
Solomon Islands	Tajikistan	United Arab Emirates	
South Africa	Tanzania, United Republic of	United States of	
Spain	Thailand	America (including Puerto Rico and all territories and	
Sri Lanka	Togo	possessions)	

90.03 The United Kingdom is not a convention country within the meaning of the Patents Act.

90.04 In s.90(2), "any colony" was originally followed by the words "or any British protectorate or protected state" which have been deleted by the Statute Law (Repeals) Act 1986 (c.12).

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MISCELLANEOUS

Section 91: Evidence of conventions and instruments under conventions

s.91(6) 91.01 This section is concerned with the status of the EPC, CPC and PCT, and instruments, publications and decisions thereunder, in legal proceedings (including those before the comptroller).

Section 91(1)

Judicial notice shall be taken of the following, that is to say -

- (a) the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty (each of which is hereafter in this section referred to as the relevant convention);
- (b) any bulletin, journal or gazette published under the relevant convention and the register of European patents kept under the European Patent Convention; and
- (c) any decision of, or expression of opinion by, the relevant convention court on any question arising under or in connection with the relevant convention.
- s.130(1)Judicial notice should be taken of those conventions and that treaty, s.91(6) publications thereunder including the EPO register of European patents, and decisions by the relevant convention courts. This means that these matters are recognised without need for formal evidence of their existence. The relevant convention court means that court or other body which under the relevant convention or treaty has jurisdiction over the proceedings in question, including (where it has such jurisdiction) any department of the EPO but excluding the national courts of the UK and other contracting states. In his judgment in the Court of Appeal in Genentech Inc's Patent [1989] RPC 147, Mustill L J said "The requirement that the court shall take judicial notice of the decision of the relevant convention court is directed (like the remainder of the section) to evidentiary matters; in this case the mode of proof of matters which might otherwise have to be proved as foreign law. The subsection does not give to rulings of other courts any greater status than they would otherwise possess, although of course, the desirability for a uniform course of decision in matters touching the Convention is manifest (see, for example, section 130(7)), and the Board of Appeal as the central decision making body of the European patent system must be hearkened to with particular attention."

Section 91(2)

Any document mentioned in subsection (1)(b) above shall be admissible as evidence of any instrument or other act thereby communicated of any convention institution.

Section 91(3)

Evidence of any instrument issued under the relevant convention by any such institution, including any judgment or order of the relevant convention court, or of any document in the custody of any such institution or reproducing in legible form any information in such custody otherwise than in legible form, or any entry in or extract from such a document, may be given

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in any legal proceedings by production of a copy certified as a true copy by an official of that institution; and any document purporting to be such a copy shall be received in evidence without proof of the official position or handwriting of the person signing the certificate.

Section 91(4)

Evidence of any such instrument may also be given in any legal proceedings -

- (a) by production of a copy purporting to be printed by the Queen's Printer;
- (b) where the instrument is in the custody of a government department, by production of a copy certified on behalf of the department to be a true copy by an officer of the department generally or specially authorised to do so;

and any document purporting to be such a copy as is mentioned in paragraph (b) above of an instrument in the custody of a department shall be received in evidence without proof of the official position or handwriting of the person signing the certificate, or of his authority to do so, or of the document being in the custody of the department.

s.91(6) 91.03 Subsections (2), (3) and (4) lay down the forms of documentation which constitute admissible evidence of instruments, decisions etc. under the relevant convention or treaty. This includes certified copies of documents in the custody of an institution established by or having functions under the relevant convention or treaty, or in the custody of a government department.

Section 91(5)

In any legal proceedings in Scotland evidence of any matter given in a manner authorised by this section shall be sufficient evidence of it.

Section 91(6)

In this section -

"convention institution" means an institution established by or having functions under the relevant convention;

"relevant convention court" does not include a court of the United Kingdom or of any other country which is a party to the relevant convention; and

"legal proceedings", in relation to the United Kingdom, includes proceedings before the comptroller.

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Section 92: Obtaining evidence for proceedings under the European Patent Convention

s.130(1) 92.01 This section relates to the provision in the UK of evidence for proceedings before a relevant convention court under the EPC, and authorises rules for that purpose. The relevant convention court is that court or other body which under the EPC has jurisdiction over the proceedings in question, including (where it has such jurisdiction) any department of the EPO.

Section 92(1)

Sections 1 to 3 of the Evidence (Proceedings in Other Jurisdictions) Act 1975 (provisions enabling United Kingdom courts to assist in obtaining evidence for foreign courts) shall apply for the purpose of proceedings before a relevant convention court under the European Patent Convention as they apply for the purpose of civil proceedings in a court exercising jurisdiction in a country outside the United Kingdom.

Section 92(2)

In the application of those sections by virtue of this section any reference to the High Court, the Court of Session or the High Court of Justice in Northern Ireland shall include a reference to the comptroller.

92.02 Appropriate provisions of the Evidence (Proceedings in Other Jurisdictions) Act 1975 are thus applied to the UK courts (including the comptroller, by virtue of s.92(2)) for the purpose of obtaining evidence for such proceedings, see 92.01. The 1975 Act was extended to the Isle of Man by SI 1979/1711.

Section 92(3)

Rules under this Act may include provision -

- (a) as to the manner in which an application under section 1 of the said Act of 1975 is to be made to the comptroller for the purpose of proceedings before a relevant convention court under the European Patent Convention; and
- (b) subject to the provisions of that Act, as to the circumstances in which an order can be made under section 2 of that Act on any such application.

r.62(1) & 92.03 An application to the comptroller under the Evidence (Proceedings in Other Jurisdictions) Act 1975 for an order for evidence to be obtained in the UK should be made in writing without notice. The application should be supported by written evidence and accompanied by the appropriate fee, the request as a result of which the application is made, and a translation of the request into English where appropriate.

92.04 After such an application has been made, an application for a further order or directions in relation to the same matter may be made to the comptroller in writing.

Section 92(4)

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Rules of the court and rules under this Act may provide for an officer of the European Patent Office to attend the hearing of an application under section 1 of that Act before the court or the comptroller, as the case may be, and examine the witnesses or request the court or comptroller to put specified questions to the witnesses.

r.62(3) 92.05 The comptroller may allow an officer of the EPO to attend the hearing of such an application as is mentioned in 92.03 and examine the witnesses or request the comptroller to put specified questions to them.

92.06 Rule 34.21 of Part 34 of the Civil Procedure Rules contains an equivalent provision with regard to an officer of the EPO where the application is made to the court and an order is made for the examination of witnesses.

Section 92(5)

Section 1(4) of the Perjury Act 1911 and article 3(4) of the Perjury (Northern Ireland) Order 1979 (statements made for the purposes, among others, of judicial proceedings in a tribunal of a foreign state) shall apply in relation to proceedings before a relevant convention court under the European Patent Convention as they apply to a judicial proceeding in a tribunal of a foreign state.

92.07 Appropriate provisions with regard to perjury are thus applied to statements made in England, Wales and Northern Ireland for the purposes of proceedings before a relevant convention court under the EPC. There is no reference to Scotland in s.92(5) since perjury is a common law offence in Scottish law.

92.08 The reference to the Perjury (Northern Ireland) Order 1979 in subsection (5) replaced a reference to the Perjury Act (Northern Ireland) 1946. This amendment was effected by S.I. 1979 No. 1714.

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Section 93: Enforcement of orders for costs

Section 93

If the European Patent Office orders the payment of costs in any proceedings before it -

- (a) in England and Wales the costs shall, if the county court so orders, be recoverable by execution issued from the county court or otherwise as if they were payable under an order of that court;
- (b) in Scotland the order may be enforced in like manner as an extract registered decree arbitral bearing a warrant for execution issued by the sheriff court of any sheriffdom in Scotland;
- (c) in Northern Ireland the order may be enforced as if it were a money judgment;
- (d) in the Isle of Man the order may be enforced in like manner as an execution issued out of the court.
- 93.01 This section provides for the enforcement in the UK of orders for costs made by the EPO. The methods of enforcement are the same as those for an award of costs by the comptroller under s.107, see 107.09.
- 93.01.1 In paragraph (b) which applies to Scotland only, the words "a recorded decree arbitral" were replaced by "an extract registered decree arbitral bearing a warrant for execution issued by the sheriff court of any sheriffdom in Scotland" by the Debtors (Scotland) Act 1987, s.108(1), Sch 6, para 20.
- 93.02 Part (d) is was added by The Patents Act (Isle of Man) Order 1978 (SI 1978 No 621). This Order has since been revoked and replaced by The Patents Act (Isle of Man) Order 2003 (SI 2003 No 1249).

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Section 94: Communication of information to the European Patent Office, etc

Section 94

It shall not be unlawful by virtue of any enactment to communicate the following information in pursuance of the European Patent Convention to the European Patent Office or the competent authority of any country which is party to the Convention, that is to say -

- (a) information in the files of the court which, in accordance with the rules of court, the court authorises to be so communicated;
- (b) information in the files of the Patent Office which, in accordance with rules under this Act, the comptroller authorises to be so communicated.

94.01 This section provides that the communication of information in pursuance of the EPC as set out below is not unlawful.

CPR 63PD para 14.1 CPR 63PD para 14.2 94.02 The Practice Direction supplementing Part 63 of the Civil Procedure Rules provides that the court may authorise the communication to the EPO or the competent authority of any country which is a party to the EPC of any such information in the files of the court as the court thinks fit. However, before authorising the disclosure of such information, the court may permit any party who may be affected by the disclosure to make representations, in writing or otherwise, on the question of whether the information should be disclosed.

r.63 r.51 94.03 The comptroller may authorise any information in the files of the Office to be communicated to the EPO or to a competent authority of any country which is a party to the EPC, except where that information cannot be communicated under s.118.

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Section 95: Financial provisions

95.01 This section has been affected by the use of powers under the Government Trading Funds Act 1973 (as amended) enabling the Patent Office to be operated as a trading fund (The Patent Office Trading Fund Order, SI 1991/1796). The effect of the provisions of the Government Trading Funds Act 1973 is to allow the establishment of new financing arrangements, which supersede any existing statutory provision for vote funding.

Section 95(1)

There shall be paid out of moneys provided by Parliament any sums required by any Minister of the Crown or government department to meet any financial obligation of the United Kingdom under the European Patent Convention or the Patent Co-operation Treaty.

Section 95(2)

Any sums received by any Minister of the Crown or government department in pursuance of that convention or that treaty shall be paid into the Consolidated Fund.

PART III: MISCELLANEOUS AND GENERAL

LEGAL PROCEEDINGS

Section 96: The Patents Court [Repealed]

96.01 Section 96 provided for the establishment of a Patents Court as part of the High Court of Justice in England and Wales, to replace the old Patents Appeal Tribunal.

Section 96 has been repealed by the Supreme Court Act 1981 (c.54) but its contents have been substantially re-enacted by provisions of that Act, which are quoted below. These provisions were amended by the Constitutional Reform Act 2005 (c.4) to provide for the Lord Chief Justice to appoint judges and deputy judges in the High Court. Proceedings before the Patents Court are regulated by the Civil Procedure Rules, particularly Part 63 titled "Patents and other Intellectual Property Claims" (CPR63). This part was introduced into the Civil Procedure Rules 1998 by the Civil Procedure (Amendment No 2) Rules 2002 (S.I. 2002 No. 3219) and entered into force on 1 April 2003. Part 63, together with the Practice Direction supplementing CPR 63, superseded Practice Direction 49E. Further information concerning procedures before the court are detailed in The Patents Court Guide available through the website of the Court Service (http://www.hmcourts-service.gov.uk/).

Supreme Court Act 1981, section 6(1)

There shall be -

- (a) as part of the Chancery Division, a Patents Court; and
- (b) as parts of the Queen's Bench Division, an Admiralty Court and a Commercial Court.

Supreme Court Act 1981, section 62(1)

The Patents Court shall take such proceedings relating to patents as are within the jurisdiction conferred to it by the Patents Act 1977, and such other proceedings relating to patents or other matters as may be prescribed.

Function of the Patents Court

- s.130(1) 96.03 The Patents Court is thus part of the Chancery Division of the High Court. Section 97 of the Patents Act 1977 provides for appeals to the Patents Court from many decisions of the comptroller under the Act or rules. Many other sections of the 1977 Act provide for proceedings (eg concerning alleged infringement of patents) to be brought in the court; as respects England and Wales, the "court" means the High Court (where proceedings are taken by the Patents Court) or a Patents County Court (as set up under ss.287-292 of the CDP Act).
- CPR 63.3 96.04 Under section 61 of the Supreme Court Act 1981 and Schedule 1 to that Act, all causes and matters in the High Court relating to patents, trade marks, registered designs or copyright are assigned to the Chancery Division. Proceedings in the High Court under the Patents Act 1977, the Registered Designs Act 1949 and the Defence Contracts Act 1958, and all proceedings for the determination of a question or the making of a declaration relating to a

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patent under the inherent jurisdiction of the High Court, shall be assigned to the Chancery Division and taken by the Patents Court.

Supreme Court Act 1981, section 6(2)

The Judges of the Patents Court, of the Admiralty Court and of the Commercial Court shall be such of the puisne judges of the High Court as the Lord Chief Justice may, after consulting the Lord Chancellor, from time to time nominate to be judges of the Patents Court, Admiralty Judges and Commercial Judges respectively.

Judges

s.97(2) 96.05 The judges of the Patents Court are normally High Court judges specially nominated by the Lord Chief Justice, after consulting the Lord Chancellor. They generally sit singly but can, for the purpose of hearing appeals from decisions of the comptroller, sit en banc.

96.06 Section 63 of the Supreme Court Act 1981 provides that any business assigned to one or more such specially nominated judges of the High Court may during vacation, illness or absence or for any other reasonable cause be dealt with by any judge of the High Court named for that purpose by the Lord Chief Justice, after consulting the Lord Chancellor. There is also provision for the appointment of deputy judges on an ad hoc basis by the Lord Chief Justice, after consulting the Lord Chancellor under Section 9(4) of the Supreme Court Act 1981.

Supreme Court Act 1981, section 70(3)

Rules of court shall make provision for the appointment of scientific advisers to assist the Patents Court in proceedings under the Patents Act 1949 and the Patents Act 1977 and for regulating the functions of such advisers.

Scientific advisers

CPR
Act, the Patents Court may direct that an independent scientific adviser be appointed to assist the court. Rule 35.15 of the Civil Procedure Rules covers the duties and remuneration of advisers or assessors. The adviser shall assist the court in dealing with a matter for which the adviser has skill and experience, and shall take part in the proceedings as the court may direct. In particular, the court may direct the adviser to prepare a report for the court on any matter at issue in the proceedings, and direct the adviser to attend the whole or any part of the proceedings to advise the court on any such matter. (The Patents Court may also order the Office to provide reports under s.99A, see 99A.01-04.)

Sup.Ct. 96.08 The above provisions regarding scientific advisers, and the provisions below regarding their remuneration, also apply in relation to the Court of Appeal in proceedings on appeal from decisions in such Patents Court proceedings.

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Supreme Court Act 1981, section 70(4)

The remuneration of any such adviser shall be determined by the Lord Chancellor with the concurrence of the Minister for the Civil Service and shall be defrayed out of money provided by Parliament.

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Section 97: Appeals from the comptroller

97.01 This section provides for appeals to the court from decisions of the comptroller. It applies, with certain exceptions (see 97.03), to all such decisions under the 1977 Act and rules.

97.02 [deleted]

Section 97(1)

Except as provided by subsection (4) below, an appeal shall lie to the Patents Court from any decision of the comptroller under this Act or rules except any of the following decisions, that is to say -

- (a) A decision falling within section 14(7) above;
- (b) a decision under section 16(2) above to omit matter from a specification;
- (c) a decision to give directions under subsection (1) or (2) of section 22 above;
- (d) a decision under rules which is excepted by rules from the right of appeal conferred by this section.

Appeals to Patents Court

r.51 CPR 52.11

Except in the case of proceedings held in Scotland by the comptroller (see 97.10), an appeal lies to the Patents Court from any decision of the comptroller under the Act or rules thereunder except as follows. The exceptions are decisions under s.14(7) regarding the abstract; decisions under s.16(2) to omit disparaging or offensive matter from a specification or from any document made available for public inspection under s.118; decisions to give directions under s.22(1) or (2) prohibiting publication of information for security or safety reasons; and other decisions under rules which are excepted by rules from the right of appeal, ie under rule 106 (remission of fees by the comptroller, see 123.16), rule 88 (refusal of an application to hold proceedings in Scotland, see 123.25 to 123.30) and rule 100(3) (certain decisions on review of a Patent Office opinion). An appeal to the Patents Court is limited to a review of the comptroller's decision, unless the court considers that in the circumstances of an individual appeal, it would be in the interests of justice to hold a rehearing. In the REEF Trade Mark case [2003] RPC 5, the Court of Appeal considered the extent that a decision of a tribunal should be reviewed. The Court confirmed that findings of primary fact would not be disturbed by a court unless the hearing officer made an error of principle or was plainly wrong on the evidence, and held that there was no error of principle simply because a judgment or decision could have been better expressed. In considering how reluctant an appellate court should be to interfere with the evaluation of, and conclusion of the primary facts of the case, there was no single standard to lay down, but the most important variables included the nature of the evaluation required, the standing and experience of the fact-finding judge or tribunal, and the extent to which the judge or tribunal had to assess oral evidence. Where no oral evidence had been heard by a tribunal, Robert Walker LJ held that "the appellate court should show a real reluctance, but not the very highest degree of reluctance to interfere in the absence of a distinct and material error of principle". The guidance from this judgment was taken into account in the appeal to the Patents Court in Hartington Conway Ltd's Patent Applications [2004] RPC 7 heard after Part 63 of the Civil Procedure Rules came into effect. In finding no error in the approach of the hearing officer either to the assessment of the witnesses or to the evidence before him, Pumfrey J held that this was a case where the highest degree of reluctance should be felt in revisiting the findings of primary fact. It would also seem necessary following the Court of

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Appeal's decision in *Merck & Co Inc's Patents* [2004] FSR 16 that a ground of appeal that the hearing officer erred "in principle" should actually identify the principle and not be used simply to mask a complaint about the assessment of evidence by the hearing officer. Furthermore, in *Dyson Ltd's Trade Mark Application* [2003] RPC 47, Patten J held that Art.6 of the European Convention on Human Rights did not compel the court to conduct a rehearing in the case of any appeal from an ex parte decision; the power to order a re-hearing was present under CPR 52.11(b) and could be exercised in rare cases in order to allow justice to be done.

97.04 The Patents Court confirmed, in *Omron Tateisi Electronics Co's Application* [1981] RPC 125, that the right to appeal under the Patents Acts and Rules against decisions of the comptroller is a general one to which the only exceptions are those in s.97(1), see 97.03. It is therefore applicable to administrative decisions under the Patents Acts and Rules such as exercise of the comptroller's power under r.110 to grant a certificate that there had been a general interruption in the postal services. The court used its right under s.99 to exercise any power which the comptroller could have done (see 99.01) to itself grant such a certificate.

97.04.1 There is no appeal from decisions of the Office in its capacity of receiving office under the PCT. However, such decisions are open to judicial review (*R v Comptroller-General of Patents*, ex parte Archibald Kenrick & Sons Ltd [1994] RPC 635, *R v Comptroller-General of Patents*, ex parte Drazil [1992] RPC 479, *R v Comptroller-General of Patents*, ex parte Celltech Ltd [1991] RPC 475, *R v Comptroller-General of Patents*, ex parte Penife International Ltd [2004] RPC 37).

CPR 63.16 97.05 The procedure for appeals to the Patents Court from decisions of the comptroller is prescribed by Rule 63.16 of the Civil Procedure Rules (CPR) which in turn directs that CPR Part 52 (and its Practice Directions) applies to appeals from decisions of the comptroller.

[See chapter 7 of the Patent Hearings Manual for procedure relating to such appeals.]

Section 97(2)

For the purpose of hearing appeals under this section the Patents Court may consist of one or more judges of that court in accordance with directions given by the Lord Chief Justice of England and Wales after consulting the Lord Chancellor.

97.06 Appeals to the Patents Court under s.97 are heard by one or more of the Patents Court judges, see 96.05 and 96.06.

97.07 [deleted]

Section 97(3)

An appeal shall not lie to the Court of Appeal from a decision of the Patents Court on appeal from a decision of the comptroller under this Act or rules -

- (a) except where the comptroller's decision was given under section 8, 12, 18, 20, 27, 37, 40, 61, 72, 73 or 75 above; or
- (b) except where the ground of appeal is that the decision of the Patents Court is wrong in law;

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but an appeal shall only lie to the Court of Appeal under this section if leave to appeal is given by the Patents Court or the Court of Appeal.

Appeals to Court of Appeal

An appeal lies to the Court of Appeal from a decision of the Patents Court on appeal from a decision of the comptroller under the Act or rules where (a) the comptroller's decision was under any of certain specified sections of the Act; or (b) the ground of appeal is that the decision of the Patents Court is wrong in law. The specified sections are s.8, 12 or 37 (entitlement), s.18 or 20 (whether the application complies with the Act and rules within the prescribed period), s.27 or 75 (amendment of specification after grant), s.40 (compensation of employee inventor), s.61 (infringement) or s.72 or 73 (revocation). In *Smith International Inc's Patent* [2006] FSR 25, the relationship between s.97(3) and s.55 of the Access to Justice Act 1999 was considered by the Court of Appeal. Unlike s.97(3), the latter provision requires permission for a second appeal to be given by the Court of Appeal and it sets special stringent requirements to grant such permission. The Court of Appeal held that there had been no express or implied repeal or amendment of the particular appeal procedure in s.97(3) for patents by s.55 of the Access to Justice Act 1999, and thus the Patents Court could grant leave to appeal further.

97.09 The procedure for appeals to the Court of Appeal is prescribed by Part 52 of the Civil Procedure Rules and its Practice Direction.

[See chapter 7 of the Patent Hearings Manual regarding such appeals.]

Section 97(4)

An appeal shall lie to the Court of Session from any decision of the comptroller in proceedings which under rules are held in Scotland, except any decision mentioned in paragraphs (a) to (d) of subsection (1) above.

Appeals from decisions in proceedings in Scotland

r.88 97.10 Where there is more than one party to proceedings, a party to those proceedings may request the comptroller to direct that the hearing or hearings, if any, in such proceedings should be held in Scotland, see 123.25 to 123.30. Where, as a result, proceedings are held in Scotland, an appeal lies to the Court of Session from any decision of the comptroller in those proceedings except any decision mentioned in the second sentence of 97.03.

Section 97(4)

The Lord Chief Justice may nominate a judicial office holder (as defined in section 109(4) of the Constitutional Reform Act 2005) to exercise his functions under subsection (2).

97.10.1 A further subsection (4) was added by the Constitutional Reform Act 2005 allowing for the Lord Chief Justice of England and Wales to nominate a judicial officer holder to exercise his functions in nominating High Court judges to sit in the Patents Court.

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Section 97(5)

An appeal shall not lie to the Inner House of the Court of Session from a decision of an Outer House judge on appeal from a decision of the comptroller under this Act or rules -

- (a) except where the comptroller's decision was given under section 8, 12, 18, 20, 27, 37, 40, 61, 72, 73 or 75 above; or
- (b) except where the ground of appeal is that the decision of the Outer House judge is wrong in law.
- 97.11 Decisions of the Outer House judge of the Court of Session from decisions of the comptroller (see 97.10) cannot be appealed to the Inner House unless the comptroller's decision was under any of certain specified sections of the Act (the same as those mentioned in 97.08) or the ground of appeal is that the decision of the Outer House judge is wrong in law.

[See chapter 8 of the Patent Hearings Manual regarding appeals in Scotland.]

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Section 98: Proceedings in Scotland

98.01 This section concerns proceedings relating to patents (other than proceedings before the comptroller) in Scotland.

Section 98(1)

In Scotland proceedings relating primarily to patents (other than proceedings before the comptroller) shall be competent in the Court of Session only, and any jurisdiction of the sheriff court relating to patents is hereby abolished except in relation to questions which are incidental to the issue in proceedings which are otherwise competent there.

s.130(1) 98.02 Court proceedings in Scotland relating primarily to patents may be in the Court of Session only and not in the sheriff court. In the 1977 Act, various powers are specifically given to the "court" which, as respects Scotland, means the Court of Session (unless the context otherwise requires). Powers in relation to appeals from decisions of the comptroller in proceedings which under r.88 are held in Scotland, are specifically given to the Court of Session by s.97(4) and (5), see 97.10 and 97.11. In addition, the Court of Session may order the Office to provide reports, under s.99B. It should be noted that procedures before the Court of Session are governed by the Act of Sederunt (Rules of Court of Session) Rules 1994 (S.I. 1994 No.1443). Chapter 55 of these Rules, which is relevant to intellectual property cases, was reproduced as [1995] RPC 1.

Section 98(2)

The remuneration of any assessor appointed to assist the court in proceedings under this Act in the Court of Session shall be determined by the Lord President of the Court of Session with the consent of the Treasury and shall be defrayed out of moneys provided by Parliament.

98.03 The reference to the "Treasury" in s.98(2) was substituted for a reference to the "Minister for the Civil Service" by S.I. 1981 No.1670 arts.2(2), 3(5).

98.03.1 Subsection (2) lays down how any assessor assisting the Court of Session in proceedings under the 1977 Act is remunerated.

Section 99: General powers of the Court

Section 99

The court may, for the purpose of determining any question in the exercise of its original or appellate jurisdiction under this Act or any treaty or international convention to which the United Kingdom is a party, make any order or exercise any other power which the comptroller could have made or exercised for the purpose of determining that question.

- Sch. 2, para 99.01 For the purpose of determining any question within its jurisdiction under the 1977 or 1949 Act or any relevant treaty etc, the court may exercise any power which the comptroller could have exercised for that purpose. This applies not only to actions initiated in the court but also to appeals to the court from decisions of the comptroller, see for example 97.04.
- s.130(1) 99.02 The "court" means (a) as respects England and Wales, the High Court (ie normally the Patents Court) and any patents county court having jurisdiction by virtue of ss.287-292 of the CDP Act; (b) as respects Scotland, the Court of Session; (c) as respects Northern Ireland, the High Court in Northern Ireland; and (d) as respects the Isle of Man, Her Majesty's High Court of Justice in the Isle of Man.

Section 99A: Power of Patents Court to order report

99A.01 The CDP Act inserted sections 99A and 99B into the 1977 Act. These sections give to the Patents Court and the Court of Session, respectively, the power to order the Office to inquire into and report on any question of fact or opinion.

[A request for a report will come to PD/CL who will pass it to a Deputy Director or Senior Examiner/Legal Adviser for action. The report may be subject to close scrutiny in the court proceedings, so it is particularly important for it to be thorough and accurate. There is likely to be an early time limit for completion. The Office will charge for this service so a record of the number of hours/days taken should be kept.]

99A.02 A similar power is given to the Patents County Court by section 291 of the CDP Act (see 291.05).

Section 99A(1)

Rules of court shall make provision empowering the Patents Court in any proceedings before it under this Act, on or without the application of any party, to order the Patent Office to inquire into and report on any question of fact or opinion.

99A.03 The Patents Court is empowered to make such an order (see 99A.01) of its own motion or on the application of any party to the relevant proceedings. Rules of court are necessary for this purpose; s.99A(1) requires those rules to make such provision. No such rules have yet been made.

Section 99A(2)

Where the court makes such an order on the application of a party, the fee payable to the Patent Office shall be at such rate as may be determined in accordance with rules of court and shall be costs of the proceedings unless otherwise ordered by the court.

Section 99A(3)

Where the court makes such an order of its own motion, the fee payable to the Patent Office shall be at such rate as may be determined by the Lord Chancellor with the approval of the Treasury and shall be paid out of money provided by Parliament.

99A.04 Subsections (2) and (3) provide for the payment of fees to the Office where the Patents Court makes such an order. These subsections cover the rate of payment and who is required to provide the money, depending on whether or not the order is made on the application of a party.

Section 99B: Power of Court of Session to order report

99B.01 The CDP Act gave the court in England and Wales (see 99A.01-02) and in Scotland the power to order reports by the Office in proceedings under the 1977 Act.

Section 99B(1)

In any proceedings before the Court of Session under this Act the court may, either of its own volition or on the application of any party, order the Patent Office to inquire into and report on any question of fact or opinion.

99B.02 The Court of Session may order the Office to inquire into and report on any question of fact or opinion, either of its own motion or on the application of any party to the relevant proceedings.

[For report procedure, see 99A.01.]

Section 99B(2)

Where the court makes an order under subsection (1) above of its own volition the fee payable to the Patent Office shall be at such rate as may be determined by the Lord President of the Court of Session with the consent of the Treasury and shall be defrayed out of moneys provided by Parliament.

Section 99B(3)

Where the court makes an order under subsection (1) above on the application of a party, the fee payable to the Patent Office shall be at such rate as may be provided for in rules of court and shall be treated as expenses in the cause.

99B.03 Subsections (2) and (3) provide for the payment of fees to the Office where the Court of Session makes such an order. These subsections cover the rate of payment and who is required to provide the money, depending on whether or not the order is made on the application of a party.

Section 100: Burden of proof in certain cases

s.60(1)(c) 100.01 This section relates to the burden of proof with regard to whether a product was obtained by a patented process. It is relevant to infringement proceedings since a person may infringe a patent for a process if he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

100.02 It applies to 1977 Act patents including European patents (UK).

s.130(7) Section 100 is so framed as to have, as nearly as practicable, the same effects as the corresponding provisions of the EPC, CPC and PCT. It corresponds to CPC Article 75 (renumbered as Article 35 [1989]), see 100.06.

Section 100(1)

If the invention for which a patent is granted is a process for obtaining a new product, the same product produced by a person other than the proprietor of the patent or a licensee of his shall, unless the contrary is proved, be taken in any proceedings to have been obtained by that process.

This section is concerned with patents where the invention is a process for obtaining a "new product". If the "same product" is produced by a person other than the patentee or his licensee, it is taken in any proceedings to have been obtained by that process unless the contrary is proved. The onus is thus on an alleged infringer to prove otherwise, ie, that the product was not obtained by that process and therefore does not infringe the patent. (This assumes that the product is not also claimed independently of the process; if it is, this section will not normally be relevant.) This moves the burden of proof from the patentee or licensee who, without s.100(1), would normally have had to show that the product constituted an infringement.

100.04.1 In Magnesium Elektron Ltd v Molycorp Chemicals & Oxides (Europe) Ltd & Anor [2015] EWHC 3596, the claimants sought permission to serve proceedings for patent infringement against a defendant based in China. In order to gain permission from the court, the claimant had to show there was a serious issue to be tried. The claims related to a process for preparing zirconium-cerium-based mixed oxides. The claimant relied on s.100 to argue that the defendant's product was obtained directly by the patented process and so there was a serious issue to be tried. The claimant said that experimental results indicated that products made by the patented process have a particular fingerprint which is unique to the patented process, and that the alleged infringing product had that fingerprint. Birss J held that the word "new" in s.100 must mean the same thing as in s.1(1)(a), that is, the "new product" must be novel. The judge also found there is nothing in s.100 which requires that the product which must be a new product is a thing defined in the same level of generality as the words used in the process claim. Whilst the patent acknowledged that zirconium-ceriumbased mixed oxides as such are not novel, the court found that the fingerprint could nevertheless make the product new for the purposes of s.100 - the fact that the patent did not assert that products made that way have a unique fingerprint did not matter. The court therefore gave permission to serve proceedings.

Section 100(2)

In considering whether a party has discharged the burden imposed upon him by this section, the court shall not require him to disclose any manufacturing or commercial secrets if it appears to the court that it would be unreasonable to do so.

100.05 Subsection (2) concerns the disclosure of manufacturing or commercial

secrets by an alleged infringer in attempting to prove that a product was not obtained by the patented process. He is not required to disclose any such secrets if the court considers that it would be unreasonable to require him to do so. Disclosure of a secret would apparently not be required if it was possible to discharge the burden of proof without it.

100.06 The wording of s.100(2) differs substantially from that of the corresponding part of CPC Article 75 (renumbered as Article 35 [1989]) which reads:-

2. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.

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Section 101: Exercise of comptroller's discretionary powers

101.01 This section applies to applications and patents under the 1977 Act. Some requirements relating to hearings are prescribed in Part 7 of the Patents Rules 2007 (Proceedings heard before the comptroller), particularly at rr. 80, 82 and 84 (see 123.05.02 and 123.05.10 – 123.05.13).

[The Patent Hearings Manual should be consulted for guidance on the conduct of hearings and procedures for appointing and conducting hearings and the giving and issuing of decisions. Some of the relevant parts of that Manual are referred to below. Further information is also given in the <u>Tribunal Patents Manual</u>.]

Section 101

Without prejudice to any rule of law, the comptroller shall give any party to a proceeding before him an opportunity of being heard before exercising adversely to that party any discretion vested in the comptroller by this Act or rules.

r.80(4) r.80(5)

r.118

r.107

This section applies to both ex parte proceedings (that is, where the proceedings involve no other party than the applicant or proprietor) and inter partes disputes. In particular, before an application for a patent is refused the applicant must be offered an opportunity to be heard; following a hearing (whether attended by the applicant or not) refusal would normally only be made by a formal decision. (See also 18.79-18.80). If a party to any proceedings wishes to be heard, he must be given notice of a date for the hearing.

101.02.1 Anyone is entitled under s.22 of the Welsh Language Act 1993 to have legal proceedings (such as hearings under s.101) which are held in Wales conducted in Welsh without prior notice. Also, if the proceedings are held in Wales then any oath or affirmation can be given in Welsh. S.24 of the Welsh Language Act provides for the use of interpreters in any such proceedings conducted in Welsh.

101.02.2 In the event that a party requests that a hearing should be conducted in Welsh, the hearing officer should ascertain that the party is unwilling to continue in English. If the request is maintained, the hearing officer should adjourn the proceedings until an interpreter can be obtained.

[There is a list of Office personnel able and prepared to act in this capacity available on Circle. If an interpreter cannot be obtained through ARD, PD/DL should be consulted.]

101.03 A hearing must be before a hearing officer who is authorised to act for the comptroller (see 130.05.1).

[See chapters 4 and 6 of the Patent Hearings Manual regarding the appointment of the hearing officer.]

101.04 [deleted]

101.05 A report of a decision of a hearing officer may be published in the Reports of Patent, etc. Cases (RPC) if this is considered to be generally useful or important.

[A hearing officer may recommend that a particular case should be reported - see chapter 5 of the Patent Hearings Manual.]

101.06 Once a hearing officer has given a decision it cannot normally be reviewed or reversed within the Office, although exceptionally it may be possible for the hearing officer

s.97(1) to re-open issues after judgment, as explained in *Interfilta (UK) Ltd's Patent* [2003] RPC 22. The decision can only be referred to the Patents Court on appeal (except where that is precluded - see s.97) or to the Divisional Court.

101.07 The way in which hearing officers conduct proceedings before them is subject to the general surveillance of the Administrative Justice and Tribunals Council (previously the Council of Tribunals), who investigate complaints from the public and publish an annual report of their investigations. A member of the Council may attend hearings.

101.08 to 101.45 [deleted]

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Section 102: Right of audience, etc., in proceedings before the comptroller

The CDP Act split the old section 102 (Right of audience in patent proceedings) of the 1977 Act into two sections 102 (Right of audience, etc., in proceedings before the comptroller) and 102A (Right of audience, etc., in proceedings on appeal from the comptroller). Section 102 has been amended by section 208(1), schedule 21, paragraph 40 of the Legal Services Act 2007. Section 102A, together with other provisions in the CDP Act, has been repealed by section 210, schedule 23 of the Legal Services Act 2007.

Section 102(1)

A party to proceedings before the comptroller under this Act, or under any treaty or international convention to which the United Kingdom is a party, may appear before the comptroller in person or be represented by any person whom he desires to represent him.

Section 102(2)

No offence is committed under the enactments relating to the preparation of documents by persons not legally qualified by reason only of the preparation by any person of a document, other than a deed, for use in such proceedings.

Section 102(2A)

For the purposes of subsection (2), as it has effect in relation to England and Wales, "the enactment relating to the preparation of documents by persons not qualified" means section 14 of the Legal Services Act 2007 (offence to carry on a reserved legal activity if not entitled) as it applies in relation to an activity which amounts to the carrying on of reserved instrument activities within the meaning of that Act.

Section 102(3)

Subsection (1) has effect subject to rules made under section 281 of the Copyright, Designs and Patents Act 1988 (power of comptroller to refuse to recognise certain agents).

- A party to patent proceedings before the comptroller may appear in person or be represented by any person of his choice, subject to rules empowering the comptroller to refuse to recognise certain agents. This applies to any proceedings before the comptroller under the 1977 Act or any relevant treaty etc.
- 102.03 The rules in question are The Patent Agents (Non-recognition of Certain Agents by Comptroller) Rules 1990 (SI 1990 No 1454) as amended by the Legal Services Act 2007 (Consequential Amendments) Order 2009 (SI 2009 No 3348) which authorise him to refuse to recognise as an agent
 - a. a person who has been convicted of an offence under s.88 of the Patents Act 1949, s.114 of the Patents Act 1977 or s.276 of the CDP Act;
 - b. a person whose name has been erased from and not restored to the register on the ground of misconduct;
 - a person who is found by the Secretary of State to have been guilty of such

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conduct as would, in the case of a person registered in the register, render the person liable to have the person's name erased from the register on the ground of misconduct:

d. a partnership or body corporate of which one of the partners or directors is a person whom the comptroller could refuse to recognise under paragraph (a), (b) or (c) above.

The "register" in the above is the register of patent attorneys required to be kept under s.275 of the CDP Act.

102.04 Subsection (2) protects any person who prepares documents (other than deeds) for use in such proceedings, but is not legally qualified. It extends to other such persons the protection previously afforded to patent agents by section 114(6) of the 1977 Act which the CDP Act repealed.

Subsection (2A) ensures the reference to "the preparation of documents by persons not legally qualified" in subsection (2) refers to section 14 of the Legal Services Act 2007 (Offence to carry on a reserved legal activity if not entitled) insofar as it has effect in England and Wales.

Section 102(4)

In its application to proceedings in relation to application for, or otherwise in connection with, European patents, this section has effect subject to any restrictions imposed by or under the European Patent Convention.

102.06 The effect of section 102 on proceedings concerning European patents is made subject to any restrictions under the European Patent Convention by subsection (4). Such restrictions relate to the need for representatives to be on the "European list" maintained by the European Patent Office.

Section 102(5)

Nothing in this section is to be taken to limit any entitlement to prepare deeds conferred on a registered patent attorney by virtue of the Legal Services Act 2007.

102.07 Sub-section (5) was added by the Courts and Legal Services Act 1990, s.125(3), Sch 18, para 20 and subsequently amended by the Legal Services Act 2007, s.208(1), Sch 21, para 40.

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Section 102A: Right of audience, etc., in proceedings on appeal from the comptroller [Repealed]

102A.01 This section provided the rights of audience and communications in proceedings on appeal from the Comptroller. This section was added to the 1977 Act by the CDP Act but derives from the previous s.102, see 102.01.

Section 102A has been repealed by the Legal Services Act 2007, section 210 and Schedule 23. The new regime established by the Legal Services Act 2007 now gives the definitions and specific authorisation for parties to take part in reserved legal activities such as the right of audience in proceedings.

Section 103: Extension of privilege for communications with solicitors relating to patent proceedings

This section declares that the privilege from disclosure enjoyed by the clients of solicitors extends to communications with solicitors for the purpose of pending or contemplated proceedings under the 1977 Act, EPC or PCT. This applies to proceedings before the comptroller or, for the EPC and PCT only, before the relevant convention court (as defined in s.130(1)).

103.02 Section 280 of the CDP Act makes similar provision in respect of communications with patent agents. Section 103 does not extend to Scotland where section 105 (and section 280(4) of the CDP Act) apply instead.

Section 103(1)

It is hereby declared that the rule of law which confers privilege from disclosure in legal proceedings in respect of communications made with a solicitor or a person acting on his behalf, or in relation to information obtained or supplied for submission to a solicitor or a person acting on his behalf, for the purpose of any pending or contemplated proceedings before a court in the United Kingdom extends to such communications so made for the purpose of any pending or contemplated -

- (a) proceedings before the comptroller under this Act or any of the relevant conventions, or
- (b) proceedings before the relevant convention court under any of those conventions.

Section 103(2)

In this section -

"legal proceedings" includes proceedings before the comptroller;

the references to legal proceedings and pending or contemplated proceedings include references to applications for a patent or a European patent and to international applications for a patent; and

"the relevant conventions" means the European Patent Convention and the Patent Co-operation Treaty.

Section 103(3)

This section shall not extend to Scotland.

The reference to a solicitor etc includes references to bodies recognised under the Administration of Justice Act 1985, s.9, by the Solicitors' Incorporated Practices Order 1991, SI 1991 No 2684.

Section 104: Privilege for communications with patent agents relating to patent proceedings [Repealed]

This section provided privilege from disclosure to communications with patent agents akin to that applying to communications with solicitors (the latter being specifically applied in relation to patent proceedings in accordance with s.103).

Section 104, together with other provisions of the 1977 Act concerning patent agents, has been repealed by the CDP Act and replaced by Part V of the CDP Act (Patent Agents and Trade Mark Agents). In particular, section 280 of the CDP Act provides privilege for communications with patent agents, see 280.01-05.

Section 105: Extension of privilege in Scotland for communications relating to patent proceedings

This section provides for certain documents relating to patent proceedings to be privileged from disclosure in Scotland. It was amended by section 303(1) and schedule 7, paragraph 21, of the CDP Act.

105.02 In addition, section 280(4) of the CDP Act declares that in Scotland the rules of law which confer privilege from disclosure in legal proceedings in respect of communications extend to such communications as are mentioned in section 280. That section is concerned with communications with, or seeking information for the purpose of instructing, one's patent agent. It is to be noted that s.105 does not contain any such restriction to patent agents.

Section 105(1)

It is hereby declared that in Scotland the rules of law which confer privilege from disclosure in legal proceedings in respect of communications, reports or other documents (by whomsoever made) made for the purpose of any pending or contemplated proceedings in a court in the United Kingdom extend to communications, reports or other documents made for the purpose of patent proceedings.

Section 105(1) declares that in Scotland the privilege from disclosure afforded to documents made for the purpose of any pending or contemplated proceedings in a court in the UK extends to those made for the purpose of patent proceedings.

Section 105(2)

In this section -

"patent proceedings" means proceedings under this Act or any of the relevant conventions, before the court, the comptroller or the relevant convention court, whether contested or uncontested and including an application for a patent; and

"the relevant conventions" means the European Patent Convention and the Patent Co-operation Treaty.

105.04 [deleted]

Section 106: Costs and expenses in proceedings before the Court

106.01 This section concerns costs (expenses in Scotland) in proceedings before the court.

- PA 2004, 106.02 For proceedings launched on or after 1 January 2005, s.106 applies to proceedings under s.40 (i.e. applications for compensation by employee inventors), proceedings for infringement (i.e. proceedings under s.61 or s.69), proceedings in respect of an actionable threat under s.70A (i.e. proceedings against a person making unjustified threats to bring infringement proceedings), or proceedings under s.71 (i.e. applications for a declaration of non-infringement of a patent). For proceedings launched before 1 January 2005, s.106 only applies to proceedings under s.40. In either case, section 106 applies only to proceedings before the court, whether initiated before the court or on appeal from a decision of the comptroller. Proceedings before the comptroller only are not covered by this section.
- CPR 44.3 106.03 When deciding on an award of costs in proceedings, this section requires the court to consider the financial position of both parties amongst other circumstances normally required to be taken into account, including their conduct before and during the proceedings, whether a party has been successful in proving part, if not all, of its case, and whether any effort was made to settle the case.

Section 106(1)

In proceedings to which this section applies, the court, in determining whether to award costs or expenses to any party and what costs or expenses to award, shall have regard to all the relevant circumstances, including the financial position of the parties.

Section 106(1A)

This section applies to proceedings before the court (including proceedings on appeal to the court) which are -

- (a) proceedings under section 40;
- (b) proceedings for infringement;
- (c) proceedings in respect of an actionable threat under section 70A; or
- (d) proceedings on an application for a declaration or declarator under section 71.
- In determining whether to award costs and the amount of such costs in proceedings to which this section applies, the court is required to have regard to all the relevant circumstances including the financial position of the parties. Where other issues are raised in these proceedings (e.g. where the issue of validity is raised as a defence to infringement proceedings), s.106 also applies to any award of costs relating to the other issues raised in the proceedings.
- s.130(1) 106.05 This subsection, unlike subsection (2), applies to the court in general, ie the appropriate High Court (or patents county court) or, in Scotland, the Court of Session (as set out more fully in 99.02).
 - 106.05.1 Section 106(1A)(c) was amended by the Intellectual Property (Unjustified Threats) Act 2017 to refer to the relevant part of the threats provisions as reformed by that Act,

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namely to an actionable threat under section 70A.

Section 106(2)

If in any such proceedings the Patents Court directs that any costs of one party shall be paid by another party, the court may settle the amount of the costs by fixing a lump sum or may direct that the costs shall be taxed on a scale specified by the court, being a scale of costs prescribed by the Rules of the Supreme Court or by the County Court Rules.

106.06 Subsection (2) applies only to the Patents Court. It gives that court discretion to award a lump sum or costs taxed on a specified scale, when directing that one party should pay any costs of another. The Rules of the Supreme Court and the County Court Rules have both been superseded by the Civil Procedure Rules.

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Section 107: Costs and expenses in proceedings before the comptroller

107.01 This section provides for the award of costs (expenses in Scotland) by the comptroller in proceedings before him. It also provides for enforcement of orders made by the comptroller awarding costs, and allows the comptroller to require security for the costs of certain proceedings before him.

Section 107(1)

The comptroller may, in proceedings before him under this Act, by order award to any party such costs or, in Scotland, such expenses as he may consider reasonable and direct how and by what parties they are to be paid.

Award of costs by comptroller

The comptroller is empowered to award by order any party in proceedings before him under the 1977 Act such costs as he may consider reasonable and direct how and by what parties they are to be paid.

107.03 As explained in Tribunal Practice Notice 4/2007 (reproduced in the "Relevant Official Notices and Directions" section of this Manual), costs in proceedings before the comptroller are not intended to compensate parties for the expenses to which they have been put; they are a contribution to costs in the form of a lump sum.

[Guidance on the assessment of costs is given in chapter 5 of the Patent Hearings Manual.]

107.04 to 107.08 [deleted]

Section 107(2)

In England and Wales any costs awarded under this section shall, if the county court so orders, be recoverable by execution issued from the county court or otherwise as if they were payable under an order of that court.

Section 107(3)

In Scotland any order under this section for the payment of expenses may be enforced in like manner as an extract registered decree arbitral bearing a warrant for execution issued by the sheriff court of any sheriffdom in Scotland.

Enforcement of order for costs

107.09 An award of costs by a hearing officer cannot be enforced by the Office, but a successful party who is unable to obtain the awarded amount from the other party is at liberty to seek the assistance of the courts in enforcing the award, in accordance with subsection (2), (3), (5) or (6) as appropriate.

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Section 107(4)

The comptroller may make an order for security for costs or expenses against any party to proceedings before him under this Act if -

(a) the prescribed conditions are met, and

are that the party against whom the order is made:

(b) he is satisfied that it is just to make the order, having regard to all the circumstances of the case;

and in default of the required security being given the comptroller may treat the reference, application or notice in question as abandoned.

Security for costs

- r.85 107.10 The comptroller may require a party to give security for costs or expenses in proceedings. The conditions for making an order, which are similar to those applicable to the courts under rule 25.13(2) of the Civil Procedure Rules, are prescribed by r.85. These
 - (a) is resident outside the UK, but not resident in a Brussels Contracting State, a Lugano Contracting State, or a Regulation State, as defined in section 1(3) of the Civil Jurisdiction and Judgments Act 1982;
 - (b) is a company or other body (whether incorporated inside or outside the UK) and there is reason to believe that it will be unable to pay another party's costs if ordered to do so:
 - (c) has changed his address for service with a view to evading the consequences of the litigation;
 - (d) has furnished an incorrect address for service; or
 - (e) has taken steps in relation to his assets that would make it difficult to enforce an order for costs against him.

In practice, the comptroller will only require such security following successful application from another party to the proceedings.

[Guidance on security for costs is given in chapter 2 of the Patent Hearings Manual.]

107.11 When an application asking the comptroller to require security for costs has been successful, security for a fixed sum will generally be required when the proceedings are initiated. If it does not accompany the reference, application or notice, a letter is issued requiring provision thereof. It suffices for the person's patent agent in the UK to guarantee the sum in writing.

[The matter of security for costs is dealt with by Tribunal Section. The letter should identify the writer and provide a contact telephone number.]

107.12 If the required security is not given, the reference, application or notice may be treated as abandoned.

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Section 107(5)

In Northern Ireland any order under this section for the payment of costs may be enforced as if it were a money judgment.

Section 107(6)

In the Isle of Man, any order under this section for the payment of costs may be enforced in like manner to an execution issued out of the court.

107.13 See 107.09. Subsection (6) was added by the Patents Act 1977 (Isle of Man) Order 1978 SI 1978 No. 621, and is now a consequence of the Patents Act 1977 (Isle of Man) Order 2003 SI 2003 No. 1249, which repealed the earlier Order.

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Section 108: Licences granted by order of comptroller

Section 108

Any order for the grant of a licence under section 11, 38, 48 or 49 above shall, without prejudice to any other method of enforcement, have effect as if it were a deed, executed by the proprietor of the patent and all other necessary parties, granting a licence in accordance with the order.

The grant of a licence may be ordered by the comptroller (or by the court on appeal) under s.11 or 38 (order in favour of original applicant, patentee or licensee who worked the invention prior to a reference under s.8 or 37 resulting in substitution of new applicant or patentee) or s.48 or 49 (order for compulsory licence because invention not being adequately worked or activities being unfairly prejudiced by actions of patentee).

Section 108 ensures that such an order under one of those sections will be effective even if the parties affected take no action in response to it. The order has effect as if it were a deed, executed by the patentee and all other necessary parties, granting a licence in accordance with the order.

108.03 This section applies to 1977 Act patents including European patents (UK).

OFFENCES

Section 109: Falsification of register etc

Section 109

If a person makes or causes to be made a false entry in any register kept under this Act, or a writing falsely purporting to be a copy or reproduction of an entry in any such register, or produces or tenders or causes to be produced or tendered in evidence any such writing, knowing the entry or writing to be false, he shall be liable -

- (a) on summary conviction, to a fine not exceeding the prescribed sum,
- (b) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine, or both.

109.01 This section lays down penalties for certain offences relating to entries in any register kept under the 1977 Act. It thus applies to the register of patents kept under s.32 of the 1977 Act. The offences in question are, in essence, to procure a false entry or falsely represent an entry.

The maximum fine on summary conviction corresponds to that applicable under s.22(9) (see 22.26.1).

109.03 The reference to "indictment" in s.109(b) is treated as a reference to "information" for the Isle of Man only (SI 2003 No 1249).

Section 110: Unauthorised claim of patent rights

s. 77(1) 110.01 This section relates to false representation that a product is patented, and the circumstances in which this constitutes an offence, and applies in relation to both patents granted under the 1977 Act and European patents (UK).

110.02 Section 111 makes similar provision with regard to unauthorised claims to the existence of a patent application in respect of an article.

Section 110(1)

If a person falsely represents that anything disposed of by him for value is a patented product he shall, subject to the following provisions of this section, be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

s. 130(1)

110.03 It is an offence, except as provided for in subsections (3) and (4), see 110.07 and 110.08, for a person to falsely represent that anything disposed of by him for value is a patented product. By a "patented product" is meant a product which is a patented invention or, in relation to a patented process, a product obtained directly by means of the process or to which the process has been applied. A representation that something is a patented product is false if a patent has not yet been granted or is no longer in force.

[Any queries relating to offences under this section should be referred to Patents Legal Section.]

110.04 The maximum fine was converted to a level on the standard scale by the Criminal Justice Act 1982.

Section 110(2)

For the purposes of subsection (1) above a person who for value disposes of an article having stamped, engraved or impressed on it or otherwise applied to it the word "patent" or "patented" or anything expressing or implying that the article is a patented product, shall be taken to represent that the article is a patented product.

Marking of an article to the effect that it is patented, eg by use of the word "patent" or "patented", is taken (for the purposes of subsection (1)) to represent that the article is a patented product. In *Cassidy v Eisenmann & Co Ltd* [1980] FSR 381 (a private prosecution in a Magistrates' Court), the defendants were found to have contravened s.110 by selling an article marked "Brevettato" (the English translation of which is "patented") followed by a list of countries including "Great Britain" at a time when a UK patent had not been granted.

s.62(1) 110.06 In order to be effective in providing protection against infringement, however, such marking must be accompanied by the number of the patent or marked with a relevant web address (see 62.04).

Section 110(3)

Subsection (1) above does not apply where the representation is made in respect of a product after the patent for that product or, as the case may be, the process in question has expired or been revoked and before the end of a period which is reasonably sufficient to enable the accused to take steps to ensure that the representation is not made (or does not

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continue to be made).

There is a period of grace following the expiry or revocation of the relevant patent during which representation as a patented produced does not constitute an offence under this section. That period is of a length regarded as "reasonably sufficient" for the person in question to prevent or cease such representation.

Section 110(4)

In proceedings for an offence under this section it shall be a defence for the accused to prove that he used due diligence to prevent the commission of the offence.

110.08 It is a defence for a person accused of an offence under this section to have used due diligence to prevent its commission, but the onus is on that person so to prove.

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Section 111: Unauthorised claim that patent has been applied for

s. 78(2) s. 111.01 This section relates to representation that a patent has been applied for in respect of an article, and the circumstances in which this constitutes an offence. It applies to claims to the existence of applications under the 1977 Act, including applications for European patents (UK) and international applications for a patent (UK).

111.02 It is similar to s.110 whereby a false claim to patent rights may be an offence.

Section 111(1)

If a person represents that a patent has been applied for in respect of any article disposed of for value by him and -

- (a) no such application has been made, or
- (b) any such application has been refused or withdrawn,

he shall, subject to the following provisions of this section, be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Representation by a person that a patent has been applied for in respect of an article may be an offence if such an article is disposed of for value by him. In order for it to be an offence, any such application for a patent must have either been refused or withdrawn, or never been made. This is subject to the exceptions in subsections (2) and (4), see 111.05 and 111.07. With regard to what constitutes such representation, see 111.06.

[Any queries relating to offences under this section should be referred to Patents Legal Section.]

111.04 The maximum fine was converted to a level on the standard scale by the Criminal Justice Act 1982.

Section 111(2)

Subsection (1)(b) above does not apply where the representation is made (or continues to be made) before the expiry of a period which commences with the refusal or withdrawal and which is reasonably sufficient to enable the accused to take steps to ensure that the representation is not made (or does not continue to be made).

There is a period of grace following the refusal or withdrawal of the relevant application during which representation that a patent has been applied for does not constitute an offence under this section. That period is of a length regarded as "reasonably sufficient" for the person in question to prevent or cease such representation.

Section 111(3)

For the purposes of subsection (1) above a person who for value disposes of an article having stamped, engraved or impressed on it or otherwise applied to it the words "patent applied for" or "patent pending", or anything expressing or implying that a patent has been applied for in respect of the article, shall be taken to represent that a patent has been

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applied for in respect of it.

111.06 Marking of an article to the effect that a patent has been applied for in respect of it, eg by use of the words "patent applied for" or "patent pending", is taken (for the purposes of subsection(1)) to represent that a patent has been applied for in respect of it.

Section 111(4)

In any proceedings for an offence under this section it shall be a defence for the accused to prove that he used due diligence to prevent the commission of such an offence.

111.07 It is a defence for a person accused of an offence under this section to have used due diligence to prevent its commission, but the onus is on that person so to prove.

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Section 112: Misuse of title "Patent Office"

Section 112

If any person uses on his place of business, or on any document issued by him, or otherwise, the words "Patent Office" or any other words suggesting that his place of business is, or is officially connected with, the Patent Office, he shall be liable on summary conviction to a fine not exceeding level 4 on the standard scale.

112.01 It is an offence under s.112 to suggest that a place of business (other than the Patent Office) is, or is officially connected with, the Patent Office.

[Any queries relating to offences under this section should be referred to Patents Legal Section.]

