

Examination Guidelines for Patent Applications at IPOS

These Guidelines will be updated at regular intervals to take account of recent developments including changes in the law and judicial decisions. They are based on IPOS's interpretation of the currently applicable law and practice of patents. These Guidelines should not be used as a set of legal requirements, and should not be taken as a substitute for any legislation or case law or as a conclusive view of the law.

It follows that no update can ever claim to be complete. Any feedback from readers drawing attention to errors as well as suggestions for improvement will be greatly appreciated and this may be sent by e-mail to: Operation@iposinternational.com.

These Guidelines refer to the Singapore Patents Act and Rules with effect from 14th Feb 2014.

REVISION HISTORY

Version	Description of revisions	Release date
Feb 2014	First version.	14 Feb 2014
Apr 2015	Addition of Chapter 9 relating to Supplementary Examination.	16 Apr 2015
May 2016	Revision of Chapter 8, Section A in relation to Patentable Subject Matter.	16 May 2016
Apr 2017	<p>Revisions to Chapters 1-9 to improve clarity.</p> <p>Expansion of Chapter 8, Sections C, D and E in relation to Methods of medical treatment, Medical use and Morality respectively.</p> <p>Addition of Chapter 10 relating to Examination Review.</p> <p>Revisions to all Chapters to refer to the Patents Act and Rules with effect from 14th Feb 2014.</p> <p>Revisions made to the previous version (May 2016 version) are denoted by vertical bars in the left margin. Page numbers and paragraph numbers have been updated accordingly.</p>	20 Apr 2017

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1. INTRODUCTION

A. Statutory requirements

1.1 Upon receiving a request from the applicant for a search and examination or an examination under Section 29, Rule 2A(1)¹ sets out the matters to be determined by an Examiner when conducting an examination are, *inter alia* —

- (a) whether, taking into consideration all the relevant prior art, if any, that the Examiner is aware of or that has been discovered in a search —
 - (i) each claim of the invention disclosed in the application satisfies each condition or requirement for patentability under section 13;
 - (ii) the conditions specified in section 25(4) and (5) have been complied with;
 - (iii) the application discloses any additional matter referred to in section 84(1) or (1A) or any matter referred to in section 84(2);
- ...
- (d) whether there is —
 - (i) any other application for a patent for the same invention, with the same priority date, filed by the same applicant or his successor in title; and
 - (ii) any earlier grant of a patent for the same invention, with the same priority date, to the same applicant or his successor in title.

1.2 The Guidelines aims to provide the Examiner with a better understanding to the application of the Patents Act and Rules during the course of their work.

¹ In the *Patents Act* with effect immediately before 14/02/2014, the matters to be determined during an examination were prescribed in Section 29.

B. Standard of proof

1.3 While the Patents Act and Rules set out the requirements for patentability, there is no legislative standard of proof set out in the Act for applicants to meet these requirements. In this regard, legal precedent in the UK may provide some guidance for Examiners in Singapore.

1.4 The standard of proof for patentability in the UK was recently considered by Floyd J in the UK Patents Court (*Blacklight Power Inc v The Comptroller-General of Patents* [2008] EWHC 2763 (Pat)). Floyd J reviewed the authorities (*Fujitsu's Application* [1996] RPC 511, *Macrossan's Application* [2006] EWHC 705 which was heard on appeal together with *Aerotel's Application* [2007] RPC 7). These were cases related to patentable subject matter, but Floyd J considered they were applicable more broadly. He stated that:

“I think that the effect of these authorities is as follows. It is not the law that any doubt, however small, on an issue of fact would force the Comptroller to allow the application to proceed to grant. Rather he should examine the material before him and attempt to come to a conclusion on the balance of probabilities. If he considers that there is a substantial doubt about an issue of fact which could lead to patentability at that stage, he should consider whether there is a reasonable prospect that matters will turn out differently if the matter is fully investigated at a trial. If so he should allow the application to proceed.”

1.5 He went on to detail the approach that an Examiner should take:

“The examiner will first raise an objection and put it to the applicant. The applicant then has an opportunity of persuading the Comptroller that his basis for considering that the objection applies is not sound. If the applicant does not persuade him to withdraw the objection he may refuse the application... But at that stage he should consider whether, because there is a substantial doubt about an issue of fact, there is a reasonable prospect that matters may turn out differently at a trial, when there will be a full exploration of the matter with the benefit of expert evidence. If there is such a reasonable prospect he should allow

the matter to proceed to grant. It goes without saying that mere optimism and a reasonable prospect of matters turning out differently are not the same thing. 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 him the benefit of the doubt will lead to a different conclusion.”

1.6 Thus Examiners should consider the material before them on the balance of probabilities. If there is a fact in contention, the Examiner should consider whether there is a reasonable prospect that the matters may turn out differently at a trial, when there will be a full exploration of the matter with the benefit of expert evidence. Thus, for example, there would be little prospect of success that an applicant would be able to produce evidence that a perpetual motion machine could operate in the real world, and on that basis an objection would be maintained.

1.7 However, questions as to the common general knowledge in a particular area may be less clear cut and a full consideration with the benefit of expert evidence may give a reasonable prospect of a different outcome. Indeed in *Martek Biosciences Corporation v Cargill International Trading Pte Ltd* [2012] SGHC 35, the Court cautioned against a Tribunal making decisions in the absence of clear evidence on the common general knowledge:

“... the basis upon which the Tribunal arrived at the conclusion that claim 1 lacked inventive step was an assertion that it would have been obvious to a skilled reader to combine different features of the various prior art. With respect the Tribunal erred in doing so. The Tribunal did not possess the expertise to determine for itself, on the face of the prior art and the Patent, whether the invention would have been obvious to a skilled reader without any basis in evidence as to what a skilled reader would have known or understood. The test of whether a claim involves an inventive step is premised on the viewpoint of the skilled reader.”

1.8 This of course does not absolve applicants from their onus of providing the Examiner with compelling submissions, or indeed evidence that addresses an objection. An

objection that is soundly based in the principles of inventive step and where the Examiner has construed the documents according to the established law is likely to only be overcome by evidence from the applicant addressing the objection, rather than by an argument as to the Examiner lacking evidence of the common general knowledge.

2. CONSTRUING THE SPECIFICATION AND CLAIMS

A. Background

- 2.1 The patent when granted will only confer protection on the invention as defined by the claims, but the claims are interpreted in light of the description and drawings. Construction of claims is pivotal to any consideration of infringement and validity and to almost every aspect of examination including novelty, inventive step, searching of the claim and claim amendments.
- 2.2 In order to provide certainty for the public and patentees, there should be consistent construction of the claims of a patent specification, irrespective of the subject matter at hand. In an examination context, this might mean that the Examiner should avoid construing terms broadly for the purpose of novelty but narrowly for the purpose of support. In a broader perspective this means that the claims should be interpreted in the same way for both infringement and validity considerations.
- 2.3 From a practical point, Examiners may find the following tips helpful when construing a patent document:
- (a) Read the claims before the description.
 - (b) Draw the invention from the definition given in the claims.
 - (c) Consult with other Examiners.
- 2.4 These techniques will particularly help to avoid introducing any “gloss” from the description and drawings (that is, reading limitations from the description and drawings into the claims that are not defined by the language of the claims themselves).

B. Scope of the patented invention

2.5 The extent of protection conferred by a patent is set out in Section 113(1) as follows:

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.

2.6 This provision essentially codifies a “purposive approach” to patent construction as set out by the House of Lords in *Catnic Components Limited v Hill & Smith Limited* [1982] RPC 183, and forbids a purely literal interpretation of the terms used in the claims.

2.7 In Singapore, this provision has been considered by the Court of Appeal in *First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd* [2008] 1 SLR 335, *FE Global Electronics Pte Ltd v Trek Technology (Singapore) Pte Ltd* [2006] 1 SLR 874, *Bean Innovations Ltd v Flexon Ltd* [2001] 3 SLR 121 and *Genelabs Diagnostics Pte Ltd v Institut Pasteur & Anor* [2001] 1 SLR 121. In each decision, the Courts have adopted a purposive approach.

C. Purposive construction to be used in examination

- 2.8 A purposive approach should always be adopted during the course of examination. Claim construction is a matter of law, and construction is **not** concerned with what the patentee himself actually **meant** to say. The patent should be construed in order to determine what the person skilled in the art would have understood the patentee to mean by using the language of the claims.
- 2.9 It is a convention in infringement and validity actions neither the patentee nor witnesses are consulted on that matter (*British Celanese v Courtaulds* [1935] 52 RPC 171 at 196). The specification is fixed in time and cannot be subject to the possibility that the patentee might change their mind about what he meant by the words he used.
- 2.10 This was also noted by the Court of Appeal in *First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd* [2008] 1 SLR 335. As set out by the Court of Appeal, the starting point of construction is what the person skilled in the art would have understood the patentee to mean by the use of the language of the claims. In this regard the Court of Appeal cited Lord Hoffmann in *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9 and further guidance can be taken from this UK decision.
- 2.11 Construction is therefore objective in as much as it is concerned with what the person skilled in the art would have understood the patentee to mean by the words he used. The specification is to be read through the eyes of the person skilled in the art attempting to give it practical meaning (*Ratiophram v Alza* [2009] EWHC 213). Wherever possible the specification should be construed so as not to lead to a “foolish” result (*EMI v Lissen* 56 RPC 23).

- 2.12 Generally, a document will destroy the novelty of a claim only if it discloses each and every feature of the claim. If the claim contains equivalent or additional features, then the question normally becomes one of obviousness. However, since a patent specification should be given a purposive construction rather than a purely literal one, the protection conferred may go beyond the literal wording of the claim. One possible consequence of purposive construction is that a term may be construed to encompass variants which the person skilled in the art would have realised to have no material effect upon the way the invention worked, and excluded those which would have been thought to have a material effect. As held by Lord Diplock in the *Catnic Components Ltd and another v Hill and Smith Ltd* [1982] RPC 183, 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. Therefore, depending on the facts of the case, a disclosure comprising only variations in “unessential” features from the claimed invention may still fall within the scope of the claims because the person skilled in the art would have understood the patentee had intended to claim these variations by using the language in the claim and reading the specification as a whole.
- 2.13 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 9 made it clear that there is no “doctrine of equivalents” in the UK in the sense that the protection afforded by the patents cannot extend beyond the claims. The purposive construction approach therefore combines a fair degree of protection for the patentee with a reasonable degree of certainty for third parties.
- 2.14 The purposive construction approach adopted since the *Catnic* decision was reaffirmed in the case of *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181. The “**Improver questions**” (subsequently dubbed the “**Protocol questions**”) provide a guidance for applying the principle of purposive construction in the context of equivalents, which can be used when assessing whether or not a variant falls within a claim (*Wheatley v Drillsafe Ltd* [2001] RPC 7).
- 2.15 *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181 involved a consideration of an infringement of claims defining a depilatory (hair removal)

device which comprised a rotating spring. In the opposing device the spring had been replaced by a rubber rod that comprised a number of parallel slits. The Court applied the following general questions to the variant:

- (1) Does the variant have a material effect upon the way the invention works?
If yes, the variant falls outside the claim. If no:
- (2) Would this fact (i.e., that the variant has no material effect) have been obvious to the person skilled in the art at the date of publication of the patent?

Or alternatively:

Would this fact solve the problem underlying the invention by means which have the same technical effect?

If no, the variant falls outside the claim. If yes:

- (3) Would the person skilled in the art nevertheless 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?

Or alternatively:

Whether it would have been apparent to the person skilled in the art from the wording of the claim that a limitation to exclude the variant could have been intended by the patentee? If yes, the variant is outside the claim. If no, then the variant falls within the scope of the claim.

2.16 The Court determined that the change to a rubber rod had no material effect on the way the invention worked and it would have been obvious to the person skilled in the art that this variant would work in the same way. However, the person skilled in the art would have understood from the patent that the patentee meant to limit the claim to a “helical spring”. Thus, the variant did not meet the third requirement and was considered as not infringing the claims.

2.17 However, the **Improver/Protocol** questions may not be useful in determining the extent of protection in rapidly-developing, high-technology fields. In these cases, a claim could, on its proper construction, cover products or processes which involve the

use of technology unknown at the time the claim was drafted if the person skilled in the art would have understood the description in a way which was sufficiently general to include the new technology.

- 2.18 Difficulties in applying the **Improver/Protocol** questions also occur where there is no common understanding of whether a word was being used in a strictly conventional or looser sense. In *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 9 the Court cautioned that the **Improver** questions should only be considered as guidelines for applying the principle of purposive construction and not as rules for determining the scope of protection – there is only one compulsory question, namely what would a person skilled in the art have understood the patentee to have used the language of the claim to mean? In this case there was no suggestion that “an exogenous DNA sequence coding for erythropoietin” could have some looser meaning to include “an endogenous DNA sequence coding for erythropoietin”. Rather, the question was whether the person skilled in the art would have understood the invention as operating at a level of generality which made it irrelevant whether the DNA which coded for erythropoietin was exogenous or not.
- 2.19 It should also be noted that in most cases the **Improver/Protocol** questions are most relevant in the context of infringement. During examination variants are more likely to be considered under inventive step.

D. The person skilled in the art

2.20 The specification is construed through the eyes of the person skilled in the art and is considered as a whole in the light of the surrounding circumstances without reference, as relevant, to an alleged infringement, prior art, documents subsequent to the specification, etc (*Glaverbel v British Coal* [1995] RPC 255). The addressee is taken to be a person of ordinary skill in the art who possesses the common general knowledge in the particular art at the earliest validly claimed priority date of the invention.

2.21 In *Peng Lian Trading v Contour Optik* [2003] 2 SLR 560, the Court referred to the English case of *Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd* [1972] RPC 346 which stated that:

“... the hypothetical addressee is a skilled technician who is well acquainted with workshop technique and who has carefully read the relevant literature. He is supposed to have an unlimited capacity to assimilate the contents of, it may be, scores of specifications but to be incapable of a scintilla of invention.”

2.22 In *Institut Pasteur & Anor v Genelabs Diagnostics & Anor* [2000] SGHC 53, the Court referred to various definitions from UK case law:

- (1) he is not the “*mechanician of genius nor... the mechanical idiot*”, *Van der Lely NV v Bamfords Ltd* [1961] RPC 296;
- (2) he is “*assumed to be of standard competence at his work without being of an imaginative or inventive turn of mind*”, *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd & Ors* [1972] RPC 457;
- (3) he is “*the normally skilled but unimaginative addressee in the art at the priority date*”, *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd* [1985] RPC 59;
- (4) he is “*not the man of inventive imagination who might see straightaway what was required, but a hypothetical unimaginative technician skilled in the particular art*”.

- (5) the person skilled in the art may comprise a team if more than one skill is required in the technology where the invention lies.

2.23 Prakash J in *Ng Kok Cheng v Chua Say Tiong* [2001] SGHC 143 summed up the essential indicators of a person skilled in the art as a person who:

- (1) possesses common general knowledge of the subject matter in question;
- (2) has a practical interest in the subject matter of the patent or is likely to act on the directions given in it; and
- (3) whilst unimaginative is reasonably intelligent and wishes to make the directions in the patent work.

E. The common general knowledge

2.24 Possession of the common general knowledge in the art is one of the most significant aspects of the hypothetical person skilled in the art. To a large extent this can be said to be what characterises the person skilled in the art. In a purposive construction it is this knowledge that the person skilled in the art uses to construe the specification, and it is with such a background and context that the person skilled in the art reads the prior art.

2.25 A good description of common general knowledge was given by Laddie J in *Bourns Inc v Raychem Corp* [1998] RPC 31:

“The common general knowledge is the technical background of the notional [skilled person] ... This is not limited to material he has memorised 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 him understand the pleaded prior art.”

2.26 It is important to distinguish common general knowledge from public knowledge – just because something is in the public domain does not make it part of the common general knowledge. As Laddie J also explained:

“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.”

2.27 However he went on to say that it may be assumed in most cases that standard textbooks or readily available trade literature may be considered common general knowledge in the art.

2.28 Sachs LJ (*General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457) noted that patent documents would not normally be considered common general knowledge, but if a particular patent is well known or one that skilled persons in a

particular industry would routinely consider, this may not be the case:

“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.”

2.29 In the case of scientific papers, he referred to Luxmoore J in *British Acoustic Films* [1936] 53 RPC 221:

*“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.***

... 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.” [emphasis added]

2.30 The choice of person skilled in the art will depend on the nature of the technology. In some cases this may mean that the common general knowledge in the field is

possessed by relatively few people. For example, in *Apimed Medical Honey Ltd v Brightwake Ltd* [2011] RPC 16, the invention related to surgical dressings comprising honey and a gelling agent. The Court determined that even though there were few people having the knowledge of treating wounds with honey, this still formed part of the common general knowledge in that field.