112.02 The maximum fine was converted to a level on the standard scale by the Criminal Justice Act 1982.

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Section 113: Offences by corporations

This section relates to the liability of officers of a body corporate for offences committed by the body corporate.

Any of certain officers of the body corporate, as well as the body corporate itself, is guilty of such an offence if it is proved to have been committed with the consent or connivance of, or as a result of neglect by, that officer. The officers in question are directors, managers, secretaries and "other similar officers" of the body corporate (or any person purporting to act in any such capacity) and, in accordance with subsection (2), the members of a body corporate managed by its members.

Section 113(1)

Where an offence under this Act which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to act in any such capacity, he, as well as the body corporate, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Section 113(2)

Where the affairs of a body corporate are managed by its members, subsection (1) above shall apply in relation to acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

PATENT AGENTS

Section 114: Restrictions on practice as patent agent [Repealed]

This section imposed limitations on who could do business as a patent agent. It also allowed patent agents to prepare certain instruments without committing an offence.

114.02 Section 114, together with other provisions of the 1977 Act concerning patent agents, has been repealed by the CDP Act (section 303(2) and schedule 8). Those provisions have been replaced by the new regime provided by Part V of the CDP Act (Patent Agents and Trade Mark Agents), see 274.01 et al.

Section 115: Power of comptroller to refuse to deal with certain agents [Repealed]

115.01 This section authorised the provisions of rule 90 of the 1982 Rules whereby the comptroller could refuse to recognise persons in certain categories as agents. It also concerned recognition of agents not residing or having a place of business in the UK.

Section 115, together with other provisions of the 1977 Act concerning patent agents, has been repealed by the CDP Act and replaced by Part V of the CDP Act (Patent Agents and Trade Mark Agents), see particularly s.281 discussed in 281.01-04.

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IMMUNITY OF DEPARTMENT

Section 116: Immunity of department as regards official acts

Section 116

Neither the Secretary of State nor any officer of his -

- (a) shall be taken to warrant the validity of any patent granted under this Act or any treaty or international convention to which the United Kingdom is a party; or
- (b) shall incur any liability by reason of or in connection with any examination or investigation required or authorised by this Act or any such treaty or convention, or any report or other proceedings consequent on any such examination or investigation.

116.01 This section protects the Secretary of State and his officers, including officials of the Patent Office, from any liability arising from official acts connected with examination or investigation under the 1977 Act or the EPC or PCT. It also provides that no warranty is given in respect of the validity of patents, including 1977 Act patents and European patents.

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ADMINISTRATIVE PROVISIONS

Section 117: Correction of errors in patents and applications

117.01 This section is concerned with the correction of errors in specifications and in other documents filed in connection with patents and applications. Prescribed conditions are set out in r.105. (For the distinction between correction and amendment, see 19.03-19.04). S.117 and r.105 do not cover failure to file a document within a prescribed period; they are concerned solely with correcting errors in documents, and not with procedural errors or omissions, which are the province of r.107 (*Klein Schanzlin & Becker AG's Application* [1985] RPC 241; *Tokan Kogyo KK's Application* [1985] RPC 244). Subsections (3) and (4) were added by the Regulatory Reform (Patents) Order 2004, with effect from 1 January 2005.

117.02 S.117 does not govern correction of the Register nor of documents filed in connection with registration, for which see 32.14. If, however, an error in the Register has resulted from an error in a document which is subsequently corrected under s.117 then the Register will be corrected accordingly.

[A request to correct an error or mistake under this section must be made in writing and identify the proposed correction.]

Section 117(1)

The comptroller may, subject to any provision of rules, correct any error of translation or transcription, clerical error or mistake in any specification of a patent or application for a patent or any document filed in connection with a patent or such an application.

r.105(1)-(2) r.49 117.03 Except in the case of a name (where correction must be requested on Form 20, see 16.23), a request to correct a document under this section must be made in writing clearly identifying the proposed correction. (The comptroller may require the filing of a copy of the defective document on which the correction is shown, and may request that it be shown in red ink.) For correction of an error in an address or address for service, see also 117.17. See 80.03-06 with regard to translations corrected under s.80(3).

[A request to correct an error in a specification should be referred by the formalities examiner via the Formalities Manager to the case examiner. The Formalities Examiner should add a minute to the dossier for the case examiner and send the appropriate PDAX message to the examiner. If the request is allowable the correction should be effected; if this cannot readily be done on the existing documents and replacements have not been filed they should be asked for. The Formalities Examiner should create a working copy annotated appropriately and place a "P" against the documents for publication. If the application is a paper case, replacement drawings should be stamped as under 15A.06 and superseded drawings, other than any marked "not to be amended", should be cancelled.]

117.04 Although the request will normally be made by the applicant or proprietor, any person able to give evidence as to the occurrence of an error may request its correction.

117.05 If an examiner notices an apparent error of significance during substantive examination it should be drawn to the applicant's attention. Exceptionally, as the wording of s.117(1) allows the comptroller to make corrections on his own initiative the examiner may make clearly allowable corrections of obvious minor errors but should inform the applicant that he has done so.

117.06 Provided the request for correction has been allowed before the completion of

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preparations for publication the application published under s.16 will be published as corrected (see 16.23) and the published document will bear a notice (see 16.29) that it embodies a correction made under s.117(1).

CORRECTION OF THE SPECIFICATION

Allowability

- r.105(3) 117.07 No correction may be made in a specification unless the correction is obvious (meaning that it is immediately evident that nothing else could have been intended in the original specification). This is construed as imposing a two-fold test:-
 - (a) is it clear that there is an error, and
 - (b) if so, is it clear what is now offered is what was originally intended?

A very similar two-fold test was at the centre of judicial reviews under PCT r.91 in *R. v the Comptroller-General of Patents ex parte Celltech Ltd* [1991] RPC 475 and in *Drazil's Application* [1992] RPC 479. These judgments may not be fully applicable to corrections under s.117 since there are differences in the wording between r.105 and PCT r.91 and s.117 is not one of those sections listed under s.130(7) as having the same effect as corresponding provisions in the EPC, CPC and PCT. Rule 139 EPC has similar wording to r.105(3) but the Enlarged Board of Appeal of the EPO has decided in Decision G11/91 (OJEPO 3/93) that no correction can be allowed which would extend the disclosure. As indicated in 19.04, that limitation does not arise under the 1977 Act.

r.105(4)

[However, the test set out above does not apply where the error in the specification is connected to the delivery of the application in electronic form or using electronic communications, i.e. where an error was caused by the conversion from one electronic format to another, a correction to the specification should be allowed.]

[If it appears to the case examiner that the alteration sought does not meet the tests for a correction but it appears that it would be allowable as an amendment under s.19 or s.27 this course may be suggested to the applicant.]

117.08 In order to pass the first test it must be apparent on the face of the documents that something is amiss. This would clearly be the case if a passage did not read on, or if a page were missing. It is not, however, necessary that the error be as readily apparent as this; the notional addressee of the specification is a person who is reading the document with the intention of extracting all the teaching from it, and who is aware of everything of common knowledge in the art concerned. For example, while a casual reader might not realise that the quoted serial number of another patent is incorrect, the notional reader will turn up every reference as he comes to it, and it will then be apparent (if for example the patent apparently referred to relates to completely different subject-matter) that the reference given would not have been intended. Likewise if an error is made in giving a known physical parameter, for example a eutectic temperature, the reader may be deemed to recognise this, even if he has to refresh his memory from a reference book. Also, a knowledge of all the contents of the open part of the file of the application should be attributed to the reader, so that, for example, a discrepancy between the specification and an otherwise similar priority document should be regarded as enough to put the reader on enquiry. If, however, the specification makes technical and linguistic sense, then it is not immediately evident that this would not have been what was originally intended, so that, irrespective of what is proposed as the correction, it cannot be said that nothing else than what is offered would have been intended. In such a case the matter cannot be dealt with as the correction of an error.

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117.09 Although it will sometimes be apparent on the face of the documents what the correction should be, this will not generally be the case if for example the error lies in an omission or in an incorrect document reference or numerical data. It is not however necessary that the reader be able to correct the error unaided; in considering an offered correction regard must be had to the view which the fully-informed and inquisitive skilled reader would take of the documents originally filed and the most likely solution to the difficulty apparent to him from them. Often the correct version will be unique and will be apparent from the documents filed at the time at which the application was made. Otherwise evidence will be necessary to establish that the correction offered is what was originally intended. In Dukhovskoi and Others Applications [1985] RPC 8 where it became accepted during the proceedings that the error was apparent, the Patents Court held that the original document which it was asserted has been mistranslated (which was neither the priority document nor one of the documents available to the Office at the date of filing) could be considered when the application for correction was made and, with the aid of a dictionary, could establish that the correct translation was what was suggested by the correction. A priority document filed later than the date on which the declaration of priority was made (see 5.08 to 5.11) may be taken into consideration provided that it can be shown it was intended at the time the declaration of priority was made to claim priority from that document rather than some other application. This will be shown if its file number was included on the date the declaration of priority was made. If however this number is supplied later (as under rule 8(1), it may be) and there is a reasonable doubt as to its veracity, suitable evidence may take the form of a sworn statement from the applicant or an extract from the official Gazette of the country of filing indicating that it was the only application filed by the applicant on the date in question. A later-filed document may also be used to show that a particular process or construction is well-known in the art and could be assumed to be known to the skilled reader. The expression "immediately evident" is however taken as requiring that, when all the evidence is considered, it is abundantly clear that nothing else other than what is now offered as the correction was originally intended. It is not sufficient merely to show that, on balance of probabilities, the correction offered is the most likely version.

[Borderline cases under r.105(3) and any where the strict application of the rule would apparently lead to a ridiculous result should be referred to the Divisional Director.]

117.10 Section 15(8) states that s.15(6) and (7) in relation to "missing parts" do not affect the comptroller's discretion under s.117(1) to correct an error or mistake. Thus, if all of the requirements of s.117 and r.105 have been met (see 117.03-09), it is possible for the comptroller to allow a missing part to be filed as a correction under s.117(1) without redating. Applicants should be asked to indicate, in writing, whether any drawing(s) filed with such a request under s.117 is/are to be regarded as a filing where ss.15(5) to (7) apply, should the s.117 request be disallowed.

117.11 A request to correct an error in the specification of a European patent (UK) should be dealt with in the same way as in the case of a patent granted under the Act. However, the comptroller does not entertain a request for correction of the text of a European patent (UK) under s.117 if the EPO has already allowed the correction. The formal publicising of such a correction is also solely a matter for the EPO. If a request under s.117 to correct an error in the specification of a European patent (UK) is received before the nine months allowed for opposing the patent has expired or when there is an opposition outstanding, the possibility exists that the specification may be amended before the EPO. In such circumstances the agent is given the option of either (a) staying the request until the opposition period has expired or the opposition proceedings have been settled or (b) proceeding with the request to correct under s.117 on the understanding that the desired correction may be negated as a result of subsequent amendment before the EPO. If it is not possible to determine the allowability of the correction solely by reference to the published specification, the applicant should be required to furnish the necessary documentary evidence, for example copies of any relevant documents indicating the "as filed" state of the application.

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[Where a request under s.117 is received to correct a European patent (UK), Restoration and Post Grant Section (RAPS) will check on the EPO online file inspection service in order to ascertain (a) whether the period allowed for opposing the patent has expired and whether any opposition was entered and (b) whether any application for central amendment of the patent has been made and whether any amendment has been allowed. Where necessary the proprietor or agent will be given the option of staying the request. If the applicant is to be given the option of staying the proceedings, the requested correction should be scrutinised by a Deputy Director and any prima facie objection to it should be communicated to the applicant in a letter giving him the choice on stay. A request to correct a document in a European patent (UK) other than the specification will be referred by RAPS to the Deputy Director].

Correction of translations of the specifications of European patents (UK)

- 117.11.1 A request to correct a translation of the specification of a European patent (UK) filed under s.77(6)(a) should also be dealt with in the same way as a patent granted under the Act but unlike a request to correct the text of a European patent (UK), it should never be deferred pending the expiry of the opposition period. An additional consideration is whether the correction requested properly comes under s.117 or s.80(3). If the correction of the translation would seem to broaden the protection conferred by the patent or application, it should be made under s.80(3) in accordance with the procedure in 80.03-06, for which purpose a fresh application on Form 54 is necessary. Correction of the translation will not be appropriate where the error lies in the specification of the European patent (UK) but the translation is nevertheless a correct representation of the incorrect text. In such cases a request should be made to correct the specification. If this necessitates a fresh verified translation then such a translation should be filed pursuant to r.113(1).
 - [(i) The procedure for correction of such a translation under s.117 generally follows along the same lines as for correction of UK national patents after grant, as follows.
 - (ii) After stamping and scanning, the request for correction is passed to RAPS for the request for correction to be noted in the Register and advertised in the Journal.
 - (iii) RAPS will send the file to the Deputy Director for consideration as to whether the correction requested properly comes under s.117 or s.80(3) and whether or not the correction is allowable.

If it is decided that s.117 is appropriate, the considerations as to the allowability of the correction set out in 117.07-117.10 apply. However, if the requested correction would seem to broaden the protection conferred by the translation the correction should be made under section 80(3). In this case a minute should be created to that effect, in a form suitable for communication to the agent/proprietor, and a PDAX message sent to RAPS for preparation and issue of a letter embodying the minute. The letter should also invite the agent/proprietor to initiate action under s.80(3) by filing Form 54 with appropriate fee, see 80.03-06.

- (iv) Subsequent procedure is basically as in the second square bracket paragraph of 117.14 except that:
 - (a) unless the corrections are of minimal extent, RAPS will call upon the proprietor to provide, within a specified period, a new translation incorporating the corrections instead of correcting the original copy of the translation,

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- (b) RAPS should ensure that the file copy is updated accordingly and that a copy of the corrected translation is also sent to the British Library, and
- (c) since the correction relates to the translation of the specification, it is not necessary for Publishing Section to issue a C publication.]

Procedure before publication

(See also 117.06)

117.12 [deleted]

117.13 If an examiner notices a clerical error which would be likely to impede the understanding of a specification when published he should inform the applicant or agent. However, the initiation of a correction is a matter for the applicant, and if he does not respond the matter should be deferred until substantive examination. Publication should not be unduly delayed. Purely formal editorial matters, such as the re-arrangement and renumbering of accidentally transposed pages, may be effected by the examiner with the applicant's or agent's agreement, provided that the nature of the error and its correction are beyond reasonable doubt.

[If a page of text appears to be missing from the specification the formalities examiner should draw this to the attention of the case examiner. If the case examiner considers that the matter may be rectified as a correction he may invite the applicant to make a request for correction. In no case should action be taken which would be likely to provoke a request to correct if it appears that such a request would not be allowable.]

Procedure between publication and grant

117.13.1 Any request to correct an error received after the completion of preparations for publication of an application but before grant should be considered as soon as possible and not deferred until substantive examination, for example. An erratum should be issued once the correction has been allowed. Where there is doubt whether the desired alteration is intended to be by way of correction or amendment (see 19.03-19.19), the situation should be clarified with the applicant.

[Where such a correction is considered allowable, the examiner should create a minute addressed to Formalities, noting that a correction has been allowed under s.117, and requesting that an erratum is issued. If a correction is not allowable, the examiner should create a minute addressed to Formalities outlining the objection to the correction. Formalities will then issue a letter to the applicant.]

Procedure after grant

117.14 The examiner to whom the request is referred must consider it according to the tests set out in paragraphs 117.07 to 117.09. He must also consider whether it is necessary to advertise the correction (see 117.23-117.24). When allowed, the correction is published as a C publication. The C publication is a front page either with a schedule of the corrections on the reverse or associated with a new corrected specification if one has been filed, the procedure being the same as for a C publication for amendment of a granted specification, see 27.20. A C publication is not normally issued for correction of printer's errors or of errors in the bibliographic information on the front page of a published specification, these being

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dealt with by issuing errata. However, if a C publication is being issued for other reasons, any such errors are corrected at the same time.

[A request received after grant is handled by RAPS who arrange for the preliminary notice of the request to appear in the Journal (see 117.23). If it relates to an error in a specification it should be referred to the Deputy Director of the group dealing with the relevant subject matter, who may refer it to a member of his group. Any objections to the proposed correction should be set out in terms suitable for embodiment in an official letter which is issued by RAPS. (See also 117.07).

[When the examiner is satisfied that the correction is allowable he should so report and send a PDAX message to RAPS. The Deputy Director should instruct RAPS as to whether or not the correction should be advertised. If the correction is not being advertised, or if the period allowed for opposing the correction (see 117.25) has expired, or if any opposition has been concluded, RAPS should assemble the specification. The corrections should be checked in the examining group before the Deputy Director confirms the certificate should be applied. The case should then be returned to RAPS who should notify the person making the request that it has been allowed, date the certificate with the date of such notification, arrange for the outcome of the s.117 proceedings to be entered in the register and advertised in the Journal, create a minute and send a PDAX message to Publishing Section for issue of a C publication (and also an erratum as in 117.06 if the correction is applicable to the A publication as well as to the B publication).]

117.15 If a request to correct is received after the issue of the letter informing the applicant that a patent has been granted but before the date of publication of the patent, the applicant should be informed that consideration of the request is deferred until after publication. Following publication of the patent, the post-grant procedure as set out in 117.14 should then be followed.

117.16 If proceedings to correct a patent are initiated or are outstanding whilst an action for revocation of the patent is pending the comptroller may decide whether the s.117 proceedings are to be stayed or resolved.

CORRECTION OF THE REQUEST FOR GRANT

117.17 If the applicant's address or address for service was given incorrectly on Form 1 then it may be corrected by means of any suitable written notification. However, a request under r.49(1)(a) to correct a name must be made on Patents Form 20. If, however, the name was correct at the time of filing and has changed subsequently then alteration of the form to reflect this must be effected either as an amendment under s.19 (if more than just the name requires amendment) or a correction to the register under s.32(2)(d) (if only the name has changed), see 19.05-19.07 and 32.06. If there are reasonable doubts about whether the correction should be made, the comptroller should inform the person making the request of the reason for his doubts and ask that person to file evidence in support of the request, i.e. proof that the name was entered incorrectly and that the name that is to replace it is the name that the applicant always intended entering on the form. If a request to correct an error or mistake in a name is allowed the change is effected in the same way as in the case of an amendment (see 19.07).

[The procedure is the same as that described for amendments in paragraphs 19.06-19.07.]

- 117.18 A request to correct the title of the invention should be considered in the same way as a proposed correction of the specification (see 117.07-117.09).
- 117.19 A declaration of priority at part 5 of Form 1 (or a claim in part 6 of that Form, or a declaration in part 6 of Form 3) may be corrected provided the Office is satisfied that the discrepancy was due to an error in translation or transcription or a clerical error or mistake.

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r.49

r.86

r.87

If the error lies in the details of the priority document or earlier application or patent then this document itself may be sufficient evidence. Otherwise, where there is reasonable doubt that the alleged mistake is in fact a mistake (or where there is reasonable doubt as to the veracity of any matter contained in the request or of any document filed in connection with it) evidence may be requested which demonstrates that what is now proposed was the applicant's intention at the time of filing. It is, however, a condition of Rule 5 of the Patent Law Treaty that when such evidence is requested, the nature of the doubt must be communicated to the applicant, and this practice should always be observed. A copy of the applicant's instructions to his agent may suffice; otherwise sworn evidence should be asked for before the request is given further consideration, and a period of two months should be specified for reply. Any priority document or translation in support of a new declaration must be filed within the period prescribed. In Payne's Application [1985] RPC 193 the applicant sought to delete the two earliest claims to priority by way of correction but, before the matter was decided, the applicant was informed by the Office that the application had been treated as withdrawn through failure to file the request for search. The applicant subsequently argued that the correction should be allowed (in which case the search request could have been filed in time) notwithstanding that the application had ceased to exist. It was held in the Patents Court that section 117 could not be invoked to overcome this mandatory requirement, see 15.56.

[A request to correct the declaration of priority should be referred by the Formalities Examiner via the Formalities Manager to the divisional Head of Administration, who will, if the request is allowable, correct Form 1.

<u>PDAX dossiers:</u> Form 1 should be corrected using the Enhance function in PDAX, and an action added to the dossier. The Head of Administration should add a minute to the dossier and ensure the appropriate COPS action is carried out.

<u>Paper cases</u>: Form 1 should be corrected in red ink, initialled and dated, and the appropriate COPS action carried out. The Formalities Manager should then correct the priority details on the front of the shell.

The applicant should be informed of the allowance of the request. If the request has been received before the completion of preparations for publication, a minute and the appropriate PDAX message should be sent via the Examination Support Officer outlining the publication instructions. If the application is a paper case, an appropriately-completed "Notices for front page of 'A' document" form (see 117.06) should be placed on file. If the request was received later than this, arrangements should be made for an erratum to issue in respect of the A document (and B document if appropriate).]

- r.6(2)

 117.20 Where the only matter to be corrected is the priority document file number quoted on Form 1 or Form 3, then no evidence is required provided the error is notified to the Office within the period which is allowed for supplying this number. (For the case where the details on Form 1 are correct but there is a discrepancy in the priority document, see paragraph 15A.16).
- r.3 117.21 Since correction is deemed to have effect ex tunc, a correction of the declarations of priority may affect the declared priority date even if the change was effected after the completion of preparations for publication.

OTHER CORRECTIONS

r.49
117.22 An error in Form 7 may be corrected after the end of the period allowed for filing this form following a request in writing, except for correction of a name which must be made on Patents Form 20. (For effecting a change in Form 7 before the end of this period, see 13.14). If there are reasonable doubts about whether the correction should be made, the comptroller should inform the person making the request of the reason for his doubts and ask that person to file evidence in support of the request. A copy of the corrected Form 7 should be sent to each inventor. The decision in *Payne's Application* (see 117.19) means

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that s.117 cannot be invoked to overcome the mandatory requirements of s.13(2) (see 13.14).

[A request to correct the inventor details on Form 7 should be referred by the formalities examiner via the Formalities Manager to the Assistant Head of Administration, who will, if the request is allowable correct the details on Form 7 using the "Enhance" function on PDAX, add a minute to the dossier and annotate Form 7. If the application is a paper case, the Assistant Head of Administration should, if the request is allowable, correct Form 7 in red ink, initial and date the correction and carry out the appropriate COPS action. Where an inventor has been added or deleted after the completion of preparations for publication, the formalities examiner should send a message to Publishing Section for issue of an erratum.]

s.14(10)117.22.1 An error or mistake in a withdrawal of an application may be corrected upon request in writing. A written explanation or evidence will be needed in support of the request.

ADVERTISING A CORRECTION

r.75 117.23 Notice of a request for correction of an error or mistake in the withdrawal of a published patent application will be published by advertisement in the Journal - see 117.31. r.105(5) In all other circumstances, except where the comptroller determines that no person could reasonably object to the correction, the fact of a request for correction and the nature of the proposed correction are advertised in the Journal. Preliminary notice of a request made post-grant is inserted in the Journal, and the proposed correction should be advertised if it would alter the meaning or extend the scope of the specification of a granted patent, or if the rights of a third party could be adversely affected. Other corrections sought before grant are not normally advertised.

> For procedure post-grant see under 117.14. Corrections pre-grant are not normally advertised and the procedures described under 117.13 or 117.13.1 should be followed.]

117.24 When it appears to the Office that a correction may be allowed the applicant should be so informed and if appropriate the correction should be advertised. If the period allowed for opposing the correction (see 117.25) has expired without any opposition being filed the correction should then be effected as soon as possible. This must be by order for certain corrections of withdrawals - see 117.31. On the other hand, if agreement is not reached with the applicant, a hearing should be offered. If the applicant requests to be heard he should be informed that an ex parte hearing will be appointed subject to advertisement of the proposed correction and the absence of opposition.

[For procedure see under 117.14.]

Section 117(2)

Where the comptroller is requested to correct such an error or mistake, any person may in accordance with rules give the comptroller notice of opposition to the request and the comptroller shall determine the matter.

117.25 Any person may oppose a correction; there is no need for an opponent to show a locus standi. Notice of opposition should be given on Form 15, which should be filed within four weeks of the date of advertisement of the correction in the Journal; this period may not be extended. The Form should be accompanied by a copy thereof and by a statement of grounds (in duplicate). This starts proceedings before the comptroller, the procedure for which is discussed at 123.05 - 123.05.13.

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r.75

r.75

r.76(3) r.108(1) 117.26 [deleted]

- s.74(2) 117.27 The notice of opposition and supporting statement must be directed solely to the allowability of the correction. In particular, the validity of the patent may not be put at issue.
- r.82 117.28 The comptroller may give such directions as he thinks fit with regard to the subsequent procedure. If a form of correction acceptable to the parties and the Office is not arrived at, the matter will need to be decided at a hearing.

117.29 Where an opposition to the correction has been properly launched by the filing of Form 15 accompanied by a supporting statement, but the opponent subsequently withdraws at any stage, the comptroller nevertheless takes account of matters raised by the opponent in deciding whether the correction is allowable. If no agreement is reached with the applicant, an ex parte hearing is held.

[The procedure is the same as that described in 27.31.]

Section 117(3)

Where the comptroller is requested to correct an error or mistake in a withdrawal of an application for a patent, and-

- (a) the application is published under section 16 above; and
- (b) details of the withdrawal were published by the comptroller;

the comptroller shall publish notice of such a request in the prescribed manner.

Section 117(4)

Where the comptroller publishes a notice under subsection (3) above, the comptroller may only correct an error or mistake under subsection (1) by order.

117.30 Subsections (3) and (4) were added by Article 17 of the Regulatory Reform (Patents) Order 2004. These provisions relate to the power of the comptroller, alluded to in section 14(10), to correct an error or mistake in a withdrawal of a patent application (see 14.209). This is effective from 1 January 2005 and applies to applications irrespective of whether their filing date is before or after that date.

r.105(6)

117.31 These provisions ensure that in the case of a published application whose withdrawal was published in the Journal, the request for correction of that withdrawal will likewise be published. This will be done by advertisement in the Journal and an entry in the register. The advertisement concludes the period referred to in s.117A(4), see 117A.02. If the correction is made it must then be effected by order.

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Section 117A: Effect of resuscitating a withdrawn application under section 117

117A.01 Sections 117A(1) to (6) were added by Article 18 of the Regulatory Reform (Patents) Order 2004, while subsection 117A(7) was added by the Patents Act 2004, all with effect from 1 January 2005. This section provides protection to those persons affected by resuscitation of a published withdrawn application under section 117, similar to the protection provided by section 28A in the case of a restoration of a lapsed patent under section 28.

Section 117A(1)

Where -

- (a) the comptroller is requested to correct an error or mistake in a withdrawal of an application for a patent, and
- (b) an application has been resuscitated in accordance with that request,

the effect of that resuscitation is as follows.

Section 117A(2)

Anything done under or in relation to the application during the period between the application being withdrawn and its resuscitation shall be treated as valid.

Section 117A(3)

If the comptroller has published notice of the request as mentioned in section 117(3) above, anything done during that period which would have constituted an infringement of the rights conferred by publication of the application if the application had not been withdrawn shall be treated as an infringement of those rights if it was a continuation or repetition of an earlier act infringing those rights.

Section 117A(4)

If the comptroller has published notice of the request as mentioned in section 117(3) above and, after the withdrawal of the application and before publication of the notice, a person -

- (a) began in good faith to do an act which would have constituted an infringement of the rights conferred by publication of the application if the termination had not taken place, or
- (b) made in good faith effective and serious preparation to do such an act,

he has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the resuscitation of the application and the grant of the patent; but this right does not extend to granting a licence to another person to do the act.

Page 1 of 2 April 2007

Section 117A(5)

If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (4) above may-

- (a) authorise the doing of that act by any partners of his for the time being in that business, and
- (b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.

Section 117A(6)

Where a product is disposed of to another in exercise of a right conferred by subsection (4) or (5) above, that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the applicant.

Section 117A(7)

The above provisions apply in relation to the use of a patented invention for the services of the Crown as they apply in relation to infringement of the rights conferred by publication of the application for a patent (or, as the case may be, infringement of the patent).

"Patented invention" has the same meaning as in section 55 above.

Subsections (4) to (6) give protection to persons who take steps to work an invention which is the subject of a withdrawn published patent application before notice is published of a request to correct an error or mistake in the withdrawal (see 117.31). They are free not only to continue what they have started without infringing the rights conferred by the resuscitated application and the granted patent, but also to pass their right to work the invention to others (but not to license others to work the invention). Subsection (7) ensures that the Crown is not liable for payment of compensation to the patent proprietor for Crown use if it takes steps to work an invention which is the subject of a withdrawn patent application before notice of a request to resuscitate the application is published.

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Section 117B: Extension of time limits specified by comptroller

117B.01 This section was added by Article 18 of the Regulatory Reform (Patents) Order 2005. It is effective from 1 January 2005 and applies to applications and patents of any date. It implements the requirements of Article 11 of the Patent Law Treaty.

Section 117B(1)

Subsection (2) below applies in relation to a period if it is specified by the comptroller in connection with an application for patent, or a patent.

Section 117B(2)

Subject to subsections (4) and (5) below, the comptroller shall extend a period to which this subsection applies if -

- (a) the applicant or the proprietor of the patent requests him to do so; and
- (b) the request complies with the relevant requirements of rules.

r.109(1) 117B.02 The applicant (or proprietor of the patent, as the case may be) is entitled on request to a single extension of a period that is specified by the comptroller in connection with the application or patent, provided that the requirements of r.109(1) are satisfied, viz that the request is made in writing (e.g. by letter, fax or email) and is made before the end of the extended period. Directions have been made under section 124A for making a request to extend a specified time limit by electronic means and are reprinted in the "Official Notices and Directions" section of the Manual. An email request to request an extension of a specified time limit should be sent to patent@ipo.gov.uk and should identify the patent application or patent to which the request relates, and the specified period for which an extension is requested.

Section 117B(3)

An extension of a period under subsection (2) above expires -

- (a) at the end of the period prescribed for the purposes of this subsection, or
- (b) if sooner, at the end of the period prescribed for the purposes of section 20 above.
- r.109(2) 117B.03 The s.117B(2) extension is two months, unless the end of the section 20 period ("compliance period") intervenes.

Section 117B(4)

If a period has already been extended under subsection (2) above-

- (a) that subsection does not apply in relation to it again;
- (b) the comptroller may further extend the period subject to such conditions as

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he thinks fit.

117B.04 A period may be extended only once under s.117B(2); further extensions are at the comptroller's discretion and may be subject to conditions. Any request for a further extension should include a statement of reasons for the request.

Section 117B(5)

Subsection (2) above does not apply to a period specified in relation to proceedings before the comptroller.

117B.05 Periods that are specified in relation to proceedings before the comptroller, for example if a hearing officer specifies a period for producing a particular document, cannot be extended under section 117B(2).

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Section 118: Information about patent applications and patents, and inspection of documents

This section concerns the availability to the public of information and documents relating to patents and applications for patents under the Act, including the effects of publication of an application under s.16 on such availability. It applies to international applications which have been published under the PCT and entered the UK national phase (and are therefore treated as published under s.16). Relevant procedures are prescribed by rules 51 to 55.

Section 118(1)

After publication of an application for a patent in accordance with section 16 above the comptroller shall on a request being made to him in the prescribed manner and on payment of the prescribed fee (if any) give the person making the request such information, and permit him to inspect such documents, relating to the application or to any patent granted in pursuance of the application as may be specified in the request, subject, however, to any prescribed restrictions.

Information

- r.54 118.02 A person may request to be notified of each of the following events:-
- r.54(5) in relation to an application for a patent,
 - (a) an applicant requesting, or failing to request, a substantive examination before the end of the period prescribed for the purposes of section 18(1);
 - (b) the application being published;
 - (c) the notice of grant of the patent being published under section 24;
 - (d) the application being terminated or withdrawn;
- r.54(6) in relation to a patent,
 - (a) a request for an opinion under section 74A;
 - (b) the patent ceasing to have effect by reason of section 25(3);
 - (c) the renewal fee and any additional fee being paid during the period specified in section 25(4);
 - (d) an application being made for the restoration of the patent which has ceased to have effect;
- r.54(7) in relation to a patent or application for a patent,
 - (a) an entry being made in the register;
 - (b) a document becoming available for inspection under section 118 (by reason of a prescribed restriction no longer applying to the document);
 - (c) an application to register a transaction, instrument or event being made

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under rule 47;

(d) a matter being published in the journal.

118.03 [deleted]

r.54(1) r.54(4) 118.04 Requests for any of the information listed in 118.02 are often known as caveats. Any such request should be made on Patents Form 49 accompanied by the appropriate fee. A separate form and fee are required in respect of each item of information requested.

[Such caveats are dealt with by the appropriate formalities group – for further details see paragraphs 11.56 to 11.58 of the Patents Formalities Manual at http://www.ipo.gov.uk/formalities-chapter11.pdf.

[When a Form 49 is received, it should be checked that the correct fee has been paid. If an underpayment has occurred, the appropriate note should be sent to the applicant advising him that the Form is underpaid. When it is found that three months or more have elapsed since the issue of the note, the applicant should be sent a reminder letter advising him that unless the outstanding balance is paid within one month the request under r.54 will be considered as abandoned.

[For all Forms 49 on which the correct fee has been paid, whether initially or subsequently, details from the Form should be entered into the Caveat Record Book which provides a source of statistical information.

[If more than one of the items listed under r.54 is mentioned on the Form 49 or it is not clear what information is required, confirmation should be sought by telephone and the result registered on the Form together with the name of the person consulted.

[The information given on Form 49 should be cross-checked with details shown on the Register or held by the appropriate formalities group.

[Forms 49 on which the correct fee has been paid should be kept as confidential documents with the cashiers until the caveat action has been completed.]

118.05 If an application has been published under s.16, the Office is obliged to give any properly-requested information listed in 118.02 relating to that application or any patent granted thereon; if it has not been so published, the provisions of s.118(2) to (5) determine the response to a request (see 118.16-23). Information relating to a published application or resultant patent is in many cases not immediately available because the event (eg filing of Patents Form 10) to which the request relates has not yet occurred; in such cases the request is retained until the event occurs and the information is then given.

[When the requested information can be provided, it should be sent to the applicant with the standard letter. If the request relates to a paper case then Form 49 should be removed from the File and, with the duplicate of the letter stapled thereto, placed in numerical order on the Dead File for the year. Dead Files should be destroyed after five years. If the application is a PDAX dossier a copy of the form will be archived.]

Inspection of documents

r.51

118.06 Subject to certain restrictions (see 118.07), after the date of publication of an application under s.16, all documents filed at or kept in the Office in relation to the application or any patent granted thereon can be inspected at the Office on request and payment of the prescribed fee. Documents filed at or kept in the Office in relation to

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European patents (UK) are similarly open to inspection. In addition, certain documents are available free of charge on the Office website through Ipsum, the Office's online patent information and document inspection service. (With regard to applications containing computer programs or biological sequence listings, see 16.27). It should be noted that documents filed at or kept in the Office in relation to applications and patents are generally not kept indefinitely. Files of applications under the Patents Act 1977, either published or unpublished, which have been irrevocably abandoned, withdrawn, deemed to be withdrawn, refused, voided or otherwise terminated before grant are kept for at least seven years from termination. Files of patents (including European patents with UK designation) which have irrevocably ceased to be effective (due, e.g. to expiry of term, revocation, surrender, failure to renew) are kept for at least seven years from the date on which the patent ceased.

- r.51(2), (4) 118.07 No document (or part of a document) may be inspected—
 - (a) where that document was prepared by the comptroller, an examiner or the Office for internal use only;
 - (b) where the circumstances specified in section 118(4) exist, before the end of the period of 14 days beginning immediately after the date of the notification under rule 52(2);
 - (c) where that document is a request or application made under section 118 or rule 46(2), 48(2) or 54(1); or
 - (d) where that document includes matter—
 - (i) which in the comptroller's opinion disparages any person in a way likely to damage him, or
 - (ii) the inspection of which would in his opinion be generally expected to encourage offensive, immoral or anti-social behaviour.

The power mentioned in (d) (i) and (ii) above extends to all documents on file for the patent or application for a patent. Section 16(2) provides this power in respect of the published application. The procedure in 16.34-37 should be applied *mutatis mutandis*.

[Where an examiner identifies matter as detailed in (d)(i) or (ii) above after publication they should immediately annotate the document NOPIE and 'save' the dossier. This will ensure that the document is not available on Ipsum while the procedure detailed in 16.34 is carried out.]

- r.51(3), (4) Furthermore, no document (or part of a document) may be inspected if it falls into the PCT a.38(1) following categories, unless in a particular case the comptroller otherwise directs -
 - (a) where that document was filed at the Office in connection with an application under section 40(1) or (2) or 41 (8);
 - (b) where that document is treated as a confidential document under rule 53;
 - (c) where—
 - (i) that document was prepared by the comptroller, an examiner or the Office other than for internal use, and
 - (ii) it contains information which the comptroller considers should remain confidential;
 - (d) where that document relates to an international application for a patent and

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the International Bureau would not be permitted to allow access to that document under the Patent Co-operation Treaty; or

(e) where—

- (i) the comptroller has accepted a person's application under rule 11(1)(a) or (b), and
- (ii) that person's name and address can be identified from that document as those of the inventor or of the person believed to be the inventor (or, as the case may be, his address can be so identified).

Documents open to inspection through Ipsum may be redacted so that certain personal or sensitive information cannot be viewed on-line (see 16.29), albeit that they will still be open for inspection in person, by post or email. This is in addition to any redaction of documents for the reasons given above. An applicant or third party may request that a document or entire file relating to an application or patent which is open to inspection via Ipsum be removed from the system because of the personal or sensitive information contained within it. If this is requested, the document or file will be taken off Ipsum as soon as possible, and the Office will then consider the request and decide what action should be taken in respect of online availability of the document or file.

[To remove an entire file from Ipsum, raise a call with the IT Helpdesk. To remove an individual document from Ipsum, annotate it as "NOPIE" and then 'save' the dossier. In both cases, a minute should be added to the file explaining when and why the document or dossier was taken down and any issues that should be considered before it is returned to Ipsum. When any document or file is removed from Ipsum using these procedures the details should be recorded in the NOPIE spreadsheet. This will permit the reinstatement of the NOPIE marking in the event of a failure of PDAX and also allows the reasons for making material NOPIE to be monitored and reviewed.].

118.07.1 Inspection of the file relating to s.12 proceedings on a PCT application, which had not entered the UK national phase under s.89 but had entered the regional phase as a Euro-PCT application designating UK, was allowed by analogy with the provisions both of the EPC permitting public inspection of the file of the published application, and of s.118 permitting public inspection of any file relating to a patent application under the Act.

Inspection of documents filed before 1 June 1978 is permitted under s.118 at the Comptroller's discretion. The exercise of this discretion beyond what would have occurred under the 1949 Act should occur only under exceptional circumstances, having considered the rights and expectations of the patentee as well as the desires of the individual making the request for inspection. For example, reports from the examiner and the specification as filed were not open to public inspection under the 1949 Act. It should be noted that where a copy of a specification as filed has been used to support a claim for priority for a subsequent application, and the subsequent application was published, this specification as filed would have been published as part of the later application. Documents filed after 1 June 1978 for applications under the 1949 Act are available for inspection under s.118 by virtue of paragraphs 1 and 2(g) of Schedule 2 (see 127.06-07).

[Advice should be sought from PD/CL before allowing inspection of documents filed before 1 June 1978 over and above what was allowed under the 1949 Act following the procedures set out in Chapter 79 of the 1975 edition of the Manual of Office Practice. Where such a question arises, PD/CL should also liaise with Security Section if the application was at any time subjected to security restrictions].

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Copies of documents and of entries in Register

r.46(1)-(2) r.48(1)-(4) r.44(1) Copies of or extracts from the Register (including entries relating to European patents (UK) and applications therefor) or any document referred to in rule 48(4) are supplied upon request made on Patents Form 23. An entry in the Register in respect of a particular application is not made until the application has been published under s.16 (or under EPC Article 93 in the case of an application for a European patent (UK)). Section 32(11)(b) refers to any document kept in the Office or an extract therefrom, any specification of a patent or any application for a patent which has been published. However, a person is not supplied with a copy of a document not open to public inspection unless he is entitled to a copy, eg in the case of an unpublished application he is the applicant or his agent. Furthermore, a person is not supplied with a copy of a document where making or providing such a copy would infringe copyright. Where a copy cannot be supplied, the person is so informed, normally by telephone. For certified copies, see 32.19-20. The restrictions in 118.07 also apply to the supply of copies or extracts, whether certified or not.

118.09 A single Form 23 may be used to request uncertified copies relating to more than one patent or patent application. On the other hand, when requesting certified copies, a separate Form 23 should be used for each patent or patent application. Certified and uncertified copies should not be requested on the same Form 23.

118.09.1 An electronic uncertified copy of documents from a published UK patent or patent application can be requested using the online Form 23 service available via http://www.ipo.gov.uk/p-apply-online-uk-uncertified-checklist.htm. However, it is not possible to use the online service to request a paper uncertified copy, and it is not possible to request an electronic uncertified copy by filing a paper Form 23.

118.09.2 Electronic uncertified copies of certain documents are available free of charge on the Office website through lpsum.

Confidential documents

r.53 r.108(1) The comptroller has discretion to direct that a document (or part of a document) filed at the Office or sent to an examiner or the comptroller be treated as a confidential document, when so requested by any person. However the comptroller must refuse any such requests in relation to a Patents Form or a document filed in connection with a request for an opinion under section 74A. Documents filed on or after 1 April 2007 will be open to public inspection upon filing, and a request for confidentiality can be made at the time of filing or within fourteen days of the filing or sending of the document (extensible at the discretion of the comptroller) and reasons must be given. If only part of a document contains confidential matter, for example financial figures, then confidentiality will not be accorded to the whole document. The person seeking confidentiality may be asked to identify the confidential matter in a document. The document, with the confidential matter removed, will be open to public inspection.

118.11 [deleted]

r.53(4)

If a request for confidentiality is made, the document in question is not open to public inspection while the matter is being determined.

[While the matter is being determined and if s.16 publication has occurred, the document should be imported into the dossier and appropriately annotated and given the document code CONFIDENTIAL. If the request relates to a paper case, the document should be kept in an envelope of A4 size, prominently marked NOT

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OPEN TO PUBLIC INSPECTION and placed adjacent to the proceedings sheets. The appropriate formalities group normally attends to this when the document is filed: if however a case examiner should receive a file where this has not been done he should do it himself. Further details are given in paragraphs 12.39-12.50 of the Formalities Manual.]

- 118.13 Since the public are generally entitled to inspect documents relating to a patent or, after publication of an application, to the application, a request for confidentiality should not be granted unless it is considered justified for the reasons given. It is a matter of judging whether a party's reasons for desiring confidentiality outweigh the generally overriding public interest for disclosure in each case. Observations by an applicant in rebuttal to an official objection, for example one of lack of novelty or inventive step, communications concerning disclosure of matter obtained unlawfully or in breach of confidence (see 2.39), and observations which are to be taken into consideration under s.21 (see 21.05) should not be treated as confidential. Subject to the above comments correspondence which relates to procedural matters, for example to reasons in support of a request for exercise of the Comptroller's discretion, may be treated as confidential. It is likely to be appropriate for information concerning individuals' health or personal circumstances to be treated as confidential. In inter partes proceedings, evidence filed by one party, for example details of licence agreements, may be treated as confidential if its disclosure risks being harmful (eg commercially) to the party or the party's associates to an extent which overrides the requirement for public access. Regard should be had in particular to the interests of a third party who has not consented to a private agreement being open to public inspection. Following the judgment of the Patents Court in Diamond Shamrock Technologies S.A.'s Patent [1987] RPC 91 the criteria to be applied in considering requests for confidentiality were summarised as follows:-
 - (a) The fact that a document is said to contain "sensitive commercial information" does not necessarily mean that this material, which would otherwise become public property, is to be excluded from public inspection; apart from generalities there must be some real indication as to why disclosure would be harmful.
 - (b) Those requesting confidentiality should put in evidence, although this is not necessarily required before the comptroller.
 - (c) Material which is going to form no part of the decision can remain confidential.
 - (d) Material supplied by a third party on the basis of confidence, which involves minimal excisions from a decision, should be maintained as confidential unless there is some overwhelming public interest, which makes it desirable that the public should have sight of it.
 - (e) The appropriate procedure is for the matter to be dealt with prior to a substantive hearing so that if ruled against, the person proffering the document can make up his mind whether he will go forward publicly, or have the material withdrawn.

In *Diamond Shamrock Technologies S.A.'s Patent*, the Court allowed confidentiality in the cases of one category of material (relating to royalties agreed with licensees other than I.C.I.) none of which formed any part of the hearing officer's decision and the disclosure of which had no relevance to anything the public might have an interest in; and another category of material (relating to information touching royalties and prices supplied to the patentees by an associate company on a confidential basis) where disclosure would quite plainly be against the wishes of a third party. Confidentiality was refused for a further category of material (relating to royalties agreed in connection with a previous licence to I.C.I. by the patentees) where I.C.I. did not object to disclosure and, apart from generalities, no real indication had been given as to why disclosure would be harmful to the patentees. In *Neo-Inhalation Products* Limited's *Application* (BLO/154/13) the hearing officer refused a

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request for confidentiality in respect of a document filed as evidence to rebut an inventive step objection. The request was made on the grounds that the document contained valuable and commercially sensitive information, though no argument was advanced as to why putting the document in the public domain would be harmful to the applicant.

However, evidence treated as confidential must of course be accessible to at least the advisers of the other party or parties. As decided by Upjohn L J in Re K (Infants) [1963] Ch 381 and followed in VNU Business Publications BV v Ziff Davis (UK) Limited [1992] RPC 269, any party to the proceedings has a right to see all the evidence before the comptroller on which the other party relies. In suitable cases access to confidential evidence may be restricted to a party's legal representative and not given to of the party himself. In re Schering A G's Patent [1986] RPC 30 it was decided by the hearing officer (and upheld by the Patents Court) that certain documents filed by applicants for a licence would be kept confidential from both the public and the patentees but that the agent who was acting for the patentees and was an employee of a subsidiary of the patentees would have access to the documents subject to undertakings as to the confidentiality of the documents to be given by the agent, his employers and the patentees. Since patent agents, solicitors etc are subject to a professional code of conduct, undertakings are not normally required to be given by an independent agent or solicitor. In Coal Industry's Patent (BL O/11/90), the hearing officer refused to order confidentiality in respect of evidence which had already been filed in High Court proceedings in which there was no suggestion that it was to be treated as confidential.

[Requests under rule 53(1) are handled by the relevant formalities group or Tribunal Section, as appropriate, if the documents relate to formal matters. If however the document relates to substantive matters, the request is considered by the group Deputy Director (as in the case of observations filed in response to a report under s.18(3)) or by the hearing officer. The Deputy Director should freely consult his Divisional Director for guidance if necessary.

118.14 When a direction is given to treat a document, or part of a document, as confidential, the decision should be recorded on the file to which the document relates. Furthermore, the person who made the request for confidentiality should be notified that their request has been allowed.

[When a Deputy Director or other officer decides to allow a request for confidential treatment he should enter the reasons for his decision as a minute, identifying the document(s) and directing that it is (or they are) to be treated as confidential under rule 53(1) of the Patents Rules 2007. When signing, he should indicate that he is acting for the comptroller. The file should then be referred to the divisional Head of Administration or to the Head of Tribunal Section, as appropriate. If the request relates to a paper case, they will arrange for the document(s) to be stamped appropriately and placed on the appropriate part of the file (details are given in Chapter 12 of the Patents Formalities Manual). They will also arrange for a letter to be sent to the person who made the request, notifying them that their request has been allowed. In the very rare case where confidential treatment is to be accorded for a limited period only, the instructions in the minute should make this clear, so that the formalities group or Tribunal Section can arrange for the file to be reviewed at the appropriate time. See also paragraphs 12.39-12.50 of the Formalities Manual.]

118.15 Where the comptroller believes there is no longer a good reason for the document to be treated as a confidential document, he should revoke the direction. However, before revoking a direction under r.53(5) or allowing any person to inspect a document to which such a direction applies, the comptroller should consult with the person at whose request the direction was given, unless the comptroller is satisfied that such prior consultation is not reasonably practicable. When a direction is withdrawn, a record of that fact is filed with the relevant document.

r.53(6)

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Section 118(2)

Subject to the following provisions of this section, until an application for a patent is so published documents or information constituting or relating to the application shall not, without the consent of the applicant, be published or communicated to any person by the comptroller.

UNPUBLISHED APPLICATIONS

118.16 Thus documents and information constituting or relating to a particular application cannot be published or communicated, without the consent of the applicant, unless the application has been published under s.16 (except as provided for in s.118(3) to (5), see 118.17-23). Prior to s.16 publication, a person making a request on Patents Form 23 or wanting to inspect a file which thus cannot be met is so informed (see also 118.08): but any requests for information on Patents Form 49 which cannot be met are merely retained and attended to after publication (see 118.02-05). Furthermore, if an examiner is aware of any unpublished applications, even if by the same applicant, which if published would be relevant to the application in suit, they should not be mentioned in a search or examination report or any other communication relating to the application in suit until after they have been published since the report or communication might become open to public inspection prior to publication of the other application and thereby provide an indication of the contents of the unpublished application. A limited exception to this is in the case of divisional applications, where it is already known that the later application is divided from an earlier one. Here it may be appropriate to make an objection under section 18(5) before an application is published. Even in that case detailed information concerning the unpublished application should not be included in a report on the other application.

118.16.1 All examiners, formalities staff and other Office staff dealing with unpublished patent applications should be aware of the need to maintain the security and confidentiality of material and information relating to such cases. For example, if a telephone call is made or received concerning an unpublished application, reasonable steps should be taken to verify that the person being spoken to is in fact the applicant or their designated representative. Documents (whether paper or electronic) should be given the appropriate level of protection. Particular care should be taken with email, as this is not a secure means of communication, and is moreover prone to misdirection. Documents (such as search reports) or information (beyond that set out in 118.18) relating to unpublished applications should not under normal circumstances be sent by email. If, exceptionally, email is to be used for this purpose, this should only be done if the circumstances warrant it, and with the informed consent of the applicant or agent. In such circumstances great care should be taken to ensure that the email is correctly addressed.

[Where the applicant or agent has provided his informed consent to the sending by email of documents or information (other than that set out in 118.18) concerning an unpublished application, a record of that informed consent must be placed on the PDAX dossier together with the emailed correspondence and any attached documents.]

Section 118(3)

Subsection (2) above shall not prevent the comptroller from -

- (a) sending the European Patent Office information which it is his duty to send that office in accordance with any provision of the European Patent Convention;
- (aa) sending any patent office outside the United Kingdom such information about

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unpublished applications for patents as that office requests; or

(b) publishing or communicating to others any prescribed bibliographic information about an unpublished application for a patent;

nor shall that subsection prevent the Secretary of State from inspecting or authorising the inspection of an application for a patent or any connected documents under section 22(6) above.

Section 118(3A)

Information may not be sent to a patent office in reliance on subsection (3)(aa) otherwise than in accordance with the working arrangements that the comptroller has made for that purpose with that office.

Section 118(3B)

Those arrangements must include provision for ensuring that the confidentiality of information of the kind referred to in subsection (3)(aa) sent by the comptroller to the patent office in question is protected.

Section 118(3C)

The reference in subsection (3)(aa) to a patent office is to an organisation which carries out, in relation to patents, functions of the kind carried out at the Patent Office.

- 118.17 The prohibition in s.118(2) does not apply to the transmission of information to the EPO as required by the EPC. The UK Office, as the central industrial property office of a contracting State, is obliged by EPC Article 130 to communicate to the EPO, on request, information regarding the filing of national or European patent applications and proceedings concerning such applications and the resulting patents. Under this obligation, the Office now provides the EPO with citation data on live (i.e. not withdrawn) unpublished applications searched in the UK Office. This data is provided for the EPO's utilisation scheme, the purpose of which is to provide the EPO with the results of searches performed on priority applications from national offices.
- 118.17.1 Sections 118(3)(aa), 118(3A), 118(3B) and 118(3C) were inserted on 1 October 2014 by the Intellectual Property Act 2014. These provisions mean that the prohibition in s.118(2) does not apply to the sending of pre-publication information to other patent offices, as long as it is done in accordance with a working agreement between the Office and that other office.
- 118.17.2 Under section 118(3B), the working agreement required by section 118(3A) must ensure that any pre-publication information shared is treated confidentially by the other office whilst that information remains confidential in the UK.
- 118.17.3 In practice, any working agreements put in place will restrict the sharing of pre-publication information to those circumstances where doing so is likely to lead to a reduction in duplication of work. Information relating to a UK patent application will therefore not be shared until a search has been conducted by the IPO in relation to that patent application. The agreements may also limit pre-publication worksharing to situations where that other office is dealing with an application which claims priority from the unpublished UK patent application. Only information likely to reduce duplication will fall

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within the scope of the worksharing arrangements, such as:

- UK search and examination reports
- examination opinions issued during the search/examination process
- patent claims (so that the other office has the context of the search/examination)
- classification data.
- 118.17.4 The IPO will not enter into a worksharing agreement if sharing such information would not conform with the UK's robust requirements for sending data abroad, as set out in the Data Protection Act 1998.
- 118.17.5 Details of current and future worksharing arrangements may be found on the IPO's pages on www.gov.uk.
- r.55 The bibliographic information about an unpublished application which can be published or communicated is -
 - (a) the name of the applicant;
 - (b) the title of the invention;
 - (c) the number of the application;
 - (d) the date of filing of the application;
 - (e) where a priority declaration has been made for the purposes of s.5(2)—
 - (i) the date of filing of each earlier relevant application specified in the declaration,
 - (ii) its application number, and
 - (iii) the country it was filed in or in respect of;
 - (f) where an application has been terminated or withdrawn, that information; and
 - (g) where a transaction, instrument or event mentioned in section 32(2)(b) or 33(3) is notified to the comptroller, that information.

Items (a) to (e) in fact appear in the Journal for all applications about five weeks after the date of filing of each application.

s.22(5)(c) s.22(6)(a) s.22(6)(b) The Secretary of State is required to periodically review prohibition directions given under s.22 with respect to any application, see 22.12 to 22.15. For that purpose, where the application contains information relating to the production or use of atomic energy or research into matters connected with such production or use, the Secretary of State may at any time inspect and/or authorise the United Kingdom Atomic Energy Authority to inspect the application and any documents sent to the comptroller in connection with it. In other cases, the Secretary of State may inspect the application and any such documents at any time after (or, with the applicant's consent before) the end of the eighteen month period prescribed for s.16 publication (see 16.01). The prohibition in s.118(2) does not apply to such inspection or authorisation. The scope of this exclusion was extended to cover s.22(6)(b) as well as s.22(6)(a) by paragraph 28 of schedule 5 to the CDP Act.

Section 118(4)

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Where a person is notified that an application for a patent has been made, but not published in accordance with section 16 above, and that the applicant will, if the patent is granted, bring proceedings against that person in the event of his doing an act specified in the notification after the application is so published, that person may make a request under subsection (1) above, notwithstanding that the application has not been published, and that subsection shall apply accordingly.

The documents and information available under s.118(1) in respect of published applications are also available in respect of an unpublished application to a person in the circumstances set out in s.118(4), ie a potential infringer who has been warned (between filing and s.16 publication of the application) that proceedings may be brought after grant if he does a specified act after s.16 publication. Where s.118(4) bites, there is nothing in s.118(1) that permits the Comptroller to prescribe any additional restrictions unique to inspection under s.118(4). In *Buralls of Wisbech Ltd's Applications* [2004] RPC 14, the hearing officer refused a request from the patent applicant to impose confidentiality restrictions on the inspection of documents since these could not be prescribed under s.118(1).

r.52 r.51(2)(b) r.48(3)(b) 118.21 Where circumstances set out in s.118(4) exist, a request under s.118(1) should be accompanied by evidence verifying their existence. Tribunal Section sends a copy of the request and the accompanying evidence to the applicant for the patent and until the expiry of a fourteen day period thereafter the request is held in abeyance in accordance with rule 51(2)(b). In accordance with established practice, a person who is entitled to inspect a document is also entitled to be supplied with a copy of that document (subject to the payment of any fee for the copy and where making or providing such a copy does not infringe copyright).