- 2.31 However, even if a matter may be well-known to a few, it is not considered 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 stated that:

“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 providing evidence that a fact is known or even well-known to a witness does not establish that the 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.”

- 2.32 In most cases an assertion that certain information forms part of common general knowledge should be supported by documentary evidence. As noted above a description in standard textbooks may provide a strong indication of being the common general knowledge. It may also be assumed that a scientific paper that is widely cited has entered into the common general knowledge. A set of industry standards may be considered to be part of the common general knowledge. It is not

expected that the person skilled in the art would know the information, but rather that he would know where to find the relevant information (*Nokia v Ipcom* [2010] EWHC 3482). In other cases, an Examiner may assert that a document is common general knowledge based on evidence ascertained (for example, that the document has been published in a widely-read or respected publication, or where patents would form part of the common stock of knowledge of persons skilled in that technology). However evidence to the contrary from the applicant may be sufficient to overcome such an assertion.

F. Guide to construction

- 2.33 While the description and claims are to be read together, they serve different functions: the description is intended to convey to the public what the patentee considers is the invention, and the claims set out the monopoly the patentee has chosen to obtain. These are not necessarily the same (*First Currency v Mainline* [2008] 1 SLR 335, citing Laddie J in *Merck & Co. Inc. v Generics (UK) Ltd* [2004] RPC 31). To this end, the claims may be narrower than what is disclosed in the specification, but the claim must never be broader than what is supported by the specification.
- 2.34 Each claim should be read giving the words the meaning and scope which they normally have. However, the everyday 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 (*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). Therefore, 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 a claim ([see subsection i of this Section on “Special meanings”](#)).
- 2.35 Prior art references may be useful when construing terms used in a specification. For example if the specification identifies a particular feature of the prior art as having a problem that the inventor has overcome, then the terms used in relation to that particular solution may be construed as excluding the prior art feature. However, even where a purposive approach is taken to construing specifications, if a term in a claim is used in a manner that is inconsistent with the meaning given to it when the specification is considered as a whole, then the claim will lack clarity (*IGT/Acres Gaming Inc.’s Application* [2008] EWHC 568). In such cases the scope of the claim would be rendered unclear to the person skilled in the art. As noted in *Glaverbel SA v British Coal Corporation* [1995] RPC 255, the claims should be read together with the body of the specification; but if a claim is expressed in clear language, the monopoly sought cannot be extended or cut down by reference to the rest of the specification.

2.36 During examination, Examiners should avoid making the claim say something that it does not say at all, or create ambiguities which do not reasonably exist. Where there is a choice between two meanings of a claim, one should, if possible, reject that meaning which leads to an absurd result in favour of one that works.

i. Special meanings

2.37 When interpreting the words in a claim, one should initially assume that the words take the meanings they would ordinarily have been given by the person skilled in the art at the time of the invention. If a term is given a special meaning by the author, this needs to be taken into account (*Kirin-Amgen Inc. v Roche Diagnostics GmbH* [2002] RPC 1). A general approach would be to consider:

- (1) Does a term in a claim have a plain meaning to the person skilled in the art?
- (2) Does the context in which the term is used in the specification change the meaning of the term?
- (3) Does the specification impose a special meaning on the term?

2.38 For example, if the claim defines “a crane hook comprising features X, Y and Z”, the plain meaning would impart a particular shape in the form of a hook and certain limitations on the size of the hook. If the specification provided a special meaning “as used herein the term crane hook is taken to mean a sling hook” then the claim would be interpreted as being a sling hook and not, for example, a ramshorn hook (a double hook used in cranes for lifting heavy loads). If this special meaning was not given, then the term would most likely be read as including any type of crane hook, unless, for example, the person skilled in the art would read the invention as only being a particular type of crane hook because of the features defined or the context.

2.39 Generally, if the specification provides a special meaning for a particular term, it should, as far as possible, be clear from the wording of the claim alone that the term is defined in such a manner (T 1568/06 *Methods for improving damaged retinal cell function/Optobionics Corporation*). This applies for example when a claim contains terms where the special meaning given to the terms deviates from what the skilled person would understand the terms to mean. If it is unclear what meaning a particular term in a claim is supposed to take on, then a clarity objection may be raised.

2.40 A reference in the claim such as the phrase “as hereinbefore defined” can indicate that the term is limited to a special meaning previously defined in the description or in an earlier claim. This should not be confused with the use of similar phrases in omnibus

claims ([see Section E in Chapter 5](#)), which would not be allowable under Rule 19(9).

2.41 Moreover it should be clear from the specification that the special meaning given to the term is the only intended meaning. This will be obvious from phrases such as:

“as used herein, the term alkyl means C1 to C5 straight or branched chain alkyl ...”.

If the term is defined in a less definite manner then it should not be considered a special meaning. Some of these non-limiting phrases are:

“suitable elastomers include ...”

“the elastomers may be ...”

“The term elastomeric includes but is not limited to ...”

2.42 If a special meaning is indicated in one part of the description but there is departure from that meaning in another part, then the special meaning should not be given when interpreting the claims.

ii. Avoid importing gloss or re-drafting claims

2.43 While the description and claims should be read together also taking into account special meanings, care should be taken not to import a gloss or rewrite the claims by relying on the limitations in the description (*First Currency v Mainline* [2008] 1 SLR 335). This is not the intention of taking a purposive approach to construction. This was affirmed by Rubin J in *Flexon (Pte) Ltd v Bean Innovations Pte Ltd and another* [2000] SGHC 219, where he cited Lord Russell of Killowen in *Electric & Musical Industries, Ltd v Lissen Ltd* [1938] 4 All ER 221 at 227:

“I know of no canon or principle which will justify one in 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 which will justify one in using stray phrases in the body of the specification for the purpose of narrowing or widening the boundaries of the monopoly fixed by the plain words of a claim.”

2.44 For example, if the ordinary meaning of the term “slit” is a long narrow opening, then it would not be appropriate to read this in a narrower manner based on the embodiments given in the specification (*Fabio Perini SPA v LPC Group plc & others* [2010] EWCA Civ 525). Similarly if the description gives certain preferred ranges or embodiments for a feature in a claim, then these should not be read into the claim (unless they clearly indicate a special meaning). However, if a term in the claim could *only* be read to take a particular meaning, then it would be permissible to read the claim more narrowly (*Glatt’s Application* [1983] RPC 122).

iii. Independent and dependent claims

2.45 Claims can either be independent or dependent. Generally an independent claim is one that does not refer to any other claim. Some independent claims may refer to other claims. For example, in chemistry, an independent claim appended on another claim may be encountered. It stands alone in defining the invention or an aspect of it. An independent claim is not necessarily the broadest claim in the application, but the broadest claim in an application is normally an independent claim. This is because there may be numerous independent claims, each covering a different aspect of the invention.

2.46 A dependent claim can depend upon one or more independent claims or one or more dependent claims. It should be noted that while some countries will not allow multiple dependent claims (that is, claims that are dependent on several claims), these are allowed under the Singapore law. Singapore law also allows claims to be dependent on multiple dependent claims. Examples of multiple dependent claims are:

“The method of claim 1 or 2, further comprising ...”

“The process of any of claims 1-4 ..., comprising ...”

“The composition according to any one of the preceding claims, wherein ...”

2.47 Furthermore, a claim may refer to a later claim or claims rather than a preceding claim or claims. In most cases this may be due to an error in drafting and the Examiner may, as a matter of courtesy, bring it to the attention of the applicant. However, unless the error results in a lack of clarity, no objection is necessary.

2.48 Independent claims should define all of the essential features of an invention. Generally, the preamble will indicate the subject matter of the claim:

“A compound of Formula I ...” (the subject is a compound)

“A method of preparing article X ...” (the subject is a method)

“An apparatus comprising ...” (the subject is an apparatus)

2.49 Claims which are appended to another claim will generally import all of the features of the claims to which they are appended, and serve to narrow the scope of the claim,

for example:

1. An apparatus comprising component A and component B.
2. The apparatus of Claim 1 wherein component B is an in-line filter.

2.50 In this case Claim 2 is dependent on Claim 1 and all of the features of Claim 1 are imported into Claim 2. The scope of the claim is then narrowed to the apparatus in which component B is a particular embodiment.

2.51 In contrast, the following claim, while appended is not truly dependent.

1. A method of preparing Article X comprising the steps of ...
2. Article X as defined in Claim 1 having features ...

In this case the preamble of Claim 2 suggests that the claim is directed to the article *per se* and not to the process of making the article. This appendence does not import the features of Claim 1 (in this case the steps of the method), and may simply be a shorthand way of defining the article without reiterating matter that has already been defined in the previous claim (for example in the case of chemicals, it might avoid re-defining large numbers of substituents). This claim is not dependent despite the fact that it is appended to Claim 1. Furthermore, this impacts on the scope of the search since a search of Claim 2 would not necessarily be limited to the features defined in Claim 1.

2.52 Other examples of this type are the following:

1. Process for the preparation of compounds of Formula X wherein R is alkyl, halo or aryl comprising the steps of ...
2. Compound of Formula X wherein R is halo or aryl.

In this case the inventor has found a new way of preparing compounds of Formula X and has claimed it for the preparation of compounds of Formula X wherein R is alkyl, halo or aryl. Claim 2 appears to be directed to a subgroup of compounds of Formula X – presumably the inventor considers these are novel and is seeking to claim the compound *per se*. The search in this case would need to cover both the general

preparation, as well as the compounds of Formula X having R as halo and aryl.

2.53 In the following case:

1. Apparatus comprising component A and component B.
2. Component B as defined in Claim 1 comprising ...

Claim 2 would be interpreted as having a kind of “partial dependency” where the claim is directed to component B only and would not include component A. A search would need to cover both the apparatus of claim 1 and the component B of claim 2.

2.54 In some cases, a dependent claim will include embodiments that do not fall within the scope of the claim to which it is appended. This situation can often occur in the chemistry area where a novelty objection results in amendment of the independent claim to remove some matter, but the dependent claim is not amended accordingly to remove specific embodiments. In such cases a clarity objection will probably be required.

2.55 A similar situation occurs where a claim that appears to be dependent removes a feature, for example:

1. A composition comprising A, B and C.
2. The composition of Claim 1 wherein C is absent.

In this case, Claim 2 is actually broader than Claim 1. However, this may not be objectionable since it is not mandatory that the broadest claim be the first claim. Indeed in some cases the broadest claim may be a later claim. The key consideration when determining whether an objection is required will be whether the person skilled in the art could readily ascertain the scope of the claim. Full support will be a consideration – is component C indicated as being essential to the invention, or merely optional? Are there inconsistencies between these and other claims that result in a lack of clarity as to the scope of the claims? In any case, the Examiner will also need to ensure that the search covers the broadest claim.

iv. **Open- and closed-ended terms**

- 2.56 The term “**consisting of**” is generally interpreted to be closed ended – the feature will be selected only from the listed alternatives. Thus, “a combination consisting of components A and B” would not include a combination of components A, B and C.
- 2.57 The term “**comprising**” is generally interpreted as being open-ended – other alternatives might be included. For example, “a combination comprising components A and B” would include a combination of components A, B and C. The terms “**contains**” and “**including**” are similarly considered open-ended terms.
- 2.58 The term “**consisting essentially of**” is construed to include the specified materials or steps , as well as other materials or steps that do not materially affect the working of the claimed invention (T 0759/10, Raision Nutrition Ltd/ Texturizing Compositions for use in fat blends in food).

v. Reference numbers in claims

2.59 Claims may refer to reference signs used in drawings, if a specification contains drawings. Reference signs do not limit the scope of the claims to the particular drawing, but merely assist the reader to understand the definition (*Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2010] RPC 8). Unless necessary, the presence of the reference signs should not form the basis for an objection.

vi. “Use of ... in ...” claims

2.60 “Use of ... in ...” claims are interpreted as claims to a method, and are not interpreted as directed to the substance intended for use. This will be particularly pertinent in pharmaceutical applications where claims of the following type will be interpreted as a non-patentable medical use:

“Use of compound X in the treatment of disease Y.”

2.61 “... when used ...” claims are interpreted as defining a method. Thus the following claim is interpreted as a method of using compound X as an initiator:

“Compound X when used to initiate polymerisation in a system of ...”

2.62 A claim to a product when used in a particular method is interpreted as a claim to a method *per se*. A claim to an apparatus or material “when used in” a particular process is regarded as protecting the use of the apparatus or material in such a process, and its novelty is therefore destroyed only by a disclosure referring to such use.

vii. “Product for ...” claims and “Method for ...” claims, etc.

2.63 A claim to an apparatus or material for a particular purpose is generally construed as a claim to any apparatus or material suitable for that purpose (*Adhesive Dry Mounting Co Ltd v Trapp and Co* [1910] 27 RPC 341; *G.E.C’s Application* [1943] RPC 60). Thus “Product for ...” claims are interpreted as requiring the particular apparatus or material to be suitable for the defined purpose.

However, the suitability for a particular purpose does not limit the scope of the claim to the apparatus when used in that way (*L’Air Liquide Societe’s Application* 49 RPC 428). Thus if a prior art document otherwise discloses all of the features of the invention and would be suitable for that purpose, then it will constitute a novelty-destroying disclosure. On the other hand, a known product that has the same material or composition as defined in the claim, but which is in a form which is clearly *unsuitable* for the stated use, would not deprive the claim of novelty. Likewise, an apparatus which has to undergo physical modification before it can be used for the stated purpose, would not be suitable for the particular use.

2.64 For example, in the claim “Hook for fishing comprising features X, Y and Z”, any suitable hook comprising features X, Y and Z that can be used for fishing would anticipate the claim, regardless of whether the hook was stated to be used in fishing or not in the prior art. The claim is also not saved by amending the claim to “a fishing hook comprising features X, Y and Z” as it would essentially mean the same thing. However, the claim would preclude within its scope, a crane hook comprising features X, Y and Z, which would have certain physical limitations (e.g. dimensions and weight) that make it unsuitable to be used as a fishing hook.

2.65 The terms ‘adapted to’, ‘adapted for’, ‘adapted for use’ in a product or apparatus claim would normally be construed as “suitable for”. In *FH Brundle v Perry* [2014] EWHC 475, the claims relate to a product with the following features: (i) a bracket for securing a fence panel to a fence post, (ii) the bracket being adapted to embrace a corner of a fence panel, (iii) and comprising a main body having a rectangular central portion, (iv) adapted in use to lie along the top of the panel, (v) and two contiguous triangular portions, (vi) adapted in use to lie one each side of the panel, (vii) with one

apex adjacent the post and the other spaced therefrom, (viii) and flange means, (ix) adapted in use to lie against and be attached to the post. In construing the terms “adapted to” and “adapted in use to”, Hacon, J. said

“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’.”

However, the judge also 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.”

Therefore, in most circumstances, the terms ‘adapted to’, ‘adapted for’, ‘adapted for use’ in a product or apparatus claim would normally be construed as “suitable for”. In a similar vein, the term “specially adapted for” would have the same interpretation as “adapted for” unless reading the specification as a whole indicates otherwise ([see subsection v of Section D in Chapter 6, Example 4](#)).

- 2.66 Another term which may be encountered by Examiners during examination is the term “constructed to receive”. The meaning of this term was considered by Birss J. in *Schenck Rotec GmbH v Universal Balancing Limited* [2012] EWHC 1920, which relates to a device “constructed to receive” a plurality of balancing weights. Consistent with the judgment in *FH Brundle v Perry* [2014] EWHC 475, 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 Birss J. 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, and the device can actually work this way in practice.

- 2.67 A claim to a substance or composition “for use ...” would normally be construed as a substance or composition “suitable for use ...”. However, first medical use claims are an exception to this rule ([see sub-section i of Section D in Chapter 8](#)), and the claim is interpreted as being specifically limited to the medical purpose. On the other hand, if the substance or composition has already been known to be useful for a medical purpose, then in order to protect a further new medical use of the substance or composition, a second medical use format (“Swiss type format”) must be used.
- 2.68 Similarly, in the data-processing/ computer programming field, a claim to a “means for” performing a certain function is interpreted as a means specific for performing the relevant function, rather than merely suitable for carrying out the function. Accordingly, a device without the relevant software that enabled the functions is “not suitable for” the functions in question. A bare computer would not be “suitable for” the activities in the claims because it simply could not achieve them (*Rovi Solutions Corporation & Anor v Virgin Media Ltd & Ors [2014] EWHC 1559*).
- 2.69 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. The claim should clearly specify the essential features of the apparatus unless all the integers which would constitute such apparatus are clearly implicit in the method claimed.
- 2.70 The interpretation of a claim directed to a “Method for ...” depends on the specific wording of the claim and the specification when read as a whole. When a claimed method or process comprises steps that result in the production of a product, the indication of the intended purpose of the method in a “Method for ...” claim would normally be construed as merely suitable for that purpose (i.e., production of a product), rather than as an integral method or process step. Consequently, a prior disclosure of the same method suitable for production of the product, would anticipate a claim to a method or process for that purpose, even when the purpose (i.e., production of the product) is not indicated in the prior disclosure (T 0304/08 Method for reducing malodor/ BASF).

viii. Product-by-process claims

2.71 A product-by-process claim is one in which the product is defined in whole or in part in terms of the process used to manufacture the product, instead of solely by structure, composition, properties or characteristics ([see Section L in Chapter 3 about its novelty assessment](#)). For all practical purposes, product-by-process claims fall into either the statutory category of article of manufacture or composition of matter claims.