118.22 When the circumstances specified in s.118(4) (or those specified in s.118(5), see 118.23) exist, and subject to rule 52 (see 118.21) and to the restrictions set out in 118.07, the documents relating to the unpublished application can be inspected upon request and payment of the prescribed fee.

Section 118(5)

Where an application for a patent is filed, but not published, and a new application is filed in respect of any part of the subject-matter of the earlier application (either in accordance with rules or in pursuance of an order under section 8 above) and is published, any person may make a request under subsection (1) above relating to the earlier application and on payment of the prescribed fee the comptroller shall give him such information and permit him to inspect such documents as could have been given or inspected if the earlier application had been published.

Where a new application is filed, notably under s.8(3) or 15(9), in respect of any part of an earlier, unpublished application as specified in s.118(5) and is published, the documents and information available under s.118(1) in respect of published applications may be obtained in respect of the unpublished application. With regard to requests for inspection of documents relating to the unpublished application, see 118.02 (but note that r.52 does not apply to the circumstances specified in s.118(5). Note also that the files of applications from which priority is claimed under s.5 are not open to inspection by virtue of s.118(5)).

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Section 118A: Copyright in documents made available electronically for inspection under section 118(1) [Repealed]

118A.01 Section 118A was introduced into the Patents Act 1977 on 1 October 2011. The section provided that copyright was not infringed if documents from the published patent file were made available under section 118(1) electronically so that the public can access them. Copyright was also not infringed by copying the documents in order to enable this electronic access.

118A.02 Section 118A was repealed by the <u>Copyright (Public Administration)</u> Regulations 2014 (SI 2014/1385) which came into force on 1st June 2014. These Regulations introduced into the Copyright, Designs and Patents Act 1988 new exceptions to copyright infringement, which apply to certain documents which are published online by the relevant public body, such as the Comptroller. The documents must be ones which are open to public inspection or on an official register and concern material communicated to the Crown in the course of public business. The new exceptions mean that section 118A became redundant.

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Section 119: Service by post

Section 119

Any notice required or authorised to be given by this Act or rules, and any application or other document so authorised or required to be made or filed, may be given, made or filed by post.

This section allows any notice or document required or authorised by the 1977 Act or rules thereunder to be served by post. It does not preclude other methods of service, eg by hand or by facsimile transmission (fax), see 14.02. The reference to "post" is construed widely to mean any item of mail delivered by any service in exchange for payment, and is thus not restricted to delivery services operated by the Post Office.

Service of a document by post is deemed to be effected by properly addressing, paying for and posting a letter containing the document.

119.03 Documents are accorded the date of receipt within the Office. This contrasts with practice under r.97 of the Patents Rules 1995, where a document sent by post was deemed to have been received at the Office on the day when it would have been delivered in the ordinary course of post. This deeming arrangement applied to any document posted prior to 17 December 2007.

119.04 [deleted]

119.05 [deleted]

119.06 [deleted]

s.120

119.07 Where a communication sent by post is received at the Office on an excluded day (see 120.05) it is treated as having been received on the next non-excluded day, any time limit expiring on the former day being extended to the latter. However, if its receipt on the excluded day was the result of postal delay, r.110 or r.111 may apply, see 119.08.

r.110 119.08 Under r.110 the comptroller is empowered to certify any day where there r.111 is a general interruption or subsequent dislocation in the UK postal services as an interrupted day; any time limits expiring on such an interrupted day are automatically extended to the next day which is not an interrupted day, see 123.43 to 123.45. Under r.111 the comptroller may extend any period of time specified in the Act or Rules, in a particular case of failure to meet that time period, where he is satisfied that the failure was wholly or mainly attributable to a failure or delay in a communication service, see 123.46-47.

[Where correspondence from the Office is reported as never having arrived at its intended destination, or is reported as being misdirected or delayed, this fact should be recorded by sending a minute to the relevant formalities group with any relevant details.]

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Section 120: Hours of business and excluded days

The section enables the comptroller to give directions regarding the hours of business and excluded days in relation to patents matters. This power was brought in by paragraph 24 of Schedule 2 to the Patents Act 2004, which amended s.120 and came into force on 22 September 2004 through the Patents Act 2004 (Commencement No. 1 and Consequential and Transitional Provisions) Order 2004 (SI 2004 No. 2177). The power to give directions replaced the provision which authorised rules prescribing the days and hours when the Office is closed for business. The latest directions to be made under this section and came into force on 15 July 2011. These are reproduced under the "Relevant Official Notices and Directions" section of this Manual. The official addresses of the Office for the purpose of the filing of documents etc are Concept House, Cardiff Road, Newport, South Wales, NP10 8QQ and 4 Abbey Orchard Street, London, SW1P 2HT. Documents may also be sent to the Office in Newport using the DX system. The Office has three DX numbers: 722540, 722541 and 722542. Documents sent using this system should be addressed in the form "DX 722540 Cleppa Park 3".

Section 120(1)

The comptroller may give directions specifying the hour at which the Patent Office shall be taken to be closed on any day for purposes of the transaction by the public of business under this Act or of any class of such business, and the directions may specify days as excluded days for any such purposes.

Hours of business

120.02 The Office is not taken to be closed at any time for the purposes of filing new applications in respect of which no priority declaration under s.5(2) is made. Applications which do not claim priority can be filed on all days and at all times using the postal services, the Office's e-filing services or hand delivery to the Newport or London office.

120.03 For the purposes of filing applications in respect of which a priority declaration under s.5(2) is made and for the purposes of filing other forms and documents, the Office is closed all day on Saturday and Sunday and public holidays.

On Monday to Friday (except public holidays), the Office closes at midnight for the filing of applications, forms and other documents (except for the filing of applications in respect of which no declaration for the purposes of s.5(2) is made) but at 5 pm for all other business. The Office opens to the public at 9 am but it is possible to hand in documents prior to that time. After 5 pm and before 9 am the following working day, the documents should be handed to the custodian. During the night, it may be necessary to use the telephone at the gatehouse in order to gain access to the Newport office.

120.04.1 Applications likely to be subject to directions under s.22 (see 22.07) may be filed in person at the Newport or London office, but only between the hours of 9am and 5pm. Such applications should be in envelopes marked "For the attention of GR70" and the receptionist should be informed that the application is for GR70.

All documents handed in outside the normal 9 am to 5 pm Monday to Friday periods should be in sealed packages. The packages are stamped with the date and time of receipt. During the 9 am to 5 pm periods, documents should be handed in at the appropriate counters.

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Excluded days

Good Friday, Christmas Day and any day specified as or proclaimed to be a bank holiday in England in or under section 1 of the Banking and Financial Dealings Act 1971 are excluded days for the purposes of all business, except for the filing of applications in respect of which no declaration for the purposes of s.5(2) is made. All Saturdays immediately preceded by one of the above and all Sundays are also excluded days for the purposes of all business, except for the filing of applications in respect of which no declaration for the purposes of s.5(2) is made; all other Saturdays are similarly excluded except for the filing of applications in respect of which no declaration for the purposes of s.5(2) is made). Tuesday 4 January 2000 is also particularly specified as an excluded day for all purposes under the Act.

Section 120(2)

Any business done under this Act on any day after the hour so specified in relation to business of that class, or on a day which is an excluded day in relation to business of that class, shall be taken to have been done on the next following day not being an excluded day; and where the time for doing anything under this Act expires on an excluded day that time shall be extended to the next following day not being an excluded day.

120.07 Any business under the Act which is done when the Office is closed (i.e. after the hour of closure or on an excluded day) for the class of business in question is treated as done on the next non-excluded day. (This of course does not affect items delivered to the Office prior to 9 a.m. on a non-excluded day, such items being accorded that day's date as their date of filing.) Any time limit expiring on an excluded day is extended to the next non-excluded day. However, excluded days do not constitute a period of general interruption in the postal services as contemplated within r.110, see 123.43-45. The compliance period does not impose any additional requirement on the applicant therefore this is not extended to the next non-excluded day, see 20.02.2.

Section 120(3)

Directions under this section shall be published in the prescribed manner.

120.08 Directions under this section are required to be published in the Journal as prescribed by r.117(b).

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Section 121: Comptroller's annual report

Section 121

Before 1st December in every financial year the comptroller shall cause to be laid before both Houses of Parliament a report with respect to the execution of this Act and the discharge of his functions under the European Patent Convention and the Patent Cooperation Treaty, and every such report shall include an account of all fees, salaries and allowances, and other money received and paid by him under this Act, that convention and that treaty during the previous financial year.

121.01 The comptroller's annual report is laid before Parliament and also placed on sale to the public. It covers not only activities under the 1977 Patents Act, EPC and PCT (including trends of inventions in published 1977 Act applications) but also those under the extant Acts relating to registered designs and trade marks. Financial and other statistics in respect of such activities, and accounts of other activities in which The Office staff have been involved (e.g. international conferences concerning intellectual property), are also included.

121.02 The date of the report was changed by Article 6 of The Office Trading Fund Order 1991 (SI 1991 No 1796) to require laying of the report (for the previous financial year) before 30 November of the same year. This article was revoked by the Patents Act 2004, which changed the date required for the report in section 121 from 1 June in every year to 1 December in every financial year.

Page 1 of 1 April 2007

SUPPLEMENTAL

Section 122: Crown's right to sell forfeited articles

Section 122

Nothing in this Act affects the right of the Crown or any person deriving title directly or indirectly from the Crown to dispose of or use articles forfeited under the laws relating to customs or excise.

122.01 This section provides that nothing in the 1977 Act affects the Crown's right to dispose of or use articles forfeited under the customs and excise laws.

Page 1 of 1 February 2008

Section 123: Rules

Section 123(1)

The Secretary of State may make such rules as he thinks expedient for regulating the business of the Patent Office in relation to patents and applications for patents (including European patents, applications for European patents and international applications for patents) and for regulating all matters placed by this Act under the direction or control of the comptroller; and in this Act, except so far as the context otherwise requires, "prescribed" means prescribed by rules and "rules" means rules made under this section.

123.01 This gives a general power to the Secretary of State to make rules under the Act, see 0.03 in the "Introduction" section of this Manual. Although s.123(2), (6) and (7) refer to rules for specific purposes, the rule-making power is not limited to those purposes. The rules are applicable to business and other matters arising under the 1977 Act and also govern the business of the Office in relation to European patents, applications for European patents and international applications for patents (rr.58 to 72 being specific to such patents or applications but many others of the rules are also relevant). There are six schedules to the rules, see 0.04 in the Introduction to this Manual.

123.02 The Rules thus have the force of statute and where the applicant fails to comply with them the comptroller has power to refuse grant. However, the Rules are subordinate to the Act from which they derive their authority. The Rules therefore must be read together with the Act and cannot override express provisions in the Act.

123.02.1 Reg 4(1) of the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations states that for the purposes of s.123(1) matters relating to supplementary protection certificates shall be the business of the Office. Reg 4(2) provides that the power of the Secretary of State to make rules under s.123 shall include the power to make rules in respect of such certificates and applications for said certificates and that ss.123(2)-(7) and 124 shall apply accordingly. The Patents Rules 2007 and the Patents (Fees) Rules 2007 therefore include specific provisions for supplementary protection certificates. See the "Supplementary Protection Certificates" section of this Manual for further details.

123.03 S.123 (except for sub-sections (6) and (7)) is merely an enabling section allowing the making of rules; it does not follow that a rule must have been made providing for any particular contingency. In *Tokan Kogyo KK's Application* [1985] RPC 244 it was held that even if it were accepted that s.123(2)(b) (see 123.06 to 123.10.3) contemplates the making of rules authorising the rectification of errors and omissions on the part of applicants or their agents, the plain fact is that the only rule relating to correction of irregularities in procedure is r.107, the proviso to which mentions errors and omissions on the part of only the Office.

Section 123(2)

Without prejudice to the generality of subsection (1) above, rules may make provision-

(a) prescribing the form and contents of applications for patents and other documents which may be filed at the Patent Office and requiring copies to be furnished of any such documents;

Page 1 of 22 October 2018

Form and contents of documents

123.04 The form and presentation of documents forming a 1977 Act application are governed by the rules, especially rules 12 and 14 (together with Schedule 2), see 14.26 to 14.57, and rule 15 with regard to the abstract, see 14.169 to 14.189. Information concerning biological material should, where applicable, be included in the application in accordance with rule 13 and Schedule 1, see chapter on s.125A. Rules 76(4), 78(1) and 87 govern the form of statements of case (as defined in r.73(3)) and evidence filed at the Office. The content and layout of the Patents Forms is set out by directions made under section 123(2A) (see.123.70.1). Requirements with regard to translations of European patents (UK) and applications therefore are given in rules 56 and 57. A number of the rules require that certain documents should be filed in duplicate.

[Documents produced on machines which use thermal paper, eg some facsimile ("fax") or ordinary computer output, may fade within months if not correctly stored. Such material can be recognised by the waxy feel of the paper and the slightly blurred image. Any such documents received by staff should be photocopied as soon as possible after receipt, and both the thermal print and the photocopy should be placed on file.]

Section 123(2)

(b) regulating the procedure to be followed in connection with any proceeding or other matter before the comptroller or the Patent Office and authorising the rectification of irregularities of procedure;

Proceedings before the comptroller: procedure

123.05 Part 7 of the Patents Rules 2007 (see particularly rules 73-88) provides a general procedural code for the conduct of proceedings heard before the comptroller. It applies to the applications, requests and references mentioned in Part 1 of Schedule 3 to the Rules and to the oppositions mentioned in Part 2 of that schedule (which start proceedings), including proceedings already started when the Rules entered into force on 17 December 2007. The procedure is explained in outline below, but a more detailed explanation of how it applies in practice is given in Tribunal Practice Notice 6/2007 (which is reprinted in the "Relevant Official Notices and Directions" section of this Manual) and in the Patent Hearings Manual and Tribunal Patents Manual. Any requirements specific to particular sections are discussed in the chapters relating to such sections. The provision of security for costs or expenses in proceedings before the comptroller is governed by s.107(4) and r.85 (see 107.10).

123.05.1 The procedural code of Part 7 has the overriding objective of enabling the comptroller to deal with cases justly. The criteria for this are listed in r.74(2) and are equivalent to those applying to the court under the Civil Procedure Rules. The comptroller is required to seek to give effect to the overriding objective when he exercises any power or interprets any rule in Part 7, and the parties to proceedings are required to help the comptroller to further the overriding objective.

123.05.2 Those rules in part 7 which are listed in Part 4 of Schedule 3 (rr.74, 79, 80(2) to (6), 81, 82, 84 and 87) apply to any proceedings, including ex parte hearings, heard before the comptroller under the Patents Act 1977.

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r.74

r.75 r.76(2) 123.05.3 In the case of oppositions, Part 7 draws a distinction between those which start proceedings and those (in respect of some provisions in ss. 47 and 52 concerning licences) which arise after proceedings have started. These are listed in Parts 2 and 3 respectively of Schedule 3. Except in the case mentioned in rule 105(5) (a correction under s.117 to which no person could reasonably object), the comptroller must advertise in the journal any event which can give rise to an opposition under any of the provisions in Parts 2 and 3. For Part 2 oppositions, a person has a period of four weeks from the date of the advertisement to start opposition proceedings (see 123.05.4), except in the case of oppositions under s.75(2) to amendment in infringement or revocation proceedings for which the period is two weeks. For Part 3 oppositions, see 123.05.6.

r.44(7) r.76 123.05.4 A person must start proceedings by filing in duplicate the relevant Patents Form and a statement of grounds, whereupon he becomes a claimant. The relevant form is Form 2 for the applications, requests and references in Part 1 of Schedule 3 (except those relating to supplementary protection certificates for medicinal and plant protection products under Community legislation for which it is Form SP3), or Form 15 for the oppositions in Part 2 of Schedule 3. The fact that such an application, reference, request or opposition has been made is recorded in the register. The statement of grounds must include a concise statement of the facts and grounds on which the claimant relies and specify the remedy which he seeks. In cases involving licences, the statement must, where appropriate, also include the period or terms of the licence which the claimant believes to be reasonable.

r.77

123.05.5 The comptroller must notify the applicant for, or proprietor of, the patent in suit that proceedings have started, and may also notify any other person who appears to him likely to have an interest in the case. Generally the comptroller will notify any person named in the register of patents or in the statement of grounds and any other person who appears likely on a case-by-case basis to have an interest. The notification must be accompanied by Form 2 and the statement of grounds and must specify a period, which will normally be 6 weeks, for the persons notified to file a counter-statement; the counter-statement must be filed in duplicate before the end of that period. Any notified person who fails to file a counter-statement will be treated as supporting the claimant's case, but a person who files a counter-statement becomes a defendant in the proceedings.

r.77(7) r.77(8) r.77(10) 123.05.6 This procedure does not apply to the oppositions in Part 3 of Schedule 3 where proceedings have already started and have been advertised in the journal. In these cases, a person has a period of four weeks from the date of the advertisement to file a counter-statement in duplicate to become a defendant in the proceedings.

r.78

123.05.7 A counter-statement must state which of the allegations in the statement of grounds the defendant denies and which of them he admits, and which of the allegations he is unable to admit or deny but which he requires the claimant to prove. If he denies an allegation he must state his reasons for doing so, and, if he intends to put forward a different version of events from that given by the claimant, he must state his own version. If he fails to deal with an allegation he will be taken to admit it, except that where he has set out the nature of his case in relation to the issue to which the allegation is relevant he shall be taken to require the allegation to be proved.

r.76(4) r.78(5) 123.05.8 In order to enable them to be used in evidence, a statement of grounds and a counter-statement must be verified by a statement of truth signed by the party or his legal representative.

r.87(5) r.80(1) r.80(3)

123.05.9 As soon as practicable after the defendant has filed a counter-statement the comptroller must send it to the claimant and specify the periods within which the claimant and defendant may file evidence. Evidence shall only be considered to be filed when it has been received by the comptroller and sent to all other parties to the proceedings. (For the form of evidence and the powers of the comptroller to control

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the evidence and to compel attendance of witnesses and production of documents, see 123.17-18)

r.80(4) r.80(5) 123.05.10 After evidence has been filed, the comptroller must give the parties an opportunity to be heard and send notice of a date for the hearing where a party requests to be heard.

123.05.11 In addition to his powers to control evidence under r.82(2) (see 123.17), the comptroller has powers under r.81 to extend or shorten (or further extend or shorten) any period of time specified under the provisions of Part 7 of the Rules: under rule 82(1) to give such directions as to the management of the proceedings as he thinks fit; and, on the application of a party under r.83, to strike out a statement of case or give summary judgment. The power under r.82(1) is general, but the rule lists a number of examples of the directions which may be given. Under r.82(3) the comptroller may make any direction given under the rules in Part 7 subject to conditions and may specify the consequences of failure to comply with the directions or a condition. Hearing officers will use these powers to manage cases actively in order to meet the overriding objective, with the aim of completing proceedings within 12 months of the filing of the counter-statement. Accordingly the hearing officer will review the case after the counter-statement has been filed to assess how it can best be resolved. The hearing officer will set a timetable at the outset for the filing of evidence and the date of the hearing by agreement with (or at least after representations from) the parties. He will normally order the case to follow one of three main routes:

Alternative dispute resolution (ADR), for which a period of 2 months should normally suffice.

Standard procedure, for straightforward cases. In general the hearing officer will expect the hearing to be set for no later than 9 months from the filing of the counter-statement. This will provide a window for ADR if necessary, sufficient time for the filing of three rounds of evidence (evidence in chief from the claimant and the defendant and evidence in reply from the claimant) at 6 week intervals, and then a period of 2-3 months before the hearing.

Case management conference, usually where the case is complex or the issues do not appear to be clear cut, in order to determine how events should proceed.

r.84

123.05.12 The hearing is to be held in public unless either the comptroller has granted an application for the hearing or part of it to be held in private, or it relates to an application for a patent which has not been published. In the former case the comptroller may grant an application where he considers there is good reason for it, and all parties have had an opportunity to be heard on the matter.

r.80(6)

123.05.13 When the comptroller has decided the matter he must notify all the parties of his decision and the reasons for making it. The preparation and issue of decisions, which may be written or oral, is explained in Chapters 5 and 6 of the Patent Hearings Manual.

Rectification of irregularities

(see also 123.03)

123.06 The correction of irregularities is governed by rule 107 which reads:-

(1) Subject to paragraph (3), the comptroller may, if he thinks fit, authorise the rectification of any irregularity of procedure connected with any proceeding or other matter before the comptroller, an examiner or the Patent Office.

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- (2) Any rectification made under paragraph (1) shall be made -
 - (a) after giving the parties such notice; and
 - (b) subject to such conditions,

as the comptroller may direct.

- (3) A period of time specified in the Act or listed in parts 1 to 3 of Schedule 4 (whether it has already expired or not) may be extended under paragraph (1) if, and only if -
 - (a) the irregularity or prospective irregularity is attributable, wholly or in part, to a default, omission or other error by the comptroller, an examiner or the Patent Office; and
 - (b) it appears to the comptroller that the irregularity should be rectified.

The comptroller thus has discretion on whether to allow a rectification of an irregularity of procedure under this rule, and to impose terms when exercising this discretion favourably. For example, Coal Industry (Patents) Ltd's Application ([1986] RPC 57) concerned an application on which, following the filing of amendments, an examination report was prepared in the Office but never issued. The applicants therefore never responded and the application was treated as refused since it failed to comply with the Act and Rules. Since this was attributable to an error in the Office, the hearing officer resuscitated the application under r.100 of the Patents Rules 1995 (equivalent to r.107 of the Patents Rules 2007) but imposed terms similar to those employed in restoration proceedings under s.28 to protect the interests of third parties who may have made preparations to exploit the invention between advertisement of the refusal and the decision to resuscitate. The Patents Court upheld the hearing officer. This can be contrasted with Eveready Battery Co. Inc.'s Patent [2000] RPC 852, in which a renewal fee was correctly paid on a patent, but not recorded in the Office. The patent was therefore erroneously recorded as having ceased. The court held that, since the requirements of the Act and Rules in respect of renewal fee payment had been met, the patent had not ceased and so there was no irregularity to correct. It was therefore not open to the Office to impose third party terms.

[Advertisement of the initiation of proceedings under r.107 may be appropriate in some cases (eg where the case has been previously advertised as terminated); this advertisement will provide a "cut-off" for any third party terms, see also 123.38.]

123.07 [deleted]

123.08 In its judgment in Fater's Application [1979] FSR 647 the Patents Court ruled that the comptroller's discretionary power under the original Rule 100 [Patents Rules 1978], which by virtue of Rule 124(1)(d) [Patents Rules 1978] applied also to "existing patents and existing applications", to rectify an irregularity in procedure in or before the Office is not restricted to irregularities attributable to the Office, but extends to irregularities in procedure, however caused, in proceedings of which the Office has seisin. However the House of Lords in E's Applications [1983] RPC 231 overruled the specific judgment in Fater's Application that (the original) Rule 100 [Patents Rules 1978] could be used to extend a time limit in a manner not allowed by Rule 110 [Patents Rules 1978], since a general provision of the Rules should not be construed in such a way as to circumvent a specific provision of the Rules. Nevertheless, the proviso, added to Rule 100 [Patents Rules 1978] after the judgment in Fater, and not in point in E's Applications, enabled the comptroller to extend a time or period specified in the Act or prescribed in the Rules to correct an irregularity in procedure attributable wholly or in part to an error, default or omission on the part of the Office. Paragraph (3) of rule 107 of the Patents Rules 2007 now gives the power to extend a

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period of time specified in the Act or listed in Parts 1 to 3 of Schedule 4 (whether that period has already expired or not), only if the irregularity or prospective irregularity is attributable, wholly or in part, to a default, omission or other error by the comptroller, an examiner, or the Patent Office and it appears to the comptroller that the irregularity should be rectified. In *Alphaplan Ltd's Application* (BL O/127/93), an incorrectly (post)dated cheque was not honoured by the agents' bank which meant that the application was not entitled to the original date of filing since the filing fee could not be considered to have been paid on that date (see 15.06); the hearing officer held that rectification under Rule 100(1) [Patents Rules 1990] was not possible; however under Rule 100(2) [Patents Rules 1990] he allowed the application to take as its filing date the date by which the Office cashiers should have picked up the error.

123.09 According to the judgment of the Court of Appeal in M's Application [1985] RPC 249 (concerning failure to file Form 10 within the prescribed period) the proviso to rule 100 [Patents Rules 1982] only came into operation if the applicants showed, firstly, that the Office was guilty of an error, default or omission (the "omission" being an omission to do something which it could be said there was some sort of obligation to do), secondly, that such error, default or omission could be said to have contributed to the failure to meet the time limit, and thirdly, that the error, default or omission played an active causative role in the irregularity which had taken place. It did not have to be the sole cause but it had to be something more than a mere causa sine qua non so that it could be said to be a partial cause of the irregularity in the sense of having actively brought it about. In M's Application the Patent Agents had filed a letter stating that Form 10 was filed therewith but the fact that neither the form nor the fee was enclosed with the letter was not detected until some time later. However, the Court of Appeal held that the Office is not under an obligation to answer routine letters within any particular time limit, so the delay in detecting the defect did not constitute such an "omission" on the part of the Office. The Court also postulated the possibility that a neglect of some well-established and generally well known practice on which it is known or may be assumed that all those dealing with the Office can be said to rely even though it may not be backed up by any statutory or regulatory backing - may constitute an "error or default or omission", but declined to make a decision to that effect.

123.10 In *Mills' Application* [1985] RPC 339 the Court of Appeal endorsed the three conditions set out in M's Application for the applicability of the proviso to rule 100 [Patents Rules 1982] subject to the rider that, with regard to an "omission", the obligation need not necessarily be of a legally enforceable nature. In Mills, the applicant sought to attribute his failure to file Form 10 in time at least in part to the Office's failure (which was accepted on the balance of probabilities) to provide a free copy of the printed specification as had been promised in the section 16 publication letter and which, the applicant argued, would have served as a reminder. In overturning the decision in the Patents Court, which relied on the fact that the Office's failure was not in respect of a statutory requirement, the Court of Appeal held that the applicant could reasonably have expected the Office to fulfil a specific promise given to the Agents in accordance with a well established practice.

Rule 107 may be used to rectify an irregularity where that irregularity was attributable, at least in part, to a reasonable expectation created by well-established Office practice. As discussed in 37.20.1, the Hearing Officer in *Rigcool Ltd v Optima Solutions UK Ltd* BL O/149/11 decided that a "period of two years beginning with the date of the grant" ended the day before the second anniversary of the date of grant. However, in a subsequent decision concerning the same dispute (O/182/11), the Hearing Officer extended this period by one day under r.107, as he accepted that previous Office decisions implied that Office practice was to accept that the period expired on the second anniversary, and not the day before.

123.10.2 Furuno Electric Co. Ltd's Application (BL O/208/10) concerned the use of r.107 to rescind grant of the patent, and thereby allow a divisional to be filed. In this case it was alleged that a failure by the examiner to raise objections – most

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significantly to a statement of invention corresponding to a deleted claim – constituted a procedural irregularity. The applicant pointed to passages in this Manual (e.g. at 18.68 and 14.147) concerning inconsistencies between the claims and the description, and said these passages showed that the examiner had made a clearly wrong assessment which should be rectified using r.107. The hearing officer held that the examiner had exercised his judgement in deciding that the claims were clear and that the remaining deficiencies were of a minor nature; whether this judgement was correct or not was a separate question from whether the examiner, having come to that view, followed the correct procedure. Although the applicant disagreed with the examiner's judgement of the facts, no procedural irregularity had occurred. It was also noted that, while the Manual may be referred to in determining whether a procedural irregularity has occurred, not all the guidance in the Manual can be regarded as procedural; nor can every alleged failure to follow that guidance be regarded as a procedural failing.

s.20A

Office guidance is regularly updated, particularly when the meaning of statute is clarified by the courts, a hearing officer, or another source. This does not mean that every action the Office made under earlier guidance amounts to an error which contributed to an irregularity of procedure. Cypress Semiconductor Corporation's Application (BL 0/326/16) relates to an application which was reinstated in 2009 following a failure to respond to an examination report. The Office followed its practice at the time and did not provide a new period for compliance. The applicant was not therefore able to amend their application but could only make observations. In 2010 Office practice concerning reinstatement following the failure to respond to an examination report changed to provide an applicant with an opportunity to amend their application. In 2015 the applicant, noticing that the application had not been terminated, argued that, given the change in practice, the period for compliance should be treated as having been extended so that previously proposed amendments could be considered. The hearing officer however held that no new period for compliance could be set, either under the reinstatement provisions of section 20A or under the provisions of rule 107.

[It is possible to utilise Rule 107 to extend a period of time specified in the Act or listed in Parts 1 to 3 of Schedule 4. However, the power afforded by Rule 107 should not be applied too readily, but rather only in cases where the circumstances warrant it and in accordance with the case-law (referred to above). Whether to exercise discretion must be decided on a case-by-case basis. Therefore, any consideration of exercise of discretion under Rule 107 to extend a period of time should be referred to the Deputy Director of Patents Legal Section or Head of Administration, as appropriate.

[Whenever a lost or mislaid document comes to light an appropriate minute setting out the circumstances of its discovery should be made. Facts should not be withheld to avoid disclosing someone's error, since such facts may be of the utmost importance in determining whether or not an irregularity of procedure has occurred to justify exercise of the Comptroller's discretion should the need subsequently arise.

[Formalities should check the address on lost correspondence to ensure it matches the most recent address for service for the relevant application. It may also be necessary to look for any unactioned requests to update the address, for example by form 51 of letter. If appropriate, formalities should inspect their Post Book to confirm whether or not the correspondence was actually issued.]

[If the correspondence was never sent or was sent to an incorrect address, this constitutes an irregularity in Office procedure and may be dealt with under rule 107. In such cases, the matter should be dealt with by Formalities, who should contact the intended recipient to apologise for the error and indicate that an extension of time is being considered under rule 107. A message should then be sent to the Head of Administration, who may suggest that the correspondence be reissued with an amended reply date. The compliance

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period may also be extended if this is felt to be necessary. In the event that the correspondence was accidentally sent to a third party, a copy of the original communication should still be reissued even if the third party has forwarded the misdirected mail to the correct address.]

[When a mistake is made in the Office, and particularly when it causes inconvenience or extra work for an applicant, an apology for the mistake should be made. If it is felt that the nature or seriousness of the mistake necessitates a fuller explanation or other action then the Deputy Director should be consulted, the matter being referred up if necessary.]

[All lost or misdirected correspondence must be reported to the Head of Administration. Each instance will be logged and passed to the Information Security and Customer Insight teams for review.]

[Dispensation by comptroller - deleted]

123.11	[deleted]
123.12	[deleted]
123.13	[deleted]
123.14	[deleted]

Section 123(2)

(c) requiring fees to be paid in connection with any such proceeding or matter or in connection with the provision of any service by the Patent Office and providing for the remission of fees in the prescribed circumstances;

Fees

123.15 According to the Patents (Fees) Rules the fees to be paid in respect of any matters arising under the Act shall be those specified in those Rules and the Schedules to those Rules. Those Schedules also give, where appropriate, the number of the corresponding Patents Form to accompany the fee. The fees are periodically revised; the current Patents (Fees) Rules should always be consulted. Where any form specified in the Schedules to the current Patents (Fees) Rules is required to be filed it shall be accompanied by the specified fee (if any) or, where payment may be made within a prescribed period of time after the form has been filed. the specified fee shall be paid within that period. Under the Public Offices Fees (Patents, Designs and Trade Marks) Order 1964, all fees must be paid in money. Cash, money order, postal order, cheque, banker's draft or credit/debit card are accepted; adhesive stamps are not. Fees may also be paid by authorising debit of funds from a deposit account administered by the Office, or by direct credit to the Office's account, but in that event a fee is not deemed to have been received until this account is actually credited. Payment for statutory fees is accepted by credit/debit card, but this cannot be used for adding to a deposit account, or for international patent fees (other than the transmittal fee) payable under the PCT.

123.16 Provision for the remission of fees is made by rule 106. With regard to the remission of fees under rule 106 in the case of a divisional application, see 15.27 and 15.47-49, in the case of requests for an opinion under section 74A, see 74A.04, and in

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r.106

the case of an international application, see 89B.08. There is no appeal from any decision of the comptroller under rule 106.

Section 123(2)

(d) regulating the mode of giving evidence in any such proceeding and empowering the comptroller to compel the attendance of witnesses and the discovery of and production of documents;

Evidence

r.73(2) r.73(3) r.86 r.87

123.17 Under r.80(2) the comptroller may at any time he thinks fit give leave to a party to proceedings before him to file evidence upon such terms as he thinks fit. Under r.82(2), he may give directions (which may be subject to conditions; see 123.05.11) as to the issues on which he requires evidence, the nature of the evidence required and the way in which it is to be placed before him, and he may use these powers of control to exclude evidence which would otherwise be admissible. R.87(1) allows evidence to be given by witness statement, statement of case, affidavit, statutory declaration or any other form which would be admissible in proceedings before the court. It follows from rr.82 and 87 that the comptroller may take oral evidence in lieu of or in addition to written evidence and in particular may allow any witness to be cross-examined on his written evidence. In general however, evidence filed for the purposes of Part 7 of the Rules (Proceedings before the comptroller) is to be given by witness statement unless the comptroller directs or any enactment requires otherwise, a witness statement being defined as a written statement signed by a person and containing evidence which that person would be allowed to give orally. A witness statement or statement of case may only be given in evidence if it includes a statement of truth; for the purposes of Part 7 of the Rules (Proceedings heard before the comptroller), this must be dated and signed by the person making the statement in the case of a witness statement, and in other cases by the party or his legal representative. In relation to the attendance of witnesses and the discovery and production of documents, the comptroller has the powers of a judge of the High Court or (in Scotland) the Court of Session other than the power to punish summarily for contempt of court.

r.79 r.82(1)

123.18 Under his powers of case management, the comptroller may direct the filing of documents, information or evidence as he thinks fit. Where a "relevant statement" (defined as a witness statement, statement of case, affidavit or statutory declaration) refers to another document, a copy of that document should accompany each copy of the relevant statement that is filed. This does not apply where the relevant statement is sent to the comptroller and the document was published by the comptroller or is kept at the Office. It is desirable as a matter of convenience and practice that objections to the admissibility of evidence should be raised as early as possible but, as was noted in Peckitt's Application [1999] RPC 337, the fact that an objection was not raised as early as it might have been does not make admissible that which was not admissible. Cross-examination of witnesses and the admission of hearsay evidence, other than in Scotland, under the Registered Designs Act 1949, Patents Act 1977, Copyright, Designs and Patents Act 1988 and Trade Marks Act 1994 are subject to the provisions of the Practice Notice dated 4 January 1999 which appeared in the Patents and Designs Journal No 5727 10 February 1999 and [1999] RPC 294 (reproduced in the "Relevant Official Notices and Directions" section of this Manual).

123.19 [deleted]

123.20 The mode of giving evidence and related powers of the comptroller are

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discussed further in Chapter 3 of the Patent Hearings Manual.

Section 123(2)

(e) requiring the comptroller to advertise any proposed amendments of patents and any other prescribed matters, including any prescribed steps in any such proceeding;

Advertisement

- 123.21 Certain matters must be advertised by the comptroller, the necessary advertisements being made in the Patents Journal which the comptroller is required to publish by rule 117, see 123.72. According to rule 117(a), the Journal should *inter alia* contain particulars of applications for and grants of patents and of other proceedings under the Act.
- 123.22 An application to the comptroller for leave to amend the specification of a patent is advertised in accordance with rule 75.
- 123.23 Certain steps in other proceedings under the Act are advertised in accordance with rules 40(3), 40(9), 43(2), 75 and 105(5)-(7).
- 123.24 In accordance with rule 45, the comptroller may publish or advertise such things done under the Act or Rules in relation to the register as he thinks fit. The Journal includes a list of those patents and published applications in relation to which transactions, instruments or events affecting rights therein or thereunder have been entered in the register, see section 32. See also 123.73.

Section 123(2)

(f) requiring the comptroller to hold proceedings in Scotland in such circumstances as may be specified in the rules where there is more than one party to proceedings under section 8, 12, 37, 40(1) or (2), 41(8), 61(3), 71 or 72 above;

Proceedings in Scotland

r.88(1)	123.25 Where there is more than one party to proceedings, any party thereto may
r.88(2)	apply to the comptroller to hold proceedings in Scotland, in accordance with rule
	88(1).

123.26 The application will be granted where all the parties consent to holding proceedings in Scotland, or where the comptroller considers it appropriate.

123.27 (deleted)

PR part 7 123.28 Rule 88(1) is mentioned in Part 1 of Schedule 3 to the Patents Rules 2007 and the application must therefore be started by filing Form 2 and a statement of grounds in duplicate.

r.88(3) 123.29 There is no appeal from any decision of the comptroller refusing to grant an

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application under r.88(1).

123.30 See 123.17 with regard to the powers of the comptroller in proceedings in Scotland (rule 86), and Chapter 8 of the Patent Hearings Manual for the conduct of proceedings in Scotland.

Section 123(2)

(g) providing for the appointment of advisers to assist the comptroller in any proceeding before him;

Advisers

123.31 Rule 102 empowers the comptroller to appoint advisers to assist him in any proceeding before him and to settle any question or instructions given to them.

123.32 and 123.33 [deleted]

Section 123(2)

(h) prescribing time limits for doing anything required to be done in connection with any such proceeding by this Act or the rules and providing for the alteration of any period of time specified in this Act or the rules;

Time limits

123.33.1 The Patents Rules 2007 prescribe many periods in connection with the processes for applying for and maintaining patent rights, and for resolving disputes over those rights. Time periods prescribed in the Rules are generally calculated using the "exclusive rule", meaning that the prescribed period does not include the defining date (for example a period of one month "from 15 April" ends on 15 May). The Patents (Amendment) Rules 2011 (SI 2011/2052), which came into force on 1 October 2011, adjusted the wording used to define various time periods so that there is no doubt that these periods should be calculated using the exclusive rule. See the Practice Notice for further details.

123.34 Rule 108 of the Patents Rules 2007 reads -

- (1) The comptroller may, if he thinks fit, extend or further extend any period of time prescribed by these Rules except a period prescribed by the provisions listed in Parts 1 and 2 of Schedule 4.
- (2) The comptroller shall extend, by a period of two months, any period of time prescribed by the provisions listed in Part 2 of Schedule 4 where-
 - (a) a request is filed on Patents Form 52;
 - (b) no previous request has been made under this paragraph;and
 - (c) that request is filed before the end of the period of two months

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r.108

beginning immediately after the date on which the relevant period of time expired.

- (3) The comptroller may, if he thinks fit, extend or further extend any period of time prescribed by the rules listed in Part 2 of Schedule 4 where-
 - (a) a request is filed on Patents Form 52; and
 - (b) the person making the request has furnished evidence supporting the grounds of the request, except where the comptroller otherwise directs.
- (4) Each request under paragraph (2) or (3) for a period of time to be extended must be made on a separate form unless-
 - (a) each of those requests relate to the same patent or application for a patent; and
 - (b) the grant of each of those requests would result in the expiry of all the extended periods of time on the same date,

in which case those requests may be combined and made on a single form.

- (5) Any extension made under paragraph (1) or (3) shall be made-
 - (a) after giving the parties such notice; and
 - (b) subject to such conditions,

as the comptroller may direct, except that a period of time prescribed by the rules listed in Part 3 of Schedule 4 may be extended (or further extended) for a period of two months only.

- (6) An extension may be granted under paragraph (1) or (3) notwithstanding the period of time prescribed by the relevant rule has expired.
- (7) But no extension may be granted in relation to the periods of time prescribed by the rules listed in Part 3 of Schedule 4 after the end of the period of two months beginning immediately after the period of time as prescribed (or previously extended) has expired.
- 123.35 The rules listed in the above-referenced Parts of Schedule 4 of the Patents Rules 2007 are given below.
- r.108(1) 123.36 Times or periods prescribed by the Rules thus fall into four categories I to IV with regard to extension under rule 108:

I periods which cannot be altered

PR Sch 4, 123.36.1 These are the periods prescribed in the following parts of the Patents Rules 2007: rules 6(2)(b), 7(1), 32(1), 37, 38, 40(1), 43(4), 58(3), 59(1), 66(3), 76(2), 77(8) and (10), 109, 116(2), paragraph 8(5) of Schedule 1 (new deposits of biological material).

123.36.2 [deleted]

123.36.3 [deleted]

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123.36.4 [deleted]

If periods which can be extended (1) by a single period of two months as of right on request and payment of a fee; and (2) by an alternative or additional period(s) at discretion on request and payment of fees

r.108(2) r.108(3) PR Sch 4, Part 2 123.36.5 These are the periods prescribed in the following parts of the Patents Rules 2007: rules 8(1) and (2), 10(3), 18(1), 21, 22(1), (2) and (5), 28(2), (3) and (5), 30, 56(6) and (7), 58(4), 59(3), 60, 66(1) and (2), 68, 104(2), paragraph 3(2) of Schedule 1 (filing of information in relation to the deposit of biological matter).

123.36.6 [deleted]

123.36.7 A single two-month extension under rule 108(2) is obtainable for these periods as of right on filing Patents Form 52 together with the appropriate fee.

r.108(2) r.108(3) r.108(6) 123.36.8 The alternative or additional extension available at discretion under rule 108(3) has to be requested on Patents Form 52 together with the appropriate fee, and evidence supporting the grounds for the request is required for the comptroller to consider extension. The request may be made after expiry of the period to be extended (but see category IV below). Factors influencing the exercise of discretion are dealt with in 123.37.

[If the request under r.108(3) concerns formalities matters it is normally considered by the relevant formalities group, but may only be allowed by the divisional Head of Admin (or above), provided it is unopposed. If the request concerns substantive matters it is normally considered by the relevant examiner, but may only be allowed by the group head. Furthermore, where extensions of both the s.18(3) reply period (which can be allowed by the examiner) and, under r.108(3), the compliance period are required the group head decides both questions. However, an opposed request can only be decided upon by a Divisional or Deputy Director. If the request to extend the compliance period or the s18(3) reply period is made whilst an application is awaiting a hearing or decision, then the relevant hearing officer should consider the request.]

III periods (other than in I and II) which can be extended at discretion

r.108(1) r.108(6) 123.36.9 Extension at the discretion of the comptroller under rule 108(1) is applicable to many times and periods prescribed by the Rules. The discretionary power under rule 108(1) is a general one to which the only exceptions are times or periods prescribed by any of the rules specified in either category I (no alteration possible) or category II (extensible by two months and/or at the discretion of the comptroller). The request may be made after expiry of the period to be extended (but see category IV below). Factors influencing the exercise of discretion are dealt with in 123.37.

/V periods in // or /// which can be extended subject to further conditions

r.108(5), (7)
PR Sch 4,
Part 3

123.36.10 These are the periods prescribed in the following rules of the Patents Rules 2007: 10(3), 12(3) and (9), 19, 21(1)(a) and (2)(a), 22, 28, 30, 58(4), 59(3), 60, 66(1) and (2) 68.

123.36.11 [deleted]

r.108(5) 123.36.12 The further conditions that apply to extension of these periods are r.108(7) that-

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- (a) any extension must be for two months, and
- (b) no extension is possible if two months have elapsed since the last period expired.

These conditions limit the retrospective availability of extension of these time periods, but reinstatement of the patent application under section 20A becomes possible in situations where extension is not available (section 20A(3)(a) - see 20A.01 to 20A.13)

Exercise of discretion; conditions

s.20A

123.37 Discretion should be exercised favourably if it is shown that the failure to meet the time period was unintentional at the time that the period expired (except where the extension of time is for the filing of a divisional application - see 15.21). This is consistent with the statutory test that applies to requests for reinstatement under s.20A (see 20A.13-16 for guidance on the meaning of unintentional). However, since rule 108 sets out no statutory test for discretionary extensions of time, discretion may be exercised favourably in appropriate circumstances even if the unintentional criterion does not appear to have been met. Prior to the introduction of the reinstatement provisions under s.20A, a number of cases were decided on the basis that there must have been a continuing underlying intention to proceed with the application or patent; a change of mind regarding whether to proceed on the part of those responsible for its prosecution was held in Heatex Group Ltd's Application ([1995] RPC 546) not to be a legitimate reason for favourable exercise. In Meunier's International Application (BL O/013/01), the applicant had chosen to acquire patent protection in the UK via an EP(GB) designation of his international application, rather than by continuing with a GB designation and national phase entry. When it was discovered that, by mistake, EP(GB) had not been designated, a request for the application to belatedly enter the national phase directly was refused by the hearing officer, who regarded this as a change of mind, despite a continuing underlying intention on the part of the applicant to protect his invention in the UK. In a broadly similar set of circumstances, the hearing officer in Pilat's International Application [2003] RPC 13 came to the same conclusion. In MacMullen's Application (BL O/307/03), the hearing officer held that in order to demonstrate a continuing underlying intention to proceed with an application where a form and required fee had not been filed within the prescribed period due lack of funds, it was necessary for the applicant to show that he had insufficient funds to pay the fee and that he made genuine and continuing efforts to obtain the required sum during this period. These cases may also be useful in determining whether discretion can be exercised However, in order to ensure consistency with the reinstatement provisions, if the evidence provided shows that the failure to meet the time period was unintentional, discretion should be exercised favourably regardless of whether or not there has been a continual underlying intention to proceed.

r.108(5)

123.38 The comptroller has discretion to impose conditions when making an alteration under r.108(1) or r.108(3), after giving the parties such notice as he may direct. For example, in *Chitolie's Application* (BL O/078/04, upheld on appeal [2004] EWHC 1549 (Ch)), terms analogous to those employed in restoration proceedings under s.28 were applied where an application was resuscitated by the extension after having been advertised as terminated (much as described in 123.06 where the resuscitation was under r.100).

[Third party terms will normally be appropriate where the case has been published and previously advertised as terminated (or void in the case of a European patent (UK) for which a translation was not filed in time under s.77(6)). The "cut-off" for such terms will then be the date on which the filing of Form 52 is advertised in the Journal.]

Other matters

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- 123.39 Although the wording of rule 108 permits certain of the times or periods prescribed by the Patents Rules for doing any act or taking any proceeding thereunder to be extended at the Office discretion, no provisions are included for extending times or periods prescribed by the Act itself (confirmed by the hearing officer in *ITT Industries Inc's Application* [1984] RPC 23).
- 123.40 Rule 108(4) provides that each request under rule 108(2) or (3) must be made on a separate Form 52 unless each of those requests relate to the same patent or application and the extended periods would expire on the same date.
- 123.41 The relationship of rule 108 with rule 107 is discussed in 123.06 to 123.10, particularly in connection with the period for filing Form 10 which is defined by rule 28, 60 or 68 (see 18.02) and extensible under rule 108(2) or (3) to (7).

123.42 [deleted]

Rule 110

123.43 Rule 110 of the Patents Rules 2007 reads as follows -

- (1) The comptroller may certify any day as an interrupted day where -
 - (a) there is an event or circumstance causing an interruption in the normal operation of the Patent Office; or
 - (b) there is a general interruption or subsequent dislocation in the postal services of the United Kingdom.
- (2) Any certificate of the comptroller given under paragraph (1) shall be displayed in the Patent Office and advertised in the journal.
- (3) The comptroller shall, where the time for doing anything under the Act expires on an interrupted day, extend that time to the next following day not being an interrupted day (or an excluded day).
- (4) In this rule -

"excluded day" means a day specified as an excluded day in direction given under section 120; and:

"interrupted day" means a day which has been certified as such under paragraph (1).

123.44 The comptroller has power under rule 110(1) to certify a day as an interrupted day where there is an event or circumstances causing an interruption in the normal operation of the Office, or where there is a general interruption or subsequent dislocation in UK postal services. A period of time specified under the Act or Rules for the giving, making or filing of any notice, application or other document which expires on a day so certified is extended to the first non-excluded day following the end of the certified interruption. Rule 110(2) requires any such certificate to be displayed in the Office. Although the comptroller's powers under rule 110(1) are couched in discretionary terms, in practice he is under an obligation to issue a certificate where the circumstances are such as to fall within the words of the rule, and the effect of such a certificate may be retrospective or prospective or both as the case may require (judgment of Patents Court in *Omron Tateisi Electronics Co's Application* [1981] RPC 125).

123.45 In Armaturjonsson AB's Application [1985] RPC 213, the Patents Court held that the old form of rule 110 (formerly rule 111) was in no way concerned with

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individual difficulty or problems of a purely personal kind; it was concerned only with a state of affairs where not just one individual applicant but many applicants or indeed anybody who is under duty to do some act within some prescribed time may be affected. It further held that rule 110 was concerned only with special circumstances which may bring about interruption, which are not going to be catered for by the excluded days provisions. Excluded days (such as the Christmas holiday period in the application in suit) do not constitute a period of general interruption as contemplated within rule 110.

[To certify that there has been an interruption, the comptroller must issue a certificate. The certificate need not be signed by the comptroller himself. The Director of Patents, Director of IPID and PD Divisional and Deputy Directors are all authorised to sign on behalf of the comptroller. Clearly, however, the most senior available officer should be used. Once the certificate is signed, a copy must be displayed in the Office (Concept House and 4 Abbey Orchard Street). A copy must also appear as soon as possible in the various official Journals. Although not a legislative requirement, a prominent website notice is clearly appropriate too. It is very desirable to issue the certificate on the interrupted day in question, but it is not essential to do this. It is possible to certify either before or after the event that the normal operation of the Office will be, or was, interrupted on a particular day. The same publication requirements apply. If the certificate says that a particular day or days were interrupted, then there is no need to issue a further notice. However, if the certificate is open-ended, then we must notify the public when the interrupted period has come to an end. The original certificate may be attached to the notice for reference. The notice should be publicised in the same way as the original certificate - on the website, in Journals and displayed at the Office. The notice need not be made by the same person who signed the certificate, but can be anyone (as identified earlier) who can act on behalf of the comptroller in this respect. It may be helpful to attach an explanatory note to the notice, so that the effect on users is clear.]

[The certificate applies to time periods set out in the Acts and Rules, and to periods that have been specified by the comptroller. Thus it does not apply to time periods set out under the Patent Co-operation Treaty or the European Patent Convention. Nor does it apply to time periods set out in international trade mark legislation. Some of these treaties and other instruments contain provisions which cater for certain types of disruption in the UK and other states (see, for example, rule 134 EPC). Such provisions are usually more restrictive in their effect than the UK certificate of interruption. So where the filing of documents at the Office is not possible at all, users who wish to meet a deadline under one of these treaties or other instruments will be advised to try and file the relevant documents at an alternative location, if the relevant law allows. There is no simple rule that can be applied, and the position will be determined on a case-by-case basis.]

Rule 111 r.110(2)&(4) 123.46 Rule 111 of the Patents Rules 2007 reads as follows -

r.6(1)

- (1) The comptroller shall extend any period of time specified in the Act or these Rules where he is satisfied that the failure to do something under the Act or these Rules was wholly or mainly attributable to a delay in, or failure of, a communication service.
- (2) Any extension under paragraph (1) shall be made -
 - (a) after giving the parties such notice, and
 - (b) subject to such conditions,

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as the comptroller may direct.

(3) In this rule "communication service" means a service by which documents may be sent and delivered and includes post, facsimile, email and courier.

123.47 Rule 111 allows the comptroller to extend time periods if a particular case of failure to do something under the Act or Rules was wholly or mainly attributable to a delay in, or failure of, a communication service involving the sending and delivery of documents. This includes post, facsimile, email and courier, both inside and outside the UK. Before allowing any extension under r.111(1), the comptroller is required to give the parties notice, and an extension may be subject to conditions as the comptroller may direct. Rule 111 may be used to extend a prescribed time period regardless of whether or not it has expired. Details of how to deal with lost post in relation to specified time periods can be found below in paragraph 123.47.2.

123.47.1 It is worth noting, that whilst rule 111 allows for relief where an official communication can, on the balance of probabilities, be demonstrated to have gone astray in the post, the rule requires that the failure to meet a deadline is 'wholly or mainly' attributable to the communication failure. If an application is found not to comply with the Act and Rules by the end of the compliance period, it may not be possible to extend the compliance period under rule 111 simply because an examination report was not received. In *Daihatsu Motor Co Ltd and others' Patent* (BL O/234/14) the hearing officer determined that it was the "lack of systematic rigour" by the attorney in monitoring the compliance period and tracking the application status, and not the non-arrival of a report of re-examination under section 18(3), that was the main reason for the failure to bring the application in order in time.

Where correspondence from the Office is reported as never having arrived at its intended destination, or is reported as being misdirected or delayed, this fact should be recorded by sending a minute to the relevant formalities group with any relevant details. The relevant Head of Administration will then decide whether a prescribed period can be extended under rule 111. The head of administration will need to be satisfied 'that the failure to do something under the Act or these Rules was wholly or mainly attributable to a delay in, or failure of, a communication service'. Duplicate copies of the original reports should be sent to the address for service, along with PROSE letter RULE 111. If the application has been published, the applicant/agent may also be directed to the online IPSUM service, which contains links to patent citations. When a period of time set out in the Act or Rules is due to expire imminently, a reminder should also be included. The RULE 111 letter invites the applicant or attorney to provide evidence that the delay or failure to respond was wholly or mainly attributable to a problem with a communication service (as opposed to a report having been mislaid after it was received). Such evidence might include a copy of their office records relating to the application in question and/or a signed statement briefly describing their usual mail delivery arrangements and any procedures used to record when a piece of correspondence arrives. Once evidence has been supplied, Formalities should refer the application to the Head of Administration, who will determine whether or not rule 111 may be used to allow an extension of time. The length of any extension will depend on the circumstances of the case. Once the Head of Administration has determined what action is to be taken, the formalities manager should ensure that the applicant or attorney is informed in writing as to the outcome. If an extension under rule 111 has been allowed, the necessary changes should be made to the patents database and the case dossier. If the applicant or attorney is unhappy with the Office's decision in the matter, they can request to be heard on the matter. Under no circumstances should reports be reissued with new dates unless an extension of time has been agreed by one of the Heads of Administration. If required, advice should be sought from Patents Legal Section.]

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123.47.2 Specified periods of time are not covered by the provisions of rule 111. Therefore the only option available for the applicant or attorney is to request an extension of time under section 117B of the Patents Act (see MoPP 18.53, 18.54 and 15A.23). An examiner may consider it necessary to use rule 111 to extend the compliance period (which is a prescribed period) at the same time. If this is the case, the patent examiner should liaise with the Head of Administration, who will quickly consider whether or not to allow such an extension.

Section 123(2)

(i) giving effect to an inventor's rights to be mentioned conferred by section 13, and providing for an inventor's waiver of any such right to be subject to acceptance by the comptroller;

Mention of inventor

123.48 Rule 10 sets out the procedure where any person alleges that he ought to have been mentioned as the inventor or joint inventor of an invention, see 13.04 to 13.07, or that any person mentioned as sole or joint inventor ought not to have been so mentioned, see 13.17.

123.49 See 13.08 to 13.15 for details of the procedure for identifying the inventor or inventors (and derivation of the right to apply) where the applicant is not the inventor or sole inventor.

123.50 The procedure for a person named as inventor to waive his right to be mentioned is set on in rule 11, see 13.03 to 13.03.1.

Section 123(2)

(j) without prejudice to any other provision of this Act, requiring and regulating the translation of documents in connection with an application for a patent or a European patent or an international application for a patent and the filing and authentication of any such translations;

Translations

123.51 The general rule regarding translations of documents in connection with patent applications is rules 113 to 115, but rules 6 to 9, 35, 56 to 59 and 66 and 68 to 70 are also relevant.

123.52 Rule 9 relates to the translation of priority documents, see 5.11 to 5.13, and r.35(4) and (5) concerns the need for translations where it is desired to amend a patent of which the specification as published was not in English.

123.53 Rules 56 and 57 relate to translations of European patents (UK) and of claims of applications for such patents, under ss.77(6) (see 77.13-25), 78(7) (see 78.11-15) and 80(3) (see 80.02-06). Rules 58(4) and 59(3) relate to a translation of a European patent application where conversion into an application under the Act has been

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requested under section 81 (see 81.05-06).

123.54 Rule 69(1)(b) and (5)(b) relate to a translation of information regarding the deposit of biological material in connection with an international application (UK), see 89A.10. In addition, rules 69 and 70 relate to the required content of any translation of an international application (UK) and amendments thereof, see 89A.08-09 and 89A.25.