2.72 A claim to a product obtained by a process:

“Product X obtained/prepared by process Y”

is normally construed as a claim to the product *per se*, irrespective of whether the term “obtained”, “obtainable”, “directly obtained” or an equivalent wording is used (*Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005]RPC affirming EPO law, i.e., Decision T 150/82 *International Flavors and Fragrances Inc.* [1984] 7 OJEP 309). Such a claim lacks novelty if a prior art product, even if made by an undisclosed process, appears to be the same as, or indistinguishable from, the claimed product. The patentability of a product defined by a product-by-process claim does not depend on its method of production. Therefore, a product is not rendered novel merely by the fact that it is produced by means of a new process.

2.73 However, where a product cannot be satisfactorily characterized with reference to its structure, composition, properties or other means (such as when the structure or composition of a product is unknown), it might be allowable to claim the product using a product-by-process claim. During examination, such a claim should be construed as a claim to the product *per se* that possesses the characteristics derived from the manufacturing process as stated in the claim. For example, when a claim recites “a two-layer structured panel which is made by welding together an iron sub-panel and a nickel sub-panel.”, the process of “welding” would be considered by the Examiner in assessing patentability over the prior art since the process of welding produces physical properties in the end product which are different from those produced by processes other than welding; that is, the product can only be defined by the process step. Novelty of the claim is not brought into question unless an identical two-layer structural panel made by

means of welding is discovered in the prior art.

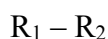
- 2.74 Where a product that can be accurately described by referring to its structure, composition or means other than its method of preparation or production, but is defined using a product-by-process claim, the Examiner may raise a clarity objection. If there is another claim to the identical product in the application, then the product-by-process claim may also lack conciseness as the two product claims might have an identical scope of protection. In order to overcome said objections, the applicant should provide evidence to the contrary.

ix. Claims to process using a known apparatus

2.75 A claim to a method of using a known apparatus may be regarded as new if the claimed method of use is new. In *Flour Oxidizing Co Ltd v Carr and Co Ltd* [1908] 25 RPC 428, Parker J stated that “*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 in order to use it*”.

x. Alternatives/Markush claims

- 2.76 In many cases some or all of the features of an invention may be substituted by similar or technically equivalent alternatives, but the properties of the product are still retained. Such claims are often referred to as Markush claims (named after the applicant on an early case of this type), and may be based on a relatively small number of alternatives or in some cases may extend to many millions of possible alternatives.
- 2.77 Markush claims are often used in chemical cases where different functional groups may be substituted at various positions and expected to retain the same properties, e.g. biological activity. In most cases the general formula will contain a consistent core element that provides the basic activity while other parts of the molecule may vary depending on the types of substituents the person skilled in the art would consider could be accommodated in the molecule.
- 2.78 A simple example of a Markush formula is as follows:



wherein R1 is phenyl or 1-naphthalene, and R2 is chlorine or bromine.

- 2.79 This claim would include chlorobenzene, bromobenzene, 1-chloronaphthalene and 1-bromonaphthalene. For novelty purposes, a disclosure of even just one of these compounds in the prior art would render the claim lacking in novelty.
- 2.80 Markush claims can be difficult to search and often a risk-management approach is required in order to search the claims efficiently. In some cases the broad nature of the claims may raise issues of lack of unity, sufficiency and support. However it should be noted that the breadth of the claim alone is not objectionable provided these requirements are satisfied.

3. NOVELTY

A. Statutory requirements

3.1 Section 14(1) provides that:

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

3.2 Sections 14(2) and 14(3) set out the state of the art as follows:

(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 Singapore or elsewhere) by written or oral description, by use or in any other way.

(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:

- (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.

3.3 Thus, an invention defined in a claim lacks novelty if the specified combination of features has already been disclosed in the prior art. In *Trek Technology (Singapore) Pte Ltd v FE Global Electronics Pte Ltd (No. 2)* [2005] 3 SLR 389, Lai Kew Chai J provided the following guidance in determining novelty:

- (1) the issue is determined by asking whether an invention forms part of the *state of the art*;
- (2) the prior art must, in order to invalidate the patent, be such that a person of ordinary skill and knowledge of the subject would at once perceive and

understand and be able to practically apply the discovery without the necessity of making further experiments;

- (3) the prior art documents must be construed as *at the date of publication* and it is not permissible to perform an *ex post facto* analysis;
- (4) each prior art document has to be *considered separately and not combined* into a mosaic to arrive at the invention;
- (5) the person skilled in the art is an unimaginative person of competent but average technical skill;
- (6) the prior art document must contain *clear directions* to do what the patent claims to have invented.

3.4 The Singapore Courts have followed UK precedent in approaching the determination of novelty. The UK approach has recently been summarized in *SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent* [2006] RPC 10, where the House of Lords held there were two requirements for anticipation: **prior disclosure** and **enablement**. These are distinct concepts, each of which has to be satisfied and each of which has its own rules.

B. Raising new prior art

- 3.5 Where the applicant requests an examination or a search and examination of the application, Rule 2A(1) requires that the Examiner take into account all the relevant prior art that has been discovered in a search, **or** that the Examiner is “aware of”.
- 3.6 Generally, when a request for an examination relying on a search report is received, the Examiner will conduct the examination based on the search report. The general principle is the claims to be examined should have been covered by the original search.
- 3.7 Where a claim relates to an invention in respect of which no search has been completed, Rule 46(1)(e) provides that an Examiner may decide not to carry out the examination in respect of that claim and advise the Registrar accordingly. In most cases this will be where in the search report no search has been carried out for a particular claim.
- 3.8 If an additional feature is introduced into a claim by amendment there may be instances where the original search may not have covered that embodiment. For example the search may have been limited to particular embodiments but as a result of the cited prior art, the claims have been amended to cover different embodiments that would not have been covered by the initial search. However, this should be an unusual circumstance – in most cases the claims will be limited to preferred embodiments provided in the specification and in other cases these should have been covered by a search of the broader claim. Additional searching may be performed in such situations, but extensive searching should be avoided.
- 3.9 During the course of the examination, the Examiner may raise new prior art that has not been identified in the search report or discovered in the search but that the Examiner has become “aware of”. Thus, for example, if a search report from a foreign family equivalent identifies highly relevant prior art that impacts on the patentability of the patent, then the Examiner may raise this new prior art. However, in the case of an examination based on a foreign search report, extensive additional or original searching should be avoided. Moreover, a new document should not be raised if it

essentially repeats the matter provided by an existing citation. To raise a new, but equivalent document would result in additional costs for the applicant.

- 3.10 Where new prior art is raised, this should be highlighted in the Examiner's report, and a copy of the document may be provided (subject to copyright restrictions). The full bibliographic details and relevant portions of the document must be provided in the opinion.

C. Prior disclosure

3.11 It would be sufficient to prove that a prior art discloses an invention, if the matter relied upon as prior art discloses subject matter which, if performed, would result in infringement of the patent (a “reverse infringement” test) as set out by the Court of Appeal in *General Tire & Rubber Company v Firestone Tyre & Rubber Company Limited* [1972] RPC 457 and followed in *Muhlbauer AG v Manufacturing Integration Technology Ltd* [2010] SGCA 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 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.”

3.12 In *Merck & Co Inc v Pharmaforte Singapore Pte Ltd* [1999] SGHC 323, the plaintiffs argued that any prior art that is relied on to destroy novelty must unequivocally point to the invention and must not merely be a signpost on the path to discovering the invention. Lai Kew Chai J in delivering the judgment of the High Court agreed that in order for anticipation to arise, the prior art must disclose to a notional instructed reader *essential integers* to the invention as claimed.

3.13 The provision of novelty therefore involves a consideration of whether the prior art discloses all of the features of the claim in question. In general a prior disclosure will destroy the novelty of a later claim only if it discloses each and every feature specified

in that claim. If the claim contains technically equivalent or additional features, then an objection of obviousness would be more appropriate.

- 3.14 However, a purposive construction of a claim may indicate that one or more features do not materially affect the working of the invention – in effect they are non-essential. In such rare occasions an objection of lack of novelty may be warranted. For example if the invention consists of a known drug in a package together with instructions for usage, an objection of lack of novelty based on a document disclosing the known drug in a package with the same manner of usage may be appropriate, since the feature of the written instructions merely makes explicit the presence of instructions describing the known manner of usage, but does not materially affect the working of the invention – that is, the biological effect of the active ingredient.
- 3.15 A disclosure which is capable of being carried out in a manner which falls within the scope of 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 objection. This was noted in *General Tire* as follows:

“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”.

- 3.16 In discussing this judgment in *SmithKline Beecham Plc’s (Paroxetine Methanesulfonate) 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.”

3.17 Thus, as Lord Hoffmann summarised the disclosure requirement as follows:

“Anticipation requires prior disclosure of subject-matter which, when performed, must necessarily infringe the patented invention.”

D. Enablement

3.18 The principle that a citation must provide an enabling disclosure of the invention was affirmed by the Singapore Court of Appeal in *Merck & Co v Pharmaforte Singapore Pte Ltd* [2000] 2 SLR(R) 708:

“for a prior publication to anticipate the patent it must be established that following the teachings in the prior publication would inevitably lead to the invention covered by the patent. The prior disclosure must not only identify the subject matter of the claim in the later patent, it must do so in a way that enables the skilled person to make or obtain it, a kind of enabling disclosure.”

3.19 Thus the person skilled in the art must be able to perform the invention (*SmithKline Beecham Plc’s (Paroxetine Methanesulfonate) Patent* [2006] RPC 10). In *Smithkline Beecham*, 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.

3.20 The two requirements of disclosure and enablement should be kept distinct (*SmithKline Beecham*). In particular, the role of the person skilled in the art is different.

3.21 In the case of disclosure, the document is read using the common general knowledge, available at the date of the disclosure, of the person skilled in the art who is trying to understand what the author meant by the language they used. Once this is determined, the person skilled in the art takes no further part in the determination.

3.22 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 person skilled in the art would think the disclosure meant, but rather whether he would be able to work the disclosed invention.

E. Publication

- 3.23 A disclosure becomes part of the state of the art on the date it first becomes available to the public. Notably, the Act does not place any requirements on the age of the disclosure, the location of the disclosure, the type of disclosure (paper or electronic), or the language of publication.
- 3.24 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). Similarly, in *Monsanto (Brignac's) Application* [1971] RPC 153, the Court held that the company had published a document by supplying it to its salesmen without a restriction on disclosure.
- 3.25 A document is available to the public even if a fee is required to view it. Furthermore, there is no need to show that the document has actually been read by a member of the public - a document is regarded as having been published provided it can be inspected as of right by the public. Guidance in the Singapore context was given by Tay Yong Kwang J in *Institut Pasteur v Genelabs Diagnostics Pte Ltd* [2000] SGHC 53 at [188]:

“The law concerning anticipation is strict to the patentee and to the challenger of the patent. A claim is invalid if it covers any item of the prior art which has been disclosed to anyone (except in confidence), by any means (written or oral or by use), anywhere in the world, at any time in history (before the priority date). Even availability to a single member of the public will suffice. Similarly, availability to the public is satisfied if the document can be found on the shelves of a public library. It is irrelevant whether anyone knew it was available or had inspected it. [Vitoria, Encyclopedia of United Kingdom and European Patent Law] Anticipation can therefore encompass a disclosure which the inventor was totally ignorant of.”

- 3.26 If a publication date is present upon a document (for example the publication date on a patent or journal article), then this is assumed to be the date of publication. In the event that this date is disputed by the applicant then evidence to the contrary will be

required. Internet dates and the like may be problematic but in general, if a date is associated with the web page it may be considered the actual date of publication. On the other hand, if the web page itself does not explicitly indicate a publication date, Examiners may utilize Internet archiving databases such as the “WayBack Machine” on archive.org to provide evidence of when the web page was published.

- 3.27 Disclosures, such as conference proceedings published before the relevant priority date may be used as a basis for a novelty objection. In the absence of evidence to the contrary, it may be assumed that the proceedings are an accurate reflection of the content of the lecture or public disclosure.
- 3.28 Generally, the Act does not require consideration of the actual time that a document was published when establishing whether or not the document forms part of the state of the art; Section 14 merely specifies that the state of the art constitutes all matter made available to the public before the priority *date* of the invention. However, in the case where a publication date is close to the priority date, the time zone of publication may be important to interpret the publication date. This is particularly pertinent to internet disclosures, which are made available to the public simultaneously worldwide at the point of publication. Hence, because of the difference in time zones, it is conceivable that a particular internet disclosure may have a different publication date in a different part of the world. It would therefore be necessary to consider a frame of reference in determining the publication date of such a disclosure.
- 3.29 In *Unwired Planet v Huawei and Samsung* [2015] EWHC 3366 (Pat), it was held that for the purposes of Section 2(2) of the UK Patents Act 1977, the equivalent provision to Section 14(2), the frame of reference should be the time zone of the patent office at which the *priority document* was filed. For example, in relation to a Singapore patent application which claims priority to a US patent application filed at the USPTO (GMT -5) on 7 February 2015, an internet disclosure on 7 February 2015 at 9 a.m. Singapore time (GMT +8) would constitute the state of the art under Section 14(2), since the publication date of said disclosure would have been 6 February 2015 at GMT -5, which is before the date on which the priority document was filed.

3.30 The prior art disclosure must be a single document. Lack of novelty cannot be argued on a mosaic of documents; an obviousness objection may be appropriate in such cases. However, two separate documents may be read as though they were a single document if the person skilled in the art would take them to be such a disclosure. This was stated by Tay Yong Kwang J in *Institut Pasteur v Genelabs Diagnostics Pte Ltd* [2000] SGHC 53 at [190]:

“Anticipation must be found within the document alleged to have anticipated the invention. It is not permissible to combine the teachings of two or more documents except where one of these directs the reader to study the other. One cannot create a ‘mosaic of extracts’ from documents spread over a number of years [Von Heydon v Neustadt, (1880) 50 LJ Ch. 126]. Similarly, ‘it is not open to you to take a packet of prior documents and by putting a puzzle together produce what you say is a disclosure in the nature of a combination of the various elements which have been contained in the prior documents. ... it is necessary to point to a clear and specific disclosure of something which is said to be like the patentee’s invention’ [Lowndes’ Patent, (1928) 45 RPC 48].”

3.31 Nevertheless, it should be noted that the mere presence of a cross-reference in a cited document to a second document is not sufficient indication that the two may be read together. It should be established that the cross-reference necessitates that part or all of the disclosure of the second referenced document be considered as part of the disclosure of the cited document. The use of expressions such as “incorporated by reference” when referring to the second document in the cited document may suggest such necessity. For example, a cited document may refer explicitly to a second document as being incorporated by reference for providing more detailed information on certain features identified in the cited document. In this case, the teaching of the second referenced document would be regarded as part of the disclosure of the cited document for the purposes of enablement, only if the second referenced document was also available to the public at the publication date of the cited document. This is because, for the purposes of novelty, the cited document must provide a sufficient disclosure at its date of publication.

F. Implicit disclosure

- 3.32 The prior art is read through the eyes of the person skilled in the art, and as a consequence the *implicit* features of a document may also be taken into account for novelty purposes. Thus, if the person skilled in the art would read a disclosure as including a particular feature without it being specifically mentioned it would be considered an implicit feature of that disclosure.
- 3.33 The teaching must be such that it would be understood by a person skilled in the art reading in the light of common general knowledge – available at the date of the disclosure – special knowledge must not be required in order for the matter to be understood (*H.Lundbeck A/S v Norpharma SpA* [2011] RPC 23). The prior art document must be construed at the date of the disclosure and not in light of the subsequent patent (*SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent* [2006] RPC 10).
- 3.34 For example the disclosure of a control 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 this is necessary. A novelty objection could therefore be raised even if a citation did not specify this feature. In contrast, it may be a common practice for the radiator to be mounted in front of the engine, but this is not necessarily always the case. In this situation, a novelty objection cannot be raised based on a citation that does not specifically disclose this feature. An objection of obviousness would then be appropriate.

G. “Inherent” disclosure

- 3.35 As noted in *General Tire v Firestone*, the claimed invention will lack novelty if carrying out the directions contained in a prior publication will **inevitably** result in something being made or done that would constitute an infringement of the claims. This is particularly relevant to claims that define the invention by reference to parameters. This may be distinguished from an implicit disclosure – in this case the person skilled in the art would not read the feature as being disclosed by the prior art, but if they were to repeat the teaching of the prior art they would inevitably obtain that result.
- 3.36 For example 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 disclose these particular parameters. However it must be noted that a determination that a prior art teaching will inevitably result in the claimed invention must be based on sound reasoning.
- 3.37 In particular, the operating conditions used in a process will need to be *very* similar in order to sustain an argument that a reaction or process will inevitably give the same product. For example, a claim defines an industrial process for preparing a product comprising a particular ratio of compounds A and B wherein a particular series of steps are carried out using specific reaction conditions (temperature, etc). A prior art citation discloses a similar process for preparing a mixture of A and B, but does not disclose the specific ratio of these components claimed in the present application. In this case, it may be necessary to consider the examples provided in the prior art document in order to determine whether the conditions are sufficiently similar that it could be concluded that the prior art disclosure would **inevitably** result in the presently claimed ratio.
- 3.38 Similarly a genetically modified organism characterized by a particular transgene *and* a particular characteristic may be novel in view of the same organism with the same transgene for which there is no discussion of the same characteristic. This will particularly be the case where there has been an intermediate selection step for the specific traits.

3.39 However, inevitability does not require 100% certainty on every occasion the prior art process is carried out. In *Kirin-Amgen Inc. v Roche Diagnostics GmbH* [2002] RPC 1, Neuberger J held that “*the law of patents is ultimately concerned with practicality*”. He considered that a prior art experiment which reliably produced a particular result on more than 99 percent of the occasions on which it is conducted would be regarded as “inevitably” leading to the claimed result.

3.40 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.*”

3.41 In *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76 the invention related to an acid metabolite of the known pharmaceutical terfenadine. The metabolite formed in the liver following administration of terfenadine. The acid metabolite was held to be anticipated not by prior use ([see paragraph 3.70](#)) but because its formation was the inevitable result of carrying out the directions in the earlier terfenadine patent. In this regard, Lord Hoffmann held that Section 2(2) – the equivalent provision to Section 14(2) of the Singapore Patents Act – does not require that the state of the art include a knowledge of the chemical composition. Rather, it is *the invention* which must be new and which must therefore not be part of the state of the art. In this case, there was sufficient information disclosed in the prior art to work the invention.

H. Errors in citations

- 3.42 Occasionally, citations will contain errors. The key question in such cases is what the document would disclose to the person skilled in the art, and not merely what a strictly literal interpretation of the document would provide.
- 3.43 For example, a feature of the invention may be disclosed in an abstract but the document referred to in the abstract shows that the abstract is wrong. In this case the document referred to would be regarded as providing the definitive description of the matter and the abstract would not form part of the state of the art (see T 77/87, OJ EPO 1990). The person skilled in the art would recognize the error and would know how to correct it. Only the corrected version would therefore be taken into account.
- 3.44 In *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly and Co Ltd* [2008] EWHC 2345 (Pat), the Court considered a situation where a citation apparently contained an error in a chemical formula. The invention related to the compound olanzapine (an unsubstituted 4-methylpiperazinyl-10H-thienobenzodiazepine). A table showed a formula corresponding to olanzapine, but in which the piperazine ring was piperidine. Furthermore, the article was entitled "A Free-Wilson Study of 4-piperazinyl-10H-thienobenzo diazepine analogues". Reddy's argued that the person skilled in the art would recognize that the citation contained an error on the basis that:
- (a) the numbering in the ring was consistent with a piperazine derivative rather than piperidine;
 - (b) the document title referred to "piperazines" and it was easier to make an error in a formula rather than a title;
 - (c) if the bridge carbon was carbon rather than nitrogen then it would be chiral but this was not indicated in the formula.

- 3.45 The second and third points were not considered persuasive since the authors may not have been concerned with stereochemistry and there was no basis for concluding that one error would be more likely than another. The Court considered that the first point was the strongest, but accepted submissions that the person skilled in the art would not necessarily notice this point or indeed consider it important. The Court noted a finding

where the person skilled in the art would, on balance, conclude that citation was disclosing piperazines is not the same as a finding where he would conclude that it was doing so clearly and unambiguously.

3.46 Thus:

- (a) if the person skilled in the art would have recognised that the document contained an error, and would have known how to correct it, the corrected material forms part of the state of the art;
- (b) if the person skilled in the art would have recognised the error, but not known how to rectify it, neither the error nor the corrected matter form the state of the art; and
- (c) if the person skilled in the art would not have recognised the error, but submissions or evidence from the applicant establishes that there is an error, then the matters relating to that error are not part of the state of the art.

I. Anticipation by specific disclosure

- 3.47 A claim lacks novelty if there is a prior disclosure of something falling within its scope.
- 3.48 A claim which defines the invention by reference to alternatives will lack novelty if one of these alternatives is already known. For example a disclosure of a copper coil spring will anticipate a later claim to a metal coil spring. In such cases it may be possible to overcome an objection of lack of novelty by means of a disclaimer.
- 3.49 In contrast, a generic prior art disclosure will generally not anticipate a subsequent, more specific claim. Thus a prior art disclosure of a metal coil spring will not anticipate a later claim to a coil spring made of copper.
- 3.50 Nevertheless, a disclosure of a relatively small number of possible alternatives may be taken to be a disclosure of each and every member of the class. For example, in *Norton Healthcare Ltd v Beecham Group Plc* (BL C/62/95) Jacob J held that a disclosure of a combination of sodium or potassium clavulanate with amoxicillin or ampicillin trihydrate was a disclosure of each of the four possible combinations.

J. Anticipation of ranges

- 3.51 In considering the novelty of claims which define the invention by parameters within numerical ranges, the same considerations as indicated in the previous section apply. Hence, a claimed range will lack novelty if a single example falling within the range, or at its end-points, is already known.
- 3.52 A claimed invention may also be characterized by the selection of a narrower sub-range of numerical values within a broader *known* range, where said narrower sub-range has not been explicitly mentioned in the prior art. To establish the novelty of the sub-range, the selected sub-range should be narrow and sufficiently specific from the known broader range, illustrated by means of examples. The presence or absence of a particular technical effect within the sub-range appears to fall back upon considerations which should be taken into account in the assessment of inventive step, and hence, should not be considered when assessing novelty (T 230/07 *Colloidal binder/PAROC* and T 1233/05 *Refrigerant compositions/INEOS*). The meaning of “narrow” and “sufficiently removed” has to be decided on a case-by-case basis. If it is determined that the sub-range is novel, it must also meet the criteria for “selection inventions” set out in [sub-section viii of Section I in Chapter 4](#).
- 3.53 Where the claimed range overlaps with a numerical range disclosed in a prior art document, the claimed range would clearly lack novelty if there is an explicit mention in the prior art of a specific example falling in the overlapping range or at its end-points. In the absence of such a specific example, it must be considered whether the skilled person, in the light of the technical matters disclosed and taking into account the general knowledge in the field to be expected from him, would seriously contemplate applying *the technical teaching of the prior art document* in the region of overlap. If the answer is yes, then the claimed range would lack novelty. In T 26/85 *Thickness of magnetic layers*, the skilled person could not seriously contemplate working in the region of overlap, since the prior art surprisingly contained a reasoned statement clearly dissuading him from choosing the overlapping range, although said overlapping range was claimed in said prior art.

K. Anticipation of parametric claims

- 3.54 Patent claims generally define the invention in terms of specific features or function. Specific parameters, such as directly measurable physical properties (e.g. the melting point of a substance, the flexural strength of a steel, the resistance of an electrical conductor) or mathematical combinations of several variables in the form of formulae, are generally included to distinguish the invention from the prior art.
- 3.55 The key consideration for such claims with respect to novelty is whether the claim may be distinguished from prior art that *prima facie* possesses all the features of the invention, but does not specifically disclose the defined parameter; or prior art that *prima facie* possesses all the features of the invention but discloses a different parameter. For example, if the known and the claimed products are identical in all other respects (which is to be expected if, for example, the starting products and the manufacturing processes are identical), then in the first place an objection of lack of novelty would be appropriate. The burden of proof that the defined parameter is a distinguishing feature vis-à-vis the prior art is shifted to the applicant. If the applicant fails to provide convincing evidence proving otherwise, no benefit of doubt can be accorded (see for example decision T 1764/06). If, on the other hand, the applicant is able to show, e.g. by appropriate comparison tests, that differences do exist with respect to the defined parameter, it may be further considered whether the application under examination discloses all the features (e.g. process steps) essential to manufacture the claimed product having the parameters specified in the claims, or the novelty objection may otherwise be withdrawn.

L. Anticipation of “for” and “use” claims

3.56 A claim for a new method of using a known apparatus may be regarded as novel. This was established by Parker J in *Flour Oxidizing Co Ltd v Carr and Co Ltd* 25 RPC 428:

“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”.

However, the form of claim must be such as to limit the monopoly to the new use.

3.57 A claim to an apparatus *for* a particular purpose (e.g. for carrying out the process of another claim) is normally construed as a claim to an apparatus *suitable for* that purpose. That is, the intended use does not restrict the claim to the apparatus *when used* in that way (*L’Air Liquide Societe’s Application* 49 RPC 428). Accordingly any apparatus which has all of the features specified in the claim will anticipate that claim even if it is used for a different purpose. For example, 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). This is contrary to G 2/88 *Friction reducing additive*, which determined that with respect to a claim to a known compound *for* a new *non-medical* use reflecting a newly discovered technical effect of said known compound, the attaining of such technical effect should be considered as a functional technical feature of the claim. However, the approach in G 2/88 should not be followed.

3.58 Note that definitions such as “fish-hook” and “hook for fishing” are essentially equivalent. Accordingly a citation disclosing a hook that is suitable for this purpose would anticipate a claim using either form.

3.59 An exception to this approach is a claim to a known substance or composition for use in a surgical, therapeutic or diagnostic method. In this case the defined use does place a limitation on the scope of the claim. Thus a claim to “compound X for use in therapy” would only be anticipated by a disclosure of the use of compound X in

therapy and not by the disclosure of compound X in any non-therapeutic use. Anticipation of medical use claims is further discussed in [Section D in Chapter 8](#).

- 3.60 In some cases a term in a claim may appear to only require a product to be suitable for a specified use, but is in fact limited to a particular environment or interaction with another element. For example, a claim to:

*“An isolating and matching device to enable a heating element of a motor vehicle electrically heatable window, not designed specifically to be an aerial and essentially aperiodic and non-resonant at RF frequencies, **to be used** as a receiving aerial ...”*

was held to define the matching device in association with the window heating element. In this case the Court considered that in order to define the invention it was necessary to take into account the interaction with the heating element in the window since each would have different impedance (*BSH Industries Ltd’s Patents* [1995] RPC 183).

- 3.61 Furthermore, if the prior art disclosure of the claimed matter is in a form which would render it entirely unsuitable for the defined use it will not anticipate the claim. Similarly if the prior art disclosure would require modification in order for it to be suitable for the defined use, it will not anticipate the claim.
- 3.62 A claim to a product **when used** in a particular method is interpreted as a claim to a method *per se*. For example, a claim to “compound X when used as a herbicide” is a claim to a method of using compound X as a herbicide. Similarly, a claim to “the use of compound X as a herbicide” is interpreted as a method of using compound X as a herbicide. These claims would be anticipated only by a document disclosing such a method.
- 3.63 A product-by-process claim will generally be interpreted as a claim to the product *per se*, irrespective of whether the term “obtained”, “obtainable”, “directly obtained” or an equivalent wording is used. For example,

1. A method of preparing Article X comprising the steps of ...
2. Article X produced by the method of Claim 1

Since Claim 1 is a method claim and Claim 2 is a product claim, the process steps of Claim 1 would not limit product Claim 2. As a result, if the Examiner finds a prior art which discloses Article X produced by a different process, Claim 2 would still lack novelty even though Claim 1 might be novel.

- 3.64 An exception to the interpretation of a product-by-process claim will be where the process steps result in the product possessing unique properties. In such instances, the product-by-process claim would only be anticipated by a disclosure of a product with the same unique properties or by a disclosure of a product produced by the same process as defined in the claim. However, where there are no unique properties, the claim will be anticipated by any disclosure of the product *per se*. This should be factored into the search strategy for the claim.
- 3.65 A claim to a method or process *for producing a particular product*, depending on wording of the claim, should generally be understood in the sense that the method or process has to be merely *suitable for* producing said product, rather than the method limited to producing said product. Consequently, a prior disclosure of the same method or process, comprising the same steps and performed under the same conditions, but without an indication of its intended use for producing the same product would nevertheless anticipate the claim (T 304/08 Method for reducing malodor/BASF).

M. Prior use

- 3.66 The state of the art as set out by Section 14 includes matter that is made available to the public through prior use. Notably, the prior use must be in the public domain and does not include secret use (the rights of secret prior users may be protected under Section 71). The information must have been made available to at least one member of the public who, in that capacity, was free, in law and equity, to make use of it (*PLG Research Ltd v Ardon International Ltd* [1993] FSR 197). However, if the viewer is bound by confidentiality then it will not be taken to disclose the invention (*J Lucas (Batteries) Ltd v Gaedor Ltd* [1978] RPC 297).
- 3.67 In considering prior use, the UK Patents Act 1977 has determined that “it now requires the prior use, to constitute anticipation, to have made available to the public an enabling disclosure of the invention” (*Quantel Ltd v Spaceward Microsystems Ltd* [1990] RPC 83). Similarly in *PLG Research v Ardon International* Aldous J stated:

“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.”

- 3.68 The information made available to the public will depend on the nature of the invention and the manner in which it has been made available. Relevant factors include whether a member of the public had access to the invention in a manner that would allow them to handle, measure and test or whether they could merely look at it. Depending on the circumstances a person skilled in the art might be able to determine how an article was constructed and operated but in other cases they may not (*Lux Traffic Controls Ltd v Pike Signals Ltd and Faronwise Ltd* [1993] RPC 107). In *Folding Attic Stairs Ltd v Loft Stairs Co. Ltd.* [2009] FSR 24 the Court determined that viewing of a prototype (in a non-public location) by a small and defined group of visitors without any duty of confidentiality was not novelty-destroying since it was

highly improbable that the visitors would or could have ascertained the features of the claimed invention.

- 3.69 In contrast, in *Milliken Denmark AS v Walk Off Mats Ltd and Anr* [1996] FSR 292 the Court 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. In this case once an inspection had been carried out, knowledge of the perforations would be sufficient to enable the person skilled in the art to perform the invention. This would provide an anticipation of the article *per se*, and furthermore of the process of preparation if this could be deduced by the person skilled in the art.
- 3.70 In *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76, 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, would not count as anticipations. However, they would amount to infringement after the grant of the patent. 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 constitute anticipation by use. In contrast, in *Evans Medical Ltd's Patent* [1998] RPC 517, a prior art vaccine had been made available to the public in such a way that it would have been possible to analyse it to determine its contents.
- 3.71 In most cases prior use will be raised by an Examiner in relation to the invention being displayed at an exhibition or read before a conference. This may be material that comes to light as a result of conference proceedings or internet disclosures (for example photographs of a show display or newspaper articles). Alternatively there may be material filed by third parties. As a consequence, the Examiner is unlikely to be in a position to test the evidence in relation to prior use, and particularly whether the disclosure would be enabling to a person skilled in the art. In the case of prior use, the Singapore approach has followed the standard of proof required by the UK Intellectual Property Office as follows:

“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 his 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.”

- 3.72 Accordingly the Examiner must weigh up the details provided in a disclosure and the evidence in response. Mere assertions (particularly by third parties) are unlikely to be sufficient without details and supporting evidence of the nature of the alleged prior use.

N. Prior art under Section 14(3)

3.74 Section 14(3) also provides for Singapore applications that were not published at the priority date of the application to be taken into account for the purpose of determining novelty:

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:

- (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.

3.75 The usual requirements for anticipation are required: namely the citation must constitute a disclosure of the invention, and must be enabling. Prior art according to Section 14(3) cannot be taken into account for assessing obviousness.