123.55 [deleted]

123.56 According to rule 113(1), any document or part thereof not in English is required to be accompanied by a translation, unless that document is listed in r.113(2). Where the document is or forms part of an application for a patent and no translation is filed see 15.06.1, 15.06.2 and 16.14.

r.115

123.57 It is not normally necessary to verify the translation. However, where the comptroller has reasonable doubts about the accuracy of any translation of a document, the person supplying the translation is notified and asked to furnish evidence to establish that the translation is accurate. If evidence is not provided following this request, the comptroller has discretion to take no further action in relation to that document. An acceptable form of verification certificate is quoted in 5.13.2.

123.58-59 [deleted]

- r.113(3) 123.60 Where more than one copy of a document is filed or sent, it should be accompanied by a corresponding number of copies of the translation.
- r.113(5)
 123.61 Where an International Search Report, an International Preliminary Report on r.113(6)
 Patentability or an International Preliminary Examination Report is filed at the Office in relation to an international application for a patent (UK) and that report cites or refers to any document in a language other than English or Welsh, a translation into English of the document may be requested. It should be filed within two months (extensible at the comptroller's discretion) of the date of the request. If it is not filed, the comptroller may, if he thinks fit, take no further action in relation to the application. See also 89B.10-11.
- r.114

 123.62 A party who institutes proceedings before the comptroller in relation to a European patent (UK), the published specification of which is in French or German, is required to furnish a translation of the specification unless such a translation has already been filed under s.77(6) or the comptroller determines that it is not necessary. This also applies to the making of a request for an opinion under section 74A. A party given leave to amend the patent during such proceedings is required to furnish a translation of the amendment into the language in which the specification was published.

Register of patent agents

123.63 Section 123(2)(k) related to registration of patent agents. Together with other provisions of the 1977 Act concerning patent agents, it has been repealed by the CDP Act and replaced by Part V of the CDP Act (Patent Agents and Trade Mark Agents), see particularly s.275 thereof.

[123.64-123.69 Deleted]

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Section 123(2)

(I) providing for the publication and sale of documents in the Patent Office and of information about such documents.

Publication and sale of documents

123.70 According to rule 119, the comptroller may arrange for the publication and sale of copies of documents (in particular, specifications of patents and applications for patents) in the Office.

Section 123(2A)

The comptroller may set out in directions any forms the use of which is required by the rules; and any such directions shall be published in the prescribed manner.

123.70.1 Subsection (2A) was inserted by the Patents Act 2004 and enables the comptroller to specify in directions the content and layout of the Patents Forms, which previously had to be prescribed by rules. A direction under this subsection was made on 5 December 2007 and came into force on 17 December 2007. This direction revoked the earlier direction for forms made on 30 March 2006. A further direction was made on 18 April 2008 setting out revised versions of Patents Forms 20 and 54 which came into force on 1 May 2008. Both directions are reprinted in the "Relevant Official Notices and Directions" section of this Manual. Directions given under s.123(2A) are required to be published in the Journal under r.117(c).

Section 123(3)

Rules may make different provision for different cases.

Section 123(3A)

It is hereby declared that rules -

- (a) authorising the rectification of irregularities of procedure, or
- (b) providing for the alteration of any period of time,

may authorise the comptroller to extend or further extend any period notwithstanding that the period has already expired.

123.70.2 The CDP Act inserted subsection (3A) into section 123 of the 1977 Act which is concerned with the power to make rules under that Act. The rules prescribe various times or periods for performing particular actions. The rules also empower the comptroller to extend some of those times or periods. It has always been assumed that such extension can be made even though the time or period has already expired, and the rules have always been operated on that basis. Subsection (3A) has been added as an "avoidance of doubt" provision. This paragraph came into effect on Royal Assent (15 November 1988). See 123.34 to 123.47 for details of such

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extensions of periods.

[Sections 123(4) and (5) Repealed]

123.71 Subsections (4) and (5) of s.123 required Treasury consent in order to make rules prescribing fees and to determine the remuneration of advisers appointed to assist the comptroller in proceedings. These requirements were removed by the repeal of these subsections by Schedule 2 paragraph 26 of the Patents Act 2004.

123.71.1 [deleted]

Section 123(6)

Rules shall provide for the publication by the comptroller of a journal (in this Act referred to as "the journal") containing particulars of applications for and grants of patents, and of other proceedings under this Act.

The Journal

123.72 The Patents Journal contains particulars of applications for and grants of patents (see 14.04.3) and of other proceedings under the Act and any other information that the comptroller considers to be generally useful or important, as required by rule 117. It is published weekly, usually on a Wednesday.

123.73 Publication of applications and grant of patents are advertised in the Journal as required by sections 16 (see 16.02) and 24 (see 24.01-24.02) respectively. Other particulars of proceedings under the Act given in the Journal include those mentioned in 123.22 to 123.24.

123.74 Certain information about European Patents (UK) is also listed, viz such patents granted under Article 97 of the European Patent Convention, such patents revoked under Article 101 of that Convention, such patents declared void under s.77(7) for failure to file a translation into English and such patents ceased through non-payment of renewal fees.

123.75 In addition, the Journal includes information about Office publications, official notices issued by the Office, brief particulars of recent judgments and decisions, proceedings under the Registered Designs Act 1949 and information concerning the Science Reference Library.

Section 123(7)

Rules shall require or authorise the comptroller to make arrangements for the publication of reports of cases relating to patents, trade marks, registered designs or design right decided by him and of cases relating to patents (whether under this Act or otherwise) trade marks, registered designs, copyright and design right decided by any court or body (whether in the United Kingdom or elsewhere).

Reports of cases

r.118

123.76 The comptroller is required by rule 118 to make arrangements for the

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publication of reports of cases relating to patents, trade marks, registered designs or design right decided by him and reports of cases relating to patents (whether under the Act or otherwise), trade marks, registered designs, copyright and design right decided by any court or body (whether in the United Kingdom or elsewhere). The Office therefore arranges for the publication of the Reports of Patent, Design and Trade Mark Cases (RPCs).

123.77 The CDP Act amended s.123(7) to cover cases relating to Design Right, whether decided by the comptroller or by any court or body in the UK or elsewhere.

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Section 124: Rules, regulations and orders; supplementary

124.01 The ways in which rules, orders etc under the Act are made are governed by this section.

Section 124(1)

Any power conferred on the Secretary of State by this Act to make rules, regulations or orders shall be exercisable by statutory instrument.

The Secretary of State is given a general power to make rules by s.123 and also has the power to make rules for specific purposes under a number of other sections, eg s.125A concerning biological material; s.25(5) concerning notification of non-payment of renewal fees; s.32(1) and (2) concerning entries in the register; s.92(3) and (4) concerning evidence for use under the EPC; s.130(2) concerning international exhibitions; and supplementary protection certificates (see 123.02.1).

124.03 Certain provisions of the Act may be varied by rules made under s.25(2) (to vary the effective date of grant), s.48(2) (to vary the period after which compulsory licences become available) and ss.77(9) and 78(8) (to bring into effect, and to remove, requirements regarding translations of European patents (UK) and of the claims of applications for such patents).

124.04 [deleted]

124.05 The Secretary of State may by order under s.1(5) vary those things excluded from being treated as inventions.

124.06 All rules, regulations or orders such as mentioned above are made by statutory instrument.

Section 124(2)

Any Order in Council and any statutory instrument containing an order, rules or regulations under this Act, other than an order or rule required to be laid before Parliament in draft or an order under section 132(5) below, shall be subject to annulment in pursuance of a resolution of either House of Parliament.

124.07 Orders in Council which may be made under the Act are under s.54(1) where a patented invention is being worked abroad, under s.59(3) and (4) regarding Crown use during a period of emergency, under s.90(1) and (2) to declare a country to be a convention country and under s.132(2) to modify the Act as it applies in the Isle of Man.

124.08 Such Orders in Council and statutory instruments, with the following exceptions, are annulled if either House of Parliament so resolves. The exceptions are statutory instruments containing an order or rule required to be laid before Parliament in draft, ie an order under s.1(5) as referred to in 124.05 or a rule under s.25(2) or s.48(2) as referred to in 124.03, or an order under s.59(3) and (4) as referred to in 124.07 or under s.132(5) as referred to in 124.05.

Page 1 of 2 April 2007

Section 124(3)

Any Order in Council or order under any provision of this Act may be varied or revoked by a subsequent order.

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Section 124A: Use of electronic communications

124A.01 This section was introduced by the Patents Act 1977 (Electronic Communications) Order 2003 (S.I. 2003 No. 512), made under the provisions of Sections 8 and 9 of the Electronic Communications Act 2000, and came into force on 1 April 2003. It allows the comptroller to make directions on the form of electronic patent documents and the manner by which they are delivered by electronic communications to the Office. The provisions came into force in the Isle of Man by virtue of the Patents Act 1977 (Isle of Man) Order 2003 (SI 2003 No. 1249).

The comptroller has made Directions governing the following activities: filing patent applications by electronic means; filing documents relating to pending patent applications by electronic means; electronic delivery of applications to amend patents under s.27 and s.75; withdrawal of patent applications by email; email requests for extensions of specified periods; submitting third party observations by electronic means; submitting opinion observations by electronic means; and requesting electronic uncertified copies from patent files. The current Directions are reprinted in the "Relevant Official Notices and Directions" section of this Manual, and are available on the Office website at http://www.ipo.gov.uk.

Section 124A(1)

s.21

The comptroller may make directions as to the form and manner in which documents to be delivered to the comptroller –

- (a) in electronic form; or
- (b) using electronic communications,

are to be delivered to him.

Section 124A(2)

A direction under subsection (1) may provide that in order for a document to be delivered in compliance with the direction it shall be accompanied by one or more additional documents specified in the direction.

Section 124A(3)

Subject to subsections (14) and (15), if a document to which a direction under subsection (1) or (2) applies is delivered to the comptroller in a form or manner which does not comply with the direction the comptroller may treat the document as not having been delivered.

Section 124A(4)

Subsection (5) applies in relation to a case where -

- (a) a document is delivered using electronic communications, and
- (b) there is a requirement for a fee to accompany the document.

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Section 124A(5)

The comptroller may give directions specifying -

- (a) how the fee shall be paid;
- (b) when the fee shall be deemed to have been paid.

Section 124A(6)

The comptroller may give directions specifying that a person who delivers a document to the comptroller in electronic form or using electronic communications cannot treat the document as having been delivered unless its delivery has been acknowledged.

Section 124A(7)

The comptroller may make directions specifying how a time of delivery is to be accorded to a document delivered to him in electronic form or using electronic communications.

Section 124A(8)

A direction under this section may be given -

- (a) generally
- (b) in relation to a description of cases specified in the direction;
- (c) in relation to a particular person or persons.

Section 124A(9)

[repealed]

Section 124A(10)

[repealed]

Section 124A(11)

A direction under this section may be varied or revoked by a subsequent direction under this section.

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Section 124A(12)

[repealed]

Section 124A(13)

The delivery using electronic communications to any person by the comptroller of any document is deemed to be effected, unless the comptroller has otherwise specified, by transmitting an electronic communication containing the document to an address provided or made available to the comptroller by that person as an address of his for the receipt of electronic communications; and unless the contrary is proved such delivery is deemed to be effected immediately upon the transmission of the communication.

Section 124A(14)

A requirement of this Act that something must be done in the prescribed manner is satisfied in the case of something that is done-

- (a) using a document in electronic form, or
- (b) using electronic communications,

only if the directions under this section that apply to the manner in which it is done are complied with.

Section 124A(15)

In the case of an application made as mentioned in subsection 14(a) or (b) above, a reference in this Act to the application not having been made in compliance with rules of requirements of this Act includes a reference to its not having been made in compliance with any applicable directions under this section.

Section 124A(16)

This section applies-

(a) to delivery at, in, with or to the Patent Office as it applies to delivery to the comptroller;

and

(b) to delivery by the Patent Office as it applies to delivery by the comptroller.

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Section 125: Extent of invention

s.130(7) 125.01 Section 125 is intended to have, as nearly as practicable, the same effect as the corresponding provisions of the EPC, PCT and CPC.

Section 125(1)

For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.

This subsection sets out the meaning of an invention as that specified in a claim as interpreted by the description and any drawings, the protection conferred being determined accordingly. (The words "for a patent" in s.125(1) have apparently been inadvertently transposed and should follow the word "application" (first appearance), so then the sub-section should read: "For the purposes of this Act an invention for which an application for a patent has been made or etc"). It thus concerns the way in which the specification should be construed in this respect but does not impose any requirement with which the applicant must comply. Objection therefore should not be raised by the examiner under s.125(1) as such, although its provision may sometimes usefully be referred to when objecting on other grounds, eg under s.14(5). For example when a claim read on its own appears to be clear and to define the invention, such an objection under s.14(5) may arise if there is matter in the description which is inconsistent with the claim or in some other way casts doubt on the true scope of the invention, see 14.129 and 14.114-14.147.

125.03 [deleted]

125.04 [moved to 125.17.1]

125.05 [moved to 125.17.2]

s.125(3) s.130(7) 125.06 [deleted]

Biotechnological inventions

125.07 [moved to 125.27]

Section 125(2)

It is hereby declared for the avoidance of doubt that where more than one invention is specified in any such claim, each invention may have a different priority date under section 5 above.

125.08 If a claim is construed to specify more than one invention, the priority date of each invention should be determined separately. Note, partial priority may arise (see section 5, particularly 5.20 to 5.25.3).

Section 125(3)

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The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article.

The Protocol on the Interpretation of Article 69 of the EPC

125.09 Article 69(1) of the EPC corresponds to s.125(1) of the Act and reads:-

The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

125.10 Both Article 69 of the EPC and s.125(1) of the Act should be construed in the light of the Protocol on the Interpretation of Article 69 of the EPC, which reads:-

"Article 1 General principles

Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.

Article 2 Equivalents

For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."

125.11 [deleted]

125.12 [deleted]

General approach to construction

125.13 The reference in the first sentence of the Protocol to "resolving an ambiguity" rejects a literal approach to the construction of patent claims, where words were given their "natural and ordinary meaning" of words, ignoring their context or background unless they were ambiguous. The courts even prior to the Protocol were instead favouring a purposive construction of claims by giving effect to what would have been understood by the notional addressee. In *Catnic Components Ltd and another v Hill and Smith Ltd* [1982] RPC 183, Lord Diplock stated (at page 243):- "A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge".

125.14 The skilled reader is taken to suppose that the patentee knew some patent law – that his claim is for the purpose of defining the monopoly and that it should be for something new, as held by the Court of Appeal in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2010] RPC 8. Knowledge of that may well affect how the claim is construed. For instance, the patentee would not be expected to have claimed what he had expressly acknowledged was old.

125.15 [deleted]

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Relationship between the Protocol and the Catnic principle

125.16 [deleted]

Equivalents as a guide to construction and the Protocol questions

125.17 [deleted]

125.17.1 In approaching the construction of the claims the specification as a whole should be read to obtain the necessary background, and in some cases the meaning of the words used in the claims may be affected or defined by what is said in the body of the specification. In *Palmaz's European Patents (UK)* ([1999] RPC 47, upheld on appeal [2000] RPC 631) Pumfrey J held that words of degree such as "thin" must take their meaning from the context. Different meanings could not be attributed either to exclude acknowledged prior art or to be consistent with representations made by the patentee's patent attorneys in a letter to a patent office. Another example is *Glatt's Application* [1983] RPC 122 at page 129, where Whitford J considered that if a particular claim were looked at alone, it would not be assumed that a certain fabric was one which was in itself necessarily and inherently airpermeable. However, against the description of the invention in question "on its true construction the claims of the specification could properly only be read as being limited to an article suitable for conditioning fabrics comprising a flexible woven or non-woven airpermeable web".

In Hoechst Celanese Corp v BP Chemicals [1999] FSR 319 the Court of Appeal held that there was no rebuttable presumption that words in a patent specification which could have a technical meaning did have that meaning. The court was entitled to hear evidence on the meaning but thereafter had to decide on the meaning from the context in which they were used. See also 14.111 with regard to words used in a claim which are given a special meaning by the description. Caution should be used in considering the purpose or advantage of the invention. In Union Carbide Corp. v BP Chemicals Ltd [1999] RPC 409, it was held that where a stated advantage of the invention was that certain equipment was not required, the fact that a person used that equipment did not mean that he was not using the invention as he may have decided to use it badly.

The Protocol and the UK Supreme Court Judgment in Actavis v Eli Lilly

- 125.17.3 The requirements of the Protocol to give fair protection for the patentee and a reasonable degree of certainty for third parties were considered by the Supreme Court in *Actavis UK Limited and others v Eli Lilly and Company* [2017] UKSC 48.
- 125.17.4 Lord Neuberger noted that he did not consider that the last part of the first sentence of Article 1 only enables the description (i.e. the specification) and the drawings to be taken into account when interpreting the claims, in cases where the claims would otherwise be ambiguous. He also noted that it is apparent from Article 2 that there is at least potentially a difference between interpreting a claim and the extent of the protection afforded by a claim and, when considering the extent of such protection, equivalents must be taken into account.
- 125.17.5 He went on to say that notwithstanding what Lord Diplock said in *Catnic Components Ltd and another v Hill and Smith Ltd* [1982] RPC 183, a problem of infringement is best approached by addressing two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, i.e. the person skilled in the relevant art. Those issues are:
 - (i) does the variant infringe any of the claims as a matter of normal interpretation; and, if not,
 - (ii) does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?

If the answer to either issue is "yes", there is an infringement; otherwise, there is not. Such

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an approach complies with Article 2 of the Protocol, as issue (ii) squarely raises the principle of equivalents, but limits its ambit to those variants which contain immaterial variations from the invention. Issue (i) self-evidently raises a question of interpretation, whereas issue (ii) raises a question which would normally have to be answered by reference to the facts and expert evidence.

125.17.6 It was further held in *Actavis* that to conflate these two issues as a single question of interpretation, as had been done by Lord Hoffman in *Kirin-Amgen v Hoescht Marion Roussel Ltd* [2005] RPC 9, following his approach in *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181 (which itself had followed Lord Diplock's analysis in *Catnic*) is wrong in principle, and can lead to error. Instead, issue (ii) involves not merely identifying what the words of a claim would mean in their context to the notional addressee, but also considering the extent if any to which the scope of protection afforded by the claim should extend beyond that meaning. With regard to issue (i), in *Icescape Ltd v Ice-World International BV & Ors* [2018] EWCA Civ 2219, Kitchin LJ said "I have no doubt that...issue (i) involves purposive interpretation". Therefore when considering infringement using issue (i), purposive interpretation must still be used.

125.17.7 In Generics (U.K.) Limited and others v Yeda Research and Development Company Limited and others [2017] EWHC 2629 (Pat), Arnold J held that the doctrine of equivalents does not apply to novelty. Additionally, in Actavis Group PTC EHF v ICOS Corporation & Ors [2017] EWCA Civ 1671 the court said that there is nothing in Actavis v Eli Lilly to change the approach to the construction of the claims, i.e. what the skilled person would have understood the patentee to mean. This adds weight to the view that the new approach to determining scope of protection set out by the Supreme Court in Actavis v Eli Lilly is relevant to determining questions of infringement only, and not to other matters which depend purely on claim construction.

The Protocol Questions

125.18 In *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181, Hoffmann J formulated Lord Diplock's approach in *Catnic* into three questions which the court should ask itself. These have subsequently become known as the '*Improver*' questions, and in *Wheatley v Drillsafe Ltd* [2001] RPC 7 were re-named by the Court of Appeal, the 'Protocol questions'. In *Actavis* it was emphasised that these questions are guidelines, not strict rules that provide helpful assistance in determining whether a variant infringed. The UKSC in *Actavis* did however reformulate the questions as follows:

- (i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?
- (ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
- (iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was "yes" and that the answer to the third question was "no".

125.18.1 The first *Improver* question, which asks whether the variant has a material effect on the way in which the invention works, is a question which was framed in the context of a mechanical patent, and is not wholly aptly expressed for every type of case. However, in practice, the question as framed by Hoffmann J, with its emphasis on how "the invention" works, should correctly involve the court focussing on the "the problem underlying the invention". In effect, the question is whether the variant achieves the same result in

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substantially the same way as the invention. If the answer to that question is no, then it would plainly be inappropriate to conclude that it could infringe. If, by contrast, the answer is yes, then it provides a sound initial basis for concluding that the variant may infringe, but the answer should not be the end of the matter.

- 125.18.2 The reformulated second question should also apply to variants which rely on, or are based on, developments which have occurred since the priority date, even though the notional addressee is treated as considering the second question as at the priority date. It seems right in principle to have the same question, including the same assumption (i.e. that the variant works) for all cases. While the notional addressee may answer the reformulated second question affirmatively even where the variant was unforeseeable at the priority date, the Supreme Court held that he is less likely to do so in such circumstances.
- 125.18.3 If the variation represents an inventive step, while it may render it less likely that the patentee will succeed on the second reformulated question that alone should not necessarily prevent the resultant variant from infringing the original invention.
- The third Improver question as expressed by Hoffmann J is whether the 125.18.4 notional addressee would have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention. Although the language of the claim is important, consideration of the third question certainly does not exclude the specification of the patent and all the knowledge and expertise which the notional addressee is assumed to have. Further, the fact that the language of the claim does not on any sensible reading cover the variant is certainly not enough to justify holding that the patentee does not satisfy the third question. Hence, the fact that the rubber rod in Improver could not possibly be said to be "an approximation to a helical spring" was not the end of the infringement issue. When considering the third question, it is appropriate to ask whether the component at issue is an "essential" part of the invention, but that is not the same thing as asking if it is an "essential" part of the overall product or process of which the inventive concept is part. Hence in Improver the question was whether the spring would have been regarded by the addressee as essential to the inventive concept, or inventive core, of the patent in suit. Finally when one is considering a variant which would have been obvious at the date of infringement rather than at the priority date, it is necessary to imbue the notional addressee with rather more information than he might have had at the priority date.
- 125.18.5 In Actavis UK Limited and others v Eli Lilly and Company [2017] UKSC 48, the Supreme Court found that pemetrexed dipotassium would infringe a claim to pemetrexed disodium. The skilled person would understand that "the reason why the claims were limited to the disodium salt was because that was the only pemetrexed salt on which the experiments described in the specification had been carried out. However, it does not follow that the patentee did not intend any other pemetrexed salts to infringe". The Supreme Court went on to say that this suggestion "confuses the disclosure of the specification of a patent with the scope of protection afforded by its claims".
- 125.18.6 The above test is for determining whether certain equivalents fall within the scope of protection of the claims. This test does not mean that all equivalents are protected by the claims. Therefore any general statement within the description stating that the scope of protection of the claims includes all equivalents is not allowable.

125.19 [deleted]

125.20 [deleted]

Application of the Protocol questions

125.21 [deleted]

125.22 [deleted]

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125.23 [deleted]

Extent of Protection and the Protocol: Summary

125.24 [deleted]

125.25 [deleted]

Prosecution History

In Actavis it was held that it is appropriate for the UK courts to adopt a sceptical, but not absolutist, attitude to a suggestion that the contents of the prosecution file of a patent should be referred to when considering a question of interpretation or infringement. However, given that the contents of the file are publicly available and are unlikely to be extensive, there will be occasions when justice may fairly be said to require reference to be made to the contents of the file. However, not least in the light of the wording of Article 69 EPC 2000, which is discussed above, the circumstances in which a court can rely on the prosecution history to determine the extent of protection or scope of a patent must be limited. The Court held that reference to the file would only be appropriate where (i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (ii) it would be contrary to the public interest for the contents of the file to be ignored. The latter would be exemplified by a case where the patentee had made it clear that he was not seeking to contend that his patent, if granted, would extend its scope to the sort of variant which he now claims infringes. In L'Oréal Ltd v RN Ventures Ltd [2018] EWHC 173 (Pat), Carr J held that reference to the prosecution history is the exception and not the rule.

Biotechnological inventions

Schedule A2 to the Act was introduced by the Patents Regulations 2000 (2000 SI No 2037) as part of the implementation of Directive 98/44/EC on the legal protection of biotechnological inventions. Paragraphs 7 to 10 of the Schedule set out certain rules for the construction of claims which relate to biological material or to processes that enable biological material to be produced - see 76A.07-09.

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Section 125A: Disclosure of invention by specification: availability of samples of biological material

This section was introduced by the CDP Act, and has subsequently been amended by the Patents Regulations 2000 (SI 2000 No.2037). It sets out the provisions as to how an invention which involves the use of or concerns biological material may be disclosed and makes clear that ceasing to comply with the requirements on availability of samples of the biological material after a patent has been granted is a ground for revocation. S.125A has four subsections which essentially re-enact pre-CDP Act law and introduce a provision that access to samples of the biological material may be restricted to prescribed persons. The Patents Regulations 2000 substituted references to "microorganisms" in the first and second subsections of s.125A with references to "biological material" (see 125A.02.1) and also introduced into s.130(1) a definition of the term "biological material" - see 130.04.1. The Patents Act 1977 (Isle of Man) Order 2003 (SI 2003 No. 1249) amended these definitions for the Isle of Man.

Section 125A(1)

Provision may be made by rules prescribing the circumstances in which the specification of an application for a patent, or of a patent, for an invention which involves the use of or concerns biological material is to be treated as disclosing the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.

125A.02 No action is necessary under this section if the biological material in question is available to the public at the date of filing of the application (and remains so throughout the life of the application and resultant patent) or can be described in the specification in such a manner as to enable the invention to be performed by a person skilled in the art. The section provides an alternative way of disclosing the invention in such a manner.

PR Sch 5. Subsection (1) enables rules to be made prescribing how such 125A.02.1 paras 7 & 8 inventions may be disclosed. The relevant rules are contained in Schedule 1 to the Patents Rules 2007 which is given effect by r.13(1) of those Rules. (However, for patent applications PR Sch 1, filed before 27 July 2000, see paragraphs 7 and 8 of Schedule 5 to the Patents Rules 2007 para 2 for details of the provisions which apply). The Rules relating to biological material were amended by the Patents (Amendment) Rules 2001 (SI 2001 No.1412) to refer throughout to "biological material" instead of "micro-organisms". The Patents (Amendment) Rules 2001 also made a number of other changes to the Schedule, most notably that it is now possible, under certain conditions, for a patent applicant to rely on biological material which has previously been deposited by another party - instead of having to deposit his own sample of the material (see 125A.04).

The specification of an application relating to such an invention is, in relation to the biological material itself, treated as complying with s.14(3) if the first and second requirements set out in paragraph 3 of Schedule 1 to the Patents Rules 2007 are satisfied, and if the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material. Similarly, the disclosure in a patent specification is treated as clear enough and complete enough in this respect, and thus to not fall foul of s.72(1)(c) in this respect, if those requirements are satisfied. The requirements in question are described in 125A.04. The requirements for an application for a European patent (UK) or an international application for a patent (UK) are described in 125A.08. If a new deposit should prove necessary it should be made in accordance with paragraph 8 of Schedule 1 to the Patents Rules 2007, see 125A.24-25.

PR Sch 1, 125A.04 The first requirement is that, on or before the date of filing of the application, the biological material has been deposited in a depository institution which is

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- para 1 able to furnish a sample of the biological material. The second requirement is that, before the end of the period prescribed by paragraph 3(3) of Schedule 1 to the Patents Rules 2007 (see 125A.06), the name of the depository institution and the accession number of the deposit are given in the specification of the application; and where the biological material has been deposited by a person other than the applicant, a statement is filed which identifies the name and address of the depositor and a statement by the depositor is filed authorising the applicant to refer to the biological material in his application and giving the depositor's irrevocable consent to it being made available to the public. A "depository institution" means an institution which carries out the functions of receiving, accepting and storing biological material and the furnishing of samples of such biological material (whether generally or of a specific type); and conducts its affairs, in so far as they relate to the carrying out of those functions, in an objective and impartial manner.
 - 125A.05 It does not follow that failure to comply with this condition renders the specification not complete enough; the effect of this rule, which takes into account the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms, to which the United Kingdom is a party, is to specify measures which will ensure that the part of the description of an invention which requires for its performance the use of biological material will be regarded as clear and complete. It is open for an applicant to argue that, despite the absence of a deposit, the specification gives sufficient directions to enable the invention to be performed. If however this argument is rejected by the Office (and, as with inventions in other areas of subject-matter, the examiner will raise objection under s.14(3) only in the clearest cases) or by the courts, it is not possible to rectify the situation; the deposit cannot be made after the date of filing the application.
 - 125A.05.1 If an application relies on a biological deposit to enable the invention to be performed by the skilled person, and the deposit was made before the filing date but after the claimed priority date, then there will be no objection under s.14(3) as sufficiency is determined at the date of filing. However, the application will not be entitled to its priority date (for those aspects of the invention that rely on the deposit for their performance) and so may lack novelty and/or inventive step over documents published in the intervening period between the priority and filing dates. This was the conclusion of the Hearing Officer in *Cellartis AB's Application* BL O/050/11, as it was observed that the test for determining whether an invention is supported by matter disclosed in an earlier relevant application under s.5 is essentially the same as the test for determining sufficiency under s.14(3) see 5.23.
- PR Sch 1, 125A.06 The information identifying the deposit, as referred to in 125A.04, para 3(3) may be added to the application after the filing date provided that this is done -
 - (a) before the end of the period of sixteen months after the declared priority date or, where there is no declared priority date, the date of filing of the application;
 - (b) where the applicant has made a request under section 16(1) to publish the application during the period prescribed for the purposes of that section, on or before the date of that request; or
 - (c) where the applicant was notified under rule 52(2) that, in accordance with section 118(4), the comptroller has received a request by any person for information and inspection of documents under section 118(1), within one month of the date of the notification.

whichever is the earliest. This period may be extended in accordance with r.108(2) or (3) (and in accordance with r.108(4)-(6)), see 123.34-41. In any such case the front page of the application as published under s.16 should carry the following notice (see 16.29): "The information required by Schedule 1 to the Patents Rules 2007 paragraph 3(2)(a) or 3(2)(b) was not contained in the application as filed, but was supplied later in accordance with paragraph 3(3) of that Schedule." This notice should be amended to avoid ambiguity when more than one biological material is disclosed. The relevant information should be reproduced on the back of the front page of the published application.

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[The case examiner should give instructions via a dossier minute and PDAX message to the appropriate formalities group to arrange for the information to be published on the back of the front page of the 'A' document. Those instructions should specify the exact wording to be used, embodying the information provided by the applicant preceded by a heading "Information required by paragraph 3(2)(a) or 3(2)(b) of Schedule 1 to the Patents Rules 2007". If the standard text for the notice for the front page needs to be amended to avoid ambiguity where more than one biological material is disclosed, it is necessary for the case examiner to make this clear in the minute or to enter a suitable non-standard text on the "Notices for front page of 'A' document" form instead.]

125A.07 Following amendment by the Patents (Amendment) Rules 2001, there is no longer a requirement to supply the date when the biological material was deposited at the depositary institution. The date of making the deposit is readily ascertainable from the name of the depository institution and the accession number. There is also no longer a requirement to mention any international agreement (eg the Budapest Treaty) under which the biological material is deposited.

PR Sch 1, para 3(4)

125A.08 In the case of an application for a European patent (UK) which has been filed under the provisions of the EPC which correspond to the second requirement set out in paragraph 3(2) of Schedule 1 to the Patents Rules 2007 (ie EPC r.31) or an international application for a patent (UK) which has been filed under the corresponding provisions of the PCT (ie PCT r.13bis.3), the second requirement should be treated as having been met.

125A.09 [Deleted]

125A.10 If not all of the requirements of paragraph 3 of Schedule 1 to the Patents Rules 2007 have been complied with, the examiner must form an opinion as to whether or not the biological material is available to the public. There are several possibilities. The biological material may be known to be readily available to those skilled in the art, eg a micro-organism such as baker's yeast or Bacillus natto which is commercially available; or it may be a standard preserved strain, or other micro-organism which the examiner knows to have been preserved in a culture collection and to be available to the public. Alternatively the applicant may have given in the description sufficient information as to the identifying characteristics of the biological material and as to the prior availability in a culture collection. In any of these cases no further action is called for. If however the applicant has given no information, or insufficient information, on public availability (and the biological material is of a particular type not falling within the known categories such as those already mentioned) then the examiner must assume that the material is not available to the public. He must also examine whether the biological material is described in such a manner as to enable the invention to be carried out by a person skilled in the art.

125A.11 If the biological material is not available to the public and if it is not described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art, and paragraph 3 of Schedule 1 to the Patents Rules 2007 has not been adequately complied with, then objection under s.14(3) will be necessary. The view is taken that it is virtually impossible to comply with s.14(3) only by deposit of biological material in accordance with paragraph 3 where the invention concerns a new species or higher classification of micro-organisms. Consequently broad claims to a new species or higher classification of micro-organism should not normally be allowed.

[If it is considered that a specification containing an invention claimed in such broad terms can meet the requirements of s.14(3) by other means the case should be referred to the Divisional Director with a brief note of the circumstances.]

125A.12 Until such matters are tested in the courts, no guidance can be given as to what extent deposit will be necessary in other circumstances, eg when claims are directed to a new micro-organism produced by genetic manipulation from a known

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micro-organism, whether a deposit of the new micro-organism will be necessary. It could be argued that in this case the new micro-organism (which is the product of the process disclosed) is not necessary for the performance of the invention. The prudent applicant will in general resolve any doubts as to whether a deposit is needed in favour of making the deposit.

- So long as paragraph 3 of Schedule 1 to the Patents Rules 2007 is satisfied in respect of a deposited strain, then claims may be allowed to the deposited strain and to mutant or variant strains derived therefrom provided that those mutants or variants produce the desired product (eg antibiotic) identified in the specification. If specific methods of producing such mutants or variants are not given in the description, it is considered that the courts will construe such claims as being restricted to mutants or variants produced by standard or conventional methods well known to those working in the micro-organism field and thus as being unobjectionable. If however the claims are restricted to a single strain of a micro-organism then deposition of a sample and disclosure of the species name of the micro-organism can be sufficient to meet the requirements of paragraph 3.
- 125A.14 Where the obtaining of novel biological material, e.g. a novel microorganism, depends on a random event with little likelihood of repetition the requirements of s.14(3) are not regarded as satisfied unless a deposit has been made. In particular, since a cell line is dependent for its origin on the random selection of a cell, a deposit will be necessary when an invention requires a cell line for its performance.
- 125A.15 Compliance with paragraph 3 of Schedule 1 to the Patents Rules 2007 ensures that the disclosure meets the requirements of s.14(3) only to the extent that the invention requires the otherwise unavailable biological material for its performance, and there are other ways in which the disclosure in a specification relating to biological material can be deficient. For example when the claims are directed to the production of a new micro-organism (from or using available micro-organisms), a description as to how the new micro-organism has been obtained will be necessary to satisfy s.14(3), even if a deposit of the new micro-organism has been made.
- 125A.16 The deposit of biological material may be made in any depository institution, anywhere in the world. The depository institution need not have International Depository Authority (IDA) status. (A deposit in an IDA is recognised for the purposes of patent procedure in all Contracting States of the Budapest Treaty and in the EPO). It is the applicant's responsibility to satisfy himself that a particular biological material will be accepted by a collection which he has selected and that samples will be made available in accordance with Schedule 1 to the Patents Rules 2007.

Section 125A(2)

The rules may in particular require the applicant or patentee -

- (a) to take such steps as may be prescribed for the purposes of making available to the public samples of the biological material, and
- (b) not to impose or maintain restrictions on the uses to which such samples may be put, except as may be prescribed.
- Rules made under this section may prescribe how samples of the biological material shall be made available to the public. The giving of the information identifying the deposit, as referred to in 125A.04, is interpreted as providing the applicant's consent to the release of a sample by the depository institution on receipt of the comptroller's certificate authorising such release to the person who is named therein and who makes a valid request to the institution.

PR Sch 1, 125A.18 In order to obtain the comptroller's certificate, Patents Form 8

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- paras 4 (Request for a certificate authorising the release of a sample of biological material) should be submitted to the Office. After the publication of an application for a patent, Form 8 may be filed by any person desiring a sample; before such publication, it should only be filed by a person who has been notified in accordance with section 118(4) (see 125A.06(c)). If the patent applicant has given notice to the comptroller on Patents Form 8A of his intention that a sample of the biological material should be made available only to an expert, see 125A.26-33; otherwise, the following procedure should be used.
- PR Sch 1, 125A.19 If the depository institution in which the material has been deposited is an international depository authority (in accordance with Article 7 of the Budapest Treaty), the form provided for by the Regulations under that Treaty (BP12) should be filed with Form 8. Blank Forms BP12 are obtainable from the Office.

125A.20 Form 8 includes an undertaking by the person making the request -

- PR Sch 1, (a) not to make the biological material, or any material derived from it, available para 5(1) to any other person; and
 - (b) not to use the biological material, or any material derived from it, otherwise than for experimental purposes relating to the subject matter of the invention.
- PR Sch 1, paras 5(2) application or any resultant patent is extant but the undertaking apply for as long as the application or any resultant patent is extant but the undertakings shall cease to have effect when the application is terminated or withdrawn or when the patent ceases to have effect. These periods include any extension allowed under r.107 or 108 (but not any period prior to reinstatement under either rule). For the purpose of any act of Crown use specified in s.55 in relation to the biological material, such an undertaking is not required of, or is ineffective if given by, any government department or person suitably authorised thereby. The undertaking may be varied by way of derogation by agreement between the parties; and the undertaking is ineffective to the extent necessary for effect to be given to any licence of right or compulsory licence under the patent in question.
- PR Sch 1, 125A.22 The Office sends a copy of Form 8 (and BP12, if filed) and of the comptroller's certificate authorising the release of the sample to the patent applicant or proprietor, the depository institution and the person making the request.
 - 125A.23 If the patent applicant or proprietor and the depository institution are agreeable to the release of a sample merely upon the request of a third party, there is no need for Form 8 to be filed or the comptroller's certificate to be issued.
- PR Sch 1, 125A.24 Where a deposit (either original or a replacement) of biological para 8 material has been made at a depository institution, and either -
 - (a) the biological material ceases to be available from the institution because the biological material is no longer viable;
 - (b) the depository institution is, for any other reason, unable to supply the biological material;
 - (c) the place where the biological material is deposited is no longer a depositary institution for that type of material (whether temporarily or permanently); or
 - (d) the biological material is transferred to a different depositary institution;
- PR Sch 1, the first and second requirements described in 125A.04 are treated as having been complied with if, by the end of the period of three months after the date on which the depositor is notified by the depositary institution that (a), (b), (c) or (d) occurred or, where it expires later, three months after the date on which that circumstance is advertised in the journal:

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- (a) where (a), (b) or (c) above occurs:
 - (i) a new deposit of biological material is made at the relevant depositary, and
 - that deposit is accompanied by a statement, signed by the person making the deposit, that the biological material deposited is the same as that originally deposited; and
- (b) in all circumstances set out above, the applicant or proprietor applies to the comptroller to amend the specification of the application for the patent, or the patent, so that it meets the second requirement.

Where the biological material is no longer viable, the new deposit should be made with the same depository institution as the original deposit. In any other case, it may be made with another depositary institution.

PR Sch 1, 125A.25 No interruption is deemed to have occurred in the availability of the deposit if the actions described in 125A.24 are carried out within three months of the date on which the depositor was notified of the interruption by the depositary institution or, where it expires later, three months after the date on which that circumstance is advertised in the journal.

Section 125A(3)

The rules may provide that, in such cases as may be prescribed, samples need only be made available to such persons or descriptions of persons as may be prescribed; and the rules may identify a description of persons by reference to whether the comptroller has given his certificate as to any matter.

125A.26 The rules may qualify the public availability requirements by allowing samples to be made available only to prescribed persons or descriptions of persons. Thus, under paragraph 6 of Schedule 1 to the 2007 Rules, the patent applicant can choose to restrict the release of samples to experts, until the patent is granted or until 20 years from the filing date if the patent is never granted.

PR Sch 1, 125A.27 To take advantage of this provision, the applicant must give notice on Patents Form 8A before the preparations for s.16 publication of the application have been completed. The formalities examiner should then arrange for a standard footnote to be published on the front page of the published application (see 16.29) to state that such notice has been given.

PR Sch 1, para 6(5)
PR Sch 1, para 6(6)

125A.28

It is then not possible to obtain the comptroller's certificate authorising release of a sample (as described in 125A.18-22) until the patent is granted, or until 20 years from the date on which the application was filed, if the application is terminated or withdrawn. The following procedure must instead be followed. (This restriction to experts is however inapplicable to Crown use by a government department or any person authorised in writing by a government department, under s.55.)

PR Sch 1, para 7(1), 7(2) and 5(1) if the depository institution is an international depository authority, as described in 125A.29. Any third party wishing to have a sample made available has to apply on Patents Form 8 (in duplicate) nominating a particular expert. This should be accompanied by the form provided for by the Regulations under the Budapest Treaty (BP12) if the depository institution is an international depository authority, as described in 125A.19. The undertaking as in 125A.20-21 must be signed by the nominated expert.

PR Sch 1, paras 7(3) The Office sends a copy of Form 8 to the applicant for the patent, giving him a period of one month (which may be extended by a further month under r.108(1) if an adequate reason is given) in which to object to a sample being made available to the expert.

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[The decision whether to extend the period for objection should be taken by the appropriate divisional Head of Admin.]

PR Sch 1, 125A.31 If the applicant does not object, the Office sends a copy of Form 8 (and BP12, if filed) and of the comptroller's certificate authorising the release of the sample to the applicant for the patent, the depository institution where the sample of the biological material is stored, the person making the request and the expert.

PR Sch 1, para 7(4) r.73(1) PR part 7 125A.32 Where the applicant does object, the comptroller has to determine the matter, having given the applicant and the third party making the request the opportunity of being heard. The applicant should notify his objection by filing (in duplicate) Form 2 and a statement of grounds. This starts proceedings before the comptroller, which give an opportunity for the filing of a counter-statement by the third party and if necessary evidence from the applicant and the third party before the matter is heard; the procedure is discussed at 123.05 – 123.05.13. Evidence may be filed as to the knowledge, experience, independence and technical qualifications of the expert. If the comptroller decides to authorise the release of the sample to the expert, action is taken as in 125A.31.

125A.33 If the comptroller decides not to issue his certificate in favour of the expert, the third party may nominate another person as the expert and (subject to such directions as the comptroller thinks fit) the above procedure may be repeated until an expert is accepted.

Section 125A(4)

An application for revocation of the patent under section 72(1)(c) above may be made if any of the requirements of the rules cease to be complied with.

125A.34 Ceasing to comply with the requirements of rules made under this section, eg by ceasing to make samples accessible to the public, is a ground for revocation of a patent. Compliance with the provisions of Schedule 1 to the 2007 Rules, so that the patent discloses the invention clearly enough and completely enough for it to be performed by a person skilled in the art, is necessary.

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Section 126: Stamp duty [repealed]

This section was neither concerned with applications made, or patents granted, under the 1977 or 1949 Act, nor to European patents (UK). It concerned the liability for stamp duty of instruments (e.g. assignments) relating to Community patents or to applications for certain European patents which were intended to mature into Community patents. However, the section never had any effect because the Community Patent Convention did not come into force prior to the section being repealed by s.156 of, and Schedule 40 to, the Finance Act 2000.

See 32.09 for details of stamp duty requirements for instruments relating exclusively to intellectual property or in part to intellectual property and in part to other property.

126.02 [deleted]

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Section 127: Existing patents and applications

127.01 This section provided for the position of 1949 Act patents and applications as a result of the advent of the 1977 Act. It authorises Schedules 1 to 4 to the 1977 Act which respectively set out which provisions of the 1949 Act and of the 1977 Act applied in relation to 1949 Act patents and applications, repealed certain provisions of the 1949 Act and made transitional provisions. All patents granted under the 1949 Act have now expired.

Section 127(1)

No application for a patent may be made under the 1949 Act on or after the appointed day.

s.130(1) 127.02 The "appointed day" on which s.127 came into operation was 1 June 1978. From that day onwards, it has not been possible to make an application for a patent under the Patents Act 1949.

Section 127(2)

Schedule 1 to this Act shall have effect for securing that certain provisions of the 1949 Act shall continue to apply on and after the appointed day to -

- (a) a patent granted before that day:
- (b) an application for a patent which is filed before that day, and which is accompanied by a complete specification or in respect of which a complete specification is filed before that day;
- (c) a patent granted in pursuance of such an application.

127.03 Certain provisions of the 1949 Act as set out in Schedule 1 applied to 1949 Act applications for which a complete specification was filed before 1 June 1978 and to patents granted before 1 June 1978 or in pursuance of such an application. Those 1949 Act provisions applied subject to various qualifications given in Schedules 1, 3 and 4.

127.04-05 [deleted]

Section 127(3)

Schedule 2 to this Act shall have effect for securing that (subject to the provisions of that Schedule) certain provisions of this Act shall apply on and after the appointed day to any patent and application to which subsection (2) above relates, but, except as provided by the following provisions of this Act, this Act shall not apply to any such patent or application.

127.06 Certain provisions of the 1977 Act as set out in Schedule 2 have, from 1 June 1978, applied to the 1949 Act applications and patents mentioned in 127.03. Those 1977 Act provisions applied subject to various qualifications given in Schedules 2 and 4.

127.07 [deleted]

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Section 127(4)

An application for a patent which is made before the appointed day, but which does not comply with subsection (2)(b) above, shall be taken to have been abandoned immediately before that day, but, notwithstanding anything in section 5(3) above, the application may nevertheless serve to establish a priority date in relation to a later application for a patent under this Act if the date of filing the abandoned application falls within the period of fifteen months immediately preceding the filing of the later application.

127.08 1949 Act applications for which a complete specification was not filed before 1 June 1978 were treated as abandoned. However, such an application could provide priority for a subsequent 1977 Act application filed within fifteen months of the date of filing of the abandoned application.

Section 127(5)

Schedule 3 to this Act shall have effect for repealing certain provisions of the 1949 Act.

127.09 Certain provisions of the 1949 Act which have no counterpart in the 1977 Act were repealed, as set out in Schedule 3 but subject to the transitional provisions of Schedule 4.

Section 127(6)

The transitional provisions and savings in Schedule 4 to this Act shall have effect.

Sch. 4, 127.10 Schedule 4 makes provision for the transition from the 1949 Act to the 1977 Act. It provides that anything done under a 1949 Act provision (since repealed by the 1977 Act) which could have been done under a corresponding 1977 Act provision has effect as if done under the latter. It also makes specific provision with regard to the use of patented inventions for services of the Crown, infringement, notices of opposition to the grant of 1949 Act patents, secrecy directions, revocation (including appeals from the court), licences of right and compulsory licences, convention countries, appeals from the comptroller under continuing or repealed provisions of the 1949 Act, appeals from the Patents Appeal Tribunal to the Court of Appeal and the power to make rules.

Section 127(7)

In Schedules 1 to 4 to this Act "existing patent" means a patent mentioned in subsection (2)(a) and (c) above, "existing application" means an application mentioned in subsection (2)(b) above, and expressions used in the 1949 Act and those Schedules have the same meanings in those Schedules as in that Act.

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Section 128: Priorities between patents and applications under 1949 Act and this Act [spent]

128.01 This section provided transitional provisions to resolve questions of priority between 1949 Act and 1977 Act patents and applications (including European patents (UK)), and is now spent.

Section 128(1)

The following provisions of this section shall have effect for the purpose of resolving questions of priority arising between patents and applications for patents under the 1949 Act and patents and applications for patents under this Act.

Section 128(2)

A complete specification under the 1949 Act shall be treated for the purposes of sections 2(3) and 5(2) above -

- (a) if published under that Act, as a published application for a patent under this Act;
- (b) if it has a date of filing under that Act, as an application for a patent under this Act which has a date of filing under this Act;

and in the said section 2(3), as it applies by virtue of this sub-section in relation to any such specification, the words "both as filed and" shall be omitted.

Section 128(3)

In section 8(1), (2) and (4) of the 1949 Act (search for anticipation by prior claim) the references to any claim of a complete specification, other than the applicant's, published and filed as mentioned in section 8(1) shall include references to any claim contained in an application made and published under this Act or in the specification of a patent granted under this Act, being a claim in respect of an invention having a priority date earlier than the date of filing the complete specification under the 1949 Act.

Section 128(4)

In section 32(1)(a) of the 1949 Act (which specifies, as one of the grounds of revoking a patent, that the invention was claimed in a valid claim of earlier priority date contained in the complete specification of another patent), the reference to such a claim shall include a reference to a claim contained in the specification of a patent granted under this Act (a new claim) which satisfies the following conditions -

- (a) the new claim must be in respect of an invention having an earlier priority date than that of the relevant claim of the complete specification of the patent sought to be revoked; and
- (b) the patent containing the new claim must be wholly valid or be valid in those respects which have a bearing on that relevant claim.

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Section 128(5)

For the purposes of this section and the provisions of the 1949 Act mentioned in this section the date of filing an application for a patent under that Act and the priority date of a claim of a complete specification under that Act shall be determined in accordance with the provisions of that Act, and the priority date of an invention which is the subject of a patent or application for a patent under this Act shall be determined in accordance with the provisions of this Act.

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Section 128A: EU compulsory licences

This section was introduced by regulation 2 of the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007 (SI 2007 No. 3293), on 17 December 2007. It sets out how certain provisions of the Act apply to EU compulsory licences, and applications for such licences, under the Compulsory Licensing Regulation (namely, Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems). The Compulsory Licensing Regulation provides for the availability of a compulsory licence for anyone who wishes to make a specific patented pharmaceutical product solely in order to export it to a developing country with a particular public health problem. Section 128A does not implement those provisions of the Regulation that are directly applicable in relation to UK patents.

PR rr.73-88

The Compulsory Licensing Regulation sets out a number of proceedings which may take place before the comptroller in relation to these EU compulsory licences. These include proceedings to apply for, modify or revoke such a licence. All proceedings in relation to such licences fall within the scope of Part 7 of the Patents Rules 2007, which governs procedures in relation to all proceedings before the comptroller in relation to patents. Reference should be made to paragraphs 123.05 to 123.05.13, which set out in general terms how proceedings (such as an application for an EU compulsory licence) are launched under Part 7 of the Rules, and how such proceedings would then progress.

128A.03 Section 128A and related provisions in the Rules to EU compulsory licences do not apply in the Isle of Man.

Section 128A(1)

In this Act an "EU compulsory licence" means a compulsory licence granted under Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (referred to in this Act as "the Compulsory Licensing Regulation").

128A.04 Subsection (1) defines the terms "EU compulsory licence" and "the Compulsory Licensing Regulation".

Section 128A(2)

In the application to EU compulsory licences of the provisions of this Act listed in subsection (3) -

- (a) references to a licence under a patent,
- (b) references to a right under a patent, and
- (c) references to a proprietary interest under a patent,

include an EU compulsory licence.

Section 128A(3)

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The provisions referred to in subsection (2) are -
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sections 32 and 33 (registration of patents etc);
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section 37 (determination of right to patent after grant);

section 38 (effect of transfer etc of patent under section 37), apart from subsection (2) and subsections (3) to (5) so far as relating to subsection (2);

section 41 (amount of compensation);

section 46(2) (notice of application for entry that licences are available as of right);

section 57(1) and (2) (rights of third parties in respect of Crown use).

Subsections (2) and (3) together make clear that certain references in the Act to a licence or a right or a proprietary interest under a patent include within their meaning an EU compulsory licence granted under the Compulsory Licensing Regulation. In particular, subsection (3) identifies the sections of the Act to which the gloss set out in subsection (2) applies. Thus, for example, references in section 38(1) to the continuation in force of licences (in certain circumstances following an entitlement dispute) include not only licences granted under the Act but also EU compulsory licences granted under the Compulsory Licensing Regulation. It should be noted that references to licences in section 38(2) do not include EU compulsory licences. This is because section 38(2) sets out that in certain circumstances a licence under a patent may lapse when a person becomes the new proprietor of the patent following entitlement proceedings – but the Compulsory Licensing Regulation does not envisage that an EU compulsory licence could lapse in such circumstances.

Section 128A(4)

In the following provisions references to this Act include the Compulsory Licensing Regulation –

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sections 97 to 99B, 101 to 103, 105 and 107 (legal proceedings);
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section 119 (service by post);

section 120 (hours of business and excluded days);

section 121 (comptroller's annual report);

section 123 (rules);

section 124A (use of electronic communications);

section 130(8) (disapplication of Part 1 of Arbitration Act 1996).

Subsection (4) makes clear that certain references in the Act to the Act itself include within their meaning the Compulsory Licensing Regulation. For example, the reference in section 120 to the Office's opening hours and business done "under this Act" includes business done by the Office under the provisions of the Compulsory Licensing Regulation.

Section 128A(5)

In section 108 (licences granted by order of comptroller) the reference to a licence under section 11, 38, 48 or 49 includes an EU compulsory licence.

Subsection (5) makes clear that the reference to "a licence under section 11, 38, 48 or 49" includes within its meaning a licence under the Compulsory Licensing

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Regulation. Thus any order for the grant of an EU compulsory licence shall, without prejudice to any other method of enforcement, have effect as if it were a deed (executed by the patent proprietor and all other necessary parties) granting a licence in accordance with the order. This ensures that such an order under the Compulsory Licensing Regulation will be effective even if the parties affected take no action in response to it.

Section 128A(6)

References in this Act to the Compulsory Licensing Regulation are to that Regulation as amended from time to time.

128A.08 Subsection (6) ensures that, if the Compulsory Licensing Regulation is amended in the future, the references to it in the Act will continue to apply without further amendment being needed.

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Section 128B: Supplementary Protection Certificates

This section was introduced by regulation 2 of the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007 (SI 2007 No. 3293), on 17 December 2007. In combination with Schedule 4A to the Act, it sets out how certain provisions of the Act apply to supplementary protection certificates, and applications for such certificates. These certificates exist under the two supplementary protection certificates Regulations – namely Regulation (EC) No 469/2009 of 6 May 2009 (which superseded Council Regulation (EEC) No 1768/92 of 18 June 1992) concerning the supplementary protection certificate for medicinal products, and Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products. These two Regulations are referred to in the Act as "the Medicinal Products Regulation" and "the Plant Protection Products Regulation". Section 128B and Schedule 4A do not implement those provisions of the Regulations that are directly applicable.

The Medicinal Products and Plant Protection Products Regulations provide for the availability of a supplementary protection certificate in order to compensate a patentee for the loss of effective protection arising out of the time taken to obtain regulatory approval for a medicinal or plant protection product which is protected by a patent. The Medicinal Products Regulation also provides for the possibility of a six month extension to a certificate if the product in question has undergone an approved investigation plan for use on children.

The 1992 Medicinal Products Regulation and Plant Protection Products Regulation were originally implemented in the UK by the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 (SI 1992 No 3091) and the Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996 (SI 1996 No 3120). On the introduction of section 128B and Schedule 4A, these original implementing Regulations were revoked. The general application of the Act to supplementary protection certificates that they set out was replaced, in Schedule 4A, with a more specific list of provisions in the Act which apply (with the necessary glosses) to supplementary protection certificates in the UK. Legislation equivalent to the 1992 and 1996 implementing Regulations continued to apply in the Isle of Man until the Patents (Isle of Man) Order 2013 (SI 2013/2602), which modified the Patents Act as it applies to the Isle of Man to introduce section 128B and Schedule 4A (see paragraph SP0.05).

The Medicinal Products and Plant Protection Products Regulations set out a number of proceedings which may take place before the comptroller in relation to supplementary protection certificates. These include proceedings to apply for a declaration of invalidity of a certificate, or to apply for revocation of a "paediatric" extension to a certificate. All proceedings before the comptroller in relation to certificates fall within the scope of Part 7 of the Patents Rules 2007, which also governs procedures in relation to all proceedings before the comptroller in relation to patents. Reference should be made to paragraphs 123.05 to 123.05.13, which set out in general terms how proceedings are launched under Part 7 of the Rules, and how such proceedings would then progress.

Detailed commentary on the Medicinal Products and Plant Protection Products Regulations, and on UK implementation and practice, is provided in the separate part of this Manual which is dedicated to supplementary protection certificates.

Section 128B(1)

Schedule 4A contains provision about the application of this Act in relation to supplementary protection certificates and other provision about such certificates.