3.76 It is a requirement that the relevant document is an application under the Singapore Patents Act. This means that if the disclosure is in a PCT application, then that application must have entered the Singapore national phase in order for it to be taken into account under Section 14(3). Once the prior application has entered the Singapore national phase, the subsequent fate of the application (whether it has been withdrawn, lapsed, etc.) is not a relevant consideration and the document remains citable prior art.

3.77 In the event that a PCT application is cited in a search report as a P,X or E category citation and it has been considered that the said PCT application may be relevant to the opinion for novelty under Section 14(3), the IPOS IP2SG site (“IP2SG”) may be consulted in order to confirm whether the application has entered the national phase in Singapore. In the event that the period for the citation to enter the national phase in Singapore has yet to expire (30 months from earliest priority), the Examiner should warn the applicant that it may become relevant under Section 14(3) if it later enters the national phase in Singapore and reserve further comment.

3.78 Only matter that was present both in the specification as filed and as published forms part of the state of the art under Section 14(3).

O. Priority dates

3.79 Section 17 of the Act sets out the relevant considerations for priority:

(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 the application is, except as provided by the provisions of this Act, the date of filing the application.

(2) Where in or in connection with an application for a patent (referred to in this section as 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 the 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, within the period referred to in subsection (2A) (a) or (b), 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; and
- (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.

3.80 Section 17(2) therefore permits the applicant to specify one or more earlier relevant applications for the purposes of establishing the priority date of the invention to which an application for a patent relates. Section 17(5) further specifies that a “relevant application” may refer to:

- (a) an application for a patent under this Act; or

- (b) an application in or for a convention country 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 such an application.

- 3.81 Hence, Section 17(5) prescribes the kinds of applications that may serve as the basis of a valid priority claim under Section 17(2). Notably, what constitutes “protection in respect of an invention” is not specified in the Act; however it is likely that an application for a patent (in a convention country) would fall under such a definition and hence be considered a relevant application. In addition, an application for the registration of a utility model (e.g. German Gebrauchsmuster), for a utility certificate or for an inventor’s certificate would each appear to be a relevant application so long as the laws of the respective countries in which they are applied indicate that said application is for protecting an invention. For example, a US provisional patent application would also be considered as a relevant application. However, an application for a registered design is not a relevant application (*Agfa-Gevaert AG’s Application* [1982] RPC 441).
- 3.82 In order for the invention in an application to be accorded its claimed priority date, Section 17(2) further prescribes that said invention must be **supported** by matter disclosed in the earlier relevant application or applications that are the subject of the priority claim. 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 [Section J](#) and [Section K](#) in Chapter 5).
- 3.83 Since Section 17(2) permits the applicant to specify one or more earlier relevant applications for the purposes of priority claims, it is therefore possible for the claims in the application under examination to have different priority dates, depending on the filing date of each of the earlier relevant applications. The priority date of a feature or combination of features, as defined in a particular claim, is the filing date of the earliest application whose disclosure supports that feature or combination.
- 3.84 Examiners should exercise caution when dealing with applications claiming priority

from multiple earlier relevant applications with different filing dates. For such applications, a prior disclosure occurring after the earliest claimed priority date may still be relevant for both novelty and inventive step for claims that are accorded a priority date that is later than the earliest claimed priority date. The aforementioned principle was illustrated in G 3/93 *Priority interval*, which provided the following example:

01.01.90	01.02.90	01.03.90	01.06.90
P1 A + B	Publication D A + B	P2 A + B + C	European Application Claim 1: A + B Claim 2: A + B + C
not the same invention			

- On 1 January 1990, an applicant files an application P1 containing the elements A + B;
- On 1 February 1990, a document D is published containing the elements A + B;
- On 1 March 1990, the same applicant files an application P2 containing the elements A + B + C;
- On 1 June 1990, the same applicant files a European patent application with Claim 1 containing the elements A + B, and Claim 2 containing the elements A + B + C; priority is claimed from P1 and P2;

3.85 The Enlarged Board of Appeal stated that claim 2 in the European patent application cannot derive priority from application P1, since P1 and claim 2 do not concern the same invention. Therefore, claim 1 would be accorded the priority date of P1, whereas claim 2 would only be accorded the priority date of application P2, which is later than the publication date of document D. As a consequence, D forms part of the state of the art in respect of claim 2, and is citable against claim 2. Under the same circumstances, document D would analogously form part of the state of the art in respect of claim 2 should said claim have been filed in a Singapore patent application since the combination of A + B + C is only supported by P2, and would hence be accorded the priority date of P2.

3.86 As stated in Section 17(2A), for the purposes of a priority claim, the application in suit may be filed in the the period of 12 months immediately following the date of filing of the specified earlier relevant application or, if there is more than one relevant application, the earliest of them. Sections 17(2B)-(2D) indicate certain exceptions in respect of the aforementioned period.

3.87 Section 17(3) further prescribes that:

Where an invention or other matter contained in the application in suit was also disclosed in 2 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 it 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 Singapore or elsewhere;
 - (ii) leaving any right outstanding; and
 - (iii) having served to establish a priority date in relation to another application, wherever made.

3.88 Section 17(3) deals with the situation where two (or more) earlier relevant applications both contain the subject matter of the application in suit. The effect of this subsection is that, in most circumstances, a valid priority claim may only be made to the first (or earliest) relevant application by the same applicant containing that matter. Notably, a relevant application in the context of Section 17(3), is the same as that described in [paragraphs 3.80 and 3.81](#) above. However, the subsection also provides an exception to that position by which the applicant may validly claim priority to a second (or subsequent) earlier relevant application. This exception only applies when certain specific conditions have been met.

- 3.89 In particular, an applicant who files, in the same country, 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 unconditionally withdrawn, abandoned or refused “without leaving any rights outstanding”. Such outstanding rights may include the right to request for an extension of time limits under Rule 108. In order for a priority claim to the second application to be valid, the applicant therefore needs to ensure that any such outstanding rights on the first application have explicitly been given up before or on the date of filing of the second application. Withdrawing the first application and filing a second application while meeting these conditions is often referred to as “regenerating the priority date”.
- 3.90 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 (Section 17(2A)), 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 is the date of filing of the application in suit. If either of the earlier (first or second) applications has been published, then that disclosure will also form part of the state of the art with respect to the application in suit.
- 3.91 In summary, for the application in suit to make a valid priority claim to an earlier relevant application, the following conditions must be satisfied:
- (i) the earlier relevant application that is the subject of the priority claim must be one of those referred to in [paragraphs 3.80 and 3.81](#) (Sections 17(2) and 17(5));
 - (ii) the earlier relevant application must be filed by the same applicant or a predecessor in title of his (Section 17(2));
 - (iii) the invention to which the application in suit relates must be supported by matter disclosed in the earlier relevant application (Section 17(2));
 - (iv) the application in suit must be filed in the period of 12 months immediately following the date of filing of the earlier relevant application (Section 17(2A), subject to certain exceptions in Sections 17(2B)-(2D)); and

- (v) the earlier relevant application must have been the first (earliest) application containing the same subject matter as that in the application in suit (Section 17(3)).

- 3.92 During the search process, Examiners should identify as far as possible, all relevant prior art immediately before the date of filing of a patent application, regardless of whether there is a priority declaration made in the patent application.
- 3.93 During the examination process, the Examiner will generally not investigate the validity of the priority claim. However, the Examiner shall do so when: i) there is a potential prior art that is published on or after the priority date but before the date of filing of the application under examination; or ii) there is a prior application that is potentially relevant under Section 14(3) whose priority date is on or after the priority date but before the date of filing of the application under examination.
- 3.94 In addition, particular care should also be taken when the Examiner discovers a potentially relevant disclosure that is an application made by the same applicant (or his predecessor in title) with an earlier priority date or date of filing, and is not the priority document of the application under examination. In such an instance, the validity of the priority claim of the application under examination may be called into question under Sections 17(2) and 17(3) since, *prima facie*, the priority document is not the earliest application containing the same subject matter as that in the application under examination.
- 3.95 In Singapore, priority documents are not furnished by the applicants as a matter of course in all cases. They are to be furnished by the applicants when the Examiner informs the Registrar of the need. However, the Examiner should exhaust all readily available avenues first, including databases such as Patentscope, the European Patent Register and USPTO Public PAIR, prior to requesting documents through the Registry.
- 3.96 Likewise, in the case of non-English priority documents, Rule 9C states that translations need to be furnished only when required and where the validity of the claim to priority is relevant to determining whether the invention concerned is patentable.

P. Exceptions to novelty: grace period

3.97 Sections 14(4)-(6) provide for certain matter to be disregarded for the purposes of determining novelty – if the disclosure was made under certain circumstances, and within a 12-month “grace period”:

(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 12 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) 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;
- (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 condition; or
- (d) the disclosure was due to, or made in consequence of, the inventor describing the invention in a paper read by him or another person with his

consent or on his behalf before any learned society or published with his consent in the transactions of any learned society.

(5) In subsection (4)(d), —learned society includes any club or association constituted in Singapore or elsewhere whose main object is the promotion of any branch of learning or science.

(6) In this section, references to the inventor include references to any proprietor of the Invention for the time being.

3.98 These circumstances include disclosures made as a result of a breach of confidence or where the inventor revealed the invention at an International Exhibition or before a learned society. If an applicant wishes to invoke these provisions, 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 is satisfied.

3.99 Notably the provisions only apply to disclosures within **12 months** of the filing date of the application. This means the filing date of the **application in Singapore** and not the filing date of the priority document (for example the basic document in a foreign country).

i. Learned society

3.100 A learned society includes any club or association constituted in Singapore or elsewhere whose main object is the promotion of any branch of learning or science (Section 14(5)). This suggests that a “learned society” includes any body of persons seeking to promote and organize the development of specific subjects, usually by the provision of a forum for the exchange and discussion of ideas and the dissemination of information, usually through the publication of its proceedings. However, some caution should be exercised in how this provision is applied. For example a meeting organized by a government department, university department or company may in some instances not constitute a learned society. On the other hand a conference organized by the Royal Society of Chemistry or IEEE would generally be considered a learned society.

3.101 In *Ralph M. Parsons Co (Beavon’s) Application* [1978] FSR 226, it was considered that learned societies would disseminate the relevant learning without consideration of economic gain. Thus, a learned society would normally be a non-commercial body of persons, and is not typically associated with commercial exploitation. For a publication to be regarded as a “transaction” of a learned society, it has to be published under the auspices of and finally be the responsibility of the learned society. Therefore, a publication that occurs via a third party, such as a reporter, who is present at the conference, would not be regarded as a publication by the society.

3.102 In *Western Minerals Technology Pty Ltd v Western Mining Corporation Limited* [2001] APO 32, a conference organized by the Camborne School of Mines (CSM) was considered to be a conference organized by “an institution of higher learning, conducting teaching and research at the undergraduate and postgraduate level”. CSM was not regarded as a learned society as there was no evidence that it was “a society made up of persons seeking to promote and organize the study of specific subjects by the provision of a forum for discussion and a means of contact for those of a common interest”. The participants at the conference, which might comprise highly learned individuals, were not a consideration for the case. The Delegate considered the participants to represent an *ad hoc* group – “a wide range of people, for example from academia, research institutes, industry and consultancy” who had responded to

“notices placed in international journals and the like”. The publication of the conference proceedings in the journal *Minerals Engineering* Vol. 4, Nos.7-11, 1991, entitled Special Issue Material Engineering '91 was also clearly not by a learned society, but by Pergamon Press Plc, a publishing company.

ii. International exhibitions

3.103 In the case of a disclosure at an International Exhibition, Rule 8 of the Patents Rules details the requirements that applicants are required to comply with:

(1) An applicant for a patent who wishes the disclosure of matter constituting an invention to be disregarded in accordance with Section 14(4)(c) shall, within the same day of filing the application for the patent, inform the Registrar in writing that the invention has been displayed at an international exhibition.

(2) The applicant shall, within 4 months from the day of filing the application, file a certificate, issued by the authority responsible for the exhibition, stating that the invention was in fact exhibited there.

(3) The certificate shall also state the opening date of the exhibition and, where the first disclosure of the invention did not take place on the opening date, the date of the first disclosure.

(4) The certificate shall be accompanied by an identification of the invention, duly authenticated by the authority.

(5) For the purposes of Section 2(2), a statement may be published in the journal that an exhibition described in the statement falls within the definition of international exhibition in Section 2(1).

(6) In the case of an international application for a patent (Singapore), the application of this rule shall be subject to Rule 86(4).

3.104 Examiners will be informed of whether such a disclosure has been made in the Patents Form 1 filed by the applicant. The patent request form (see extract of Patents Form 1 below) of the patent application contains a section which facilitates the applicant in making such a disclosure. Patents Form 1 is also enclosed together with the request for search and/or examination, when the request is forwarded to the Examiner.

7. SECTION 14(4)(C) REQUIREMENTS (see note 8)

Invention has been displayed at an international exhibition. Yes

No

3.105 For PCT national-phase (SG) entry applications, where applicants file a request for examination with IPOS, the Examiner will note that such a disclosure is made at the

International phase and this fact is revealed in the International Search Report (Rule 33.1 of the PCT Regulations).

4. INVENTIVE STEP

A. Statutory requirements

4.1 Section 13(1)(b) states that a patentable invention is one that involves an inventive step.

4.2 Section 15 sets out the meaning of an inventive step:

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 14(2) and without having regard to Section 14(3).

4.3 Section 14 sets out a definition for the state of the art as follows:

(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 Singapore or elsewhere) by written or oral description, by use or in any other way.

(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:

- (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.

B. General principles

4.4 A claim lacks novelty if every element or step is explicitly or inherently disclosed within the prior art. The condition of inventive step is a separate consideration which essentially involves a consideration of whether the invention, when compared to the state of the art at the priority date of the application, would have been obvious to a person skilled in the art. As a consequence, inventive step may alternatively be referred to as obviousness.

4.5 Lord Hoffmann gave an overview of inventive step 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.”

4.6 As noted in *Trek Technology (Singapore) Pte Ltd v FE Global Electronics Pte Ltd* [2005] 3 SLR(R) 389, the legal test for inventive step in Singapore is as set out in *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 (see [Section D in this Chapter](#)).

4.7 Objections should be structured to reflect these considerations. However, there is no need to specifically address each consideration if the particular issue is self-evident from the material on file. In *First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd and Another Appeal* [2007] SGCA 50, the Court considered the rationale underpinning the requirement of obviousness was as set out by Millett LJ in *PLG Research Ltd v Ardon International Ltd* [1995] RPC 287:

“[T]he public should not be prevented from doing anything which was merely an obvious extension or workshop variation of what was already known at the priority date ...

... There are many cases in which obviousness has been held not to have been established, even though the prior art relied upon was very close ... Where the prior art yields many possible starting points for further development, it may not be obvious without hindsight to select a particular one of them for the development which leads to the invention claimed. If the patentee has come up with a solution to his problem which is no more than an obvious extension or workshop variation to some piece of the prior art, he cannot have a monopoly for his solution whether or not the skilled man would be likely to have known of the prior art in question. On the other hand, if it is found that, even if he had known of it, the skilled man would not have regarded it as the obvious starting point for the solution of the problem with which he was confronted, this will usually demonstrate that his discovery was not an obvious extension or mere workshop variation of that prior art.”

- 4.8 Inventive step is assessed at the **priority date** of the claim in question. As noted by Jacob LJ:

“... 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.”

- 4.9 Inventive step is an objective determination. As noted by the Court of Appeal in *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd* [1985] RPC 59:

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

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.”

- 4.10 The key question is whether the invention would have been obvious to a hypothetical person skilled in the art, and not whether it would have been obvious to the inventor or a particular expert in the particular technology. Moreover, the particular circumstances by which the inventor developed the invention are also not a relevant consideration. For example, it is not a relevant consideration that the inventor developed an invention in a field which is remote from their own field of expertise (see for example EP Board of Appeal decision in T36/82). Similarly the fact that a researcher has developed an invention with no knowledge of particular prior art would not be a relevant consideration (*Allmanna Svenska Elektriska AB v The Burntisland Shipbuilding Co Ltd* 69 RPC 63).
- 4.11 “Inventive step” determination is a wholly objective qualitative test and is not a quantitative test in as much as it does not involve a consideration of whether the patent discloses something sufficiently inventive to deserve the grant of a monopoly. That is, a small inventive step will suffice for the grant of a patent (Prakash J in *Ng Kok Cheng v Chua Say Tiong* [2001] 3 SLR 487, citing *Molnlycke AB v Procter & Gamble Ltd* [1994] RPC 49).
- 4.12 As noted by the Court in *FE Global Electronics Pte Ltd v Trek Technology (Singapore) Pte Ltd* [2006] 1 SLR 874, care should be taken in assessing inventiveness, particularly where the technology appears relatively simple:
- “... some may view the invention as a simple one but simplicity has never been a bar to inventiveness and it has been reiterated often enough that ex post facto analysis can often be unfair to inventors”*
- 4.13 As stated by Aldous L. J in *Beloit Technologies Inc v Valmet Paper Machinery Inc* [1997] RPC 489:

“The court must put on ‘the spectacles’ of the notional skilled addressee at the priority date of the patent and, using such contemporary evidence as there may be, make sure that any conclusion reached is not the result of hindsight.”

4.14 In a similar vein, Lawton L. J in *Jamesigns (Leeds) Ltd’s Application* [1983] RPC 68 noted that:

“[H]indsight is not the mother of invention”.

C. Avoiding hindsight: the test for inventive step

4.15 A significant issue in examination is the use of hindsight or *ex post facto* analysis. The Examiner should attempt to place themselves in the shoes of the person skilled in the art faced with the problem. This is difficult in practice since the Examiner approaches the consideration having both the problem and the solution in hand. Various approaches have been developed by the Courts to minimise the danger of hindsight in their considerations, and in Singapore the Courts have adopted the so-called “Windsurfing approach”. Wherever possible the principles of this test should be followed in examination.

4.16 Nevertheless, as noted by Jacob LJ in *Angiotech Pharmaceuticals v Conor Medsystems Inc* [2007] EWCA Civ 5, the threshold question is a relatively simple one:

“... one can over-elaborate a discussion of the concept of — obviousness so that it becomes metaphysical or endowed with unwritten and unwarranted doctrines, sub-doctrines or even sub-sub-doctrines. ... In the end the question is simply — was the invention obvious?”

4.17 Similarly, in *First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd* [2008] 1 SLR(R) 335, the Court recognised that it may be appropriate in some cases to apply a simpler approach:

*“Be that as it may, simplicity is certainly to be appreciated, and, in assessing the obviousness of an alleged invention, it may sometimes suffice in straightforward cases to refer to the test formulated by Lord Herschell in *Vickers, Sons And Co, Limited v Siddell* (1890) 7 RPC 292, where he stated (at 304) that an invention lacked an inventive step if what was claimed was ‘so obvious that it would at once occur to anyone acquainted with the subject, and desirous of accomplishing the end’. Quite often, it is difficult, in practice, to break down the Windsurfing test ... into its component parts. Thus, while the Windsurfing test remains a useful guide, it is no more than that. Above all, it should be borne in mind that the Windsurfing test is merely a manifestation of judicial inventiveness on how best to pragmatically interpret and elucidate the requirements of s 15 of the Act.”*

D. The “Windsurfing test”

4.18 The test set out in *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 has been adopted in a number of Singapore Court decisions, including: *V-Pile Technology (Luxembourg) SA and Others v Peck Brothers Construction Pte Ltd* [2000] 3 SLR 358; *Merck & Co Inc v Pharmaforte Singapore Pte Ltd* [2000] 3 SLR 717; *Genelabs Diagnostics & Anor v Institut Pasteur & Anor* [2001] 1 SLR 121; *Ng Kok Cheng v Chua Say Tiong* [2001] 3 SLR 487; *Peng Lian Trading Co v Contour Optik Inc & Ors* [2003] 2 SLR 560; *Trek Technology (Singapore) Pte Ltd v FE Global Electronics Pte Ltd* [2005] 3 SLR(R) 389; *First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd and Another Appeal* [2007] SGCA 50; and *Martek Biosciences Corporation v Cargill International Trading Pte Ltd* [2012] SGHC 35.

4.19 The UK Court of Appeal in *Windsurfing* 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.”

4.20 In order to reduce the risk of hindsight, the Court formulated a four-step approach to assessing obviousness:

- (1) Identify the claimed inventive concept.
- (2) 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 person skilled in the art or whether they require any degree of invention.

4.21 When using this framework, Examiners should note that the third step refers to matter cited as being “known or used”. This was the language of the previous UK Patents Act. Examiners should ensure that they have regard to the “state of the art” and use such a term in the objection.

E. The modified “Windsurfing test”: the “Pozzoli” approach

4.22 The “Windsurfing approach” was elaborated upon by Jacob LJ in *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588. Singapore Courts have not formally adopted this modified test, but in any case the differences are essentially in form rather than substance. Jacob LJ provided the following reasoning:

“First one must actually conduct the first two operations in the opposite order – 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.”

4.23 Thus, the modified test can be summarised as follows:

- (1) (a) Identify the notional “person skilled in the art”
(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?

4.24 While this modified test has not formally been adopted by the Singapore Courts, Examiners may use the “Pozzoli” approach when formulating an inventive step objection. Steps (1)(a) and (1)(b) are required in any case when construing a claim, so in essence the “Pozzoli” approach merely articulates an implicit step in the Windsurfing test.

F. The inventive concept

4.25 The inventive concept is determined by the technical facts of the case in question. In *Generics (UK) Limited v H Lundbeck A/S* [2009] UKHL 12, Lord Walker stated that:

“‘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.”

4.26 Lord Neuberger agreed with Lord Walker stating:

“‘Inventive step’ suggests how something has been done, and, in the case of a product claim at any rate, one is primarily concerned with what has been allegedly invented, not how it has been done. On the other hand where the claim is for a process or (as in Biogen, [1997] RPC 1) includes a process, the issue of how the alleged invention has been achieved seems to be more in point.”

4.27 Jacob J observed in *Unilever PLC v Chefaro Proprietaries Ltd* [1994] RPC 567 at page 580 (cited with favour in *ASM Assembly Automation Ltd v Aurigon Technology Pte Ltd and Others* [2009] SGHC 206):

“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 of identification of the concept is likely to be a question of construction: what does the claim mean? It might be thought there is no second stage -- the concept is what the claim covers and that is that. But that is too wooden and not what courts, applying Windsurfing stage one, have done. It is too wooden because if one merely construes the claim one does not distinguish

between portions which matter and portions which, although limitations on the ambit of the claim, do not. One is trying to identify the essence of the claim in this exercise.”

- 4.28 Finding the essence of a claim will involve constructing something akin to a précis of the claim – essentially stripping out unnecessary verbiage from the purposively construed claim. In *Raychem Corp.’s Patents* [1998] RPC 31 it was noted that a properly drafted claim will state the inventive concept concisely. However, where claims are prolix and opaque the Court should break free of the language and concern itself with what they really meant. In particular, Laddie J noted:

“One of the arguments advanced ... was that Raychem’s patents were an exercise in what has become known amongst patent lawyers as parametritis. This is the practice of seeking to repatent the prior art by limiting claims by reference to a series of parameters which were not mentioned in the prior art. Sometimes it includes reference to parameters measured on test equipment which did not exist at the time of the prior art. The attraction of this to a patentee is that it may be impossible to prove now that the prior art inevitably exhibited the parameters and therefore it is impossible for an opponent to prove anticipation ...

There is another practice which can be used to obscure the patentee’s contribution, if any, to the art. This takes the form of drafting claims in an unnecessarily complicated way so that they are difficult to work through ... Unnecessary obscurity is not a separate ground for invalidating a claim. Within wide limits a patentee can use what language he likes to define his invention. But the court has to guard against being impressed by the form and language of the claims rather than the substance of the patentee’s alleged technical contribution.

*In all cases, and no matter what the nature of the attack on validity or arguments on infringement, the court must have in mind the first of the four steps set out in *Windsurfing International Inc. v. Tabur Marine (Great Britain)*, [1985] RPC 59. It must identify the inventive concept embodied in the claims. In many cases the claim will state that concisely. That is what a properly drafted claim should do. The first step in *Windsurfing* does not require the court to substitute its own*

language for that of the patentee if the latter is clear. But where, as here, the claims are prolix and opaque it should break free of the language and concern itself with what the claims really mean.”

4.29 Furthermore, while the inventive concept can be broader than the claim (because immaterial features of the claim may be ignored), it cannot be narrower than the claim. In *Datacard Corp. v Eagle Technologies Ltd* [2011] RPC 17, 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.

G. The starting point for the inventive step consideration

4.30 The applicant may set out the starting point for the inventive step consideration, often by stating the problem to be solved, or by setting out the prior art. However, Examiners are not bound by such statements by the applicant, and can approach the consideration from a different direction. In some cases, the same invention may be arrived at from an attempt to solve different problems, in some cases with a different level of inventive step.

4.31 Any document from the state of the art as set out in Section 14(2) may be used as the starting-point for an inventive step objection. The 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.”

4.32 As a consequence an inventive step objection will not be overcome by merely arguing that the person skilled in the art would have been unaware of the document, if that document has been made public anywhere in the world, in any language, at any time before the priority date. See also *Wake Forest University Health Sciences & Ors v Smith & Nephew Plc & Anor* [2009] EWCA Civ 848, where a document that was shown to be available in only four libraries in the former Soviet Union was nonetheless available for use in an inventive step argument.

4.33 Two additional considerations in selecting the starting point for the inventive step consideration are:

- (1) whether the person skilled in the art could reasonably be expected to find

the document when conducting a diligent search for material relevant to the problem in hand; and

- (2) whether if he had found the document, he would have given it serious consideration. In some cases the age of the document may be relevant, as may be whether, if it is one of a large number of relevant documents, there was any reason why the person skilled in the art should have selected this particular document.

4.34 However, any piece of prior art must be viewed through the eyes of the person skilled in the art at the priority date. The prior art may teach towards the invention, but on the other hand, it may cause the person skilled in the art to disregard it. Examiners should ensure that they take all common general knowledge into consideration, including prior art that teaches away from the invention. For example, in *Actavis v Merck*, [2008] RPC 26, the invention involved the treatment of alopecia (baldness). A published document indicated that a particular drug was useful for the treatment of this ailment. However, the Court of Appeal found that at the priority date of the application, the common general knowledge in the field was that this drug was ineffective at any dosage. Accordingly, claims to the treatment at a particular dosage were found inventive.

4.35 In some cases, there may be a relatively short time lapse between the publication of a document and the priority date of the application under consideration. However, this is not a consideration – the question 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 (*Merck Sharp & Dohme Corp v Teva UK Ltd* [2011] EWCA Civ 382).

4.36 On the other hand, a document may be relatively old, and submission made along the lines that if it was obvious why wasn't it done sooner? This argument was addressed by Laddie J in *Brugger and others v Medic-Aid Ltd* [1996] RPC 635:

“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.

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." [emphasis added]

- 4.37 Another area in which old documents are particularly relevant in a consideration of inventive step is where technological advances make a previously impractical invention viable. For example, a particular invention may not be commercially viable because the cost of materials render it too expensive. However, the development of new materials or new processes for the preparation of materials may make such inventions commercially viable.

H. Combining disclosures (“mosaicing”) for inventive step

4.38 While any single disclosure forming the state of the art may be used for a consideration of inventive step, when combining two or more disclosures an assessment of whether the person skilled in the art *would* combine such disclosures must first be undertaken.

4.39 In *ASM Assembly Automation Ltd v Aurigin Technology Pte Ltd and others* [2009] SGHC 206, Tan J stated that:

“one is entitled to make a ‘mosaic’ out of relevant documents if it can be put together by an unimaginative man with no inventive capability (see Technograph v Mills & Rockely, [1972] RPC 346)”

4.40 Tay JC referred to the UK decision in *Lowndes Patent* [1928] 45 RPC 48:

“it is not open to you to take a packet of prior documents and by putting a puzzle together to produce what you say is a disclosure in the nature of the various elements which have been contained in the prior documents ... it is necessary to point to a clear and specific disclosure of something which is said to be like the patentee’s invention.”

4.41 In *Martek Biosciences Corporation v Cargill International Trading Pte Ltd* [2012] SGHC 35, Tay J referred to an article by Ng-Loy Wee Loon in *Law of Intellectual Property of Singapore* (Sweet & Maxwell Asia, Rev Ed, 2009) at 30.1.50:

“... the skilled addressee assesses the obviousness of an invention by reference to the whole of the state of the art relevant to this invention, whereas he assesses the novelty of the invention by reference to each individual piece of prior art in this state of the art. There is, however, an exception to this scenario: ‘mosaicing’ is not permitted in the obviousness inquiry if it would not be obvious to the skilled addressee to ‘mosaic’ the different pieces of prior art.”

4.42 Tay J went on to consider whether it would have been obvious to the person skilled in the art to mosaic the documents. Notably, this “obvious to combine” does not

necessarily require an express cross reference in the documents in order for an inventive step argument to be raised on the basis of a mosaic of documents. In this regard, the statements by Laddie J in *Pfizer Ltd's Patent* [2001] FSR 16 may provide useful guidance:

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

4.43 In deciding whether it is obvious to combine the disclosure in two or more documents, the UK Manual of Patent Practice (April 2009) states that the following considerations are likely to be relevant:

- (1) 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.
- (2) Whether the documents came from the same technical field or from neighbouring or remote technical fields.
- (3) The presence of references in one document to another.
- (4) The amount of selection required to isolate the separate disclosures from the surrounding documentary material.
- (5) Whether the contents of one document are so well known that the person

skilled in the art would always have them in mind in reading other documents.

- 4.44 Notably, Section 14(2) sets out that the state of the art comprises all “matter (whether a product, a process, information about either, or anything else)”. Section 15 states that the invention will involve an inventive step if it is not obvious having regard to any such matter. Thus for example a “mosaic” does not require a combination of separate documents – in particular, a mosaic of different pieces of information from within a single document may be appropriate.
- 4.45 If the invention can be produced by combining the teaching of one document with common general knowledge, there is a strong presumption that such a combination would be obvious to the person skilled in the art. In raising such an objection, the Examiner should clearly detail the basis for asserting that certain features are common general knowledge. This should be based on legal precedent as to what constitutes common general knowledge, but may also be taken from the application. For example, if the application 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).
- 4.46 There is no limit to the number of pieces of information that may be combined for an inventive step objection. However, in general the greater the number of features to be combined the greater the chance of there being an inventive step. However, if the invention constitutes no more than a combination of separate entities, each performing its usual function, then the invention is likely to be a mere collocation.

I. Is the invention obvious?

- 4.47 The last two questions in the “Windsurfing approach” require the Examiner to identify the differences that exist between the prior art and the invention in question, and then to determine whether those differences constitute steps which would have been obvious to the person skilled in the art or whether they require any degree of invention.
- 4.48 Examiners will often have technical skills relevant to the technology or will have acquired a good working knowledge of the areas in which they examine. As a consequence they will generally be in a position to decide based on the material before them, including application and the prior art, whether the invention possesses an inventive step. The Examiner should reassess their position once further submissions and/or evidence have been provided by the applicant. In most cases, the Examiner will not be in a position to refute expert evidence from a person working in the particular field. In such cases the Examiner is unlikely to be able to maintain an objection unless they are able to produce documentary evidence to the contrary. However, if the response from the applicant consists of assertions without any supporting material (such as documents or experimental results), then the documentary support for a rebuttal will be relatively low.
- 4.49 While the Windsurfing test sets a framework by which inventive step is assessed, the ultimate question is essentially the same question facing the Examiner at the start – is the invention obvious? As cautioned by Warren J in *Actavis UK Ltd v Novartis AG* [2009] EWHC 41:

“It is in this context always important, in assessing obviousness, as it is with novelty, to bear carefully in mind the statutory words. It is easy to find in the cases words more or less apposite to the facts of the case (e.g., would/could, motive, expectation of success, workshop variants, whether there is a reason for taking the step from the prior art) to describe how the court has made its decisions, using concepts which cannot be of universal application. Time and time again, the Courts have emphasised that the correct question is that laid down in the statute, namely whether the invention was obvious to the person

skilled in the art: see in particular ... Conor (Conor Medsystems Incorporated v Angiotec Pharmaceuticals Incorporated, [2008] RPC 28). In that case, Lord Hoffmann cited with approval the observations of Kitchin J in Generics v Lundbeck [2007] RPC 32 at 72 in considering how a number of different factors should be taken into account:

‘The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success.’”