128B.06 Paragraph 1(1) of Schedule 4A makes clear that certain references in the

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Act which relate to patents should, in relation to supplementary protection certificates, be construed differently. Thus, for example, references to a patent proprietor are construed as references to the holder of a certificate, and references to a patented product or invention are construed as references to a product for which a certificate has effect. Paragraph 1(2) of the Schedule identifies the sections of the Act to which these various glosses set out in paragraph 1(1) apply. Thus, for example, section 19(1) applies to an application for a certificate, but the references in section 19(1) to the ability of a patent applicant to amend his application before grant are construed as references to the ability of an applicant for a certificate to amend his application for a certificate before that certificate is granted.

128B.07 Paragraph 2 of the Schedule makes clear that certain provisions of the Act which refer to a patent application are only construed as referring to an application for a certificate in the circumstances where the patent has expired while the application for the certificate is still pending. This ensures that certain rights associated with a patent application (notably, the provisional protection provided by section 69) only become rights associated with an application for a certificate in the circumstances where there are no patent rights still in force.

128B.08 Paragraph 3 of the Schedule makes clear that certain references in the Act to the Act itself include within their meaning the Medicinal Products and Plant Protection Products Regulations, and similarly that certain references in the Act to a section of the Act include within their meaning the equivalent provision of those Regulations. For example, the references in section 124A to "requirements of the Act" are taken to include requirements set out within the provisions of the Medicinal Products or Plant Protection Products Regulations.

Paragraph 4 of the Schedule deals with two specific glosses which require more detailed explanation than those set out in the list in paragraph 1(1) of the Schedule. In accordance with paragraph 4, the reference in section 21(1) to the question of whether the invention is a patentable one is to be construed, for the purposes of supplementary protection certificates, as a question of whether the product is one for which a certificate may have effect. Also, the condition in section 69(2)(b) is to be construed as being that the act in question would, if the certificate had been granted on the date of publication of the application, have infringed not only the certificate as granted but also the certificate for which the application was made.

128B.10 Paragraph 5 of the Schedule states that a certificate does not take effect unless the prescribed fee is paid before the end of the prescribed period, or the prescribed fee and any prescribed additional fee are paid before the end of the period of six months beginning immediately after the prescribed period. See paragraphs SPM12.01 to 12.14 for a detailed discussion of fees in relation to certificates.

Paragraph 6 of the Schedule states that expressions used in the Act that are defined in the Medicinal Products or Plant Protection Products Regulations have the same meaning as in those Regulations. Furthermore, paragraph 6(2) ensures that, if those Regulations are amended in the future, the references to them in the Act will continue to apply without further amendment being needed. Paragraph 7 of the Schedule defines the terms "Medicinal Products Regulation" and "Plant Protection Products Regulation". This paragraph was amended by the Patents (Supplementary Protection Certificate) Regulations 2014 (SI 2014 No. 2411) in order to update the definition of the Medicinal Product Regulation to refer to the 2009 EC Regulation. Paragraph 8 of the Schedule sets out transitional provisions which ensure that a reference in the Act to the 2009 EC Regulation is read as being, or including, a reference to the superseded 1992 EEC Regulation for all relevant purposes.

Section 128B(2)

In this Act a "supplementary protection certificate" means a certificate issued under—

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- (a) Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6th May 2009 concerning the supplementary protection certificate for medicinal products, or
- (b) Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.
- Subsection (2) defines the term "supplementary protection certificate" for the purposes of the Act (and rules made under it). It was amended by the Patents (Supplementary Protection Certificate) Regulations 2014 (SI 2014 No. 2411) in order to update the reference to the Medicinal Product Regulation.

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Section 129: Application of Act to Crown

Section 129

This Act does not affect Her Majesty in her private capacity, but subject to that, it binds the Crown.

129.01 The Crown (except the Sovereign) is thus bound by the Act. However the Act gives specific rights to the Crown in respect of use of patented inventions for the services of the Crown, under ss.55 to 59, and use or disposal by the Crown of articles forfeited under customs or excise law, under s.122.

Page 1 of 1 April 2007

Section 130: Interpretation

130.01 This section defines certain terms used in the Act and, in subsections (7) and (9), is concerned with the interpretation and construction of certain provisions and references. It should be noted that other terms are defined in other sections of the Act, for example "relevant application" is defined in s.5(5) (see 5.30), although some of those definitions apply only in specified section(s).

Section 130(1)

In this Act, except so far as the context otherwise requires -

"application fee" means the fee prescribed for the purposes of section 14(1A) above;

"application for a European patent (UK)" and (subject to subsection (4A) below)
"international application for a patent (UK)" each mean an application of the relevant description which, on its date of filing, designates the United Kingdom;

130.02 The definitions in subsection (1) thus apply throughout the Act unless the context otherwise requires.

The terms "date of filing", "designate", "European patent (UK)" and "international application for a patent" (used in the above definitions) are defined later in subsection (1), see below.

Section 130(1)

"appointed day", in any provision of this Act, means the day appointed under section 132 below for the coming into operation of that provision;

130.04 See 132.06 to 132.08.

Section 130(1)

"biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

"biotechnological invention" means an invention which concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used;

130.04.1 These definitions were introduced into s.130(1) by the Patents Regulations 2000 (SI 2000 No.2037). Schedule A2 to the Act (also introduced by the Patents Regulations 2000 under s.76A) makes certain specific provisions concerning "biotechnological inventions", as defined above. References to "biological material" in that Schedule and elsewhere in the Act are also to be interpreted in the light of the above definition.

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Section 130(1)

"Community Patent Convention" means the Convention for the European Patent for the Common Market;

Section 130(1)

"comptroller" means the Comptroller-General of Patents, Designs and Trade Marks;

130.05 It is a requirement of the Patents and Designs Act 1907 that there is a "Comptroller General of Patents, Designs, and Trade Marks"; the definition in s.130(1) is therefore intended to allow for brevity in the Patents Act 1977 whilst ensuring consistency with the 1907 Act. The comptroller is appointed by the Secretary of State under s.63(1) of the 1907 Act.

130.05.1 Any act or thing directed to be done by or to the comptroller may be done by or to any officer authorised by the Secretary of State (see s.62(3) of the 1907 Act) or any officer authorised by the comptroller himself (see s.74 of the Deregulation and Contracting Out Act 1994). The current authorisation, dated 11 August 2014, authorises various officers of the Office to perform functions of the comptroller in accordance with the following schedule. Like previous authorisations, it is drawn in broader terms than will normally be applied in practice.

130.05.2 The comptroller's tribunal function in respect of patent disputes under the Patents Act 1977 was considered to be a court for the purposes of Article 24 of the Council Regulation (EC) 44/2001 (now Article 26 of Regulation (EU) No. 1215/2012) in Future New Developments Ltd v B & S Patente Und Marken GmbH [2014] EWHC 1874 (IPEC).

SCHEDULE

Column 1	Column 2
DIRECTOR (REGISTERED RIGHTS), DIVISIONAL DIRECTORS (PATENTS) AND DEPUTY DIRECTORS (PATENTS)	 All the provisions of: (i) the Patents Acts 1949 and 1977, (ii) the Registered Designs Act 1949, (iii) the Copyright, Designs and Patents Act 1988, and (iv) the Trade Marks Acts 1938 and 1994. The relevant Rules, Orders and Regulations made under the above Acts. All the provisions of the Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002.

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	4.	Regulation 36 of the European Communities (Recognition of Professional Qualifications) Regulations 2007.
OFFICERS OF SPAN D1 (PATENTS), SENIOR PATENT EXAMINERS	1.	All the provisions of the Patents Acts 1949 and 1977 except insofar as they involve: (i) opposed requests, references and applications, or (ii) the refusal of any application or
		request where the refusal is disputed by the applicant or requester and where the technical content of specifications is involved.
	2.	All the provisions of the Registered Designs Act 1949.
	3.	The relevant Rules, Orders and Regulations made under the above Acts.
PATENT EXAMINERS, ASSOCIATE PATENT EXAMINERS AND PRIVATE APPLICANT UNIT EXAMINERS	1.	All the provisions of the Patents Act 1977 except insofar as they involve:
		(i) opposed requests, references and applications, or
EXAMINENO		(ii) the refusal of any application or request where the refusal is disputed by the applicant or requester.
	2.	The relevant Rules, Orders and Regulations made under the above Act.
DIRECTOR (FINANCE),	1.	All the provisions of:
DIVISIONAL DIRECTOR (TRADE MARKS AND DESIGNS), Where not already mentioned OFFICERS OF SPAN C2 OR HIGHER		(i) the Patents Acts 1949 and 1977, including
		opposed requests, references and applications insofar as these relate to preliminary or procedural matters,
		except insofar as these involve the technical content of specifications,
		(ii) the Registered Designs Act 1949, and
		(iii) the Trade Marks Acts 1938 and 1994.
	2.	The relevant Rules, Orders and Regulations made under the above Acts.
Where not already mentioned	1.	All the provisions of:

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OFFICERS OF SPAN B3 OR HIGHER, ASSISTANT HEADS OF ADMINISTRATION (PATENTS)	2.		the Patents Acts 1949 and 1977 except insofar as opposed requests, references and applications made thereunder or the technical content of specifications are involved, the Registered Designs Act 1949, and the Trade Marks Acts 1938 and 1994. relevant Rules, Orders and Regulations ade under the above Acts.
	<u> </u>		ac under the above 7665.
ALL OFFICERS OF SPAN B1	1.	The p	provisions of:
OR B2		(i)	Sections 25, 27(3), 34, 37, 38, 39, 40, 43, 44, 46, 47, 63(2), 63(3), 64, 65 and 67 of the Trade Marks Act 1994,
		(ii)	Sections 1(5) and (8), 17, 22, 23, 25, 28, 34, 35 and 36 of the Trade Marks Act 1938,
		(iii)	Section 73(2) of the Patents Act 1977,
		(iv)	Sections 28, 47 and 117 of the Patents Act 1977 except insofar as opposed requests or the technical content of specifications are involved,
		(v)	the relevant related Rules made under the above Acts,
		(vi)	Orders made under Sections 8 and 54 the Trade Marks Act 1994,
		(vii)	Regulations made under the Trade Marks Act 1994,
		(viii)	Rules made under Sections 41, 52, 68, 69, 78 and 81 of the Trade Marks Act, and
		(ix)	the following Rules:
			(a) Rules 53, 106, 108(1), 111(1) and 113(4) of the Patents Rules 2007,
			(b) Schedule 1 to the Patents Rules 2007 in connection with certificates authorising the release of biological material except insofar as an objection to release to a named expert is raised,
			(c) Rule 39 of the Registered Designs Rules 2006, and
			(d) Rule 20(1) of the Design Right (Proceedings before Comptroller) Rules 1989.

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ALL OFFICERS OF SPAN A2, A3 OR HIGHER	1.	The p	provisions of:
AS OR HIGHER		(i)	Sections 117B(2), 118(1) and 118(5) of the Patents Act 1977 and the relevant related Rules made under the Act, except insofar as opposed requests or the technical content of specifications are involved,
		(ii)	Rules 11(3), 35(3), 35(5), 35(6), 47(2), 104(1) and 108(2) of the Patents Rules 2007,
		(iii)	the Registered Designs Act 1949 and the Rules made under the Act insofar as the examination of design applications and the registration, renewal, restoration, assignment, licensing, cancellation and invalidation of registered designs is concerned,
		(iv)	Section 21 of the Registered Designs Act 1949, and
		(v)	Rules made under Section 30 of the Registered Designs Act 1949.
	2.	Se cop 32 acc	fying certificates for the purposes of ction 32(10) of the Patents Act 1977 and pies or extracts falling within Section (11) and (13) of the Patents Act 1977 in cordance with the relevant Rules made der the Act.
	3.	an pro Ma rele	fying copies of an entry in the register or extract from the register under the ovisions of Section 63(3) of the Trade trks Act 1994 in accordance with the evant Rules and Regulations made der the Act.
	4.	Se Ac wit Re acc	fying certificates for the purposes of ction 17(9) of the Registered Designs t 1949 and copies or extracts falling hin Section 17(10) and (12) of the gistered Designs Act 1949 in cordance with the relevant Rules made der the Act.
	1.	The p	provisions of:
ALL OFFICERS OF SPAN A1 OR HIGHER			ons 117B(2) of the Patents Act 1977 d Rule 109 of the Patent Rules 2007.
	2.	the	dinary administrative functions under Acts, Rules, Regulations and Orders entioned in this Schedule, such as where

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the comptroller is required to send or issue any document, notify or give notice of any event or requirement, request information or payment of a fee, specify a period, publish or advertise any information, or enter or amend information in the register.

Section 130(1)

"Convention on International Exhibitions" means the Convention relating to International Exhibitions signed in Paris on 22 November 1928, as amended or supplemented by any protocol to that convention which is for the time being in force;

Section 130(1)

"court" means

- (a) as respects England and Wales, the High Court;
- (b) as respects Scotland, the Court of Session;
- (c) as respects Northern Ireland, the High Court in Northern Ireland;
- (d) as respects the Isle of Man, Her Majesty's High Court of Justice of the Isle of Man;

130.06 Part (d) of the definition of "court" was added by the Patents (Isle of Man) Order 2013 (SI 2013/2602), which is the current Order in force. See 132.03 for information on previous Orders. The reference to patents county courts added to part (a) by the CDP Act 1988 was repealed by the Crimes and Courts Act 2013.

Section 130(1)

"date of filing" means -

- (a) in relation to an application for a patent made under this Act, the date which is the date of filing that application by virtue of section 15 above; and
- (b) in relation to any other application, the date which, under the law of the country where the application was made or in accordance with the terms of a treaty or convention to which that country is a party, is to be treated as the date of filing that application or is equivalent to the date of filing an application in that country (whatever the outcome of the application);

130.07 The date of filing of an application under the Act is thus the date accorded under section 15.

Section 130(1)

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"designate" in relation to an application or a patent, means designate the country or countries (in pursuance of the European Patent Convention or the Patent Co-operation Treaty) in which protection is sought for the invention which is the subject of the application or patent and includes a reference to a country being treated as designated in pursuance of the convention or treaty;

EPC r.41 PCT rr. 3 and 4 130.08 "European Patent Convention" (EPC) and "Patent Co-operation Treaty" (PCT) are defined later in subsection (1), see below. Designations are made on the relevant EPC or PCT request form – although in both cases it is now the case that all states and regions are by default treated as being designated on filing.

Section 130(1)

"electronic communication" has the same meaning as in the Electronic Communications Act 2000:

130.08.1 This definition was inserted into s.130(1) by the Patents Act 1977 (Electronic Communications) Order 2003 (S.I. 2003 No. 512), which inserted s.124A into the Act.

Section 130(1)

"employee" means a person who works or (where the employment has ceased) worked under a contract of employment or in employment under or for the purposes of a government department or a person who serves (or served) in the naval, military or air forces of the Crown;

The part of the definition of "employee" following the word "department" was added by the Armed Forces Act 1981 (c.55), section 22.

Section 130(1)

"employer" in relation to an employee, means the person by whom the employee is or was employed;

Section 130(1)

"enactment" includes an Act of Tynwald;

130.09.1 The definition of "enactment" was added by the Patents Act 1977 (Isle of Man) (Variation) Order 1990. This Order was revoked by the Patents Act 1977 (Isle of Man) Order 2003 (S.I. 2003 No. 1249), which re-inserted this definition into the Patents Act.

Section 130(1)

"European Patent Convention" means the Convention on the Grant of European Patents, "European patent" means a patent granted under that convention, "European patent (UK)" means a European patent designating the United Kingdom, "European Patent Bulletin" means the bulletin of that name published under the convention, and "European Patent

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Office" means the office of that name established by that convention;

Section 130(1)

"exclusive licence" means a licence from the proprietor of or applicant for a patent conferring on the licensee, or on him and persons authorised by him, to the exclusion of all other persons (including the proprietor or applicant), any right in respect of the invention to which the patent or application relates, and "exclusive licensee" and "non-exclusive licence" shall be construed accordingly;

130.09.2 See 67.04.

Section 130(1)

"filing fee" means the fee prescribed for the purposes of section 14

s.14(1)(b) s.89A(3) 130.10 A filing fee may be payable when an application under the Act is filed (see 15.06) or when (or before) an international application enters the national phase (see 89A.04-21).

Section 130(1)

"formal requirements" means those requirements designated as such by rules made for the purposes of section 15A above;

130.11 The formal requirements are set out in r.25 (see 17.07).

Section 130(1)

"international application for a patent" means an application made under the Patent Cooperation Treaty;

"Patent Co-operation Treaty" is defined later in subsection (1), see below.

Section 130(1)

"International Bureau" means the secretariat of the World Intellectual Property Organization established by a convention signed at Stockholm on 14 July 1967;

Section 130(1)

"international exhibition" means an official or officially recognised international exhibition falling within the terms of the Convention on International Exhibitions or falling within the terms of any subsequent treaty or convention replacing that convention;

130.13 "Convention on International Exhibitions" is defined earlier in subsection (1),

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see above. See also 2.40-41.

Section 130(1)

"inventor" has the meaning assigned to it by section 7 above;

130.14 See 7.12.

Section 130(1)

"journal" has the meaning assigned to it by section 123 (6) above;

130.15 See 123.72.

Section 130(1)

"mortgage", when used as a noun, includes a charge for securing money or money's worth and, when used as a verb, shall be construed accordingly;

Section 130(1)

"1949 Act" means the Patents Act 1949;

Section 130(1)

"patent" means a patent under this Act;

s.86(4) 130.16 Thus the provisions of the Act apply only to "patents" granted, or applications for "patents" filed, under the Act except where there is provision to the contrary.

applications for "patents" filed, under the Act except where there is provision to the contrary. There are such exceptions making parts of the Act applicable in the cases of 1949 Act patents and applications, in accordance with s.127 and Schedules 2 and 4 (see 127.06-07 and 127.10); European patents (UK), in accordance with s.77 (see 77.03 et seq); applications for European patents (UK), in accordance with s.78 (see 78.05); and international applications for patents (UK), in accordance with s.89 (see 89.05 et seq). However, the provisions of the Act are not applicable to Community patents.

[130.17 Deleted]

Section 130(1)

"Patent Co-operation Treaty" means the treaty of that name signed at Washington on 19 June 1970;

Section 130(1)

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"patented invention" means an invention for which a patent is granted and "patented process" shall be construed accordingly;

Section 130(1)

"patented product" means a product which is a patented invention or, in relation to a patented process, a product obtained directly by means of the process or to which the process has been applied;

Section 130(1)

"prescribed" and "rules" have the meanings assigned to them by section 123 above;

130.18 See 123.01.

Section 130(1)

"priority date" means the date determined as such under section 5 above;

130.19 See 5.03 et seq.

Section 130(1)

"published" means made available to the public (whether in the United Kingdom or elsewhere) and a document shall be taken to be published under any provision of this Act if it can be inspected as of right at any place in the United Kingdom by members of the public, whether on payment of a fee or not; and "republished" shall be construed accordingly;

130.20 Thus an application laid open to public inspection in the Office (see 16.03) has been "published". Similarly, documents relating to an application and available to inspection under s.118(1) are therefore "published" and thus form part of s.2(2) art.

Section 130(1)

"register" and cognate expressions have the meanings assigned to them by section 32 above;

130.21 See the chapter on s.32.

Section 130(1)

"relevant convention court", in relation to any proceedings under the European Patent Convention, or the Patent Co-operation Treaty, means that court or other body which under that convention or treaty has jurisdiction over those proceedings, including (where it has such jurisdiction) any department of the European Patent Office;

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130.22 "European Patent Convention" "European Patent Office", and "Patent Cooperation Treaty" are defined earlier in subsection (1), see above. The "relevant convention court" appears to include a national office acting in its capacity as a receiving office under the appropriate convention or treaty. However, it does not include a national office, e.g. that of the USA, processing an international application which was made under the PCT but has entered its national phase before that office and is proceeding under that national law instead of under the treaty (*Sonic Tape PLC's Patent* [1987] RPC 251).

Section 130(1)

"right", in relation to any patent or application, includes an interest in the patent or application and, without prejudice to the foregoing, any reference to a right in a patent includes a reference to a share in the patent;

130.22.1 It was held in *Hartington Conway Ltd's Patent Applications* [2004] RPC 6 that the term "right", in relation to an application, encompassed not only a right in relation to an existing application, but also a right to file an application for grant of a patent (see 30.05 and 30.08).

Section 130(1)

"search fee" means the fee prescribed for the purposes of section 17(1) above;

See 17.02-06. The definition of "search fee" was amended by the CDP Act to make it clear that this term alludes to the fee for a preliminary examination and search, and not to the fee for a supplementary search under s.17(8) and s.18(1A).

Section 130(1)

"services of the Crown" and "use for the services of the Crown" have the meanings assigned to them by section 56(2) above, including, as respects any period of emergency within the meaning of section 59 above, the meanings assigned to them by the said section 59.

130.24 See the chapters on ss.56 and 59.

Section 130(2)

Rules may provide for stating in the journal that an exhibition falls within the definition of international exhibition in subsection (1) above and any such statement shall be conclusive evidence that the exhibition falls within that definition.

130.25 Rule 5 is made under this subsection (see 2.40-41). See also 130.13.

Section 130(3)

For the purposes of this Act matter shall be taken to have been disclosed in any relevant application within the meaning of section 5 above or in the specification of a patent if it was either claimed or disclosed (otherwise than by way of disclaimer or acknowledgment of prior

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art) in that application or specification.

See 5.23-5.25 with regard to disclosure in an earlier relevant application from which priority is claimed. For the meaning of "relevant application", see 5.30. The term "disclaimer" was held by the Patents Court in Secretary of State for Education and Skills v Frontline Technology [2005] EWHC 37 (Ch) to relate to disclaimers relating to accidental anticipations. In joined cases G1/03 and G2/03 of the EPO Enlarged Board of Appeal, followed in *M-Systems Flash Disk Pioneers Ltd v Trek Technology (Singapore) Pte Ltd* (BL O/318/06), the term "disclaimer" was further held to relate to delimiting a claim against anticipations under s2(3) and subject matter excluded from patentability for non-technical reasons.

Section 130(4)

References in this Act to an application for a patent, as filed, are references to such an application in the state it was on the date of filing.

An application as filed does not include an abstract or claims filed after the date of filing (see 130.07) but does incorporate any alterations filed on that date (see 16.08-14, especially 16.10).

Section 130(4A)

An international application for a patent is not, by reason of being treated by virtue of the European Patent Convention as an application for a European patent (UK), to be treated also as an international application for a patent (UK).

PCT r.4.9(a) 130.27.1 Subsection (4A) was inserted by the Patents Act 2004 and replaced section 89(4). An international application under the PCT automatically designates all contracting states and regions of the PCT on filing. However, if the UK designation on an international application is later withdrawn, that application cannot be considered to be an international application for a patent (UK) on the basis that the EP(UK) designation remains.

Section 130(5)

References in this Act to an application for a patent being published are references to its being published under section 16 above.

130.28 See 16.01.

Section 130(5A)

References in this Act to the amendment of a patent or its specification (whether under this Act or by the European Patent Office) include, in particular, limitation of the claims (as interpreted by the description and any drawings referred to in the description or claims).

130.28.1 This section glosses references to amendment wherever they appear in the 1977 Act. However, this only applies to amendment of a patent, and so does not include references to amendment of a patent application. The paragraph makes it clear that amendment of a patent includes an amendment which limits the scope of the claims – and so limits the protection afforded by the patent. A limitation of the claims may be made under the provisions of this Act or, in the case of a European patent (UK), the claims may be

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limited at the European Patent Office (under the new procedure introduced by Article 138(3) EPC).

Section 130(6)

References in this Act to any of the following conventions, that is to say -

- (a) The European Patent Convention;
- (b) The Community Patent Convention;
- (c) The Patent Co-operation Treaty;

are references to that convention or any other international convention or agreement replacing it, as amended or supplemented by any convention or international agreement (including in either case any protocol or annex), or in accordance with the terms of any such convention or agreement, and include references to any instrument made under any such convention or agreement.

EPC a.33 130.29 The Administrative Council of the EPO has from time to time amended the Implementing Regulations and the Rules relating to Fees under the EPC. The PCT was amended on 28 September 1979 and modified on 3 February 1984, and the Regulations including the Schedule of Fees under the treaty have been amended on several occasions.

Section 130(7)

Whereas by a resolution made on the signature of the Community Patent Convention the governments of the member states of the European Economic Community resolved to adjust their laws relating to patents so as (among other things) to bring those laws into conformity with the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty, it is hereby declared that the following provisions of this Act, that is to say, sections 1(1) to (4), 2 to 6, 14(3), (5) and (6), 37(5), 54, 60, 69, 72(1) and (2), 74(4), 82, 83, 100 and 125, are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty have in the territories to which those Conventions apply.

In the resolution, the governmental signatories recognised that differences between national laws and the provisions of the CPC would entail a duality of standards in patent laws in the contracting states and decided to adjust their national laws to permit ratification of the Strasbourg Convention on the unification of certain points of substantive law on patents for invention and to bring their laws into conformity as far as practical with corresponding provisions of the EPC, CPC and PCT. It would also be anomalous if the provisions of patentability and interpretation differed between the EPC which is applicable to applications for European patents (UK) and to European patents (UK) during the opposition period and our national law which applies to European patents (UK) after grant. Similarly conformity with many other aspects of the EPC and with the PCT is desirable.

The particular provisions of the EPC, CPC and PCT corresponding to the sections of the Act specified in s.130(7) are identified in the chapters relating to those sections. When applying s.130(7) to those sections, the principle of construction quoted by Lord Diplock in *The Jade* [1976] 1 All ER 920, 924 (not a patent case) should be followed. He stated that "As the Act was passed to enable Her Majesty's Government to give effect to the obligations in international law which it would assume on ratifying the convention if there be any difference between the language of the statutory provision and that of the corresponding provisions of the Convention, the Statutory language should be construed in

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the same sense as that of the Convention if the words of the Statute are reasonably capable of bearing that meaning". Furthermore, in *Merrell Dow Pharmaceuticals Inc. v H.N. Norton & Co Ltd* [1996] RPC 76, the House of Lords held that in construing a section of the Patents Act 1977 said by section 130(7) to have, as nearly as practicable, the same effects as the corresponding provisions of the European Patent Convention, the United Kingdom courts must have regard to the decisions of the EPO. Lord Hoffmann said (at page 82): "These decisions are not strictly binding upon the courts in the United Kingdom but they are of great persuasive authority; first, because they are decisions of expert courts (the Boards of Appeal and Enlarged Board of Appeal of the EPO) involved daily in the administration of the EPC, and secondly, because it would be highly undesirable for the provisions for the EPC to be construed differently in the EPO from the way they are interpreted in the national courts of a contracting state".

In the judgment given by Jacob LJ in *Actavis UK Ltd v Merck* [2008] EWCA Civ 444, it was held that the Court of Appeal can (but is not bound to) depart from its own precedent if it is satisfied that the EPO Boards of Appeal have formed a settled view of European Patent law which is inconsistent with the Court of Appeal earlier decision. Generally the Court of Appeal will follow settled view of the EPO (see para 107 of the decision).

See also the discussion in 0.08-09.

However Lord Diplock himself stated in *E's Applications* [1983] RPC at page 251 that resort to the PCT was not permitted under the principle of construction enunciated in The Jade if the wording of the Act is incapable of any other meaning.

130.33 When construing the EPC, CPC or PCT it is legitimate to consider the intention behind any provision as indicated in the papers of the conference resulting in the Convention or Treaty. Following the judgment of the House of Lords in *Pepper v Hart* [1992] 3 WLR 1032, the rule excluding reference to Parliamentary material as an aid to statutory construction has been relaxed so as to permit such references where (a) legislation was ambiguous or obscure or led to absurdity; (b) the material relied upon consisted of one or more statements by a minister or other promoter of the Bill together if necessary with such other Parliamentary material as was necessary to understand such statements and their effect and (c) the statements were clear.

The Patent Law Treaty (PLT) was signed by the United Kingdom in 2000 and entered into force for the United Kingdom on 22 March 2006. It is by nature a different type of treaty than those listed in section 130(7), being essentially a minimum standards treaty setting out provisions aimed at providing patent applicants with certain flexibilities. However in *Abaco Machines (Australasia) Pty Ltd's Application* [2007] EWHC 347 (Pat), which concerned a request to make a late declaration of priority under section 5(2B), Lewison J commented that the PLT is at least part of the background against which section 5 should be viewed. He agreed in principle with the submission put to him that section 5 of the Act should be interpreted in the light of the PLT itself. He then went on to assess the facts of that case using the language of the PLT, although he did also confirm that this was consistent with the language of section 5. Accordingly the Patent Law Treaty may be of relevance when interpreting provisions in the Act or rules that were inspired by this Treaty.

130.35 [deleted]

Section 130(8)

Part I of the Arbitration Act 1996 shall not apply to any proceedings before the comptroller under this Act.

130.35.1 The words "Part I of the Arbitration Act 1996" were substituted for "The Arbitration Act 1950" by Schedule III of the Arbitration Act 1996.

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Section 130(9)

Except so far as the context otherwise requires, any reference in this Act to any enactment shall be construed as a reference to that enactment as amended or extended by or under any other enactment, including this Act.

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Section 131: Northern Ireland

Section 131

In the application of this Act to Northern Ireland -

- (a) "enactment" includes an enactment of the Parliament of Northern Ireland and a Measure of the Northern Ireland Assembly;
- (b) any reference to a government department includes a reference to a Department of the Government of Northern Ireland;
- (c) any reference to the Crown includes a reference to the Crown in right of Her Majesty's Government in Northern Ireland;
- (d) any reference to the Companies Act 1985 includes a reference to the corresponding enactments in force in Northern Ireland; and
- (e) [repealed]
- (f) any reference to a claimant includes reference to a plaintiff.
- 131.01 The Act extends to Northern Ireland but, in its application thereto, is interpreted in accordance with this section.
- s.130(1) 131.02 In the Act, various powers are specifically given to the "court" which, as respects Northern Ireland, means the High Court in Northern Ireland (unless the context otherwise requires).
 - 131.03 The reference to the Companies Act 1985 in (d) was substituted by the Companies Consolidation (Consequential Provisions) Act 1985 for the original reference to the Companies Act 1948. Part (e) was repealed by the Arbitration Act 1996. Part (f) was added by the Patents Act 2004 to clarify that the term "claimant" used in the Act includes "plaintiff" when the Act is applied in Northern Ireland.

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Section 131A: Scotland

131A.01 This section was introduced by the Scotland Act 1998 (Consequential Modifications)(No.2) Order 1999 (SI 1999 No. 1820). It clarifies how certain references in the Act are to be interpreted in the light of Scottish devolution and the setting up of the Scottish Parliament.

Section 131A

In the application of this Act to Scotland -

- (a) "enactment" includes an enactment comprised in, or in an instrument made under, an Act of the Scottish Parliament;
- (b) any reference to a government department includes a reference to any part of the Scottish Administration; and
- (c) any reference to the Crown includes a reference to the Crown in right of the Scottish Administration.

Page 1 of 1 April 2007

Section 132: Short title, extent, commencement, consequential amendments and repeals

132.01 This section specifies the short title of the Act (the Patents Act 1977) and certain territories and acts to which the Act applies; provides for the commencement of the Act; and authorises Schedules 5 and 6 to the Act which respectively set out consequential amendments and repeals of other enactments.

Section 132(1)

This Act may be cited as the Patents Act 1977.

Section 132(2)

This Act shall extend to the Isle of Man, subject to any modifications contained in an Order made by Her Majesty in Council, and accordingly, subject to any such order, references in this Act to the United Kingdom shall be construed as including references to the Isle of Man.

Section 132(3)

For the purposes of this Act the territorial waters of the United Kingdom shall be treated as part of the United Kingdom.

Section 132(4)

This Act applies to acts done in an area designated by order under section 1(7) of the Continental Shelf Act 1964, or specified by Order under section 10(8) of the Petroleum Act 1998 in connection with any activity falling within section 11(2) of that Act, as it applies to acts done in the United Kingdom.

Extent of Act

- Sch. 2, 132.02 Subsections (2) to (4) have the effect of extending the 1977 Act to the Isle of Man and the territorial waters of the UK; and applying those Acts to acts done in the offshore areas to which subsection (4) refers.
- s.130(1)

 132.03 Subsection (2) provides for the making of Orders in Council with regard to the application of the Act to the Isle of Man. The current Order in force is the Patents (Isle of Man) Order 2013 (SI 2013/2602) which revoked the Patents Act 1977 (Isle of Man) Order 2003 (SI 2003 No. 1249), while the 2003 Order previously revoked the Patents Act 1977 (Isle of Man) Order 1978 (S.I. 1978 No. 621) and the Patents Act 1977 (Isle of Man) (Variation) Order (SI 1990 No 2295). The 2003 Order consolidated the two earlier Orders and also gave effect to provisions introduced into the Act using powers under the European Communities Act 1972 or the Electronic Communications Act 2000. The 2013 order replaced the 2003 Order and made additional modifications to correspond to the amendments made to the Act (as it has effect in the United Kingdom) by the Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (SI 2005/2759), the Intellectual Property (Enforcement, etc.) Regulations 2006 (SI 2006/1028), the Registered Designs Act 1949 and Patents Act 1977 (Electronic Communications) Order 2006 (SI

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2006/1229), the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007 (SI2007/3293) and the Patents Act 1977 (Amendment) Regulations 2011 (SI 2011/2059). Section 130(1)(d) of the Act states that, as respects the Isle of Man, "court" in the Act means Her Majesty's High Court of Justice in the Isle of Man (unless the context otherwise requires).

132.04 The wording of subsection (4) was amended by the Oil and Gas (Enterprise) Act 1982 so as to incorporate a reference to that Act and subsequently amended by the Petroleum Act 1998 to refer to that Act instead. The application of the Patents Act was thus extended to certain offshore activities in specified areas which are in a foreign sector of the continental shelf and which comprise part of a geological structure which extends into the foreign sector from an area designated under s.1(7) of the Continental Shelf Act 1964. The activities in question are connected with the exploration of, or the exploitation of the natural resources of, the shore or bed of waters or the subsoil beneath it; and activities carried on from, by means of, or for purposes connected with, installations for the exploitation, exploration, storage or conveyance of mineral resources or accommodation for persons working on such an installation.

Section 132(5)

This Act (except sections 77(6), (7) and (9), 78(7) and (8), this subsection and the repeal of section 41 of the 1949 Act) shall come into operation on such day as may be appointed by the Secretary of State by order, and different days may be appointed under this subsection for different purposes.

Commencement of Act

The passing of the 1977 Act (on 29 July 1977) brought into immediate effect only s.132(5) of the Act. It also had the effect of repealing s.41 of the 1949 Act which made special provision for licences in the case of patents for inventions relating to food, medicine or surgical or curative devices. Although ss.77(7) and (9) and 78(8) of the 1977 Act (concerning translations of European patents (UK) and of claims of applications therefor) came into operation at the same time, they had no effect except to provide for the making of rules under ss.77(9) and 78(8) to bring s.77(6) and s.78(7) into force.

Subsection (5) provides for the making of orders by the Secretary of State whereby the remaining sections of the 1977 Act come into operation on respective appointed days.

The Patents Act 1977 (Commencement No. 1) Order 1977 (S.I. 1977 No. 2090) appointed 31 December 1977 as the day for coming into operation of ss.84, 85 and 114 (concerning patent agents and other representatives) and s.130 (interpretation) of the 1977 Act. It is also repealed s.88 of the 1949 Act containing restrictions on practice as a patent agent.

132.08 Subsequently, the Patents Act 1977 (Commencement No. 2) Order 1978 (S.I. 1978 No. 586) appointed 1 June 1978 as the day for coming into operation of the rest of the 1977 Act (with the exception of provisions in respect of Community patents, ie ss.53(1), 60(4) and 86 to 88).

132.09 See also 124.03 to 124.06 and 124.08 with regard to the making of such rules and orders.

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Section 132(6)

The consequential amendments in Schedule 5 shall have effect.

Consequential amendments of other enactments

Schedule 5 set out consequential amendments of the Crown Proceedings Act 1947, Registered Designs Act 1949, Defence Contracts Act 1958, Administration of Justice Act 1970, Atomic Energy Authority (Weapons Group) Act 1973, Fair Trading Act 1973 and Restrictive Trade Practices Act 1976. The paragraphs of Schedule 5 relating to the Crown Proceedings Act 1947, the Fair Trading Act 1973 and the Restrictive Trade Practices Act 1976 were deleted, and those relating to the Registered Designs Act 1949 were amended, by the CDP Act.

Section 132(7)

Subject to the provisions of Schedule 4 to this Act, the enactments specified in Schedule 6 to this Act (which include certain enactments which were spent before the passing of this Act) are hereby repealed to the extent specified in column 3 of that Schedule.

Repeals of other enactments

132.11 Certain provisions of a number of enactments, as set out in Schedule 6, were repealed under s.132(7). The enactments affected include the Patents and Designs Act 1907, Patents Act 1949, Patents Act 1957 and Patents and Designs (Renewals, Extensions and Fees) Act 1961. The list in Schedule 6 of repealed sections of the 1949 Act includes those listed in Schedule 3, see 127.09. The repeals were subject to the transitional provisions of Schedule 4, see 127.10.

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PART V - PATENT AGENTS AND TRADE MARK AGENTS

PATENT AGENTS

Section 274: Persons permitted to carry on business of a patent agent

Part V of the CDP Act comprises sections 274 to 286 and deals with patent attorneys and trade mark attorneys. It came into force on 13 August 1990 and completely replaced sections 84, 85, 104, 114, 115, 123(2)(k) and 130(1) (definition of "patent agent" only) of the Patents Act 1977. Qualified patent attorneys had for many years enjoyed what was effectively an exclusive right to represent patent applicants before the Office. (Solicitors have also been entitled to do so, but have in fact done so only rarely.) To practice, patent attorneys had to be entered on a register which was maintained under the Patents Act 1977 (and continues under s.275 of the CDP Act). Getting on to the register involves the passing of examinations and serving a period of supervised practice, and it has been a criminal offence for an unqualified person to charge money for acting as a patent attorney, or even use the title.

This part of the CDP Act allows increased competition among those offering patent agency services by lifting restrictions on who may represent patent applicants. It also improves the position of clients seeking advice from qualified patent attorneys and trade mark attorneys by providing that communications with these attorneys are privileged from disclosure in legal proceedings just as communications with lawyers are. The Legal Services Act 2007 amended various sections of this part of the CDP Act on 1 January 2010.

274.03 Section 274 to 281 relate to patent attorneys, sections 282 to 284 being concerned with trade mark attorneys and sections 285 and 286 being supplementary and applying to both classes of attorney. Section 274 abolishes the so-called "patent agents' monopoly" of rights of representation of patent applicants in proceedings before the Office which existed under the 1977 Act, see 274.01.

Section 274(1)

Any individual, partnership or body corporate may, subject to the following provisions of this Part and to the Legal Services Act 2007, carry on the business of acting as agent for others for the purpose of -

- (a) applying for or obtaining patents, in the United Kingdom or elsewhere, or
- (b) conducting proceedings before the comptroller relating to applications for, or otherwise in connection with, patents.

Any person (or partnership or company) may, subject to provisions elsewhere in this Part, carry on the business of acting for others in (a) applying for patents or (b) conducting proceedings before the comptroller in connection with patents. The main effect is to replace the requirement, in section 114(1) of the Patents Act 1977, that only registered patent attorneys may practise as patent attorneys, that is represent patent applicants for gain (contravention of this provision was a criminal offence). Unregistered persons wishing to offer patent agency services are now able to do so. The only constraints are that they are unable to use the title "patent attorney" or similar expressions (section 276) and the comptroller may refuse to deal with them on certain limited grounds (chiefly

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misconduct) (section 281).

[Staff should be alert to the possibility that representatives who are not registered patent attorneys may be less familiar with the patent system than a registered patent attorney. Any agent should be given assistance if needed and in this respect unregistered agents should be treated in the same way as registered attorneys; however their cases should not generally be given "private applicant" treatment unless the unregistered agent requests this.]

r.101 274.05 Unless the comptroller otherwise directs in any particular case, all attendances upon him may be made by or through an agent. Further, every notice, application or other document filed under the 1977 Act may be signed by an agent. Where after a person has become a party to proceedings before the comptroller he appoints an agent for the first time or appoints one agent in substitution for another, the newly appointed agent should make a declaration of authorisation. This should be made on Patents Form 51 which should be filed (no fee) on or before the first occasion when he acts as agent. A copy of the Form 51 should be sent by the comptroller to the former agent.

In accordance with s.102 of the Patents Act 1977, as amended by the CDP Act and Legal Services Act 2007, a party to patent proceedings before the comptroller may appear in person or be represented by any person of his choice (subject to rules empowering the comptroller to refuse to recognise certain agents). Thus a person acting as agent under s.274 may also appear before the comptroller. However, under the Legal Services Act 2007, only registered patent attorneys (see s.275) and legal practitioners can appear on behalf of a party to an appeal from a decision of the comptroller to the Patents Court.

Section 274(2)

This does not affect any restriction under the European Patent Convention as to who may act on behalf of another for any purpose relating to European patents.

274.07 Section 274 does not affect the restrictions imposed by Article 134 of the European Patent Convention (EPC) and rules made thereunder. These restrictions provide that professional representation before the European Patent Office can only be undertaken by those who names appear on a list maintained for the purpose.

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Section 275: The register of patent attorneys

275.01 This provides for the continued existence of a register of patent attorneys (other sections of Part V of the CDP Act and the Legal Services Act 2007 provide that those on the register are entitled to certain benefits not available to the lay person). Provision is also made for the regulation of patent attorneys under section 275A introduced through section 185(3) of the Legal Services Act 2007.

275.02 In addition to the rights of registered patent attorneys provided by statute, it has long been the accepted practice that in patent proceedings before the comptroller, and on appeals from any decision of his in those proceedings, counsel may be instructed by registered patent attorneys without the intermediary of a solicitor (confirmed by the Patents Court in *Reiss Engineering Co Ltd v G J Harris* [1987] RPC 171).

275.03 This section was amended by the Legal Services Act, section 185(3) on 1 January 2010.

Section 275(1)

There is to continue to be a register of persons who act as agent for others for the purpose of applying for or obtaining patents.

Section 275(2)

In this Part a registered patent attorney means an individual whose name is entered on the register kept under this section.

Section 275(3)

The register is to be kept by the Chartered Institute of Patent Attorneys.

The CDP Act previously empowered the Secretary of State to make rules requiring the keeping of a register of patent attorneys (the Register of Patent Agent Rules 1990 (SI 1990/1457) which required the Chartered Institute of Patent Attorneys (CIPA) to keep the register and appoint the registrar). Following amendment of section 275 by section 185(3) of the Legal Services Act 2007 this power has been replaced by the requirement for a register of patent attorneys to be kept by CIPA.

Section 275(4)

The Secretary of State may, by order, amend subsection (3) so as to require the register to be kept by the person specified in the order.

Section 275(5)

Before making an order under subsection (4), the Secretary of State must consult the Legal Services Board.

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Section 275(6)

An order under this section must be made by statutory instrument.

Section 275(7)

An order under this section may not be made unless a draft of it has been laid before, and approved by a resolution of, each House of Parliament.

275.05 Under subsections (4) to (7), the Secretary of State is empowered to amend by order subsection (3) to require someone other than CIPA to be the keeper of the register. The Secretary of State must consult the Legal Services Board and enact a statutory instrument which has been laid and approved by each House of Parliament.

Page 2 of 2 July 2012

Section 275A: Regulation of patent attorneys

275A.01 This section provides for the regulation of patent attorneys and is introduced into the CDP Act by section 185(3) of the Legal Services Act 2007. Section 275A replaces the rules (The Register of Patent Agents Rules (SI 1990/1457)) previously made under section 275(2) and 275(3) of the CDP Act 1988.

Section 275A(1)

The person who keeps the register under section 275 may make regulations which regulate—

- (a) the keeping of the register and the registration of persons;
- (b) the carrying on of patent attorney work by registered persons.

275A.02 This subsection provides for regulations to be made concerning the registration and maintenance of the register of patent attorneys and concerning the carrying on of patent attorney work by those who have been recorded on the register.

Section 275A(2)

Those regulations may, amongst other things, make-

- (a) provision as to the educational and training qualifications, and other requirements, which must be satisfied before an individual may be registered or for an individual to remain registered;
- (b) provision as to the requirements which must be met by a body (corporate or unincorporate) before it may be registered, or for it to remain registered, including provision as to the management and control of the body;
- (c) provision as to the educational, training and other requirements to be met by regulated persons;
- (d) provision regulating the practice, conduct and discipline of registered persons or regulated persons;
- (e) provision authorising in such cases as may be specified in the regulations the erasure from the register of the name of any person registered in it, or the suspension of a person's registration:
- (f) provision requiring the payment of such fees as may be specified in or determined in accordance with the regulations;
- (g) provision about the provision to be made by registered persons in respect of complaints made against them;
- (h) provision about the keeping by registered persons or regulated persons of records and accounts;
- (i) provision for reviews of or appeals against decisions made under the regulations;

(j) provision as to the indemnification of registered persons or regulated persons against losses arising from claims in respect of civil liability incurred by them

275A.03 Subsection (2) sets out the areas which may be covered by the regulations. These include provisions for regulating the educational and training qualifications, the requirements which must be met by corporate or incorporate bodies and the payment of fees by those wishing to be registered as patent attorneys.

275A.04 The regulations may include provisions on the practice, conduct and discipline of registered persons, including provisions in respect of complaints made against patent attorneys, the right to reviews and appeals of any decisions made under the regulations and the provisions for the removal of the names of patent attorneys from the register.

Section 275A(3)

Regulations under this section may make different provision for different purposes.

Section 275A(4)

Regulations under this section which are not regulatory arrangements within the meaning of the Legal Services Act 2007 are to be treated as such arrangements for the purposes of that Act.

The provisions in the regulations can differ according to their purpose and can encompass aspects which are not regulatory arrangements within the meaning of the Legal Services Act 2007.

Section 275A(5)

Before the appointed day, regulations under this section may be made only with the approval of the Secretary of State.

275A.06 The regulations made under this section come into force on the "appointed day" as defined in subsection (7) below and which is 1 January 2010. Any regulations made under this section prior to the appointed day (none have been made) may only be made with the approval of the Secretary of State.

Section 275A(6)

The powers conferred to make regulations under this section are not to be taken to prejudice—

- (a) any other power which the person who keeps the register may have to make rules or regulations (however they may be described and whether they are made under an enactment or otherwise);
- (b) any rules or regulations made by that person under any such power.

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Section 275A(7)

In this section-

"appointed day" means the day appointed for the coming into force of paragraph 1 of Schedule 4 to the Legal Services Act 2007;

"manager", in relation to a body, has the same meaning as in the Legal Services Act 2007 (see section 207);

"patent attorney work" means work done in the course of carrying on the business of acting as agent for others for the purpose of—

- (a) applying for or obtaining patents, in the United Kingdom or elsewhere, or
- (b) conducting proceedings before the comptroller relating to applications for, or otherwise in connection with, patents;

"registered person" means-

- (a) a registered patent attorney, or
- (b) a body (corporate or unincorporate) registered in the register kept under section 275;

"regulated person" means a person who is not a registered person but is a manager or employee of a body which is a registered person.

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Section 276: Persons entitled to describe themselves as patent agents

276.01 The main effect of this section is to reserve the use of the title "patent attorney" and patent agent to individuals who are registered patent attorneys, and partnerships and bodies corporate in which registered patent attorneys are involved. Use of the title by any person not authorised to do so is a criminal offence.

Section 276(1)

An individual who is not a registered patent attorney shall not -

- (a) carry on a business (otherwise than in partnership) under any name or other description which contains the words "patent agent" or "patent attorney"; or
- (b) in the course of a business otherwise describe himself, or permit himself to be described, as a "patent agent" or "patent attorney".
- Subsection (1) relates to individuals who are not registered patent attorneys. Paragraph (a) provides that such a person may not carry on a business under a name or other description including the words "patent agent" or "patent attorney". This paragraph does not extend to partnerships, as these are dealt with in subsection (2). Paragraph (b) extends the prohibition to otherwise describing himself, or permitting himself to be described, as a "patent agent" or "patent attorney".

Section 276(2)

A partnership or other unincorporated body shall not -

- (a) carry on a business under any name or other description which contains the words "patent agent" or "patent attorney"; or
- (b) in the course of a business otherwise describe itself, or permit itself to be described as, a firm of "patent agents" or "patent attorneys",

unless the partnership or other body is registered in the register kept under section 275.

- Subsection (2) relates to partnerships and other unincorporated bodies. It stipulates that for a partnership or other such body to be able to use the title "patent agent" or "patent attorney", it must be registered in the register kept under section 275 of the CDP Act. Paragraphs (a) and (b) are analagous to paragraphs (a) and (b) of subsection (1). Under s.276(3) similar provision is made in respect of a body corporate and its directors.
- 276.03.1 Previously, if all the partners were not registered patent attorneys, certain prescribed conditions had to be met for a partnership to use the title "patent agent" or "patent attorney". The conditions were prescribed in rules made under section 279 of the CDP Act, namely the Patent Agents (Mixed Partnerships and Bodies Corporate) Rules 1994 (SI 1994 No. 362) which came into force on 24 March 1994. These Rules set out the conditions to be satisfied. However, on 1 January 2010 section 185(4) of the Legal Services Act 2007 amended this section of the CDP Act to change the prescribed condition to that detailed in subsection (3) see paragraph 276.03 above. The Patents Agents (Mixed Partnerships and Bodies Corporate) Rules 1994 no longer apply as section 279 of the CDP Act was repealed under s.185(5) of and Sch.23 to the Legal Services Act 2007.

Section 276(3)

A body corporate shall not -

- (a) carry on a business (otherwise than in partnership) under any name or other description which contains the words "patent agent" or "patent attorney"; or
- (b) in the course of a business otherwise describe itself, or permit itself to be described as, a "patent agent" or "patent attorney",

unless the body corporate is registered in the register kept under section 275.

276.04 Subsection (3) relates to bodies corporate entitled to use the title "patent agent" or "patent attorney" and makes similar provisions to those of subsection (2) in respect of partnerships, with the requirement for the body corporate to be registered in the register kept under section 275 of the CDP Act.

Section 276(4)

Subsection (3) does not apply to a company which began to carry on business as a patent agent before 17th November 1917 if the name of a director or the manager of the company who is a registered patent attorney is mentioned as being so registered in all professional advertisements, circulars or letters issued by or with the company's consent on which its name appears.

276.05 There is a special saving for certain companies which began carrying on the business of a patent attorney before 17th November 1917. This re-enacts section 114(2)(a) of the Patents Act 1977 (which in turn re-enacted earlier provisions).

Section 276(5)

Where this section would be contravened by the use of the words "patent agent" or "patent attorney" in reference to an individual, partnership or body corporate, it is equally contravened by the use of other expressions in reference to that person, or his business or place of business, which are likely to be understood as indicating that he is entitled to be described as a "patent agent" or "patent attorney".

276.06 The prohibition on use of the descriptions "patent agent" and "patent attorney" extends to other expressions which are likely to be understood as indicating entitlement to such a description, for example "patent agency".

Section 276(6)

A person who contravenes this section commits an offence and is liable on summary conviction to a fine not exceeding level 5 on the standard scale; and proceedings for such an offence may be begun at any time within a year from the date of the offence.

276.07 Contravention of the section is an offence punishable on summary conviction by a fine not exceeding level 5 on the standard scale. Proceedings may be begun within one year of the date of an offence. These provisions echo the repealed section 114(3) and (4) of the

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Patents Act 1977.

Section 276(7)

This section has effect subject to -

- (a) section 277 (persons entitled to describe themselves as European patent attorneys, &c), and
- (b) section 278(1) (use of term "patent attorney" in reference to solicitors).

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Section 277: Persons entitled to describe themselves as European patent attorneys, &c

Article 134 of the European Patent Convention (EPC) provides that professional representation in proceedings under the Convention may only be undertaken by persons whose names appear on the list maintained for the purpose by the European Patent Office (the "European list"). This section provides that an individual who is on the European list is allowed to use the title "European patent attorney" or "European patent agent" (EPA). It also relates to the composition of partnerships and bodies corporate practising as EPA's in a similar manner to section 276 in respect of UK patent attorneys. The section replaced section 84 of the Patents Act 1977 but with changes parallelling the relaxation of rules governing practice as a UK patent attorney. In particular, it is no longer an offence under UK law for a person not on the European list to carry out the functions of an EPA although such people will be prevented by the operation of the EPC from being recognised as agents.

Section 277(1)

The term "European patent attorney" or "European patent agent" may be used in the following cases without any contravention of section 276.

Section 277(2)

An individual who is on the European list may -

- (a) carry on business under a name or other description which contains the words "European patent attorney" or "European patent agent", or
- (b) otherwise describe himself, or permit himself to be described, as a "European patent attorney" or "European patent agent".

Subsection (1) provides that section 276 is not contravened by the use of the titles "European patent attorney" and "European patent agent" in the cases set out in the following subsections. Paragraph (a) of subsection (2) provides that a person may carry on a business using these titles if he is entered in the European list. Paragraph (b) relates to the act of otherwise describing oneself or permitting oneself to be described as an EPA.

Section 277(3)

A partnership of which not less than the prescribed number or proportion of partners is on the European list may -

- (a) carry on a business under a name or other description which contains the words "European patent attorneys" or "European patent agents", or
- (b) otherwise describe itself, or permit itself to be described, as a firm which carries on the business of a "European patent attorney" or "European patent agent".

Section 277(4)

A body corporate of which not less than the prescribed number or proportion of directors is

on the European list may -

- (a) carry on a business under a name or other description which contains the words "European patent attorney" or "European patent agent", or
- (b) otherwise describe itself, or permit itself to be described as, a company which carries on the business of a "European patent attorney" or "European patent agent".

277.03 Subsections (3) and (4) relate to the activities of partnerships and bodies corporate. They may use the titles "European patent attorney" or "European patent agent" if a prescribed number or proportion of partners or directors are on the European list. 'Directors' may include 'members' in accordance with section 286. Paragraphs (a) and (b) of each subsection mirror paragraphs (a) and (b) of subsection (2).

Section 277(5)

Where the term "European patent attorney" or "European patent agent" may, in accordance with this section, be used in reference to an individual, partnership or body corporate, it is equally permissible to use other expressions in reference to that person, or to his business or place of business, which are likely to be understood as indicating that he is entitled to be described as a "European patent attorney" or "European patent agent."

The entitlement extends to other expressions likely to be understood as indicating a right to be described as a European patent attorney or European patent agent, for example "European patent agency".

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Section 278: Use of the term "patent attorney": supplementary provisions

278.01 This provides that certain uses of the term "patent attorney" do not contravene certain provisions.

Section 278(1)

The term "patent attorney" may be used in reference to a solicitor, and a firm of solicitors may be described as a firm of "patent attorneys", without any contravention of section 276.

278.02 Use of that term by solicitors is allowed without contravening section 276.

Section 278(2)

No offence is committed under the enactments restricting the use of certain expressions in reference to persons not qualified to act as solicitors -

- (a) by the use of the term "patent attorney" in reference to a registered patent agent, or
- (b) by the use of the term "European patent attorney" in reference to a person on the European list.

Section 278(3)

The enactments referred to in subsection (2) are section 21 of the Solicitors Act 1974, section 31 of the Solicitors (Scotland) Act 1980 and Article 22 of the Solicitors (Northern Ireland) Order 1976.

278.03 Use of the term "patent attorney" by registered patent agents, and the term "European patent attorney" by persons on the European list, is allowed without committing any offence under the enactments listed in subsection (3) concerning titles reserved for solicitors.

Section 279: Power to prescribe conditions etc for mixed partnerships and bodies corporate [Repealed]

279.01 This section empowered the Secretary of State to make rules governing the composition and business practices of partnerships and bodies corporate doing business as patent agents or European patent attorneys, where not all the partners or directors are qualified persons ("mixed" firms). Prior to the coming into force of this section, such firms were not permitted with the exception of the special case of pre-1917 companies (section 114(2)(a) of the Patents Act 1977, re-enacted as section 276(4)). Such rules were only made in respect of s.276 (see 276.03.1).

279.02 This section was repealed on 1 January 2010 by the Legal Services Act 2007, sections 185(5) and 210 and schedule 23. The rules made under the section (The Patent Agents (Mixed Partnerships and Bodies Corporate) Rules 1994 SI 1994/362) therefore also ceased to have effect on that date.

Section 280: Privilege for communications with patent agents

280.01 This replaced section 104 of the Patents Act 1977. It provides that communications between a person and his patent agent (who may be a registered patent attorney, a person on the European list or a partnership or company entitled to describe itself as one of these) are privileged from disclosure in legal proceedings. The scope of the privilege is extended beyond that conferred under the 1977 Act (which was limited to proceedings under that Act) to cover other industrial property topics. Following amendments to the section on 1 January 2010 by the Legal Services Act 2007, the application of privilege is widened to encompass documents, materials and information as detailed in paragraph 77 of Schedule 21 to the Legal Services Act 2007.

Section 280(1)

This section applies to-

- (a) communications as to any matter relating to the protection of any invention, design, technical information, or trade mark, or as to any matter involving passing off, and
- (b) documents, material or information relating to any matter mentioned in paragraph (a).

Subsection (1) defines the scope of the privilege with regard to the topics and format to which communications may relate. They are the protection of any invention, design, technical information, or trade mark; and passing off. Any matter including documents, materials or information relating to these is covered, with the intention of affording privilege to all advice that patent agents are competent to give, sometimes going beyond the strict boundaries of the listed subjects, eg to include copyright issues relating to the 'get-up' of a product.

Section 280(2)

Where a patent attorney acts for a client in relation to a matter mentioned in subsection (1), any communication, document, material or information to which this section applies is privileged from disclosure in like manner as if the patent attorney had at all times been acting as the client's solicitor.

Section 280(3)

In subsection (2) "patent attorneys" means -

- (a) a registered patent attorney or a person who is on the European list,
- (b) a partnership entitled to describe itself as a firm of patent attorneys or as a firm carrying on the business of a European patent attorney, or
- (ba) an unincorporated body (other than a partnership) entitled to describe itself as a patent attorney, or
- (c) a body corporate entitled to describe itself as a patent attorney or as a company carrying on the business of a European patent attorney.

Such communications and information are privileged from disclosure in legal

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proceedings in England, Wales, Scotland and Northern Ireland in the same way as communications with a solicitor. The information is treated as if the patent attorney had been acting as a solicitor.

In Sonic Tape PLC's Patent [1987] RPC 251, the hearing officer found the parties to be joint holders of privilege in one letter. This privilege could be claimed vis-a-vis a third party but not against the other joint holder; the letter could therefore be used in evidence. Aldous J in Lubrizol Corpn v Esso Petroleum [1993] FSR 64 found that privilege did not attach to documents in the possession of both parties unless they would indicate either the advice that might be sought or the advice that was given. In the same case Aldous J observed that it was incredible that any distinction concerning privilege could be drawn between an original document and a copy of it.

[Section 280(4) Repealed]

280.05 Section 280(4) extended with equivalent effect the privilege from disclosure in legal proceedings to legal proceedings in Scotland. The section has now been omitted under s.208 and paragraph 77(e) of schedule 21 of the Legal Services Act 2007.

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Section 281: Power of comptroller to refuse to deal with certain agents

281.01 This enables the making of rules governing the circumstances in which the comptroller may refuse to recognise persons acting as agent in patent or registered design proceedings. It also forbids the recognition of agents who neither reside nor practice in the UK or another state in the European Economic Area. The references to "patent agents" have been amended to "patent attorneys" by section 208(1) and Schedule 21, paragraph 78 of the Legal Services Act 2007.

Section 281(1)

This section applies to business under the Patents Act 1949, the Registered Designs Act 1949 or the Patents Act 1977.

Section 281(2)

The Secretary of State may make rules authorising the comptroller to refuse to recognise as agent in respect of any business to which this section applies -

- (a) a person who has been convicted of an offence under section 88 of the Patents Act 1949, section 114 of the Patents Act 1977 or section 276 of this Act;
- (b) a person whose name has been erased from and not restored to, or who is suspended from, the register of patent attorneys on the ground of misconduct;
- (c) a person who is found by the Secretary of State to have been guilty of such conduct as would, in the case of a person registered in the register of patent attorneys, render the person liable to have the person's name erased from the register on the ground of misconduct;
- (d) a partnership or body corporate of which one of the partners or directors is a person whom the comptroller could refuse to recognise under paragraph (a), (b) or (c) above.

281.02 The Secretary of State is empowered to make rules authorising the comptroller to refuse to recognise persons acting as agent in respect of any of the business listed in subsection (1). Such rules (The Patent Agents (Non-recognition of Certain Agents by Comptroller) Rules 1990) came into force on 13 August 1990 and were amended by the Legal Services Act 2007 (Consequential Amendments) Order 2009 (SI 2009 No.3348). The types of person whom the rules may specify are listed in subsection (2)(a) to (d); rule 3(a) to (d) of the above-mentioned rules specifies those same types of person. (Similar provisions apply to the right of audience in proceedings before the comptroller, see 102.03.) Paragraphs (b) and (c) of subsection (2), and subsection (3) below, effectively place registered and unregistered agents on the same footing as regards the consequences of "misconduct" in relation to recognition by the comptroller.

Section 281(3)

The rules may contain such incidental and supplementary provisions as appear to the Secretary of State to be appropriate and may, in particular, prescribe circumstances in which a person is or is not to be taken to have been guilty of misconduct.

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281.03 Subsection (3) provides that the rules may contain additional provisions, in particular in relation to what may or may not be regarded as misconduct. Such provisions might facilitate the treatment of unregistered persons in the same way as registered patent attorneys in this respect. In fact, the above-mentioned rules do not contain any such provisions.

Section 281(4)

Rules made under this section shall be made by statutory instrument which shall be subject to annulment in pursuance of a resolution of either House of Parliament.

Section 281(5)

The comptroller shall refuse to recognise as agent in respect of any business to which this section applies a person who neither resides nor has a place of business in the United Kingdom, the Isle of Man or another member State of the European Union.

281.04 Subsection (5) concerns the need for a residence or place of business in the UK or European Economic Area in order to be recognised as agent. The Patents and Registered Designs Acts extend to the Isle of Man but not the Channel Islands, hence the latter are not included.

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SUPPLEMENTARY

Section 285: Offences committed by partnerships and bodies corporate

285.01 This contains standard procedural provisions relating to criminal proceedings against bodies corporate and partnerships. It provides inter alia that where offences are committed with the consent or connivance of a director or partner those persons may in addition be proceeded against in their own personal capacities. It also provides that for some purposes, partnerships should be treated in the same way as bodies corporate.

Section 285(1)

Proceedings for an offence under this Part alleged to have been committed by a partnership shall be brought in the name of the partnership and not in that of the partners; but without prejudice to any liability of theirs under subsection (4) below.

285.02 Where proceedings are brought against a partnership, they are to be brought in the name of the partnership as a whole. This applies to proceedings for an offence under Part V of the CDP Act (patent agents and trade mark agents). Individual partners may still be held liable, however, under subsection (4) of this section.

Section 285(2)

The following provisions apply for the purposes of such proceedings as in relation to a body corporate -

- (a) any rules of court relating to the service of documents;
- (b) in England, Wales or Northern Ireland, Schedule 3 to the Magistrates' Courts Act 1980 or Schedule 4 to the Magistrates' Courts (Northern Ireland) Order 1981 (procedure on charge of offence).

285.03 Certain provisions applicable to proceedings against bodies corporate also apply to partnerships.

Section 285(3)

A fine imposed on a partnership on its conviction in such proceedings shall be paid out of the partnership assets.

Section 285(4)

Where a partnership is guilty of an offence under this Part, every partner, other than a partner who is proved to have been ignorant of or to have attempted to prevent the commission of the offence, is also guilty of the offence and liable to be proceeded against and punished accordingly.

285.04 Should a partnership be guilty of an offence under this Part, any fine imposed on the partnership should be paid out of the partnership assets; but every partner is also guilty and liable to be proceeded against. However, this does not apply to any partner who was

ignorant of or attempted to prevent the commission of the offence, but the onus is on such a partner so to prove.

Section 285(5)

Where an offence under this Part committed by a body corporate is proved to have been committed with the consent or connivance of a director, manager, secretary or other similar officer of the body, or a person purporting to act in any such capacity, he as well as the body corporate is guilty of the offence and liable to be proceeded against and punished accordingly.

285.05 Where an offence has been committed by a body corporate with the consent or connivance of a director or other officer of the company, that person is also guilty and is liable to be proceeded against.

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Section 286: Interpretation

286.01 This defines certain terms used in Part V of the CDP Act (patent agents and trade mark agents). This section was amended on 1 January 2010 by section 208(1) and Schedule 21, paragraph 79 of the Legal Services Act 2007.

Section 286

In this part -

"the comptroller" means the Comptroller-General of Patents, Designs and Trade Marks:

"director", in relation to a body corporate whose affairs are managed by its members, means any member of the body corporate;

"the European list" means the list of professional representatives maintained by the European Patent Office in pursuance of the European Patent Convention;

"registered patent attorney" has the meaning given by section 275(2).

286.02 The comptroller means the Comptroller-General of Patents, Designs and Trade Marks. "Proceedings before the comptroller" therefore includes proceedings in the Patent Office, the Trade Marks Registry and the Designs Registry.

286.03 Director includes "member" in the case of a body corporate managed by its members. The normal operation of company law means that a chief executive or other most senior manager who is not a director would also be deemed to be a director for the purposes of this Act.

The European list is defined to mean the list of persons qualified to represent applicants before the European Patent Office. This list is established under Article 134(1) of the European Patent Convention.

A registered patent attorney is a person whose name is entered in the register of patent agents (see 275.04). The reference to registered trade mark attorney in section 286 was repealed by Schedule 5 to the Trade Marks Act 1994. A registered trade mark attorney is now a person whose name is entered on the register of trade mark attorneys in accordance with s.83 of the Trade Marks Act 1994.

PART VI - PATENTS

PATENTS COUNTY COURTS

Section 287: Patents county courts: special jurisdiction [Repealed]

287.01 Sections 287 to 292 of the CDP Act introduced a new arena for proceedings concerning patents or designs and provided for patents cases to be conducted in a county court, and patent agents to conduct such litigation. Sections 287 to 292 were brought into force on 1 August 1989. Section 287 was amended by the Constitutional Reform Act 2005 to provide a role for the Lord Chief Justice of England and Wales or a judicial office holder appointed by him to exercise functions under the section.

287.02 Section 287 set out the framework for the establishment of a county court jurisdiction over patents and designs in England and Wales.

287.03 Section 287 has been repealed by Schedule 9, paragraph 30 of the Crimes and Courts Act 2013.

Section 288: Financial limits in relation to proceedings within special jurisdiction of patents county court [Repealed]

288.01 This section enabled a financial limit to be set for proceedings within the patents county court's jurisdiction.

288.02 Section 288 has been repealed by Schedule 9, paragraph 30 of the Crimes and Courts Act 2013

Section 289: Transfer of proceedings between High Court and patents county court [Repealed]

289.01 This section dealt with the transfer of cases between the patents county court and the High Court.

289.02 Section 289 has been repealed by Schedule 9, paragraph 30 of the Crimes and Courts Act 2013

Section 290: Limitation of costs where pecuniary claim could have been brought in patents county court [Repealed]

s.290(6) 290.01 This section imposed a costs sanction on any claimant who without good reason brought a case in the Patents Court which he could have brought in the patents county court, if he recovered damages of less than a certain figure.

290.02 Section 290 has been repealed by the Courts and Legal Services Act 1990.

Section 291: Proceedings in patents county court [Repealed]

291.01 This section covered two distinct areas affecting proceedings in the patents county court: the first the nomination and duties of a judge, and secondly the appointment and remuneration of advisers or assessors to assist the Court, and the provision of reports by the Office.

291.02 Section 291 required county court rules to make appropriate provision in the above respects, and such provision was made in the Civil Procedure Rules, particularly Part 63. This section was amended by the Constitutional Reform Act 2005 to provide a role for the Lord Chief Justice of England and Wales or a judicial office holder appointed by him to nominate a judge of the patents county court.

291.03 Section 291 has been repealed by Schedule 9, paragraph 30 of the Crimes and Courts Act 2013

Section 292: Rights and duties of registered patent agents in relation to proceedings in patents county court [Repealed]

292.01 This section provided registered patent agents rights of audience before the patents county court and the right to conduct the rest of proceedings outside the courtroom.

Section 292 has been repealed by section 208(1), Schedule 21, paragraph 80 and Schedule 23 of the Legal Services Act 2007. The new regime established by the Legal Services Act 2007 gives the definitions and specific authorisation to take part in reserved legal activities such as the rights and duties in the patents county court.

LICENCES OF RIGHT IN RESPECT OF CERTAIN PATENTS

Section 293: Restriction of acts authorised by certain licences

293.01 The second group of sections in Part VI of the CDP Act amended the provisions for licences of right under certain patents which were granted under the Patents Act 1949. Section 293 inserted a new paragraph 4A into paragraph 4(2)(c) of Schedule 1 to the Patents Act 1977. As all 1949 Act patents have now expired, the provisions of this section are now spent.

293.02-10 [deleted]

Section 293

In paragraph 4(2)(c) of Schedule 1 to the Patents Act 1977 (licences to be available as of right where term of existing patent extended), at the end insert ", but subject to paragraph 4A below", and after that paragraph insert -

"4A - (1) If the proprietor of a patent for an invention which is a product files a declaration with the Patent Office in accordance with this paragraph, the licences to which persons are entitled by virtue of paragraph 4(2)(c) above shall not extend to a use of the product which is excepted by or under this paragraph.

4A(2)

Pharmaceutical use is excepted, that is -

- (a) use as a medicinal product within the meaning of the Medicines Act 1968, and
- (b) the doing of any other act mentioned in section 60(1)(a) above with a view to such use.

4A(3)

The Secretary of State may by order except such other uses as he thinks fit; and an order may -

- (a) specify as an excepted use any act mentioned in section 60(1)(a) above, and
- (b) make different provision with respect to acts done in different circumstances or for different purposes.

4A(4)

For the purposes of this paragraph the question what uses are excepted, so far as that depends on -

- (a) orders under section 130 of the Medicines Act 1968 (meaning of "medicinal product"), or
- (b) orders under sub-paragraph (3) above,

shall be determined in relation to a patent at the beginning of the sixteenth year of the patent.

4A(5)

A declaration under this paragraph shall be in the prescribed form and shall be filed in the prescribed manner and within the prescribed time limits.

4A(6)

A declaration may not be filed -

- (a) in respect of a patent which has at the commencement of section 293 of the Copyright, Designs and Patents Act 1988 passed the end of its fifteenth year; or
- (b) if at the date of filing there is -
 - (i) an existing licence for any description of excepted use of the product, or
 - (ii) an outstanding application under section 46(3)(a) or (b) above for the settlement by the comptroller of the terms of a licence for any description of excepted use of the product,

and, in either case, the licence took or is to take effect at or after the end of the sixteenth year of the patent.

4A(7)

Where a declaration has been filed under this paragraph in respect of a patent -

- (a) section 46(3)(c) above (restriction of remedies for infringement where licences available as of right) does not apply to an infringement of the patent in so far as it consists of the excepted use of the product after the filing of the declaration; and
- (b) section 46(3)(d) above (abatement of renewal fee if licences available as of right) does not apply to the patent".

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Section 294: When application may be made for settlement of terms of licence [spent]

294.01 Section 294 inserted paragraph 4B into Schedule 1 to the Patents Act 1977. It gives statutory force to the existing practice of the comptroller not to deal with applications for the settlement of terms for licences of right available under the transitional provisions of the Patents Act 1977 more than one year before the relevant patent becomes subject to the licence of right provisions. This section can now be considered to be spent.

294.02-04 [deleted]

Section 294

In Schedule 1 to the Patents Act 1977, after the paragraph inserted by section 293 above, insert -

"4B - (1) An application under section 46(3)(a) or (b) above for the settlement by the comptroller of the terms on which a person is entitled to a licence by virtue of paragraph 4(2)(c) above is ineffective if made before the beginning of the sixteenth year of the patent.

4B(2)

This paragraph applies to applications made after the commencement of section 294 of the Copyright, Designs and Patents Act 1988 and to any application made before the commencement of that section in respect of a patent which has not at the commencement of that section passed the end of its fifteenth year."

PATENTS: MISCELLANEOUS AMENDMENTS

Section 295: Patents: miscellaneous amendments

Section 295

The Patents Act 1949 and the Patents Act 1977 are amended in accordance with Schedule 5

295.01 This section makes various amendments to the Patents Acts 1949 and 1977 mainly to remove anomalies and simplify procedures. The amendments are specified in Schedule 5 to the CDP Act, the first paragraph of which relates to the 1949 Act. The remaining twenty-nine paragraphs relate to the 1977 Act and their effects are discussed in the chapters about the particular provisions in question.

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RELEVANT OFFICIAL NOTICES AND DIRECTIONS

Practice notices can be found at

www.gov.uk/government/collections/patents-practice-notices

Directions can be found at

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Subject matter	Manual paragraph(s)
Inventions involving human embryonic stem cells (25 March 2015)	76A.02.1
Ceasing of Patents Form 10 Reminder letter (13 December 2013)	
Calculation of the duration of a Supplementary Protection Certificate (20 November 2013)	SPM 13.05.1
Relaxation of requirements for PCT(UK) Fast Track (8 June 2012)	89B.17
Inventions involving human embryonic stem cells (17 May 2012)	Superseded by <u>Inventions involving</u> human embryonic stem cells (25 March 2015)
Patents Act 1977: Patentability of Mental Acts (17 October 2011)	1.21.1
Patents Act 1977: Time periods defined in the Patents Rules 2007 (23 August 2011)	123.33.1
Hours of business and excluded days (15 July 2011)	120.01
<u>Direction made under section 124A: Requests for electronic uncertified copies of documents from the patent files to be viewed, downloaded or printed online</u>	124A.02
Japan earthquake and tsunami of 11 March 2011	
Patents Act 1977: Reinstatement of patent applications (15 March 2011)	20A.11.1
Patents Act 1977: Periods for response to first examination reports and timescales for further examination reports (6 December 2010)	18.49, 18.64
PCT(UK) Fast Track (28 May 2010)	18.07, 89A.21, 89B.10
Patents Act 1977: Second medical use claims (26 May 2010)	4A27-27.1
Patents Act 1977: Withdrawing patent applications with no rights outstanding (14 May 2010)	5.27-28.5
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Patents Act 1977: Changes to procedure for dealing with foreshadowed divisional applications (1 November 2006)	15.46
Patents Act 1977: Patentability of games (25 November 2005) (also reproduced at [2006] RPC 8) [amended by Patents Act 1977: Patentable subject matter (2 November 2006)]	1.22
Patent applications relating to methods of doing business (2004)	Superseded by Patents Act 1977: Patentable subject matter (2 November 2006)
Inventions involving human embryonic stem cells (April 2003)	Superseded by Inventions involving human embryonic stem cells (3 February 2009)
Applications to Amend the Specification of a Patent under Sections 27 and 75 of the Patents Act 1977 (1 April 2003)	27.03.1, 75.02.1
A number of notices are reproduced <u>here</u> including the following:	
Directions made under section 123(2A)	14.04.13, 123.70.1
Direction made under section 120(1)	120.01
Patents Act 1977: Examining for patentability (also reproduced at [2006] RPC 6)	Superseded by Patents Act 1977: Patentable subject matter (2 November 2006)
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Tribunal Practice Notice 4/2007: Costs in Proceedings before the Comptroller	107.03
Tribunal Practice Notice 2/2000 (also reproduced at [2000] RPC 598): Costs in proceedings before the comptroller	107.03
Tribunal Practice Notice 6/2007:Practice in Patent Proceedings before the Comptroller	123.05
Practice Notice on Evidence (also reproduced at [1999] RPC 294)	123.18
Practice Notice on Computer Programs (also reproduced at [1999] RPC 563)	Superseded by Patents Act 1977: Patentable subject matter (2 November 2006)
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SUPPLEMENTARY PROTECTION CERTIFICATES

FOR MEDICINAL AND PLANT PROTECTION PRODUCTS

INTRODUCTION

Note

This section relates to Supplementary Protection Certificates for Medicinal and Plant Protection Products and is divided into three parts, with the paragraphs numbered using the prefixes below:

SP: the general introduction below;

SPM: a discussion of the details of the Medicinal Regulation by Article, including those aspects common to both the Medicinal and Plant Protection Regulations;

SPP: a discussion of the details specific to the Plant Protection Regulation by Article.

In the margins:

"ArtM" refers to the relevant Article of Regulation (EC) No 469/2009 of the European Parliament and of the Council (for Medicinal Products) ("the Medicinal Regulation" or "the EC Medicinal Regulation").

"ArtP" refers to the relevant Article of Regulation (EC) No 1610/96 of the European Parliament and of the Council (for Plant Protection Products) ("the Plant Protection Regulation").

"ArtPd" refers to the relevant Article of Regulation (EC) No 1901/2006 of the European Parliament and of the Council (on medicinal products for paediatric use) ("the Paediatric Regulation" or "the EC Paediatric Regulation").

"PA 1977" refers to the Patents Act 1977, "s" refers to the relevant section of the Act, "para" and "sch" refer to the relevant paragraphs of the relevant Schedules to the Act.

"reg" refers to the relevant regulation of the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007 (SI 2007/3293) (the "2007 Regulations").

"r" refers to the relevant rule of the Patents Rules 2007 (SI 2007/3291) (the "2007 Rules") and "part" refers to the relevant part of those Rules.

"Fr" refers to the relevant rule of the Patents (Fees) Rules 2007 (SI 2007/3292) (the "2007 Fees Rules") and "FSch" refers to the relevant Schedule of those Rules.

SP0.01 Council Regulation (EEC) No 1768/92 creating a Supplementary Protection Certificate for medicinal products was published in the Official Journal of the European Communities on 2 July 1992, with consequential entry into force on 2 January 1993. This Regulation has subsequently been codified under Regulation (EC) No 469/2009 of the European Parliament and of the Council, which was published in the Official Journal of the European Union L152 on 16 June 2009 and entered into force on 6 July 2009.

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ArtM 22

Various amendments that had been made to Regulation (EEC) No 1768/92 were consolidated but no substantive changes were made. Regulation (EC) No 469/2009 repealed Regulation (EEC) No 1768/92 and provides for references to it to be construed as references to Regulation (EC) No 469/2009. Regulation (EC) No 1610/96 of the European Parliament and of the Council creating a Supplementary Protection Certificate for plant protection products was published in the Official Journal of the European Communities on 8 August 1996 and entered into force on 8 February 1997. As set out in the recitals to both Regulations, the certificate is intended to compensate a patentee for the loss of effective protection arising out of the time taken to obtain regulatory approval to place on the market as either a medicinal or plant protection product a product which is protected by a patent ("the basic patent").

SP0.02 The basic patent may protect the product as such, a process to obtain the product or an application of the product (see SPM1.05).

SP0.03 A certificate takes effect at the end of the lawful term of the basic patent but does not extend the term of the patent itself. It extends the protection conferred by the patent in respect of the product covered by the authorisation to place the corresponding medicinal or plant protection product on the market, and any use of the product as a medicinal or plant protection product that has been authorized before expiry of the certificate.

SP0.04 In the UK, the marketing authorisation for medicinal products takes the form of a Product Licence or Marketing Authorisation granted by the appropriate authority (see SPM2.01). Details of granted Licences, including the product, are no longer published in the London, Edinburgh and Belfast Gazettes but are now advertised on the Medicines and Healthcare products Regulatory Agency (MHRA) website (see SPM1.02). Marketing authorisation for plant protection products may be an Approval or Authorisation granted by the relevant authority (see SPP2.01) and details are published in the Pesticides Register (monthly).

reg 1

SP0.05 A certificate only has effect in the EU State in which it is granted. Certificates granted by the Office have effect in Great Britain and Northern Ireland pursuant to the 2007 Regulations, as well as in the Isle of Man, where the provisions of the 2007 Regulations were given effect by the Patents (Isle of Man) Order 2013 (SI 2013/2602) (the previous application of the 1992 and 1996 Regulations to the territory being revoked by the Isle of Man Patents (Supplementary Protection Certificates) Regulations 2014 (Statutory Document 2014/0091)). See also paragraph 128B.03.

reg 2

SP0.06 The 2007 Regulations amended the Patents Act 1977 to introduce s.128B and Schedule 4A. These make clear how the Act applies in relation to supplementary protection certificates for medicinal products as they relate to certificates and applications for certificates that exist under "the old Regulation" Council Regulation (EEC) No 1768/92; the new Regulation (EC) 469/2009 and to plant protection products as they relate to certificates and applications for certificates that exist under Regulation (EC) No 1610/96.. The operation of these provisions is discussed in paragraphs 128B0.1 to 128B.12. The 2007 Rules and 2007 Fees Rules provide specific procedures for certificates and applications for certificates which differ from patents and applications for patents, including the payment and amount of fees.

ArtM 19, ArtP 18 SP0.07 Where neither the Medicinal or Plant Protection Regulations nor the 2007 Rules lays down a special procedure for certificates, the provisions of the Patents Act 1977 and respective Rules apply to certificates and applications for certificates as they do to patents and applications for patents.

SP0.08 Regulation (EEC) No 1768/92 entered into force with effect from 1 July 1994 in those EFTA States which were at that date party to the European Economic Area Agreement (Austria, Finland, Iceland, Norway and Sweden). This necessitated amendment of the Regulation for the purposes of the application of the Regulation to those States, but the amendments do not have retrospective effect on applications for

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certificates lodged in an existing EU Member State before 1 July 1994. This position was not affected by the accession to the EU of Austria, Finland and Sweden with effect from 1 January 1995. Liechtenstein became a party to the European Economic Area Agreement with effect from 1 May 1995, but did not adopt the Regulation (EEC) No 1768/92 and has not adopted the EC Medicinal Regulation (see SP0.10).

SP0.08.1 The accession to the EU of the ten States (the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic) on 1 May 2004 also necessitated the amendment of Regulation (EEC) No 1768/92 and the Plant Protection Regulation for the purposes of their application to those States (see SPM13.04.2). The accession of Bulgaria and Romania on 1 January 2007 further amended Regulation (EEC) No 1768/92 and the Plant Protection Regulation for the purposes of applying it to these States. The accession of Croatia on 1 July 2013 has amended Regulation (EC) No 469/2009 for the purpose of applying it to this State.

SP0.09 Paragraph 8 of Protocol 1 on Horizontal Adaptations to the European Economic Area Agreement reads:

"Whenever the acts referred to contain references to the territory of the "Community" or of the "common market" the references shall for the purposes of the Agreement be understood to be references to the territories of the Contracting Parties as defined in Article 126 of the Agreement."

This has the effect that for medicinal product applications lodged under Regulation (EEC) No 1768/92 on or after 1 July 1994, or under the EC Medicinal Regulation, references to the Community in Articles 8(1)(a)(iv), 8(1)(c), 9(2)(e), 11(1)(e) and 13(1) of the Regulation are understood to be references to the Contracting Parties to the Agreement (see SP0.08, SPM8.02, SPM9.02, SPM11.01 and SPM13.04). Accordingly, for such applications lodged on or after 1 July 1994 but before 1 May 1995 a first authorisation to place the product on the market in the Community included a first authorisation in Austria, Finland, Iceland, Norway or Sweden. For applications lodged on or after 1 May 1995, it also included a first authorisation in Liechtenstein, even though Liechtenstein has not adopted Regulation (EEC) 1768/92 or the EC Medicinal Regulation. In practice this will be an authorisation in Switzerland, since Swiss authorisations are effective in Liechtenstein and Liechtenstein has not always granted marketing authorisations. However, from 1 June 2005 the bilateral agreement between Switzerland and Liechtenstein was amended so that Liechtenstein now maintains a list of medicinal products whose Swiss authorisations are not automatically recognised. Normally this recognition will be 12 months after the Swiss authorisation.

SP0.10 Similarly, following Decision No 59/97 of the EEA Joint Committee of 31 July 1997 to adopt the Plant Protection Regulation from 1 August 1997, it entered into force in Liechtenstein on 1 August 1997 and in Iceland and Norway on 2 January 1998, these being the EFTA States which were then party to the European Economic Area Agreement. It follows from paragraph 8 of Protocol 1 on Horizontal Adaptations to the Agreement that, for applications for certificates for plant protection products lodged with the Office under Regulation 1610/96 on or after 1 August 1997, the first authorisation within the territories of the existing EU Member States and Iceland, Norway and Liechtenstein constitutes the first authorisation in the Community for the purposes of Articles 8(1)(a)(iv), 8(1)(c), 9(2)(e), 11(1)(e) and 13(1) of Regulation 1610/96 (see SP0.08 and SP0.09). As with the Medicinal Regulation, in practice a first authorisation in Liechtenstein will be a first authorisation in Switzerland (see SP0.09).

SP0.11 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use was published in the Official Journal on 27 December 2006 and entered into force on 26 January 2007. This amended the Regulation (EEC) 1768/92 to provide for a six month extension of a SPC when a requirement was introduced that at the time of marketing authorisation

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application, data on the use of the medicine in children was included. The amendments relating to medicinal products for paediatric use are incorporated in the EC Medicinal Regulation. Note that Article 7 of Regulation (EC) No 1901/2006 does not apply until 26 July 2008 and Article 8 does not apply until 26 January 2009.

REGULATION (EC) NO 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (MEDICINAL PRODUCTS)

RECITALS TO THE REGULATION

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (OJ C 77, 31.3.2009, p 42),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (Opinion of the European Parliament of 21 October 2008 (not yet published in the Official Journal) and Council Decision of 6 April 2009),

Whereas

- (1) Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, p. 1) has been substantially amended several times. In the interests of clarity and rationality the said Regulation should be codified.
- (2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.
- (3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.
- (4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.
- (5) This situation leads to a lack of protection which penalizes pharmaceutical research.
- (6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.
- (7) A uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market.
- (8) Therefore, the provision of a supplementary protection certificate granted,

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under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary. A Regulation is therefore the most appropriate legal instrument.

- (9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorization to be placed on the market in the Community.
- (10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product.
- (11) Provision should be made for appropriate limitation of the duration of the certificate in the special case where a patent term has already been extended under a specific national law,

HAVE ADOPTED THIS REGULATION

As is stated in Halsbury's Laws of England (4th Edition, vol 51, pages 346-348), reference may be made to the recitals in the preamble of a measure in order to confirm the interpretations to be given to a provision of EU law. This may be necessary in order to arrive at the clear, as opposed to the literal meaning of a provision: literal analysis of a text is not always appropriate when regard is had to the nature and scheme of a measure, or the circumstances in which a provision was adopted. In Research Corp's SPC ([1994] RPC 667), the Patents Court, upholding a decision of the hearing officer ([1994] RPC 387), found that Article 5 of the Regulation was clear in the context of Community law as a whole: neither the recitals nor an explanatory memorandum issued by the Commission in 1990 contained anything to suggest that the phrase "same limitations" should exclude endorsement licences of right of a "new existing patent" under the Patents Act 1977. (see also SPM5.01.) The court found the matter acte claire and declined to refer the construction of Article 5 to the European Court of Justice. Similarly, in Draco AB's SPC Application [1996] RPC 417 the Patents Court declined to refer the decision of the hearing officer (see SPM1.04) to the European Court. However, in Re Yamanouchi Pharmaceuticals Co. Ltd (unreported judgment of 31 October 1994) the Patents Court decided to refer the construction of the transitional provisions of Article 19 of Regulation (EEC) No 1768/92 to the European Court (see SPM19.02 and Yamanouchi Pharmaceuticals Co. Ltd v Comptroller-General [1997] RPC 844). The Patents Court has also referred Novartis AG and University College London & Novartis AG and Institute of Microbiology and Epidemiology SPC Applications (BL O/044/03) and [2005] RPC 33 (see SPM8.02 and SPM13.04) and Yissum Research and Development Company of the Hebrew University of Jerusalem (BL O/222/04) (see SPM1.02, SPM1.04 and, SPM3.05)) to the European Court.

SPM0.02 In *Draco AB's SPC Application the Patents Court*, also refusing leave to appeal, held that if the court considered the matter to be *acte claire*, then leave to appeal to the Court of Appeal should logically be refused. The court also observed obiter that where a point turned on material leading to the enactment of a European instrument (the travaux preparatoires), it was unlikely to be *acte claire*.

SPM0.03 The Patents Court in *Draco AB's SPC Application*, considering the recitals to Regulation (EEC) No 1768/92, held that the scheme of the Regulation was not for the general protection of the fruits of research. It was to compensate for lost time in the exploitation of inventions which were patented.

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SPM0.04 Recital 10 of the EC Medicinal Regulation (i.e. "Whereas all the interests at stake...") is, following the entry into force of the Plant Protection Regulation on 8 February 1997, to be interpreted as directed in recital (17) of the latter regulation which states:

(17) Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3(2), 4, 8(1)(c) and 17(2) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of recital 9 and Articles 3, 4, 8(1)(c) and 17 of Council Regulation (EEC) No 1768/92.

In accordance with Article 22 of the EC Medicinal Regulation, reference to recital 9 of Regulation (EEC) No 1768/92 is to be read as reference to recital 10 of the EC Medicinal Regulation. Recitals 12, 13 and 14 of the Plant Protection Regulation are as follows:

- (12) Whereas all the interests at stake in a sector as complex and sensitive as plant protection must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years;
- (13) Whereas the certificate confers the same rights as those conferred on the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection;
- (14) Whereas the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them;

This amplification of recital 10 is consistent with the approach that had already been adopted by the UK Office with regard to the inclusion of salts and esters in the definition of the product (see SPM1.03, SPM2.03, SPM2.04 and SPP1.03-04).

ARTICLE 1: DEFINITIONS

For the purposes of this Regulation, the following definitions shall apply:

- (a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medicinal diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals:
- (b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;
- (c) 'basic patent' means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate:
- (d) 'certificate' means the supplementary protection certificate.
- (e) 'application for an extension of the duration' means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and of Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for

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Product and Medicinal Product

SPM1.01 Article 1 distinguishes between the terms "medicinal product" and "product". Although the Medicinal Regulation creates a certificate for medicinal products, it is the product - defined by Article 1(b) as the active ingredient or combination of active ingredients - which is the subject of the certificate pursuant to Article 2.

SPM1.02 These definitions do not always correspond to the terminology used in UK Product Licences and Marketing Authorisations, or the details published in the official Gazettes (see SP0.04). Thus, the product specified in a Product Licence or Marketing Authorisation is generally broadly equivalent to the "medicinal product" as defined by Article 1(a), and the "active constituent(s)" or "active ingredient(s)" are generally broadly equivalent to the "product" as defined by Article 1(b). However, as the hearing officer determined in *Yissum Research & Development Company of the Hebrew University of Jerusalem* BL O/222/04 such definitions need not restrict the definition of active ingredient in accordance with Article 1(b) (see SPM1.04.1).

SPM1.03 In view of the imposition of the terms of recital (14) of the Plant Protection Regulation through recital (17) therein in the interpretation of recital 10 of the EC Medicinal Regulation, the term "active ingredient" in Article 1(b) is generally interpreted as including any closely related derivative, in particular a salt or ester, which has obtained an authorisation to be placed on the market and is protected by the basic patent, unless the derivative in question can be regarded as a new active ingredient. (See also SPM0.04 and SPM2.03 - 04.)

In the case of Draco AB's SPC Application [1996] RPC 417, the applicants applied for a certificate based on a product licence for an unpressurised asthma inhaler containing the corticosteroid budesonide in the form of agglomerated micronised particles. However, two earlier product licences had been granted for inhalers containing budesonide in the form of micronised particles together with a propellant and surfactant as "other constituents". The hearing officer found that the "product" as defined in Article 1(b) was "budesonide" in the case of all three inhalers and thus rejected the applicant's submission that it was "additive free budesonide in the form of agglomerated micronised particles" in the case of the later inhaler and a combination of "budesonide, a propellant and a surfactant" in the two earlier inhalers. The applicant's alternative submission that the agglomerated form of budesonide was a different "product" from the non-agglomerated form used in the earlier inhalers was similarly rejected. The Patents Court upheld the decision, holding that the scope of protection was strictly confined to the active ingredient in view of the definitions in Articles 1(a) and 1(b) (See also SPM4.02). The applicants obtained leave to appeal to the Court of Appeal but withdrew their appeal before being heard.

SPM1.04.1 In *Yissum Research & Development Company of the Hebrew University of Jerusalem* (BL O/222/04) the hearing officer considered that the definition of active ingredients found in a marketing authorisation should not necessarily be used to restrict the definition of product in accordance with Article 1(b). The product "calcitriol" had been the subject of previous marketing authorisations and for the purposes of Article 3(d) it was not possible to distinguish these marketing authorisations on the basis of a different medical application. However, the hearing officer found that the active ingredients which define the product are those protected by the basic patent when strictly confined to the corresponding ingredients of the authorized medicinal product. Thus it was possible for a certificate to be granted for calcitriol in combination with the specific ointment base found in the approved medicinal product. On appeal the Patents Court [2004] EWHC 2880 referred this issue to the European Court of Justice (ECJ case C-202/05) which found that Article 1(b) is interpreted as meaning that where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product (see SPM0.01, SPM1.02 and

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SPM3.05). Questions of a similar nature regarding the interpretation of the term "combination of active ingredients of a medicinal product" were submitted by the German Federal Court to the ECJ in Massachusetts Institute of Technology (ECJ case C-431/04). The Court ruled that the interpretation of Article 1(b) does not include within the concept of this term a combination of two substances wherein only one substance has a therapeutic effect and the other substance enables a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance. Following Massachusetts Institute of Technology C-431/04 in the decision Abraxis BioScience LLC BL O/410/16, it was concluded that the product "paclitaxel formulated as albumin bound nanoparticles" comprised albumin acting as a carrier and that the product did not qualify as an active ingredient in its own right or as a combination of active ingredients. This view was upheld on appeal in Abraxis Bioscience LLC v Comptroller General of Patents [2017] EWHC 14 (Pat), Arnold J referred questions to the CJEU (C-443/17) in this regard but nonetheless opined that the ECJ has held that Article 1(b) should be strictly interpreted and that it would be inconsistent with such an interpretation for Article 3(d) to permit SPCs to be obtained for new formulations. The meaning of the term "product" has also been considered in GlaxoSmithKline Biologicals S.A. BL O/506/12, wherein the Hearing Officer rejected applications comprising an adjuvant. On appeal to the Patents Court (GlaxoSmithKline Biologicals S.A. v Comptroller General of Patents [2013] EWHC 619 (Pat)), questions were referred to the CJEU, where - in C-210/13 - it was determined that an adjuvant does not fall within the definition of "product", when considered either alone or in combination with an active ingredient. In Forsgren v Österreichisches Patentamt C-631/13 it was determined that a product, which is identified as a "carrier protein" in a MA, and is covalently bonded to other active ingredients, can itself be the subject of a SPC if it produces a "pharmacological, immunological or metabolic action of its own which is covered by the therapeutic indications of the marketing authorisation".

SPM1.04.2 In order to determine which components of a medicinal product are active ingredients and which are not this Office may refer to the summary of product characteristics and (if available) European public assessment reports as well as other evidence complied by the applicant. This practice was approved of in Abraxis Bioscience LLC v Comptroller General of Patents [2017] EWHC 14 (Pat).

Basic Patent

SPM1.05 The basic patent may be either a UK patent or a European patent (UK), and may protect the product as such, a process to obtain the product or an application of the product. However, a process for obtaining a known product may not give rise to a new product. The term "basic" does not mean that the patent must be the first patent to protect the product: it is open to a patent holder to designate any patent fulfilling the criteria of Article 1(c) as the basic patent.

ARTICLE 2: SCOPE

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67) or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1) may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

A certificate can thus be granted in the UK for a product which has received an authorisation to be placed on the market in the UK in accordance with Directive 2001/83/EC (for pharmaceutical products) or Directive 2001/82/EC (for veterinary products). The authorisation may be granted for the UK only, whereupon it takes the form of a Product Licence issued under the Medicines Acts, or a Marketing

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Authorisation issued under the Medicines for Human Use (Marketing Authorisation etc) Regulations 1994 (SI 1994/3144) or the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (SI 1994/3142). UK (only) Product Licences and Marketing Authorisations are granted either by the Medicines and Healthcare Products Regulatory Agency of the Department of Health for a pharmaceutical product, or by the Veterinary Medicines Directorate of the Department for Environment, Food and Rural Affairs for a veterinary product. Alternatively there is a centralised system for granting marketing authorisations for medicinal products for human and veterinary use, established under Council Regulation (EEC) No 2309/93, now repealed and replaced with Regulation (EC) No 726/2004, which provides authorisations which are simultaneously granted in all Member States of the European Union. This type of authorisation is granted by a decision of the European Commission following a favorable opinion from the European Medicines Agency (EMA) and is accepted by the Office as equivalent to a national authorisation. In Generics (UK) Ltd v Synaptech Inc (C-427/09) and Synthon BV v Merz Pharma Gmbh & Co KG (C-195/09) the Court of Justice of the European Union held that Article 2 should be interpreted as meaning that a product which was placed on the market in the European Community as a medicinal product for human use before obtaining a marketing authorisation in accordance with Council Directive 65/65/EEC (now Directive 2001/83/EC) and, in particular, without undergoing safety and efficacy testing, is not within the scope of the Regulation, and may not be the subject of a supplementary protection certificate. It went on to confirm that any SPC granted for a product which was outside the scope of the Regulation was invalid (see also SPM13.04.1). In Leibniz-Institut für Neue Materialien Gemeinnützige GmbH BL O/328/14, Cerus Corporation BL O/141/14 and Angiotech Pharmaceuticals Inc. And University of British Columbia BL O/466/15 the hearing officer found the application out of scope, in that the device was subject of an EC Design Examination Certificate under Directive 93/42/EEC as opposed to Marketing Authorisations under Directive 2001/83/EC. In Boston Scientific Ltd v Deutsches Patent-und Markenamt (C-527/17) the Court of Justice of the European Union has confirmed that an authorization procedure under Directive 93/42 for a device incorporating, as an integral part, a substance which if used separately may be considered a medicinal product, cannot be treated as a marketing authorization granted under Directive 2001/83, see also SPM3.03.2.

SPM2.02 A certificate is granted for a product which constitutes the active ingredient or combination of active ingredients of a medicinal product (see SPM1.01).

SPM2.03 A certificate can only cover a single product, i.e. a single active ingredient or combination of active ingredients. Different products will need to be the subject of different certificates, even if they are protected by the same basic patent. Whether a new certificate is required for a derivative (eg a salt or ester) of a product which has already been granted a certificate depends on whether or not the derivative can be regarded as a new active ingredient (see SPM0.04 and SPM1.03). A new certificate may only be granted for a combination of (a) an active ingredient for which a certificate has already been granted with (b) one or more other active ingredients, if the combinations are themselves the subjects of separate patents or separate core inventive advances within the same patent. A further certificate will not be granted for the same active ingredient notwithstanding any changes to the physical form of that ingredient or to other features of the medicinal product (eg use of a different excipient or different pharmaceutical presentation). (See also SPM1.04.)

ArtM 3(a) (ArtP 3(1)(a)) SPM2.04 A certificate may be granted for a compound optionally in derivative form to the extent that derivatives are protected by the basic patent (see SPM0.04). Examples of wording which have been accepted are:

X optionally in the form of the hydrochloride;

X optionally in the form of a pharmaceutically acceptable salt such as the hydrochloride;

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X optionally in the form of a pharmaceutically acceptable salt.

(see also SPM3.02 and SPM3.02.1).

ARTICLE 3: CONDITIONS FOR OBTAINING A CERTIFICATE

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

- (a) the product is protected by a basic patent in force;
- (b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
- (c) the product has not already been the subject of a certificate;
- (d) the authorization referred to in point (b) is the first authorization to place the product on the market as a medicinal product.

SPM3.01 The conditions of Article 3 must be satisfied at the date of making an application. Thus, at that date:

the basic patent protecting the product must be in force in the UK;

the product must not previously have been the subject of a certificate in the UK;

a valid authorization to place the product on the market in the United Kingdom as a medicinal product must have been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC (see SPM2.01);

this authorisation must be the first authorisation to place the product on the market as a medicinal product in the United Kingdom (although there may have been an earlier authorisation elsewhere in the EU).

SPM3.02 The question of whether the product is protected by the basic patent is determined in accordance with the usual canons of construction of patent claims, as was confirmed by the European Court of Justice in Farmitalia Carlo Erba S.r.l.'s SPC Application (2) ([2000] RPC 580 - ECJ Case C-392/97). In Takeda Chemical Industry's Application (unreported oral decision on application No SPC/GB93/017), the hearing officer held that a product comprising the acetate salt of a peptide was protected by a basic patent, even though the claims did not on a literal construction include derivatives of the polypeptide, on the grounds that the description made it clear that the polypeptide could be obtained in the form of the acetate. In Centocor Inc's SPC Application [1996] RPC 118, the hearing officer held that a product consisting of a monoclonal antibody was not protected by claims to a combined preparation of a monoclonal antibody and an anti-microbial agent. In Takeda Chemical Industries Ltd's Applications [2004] RPC 1 (upheld on appeal to the Patents Court [2004] RPC 3) the hearing officer held that products comprising a combination of ingredients were not protected by patents which related to only one of the ingredients. The basic patents contained no reference to the combinations specified in the SPC applications. The Court of Appeal in Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd [2009] EWCA Civ 646, [2009] RPC 23 upheld the earlier decision of the Patents Court ([2008] EWHC 2413 (Pat), [2009] RPC 4) confirming this interpretation. The Court found the SPC for levofloxacin, the (-) enantiomer of the racemic mixture, ofloxacin, to have been properly granted despite the existence of earlier marketing authorisations to this racemic mixture. Sciences, Inc. (BL O/006/08) the hearing officer held that a basic patent which protected a specific active compound and which claimed a combination of the active

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substance optionally in combination with other (unspecified) therapeutic ingredients did not protect the combination of the active compound with another specific active compound which was the subject of the SPC application. The claim and a corresponding reference in the description were the only indication of a combination of active ingredients in the basic patent. On appeal the Patents Court held (in Re Council Regulation (EEC) No 1768/92 [2008] EWHC 1902 (Pat)) that although the specific combination was not disclosed in the specification of the basic patent such a claim did protect the combination within the meaning of Articles 1(c) and 3(a) and therefore that the applicant was entitled to a certificate to the combination of specific active ingredients. In Astellas Pharma Inc.(BL O/052/09) the hearing officer similarly found that a patent which disclosed one active ingredient but did not disclose, either specifically or generically, a combination of active ingredients was not a basic patent which protected a combination of active ingredients for the purposes of Article 3(a). On appeal to the Patents Court (Astellas Pharma Inc v Comptroller-General of Patents [2009] EWHC 1916 (Pat)), Arnold J upheld the decision of the hearing officer after applying the test articulated in Gilead. Arnold J distinguished the facts of Astellas from Gilead because, unlike in Gilead, the basic patent did not specifically disclose and claim a combination of active ingredients.

SPM3.02.1 In Sankyo Company Limited (BL O/271/10) the hearing officer similarly rejected an SPC application for a combination of active ingredients on the basis that it did not meet the requirements of Article 3(a) of the Regulation. On appeal to the Patents Court (Daiichi Sankyo Company Limited v Comptroller General of Patents, [2010] EWHC 2897 (Pat)), Floyd J referred questions to the Court of Justice of the European Union (CJEU) for a preliminary ruling concerning the correct test to apply when deciding whether a product is protected by a basic patent under Article 3(a) of the SPC regulation (C-6/11, Daiichi Sankyo Company v Comptroller-General of Patents). The CJEU provided its decision by reasoned order with reference to C-322/10 (Medeva) (see SPM3.02.4 below), confirming that Article 3(a) precludes the grant of an SPC relating to active ingredients which are not identified in the wording of the claims of the basic patent relied upon in the SPC application (also see referrals to the CJEU in Georgetown et al., University of Queensland, CSL Ltd (SPM3.02.4), and Yeda Research and Development Company Ltd (SPM3.02.2)). Following Takeda where a combination is not claimed but is disclosed in the description, it may be possible to amend the granted patent under s.27 of the Patents Act 1977 to provide the protection required under Article 3(a) questions concerning this practice were referred to the CJEU in Actavis Group and Actavis UK v Boehringer Ingelheim Pharma [2013] EWHC 2927 (Pat) however in C-577/13 Actavis Group PTC EHF, Actavis UK Ltd v Boehringer Ingelheim Pharma GmbH & Co. KG these questions were not answered (see also SPM3.02.5, 10.14.1).

In Imclone Systems Inc. Ltd & Aventis Holdings Inc. (BL O/066/10), the hearing officer found that a marketing authorisation for a single active ingredient which additionally specified the clinical use of that active in conjunction with another active ingredient was not, for the purposes of Article 3(b) of the Regulation, a valid authorisation to place a combination product on the market as a medicinal product. The MA referred to how the active ingredient, an antibody known as cetuximab (medicinal product name Erbitux®), which had cytostatic properties, could be used clinically in conjunction with another active ingredient, an anti-cancer drug irinotecan, with cytotoxic properties, to treat certain types of cancer and that the presence of the cetuximab reduced the amount of irinotecan required to achieve a clinical effect. However, the hearing officer found that the MA has to be considered in its entirety and not just in respect of the clinical particulars when deciding what is the authorised medicinal product, and hence what is the product that can be protected by an SPC. Furthermore, in following the approaches taken in Takeda, Gilead, Astellas and Centocor Inc, the hearing officer found that a patent protecting a combination of active ingredients did not protect a single active ingredient for the purposes of Article 3(a). On appeal to the Patents Court (Yeda Research and Development Company Ltd v Comptroller General of Patents [2010] EWHC 1733 (Pat), [2010] RPC 29), Lewison J upheld the decision of the hearing officer to refuse the applications and dismissed the appeal, confirming the

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approaches taken in previous decisions. On appeal to the Court of Appeal (Yeda Research and Development Company Ltd v Comptroller General of Patents) the Court referred a question for a preliminary ruling to the Court of Justice of the European Union (CJEU) concerning whether or not secondary infringement should be part of any proposed infringement test for determining what is protected by the basic patent under Article 3(a) (C-518/10, Yeda Research and Development Company Ltd, Aventis Holdings Inc v Comptroller-General of Patents). The CJEU provided its decision by reasoned order with reference to C-322/10 (Medeva) (see SPM3.02.4 below), confirming that Article 3(a) precludes the grant of an SPC where the active ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone (see also the referrals to the CJEU in relation to Daiichi Sankyo Company Limited (SPM3.02.1), Georgetown et al., and University of Queensland/CSL Ltd (SPM3.02.4)).

SPM3.02.3 In Farmitalia Carlo Erba S.r.l's SPC Application (2) the Court also ruled that where an active ingredient in the form of an individual salt is referred to in the notice of authorisation, under Article 3(b) the certificate is capable of covering the active ingredient both as referred to and in its derived forms such as salts and esters as medicinal products, provided that the derived forms also enjoy the protection of the basic patent.

The requirements of Articles 3(a) and 3(b) of the Regulation have also SPM3.02.4 been considered in a number of cases relating to medicinal products in the vaccine field. In Medeva BV's SPC Applications (BL O/357/09) the hearing officer, in following the Astellas and Gilead decisions, found that a basic patent protecting only two particular active ingredients did not protect, for the purposes of Article 3(a), a product containing these two active ingredients in combination with other active ingredients. He also found that a marketing authorisation for a medicinal product comprising a combination of active ingredients which included, among others, the two active ingredients was not, for the purposes of Article 3(b), a valid authorisation to place a product consisting of these two active ingredients on the market as a medicinal product. On appeal to the Patents Court (Medeva BV v The Comptroller General of Patents, [2010] EWHC 68 (Pat), [2010] RPC 20), Kitchin J upheld the decision of the hearing officer and dismissed the appeal, noting that "...It is plain that "product" must have the same meaning in Article 1(b) and Article 3(a). If the product of Article 1(b) is the whole combination of active ingredients then so it remains for the purposes of Article 3(a)...". On appeal to the Court of Appeal (Medeva's SPC Applications, [2010] EWCA Civ 700, [2010] RPC 27), the Court referred questions concerning the interpretation of Articles 3(a) and 3(b) to the Court of Justice of the European Union (CJEU) for a preliminary ruling (C-322/10, Medeva v Comptroller-General of Patents). The CJEU ruled that, for the purposes of Article 3(a), in order to be protected active ingredients needed to be 'specified' in the wording of the claims of the basic patent filed in support of the SPC application, thereby rejecting the so-called 'infringement test'. In relation to Article 3(b), it also ruled that SPCs can be granted for a combination of active ingredients specified in the wording of the claims of the basic patent relied on where the medicinal product of the marketing authorisation submitted in the SPC application also contains other active ingredients in addition to the combination specified in the basic patent. In light of the answers from the CJEU the Court of Appeal confirmed that Medeva's applications did not meet these requirements and dismissed their appeal (Medeva BV v Comptroller General of Patents [2012] EWCA Civ 523). In Georgetown University, Loyola University of Chicago, and University of Rochester's SPC applications (BL O/401/09) the hearing officer rejected SPC applications for single active ingredients in the vaccine field on the grounds that they did not satisfy the requirements of Article 3(b) of the Regulation as the marketing authorisations provided in support of these applications related to products with multiple active ingredients. On appeal to the Patents Court, Kitchin J referred a question concerning the interpretation of Article 3(b) to the Court of Justice of the European Union (Georgetown University, University of Rochester, Loyola University of Chicago v Comptroller-General of Patents, C-422/10; the question was the same as that referred in Medeva in respect of Article 3(b)). Consistent with the approach taken in

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C-322/10, the CJEU ruled that SPCs can be granted for an active ingredient specified in the wording of the claims of the basic patent where the marketing authorisation relied upon in the SPC application is for a product that contains other active ingredients in addition to the active ingredient specified in the basic patent. The hearing officer followed similar approaches to those in BL O/357/09 and BL O/401/09 in relation to Articles 3(a) and 3(b) in rejecting multiple SPC applications in the vaccine field for either combinations of active ingredients or single active ingredients in University of Queensland & CSL Limited (BL O/335/10). On appeal to the Patents Court, Arnold J referred further questions to the Court of Justice of the European Union concerning the interpretation of Article 3(a) and 3(b) (C-630/10, University of Queensland, CSL Ltd v Comptroller-General of Patents, Designs and Trade Marks). The CJEU provided its decision by reasoned order with reference to C-322/10 (Medeva) and C-422/10 (Georgetown). The CJEU reiterated its answers from its decisions in Medeva and Georgetown, and clarified that if a basic patent relates to a process by which a product is obtained, Article 3(a) only allows an SPC to be granted for a product which is identified in the wording of the claims of the patent as the product deriving from the process in question. The Court also stated that whether it is possible to obtain the product directly as a result of the process is irrelevant in that regard. Applying the CJEU's decision, the Patents Court determined the compliance or otherwise of the applications before it (University of Queensland and CSL limited v Comptroller General of Patents, [2012] EWHC 223 (Pat)). C-630/10 University of Queensland, CSL Ltd v Comptroller-General of Patents, Designs and Trade Marks was also applied in Icahn School of Medicine at Mount Sinai BL O/552/14 which determined that Article 3(a) is complied with if the product identified in the patent claims is the product deriving from the process protected by that patent, but that it is not also necessary to establish that the product is produced by the method of the basic patent.

SPM3.02.5 The Office will determine that a product is specified/identified in the wording of the claims of the basic patent filed in support of the SPC if having regard to the normal cannons of claim interpretation it is: i) indicated in a claim; ii) encompassed by a Markush formula; iii) shown to result from the process protected by the basic patent; or iv) encompassed by a functional definition. In respect of (ii) Sandoz Ltd & Anor v G.D. Searle & Anor [2017] EWHC 987 (Pat) confirmed that Article 3(a) will be complied with if the product falls within the scope of a Markush formula; although this judgment has been appealed ([2018] EWCA Civ 49), this practice continues to apply as the proceedings have been stayed pending a referral to the CJEU on the issue (C-114/18). Similarly, the existing approach to functional definitions is subject to the outcome of a referral (C-650/17 QH) from the German courts. In respect of (iii) and (iv) it may be necessary to ask the applicant to provide evidence such as in the form of a witness statement from a suitable patent addressee that this is the case. In order to meet the requirement that the product is "...in the wording of a claim" an applicant may have recourse to section 27 of the Patents Act to amend the basic patent accordingly. Questions concerning the practice of amending a basic patent to render an application compliant with Article 3(a) were referred to the CJEU in Actavis Group and Actavis UK v Boehringer Ingelheim Pharma [2013] EWHC 2927 (Pat) however in C-577/13 Actavis Group PTC EHF, Actavis UK Ltd v Boehringer Ingelheim Pharma GmbH & Co. KG these questions were not answered (see also SPM3.02.1, 10.14.1).