4.50 Various approaches have been used by the Singapore Courts to determine obviousness:

“lying in the road” (*Peng Lian Trading Co v Contour Optik Inc & Ors* [2003] 2 SLR 560, and *Merck & Co Inc v Pharmaforte Singapore Pte Ltd* [2000] 3 SLR 717)

“workshop variation” (*ASM Assembly Automation Ltd v Aurigin Technology Pte Ltd and others* [2009] SGHC 206)

“commercial success” and **“long-felt want”** (*Muhlbauer AG v Manufacturing Integration Technology Ltd* [2009] SGHC 45 and *Trek Technology (Singapore) Pte Ltd v FE Global Electronics Pte Ltd* [2005] 3 SLR 389, upheld on appeal in *FE Global Electronics Pte Ltd v Trek Technology (Singapore) Pte Ltd* [2006] 1 SLR 876)

“so obvious” (*First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd and Another Appeal* [2007] SGCA 50)

“technical prejudice” (*Muhlbauer AG v Manufacturing Integration Technology Ltd* [2010] SGCA 6)

“overcoming practical difficulties” (*V-Pile Technology (Luxembourg) SA and Others v Peck Brothers Construction Pte Ltd* [2000] 3 SLR 358)

4.51 In addition to these tests, guidance may be taken from some UK case law, and particularly: “Why was it not done before?”, “Advantages of the invention”, “Obvious to try”, and “Selection inventions”.

i. “Lying in the Road”

4.52 In some cases the solution to a particular problem is one which uses materials that are readily available on hand and which are *prima facie* a matter of routine for the person skilled in the art. *Philips (Bosgra’s) Application* [1974] RPC 241 at page 251, Whitford J considered such issues noting that the “road” itself must be one that the research worker would naturally choose to take:

“Nothing ... would be more undesirable than that persons should be stopped ... from using materials which it is also established would lie readily to their hand, and would come to their mind as being likely materials to use. ... I think these (emulsifying) agents were obvious in this sense, indeed in the true sense of the word, that they were lying in the road, that they were there for the research worker to use, and it is quite wrong that he should be stopped from using them.”

4.53 The Court in *Peng Lian Trading Co v Contour Optik Inc & Ors* [2003] 2 SLR 560 cited a later restatement of this principle:

“In this regard, the words of Whitford J in Philips (Bosgra’s) Application, [1974] RPC 241 at 251 as expressed and approved by Dillon J in Genentech Inc’s Patent, [1989] RPC 147 at 243, are worthy of note:

‘[T]o render an invention obvious it was not necessary that the material in question should have been the first choice of the notional research worker; it was enough that the material was ‘lying in the road’ and there for the research worker to use.’”

4.54 In *Merck & Co Inc v Pharmaforte Singapore Pte Ltd* [2002] 2 SLR 515 (upheld on appeal in *Merck & Co Inc v Pharmaforte Singapore Pte Ltd* [2000] 3 SLR 717), the invention involved the purification of lovastatin to reduce the presence of a dimeric impurity. The claims were directed to lovastatin having lesser than 0.2% of dimeric impurity. Lai J was presented with evidence that processes disclosed in two of the patentee’s own previous patents could produce the desired impurity level and the Court held that the claims lacked novelty. The patent was also attacked on the ground

that it was obvious to use techniques such as recrystallization and charcoal treatment in order to reduce impurities. The Court cited *Genentech Inc's Patent* [1989] RPC 147 with favour in seeking a 'spark of imagination' beyond that which may be attributable to a man skilled in the art. Moreover, they stated that:

"if various techniques and processes were available which the man skilled in the art thought were worth trying out to yield beneficial results, or if the same could be said to be 'lying in the road' for the research worker to use (Genentech at pp 242-243), the case for 'obviousness' in the inventive idea is that much stronger. The same could be said of the myriad of processes ... which could be applied to the purification of the Lovastatin compound."

4.55 Notably, Lai J considered that an argument that the invention had required extensive research was not relevant in this case:

"The plaintiffs gave evidence that much effort had gone into researching processes of purification. The sweat of their labours is hardly relevant to the issue of inventive step. I am prepared to find that they embarked on a well-charted journey, where the purification of the compound to levels of 0.2% or less was the obvious next step, given the processes that were known at the priority date."

4.56 In general, where a claimed solution:

- (1) is one of several options that the person skilled in the art would consider in solving either the identified problem or any subsequent practical difficulty;
- (2) the options would at once suggest themselves to the person skilled in the art, e.g. the options are part of the common general knowledge, or clearly indicated in the prior art;
- (3) there is no practical difficulty in implementing the particular solution claimed; and
- (4) neither the prior art, nor the common general knowledge, teaches away from the particular solution;

then an inventive step objection will apply. In this situation, the claimed solution is said to be *ob via* (the Latin root of the word obvious), or "lying in the road".

ii. Workshop variation

4.57 If a claim is a “mere workshop improvement” over the prior art, it will lack an inventive step. This is implicit in the definition of a person skilled in the art as a person who has the skill to make routine workshop developments but not to exercise inventive ingenuity or think laterally (see *Pfizer Ltd’s Patent* [2001] FSR 16). However, whether something constitutes a mere workshop improvement or modification may be difficult to determine:

“Nobody, however, has told me, and I do not suppose that anybody ever will tell me, what is the precise characteristics or quality the presence of which distinguishes invention from a workshop improvement” (Samuel Parkes & Co Ltd v Cocker Brothers Ltd, [1929] 46 RPC 241).

4.58 Some guidance was given by Laddie J in *Hoechst Celanese Corporation v BP Chemicals Limited* [1997] EWHC 370 (Pat) as follows:

“... mere workshop modifications, none of which would be expected to produce significant technical or commercial benefits are still obvious. To adopt an example sometimes given by Jacob J., if it is known to make a 5 inch plate, it is obvious to make a 5¹/₄ inch plate. Technicians and businessmen frequently want to make trivial variations in established or known products. Similarly if the prior art discloses two wooden parts held together by screws it would be obvious to glue them, even if so doing would not be expected to advance the industry. The notional addressee is likely to want to use materials readily at hand to make essentially the same thing as is disclosed in the prior art. That is sufficient motivation and the use of those materials is, accordingly, obvious.”

4.59 In *ASM Assembly Automation Ltd v Aurigin Technology Pte Ltd and others* [2009] SGHC 206, the invention involved an apparatus and method for automatically placing an array of solder balls onto a substrate. The Court found that the claims were lacking in novelty, but nevertheless further considered their inventiveness. Notwithstanding that Tan J concluded that the evidence at trial showed that ASM’s patent involved nothing more than an “aggregation of known features in the art”, the key matter was

considered under the guise of workshop improvement. Tan J referred to *Shaw v Burnet & Co* [1924] 41 RPC 432 and *Curtis & Son v Heward & Co* [1923] 40 RPC 53 as being instructive as to workshop improvements being insufficient to establish inventiveness.

- 4.60 Evidence at trial was provided by expert witnesses as to what constituted a workshop variation in the particular technology, and in particular to the use of a tilting mechanism to reduce the risk of shearing of the solder balls by the trailing wall of the container. This type of mechanism was disclosed in two prior art documents. Based on the expert evidence the Court considered that it would be obvious to use the features disclosed in these documents to modify the known prior art devices to arrive at the claimed invention.
- 4.61 Generally, a workshop improvement will involve trivial modification of an existing product which the person skilled in the art would be expected to implement without practical difficulty and without the expectation of a significant technical or commercial improvement. Notably, the considerations under “workshop variation” are similar to those under “lying in the road”, and it may be that objection could be formulated under either. Evidence from the applicant of a practical difficulty or a surprising advantage may be sufficient to circumvent such an objection.

iii. Commercial success and long-felt want

4.62 Evidence of a long-felt want or that the invention has been commercially successful may be a relevant consideration for inventive step (see for example *Hickman v Andrews* [1983] RPC 147 and *PLG Research Ltd v Ardon International Ltd* [1993] FSR 197). Most patents are prosecuted early in the development of an invention so commercial success may be difficult to gauge at first action. However, this may be a relevant consideration later in the examination process.

4.63 A good statement of the underpinning reasons for taking commercial success into account when assessing inventive step was given by the court in *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly and Co Ltd* [2008] EWHC 2345 (Pat):

*“Commercial success can be a relevant secondary indicator of non-obviousness. Like all secondary indications it needs to be kept in its place. Why is it relevant at all? It is said that, when coupled with a long felt want which skilled researchers were attempting to meet, it is evidence that the claimed solution cannot have been obvious. In other words, **commercial incentives would have driven those skilled in the art to the claimed solution but for one thing: it was not obvious.**”*
[emphasis added]

4.64 The UK decision in *Schlumberger Holdings Limited v Electromagnetic Geoservices AS* [2009] EWHC 58 (Pat) at [77] to [78] provides a good summary as to the approach to be taken in relation to inventive step, and particularly where commercial success may be a relevant factor:

*“The leading authority on the place of this evidence is the decision of the Court of Appeal in *Mölnycke AB v Procter & Gamble Ltd*, [1994] RPC 49 ... The material points which emerge from it are:*

- 1. The expert evidence is the primary evidence; the contemporaneous evidence is relevant, and has the merit of being untainted by hindsight, but secondary. It can be used to test the expert evidence.*
- 2. There is a danger in getting too caught up in an investigation of what was and what was not obvious to certain identified (and even more so*

unidentified) individuals, because they may not all have been aware of the state of the art - the state of the art (within the meaning of the statute) is the important starting point.

- 3. The evidence may invite a degree of inadmissible speculation as to the inventiveness of the persons involved.*
- 4. Commercial success (if relied on) may be attributable to novelty (want of obviousness), but there may be other factors operating. Care must be taken to ensure that is not the case.*
- 5. The importance and weight of the evidence will vary from case to case.*

In addition, where contemporaneous evidence is relied on, and it demonstrates some sort of commercial success of the idea, one must be live to the distinction between what was commercially obvious (or not obvious) and what was technically obvious (or not obvious). A new approach may find success because it has become appreciated that it has become commercially worthwhile, rather than its being appreciated as something new which will assist. If the success is attributable to the former, then the evidence does not support novelty in patent terms.”

4.65 In *FE Global Electronics Pte Ltd v Trek Technology (Singapore) Pte Ltd*, [2006] 1 SLR 876, the invention comprised a thumb drive device that could be plugged directly into a USB. At the time commercially available memory storage devices were usually fitted within the computer (such as ROM or RAM storage), or surface based storage devices (generally discs). The thumb drive had no moving parts which enabled the memory storage device to be more compact. The Court found that:

*“In our view, Trek had an inventive concept for a new type of data storage device that was quite different from and more convenient to use than conventional data storage devices. Admittedly, all the elements required for this invention were available to those skilled in the art. Solid-state non-volatile memory was well known and USB plugs were standard. Yet before Trek applied for the patent in question, no one else thought of combining all the elements together ... **Having looked at the device, some may view the invention as a simple one but simplicity has never been a bar to inventiveness and it has been reiterated often enough***

that ex post facto analysis can often be unfair to inventors ...” [emphasis added]

4.66 Similarly, in the UK case *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] RPC33, the Court of Appeal 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 others had missed.”

4.67 In *Mühlbauer AG v Manufacturing Integration Technology Ltd* [2009] SGHC 45, Tay Yong Kwang J noted that when using commercial success as an indicator of inventive step one should be mindful of other factors that can contribute to commercial success:

“Where commercial success of an invention is concerned, this factor alone is not conclusive. A product that sells well is not necessarily novel or one involving an inventive step. Good advertising, marketing and pricing could also play a part. The converse is also true. As stated in Main-Line Corporate Holdings Ltd v United Overseas Bank Ltd, [2007] 1 SLR 1021 at [71]:

Something that is new and inventive does not automatically become an overnight success or — ‘the next big thing’. Even if it is not, like the plaintiff’s Teh Kor Lak said, — ‘a big deal’, it is nevertheless something new and inventive which, after the invention is known, others may wish they had thought of or wonder why they had never thought of it. Some patents achieve much more commercial success and are more life-changing than (many) others. The fact that the invention has not been widely adopted in the credit card industry is therefore not an adverse reflection on its inventive quality.”

4.68 Notably the Court cautioned that commercial success may be due to factors other than the inherent properties of the invention *per se*. Commercial success therefore needs to be carefully considered as to whether the success is indeed related to a long-felt need being satisfied rather than being the result of clever marketing or the price of the product.

4.69 Laddie J in *Haberman v Jackal* [1999] FSR 685, provided a number of relevant questions that may help in such a consideration:

- (1) What was the problem which the patented development addressed?
- (2) How long had that problem existed?
- (3) How significant was the problem seen to be?
- (4) How widely known was the problem and how many were likely to be seeking a solution?
- (5) 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?
- (6) What other solutions were put forward in the period leading up to the publication of the patentee's development?
- (7) To what extent were there factors which would have held back the exploitation of the solution even if it was technically obvious?
- (8) How well had the patentee's development been received?
- (9) 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?

4.70 In *Haberman v Jackal*, the invention consisted of a "trainer cup" which had been modified to make it leak-proof. The design was relatively simple and used readily available materials. Despite a relatively small advertising budget and poorly developed aesthetics, the product was well-received in the market. Such commercial success was held as being indicative that the product satisfied a long-felt want in the market.

4.71 In addition to the *Haberman* questions, other matters that the UK Courts have taken into account include:

- (1) all matter within the scope of the claim must include the features contributing to the commercial features of the invention (*Tetra Molectric Ltd v Japan Imports Ltd*, [1976] RPC 547); and
- (2) whether the absence of a product on the market could be attributed to a pre-existing patent – for example an argument based on the commercial success of an isolated enantiomer would fail if the racemic mixture were covered by a patent that would restrict its use by others (*Generics (UK) Ltd v H Lundbeck A/S*, [2007] EWHC 1040).

iv. “So obvious”

4.72 The Court of Appeal in *First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd and Another Appeal* [2007] SGCA 50 discussed the use of the Windsurfing test, noting that critics considered the Courts merely pay lip service to the first three. They went on to say that:

“Be that as it may, simplicity is certainly to be appreciated, and, in assessing the obviousness of an alleged invention, it may sometimes suffice in straightforward cases to refer to the test formulated by Lord Herschell in Vickers, Sons And Co, Limited v Siddell, (1890) 7 RPC 292, where he stated (at 304) that an invention lacked an inventive step if what was claimed was ‘so obvious that it would at once occur to anyone acquainted with the subject, and desirous of accomplishing the end’. Quite often, it is difficult, in practice, to break down the Windsurfing test ([41] above) into its component parts. Thus, while the Windsurfing test remains a useful guide, it is no more than that.”

4.73 Thus, in some cases it may be appropriate to depart from a strict application of the Windsurfing test. This is most likely to be where obviousness is so self-evident that there is little benefit in following the structured approach required by Windsurfing. However, if such an approach is taken care must be taken to avoid hindsight.

v. Technical prejudice

4.74 The common general knowledge is a key consideration in the assessment of inventive step. Importantly, the Examiner should consider what the skilled person would consider doing, but also what the skilled person would be prejudiced against doing. An invention may be regarded as non-obvious if it goes against the generally accepted views and practices in the art (see for example, *Dyson Appliances Ltd v Hoover Ltd* [2001] RPC 26).

4.75 Examples where this may be a determining factor include;

- (1) if the common general knowledge was such that the skilled person did not perceive a problem with the prior art.
- (2) if certain materials or techniques would be considered by the skilled person as unsuitable for a particular purpose and the inventor has found that this prejudice is not well-founded.
- (3) If a certain step in a method or component in an apparatus was considered essential, but the inventor has found that it may be omitted.

4.76 The technical prejudice must be one which is commonly shared in the art: that is, the prejudice must be sufficiently widespread for it to be attributed to the notional person skilled in the art. Thus if views in the art are divided in relation to a particular point, then it is not a prejudice that may be said to be widely held in the art. For example in *Glaxo Group's Patent* [2004] RPC 43, there was significant dispute in the art in relation to the use of β 2-antagonists in the treatment of asthma. The Court held that as a consequence of this dispute the technical prejudice could not be considered sufficiently widespread to be attributed to the skilled person.

4.77 Similarly, a prejudice held in one group may be in conflict with the practices of another. For example, in *Ancare New Zealand Ltd's Patent* [2003] RPC 8 the invention involved a dual treatment for round worm and tapeworm. The applicant argued that the invention lay in using an agent against tapeworm since there was a prevailing scientific prejudice against treating lambs for tapeworm. However, the Court held that despite the scientific views it was common practice for farmers to

treat lambs for tapeworm. The Court held that the invention was obvious since:

“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.”