SPM3.02.6 In Novartis Pharmaceuticals UK Limited and Medimmune Limited/Medical Research Council [2012] EWHC 181 (Pat) Arnold J commented at paragraph 53 that "the test laid down by the Court of Justice in Medeva and its progeny is unclear save in its rejection of the infringement test in combination cases. In particular, it is unclear precisely what is meant by "specified (or identified) in the wording of the claims"". However, after interpreting and applying the Medeva C-322/10 decision (along with the decisions C-422/10 Georgetown University and Others, C-630/10 University of Queensland and CSL, C-6/11 Daiichi Sankyo, and C-518/10 Yeda Research and Development) he went on to find that a claim to a general method of producing a molecule with binding specificity for a particular target did not adequately specify or identify the specific antibody ranibizumab for the purposes of Article 3(a). In Actavis Group PTC EHF / Actavis UK Limited and Sanofi and Sanofi Pharma Bristol-Myers Squibb SNC [2012] EWHC 2545 Arnold J reiterated his doubt surrounding what

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is meant by "specified (or identified) in the wording of the claims" and that the proceeding references do not provide a clear test which can be applied to cases such as the present. Accordingly he referred a further question on the interpretation of Article 3(a) to the Court of Justice of the European Union for a preliminary ruling (C-443/12). The court established that an SPC is to compensate for delay in marketing "the core inventive advance" of a patent. Further questions were referred to the CJEU for a preliminary ruling (C-493/12) from the Patents Court in Eli Lilly & Company v Human Genome Sciences Inc [2012] EWHC 2290 (Pat), the court determined that a functional definition may suffice for a product to be protected by a basic patent if "the claims relate, implicitly but necessarily and specifically to the active ingredient in question." On coming back before the High Court, the judgment in Eli Lilly & Company v Human Genome Sciences Inc [2014] EWHC 2404 (Pat) confirmed that the question of compliance with Article 3(a) is simply 'does the product fall within the scope of the claims', but that in the case of combination products a proviso exists, in that a product is not protected solely by wording such as "comprises" that extends the claim beyond its principle scope. The law as regards protection by the basic patent for combination products was considered by the Hearing Officer in Merck Sharp & Dohme Corporation BL O/117/16: on reviewing the rulings C-443/12 and C-577/13, it was determined that a combination of active ingredients was protected as such by the patent because it was part of the subject matter or innovation of the patent and fell within the core inventive advance disclosed, this decision has been appealed. Arnold J in Teva UK & Ors v Gilead [2017] EWHC 13 (Pat) reviewed the judgments of the CJEU in respect of how combination products at least may satisfy Article 3(a) and again referred to the CJEU (C-121/17) the question "what are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a)". The Grand chamber of the CJEU in C-121/17 has ruled that a combination of active ingredients is protected by a basic patent if the claims relate necessarily and specifically to the combination, and that this is to be judged form the point of view of a person skilled in the art on the basis of the prior art at the priority date of the basic patent. The combination must necessarily, in light of the description and drawings fall under the invention of the basic patent and each of the ingredients must be specifically identifiable in light of all the information disclosed. The German Federal Patents court judgment 14W (pat) 12/17 referred guestions to determine if Article 3(a) requires an individualised embodiment of the product or if a functional definition will suffice.

SPM3.02.7 In *Forsgren v Österreichisches Patentamt C-631/13* it was determined that an SPC is precluded for an active ingredient whose effect does not fall within the therapeutic indications covered by the wording of the marketing authorisation.

SPM3.03 Although Article 3(b) requires a valid authorisation to have been granted, there appears to be no requirement that the authorisation should still be in force at the date of making the application for a certificate (e.g. it may be withdrawn or have lapsed before the date of the application for the certificate). In *Merck Sharp & Dohme Corporation v Comptroller General of Patents* [2016] EWHC 1896 (Pat) Arnold J proposed that the absence of a granted marketing authorisation is not an irregularity that may be cured after the date of application, he nonetheless referred a question on this point to the CJEU.

SPM3.03.1 In *British Technology Group Ltd's SPC Application* [1997] RPC 118 the hearing officer found that a letter from the Medicines Control Agency granting permission for a product to be supplied for a proposed clinical trial was not an acceptable market authorisation in that it was not issued in accordance with Directive 65/65/EEC or Directive 81/851/EEC nor did it provide a summary of product characteristics as required by Article 8(1)(b) (see SPM2.01, SPM10.17.1 and SPP3.02). Directives 65/65/EEC and 81/851/EEC were the Directives in accordance with which the authorisation had to have been granted under Article 3(b) of Regulation (EEC) 1768/92. They were repealed and consolidated with Directive 75/319/EEC into 2001/83/EC and 2001/82/EC respectively. In C-567/16 *Merck Sharp & Dohme Corporation v Comptroller General of Patents* the court confirmed the views expressed by Arnold J in [2016] EWHC 1896 (Pat) (an appeal from *Merck Sharp & Dohme Corporation BL O/117/16*) that an end of procedure notice issued by a relevant national

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competent body for authorising medicines under Article 28(4) of the Medicinal Products Directive is not a valid authorisation for the purposes of Article 3(b).

SPM3.03.2 In Cerus Corporation BL O/141/14, Leibniz-Institut für Neue Materialien Gemeinnützige GmbH BL O/328/14 and Angiotech Pharmaceuticals Inc. and University of British Columbia BL O/466/15 the hearing officer found that EC design examination certificates relating to medical devices did not meet the requirements of Article 3(b). The EC design examination certificates were issued having regard to Article 1(4) of Directive 93/42/EEC because the devices incorporate as an integral part, a substance which, if used separately, may be considered a medicinal product and which acts upon the body with action ancillary to that of the device. Such "class III" devices (as defined in Article 9 and Annex IX of Directive 93/42/EEC) require the safety quality and usefulness of the substance to be assessed, in an analogous way to authorisation under Directive 2001/83/EC. However this assessment process was not found to be the same or equivalent to the process carried out to authorise a medicinal product for human use in accordance with Directive 2001/83/EC. The CJEU in Boston Scientific Ltd v Deutsches patetn-und Markenamt (C-527/17) has confirmed that the authorization procedure under Directive 93/42 cannot be treated as an authorization granted under Directive 2001/83/EC, see also SPM 2.01.

SPM3.04 Article 3(c) precludes the grant of a second certificate for a product where the first certificate has been granted before the date of application for the second certificate. However, in Chiron Corporation and Novo Nordisk A/S [2005] RPC 24 the hearing officer concluded that the grant of a supplementary protection certificate for a product to one holder of a basic patent before an application is lodged in relation to the same product by a different holder of a different basic patent on the basis of a common marketing authorisation does not provide a ground for rejecting the later application under Article 3(c) of the Regulation. The European Court of Justice in AHP Manufacturing BV v Bureau voor de Industriële Eigendom [2009] C-482/07 held that Article 3(c) of the Regulation does not prevent the grant of a certificate to the holder of a basic patent for a product if, at the time of the submission of the application for a certificate, one or more SPCs have already been granted to one or more holders of one or more other basic patents. Thus it may be possible in specific circumstances for a further certificate to be granted when a certificate already exists. In Takeda Chemical Industries Ltd's Applications [2004] RPC 2, the hearing officer held that products comprising a combination of ingredients were not precluded from grant of an SPC because one of the ingredients had already been granted an SPC. However, in light of the comment made in Medeva that "only one certificate may be granted for the basic patent", Arnold J in Actavis Group PTC EHF / Actavis UK Limited and Sanofi and Sanofi Pharma Bristol-Myers Squibb SNC [2012] EWHC 2545 determined that the correct interpretation of Article 3(c) was not clear and referred the following question to the CJEU for preliminary ruling (C-443/12), "In a situation in which multiple products are protected by a basic patent in force, does the Regulation, and in particular Article 3(c), preclude the proprietor of the patent being issued a certificate for each of the products protected?" A similar question was referred from the district court of The Hague in Georgetown University and Octrooicentrum Nederland C-484/12. In the resulting decisions, the CJEU determined that it is possible, on the basis of a patent which protects several different products, to obtain several SPCs in relation to each of those products provided that each of those products is protected by the basic patent, (C-484/12, paragraph 30), but that Article 3(c) prohibits successive SPCs based on a single patent for the same active in combination with another active not itself protected by the patent (C-443/12, paragraph 30). Commenting on Art 3(c) in C-577/13 Actavis Group PTC EHF, Actavis UK Ltd v Boehringer Ingelheim Pharma GmbH & Co. KG (paragraph 39), the CJEU held that, where an SPC has already been granted relating to an active ingredient which constitutes the sole subject matter of the invention, the patent holder is precluded from obtaining an SPC for a combination product claimed in a subsequent claim of the same patent comprising that active ingredient and another substance not constituting the subject matter of the invention. In reference to this judgment, Arnold J in Teva UK Limited & Ors v Merck Sharp & Dohme Corporation

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[2017] EWHC 539 (Pat) held that, if the combination represents a distinct invention protected by the patent, it should not matter whether it is protected by the same patent or by a different patent. In other words, it is the active ingredients found to represent the subject matter of the invention that are critical in determining what the product is, and not if aspects of the subject matter of the invention are found in one or more patents.

SPM3.04.1 Recital (17) of the Plant Protection Regulation (see SPM0.04) must also be considered in respect of Article 3(c) as, from 8 February 1997 when said regulation came into force, Article 3 of the Medicinal Regulation is to be interpreted in accordance with Article 3(2) of the new regulation which states:

ARTICLE 3(2) [EC Plant Protection Regulation]

The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

SPM3.04.2 Consequently, the grant of one certificate to each patent holder in respect of the same product on two or more applications each specifying a different basic patent protecting the product is now allowed. The hearing officer in *Takeda Chemical Industries Ltd's Applications* [2004] RPC 2 found that only one certificate for a product should be granted to the same applicant, having also considered the European Court of Justice decision in *Biogen Inc. v Smithkline Beecham Biologicals SA* ([1997] RPC 23 ECJ Case C-181-95).

SPM3.05 In Yissum Research & Development Company of the Hebrew University of Jerusalem (BL O/222/04) the hearing officer found that the condition specified in Article 3(d) will not be met if an authorisation to place the product on the market is not the first for the product, regardless of whether the earlier authorisation was for a different medical condition. The product "calcitriol" had been the subject of previous marketing authorisations and for the purpose of Article 3(d) these earlier authorisations could not be distinguished on the basis of their different therapeutic applications. This decision was appealed to the Patents Court [2004] EWHC 2880 which referred the matter to the European Court of Justice for a preliminary ruling (case C-202/05) (see SPM0.01, SPM1.02, SPM1.04.1). The ECJ found that when a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product. Questions of a similar nature regarding the interpretation of the term "combination of active ingredients of a medicinal product" were answered by the ECJ in Massachusetts Institute of Technology (case C-431/04) (see SPM 1.04.1).

SPM3.05.1 In *Neurim Pharmaceuticals* (1991) Ltd's SPC Application (BL O/384/09) the hearing officer rejected an SPC application for the product melatonin on the basis that the conditions of Article 3(d) were not met. An earlier veterinary authorisation for the active ingredient melatonin precluded the grant of an SPC based on the later human authorisation. Although the decision of the hearing officer was upheld by the Patents Court (*Neurim Pharmaceuticals* (1991) Limited v Comptroller General of Patents, [2010] EWHC 976 (Pat), [2010] RPC 22), on appeal to the Court of Appeal (*Neurim Pharmaceuticals* (1991) Ltd v Comptroller General of Patents, [2011] EWCA Civ 228, [2011] RPC 19) questions concerning the interpretation of Article 3(d) (and Article 13) were referred to the Court of Justice of the European Union (C-130/11, *Neurim Pharmaceuticals* (1991) Ltd v Comptroller General of Patents). In answering the questions referred to it from the UK Court of Appeal, the CJEU confirmed that in a case such as Neurim's, Articles 3 and 4 of the Regulation should be interpreted as meaning that:

"...the mere existence of an earlier marketing authorisation (obtained for a veterinary medicinal product) does not preclude the grant of a supplementary

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protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate".

The CJEU went on to state that Article 13(1) must be interpreted as referring to a marketing authorisation for a product which falls within the limits of protection conferred by the basic patent relied upon for the purposes of the SPC application (see SPM13.04).

SPM3.05.2 Whereas the first marketing authorisation for the product regardless of use or indication will normally constitute the first marketing authorisation having regard to Article 3(d): C-130/11. Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents delineates circumstances where an earlier marketing authorisation for the same product will not contravene Article 3(d). In Abraxis BioScience LLC BL O/410/16 it was held that these circumstances do not include a new formulation of an existing product but instead relate to a new therapeutic application of an existing product, on appeal -Abraxis Bioscience LLC v Comptroller General of Patents [2017] EWHC 14 (Pat) -Arnold J referred questions as to the correct interpretation of Article 3(d) to the CJEU (C-443/17) but nonetheless gave his own opinion that Article 3(d) does not permit SPCs for new formulations of old active ingredients. In cases similar to Neurim it may be necessary to ask the applicant to show that the indication in the marketing authorisation is within the scope of protection of the basic patent, in accordance with paragraph 26 of the judgment. The scope of an SPC granted having regard to the Neurim judgment will extend only to the authorised use, paragraph 25 of the judgment. However practice dictates that we will not seek to define this use in the product definition at item 6 of form SP1.

SPM3.06 It is considered that a process for obtaining a known product already covered by a certificate may not give rise to a new certificate (see SPM1.05).

ARTICLE 4: SUBJECT-MATTER OF PROTECTION

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.

SPM4.01 A certificate extends the protection conferred by the basic patent beyond the term of that patent but only in respect of the product covered by the authorisation to place the corresponding medicinal product on the market and any use of the product as a medicinal product that has been authorised before expiry of the certificate. It does not, however, extend the term of the patent itself.

SPM4.01.1 Article 4 of the Medicinal Regulation is to be interpreted in the same way as Article 4 of the Plant Protection Regulation in view of recital (17) of the latter which states:

ARTICLE 4 [EC Plant Protection Regulation]

Subject-matter of protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorizations to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorized before expiry of the certificate.

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SPM4.01.2 The plural "authorizations" makes clear that one certificate will suffice for the first and subsequent authorizations.

SPM4.02 In *Draco AB's SPC Application* [1996] RPC 417 the Patents Court held that Article 4 was the operative Article to confer protection on the product, which was the active ingredient as defined in Article 1(b).

SPM4.03 In *Novartis AG v Actavis UK Limited*, questions concerning the interpretation of Article 4 (and Article 5) of the Regulation were referred to the Court of Justice of the European Union (C-442/11). The Court of Justice provided its decision by reasoned order with reference to its decisions in C-322/10 *Medeva*, C-422/10 *Georgetown University and Others*, C-630/10 *University of Queensland and CSL*, and C-6/11 *Daiichi* Sankyo (see above), confirming that SPCs provide patent-like infringement protection for the duration of the SPC (also see SPM5.03).

ARTICLE 5: EFFECTS OF THE CERTIFICATE

Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

SPM5.01 Subject to Article 4, a certificate confers the same rights as the basic patent and is subject to the same limitations and obligations. Provisions under national law relating to such matters as infringement therefore apply equally to a certificate. In certain circumstances the Office will provide a non-binding opinion as to whether or not an SPC is infringed, see Section 74A.

SPM5.02 In Research Corp's SPC ([1994] RPC 667), (see also SPM0.01), the Patents Court, upholding a decision of the hearing officer reported at [1994] RPC 387, held that the endorsement of the basic patent licences of right under the provisions of paragraph 4 of Schedule 1 of the 1977 Act was a limitation within the meaning of Article 5. The comptroller therefore had jurisdiction to entertain an application to settle the terms of licence of right under a certificate, pursuant to s.46(3) of the Patents Act 1977 and Article 5 of the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992.

SPM5.03 In *Novartis AG and Actavis UK Limited*, questions concerning the interpretation of Article 5 (and Article 4) of the Regulation were referred to the Court of Justice of the European Union (C-442/11). The Court of Justice provided its decision by reasoned order with reference to its decisions in C-322/10 *Medeva*, C-422/10 *Georgetown University and Others*, C-630/10 *University of Queensland and CSL*, and C-6/11 *Daiichi* Sankyo (see above), confirming that SPCs provide patent-like infringement protection for the duration of the SPC (also see SPM4.03).

SPM5.04 To assist in determining if particular compositions or acts infringe an SPC it is possible to request this Office gives a non-binding opinion on infringement, See Section 74A or https://www.gov.uk/guidance/opinions-resolving-patent-disputes.

ARTICLE 6: EFFECTS OF THE CERTIFICATE

The certificate shall be granted to the holder of the basic patent or his successor in title.

SPM6.01 Article 6 does not prevent an application from being lodged by a person other than the proprietor of the basic patent. However, irrespective of who lodged the application, the certificate can be granted only to the person registered at the time of

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grant as the proprietor of the basic patent.

SPM6.02 The question of whether, having regard to the wording of Article 6, the holder of a marketing authorisation may refuse to give a copy to the holder of the basic patent or his successor in title where it is required by Article 8(1)(b) in order to complete the application was referred to the European Court of Justice by the Tribunal de Commerce, Nivelles, Belgium in *Biogen Inc v SmithKline Beecham Biologicals SA* [1997] RPC 833. The Court ruled that the Regulation does not require the holder of the marketing authorisation to provide a copy to the patent holder. Such an obligation may, however, be deemed to be inherent in the contractual relationship between the parties. (See also SPM8.04.1.)

SPM6.03 In *Eli Lilly & Company v Human Genome Sciences Inc* [2012] EWHC 2290 (Pat) Warren J held "that the holder of a basic patent can make an application for an SPC in reliance on an MA granted to a third party having no connection of any sort with that holder."

ARTICLE 7: APPLICATION FOR A CERTIFICATE OR AN EXTENSION OF A CERTIFICATE

- 1. The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3(b) to place the product on the market as a medicinal product was granted.
- 2. Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.
- 3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1)(d) or Article 8(2), respectively, are fulfilled.
- 4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.
- 5. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.

SPM7.01 Except where the transitional provisions of Article 19 of Regulation (EEC) No 1768/92 applied, the application must be lodged within six months of the date of grant of either the first UK authorisation or the basic patent, whichever is later. In *Abbott Laboratories' SPC Application* [2004] RPC 20 the Hearing Officer held that the relevant date in Article 7(1) is the actual date of grant of the authorisation and not the date of publication of grant in the relevant Official Gazette. It was also held that the six month deadline set out in Article 7 is extendable under r.110(1) of the Patents Rules 1995 (now rule 108(1) of the 2007 Rules), in accordance with the provisions of Article 18 of Regulation (EEC) No 1768/92 (now Art 19 of the EC Medicinal Regulation) (see SPM19.11). In respect of Article 7(2); in accordance with Article 97(4) of the European Patent Convention, the date of grant of a European Patent is the date the European Patent Bulletin mentions grant. For a UK patent, the relevant date of grant is taken to be the date of publication of the notice of grant in the Patents Journal under Section 24(1) of the Patents Act 1977 (rather than the date of grant under Section 18(4)).

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SPM7.02 An application for an extension can be lodged when an application for a certificate is filed or whilst the application for a certificate is pending or it may be filed after a certificate has been granted. When a certificate is already granted the application shall be lodged not later than two years before the expiry of the certificate. However, for five years from the entry into force of Regulation 1901/2006 an application for an extension must be lodged not later than six months before the expiry of the certificate.

SPM7.03 The time periods expressed in Article 7 are to be determined in accordance with Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits.

ARTICLE 8: CONTENT OF THE APPLICATION FOR A CERTIFICATE

- 1. The application for a certificate shall contain:
 - (a) a request for the grant of a certificate, stating in particular:
 - (i) the name and address of the applicant;
 - (ii) if he has appointed a representative, the name and address of the representative;
 - (iii) the number of the basic patent and the title of the invention;
 - (iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3(b) and, if this authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization:
 - (b) a copy of the authorization to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 14 of Directive 2001/82/EC:
 - (c) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorised and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication.
 - (d) where the application for a certificate includes a request for an extension of the duration:
 - (i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;
 - (ii) where necessary, in addition to the copy of the authorisations to place the product on the market as referred to in point (b), proof of possession of authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

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- 2. Where an application for a certificate is pending, an application for an extended duration in accordance with Article 7(3) shall include the particulars referred to in paragraph 1(d) of this Article and a reference to the application for a certificate already filed.
- 3. The application for an extension of the duration of a certificate already granted shall contain the particulars referred to in paragraph 1(d) and a copy of the certificate already granted.
- 4. Member States may provide that a fee is to be payable upon application for a certificate and upon application for the extension of the duration of a certificate.

For a certificate

ArtM.8 ArtP.8 r.116(1) FSch 1 SPM8.01 An application for a certificate must contain a request for the grant of a certificate on Form SP1 (but see also SPM19.04) accompanied by the prescribed application fee (currently £250).

SPM8.02 This request should specify:

the name and address of the applicant (Section 3 of Form SP1);

the name of the applicant's agent (if any) and the address for service in the European Economic Area or Channel Islands (Section 4);

the EC Regulation (469/2009 or 1610/96) under which the application is made (Section 5);

the product in respect of which the certificate is sought (ie the active ingredient or combination of active ingredients of the medicinal product) (Section 6);

the number, title, expiry date and (if later than the first UK authorisation) the date of grant of the basic patent (Section 7);

the number and date of the first UK authorisation (Section 8);

(where different from the first UK authorisation) the State, number and date of the first authorisation in the EU, plus the identity of the authorised product and the legal provision under which the authorisation took place (Section 9). Although the wording of Articles 8(1)(a)(iv) and 8(1)(c) does not appear to require such a first authorisation to have been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, in Synthon BV v Merz Pharma Gmbh & Co KG (C-195/09) and Generics (UK) Ltd v Synaptech Inc (C-427/09) the Court of Justice of the European Union ruled in relation to Article 2 that a product which was placed on the market in the European Community as a medicinal product for human use before obtaining a marketing authorisation in accordance with Council Directive 65/65/EEC (now Directive 2001/83/EC) and, in particular, without undergoing safety and efficacy testing, is not within the scope of the Regulation, and may not be the subject of a supplementary protection certificate (also see SPM2.01, SPM13.04.1 and Novartis AG and University College London & Novartis AG and Institute of Microbiology and Epidemiology SPC Applications BL O/044/03). For applications lodged on or after 1 July 1994, the relevant authorisation for the purposes of Articles 8(1)(a)(iv) and 8(1)(c) includes the first authorisation in a State which is a Contracting Party to the European Economic Area Agreement. In AstraZeneca AB C-617/12 the CJEU confirmed by reasoned order referring to Novartis and others C-207/03 and C-252/03 that a Swiss authorisation automatically

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recognized in Liechtenstein was the first in the EEA and therefore constituted the first authorisation in the Community even if that authorisation was suspended at a later date (see also BL O/146/12 and SP0.08-09, SPM9.02, SPM11.01 and SPM13.04).

SPM8.03 Where more than one authorisation for the product was granted on the date of the first UK or EU authorisation, details of all of the relevant authorisations should be given at Sections 8 and 9 of Form SP1.

SPM8.03.1 The relevant date having regard to Article 8(1)(a)(iv) or 8(1)(b) will be the date of grant of the authorisation unless evidence is provided which shows a different date of legal effect, see also SPM13.05.1. Following decision BL O/418/13 (Genzyme Corporation) where the earliest authorisation is one granted by a decision of the European Commission following a favourable opinion from the EMA under Regulation (EC) 726/2004 the date of the authorisation will be taken to be the date of notification, this date may be evidenced such as by providing a suitable excerpt from the OJEU, (see SPM 13.05.1, 10.15). The relevance of the "date of notification" in these circumstances has been confirmed by the CJEU in Seattle Genetics Inc. v Österreichisches Patentamt C-471/14.

SPM8.04 The request should be accompanied by a copy of the first or each UK authorisation. This authorisation should identify the product and contain the number and date of the authorization and a summary of the product characteristics listed in Directive 2001/83/EC (for pharmaceutical products), Directive 2001/82/EC (for veterinary products) (see SPM2.01). Thus, in the case of a pharmaceutical product, it is necessary to file a copy of the Product Licence or Marketing Authorisation granted by the Medicines and Healthcare Products Regulatory Agency, the Veterinary Medicines Directorate or the European Commission following a favourable opinion from the EMA (see SPM2.01). The copy should include any enclosure or Schedule referred to in the document of grant, such as an attached authenticated copy of the licence application setting out the particulars of the product.

SPM8.04.1 The question of the applicant's obligation to provide a copy of the authorisation in the Member State was referred to the European Court of Justice by the Tribunal de Commerce, Nivelles, Belgium in Biogen İnc v SmithKline Beecham Biologicals SA [1997] RPC 833. The Court ruled that, where the owner of the basic patent and the holder of the marketing authorisation were different persons and the patent owner was unable to provide a copy of the authorisation in accordance with Article 8(1)(b) of the Regulation, the application for the Supplementary Protection Certificate could not be refused on that ground alone. It was open to the national authority granting the certificate to obtain a copy of the marketing authorisation from the national authority which issued it. In the light of the Biogen ruling, the Office will proceed on the basis that, whilst it cannot reject the application merely because the copy of the authorisation is provided by someone other than the applicant, equally it cannot waive at least the minimum requirements of Art 8(1)(b). Thus it is not sufficient for the applicant merely to ask the Office to obtain a copy of the authorisation without first having established his own inability to do so. Also, the Office will not make good the lack of a copy by referring to or copying authorisation documents held on other files, such as an SPC application filed by another patent holder. Accordingly, where an applicant is unable to obtain a copy of the authorisation from the person holding it, the Office will first require the applicant to provide evidence of this and also to provide such information as is available from the authority issuing the authorisation such information (eg a gazette notice, a letter or a database printout) as will enable the Office to verify the identity of the product and the date of the authorisation stated on Form SP1. The Office will then ask the issuing authority to supply a copy of the relevant (usually confidential) summary of product characteristics listed in Directive 2001/83/EC or Directive 2001/82/EC (see SPM2.01). It is important to note that this latter document may be covered by a request for confidentiality under Rule 53(1) of the Patents Rules 2007 from the authorisation authority and is then solely for Office use and under no circumstances will be made available to the applicant or the public. (See also SPM

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6.02.)

r.113

[Copies of confidential authorisations obtained from the authorisation authorities invoking the Biogen ruling are filed in a separate envelope marked "Not open to the Applicant or the Public"]

SPM8.05 In addition, in order to meet the requirements of Article 8(1)(c), where the UK authorisation above is not the first authorisation to place the product on the market in the EU (or, where appropriate, in a State which is a Contracting Party to the European Economic Area Agreement - see SPM 8.02), the application should be accompanied by a copy of the notice publishing the (or each) such first authorisation in the appropriate official gazette. However, Article 8(1)(c) of the Medicinal Regulation is to be interpreted in the same manner as Article 8(1)(c) of the Plant Protection Regulation (as from 8 February 1997 when the latter regulation came into force) which reads:

Article 8 [EC Plant Protection Regulation]

Content of the application for a certificate

1. (c) if the authorization referred to in (b) is not the first authorization to place the product on the market as a plant protection product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication or, failing such a notice, any other document proving that the authorization has been issued, the date on which it was issued and the identity of the product authorized.

SPM8.05.1 If no such publication in a gazette has therefore been made, the copy of the authorisation itself or any other document proving that the authorisation has been issued, such as a confirmatory letter from the authorisation authority, should be furnished in lieu. Any document not in the English language should be accompanied by a translation which need only be verified if there is reason to doubt the accuracy of the translation.

SPM8.06 Except where it is immediately apparent that the product in question is protected by the basic patent, the applicant should also provide whatever information is necessary to enable the Comptroller to confirm that this is so, eg by specifying a claim of the basic patent which refers to the product or indicating how the product is derived from a general formula in a claim.

For an extension of a certificate

SPM8.07 The application for an extension must be made on Form SP4 and accompanied by the prescribed application fee (currently £200).

SPM8.08 This request should specify:

a granted certificate number or certificate application number if these exist (Section 2 of Form SP4);

the name and address of the applicant (Section 3 of Form SP4);

the name of the applicant applicant's agent (if any) and the address for service in the EEA or Channel Islands (Section 4);

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the product in respect of which the certificate is sought (i.e. the active ingredient or active substance, or combination thereof, of the medicinal product) (Section 5):

the number, title and expiry date of the basic patent (Section 6);

the number and date of the authorisation containing the statement of compliance with an agreed paediatric investigation plan, including the state if necessary (Section 7);

whether the product has been authorised in all Member States by an authorisation issued by the EMA or by national authorisations granted by each Member state (Section 8).

ArtsPd 36(1), (2)

ArtPd 28(3)

The request should be accompanied by a copy of the statement indicating compliance with an agreed paediatric investigation plan as referred to in Art 36(1) of Regulation (EC) No 1901/2006. In Merck & Co., Inc. (BL O/035/09) the hearing officer considered whether an opinion of the Paediatric Committee of the EMEA indicating compliance with a PIP was sufficient to meet this requirement. He found that it was not and that the statement of compliance included in the marketing authorisation of the medicinal product was the necessary copy of this statement. The hearing officer considered that the applicant could rectify this deficiency by filing this document (see In his decision concerning E I Du Pont de Nemours & Co.'s SPC Application (BL O/096/09, [2010] RPC 4) the hearing officer similarly found that an application which did not contain a copy of the statement of compliance did not meet the requirements of Article 8(1)(d)(i). This decision was appealed to the Patents Court in E I Du Pont Nemours & Co.'s SPC Application [2009] EWHC 1112 (Ch), [2010] RPC 5 and the appeal on these grounds was dismissed. The Court found that while the requirement for the statement to be in the marketing authorisation is merely informative, the only substitute for it would be equivalent information on compliance from a properly reliable source. However, the Court of Appeal has since reversed the earlier decisions of the Patents Court and the Office (E I Du Pont Nemours & Co. v UK Intellectual Property Office [2009] EWCA Civ 966, [2010] RPC 6). Jacob LJ directed that failure to comply with the provisions of Article 8(d) at the time of submitting an application for an extension of the duration of an SPC is an irregularity which may be cured after the date of application under Article 10(3). Having regard to Dr Reddy's Laboratories (UK) Ltd and Dr Reddy's Laboratories Ltd v Warner-Lambert Company LLC [2012] EWHC 3715 (Pat) it was determined that studies outside the strict power of the PDCO to demand but nonetheless included in the PIP do not render the PIP unlawful or invalid, and that the requirement for studies to be "significant" in Article 45(3) of Regulation (EC) No 1901/2006 is not of general application but only refers to studies completed before entry into force of Regulation (EC) No 1901/2006.

ArtPd 36(3)

The request should also be accompanied by proof that it has authorisations to place the product on the market in all other Member States as referred to in Art 36(3) of Regulation (EC) No 1901/2006. The hearing officer in El Du Pont de Nemours & Co.'s SPC Application (BL O/096/09) found that the application did not fulfil the conditions of Article 8(1)(d)(ii) as the documents supplied did not prove that the product was approved for use in all member states and so satisfy all the requirements of Art 36 of Regulation (EC) No. 1901/2006. The appeal to the Patents Court in E I Du Pont Nemours & Co.'s SPC Application [2009] EWHC 1112 (Ch) on this matter was dismissed, the Court finding that an application for an extension that does not meet all the requirements of Art 36 is defective. The Court held that Art 36 must be considered as a whole and that the marketing authorisation application must be completed before the reward of an extension is available. However, the Court did find that there may be circumstances where if the medicinal product is being approved through the mutual recognition procedure and the reference member state has granted the authorisation then the extension could be granted lawfully, if the only issue outstanding was the administrative completion of the authorisation procedure in every member state. The

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Court held that the deficiencies in the application in this respect were not ones which could be described as irregularities that could be rectified under Art 10(3). However, as noted above, the Court of Appeal has since reversed the earlier decisions of the Patents Court and the Intellectual Property Office on this point (*E I Du Pont Nemours & Co.* [2009] EWCA Civ 966, [2010] RPC 6) and directed that such deficiencies can be rectified by the applicant under Article 10(3) after the date of application for the extension. In *Otsuka Pharmaceuticals Company Limited.* (BL O/98/15) the hearing officer found the application did not comply with article 8(1)(d) as it lacked a compliance statement resulting from the incomplete agreed PIP. In reference to obiter dicta in *E I Du Pont Nemours & Co.* [2009] EWCA Civ 966, [2010] RPC 6 the hearing officer determined this was an irregularity that could only be corrected before expiry of the SPC.

- SPM8.11 When the certificate has been granted the request should not only should state its number on Form SP4 but must be accompanied by a copy of the granted certificate.
- SPM8.12 Except where it is immediately apparent, the applicant should also provide whatever information is necessary to enable the Comptroller to confirm that the product in question satisfactorily completed the agreed paediatric investigation plan and was consequently authorized in all Member States, e.g. where the medicinal product has not been authorized through the centralised EMEA mechanism by providing a list of relevant national market authorisations for the medicinal product in all Member States that can be confirmed.

ARTICLE 9: LODGING OF AN APPLICATION FOR A CERTIFICATE

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

The application for an extension of the duration of a certificate shall be lodged with the competent authority of the Member State concerned.

- 2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:
 - (a) the name and address of the applicant;
 - (b) the number of the basic patent;
 - (c) the title of the invention;
 - (d) the number and date of the authorization to place the product on the market, referred to in Article 3(b), and the product identified in that authorization:
 - (e) where relevant, the number and date of the first authorization to place the product on the market in the Community.
 - (f) where applicable, an indication that the application includes an application for an extension of the duration.
- 3. Paragraph 2 shall apply to the notification of the application for an extension of the duration of a certificate already granted or where an application for a certificate is pending. The notification shall additionally contain an

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indication of the application for an extended duration of the certificate.

SPM9.01 The competent industrial property office for the purposes of lodging an application for a certificate or an extension of a certificate in the UK is the Intellectual Property Office, irrespective of whether the basic patent is a UK patent or a European Patent (UK).

[All new applications for certificates are referred to PD/EX06. Upon receipt of an application PD/EX06 issue a filing receipt.]

r.44(7)

- SPM9.02 The information prescribed by Article 9(2) concerning an application for a certificate is taken from Form SP1, together with the generic name of the product when this appears in the market authorisation document but not on Form SP1, and is published in the Patents Journal, together with the date of lodging the application. For applications lodged on or after 1 July 1994, the first authorisation for the purposes of Article 9(2)(e) is the first authorisation in a State which is a Contracting Party to the European Economic Area Agreement (see SP0.08-09 and also SPM8.02, SPM11.01 and SPM13.04). The application number (see SPM9.03), product in respect of which protection is sought (from Form SP1) and date of lodging the application are also entered in the register under the entry for the basic patent. However, no separate publication of the application corresponding to the 'A' publication of a patent application under the Patents Act 1977 is made.
- SPM9.02.1 Article 9(3) requires that the information prescribed by Article 9(2) is also published in the Patents Journal for an application for an extension. Any additional information necessary will be taken from Form SP4.

[PD/EX06 arrange the publication in the Journal and the entry in the register.]

SPM9.03 Applications are numbered in a yearly sequence, eg SPC/GB93/001. The granted certificate retains this number, (see SPM10.19).

SPM9.03.1 Applications for extensions will also be given the number of the application for a certificate or the granted certificate it will extend as appropriate (see SPM10.19.1).

ARTICLE 10: GRANT OF THE CERTIFICATE OR REJECTION OF THE APPLICATION FOR A CERTIFICATE

- 1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the certificate.
- 2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.
- 3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.
- 4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.
- 5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(c) and (d) are met.

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6. Paragraphs 1 to 4 shall apply mutatis mutandis to the application for an extension of the duration.

Formalities examination of an application for a certificate

ArtsM 8, 10(3) (ArtsP8, 10(3)) SPM10.01 An initial examination for formal matters is carried out to determine whether the application

is in the required form, (including the requirements of rule 14 of and Schedule 2 to the Patents Rules 2007 as to size and presentation of documents), and accompanied by the prescribed fee (see SPM8.01);

was lodged within the period prescribed by Article 7 (see SPM7.01);

contains the information prescribed by Article 8(1)(a) (see SPM8.02-03);

is accompanied by a copy of the (or each) first UK product licence (see SPM8.04-04.1);

contains, where appropriate, information regarding the first authorisation in the Community and a copy of the relevant notice (see SPM8.05);

and whether the basic patent was in force, and a marketing authorisation was granted by the date that the SPC application was lodged, it being confirmed by the CJEU in C-567/16 that the latter requirement is not "an irregularity" that can be cured having regard to Article 10(3).

[A formalities examiner in PD carries out the examination.]

SPM10.02-03 [Deleted]

Substantive examination of an application for a certificate

SPM10.04 A substantive examination is also carried out to determine whether the following conditions of Article 3 were complied with at the date of the application:

ArtM 3(a) (ArtP3(1)(a)) the product is protected by the basic patent;

ArtM 3(b) (ArtP3(1)(b)) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC (see SPM2.01);

ArtM 3(c) (ArtP3(1)(c)) the product has not already been the subject of a certificate. (The examiner carries out a search of certificates granted in the UK in order to establish this.)

Generally, the substantive examination is carried out at the same time as the formalities examination, and all objections arising are reported to the applicant in a single letter (see SPM10.12). If the basic patent has already expired or is about to expire, substantive examination should be carried out as a matter of urgency, in order to avoid delay in the entry into force of the certificate. Substantive examination may however be deferred in cases where the examiner considers it likely that the application may not be able to meet a formal objection.

[A substantive examiner in PD/EX06 carries out the examination.]

PA 1977, s.21

SPM10.04.1 The applicant may request accelerated examination giving a reasoned statement for the request. If allowed, the applicant is warned that, even when the application is found to be in order for grant at an earlier date, grant will not occur until a

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period of at least three months has elapsed from the date of publication of the notice of filing of the application in the Patents Journal to allow for third-party observations.

ArtsM 3(d), 10(5) (ArtsP3(1)(d), 10(5)) SPM10.05 Although no search is at present carried out to establish whether the authorisation specified was the first authorisation to place the product on the market in the UK as a medicinal product, the examiner should also consider whether this requirement is met where there is reason to do so (eg on the basis of information supplied by the applicant, observations by a third party (see SPM10.06) or information in another application for the same product). See also *Draco AB's SPC Application* [1996] RPC 417.

PA 1977, s.21, sch 4A, para 4

SPM10.06 Any observations by a third party, on the question whether the application meets the conditions of the Regulation should be considered by the examiner as in the case of an application for a patent. However, as in the case of a patent application such observations must be in writing and must be made before a certificate is granted.

r.82(1)(a)

SPM10.07 Where the examiner requires further information in order to make any determination, the applicant should be required to furnish this within a prescribed period.

Formalities examination of an application for an extension

ArtsM 8, 10(6)

SPM10.08 An initial examination for formal matters is carried out to determine whether the application

is in the required form, (including the requirements of rule 14 of and Schedule 2 to the Patents Rules 2007 as to size and presentation of documents), and accompanied by the prescribed fee (see SPM8.07);

was lodged within the period prescribed by Article 7 (see SPM7.02);

contains the information prescribed by Article 8 (see SPM8.08);

is accompanied by a copy of the statement indicating compliance with an agreed paediatric investigation plan as referred to in Art 36(1) of Regulation (EC) No 1901/2006 as prescribed by Article(1)(d)(i) (see SPM8.09);

contains proof that the product has been authorized in all Member States by an authorisation issued by the EMA or by national authorisations granted by each Member state as prescribed by Article(1)(d)(ii) (see SPM8.10);

where an application for a certificate is pending a reference to the certificate already filed as prescribed by Article 8(2) (see SPM8.08);

where a certificate is granted a copy of the certificate already granted as prescribed by Article 8(3) (see SPM8.11);

[A formalities examiner in PD carries out the examination.]

Substantive examination of an application for an extension

SPM10.09 A substantive examination is also carried out to determine whether, at the date of the application, it entitles the holder of the patent or certificate to the reward set out in Art 36(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council. The examiner may seek to establish that:

ArtsPd 36(1), (2)

the marketing authorisation identified includes the required statement indicating the compliance with an agreed paediatric investigation plan;

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ArtPd 36(3)

the product is authorized in all Member States;

ArtPd (5)

the product has not already been the subject of the alternative reward set out in Regulation (EC) No 1901/2006 of the European Parliament.

Generally, the substantive examination is carried out at the same time as the formalities examination and at the same time as the pending application for a certificate, if appropriate, and all objections arising are reported to the applicant in a single letter (see SPM10.12).

[A substantive examiner in PD/EX06 carries out the examination.]

PA 1977, s.21, sch 4A, para 4

SPM10.10 Any observations by a third party, on the question whether the application meets the conditions of the Regulation should be considered by the examiner as in the case of an application for a patent. However, as in the case of a patent application such observations must be in writing and must be made before an extension is granted.

r.82(1)(a)

SPM10.11 Where the examiner requires further information in order to make any determination, the applicant should be required to furnish this within a prescribed period.

Examination report

ArtsM10(2), 10(3), 10(4) (ArtsP 10(2), 10(3), 10(4))

r.108

SPM10.12 Where it appears to the examiner that formal objections arise, and/or that any of the conditions of Article 3 is not met or that the holder of the patent or certificate is not entitled to the reward set out in Art 36(1) of Regulation (EC) No 1901/2006, the applicant should be informed accordingly and allowed a specified period (generally four months for the first report, two months for the second and two months for the third) for reply. As in the case of formal or substantive examination of an application for a patent, this period may be extended at the request of the applicant. In *Medeva BV v The Comptroller General of Patents* [2010] EWHC 68 (Pat), [2010] RPC 20, Kitchin J (at paragraph 42 of his decision) confirmed that an examination report in respect of an SPC application is not a decision against which an appeal can properly be filed under s.97 of the Patents Act 1977.

SPM10.12.1 Where an application is not in the required form, does not contain all of the required particulars and documents and/or is not accompanied by the prescribed fee, the filing date will not be lost if the applicant rectifies the irregularity or settles the fee within the specified period. If the applicant wishes to extend this period, he should request this in writing before the period expires otherwise the application may be rejected under Article 10(4). The request may be made retrospectively in the covering letter accompanying the response or, alternatively by email to the pateot@ipo.gov.uk in which case an automatic acknowledgement of receipt will be issued (telephone requests are not allowable). For an application for an extension of the duration of a certificate, Jacob LJ directed in *E I Du Pont Nemours & Co.* [2009] EWCA Civ 966, [2010] RPC 6 that failure to comply with the provisions of Article 8(d) at the time of submitting the application for an extension is an irregularity which may be cured after the date of application under Article 10(3).

Amendment and correction

SPM10.13 The details on Form SP1 or SP4 may be amended or corrected in response to the examination report.

r.105

SPM10.14 Where a proposed correction affects the details of application or grant which have already been published (see SPM9.02, SPM11.01), the details of the correction will also need to be published. In such cases a request to correct should be

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made in writing identifying the proposed correction. If the Office considers that the correction is allowable, details will be advertised in the Patents Journal.

SPM10.14.1 Post-grant amendment of an SPC grant certificate may be permitted under Section 27 of the Patents Act 1977 (which applies by virtue of Schedule 4A to the Patents Act 1977). Questions concerning this practice were referred to the CJEU in Actavis Group and Actavis UK v Boehringer Ingelheim Pharma [2013] EWHC 2927 (Pat) however in C-577/13 Actavis Group PTC EHF, Actavis UK Ltd v Boehringer Ingelheim Pharma GmbH & Co. KG these questions were not answered (see also SPM3.02.1, SPM3.02.5).

SPM10.15 Where, before a certificate or extension has been granted, an applicant desires to amend Form SP1 or SP4 other than in response to an official objection (eg to add details of further relevant authorisations of which he has become aware) the amendment should be formally requested in writing. For rectification of the duration of an SPC following decision BLO/418/13 (see SPM 8.03.1, SPM 13.05.1).

Re-examination

SPM10.16 Where the applicant has amended or corrected the application, and/or made submissions in response to any objection to formal or substantive matters raised by the examiner, the application should be re-examined as soon as possible. If formal objections have been met, any deferred substantive examination should now be carried out. Where the examiner is still not satisfied that the conditions of the Regulation are met, either the outstanding objection(s) should be pursued in further correspondence, by telephone or at an interview, or the rejection procedure (see SPM10.17) should be initiated. Unlike the case of patent applications, there is no overall period within which an application for a certificate or certificate must be in order for grant. However, where the basic patent has already expired or is about to expire, re-examination should be carried out as a matter of urgency (see SPM10.04).

Rejection of application

ArtM 18 (ArtP 17)

1

r.31

SPM10.17 Where the applicant has not replied to objections raised by the examiner in respect of formal or substantive matters, or the examiner having considered any amendments, corrections and/or submissions made by the applicant in response is still not satisfied that the applicant fully meets the conditions of the Regulation, the applicant should be informed in an official letter of the examiner's opinion and the reasons therefor, and that accordingly, unless the applicant requests to be heard in the matter, the Comptroller proposes to reject the application under Article 10.2 and/or 10.4 as appropriate. As in the case of an application for a patent, any hearing will be taken by a senior officer of the Office acting for the Comptroller and any adverse decision will be subject to appeal to the Patents Court.

SPM10.17.1 In *British Technology Group Ltd's SPC Application* [1997] RPC 118, where it had been found that a valid product licence had not been granted, the Hearing Officer went on to refuse permission to keep the application open until the time that the applicants provided a valid authorisation in accordance with Article 3(b). To do otherwise would put third parties at a considerable disadvantage. The correct procedure was to file a fresh application when all the requirements of the Regulation could be met, particularly the provision of a valid market authorisation. Article 3(c) is then not contravened because the first filed application has not been granted (see SPM3.03.1).

Withdrawal of application

PA 1977, s.14(9)

SPM10.18 An applicant may request in writing that his application is to be withdrawn at any time before a certificate or an extension is granted (see 14.199-208). Any such withdrawal may not be revoked. Whilst there appears to be no bar on an application being withdrawn before grant and subsequently being refiled at a later date,

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grant of such an application would depend upon the time limits of Article 7 being met.

Grant of certificate

SPM10.19 When all requirements are met, a certificate is granted. No letter will be issued to inform applicants of the intention to grant an SPC as is current practice for patent applications. In *Merck and Co., Inc.* (BL O/108/08) the hearing officer found that where an application met the requirements of Article 10 an SPC could be granted even if by applying the calculation of Article 13(1) it would never take effect at the end of the lawful term of the basic patent. The certificate retains the application number (see SPM9.03). It states the date of expiry of the maximum possible period of its duration and indicates that entry into force is dependent upon the payment of fees.

SPM10.19.1 When an extension is granted on an application for a certificate or pending application then the certificate granted will indicate that the extension has been included in the maximum possible period of its duration. However, if the extension is granted for an existing certificate then an amended certificate stating the extended maximum possible period of duration will be granted. No letter will be issued to inform applicants of the intention to grant an extension.

ArtM 3(a)

SPM10.19.2 The Medicinal Regulation does not require that grant of the certificate must occur before the basic patent expires, merely that the latter is in force on the date of filing. Consequently, grant is retrospective to the day after the basic patent expired (see SPM13.01). Therefore, when details of filing of an application are published in the Patents Journal, the public is put on notice that grant of the certificate may occur at any time subsequently.

[PD/EX06 issue the certificate]

ArtM 19(2) (ArtP 18(2)) SPM10.20 Opposition to the grant of a certificate or an extension is not allowed (see SPM19.06; see also SPM10.06, SPM10.10 for procedure where a third party makes observations in writing).

SPM10.21 The Medicinal Regulation does not appear to invest the competent industrial property office of the Member State with the power to refuse to grant a certificate on the grounds that the marketing authorisation has lapsed or been withdrawn, provided that the requirement of Article 3(b) has been met. Action may, however, be considered after grant for declaration of lapse under Article 14(d) when the certificate has come into force (see SPM14.02 to 14.05).

ARTICLE 11: PUBLICATION

- 1. Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9(1). The notification shall contain at least the following information:
 - (a) the name and address of the holder of the certificate;
 - (b) the number of the basic patent;
 - (c) the title of the invention;
 - (d) the number and date of the authorization to place the product on the market referred to in Article 3(b) and the product identified in that authorization;
 - (e) where relevant, the number and date of the first authorization to place the product on the market in the Community;

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- (f) the duration of the certificate.
- 2. Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9(1). The notification shall contain at least the information listed in Article 9(2).
- 3. Paragraphs 1 and 2 shall apply to the notification of the fact that an extension of the duration of a certificate has been granted or of the fact that the application for an extension has been rejected.
- SPM11.01 The information prescribed by Article 11, including the generic name of the product when this appears in the market authorisation but not on original Form SP1 or Form SP4, is published in the Patents Journal, together with the date of grant or rejection. For applications lodged on or after 1 July 1994, the first authorisation for the purposes of Article 11(1)(e) is the first authorisation in a State which is a Contracting Party to the European Economic Area Agreement (see SP0.08-09 and also SPM8.02, SPM9.02 and SPM13.04). The certificate number (see SPM9.03), product, date of grant or rejection and duration of a granted certificate and extension are also entered in the register under the entry for the basic patent.

[PD/EX06 arrange the publication in the Journal and the entry in the register.]

SPM11.02 In both the Journal and the register:

the product is identified as that for which the certificate has been granted, and may differ from that published upon application (see SPM9.02);

the duration of a granted certificate is identified by the date of expiry of the maximum period of duration as determined by Article 13 and if an extension has been granted.

SPM11.03 A copy of the certificate of grant is retained on the file of the application which is open to public inspection. However, no separate publication of the certificate or an extension of a certificate corresponding to the 'B' publication of a patent under the Patents Act 1977 is made.

ARTICLE 12: ANNUAL FEES

Member States may require that the certificate be subject to the payment of annual fees.

SPM12.01 Entry into effect of the certificate is subject to the payment of annual fees in accordance with paragraph 5 of Schedule 4A to the Patents Act 1977 and rule 6 of the 2007 Fees Rules. (See paragraph 128B.10).

SPM12.01.1 The Regulation does not appear to invest the competent industrial property office of the Member State with the power to refuse to allow a certificate to come into force on the grounds that the marketing authorisation has lapsed or been withdrawn, provided that the requirement of Article 3(b) had been met. Action may, however, be considered later for declaration of lapse under Article 14(d), after the certificate has come into force (see SPM14.02 to 14.05).

[PD/EX06 deal with all matters relating to the payment of annual fees.]

Effective period of the certificate

SPM12.02 The certificate holder is required to pay annual fees for the effective period of the certificate. This is the maximum period of duration of the certificate, less

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r. 44(7)

r.116(5)

any period for which the certificate holder does not desire it to have effect.

ArtM 13(1), 13(3), (ArtP13(1)), r.116(5) SPM12.03 The effective period must consist of a single period starting the day after the expiry of the basic patent. Where the certificate holder opts for an effective period less than the maximum period of the certificate, this period cannot subsequently be extended, unless an extension of a certificate under Regulation (EC) No 1901/2006 of the European Parliament is granted.

Date for payment

- r.116(2)(a)
- SPM12.04 The date by which the annual fees are payable is normally the date on which the certificate is due to take effect at the end of the lawful term of the basic patent. The annual fees may not be paid earlier than three months before that date.
- r.116(2)(b)
- SPM12.05 However, where the certificate is granted later than three months before the expiry of the basic patent, the date for the payment of annual fees is three months after the grant date of the certificate.

Calculation of annual fees

- Fr.6(2)
- SPM12.06 An annual fee is payable for each year of the effective period of the certificate. Any final period of less than 12 months is treated as a whole year, eg an effective period of 3 years 6 months will therefore require the payment of 4 years' annual fees.
- Fr.6(2)

Fr. 6(3)

SPM12.07 The annual fees are payable as a single cumulative amount as a condition of the certificate taking effect. The level of the fees is that applying on the date the certificate is due to take effect or, paid if earlier, the actual date of payment. Currently the fees for the five successive years are £600, £700, £800, £900 and £1,000. No additional fees are payable for an extension to a certificate to take effect.

Notification that payment is due

- r.116(3)
- SPM12.08 The certificate holder is notified not later than two months before the date on which the fees are payable and of the level of the fee payable in respect of each year. Where the certificate is granted later than three months before the expiry of the basic patent, this notification is sent with the granted certificate.
- r.116(8)
- SPM12.09 The notification is sent to the address for service provided on Form SP1, or any address replacing it. It is also sent to the following address, where different:
 - (i) the United Kingdom address specified for the sending of renewal reminders on payment of the last renewal fee relating to the basic patent, or any address replacing it; or
 - (ii) where there is no address under (i), any address for service entered in the register in respect of the basic patent.

Procedure for payment of fees

r.116(5)

SPM12.10 The payment of the total sum of the annual fees for the whole effective period should be accompanied by Form SP2 (but see SP18.04). There is no electronic payment system for the payment of fees for SPCs (BL O/252/11, *Tulane Education Fund v Comptroller General of Patents* [2012] EWHC 932 (Pat)); see also SPM12.14.1 and SPM14.01.1). The Court of Appeal rejected the appeal that this regime is *ultra vires*, see *Tulane Education Fund v Comptroller General Of Patents* [2013] EWCA Civ 890 [2014] R.P.C. 10. The holder of the certificate should state on this Form the date on

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which fees are payable (the "due date"), the desired effective period of the certificate, and the amount of fees paid in consequence.

The Office confirms the payment of fees and the date of the expiry of the effective period by sending a certificate of payment to the address given in Section 6 of Form SP2. If the holder wishes this certificate to be sent to a different address, he should indicate this at Section 7 of Form SP2 and give the address on a separate sheet.

Late payment of fees

r.116(6) SPM12.12 Where the annual fees are outstanding, the holder of the certificate is notified within 6 weeks of the due date.

Fr.6(4) SPM12.13 Subject to an additional late payment fee of one-half of the amount of the unpaid fees, annual fees may be paid up to six months after the due date; this period cannot be extended. The annual fees are then treated as having been filed on the due date.

Non payment of fees

SPM12.14 If the fees are not paid by the due date or in accordance with (ArtP 14(c)) SPM12.13, the certificate is treated as having lapsed on the date of expiry of the basic patent and so does not take effect. The holder is notified accordingly.

> SPM12.14.1 In BL O/252/11 (The Administrators of the Tulane Education Fund) the hearing officer confirmed that an SPC could not be brought into effect where the applicant had failed to pay the prescribed fee within the prescribed time period or within the six months following the end of the prescribed period. In dismissing the applicant's appeal at the Patents Court, Roger Wyland QC clarified that neither Rule 107(3) of the Patents Rules 2007 or Section 28 of the Patents Act 1977 could be used to bring the SPC into effect (Tulane Education Fund v Comptroller General of Patents [2012] EWHC 932 (Pat)) see also SPM12.10 and SPM14.01.1.

ARTICLE 13: DURATION OF THE CERTIFICATE

- The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years.
- Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.
- 3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.
- Where a certificate is granted for a product protected by a patent which, before 2 January 1993, had its term extended or for which such extension was applied for, under national law, the term of protection afforded under this certificate shall be reduced by the number of years by which the term of the patent exceeds 20 years.

ArtM 12, (ArtP SPM13.01 A certificate takes effect at the end of the lawful term of the basic patent, provided that: 12)

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ArtM 14(c)

PA 1977, Sch 4A, para 5

the basic patent has not previously lapsed or been revoked;

the annual fees are paid in time (see SPM12.04-05).

SPM13.02 Article 13 defines the maximum period of duration of the certificate. The effective period may however be less than this maximum period if the certificate holder opts to pay fees for a lesser period (see SPM12.02-03).

r.44(7) SPM13.03 The date of entry into force of the certificate and the date of expiry of the effective period (see SPM12.02) are published in the Patents Journal and entered in the register under the entry for the basic patent.

[PD/EX06 arrange the publication in the Journal and the entry in the register.]

Calculation of the duration of the certificate

SPM13.04 Since the term of the basic patent is 20 years, the maximum period defined by Article 13 is either:

a period of 15 years from the date of the first authorisation to place the product on the market in the Community; or

a period of 5 years from the date on which it takes effect,

whichever is the lesser (see SPM18.02 for appeal where duration is incorrectly calculated.) For applications lodged on or after 1 July 1994, the period of 15 years runs from the date of the first authorisation to place the product on the market in a State which is a Contracting Party to the European Economic Area Agreement. European Court of Justice in Novartis AG & University College London & Novartis AG and Institute of Microbiology v Comptroller General of Patents, Designs and Trade Marks for the UK and Ministre de l'Économie v Millennium Pharmaceuticals Inc. (ECJ Joined Cases C-207/03 and C-252/03) [2005] RPC 33 held that when a Swiss authorisation automatically recognized in Liechtenstein was the first in the EEA it constituted the first authorisation in the Community for the purposes of Article 13 (see also SP0.08-09, SPM8.02, SPM9.02 and SPM11.01). In AstraZeneca AB (BL O/146/12), the hearing officer found that when a Swiss authorisation automatically recognized in Liechtenstein was the first in the EEA it constituted the first authorisation in the Community for the purposes of Article 13 even if that authorisation was suspended at a later date. This decision has been appealed and questions referred to the CJEU for a preliminary ruling in C-617/12. The court determined the questions by reasoned order referring to Novartis and others C-207/03 and C-252/03 (see also SPM 8.02). The period of 15 years also runs from the first pharmaceutical or veterinary authorisation for such a State irrespective of whether the first authorisation under Article 3(b) to place the product on the market in the UK is pharmaceutical or veterinary. Thus, in Farmitalia Carlo Erba S.r.l's SPC Application (1) [1996] RPC 111 the hearing officer held that on the plain meaning of Article 13(1), an Italian veterinary authorisation of 1987 and not a Netherlands pharmaceutical authorisation of 1992 constituted the first authorisation in the Community, in a case where the Article 3(b) authorisation was pharmaceutical. Similarly, in Pharmacia Italia SpA v Deutsches Patentamt [2005] RPC 27 (ECJ Case C-31/03), the authorisation as a veterinary product was held by the ECJ to be the first market authorisation in the Community for an SPC application made on the basis of a medicinal product for human use. The ECJ therefore ruled that the grant of the certificate was precluded by the veterinary authorisation as this took place before the date specified under Article 19(1) of Regulation (EEC) No 1768/92. In Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents [2011] EWCA Civ 228,

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[2011] RPC 19, the Court of Appeal referred questions to the Court of Justice of the European Union (C-130/11, Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents) concerning the interpretation of the phrase "the first authorisation to place the product on the market in the Community" in Article 13 (along with questions relating to Article 3(d)). In answering the referred questions, the CJEU stated that Article 13(1) must be interpreted as referring to a:

"...marketing authorisation of a product which comes within the limits of protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate".

SPM13.04.1 The question of whether the marketing authorisation which must be identified under Article 13(1) must be compliant with Council Directive 65/65/EEC or whether any marketing authorisation that enables the product to be placed on the market in the Community or EEA should count for the calculation of the duration of the SPC has been considered by the Court of Justice of the European Union in two separate cases (*Generics (UK) Ltd v Synaptech Inc*, C-427/09; and *Synthon v Merz Pharma* [2009] EWHC 656 (Pat), referred to the CJEU in *Synthon BV v Merz Pharma Gmbh & Co KG*, C-195/09). In both cases the court held that a product which was placed on the market in the European Community as a medicinal product for human use before obtaining a marketing authorisation in accordance with Council Directive 65/65/EEC and, in particular, without undergoing safety and efficacy testing, is not within the scope of the Regulation, and may not be the subject of a supplementary protection certificate. It went on to confirm that any SPC granted for a product which was outside the scope of the Regulation was invalid (see also SPM2.01).

SPM13.04.2 Following the accession of the ten new member states to the Community on 1 May 2004, and subsequent enlargements on 1 January 2007 and 1 July 2013, a national authorisation granted in one of these states from the accession date is considered to be valid in the Community. However, such authorisations would be used to determine the length of a certificate only if no other marketing authorisation had already been granted in the European Economic Area (see SP0.08.1).

SPM13.05 It follows from Article 13 that a certificate would have no effective duration in the case in which the date of the first authorisation to place the product on the market is not more than five years from the filing date of the basic patent. Previously, no certificate has been granted in such cases. Instead the applicant has been informed that, subject to any comments which he wishes to make, the Office proposes to treat the application as withdrawn. However, the hearing officer found in Merck and Co., Inc. (BL O/108/08) that where an application did meet the requirements of Article 10 an SPC can be granted even if it would never take effect and its term could not extend beyond the end of the lawful term of the basic patent unless it was extended under Article 13(3). An equivalent case arising from the German Patent and Trade Mark Office was referred to the CJEU (C-125/10 - Merck & Co Inc v Deutsche Patent- und Markenamt) where it was found that an SPC should be granted where it would have no positive term unless extended under Article 13(3) and that the duration of such an extension should start "from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between the lodging of the patent application and the grant of the first marketing authorisation".

SPM13.05.1 The duration of an SPC will be calculated having regard to the date of grant of the first authorisation unless evidence is provided to substantiate a different date of legal effect, see also SPM8.03.1. Following decision BLO/418/13 (Genzyme Corporation) in the situation where the earliest authorisation is one granted by a decision of the European Commission following a favourable opinion from the EMA the office will calculate the duration of the SPC according to Article 13(1) from the date of notification. A suitable excerpt from the OJEU may be provided as evidence of the notification date. (see SPM 8.03.1 and 10.15) the relevance of the "date of notification" in these circumstances has been confirmed by the CJEU in Seattle Genetics Inc. v

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Österreichisches Patentamt C-471/14. Applicants may apply to rectify the duration of an SPC, in this regard, until the certificate (or extensions thereto) expires, in accordance with the practice notice published on 20 November 2013. This practice has been confirmed by judgment of the court in *Incyte Corporation v Szellemi Tulajdon Nemzeti Hivatala C 492/16*.

Calculation of maximum duration period

SPM13.06 The Office will generally invite the applicant to confirm agreement with the maximum expiry date calculated by the Examiner on the basis of the facts presented on Form SP1 (see SPP17.01).

Duration of an extension

SPM13.07 An extension of a certificate increases the period of duration of the certificate by six months.

ARTICLE 14: EXPIRY OF THE CERTIFICATE

The certificate shall lapse:

- (a) at the end of the period provided for in Article 13;
- (b) if the certificate-holder surrenders it;
- (c) if the annual fee laid down in accordance with Article 12 is not paid in time;
- (d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place on the market in accordance with Directive 2001/83/EC or Directive 2001/82/EC.

The authority referred to in Article 9(1) may decide on the lapse of the certificate either of its own motion or at the request of a third party.

ArtM 17 (ArtP 16) r.44(7) SPM14.01 Notification of lapse is published in the Patents Journal, and is also entered in the register under the entry for the basic patent. (See also SPM17.01)

[PD/EX06 arrange the publication in the Journal and the entry in the register]

SPM14.01.1 In BL O/252/11 (*The Administrators of the Tulane Education Fund*) the hearing officer held that an SPC could not be brought into effect where the applicant had failed to pay the prescribed fee within the prescribed time period or within the six months following the end of the prescribed period. In dismissing the applicant's appeal at the Patents Court, Roger Wyland QC clarified that neither Rule 107(3) of the Patents Rules 2007 or Section 28 of the Patents Act 1977 could be used to bring the SPC into effect (*Tulane Education Fund v Comptroller General of Patents* [2012] EWHC 932 (Pat); see also SPM12.10 and SPM12.14.1.

Declaration of lapse under Article 14(d)

PR part 7

SPM14.02 The Comptroller may declare that a certificate has lapsed under Article 14(d), either on the application of any person, or on his own initiative.

PR part 7

SPM14.03 An application by a third party to the Comptroller for a declaration of lapse under Article 14(d) should be made on Form SP3 in duplicate (but see

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SPM19.04) with duplicate statement of grounds, this action carries a fee of £50. This starts proceedings before the comptroller to determine the matter, the procedure for which is discussed at paragraphs 123.05 - 123.05.13.

[Applications on Form SP3 for declaration of lapse are referred to Tribunal Section.]

PR part 7

SPM14.04 Where the Office becomes aware, other than by an application on Form SP3, of the withdrawal of the appropriate authorisation(s) to place on the market a product covered by a certificate, the certificate holder is informed of the withdrawal in an official letter and that, subject to any observations which the holder may make within a specified period (generally two months), the Comptroller proposes to declare that the certificate has lapsed.

ArtM18 (ArtP 17) SPM14.05 Any decision by the Comptroller, whether on the application of a third party or on his own initiative, is subject to appeal to the Patents Court.

Restoration of certificate after lapse under Article 14(d)

SPM14.06 Where a new authorisation to place the product on the market is granted, a certificate which has lapsed under Article 14(d) automatically takes effect again from the date of the new authorisation (unless the certificate has also been declared invalid or lapsed on any other ground, eg surrender).

r.44(7)

SPM14.07 The certificate-holder should advise the Office of the grant of the new authorisation. Notice of the termination of lapse under Article 14(d) is then inserted in the Patents Journal (see SPM17.01).

PR part 7

SPM14.08 Any person may apply to the Comptroller for a declaration that the ground for lapse under Article 14(d) no longer exists. This starts proceedings before the comptroller to determine the matter, the procedure for which is discussed at paragraphs 123.05 - 123.05.13.

Surrender of certificate

r. 42

SPM14.09 Any offer by the holder to surrender a certificate should be made in writing. No fee is at present required. The offer is examined in accordance *mutatis mutandis* with the procedure under s.29 of the Patents Act 1977 for the surrender of patents (see 29.02-07).

[Offers on Patents Form 2 to surrender a certificate are referred to Tribunal Section.]

r.106(5)(6)(8)

- SPM14.10 If a certificate is surrendered, a remission of annual fees is made for any complete effective year(s) subsequent to the date of surrender. Thus, if a certificate having a term of 4 years 3 months (for which five years' fees would have been paid) is surrendered after 3 years 9 months, the fifth year's fee is remitted.
- SPM14.11 No remission is made if a certificate lapses under Article 14(d) unless the holder first surrenders the certificate. This is because lapse under Article 14(d) may not be permanent whereas once surrendered a certificate cannot be re-instated.
- SPM14.12 The district court of The Hague referred questions concerning whether surrender of a certificate has retrospective effect in Georgetown University and Octrooicentrum Nederland (Dutch Patent Office) C-484/12, but given the responses to other questions referred the questions on surrender did not need to be answered.

ARTICLE 15: INVALIDITY OF THE CERTIFICATE

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- 1. The certificate shall be invalid if:
 - (a) it was granted contrary to the provisions of Article 3;
 - (b) the basic patent has lapsed before its lawful term expires;
 - (c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.
- 2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent.

ArtM 17, (ArtP 16) r.44(7)

SPM15.01 Notification of invalidity of a certificate is published in the Patents Journal and is also entered in the register under the entry for the basic patent (see SPM17.01).

[PD/EX06 arranges the publication in the Journal and the entry in the register.]

PR part 7

SPM15.02 An application for a declaration of invalidity of a certificate may be made to the Comptroller or the Court as in the case of an application for revocation of a patent. An SPC is considered invalid as a matter of fact if any of the conditions of Article 15(1) are met, an application or action under Article 15(2) is not always required. Accordingly, subject to the observations of the applicant, this Office will publish a notice of invalidity for an SPC based on a patent to which Article 15(1)(b) or 15(1)(c) applies.

SPM15.03 In *Hässle AB v Ratiopharm* (ECJ Case C-127/00)[2003] ECR I-14781 the European Court found that where a certificate had been granted contrary to the requirements of Article 19 of Regulation (EEC) No 1768/92 the certificate was invalid under Article 15. The Court held that this was the case even if it was not possible to infer that the list of grounds of invalidity of a certificate found in Article 15(1) was not exhaustive (also see SPM20.02).

SPM15.04 In *Generics (UK) Limited (trading as Mylan) and Novartis AG*, [2011] EWHC 2403 (Pat) Floyd J found the claims of the basic patent filed in support of an SPC to be obvious and invalid, and consequently also found the associated SPC be invalid.

Application to the Comptroller

SPM15.05 An application to the Comptroller for a declaration of invalidity of a certificate should be made on Form SP3 (but see SPM19.04). The procedure is the same as in the case of an application for a declaration of lapse (see SPM14.03). As occurs from time to time judgments of the Courts or CJEU will result in some granted SPCs being invalid. The office will not however re-examine granted SPCs in the period between their dates of grant and coming into force, however a check on the status of the basic patent is made before an SPC comes into force. An interested party may however seek a declaration of invalidity. Alternatively a non-binding opinion may be sought in this regard see Section 74A and https://www.gov.uk/guidance/opinions-resolving-patent-disputes.

[Applications on Form SP3 for declaration of invalidity are referred to Tribunal Section.]

ARTICLE 16: REVOCATION OF AN EXTENSION OF THE DURATION

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- 1. The extension of the duration may be revoked if it was granted contrary to the provisions of Article 36 of Regulation (EC) No 1901/2006.
- 2. Any person may submit an application for revocation of the extension of the duration to the body responsible under national law for the revocation of the corresponding basic patent.

SPM16.01 Procedures relating to revocation of an extension are in accordance with those for a certificate (see SPM15.01, SPM15.02 and SPM15.04). In *Dr Reddy's Laboratories (UK) Ltd and Dr Reddy's Laboratories Ltd v Warner-Lambert Company LLC* [2012] EWHC 3715 (Pat) it was determined that the Court had the power to revoke a paediatric extension having regard to Article 16(1).

ARTICLE 17: NOTIFICATION OF LAPSE OR INVALIDITY

- 1. If the certificate lapses in accordance with point (b), (c) or (d) of Article 14, or is invalid in accordance with Article 15, notification thereof shall be published by the authority referred to in Article 9(1).
- 2. If the extension of the duration is revoked in accordance with Article 16, notification thereof shall be published by the authority referred to in Article 9(1).

r.44(7)

ArtM 14(a)

ArtP 14(a)

SPM17.01 The notifications required by Article 17, and also notification of termination of lapse under Article 14(d) (see SPM14.07) and notification of lapse at the end of the effective period of the certificate (see SPM14.01), are published in the Patents Journal. These events are also entered in the register under the entry for the basic patent.

[PD/EX06 arranges the publication in the Journal and the entry in the register.]

ARTICLE 18: APPEALS

The decisions of the authority referred to in Article 9(1) or of the bodies referred to in Articles 15(2) and 16(2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

PA 1977, s.97 ArtM 13(1) SPM18.01 Decisions taken by the Comptroller under the Regulation are open to appeal to the Patents Court in the same manner as decisions taken in respect of patents. In *Medeva BV v The Comptroller General of Patents* [2010] EWHC 68 (Pat), [2010] RPC 20, Kitchin J confirmed the procedural details for filing an appeal against an SPC rejection by the Intellectual Property Office (also see SPM10.12).

(ArtP 13(1))

[Matters within the Office relating to appeals from decisions taken under the Regulation are dealt with by Tribunal Section.]

ArtsM 13(1), 8.1(a)(iv)

SPM18.02 Recital (17) of the Plant Protection Regulation (see SPM0.04) has the effect that, from 8 February 1997 when said regulation came into force, Article 17 of Regulation (EEC) No 1768/92 (now Article 18 of the EC Medicinal Regulation) is additionally to be interpreted in accordance with Article 17(2) of the Plant Protection Regulation which states:

Article 17(2) [EC Plant Protection Regulation]

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Appeals

The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorization to place the product on the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect.

(ArtsP 13(1), 8(1)(a)(iv))

13(1), SPM18.03 Such an appeal may be lodged by the applicant or a third party. If the appeal results in a corrected maximum expiry date for the granted certificate the details will be notified to the public in the Patents Journal.

ARTICLE 19: PROCEDURE

- 1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless that law lays down special procedural provisions for certificates.
- 2. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

SPM19.01 Procedural provisions applicable under national law to the corresponding basic patent apply to the certificate, unless:

there are procedural provisions in the Regulation; or

national law lays down special procedural provisions for certificates.

SPM19.02 In the UK such special procedural provisions are laid down in the 2007 Rules and the 2007 Fees Rules and govern:

r.116, FSch 1 the application and fee in respect of the application (Articles 8 and 9);

the certificate of grant (Article 10);

Fr.6(2) annual fees (Article 12);

r.106(5),(6),(8) declaration of lapse or invalidity of the certificate (Articles 14(d) and 15.1(a) and

(c));

part 7

r.4 forms for use in connection with certificates and applications for certificates

(Article 19.1); and

r.44(7) publication of certain details (Articles 9.2, 11.1, 11.2 and 17).

r.116 SPM19.03 In particular the Rules provide for four special Forms:

Fsch.1 SP1 (Request for grant) (see SPM8.01);

Fr.6(2) SP2 (Payment of annual fees) (see SPM12.10);

SP3 (Application for decision of lapse or declaration of invalidity) (see

SPM14.03, SPM15.04 and SPM16.01);

SP4 (Application for an extension to the duration of a certificate) (see SP0.11);

and prescribe the fees payable thereon.

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r.4(2)

SPM19.04 The requirement to use any of these Forms is satisfied by the use of a form which is acceptable to the Comptroller and contains the required information (such as a replica or photocopy of an official Form).

r.4

SPM19.05 For actions other than those covered by Form SP1, SP2, SP3 and SP4 the relevant Patent Forms should be used and the same fee (if any) paid.

SPM19.06 It follows from Article 19.2 that opposition to the grant of a certificate is not allowed (see SPM10.20).

Requests for information (caveats)

r.54

SPM19.07 Insofar as rule 54 of the Patents Rules 2007 is applicable, information relating to certificates, applications for certificates, extensions of a certificate and applications extensions of a certificate is available upon request as in the case of patents and applications for patents. Paragraphs 5(a), 5(b), 6(a) and 6(d) of rule 54 appear to have no relevance to certificates and applications for certificates. Paragraph 6(c) appears applicable *mutatis mutandis* to the provision of information concerning the payment of annual fees (see SPM12.10-12.13).

Documents open to public inspection

r.51(2)(b)

SPM19.08 Documents are normally made open to public inspection immediately after they are filed at (or sent to) the Office.

r.53

SPM19.09 The person filing or sending a document (other than a Form SP1, SP2, SP3 or SP4), or any other person, may request within 14 days that the document be kept confidential (giving reasons). The comptroller may then direct that the document in question, or part thereof, should be treated as confidential. The document is not open to public inspection while the matter is being determined. Where a request is made to keep a document confidential but no reasons are given the person filing the document is requested to provide suitable reasons within a period of 14 days.

r.46, 48

SPM19.10 Copies of any documents which are not treated as confidential are available upon request as in the case of documents relating to patents.

Extensions of time

r.108

SPM19.11 In *Abbott Laboratories' SPC Application* [2004] RPC 20 it was held that the six month time limit set out in Article 7 is extendable under r.110(1) of the Patents Rules 1995 (which is equivalent to r.108(1) of the Patents Rules 2007). There are no provisions in the Regulation relating to extension of the Article 7 time limit, and there are no special provisions for such extensions laid down by national law. Hence the applicable provision governing any such extension of time is the appropriate procedural provision under national law corresponding to the basic patent. In *Merck & Co., Inc.* (BL O/035/09) the hearing officer found that the time limit set by the examiner for rectifying an irregularity in filing the required documents was extendable under r.108 (see SPM8.09). The Court of Appeal in *E I Du Pont Nemours & Co.* [2009] EWCA Civ 966, [2010] RPC 6 directed that the time periods for curing irregularities under Article 10(3) in an application for an extension of the duration of a certificate can be extended (see SPM8.09).

ARTICLE 20: ADDITIONAL PROVISIONS RELATING TO THE ENLARGEMENT OF THE COMMUNITY

Without prejudice to the other provisions of this Regulation, the following provisions shall apply:

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- (a) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Bulgaria, provided that the application for a certificate was lodged within six months from 1 January 2007;
- (b) any medicinal product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a medicinal product was obtained:
 - (i) in the Czech Republic after 10 November 1999 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained,
 - (ii) in the Community not earlier than six months prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained:
- (c) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Estonia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or, in the case of those patents granted prior to 1 January 2000, within the six months provided for in the Patents Act of October 1999;
- (d) a medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Cyprus prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained; notwithstanding the above, where the market authorisation was obtained before the grant of the basic patent, the application for a certificate must be lodged within six months of the date on which the patent was granted;
- (e) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Latvia prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May 2004;
- (f) any medicinal product protected by a valid basic patent applied for after 1 February 1994 and for which the first authorisation to place it on the market as a medicinal product was obtained in Lithuania prior to 1 May 2004may be granted a certificate, provided that the application for a certificate was lodged within six months from 1 May 2004;
- (g) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Hungary, provided that the application for a certificate was lodged within six months from 1 May 2004;
- (h) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Malta prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May

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2004:

(i) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that the application for a certificate was lodged within six months starting no later than 1 May 2004;

(j) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 January 2007;

(k) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovenia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months from 1 May 2004, including in cases where the period provided for in Article 7(1) has expired;

(I) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovakia after 1 January 2000 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or within six months of 1 July 2002 if the market authorisation was obtained before that date.

(m) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2003 may be granted a certificate in Croatia, provided that the application for a certificate is lodged within six months from the date of accession.

SPM20.01 In the case of a product which was already authorised before entry into force of Regulation (EEC) No 1768/92 the transitional provisions of Article 19 of that regulation allowed for an application to be filed in the UK within six months of the date on which the Regulation entered into force, (ie filed on or before 2 July 1993) provided that:

on that date the product was protected by a valid basic patent; and

the first authorisation to place it on the market in the Community was obtained after 1 January 1985.

However the application must still have been filed before the basic patent expired. Such transitional provisions no longer exist in the EC Medicinal Regulation.

ArtM 3(a) (ArtP 3(1)(a)) SPM20.02 In Yamanouchi Pharmaceuticals Co. Ltd v Comptroller-General [1997] RPC 844 an application under Regulation (EEC) No 1768/92 had received its first authorisation to be placed on the market in the EC after 1 January 1985, but had not yet received an authorisation to be placed on the market in the UK. The Hearing Officer had declined to accept that the transitional provisions of Article 19 of Regulation (EEC) No 1768/92 obviated the need to comply with the requirements of Articles 3(b), 8(1)(a)(iv) and 8(1)(b) and accordingly refused the application for non-compliance with these Articles. On appeal the Patents Court (unreported judgment of 31 October 1994) decided to refer the matter to the European Court of Justice. Upholding the Hearing Officer's decision, the European Court ruled that the regulation was intended to prevent the grant of SPCs whose duration varied from one Member State to another. In those circumstances, Article 19(1) of Regulation (EEC) No 1768/92 could not be construed as meaning that the existence of an authorisation in the Member State in which the SPC

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was sought was of no relevance. Under Articles 3(b) and 4 of the regulation, entitlement to an SPC was strictly linked to the existence of a marketing authorisation granted in the Member State in which the application was submitted and to the date of that application. Accordingly, the grant of an SPC pursuant to Article 19 of Regulation (EEC) No 1768/92 was conditional on a valid authorisation to place the product on the market as a medicinal product having been granted in the Member State in which the application was submitted and at the date of the application. In Hässle AB v Ratiopharm (ECJ Case C-127/00) [2003] ECR I-14781 the European Court found that the first authorisation referred to in Article 19(1) of Regulation (EEC) No 1768/92 meant the first authorisation required under the provisions on medicinal products within the meaning of Council Directive 65/65 (now Directive 2001/83/EC, see SPM3.03.1) and not to authorisations required for legislation on the pricing or reimbursement for medicinal products in a member state (also see SPM15.03).

ARTICLE 21: TRANSITIONAL PROVISIONS

1. This Regulation shall not apply to certificates granted in accordance with the national legislation of a Member State before 2 January 1993 or to applications for a certificate filed in accordance with that legislation before 2 July 1992.

With regard to Austria, Finland, and Sweden, this Regulation shall not apply to certificates granted in accordance with their national legislation before 1 January 1995.

2. This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia prior to 1 May 2004 and the national legislation of Romania prior to 1 January 2007.

ARTICLE 22: REPEAL

Regulation (EEC) No 1768/92, as amended by the acts listed in Annex I, is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

ARTICLE 23: ENTRY INTO FORCE

This Regulation shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

SPM23.01 The EC Medicinal Regulation was published in the Official Journal of the European Union on 16 June 2009. It therefore entered into force on 6 July 2009.

ANNEX I: REPEALED REGULATION WITH LIST OF ITS SUCCESSIVE AMENDMENTS (referred to in Article 22)

Council Regulation (EEC) No 1768/92 (OJ L 182 2.7.1992, p. 1)

Annex I, point XI.F.I. of the 1994 Act of Accession (OJ C 241 29.8.1994, p. 233)

Annex II, point 4.C.II, of the 2003 Act of Accession (OJ L 236 23.9.2003, p. 342)

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Regulation (EC) No 1901/2006 of the European Parliament and of the Council, Only Article 52 (OJ L 378, 27.12.2006, p. 1)

ANNEX II: CORRELATION TABLE

Regulation (EEC) No 1768/92	This Regulation
-	Recital 1
Recital 1	Recital 2
Recital 2	Recital 3
Recital 3	Recital 4
Recital 4	Recital 5
Recital 5	Recital 6
Recital 6	Recital 7
Recital 7	Recital 8
Recital 8	Recital 9
Recital 9	Recital 10
Recital 10	-
Recital 11	-
Recital 12	-
Recital 13	Recital 11
Article 1	Article 1
Article 2	Article 2
Article 3, introductory wording	Article 3, introductory wording
Article 3, point (a)	Article 3, point (a)
Article 3, point (b), first sentence	Article 3, point (b)
Article 3, point (b), second sentence	-
Article 3, points (c) and (d)	Article 3, points (c) and (d)
Article 4 to 7	Article 4 to 7

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	1
Article 8(1)	Article 8(1)
Article 8(1a)	Article 8(2)
Article 8(1b)	Article 8(3)
Article 8(2)	Article 8(4)
Article 9 to 12	Article 9 to 12
Article 13(1), (2) and (3)	Article 13(1), (2) and (3)
Article 14 and 15	Article 14 and 15
Article 15a	Article 16
Article 16, 17 and 18	Article 17, 18 and 19
Article 19	-
Article 19a, introductory wording	Article 20, introductory wording
Article 19a, point (a), points (i) and (ii)	Article 20, point (b), introductory wording, points (i) and (ii)
Article 19a, point (b)	Article 20, point (c)
Article 19a, point (c)	Article 20, point (d)
Article 19a, point (d)	Article 20, point (e)
Article 19a, point (e)	Article 20, point (f)
Article 19a, point (f)	Article 20, point (g)
Article 19a, point (g)	Article 20, point (h)
Article 19a, point (h)	Article 20, point (i)
Article 19a, point (i)	Article 20, point (k)
Article 19a, point (j)	Article 20, point (I)
Article 19a, point (k)	Article 20, point (a)
Article 19a, point (I)	Article 20, point (j)
Article 20	Article 21
Article 21	-
Article 22	Article 13(4)
-	Article 22
Article 23	Article 23
-	Annex I

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REGULATION (EC) NO 1610/96 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (PLANT PROTECTION PRODUCTS)

RECITALS TO THE REGULATION

The European Parliament and The Council of The European Union

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (OJ No C 390, 31.12.1994, p 21 and OJ No C 335, 13.12.1995, p 15)

Having regard to the opinion of the Economic and Social Committee (OJ No C 155, 21.6.1995, p 14),

Acting in accordance with the procedure referred to in Article 189b of the Treaty (Opinion of the European Parliament of 15 June 1995 (OJ No C 166, 3.7.1995, p 89), common position of the Council of 27 November 1995 (OJ No C 353, 30.12.1995, p 36) and decision of the European Parliament of 12 March 1996 (OJ No C 96, 1.4.1996, p 30)),

- (1) Whereas research into plant protection products contributes to the continuing improvement in the production and procurement of plentiful food of good quality at affordable prices;
- (2) Whereas plant protection research contributes to the continuing improvement in crop production;
- (3) Whereas plant protection products, especially those that are the result of long, costly research, will continue to be developed in the Community and in Europe if they are covered by favourable rules that provide for sufficient protection to encourage such research;
- (4) Whereas the competitiveness of the plant protection sector, by the very nature of the industry, requires a level of protection for innovation which is equivalent to that granted to medicinal products by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ No L 182, 2.7.1992, p. 1.);
- (5) Whereas, at the moment, the period that elapses between the filing of an application for a patent for a new plant protection product and authorization to place the said plant protection product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research and to generate the resources needed to maintain a high level of research;
- (6) Whereas this situation leads to a lack of protection which penalises plant protection research and the competitiveness of the sector:
- (7) Whereas one of the main objectives of the supplementary protection certificate is to place European industry on the same competitive footing as its North American and Japanese counterparts;
- (8) Whereas, in its Resolution of 1 February 1993 (OJ No C 138, 17.5.1993, p. 1.) on a Community programme of policy and action in relation to the environment and sustainable development, the Council adopted the general approach and strategy of the programme presented by the Commission, which stressed the interdependence

of economic growth and environmental quality; whereas improving protection of the environment means maintaining the economic competitiveness of industry; whereas, accordingly, the issue of a supplementary protection certificate can be regarded as a positive measure in favour of environmental protection;

- (9) Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to hinder the free movement of plant protection products within the Community and thus directly affect the functioning of the internal market; whereas this is in accordance with the principle of subsidiarity as defined by Article 3b of the Treaty;
- (10) Whereas, therefore, there is a need to create a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a plant protection product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;
- (11) Whereas the duration of the protection granted by the certificate should be such as to provide adequate, effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the plant protection product in question first obtains authorization to be placed on the market in the Community;
- (12) Whereas all the interests at stake in a sector as complex and sensitive as plant protection must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years;
- (13) Whereas the certificate confers the same rights as those conferred by the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection;
- (14) Whereas the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them;
- (15) Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community plant protection industry to catch up to some extent with its main competitors, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the agricultural policy and environment protection policy pursued at both national and Community level;
- (16) Whereas only action at Community level will enable the objective, which consists in ensuring adequate protection for innovation in the field of plant protection, while guaranteeing the proper functioning of the internal market for plant protection products, to be attained effectively;
- (17) Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3(2), 4, 8(1)(c) and 17 (2) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of recital 9 and Articles 3, 4, 8(1)(c) and 17 of Council Regulation (EEC) No 1768/92,

HAVE ADOPTED THIS REGULATION:

SPP0.01 Council Regulation (EEC) No 1768/92 has subsequently been codified under Regulation (EC) No 469/2009 of the European Parliament and of the Council according to Article 22 of which, with reference to an annexed correlation table, all

references to Regulation No 1768/92 are to be construed as references to Regulation (EC) No 469/2009 (see SP0.01, SPM0.04 and Annex II to Regulation (EC) No 469/2009). Articles 3(1)(a) and (c), 5, 6, 8(1)(a)(i) to (iv), 8(2), 9 to 12, 13(1) and (2), 14(a) to (c), 15, 16, 17(1) and 18(2) of Regulation (EC) 1610/96 for plant protection products are identical in wording to Articles 3(a) to (c), 5, 6, 8(1)(a)(i) to (iv), 8(4), 9 to 12, 13(1) and (2), 14(a) to (c), 15, 17, 18 and 19(2) respectively, of Regulation (EC) 469/2009 for medicinal products. For commentary on the said Articles in the Plant Protection Regulation reference should be made to the corresponding paragraphs in SPM3.01 to 19.11 relating to the Medicinal Regulation. For commentary on the Recitals and the remaining Articles of the Plant Protection Regulation the following paragraphs should be consulted as well as the equivalent paragraphs in SPM0.01 to 20.02.

ARTICLE 1: DEFINITIONS

For the purposes of this Regulation, the following definitions shall apply:

- 1. "plant protection products": active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:
 - (a) protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;
 - (b) influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators);
 - (c) preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;
 - (d) destroy undesirable plants; or
 - (e) destroy parts of plants, check or prevent undesirable growth of plants;
- 2. "substances": chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;
- 3. "active substances": substances or micro-organisms including viruses, having general or specific action:
 - (a) against harmful organisms; or
 - (b) on plants, parts of plants or plant products;
- 4. "preparations": mixtures or solutions composed of two more substances, of which at least one is an active substance, intended for use as plant protection products;
- 5. "plants": live plants and live parts of plants, including fresh fruit and seeds;
- 6. "plant products": products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves as defined in point 5;
- 7. "harmful organisms": pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens;
- 8. "product": the active substance as defined in point 3 or combination of active

substances of a plant protection product;

- 9. "basic patent": a patent which protects a product as defined in point 8 as such, a preparation as defined in point 4, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
- 10. "certificate": the supplementary protection certificate.

Product and Plant Protection Product

SPP1.01 Article 1 distinguishes between the terms "plant protection product" and "product". Although the EC Plant Protection Regulation creates a certificate for plant protection products, it is the product - defined by Article 1(8) as the active substance or combination of active substances - which is the subject of the certificate pursuant to Article 2. The meaning of "product" was clarified by the European Court of Justice in BASF AG v Bureau Voor de Industriële Eigendom [2002] RPC 9. It was held that a "product" as defined by Article 1(8) includes, along with the active substance, any impurity which inevitably results from the manufacturing process of that substance. However, two products which differ only in the proportion of active substance to impurity they contain (one being more pure than the other) are considered to be one and same "product" within the definition of Article 1(8) - the court holding that a product "cannot change solely because of an alteration in the unit quantity of impurities where both the chemical compound it contains and that compound's action on its targets remain unchanged". The fact that, in the case in question, the two products of differing purity required separate marketing authorisations was not relevant in determining whether they amounted to the same "product" within the definition of Article 1. See also SPP3.01. Clarification of the meaning of the term "product" has also been sought in Bayer CropScience AG v Bundespatentgericht, C-11/13, it was determined that "product" is to be interpreted as covering a "safener", a substance added to plant protection product to eliminate or reduce phytotoxic effects of the protection product on certain plants.

SPP1.02 The definitions of the terms "plant protection products" to "product" in Article 1(1) to 1(8) are based on those specified in Article 2 of Council Directive 91/414/EEC of 15 July 1991, now repealed by Regulation (EC) No 1107/2009 with effect from 14 June 2011, concerning the placing of plant protection products on the market. However, these definitions do not always correspond to the terminology used in UK Marketing Authorizations, or the details published in official Gazettes, because Articles 2 and 3(1)(b) of the Plant Protection Regulation allow for the authorization on which the SPC application is based to be either in accordance with Article 4 of Directive 91/414/EEC (now repealed by Regulation (EC) No 1107/2009 with effect from 14 June 2011) or an equivalent provision of national (e.g. United Kingdom) law. Thus, the product specified in the Marketing Authorization is generally broadly equivalent to the "plant protection product" as defined in Article 1(1), and the "active constituent(s)" or "active ingredient(s)" are generally broadly equivalent to the "product" as defined by Article 1(8).

SPP1.03 The term "active substance" in the Plant Protection Regulation is identical in effect to "active ingredient" in the Medicinal Regulation. In accordance with recital (13) the term "active substance" in Article 1(8) is interpreted as including any closely related derivative, in particular a salt or ester, which has obtained authorization to be placed on the market and is protected by the claims of the basic patent.

SPP1.04 If the derivative in question can be regarded as a new and inventive active substance which is protected by a patent which specifically relates to it, e.g. a selection patent, recital (14) allows for the new derivative to be protected by its own certificate in spite of the fact that the non-derivatised form of the active substance and its non-inventive derivatives are the subject of a different certificate.

Basic Patent

SPP1.05 The basic patent may be either a UK patent or a European patent (UK) (see SPM1.05).

ARTICLE 2: SCOPE

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorization procedure as laid down in Article 4 of Directive 91/414/EEC (OJ L 230, 19.8.1991, p. 1. Directive as last amended by Directive 95/36/EC (OJ L 172, 22.7.1995, p. 8).), or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorization was lodged before Directive 91/414/EEC was implemented by the Member State concerned, may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

SPP2.01 A certificate can be granted in the UK for a product which has received an authorization to be placed on the market in accordance with Directive 91/414/EEC or 95/36/EEC, now repealed by Regulation (EC) No 1107/2009 with effect from 14 June 2011, or with an equivalent provision of national law. The authorization may be granted for the UK only, whereupon it takes the form of an approval issued under the Control of Pesticides Regulations (COPR) 1986 (as amended), or an authorization issued under the UK Plant Protection Product Regulations (UKPPPR) 1995 (as amended), by the Pesticides Safety Directorate of the Ministry of Agriculture, Fisheries and Food. The UKPPPR 1995 implement Directive 91/414/EEC in the UK. COPR is an equivalent provision of national law for the purposes of Article 2. Those plant protection products whose active substances(s) are already on the market in the EC continue to be regulated under UK national legislation under COPR 1986 whose continuation is permitted by virtue of the transitional provisions of EC Directive 91/414/EEC. Those plant protection products that contain active substances new to the Community fall to be regulated under UKPPPR 1995 (which implements EC Directive 91/414/EEC in the UK). Those with a combination of "old" and "new" active substances fall to be regulated under COPR.

Recital 4 of the EC Plant Protection SPC Regulation states that the level of SPP2.02 protection for innovation for plant protection products is to be equivalent to that granted to medicinal products under Regulation 1768/92, a purpose which is reflected in the similarity of wording of the two Regulations. A medicinal product which had obtained a market authorization and/or was marketed prior to 1 January 1985 would not have been granted a supplementary protection certificate because Articles 3(d) and 19 of Regulation (EEC) No 1768/92 effectively dictated that the first authorization had to be after 1 January 1985. It is therefore the view of the Office that a parallel situation must apply to plant protection products so that any marketing authorization or marketing prior to 1 January 1985 will prevent the grant of a certificate. Whereas the marketing of medicinal products has been regulated by statutory authorization schemes throughout the lifetime of all patents likely to give rise to certificates, this is not the case for plant protection products. Prior to 6 October 1986, when the statutory authorization scheme under the COPR entered into force in the UK, it was theoretically possible for applicant to have marketed a plant protection product without authorization under any provision of national law (even though he may voluntarily have delayed marketing to await authorization under the COPR). In practice, the marketing of plant protection products before this date was regulated under voluntary schemes, particularly the Pesticides Safety Precautions Scheme (PSPS). This consisted of a formal agreement between trade associations (eg the British Agrochemicals Association and the British Pest Control Association) and the UK government departments and agencies responsible for agriculture, health and safety. An agrochemical company who was a member of a trade association party to the agreement was required to apply for clearance of any new pesticide that it intended to market; in practice this was automatic, since it appears there was little likelihood of commercial acceptance of a pesticide without PSPS approval. Approval was subject to an administrative procedure involving inspection by government

authorities and marketing of the new product was inevitably delayed. It therefore appears that such products fall within the spirit, if not the strict scope, of Article 2 (see SPP19.01 as to their acceptability under Art 19(1)). In consequence, before deciding whether a certificate may be granted for a plant protection product where the basic patent has a filing date between 9 February 1977 (the earliest date allowable under Art 3(1)(a)) and 6 October 1986, the Office may request the following information in addition to the details given on the application Form SP1:

- whether any authorization under PSPS for the product was obtained, details of the authorization number and date of issue and a copy of the grant document being required;
- -whether the product was marketed in the UK prior to 1986 with or without authorization, details of the date of marketing being required;
- -whether the applicant was a member of a trade association bound by the PSPS agreement throughout the period from the filing date of the basic patent until 6 October 1986.

Insofar as the patents relating to products protected by the PSPS have expired there is no further relevance of this scheme to new SPC applications (See also SPP19.01.)

ARTICLE 3: CONDITIONS FOR OBTAINING A CERTIFICATE

- 1. A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted, at the date of that application:
 - (a) the product is protected by a basic patent in force;
 - (b) a valid authorization to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law;

for the purposes of this subparagraph and the Articles which refer to it, an authorization to place the product on the market granted in accordance with the national legislation of the EFTA State shall be treated as an authorization granted in accordance with Directive 91/414/EEC or an equivalent provision of national law of an EC Member State.

- (c) the product has not already been the subject of a certificate;
- (d) the authorization referred to in (b) is the first authorization to place the product on the market as a plant protection product.
- 2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

SPP3.01 The conditions of Article 3 must be satisfied at the date of making an application. Thus, at that date:

- the basic patent protecting the product must be in force;
- the product must not previously have been the subject of a certificate in the UK;
- a valid authorization or approval to place the product on the market in the United

Kingdom as a plant protection product must have been granted in accordance with Directive 91/414/EEC (now repealed by Regulation (EC) No 1107/2009 with effect from 14 June 2011) or a provision of UK law i.e. the Control of Pesticides Regulations (COPR) 1986 or the UK Plant Protection Product Regulations 1995 (see SPP2.01):

- this authorization must be the first authorization to place the product on the market as a plant protection product in the United Kingdom (although there may have been an earlier first authorization elsewhere in the EC).

For example, in *BASF AG v Bureau Voor de Industriële Eigendom* [2002] RPC 9 (see SPP1.01), the product in question was a plant protection product manufactured according to a patented process, which resulted in a product of higher purity than previously achieved. A marketing authorisation for this higher purity product was granted in 1987, but marketing authorisation for a lower purity product was granted in 1967. The ECJ held that the higher purity product amounted to the same "product" within the meaning of Article 3 as the lower purity product and so held that in such circumstances the conditions of Article 3(1)(d) were not satisfied. Clarification of the meaning of the term "product" has also been sought in *Bayer CropScience AG v Bundespatentgericht, C-11/13* it was determined that "product" is to be interpreted as covering a "safener", a substance added to plant protection product to eliminate or reduce phytotoxic effects of the protection product on certain plants.

SPP3.02 Under the Control of Pesticides Regulations 1986 marketing approvals are issued at three progressive levels of approval:

- Experimental permit for supply, storage and use only, for a limited period;
- Provisional approval for sale, supply, storage, use and advertisement for a limited period whilst outstanding data are obtained;
- Full (unlimited) approval for sale, supply, storage, use and advertisement, where there are no outstanding data requirements.

Experimental permits only allow experimental work on new substances or new uses to be carried out over a limited area to produce data in support of a future application for approval for commercial use. Such permits are not acceptable as a basis for making an SPC application under Article 2 or 3(1)(b) as they do not allow marketing to take place. (see also SPM3.03.1). Provisional and full authorizations under COPR both allow marketing of the product from the date of grant thereof and are granted under a relevant provision of national (UK) law equivalent to the administrative authorization procedure as laid down in Article 4 of Directive 91/414/EEC (now repealed by Regulation (EC) No 1107/2009 with effect from 14 June 2011). Consequently both provisional and full UK authorizations are acceptable under Article 3(1)(b). In *Hogan Lovells International* (C-229/09), the Court of Justice of the European Union confirmed that Article 3(1)(b) of Regulation No 1610/96 is interpreted as meaning that a supplementary protection certificate can be issued for a product in respect of which a provisional MA has been granted under Article 8(1) of Directive 91/414 (Article 30 of Regulation (EC) No 1107/2009).

SPP3.02.1 In *Sumitomo Chemical (C-210/12)*, questions relating to whether or not emergency marketing authorisations for plant protection products (under Art 8(4) of Directive 91/414/EEC, now superseded by Regulation EC/1107/2009) can be used for the purposes of Article 3(1)(b) of the Regulation, and whether such authorisations still need to be in force at the time of an application, were referred to the CJEU for a preliminary ruling. The Court confirmed that Article 3(1)(b) of the Regulation should be interpreted as precluding the issue of a SPC for a plant protection product in respect of which an emergency MA has been issued under Article 8(4) of Directive 91/414/EEC, and that Articles 3(1)(b) and 7(1) of the Regulation must be interpreted as precluding an application for a SPC being lodged before the date on which the plant protection product has obtained the MA referred to in Article 3(1)(b) of that Regulation (see SPP7.01).

SPP3.02.2 Having regard to Regulation (EC) 1107/2009 at least the following steps are relevant as concerns the grant of an Article 3(b) compliant MA. First an application to seek approval of the active substance for inclusion in plant protection products in the EU is made having regard to Article 4 of Regulation (EC) 1107/2009. This culminates in a Commission implementing decision including the substance on the list of approved substances provided by Regulation EU 540/2011. This step does not allow the Plant Protection product to be placed on the market and as such is not considered Article 3(b) compliant. Where a plant protection product is for use on an edible crop it is subsequently necessary to set a maximum residue level in the resultant food or feed, as provided by Articles 6 and 7 of Regulation EC 396/2005. Regulation (EC) 1107/2009 stipulates that before any plant protection product can be placed on the market it must be authorised according to the zonal authorisation process provided by Articles 33-39 or the mutual recognition process provided by Articles 40-42; these authorisations are capable of being considered compliant with Article 3(b) of Regulation 1610/96.

SPP3.03 Article 3(2) precludes the granting of more than one certificate for a single product to the holder of a portfolio of related patents all covering the said product, even when the SPC applications are all pending together and meet the requirements of Article 3(1)(c). When the product is protected by several patents held by an applicant e.g. by a patent for the product per se, a patent for a process for making the product and a patent for a plant protection formulation comprising the product, it is for the holder of the patents concerned to chose one of them as the basic patent, bearing in mind that the subject-matter protected by the certificate is constrained by the protection conferred by the patent.

ARTICLE 4: SUBJECT-MATTER OF PROTECTION

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorizations to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorized before the expiry of the certificate.

SPP4.01 A certificate extends the protection conferred by the basic patent beyond the term of that patent but only in respect of the product covered by the authorization or approval to place the corresponding plant protection product on the market and any use of the product as a plant protection product that has been authorized or approved before expiry of the certificate. It does not, however, extend the term of the patent itself.

ARTICLE 5: EFFECTS OF THE CERTIFICATE

Subject to Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

ARTICLE 6: ENTITLEMENT TO THE CERTIFICATE

The certificate shall be granted to the holder of the basic patent or his successor in title.

ARTICLE 7: APPLICATION FOR A CERTIFICATE

- 1. The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3(1)(b) to place the product on the market as a plant protection product was granted.
- 2. Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate

shall be lodged within six months of the date on which the patent is granted.

SPP7.01 The requirements to be met with respect to the period for filing an application under the Plant Protection Regulation are identical to those under the Medicinal Regulation (see SPM7.01, SPM7.03). In *Sumitomo C-210/12* the CJEU has confirmed that Article 7(1) is to be interpreted as precluding an application for a SPC being lodged before the date on which the plant protection product has obtained the MA referred to in Article 3(1)(b) (see SPP3.02.1).

ARTICLE 8: CONTENT OF THE APPLICATION FOR A CERTIFICATE

- 1. The application for a certificate shall contain:
 - (a) a request for the grant of a certificate, stating in particular:
 - (i) the name and address of the applicant;
 - (ii) the name and address of the representative, if any;
 - (iii) the number of the basic patent and the title of the invention;
 - (iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3(1)(b) and, if this authorization is not the first authorization to place the product on the market in the Community, the number and date of that authorization:
 - (b) a copy of the authorization to place the product on the market, as referred to in Article 3(1)(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Part A.I (points 1 7) or B.I (points 1 7) of Annex II to Directive 91/414/EEC or in equivalent national laws of the Member State in which the application was lodged:
 - (c) if the authorization referred to in (b) is not the first authorization to place the product on the market as a plant protection product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication or, failing such a notice, any other document proving that the authorization has been issued, the date on which it was issued and the identity of the product authorized.
- 2. Member States may require a fee to be payable upon application for a certificate.

SPP8.01 The request for grant of a certificate should specify:

- the name and address of the applicant (Section 3 of Form SP1);
- the name of the applicant's agent (if any) and address for service in the European Economic Area or Channel Islands (Section 4);
- the EC Regulation (469/2009, formally 1768/92; or 1610/96) under which the application is made Section 5);
- the product in respect of which the certificate is sought (i.e. the active substance

or combination of active substances of the plant protection product) (Section 6);

- the number, title, expiry date and (if later than the first UK authorization or approval) the date of grant of the basic patent (Section 7);
- the number and date of the first UK authorization or approval (Section 8);
- (where different from the first UK authorization or approval) the State, number and date of the first authorization in the EC, plus the identity of the authorized product and the legal provision under which the authorization took place (Section 9). The wording of Articles 8(1)(a)(iv) and 8(1)(c) does not appear to require such a first authorization to have been granted in accordance with Directive 91/414/EEC (now repealed by Regulation (EC) No 1107/2009 with effect from 14 June 2011). For applications lodged on or after 1 August 1997, the relevant authorization for the purposes of Articles 8(1)(a)(iv) and 8(1)(c) includes the first authorization in a State which is a Contracting Party to the European Economic Area Agreement (see SP0.09-10).

ARTICLE 9: LODGING OF AN APPLICATION FOR A CERTIFICATE

- 1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3(1)(b) to place the product on the market was obtained, unless the member State designates another authority for the purpose.
- 2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:
 - (a) the name and address of the applicant;
 - (b) the number of the basic patent;
 - (c) the title of the invention;
 - (d) the number and date of the authorization to place the product on the market, referred to in Article 3(1)(b), and the product identified in that authorization:
 - (e) where relevant, the number and date of the first authorization to place the product on the market in the Community.

ARTICLE 10: GRANT OF THE CERTIFICATE OR REJECTION OF THE APPLICATION

- 1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the certificate.
- 2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.
- 3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

- 4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the application shall be rejected.
- 5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(1)(c) and (d) are met.

ARTICLE 11: PUBLICATION

- 1. Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9(1). The notification shall contain at least the following information:
 - (a) the name and address of the holder of the certificate:
 - (b) the number of the basic patent;
 - (c) the title of the invention;
 - (d) the number and date of the authorization to place the product on the market referred to in Article 3(1)(b) and the product identified in that authorization:
 - (e) where relevant, the number and date of the first authorization to place the product on the market in the Community;
 - (f) the duration of the certificate.
- 2. Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9(1). The notification shall contain at least the information listed in Article 9(2).

ARTICLE 12: ANNUAL FEES

Member States may require the certificate to be subject to the payment of annual fees.

ARTICLE 13: DURATION OF THE CERTIFICATE

- 1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years.
- 2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.
- 3. For the purposes of calculating the duration of the certificate, account shall be taken of a provisional first marketing authorization only if it is directly followed by a definitive authorization concerning the same product.

Provisional first authorization

SPP13.01 During the substantive examination of the application the applicant will generally be requested to provide details of any full authorizations which have followed an acknowledged first provisional authorization so that the provisions of Article 13(3) can be

given effect. However, it is considered that Article 13(3) does not prevent the grant of a certificate on the basis of provisional authorizations which allow marketing of the product (see SPP3.02).

ARTICLE 14: EXPIRY OF THE CERTIFICATE

The certificate shall lapse:

- (a) at the end of the period provided for in Article 13;
- (b) if the certificate-holder surrenders it;
- (c) if the annual fee laid down in accordance with Article 12 is not paid in time;
- (d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place it on the market in accordance with Article 4 of Directive 91/414/EEC or equivalent provisions of national law. The authority referred to in Article 9(1) may decide on the lapse of the certificate either on its own initiative or at the request of a third party.

Declaration of lapse under Article 14(d)

SPP14.01 Article 14(d) of the Plant Protection Regulation is equivalent to Article 14(d) of the Medicinal Regulation but refers, naturally, to the relevant Directive 91/414/EEC (now repealed by Regulation (EC) No 1107/2009 with effect from 14 June 2011) or equivalent provisions of national (UK) law (see SPM14.02 -08).

ARTICLE 15: INVALIDITY OF THE CERTIFICATE

- 1. The certificate shall be invalid if:
 - (a) it was granted contrary to the provisions of Article 3;
 - (b) the basic patent has lapsed before its lawful term expires;
 - (c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.
- 2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent.

ARTICLE 16: NOTIFICATION OF LAPSE OR INVALIDITY

If the certificate lapses in accordance with Article 14(b), (c) or (d) or is invalid in accordance with Article 15, notification thereof shall be published by the authority referred to in Article 9(1).

ARTICLE 17: APPEALS

1. The decisions of the authority referred to in Article 9(1) or of the body referred to in Article 15(2) taken under this Regulation shall be open to the same appeals as

those provided for in national law against similar decisions taken in respect of national patents.

- 2. The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorization to place the product on the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect.
- SPP17.01 A decision to grant a certificate is open to appeals seeking to correct the duration of a certificate where the date of the first authorization to place the product on the market in the Community contained in an application is wrong. (See also SPM13.06).

ARTICLE 18: PROCEDURE

- 1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent and, where appropriate, the procedural provisions applicable to the certificates referred to in Regulation (EEC) No 1768/92, shall apply to the certificate, unless national law lays down special procedural provisions for certificates as referred to in this Regulation.
- 2. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

SPP18.01 In the UK procedural and fees provisions are laid down in the 2007 Rules and 2007 Fees Rules. (see SPM19.01-19.03).

ARTICLE 19: TRANSITIONAL PROVISIONS

- 1. Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on the market as a plant protection product in the Community was obtained after 1 January 1985 under Article 4 of Directive 91/414/EEC or an equivalent national provision may be granted a certificate.
- 2. An application made under paragraph 1 for a certificate shall be submitted within six months of the date on which this Regulation enters into force.

ARTICLE 19A: PROVISIONS RELATING TO THE ENLARGEMENT OF THE COMMUNITY

Without prejudice to the other provisions of this Regulation, the following shall apply:

- (a) (i) any plant protection product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a plant protection product was obtained in the Czech Republic after 10 November 1999 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained,
 - (ii) any plant protection product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a plant protection product was obtained in the Community not earlier than six months prior to the date of accession may be granted a certificate, provided that the application for a certificate was lodged within six months of

- (b) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Estonia prior to the date of accession may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or, in the case of those patents granted prior to 1 January 2000, within the six month period provided for in the Patents Act of October 1999;
- (c) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Cyprus prior to the date of accession may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained; notwithstanding the above, where the market authorisation was obtained before the grant of the basic patent, the application for a certificate must be lodged within six months of the date on which the patent was granted;
- (d) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Latvia prior to the date of accession may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than the date of accession;
- (e) any plant protection product protected by a valid basic patent applied for after 1 February 1994 and for which the first authorisation to place it on the market as a plant protection product was obtained in Lithuania prior to the date of accession may be granted a certificate, provided that the application for a certificate is lodged within six months of the date of accession:
- (f) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Hungary, provided that the application for a certificate is lodged within six months of the date of accession;
- (g) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Malta prior to the date of accession may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than the date of accession;
- (h) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that the application for a certificate is lodged within six months starting no later than the date of accession;
- (i) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Slovenia prior to the date of accession may be granted a certificate, provided that the application for a certificate is lodged within six months of the date of accession, including in cases where the period provided for in Article 7(1) has expired;
- (j) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Slovakia after 1 January 2000 may be granted a certificate, provided that

the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or within six months of 1 July 2002 if the market authorisation was obtained before that date:

- (k) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Bulgaria, provided that the application for a certificate is lodged within six months of the date of accession;
- (I) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than the date of accession.
- (m) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2003 may be granted a certificate in Croatia, provided that the application for a certificate is lodged within six months from the date of accession.

SPP19.01 In contrast to Article 2, Article 19(1) refers to "an equivalent national provision" rather than "an equivalent provision of national law". Consequently it appears that marketing authorizations obtained under voluntary as well as statutory procedures in the UK are acceptable as first authorizations under the transitional provisions of Article 19. The Office therefore takes the view that voluntary authorizations granted under the Pesticides Safety Precautions Scheme (PSPS) from 1 January 1985 until 5 October 1986 satisfy the requirements of Article 19(1). Insofar as the patents relating to products protected by the PSPS have expired there is no further relevance of this scheme to new SPC applications (see also SPP2.02).

ARTICLE 20:

1. In those Member States whose national law did not, on 1 January 1990, provide for the patentability of plant protection products, this Regulation shall apply from 2 January 1998.

Article 19 shall not apply in those Member States.

2. This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Croatia, Cyprus, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovakia prior to the date of accession.

ARTICLE 21: ENTRY INTO FORCE

This Regulation shall enter into force six months after its publication in the Official Journal of the European Communities.

SPP21.01 The Plant Protection Regulation was published in the Official Journal of the European Communities on 8 August 1996. It therefore entered into force on 8 February 1997.

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