- 4.78 Notably the invention must lie in recognising that a prejudice is ill-founded – there will be no invention in simply accepting the disadvantages that underpin the prejudice. For example, the prevailing view in the art may be that a ferrous metal should not be used in a particular reactor because it is susceptible to corrosion under the reaction conditions. An invention employing such a reactor would not be inventive if it was simply accepting that it would have a reduced lifespan. Similarly if the prejudice against a particular material is founded on it being unviable or expensive and a subsequent development makes the material more readily available or cheaper, then an invention merely taking advantage of that development would not be inventive. Of course the improved process of making the material itself may be patentable.

vi. Overcoming practical difficulties

4.79 In *V-Pile Technology (Luxembourg) SA v Peck Brothers Construction Pte Ltd* [2000] 3 SLR 358 followed the decision of the UK Court of Appeal in *Gadd and Mason v Manchester Corporation* (1892) 9 RPC 516, in which Rubin J held that a new use of a known contrivance may be non-obvious if the new use involves practical difficulties that the inventor has overcome by ingenuity of his own.

vii. Advantages of the invention

- 4.80 Where the invention has no advantages, or is even disadvantageous, it could be argued that it would not be obvious to the skilled person. Nevertheless, if the invention is one which a skilled person would consider, then it will lack inventive step (Technical Board of Appeal of the EPO in Decision T119/82). However if the invention has an unexpected advantage, then it may constitute a valid “selection”. Similarly if the skilled person would expect the invention to be disadvantageous but this is in fact not the case, then it may be non-obvious. “Selection” inventions will be dealt with below.
- 4.81 If the prior art leads directly to an invention then it is not made inventive by any additional advantage obtained. In *Inventa AG’s Application* [1956] RPC 45, a process of spinning nylon which had (before the introduction of nylon) been disclosed for spinning artificial filaments was held to be obvious despite having an additional advantage. In particular, no further modification of the process was required to secure this advantage. Similarly, in *Union Carbide Corporation (Hostettler’s) Application* [1972] RPC 601 at page 609, Whitford J stated 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”.
- 4.82 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).

viii. Selection inventions

4.83 If the invention is one of many possible alternatives, and there is no indication in the prior art that any particular alternative is more advantageous than another then the invention may be considered non-obvious. This most often arises in chemical applications, where Markush-style claims can cover a broad range of compounds, but only specifically disclose a limited range of embodiments. Subsequent applications which claim a specific subset of the compounds on the basis of an unexpected advantage may be patentable. Such situations are often referred to as “selections”.

4.84 The law on selection patents was first set out in *I G Farbenindustrie AG's Patent* [1930] 47 RPC 289.

4.85 However, in *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* [2010] RPC 9, 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”. Instead the criteria set out by the EPO Board of Appeal decision in T 939/92 *AGREVO/Triazoles* were followed:

- (i) the selection must not be arbitrary but must be justified by a hitherto unknown technical effect;
- (ii) a technical effect which justifies the selection of the claimed group must be one which can be fairly assumed to be produced by substantially all the selected members;
- (iii) this technical effect can only be taken into account if it can be accepted as having been indicated in the specification as filed.

4.86 Jacob LJ noted that the criteria set out in *I G Farbenindustrie AG's Patent* were formulated under the common law and did not draw a distinction between lack of novelty and obviousness. Instead these were dealt with under the general umbrella of “lack of subject-matter”. He stated that the “rules were carried over by the judges into the newly codified law in 1932 and remained, almost as a special sub-branch of patentability, as part of English law until the “new law of patents” (a recital to the Patents Act 1977) came in.”

4.87 The judge also expressed concern that the final test – that the property be peculiar to

the selected group – was not one that could be applied in practice without testing “quite a lot” of the prior class. On that basis he considered the approach taken by the EPO in AGREVO was preferable. If dealing with selections, the AGREVO approach should be taken by Examiners.

- 4.88 A selection would be regarded as obvious if it has made no real technical advance. This was noted by Jacob LJ in *Dr Reddy’s*:

“... it regards what can fairly be regarded as a mere arbitrary selection from a class as obvious. If there is no more than an arbitrary selection then there is simply no technical contribution provided by the patentee.”

- 4.89 The “hitherto unknown technical effect” should be clearly indicated. This can be by explicit statement, or may be implied from tests provided in the application at the time of filing. Later-filed evidence may be used to provide support for the first two criteria, but unexpected *bonus effects* not described in the specification cannot form the basis of a valid claim to a selection invention (*Glaxo Group Ltd’s Patent* [2004] RPC 43).
- 4.90 A “bonus effect” refers to the effects that are observed in an otherwise obvious invention. Generally, the situation is one where there is a “one-way street” – the invention is one which would be obvious to the skilled person, and any unexpected results are merely a bonus effect from following an otherwise obvious pathway.
- 4.91 If the specification as filed does not state the advantage (or if it cannot be implied from experimental data), then it cannot be amended later to include such a statement. In *Richardson-Vicks Inc.’s Patent* [1995] RPC 568 at [581], Jacob J stated that 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.”
- 4.92 In this regard the usual considerations for amendments should be made – in particular would the skilled person learn something about the invention from the amended specification that they would not have learned from the specification as filed.

ix. Why was it not done before?

4.93 A question that could be asked in response to an inventive step objection is “if it was so obvious why wasn’t it done before?”

4.94 Clearly, this is an ill-founded argument since any invention that had not been done before (that is, was new) would automatically be held inventive. Nevertheless the reasons as to why the invention has not previously been done are a relevant consideration.

4.95 In particular, 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).

4.96 However:

- (1) if a long-standing problem has been solved using materials or techniques which have only recently become available in a conventional manner;
- (2) 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; or
- (3) 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);

then it is unlikely that the invention will be considered as having an inventive step.

x. Obvious to try

4.97 The “obvious to try” test for inventive step, first used in *Johns-Manville Corporation’s Patent* [1967] RPC 479, has not been adopted by Singapore Courts in their consideration of inventive step. However, it has been applied under the UK Patents Act 1977 and as a consequence could provide some guidance.

4.98 As recently noted in Kitchen LJ in *Novartis AG v Generics (UK) Limited (t/a Mylan)* [2012] EWCA Civ 1623:

“[I]n deciding whether the invention was obvious to the skilled but unimaginative addressee at the priority date the court will 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.”

4.99 Notably, the enquiry is one as to whether there is a “reasonable or fair expectation of success” as opposed to a “hope to succeed” (*MedImmune v Novartis* [2012] EWCA Civ 1234). Thus simply including something in a research project is unlikely to be enough, but if it is self-evident that what is being tested ought to work then the invention may be considered obvious (*Saint-Gobain PAM SA v Fusion Provida Ltd and Electrosteel Castings Ltd* [2005] EWCA Civ 177). However, in *Novartis v Generics*, Kitchen LJ stated:

“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.”

4.100 Kitchen LJ went on to say that the “correct approach” was that set out in *MedImmune v Novartis*:

“[O]ne of the matters which it may be appropriate to take into account is

whether it was obvious to try a particular route to an improved product or process. There may be no certainty of success but the skilled person might nevertheless assess the prospects of success as being sufficient to warrant a trial.” [emphasis added]

4.101 If a particular route is an obvious one to take or try, it is not rendered non-obvious merely because it is one of a number of other obvious routes. As noted by Laddie J in *Brugger and others v Medic-Aid Ltd* [1996] RPC 635, there “is no rule of law or logic which says that only the option which is likely to be tried first or second is to be treated as obvious for the purposes of patent legislation”. However, this does not mean that the skilled person would pursue every avenue of research relentlessly where there were only the mildest reasons for doing so.

4.102 In *Lilly Icos Ltd v Pfizer Ltd* [2002] EWCA Civ 1, a document disclosed the use of compounds as vasodilators through inhibition of cGMP PDE. The Court found that the further use of this to treat impotence was obvious in view of a second document which disclosed that compounds that inhibited this enzyme may be useful for treating impotence. In particular, the Court considered that the claimed invention was little more than putting into practice something that the prior art suggested and which would have been considered by the skilled person as being sound and worth trying.

4.103 In *Omnipharm Limited v Merial* [2011] EWHC 3393 (Pat), the invention related to a “spot on” formulation for the treatment of fleas in pets. The closest prior art was a “spray on” formulation comprising the same active ingredient. Despite the Court considering that it would be obvious to try to develop a spot on formulation since they have advantages in terms of ease of application, there was no basis on which the skilled person would predict that a “spot on” formulation would work. That is, the skilled person would not have had sufficient expectation of success to render the invention obvious.

5. THE APPLICATION

A. Statutory requirements

5.1 Section 25 lays down what is required of a patent application. Besides formality requirements for the application, most of which will have been checked during initial processing, this section also provides a number of substantive requirements that the Examiner needs to ensure are complied with.

5.2 Section 25(4) requires that:

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

5.3 Section 25(5) states that:

The claim or claims shall —

- (1) define the matter for which the applicant seeks protection;
- (2) be clear and concise;
- (3) be supported by the description;

...

5.4 Rule 19 expands upon these formality and substantive requirements and the following section of the Guidelines deals with the application of these requirements during examination.

B. Number of claims (Rule 19(6)) and numbering of claims (Rule 19(6A)²)

- 5.5 Rule 19(6) states that the number of claims shall be reasonable in consideration of the nature of the invention claimed, and Rule 19(6A) specifies that where there are 2 or more claims, the claims shall be numbered consecutively in Arabic numerals.
- 5.6 While Rule 19(6) suggests that the number of claims shall be **reasonable**, there is no specific limitation in this regard. In practice, consideration of this Rule would be essentially the same as that required under Section 25(5)(b) (the claim or claims shall... be clear and concise). An objection under Rule 19(6) that the number of claims is excessive will be rare, and if there is any doubt in this regard it should be discussed with a Senior Examiner prior to raising the objection.
- 5.7 Rule 19(6A) also requires that the claims be numbered consecutively in Arabic numerals. An objection of this nature is likely to be raised where a claim number has been inadvertently omitted during drafting, thus resulting in a particular claim not being numbered in the application as filed. This should be indicated in Box VI of the written opinion as it would be a defect in the form of the application, and the Examiner may append a suitable label to the unnumbered claim for the purpose of examination.
- 5.8 In addition, since such omission would also affect the indication of the basis of the written opinion in Box I, an appropriate explanatory comment should be made under "4. Additional observations". Claim numbers should be whole numbers alone and other combinations (for example, 9a, 9b, 9c, etc., letters or other forms of numbering such as Roman numerals) should be objected to.
- 5.9 Notably, Rule 19(6A) states that where there are **2 or more claims** they shall be numbered consecutively in Arabic numerals. It follows that a single claim need not be numbered and no objection should be raised in such cases.

² In the *Patents Rules* with effect immediately before 14/02/2014, the requirement that the claims be numbered consecutively was specified in Rule 19(6).

5.10 It should also be noted that amendments and corrections comprising marked up changes are generally filed in which claim numbers may be omitted. Such cases may be objected to in the same manner as prescribed in [paragraphs 5.7 and 5.8](#) above.

C. Invention shall be defined in technical terms (Rule 19(7))

- 5.11 Rule 19(7) states that the definition in the claim of the matter for which protection is sought shall be in terms of the technical features of the invention which may be expressed in structural, functional or mathematical terms.
- 5.12 The fact that the technical features of the invention may be expressed in structural, functional or mathematical terms provides the applicant with a great deal of flexibility as to how they choose to define their invention. For example, an invention may be defined in terms of function rather than structure and an objection should not be raised merely on the form of the claim.
- 5.13 Rule 19(7) essentially sets out the requirements under Section 25(5)(a) in order for the claims to define the matter for which the applicant seeks protection. Accordingly, in most cases an objection will refer to Section 25(5)(a) as the statutory basis for such objections. Further details are given below in the discussion of Section 25(5)(a).
- 5.14 An objection under Rule 19(7)/Section 25(5)(a) may be appropriate to be raised in the case of applications that *prima facie* contain patentable subject matter, but where the invention has been defined in a manner that does not include a technical feature disclosed in the specification.
- 5.15 Where the claims comprise definitions of weights and measures, these should be expressed in terms of the metric system, in accordance with Rule 23(20) and Rule 23(21). Rule 23(22) prescribes that temperatures should be expressed in degrees Celsius. It should be noted the the aforementioned rules apply to the rest of the specification as well.

D. Claims drafted in two-part form or as a single sentence (Rule 19(8))

5.16 Rule 19(8) does not prescribe a particular single format to be followed by applicants in all cases. Instead claims can follow one of two formats:

1. A two-part format having the structure of
 - (a) a first part containing a statement indicating the general class of invention followed by a definition of features that appear to be part of the prior art;
 - (b) a bridging phrase (“characterised in that”, “characterised by”, “wherein the improvement comprises” or other words to the same effect); and
 - (c) a second part which is the characterising portion stating the features which add to the prior art.

2. A single statement setting out the features of the invention.

5.17 In the two-part format, there is no requirement that *all* features of the prior art be defined in the first part indicating the general class of invention. The applicant may define only those features that they consider relevant to the invention, and features that the skilled person would understand to be implicit in the invention need not be set out in the claims. For example, a bicycle would be understood to have wheels, a frame and pedals, so a claim to a bicycle incorporating a new type of handlebar arrangement would not need to set out these features.

5.18 If the search discovers prior art disclosing one or more features of the second part in combination with the features of the first part, then these features form part of the prior art and should be transferred into the first part. However, there may be alternative ways for claiming a combination, so the Examiner can take a fairly flexible approach when construing such claims provided the scope of the claim would be clear to the skilled person.

5.19 A claim having two or more sentences and other claim formality issues should be objected to if they are unclear to the skilled person.

E. Omnibus claims (Rule 19(9))

5.20 Rule 19(9) requires that the claims shall not rely, in respect of the technical features of the invention, on references to the description or drawings, unless such a reference is necessary for the understanding of the claim or enhances the clarity or conciseness of the claim.

5.21 Examples of omnibus-type claims that refer broadly to the specification, examples or figures are:

“An infant formula substantially as hereinbefore described with reference to the Examples.”

5.22 Objection should not be taken where a claim refers to sequence listings, tables of atomic coordinates and the like, where recitation of these is necessary for sake of clarity and conciseness. Similarly, if a particular feature cannot be defined in any other manner than by reference to a figure or the like then no objection should be raised. This will include situations such as the invention including a shape (for example, a curved surface) which cannot be defined by means of a formula or the like.

F. Sufficiency of disclosure (Section 25(4) and Section 25(5)(c))

- 5.23 Section 25(4) requires that the specification shall disclose the invention in a manner which is clear and complete for the invention to be performed by a person skilled in the art. Commonly known as the requirement of sufficiency of disclosure or enablement, Section 25(4) is closely related to Section 25(5)(c), which states that the claim or claims should be supported by the description.
- 5.24 Section 80(1)(c) states that a patent may be revoked if the specification of the patent does not disclose the invention clearly and completely for it to be performed by a person skilled in the art. Therefore, non-compliance with Section 25(4) is a ground for revocation of the patent under Section 80(1)(c), and unlike Section 25(5)(c) which can only be applied pre-grant, there is a large amount of case law that relates to Section 80(1)(c) that can be applied to the analysis of Section 25(4). Because Section 25(4) and 25(5)(c) are closely related, certain aspects of enablement will be considered alongside support in the discussion on the disclosure of the invention below.
- 5.25 It is not common for an objection to be raised under Section 25(4) pre-grant. The Examiner should give careful consideration when making a sufficiency of disclosure objection, and should reserve such objections for those instances where the invention cannot be readily enabled by narrowing the scope of the monopoly claimed. Usually the invention will also lack support, and Section 25(5)(c) can also be considered as well (this will become apparent when Section 25(5)(c) is discussed below).
- 5.26 The determination of whether a disclosure is sufficient is highly sensitive to the nature of the invention (*Dien Ghin Electronic (S) Pte Ltd v Khek Tai Ting* (trading as Soon Heng Digitax) [2011] SGHC 36, *Kirin-Amgen Inc v Hoechst Marion Roussel* [2005] RPC 9). Thus, the general approach to determine whether a specification complies with the requirements of Section 25(4) is to identify the invention and what it claimed to enable the skilled person to do, and then ask whether the specification enabled him to do it.

- 5.27 The specification must provide sufficient disclosure across the full scope of the claims (*Chiron Corp. v Murex Diagnostics Ltd* [1996] RPC 535). At least one embodiment of the invention or at least one method of performing the invention must be described according to Rule 19(5)(e). If the claims themselves provide an enabling disclosure and are supported by the description, then this may provide a sufficient disclosure. In many cases a single example or embodiment will suffice, but where the claims cover a broad field several examples or alternative embodiments or variations extending over the area to be protected by the claims may be necessary. The disclosure of one method of preparation of a product may provide sufficient disclosure for a claim to a single compound (*Generics (UK) Limited and others v H Lundbeck A/S* [2009] RPC 13).
- 5.28 However, if the invention is unpredictable in nature then more detail may be required. For example, where the specification claims a synergistic combination and gives little or no guidance on, for example, appropriate concentrations or ratios of the compounds that will provide the synergistic result, it may impose an undue burden on the person skilled in the art to test all possible combinations to determine those that fall within the scope of the claims.
- 5.29 Claims using functional definitions or that define the invention in terms of a desired result are dealt with in the same manner as any other claim. The specification should provide sufficient information for the skilled person to determine whether or not they have achieved the defined result without undue experimentation and without exercising any inventive ingenuity. For example, a specification defining a device in terms of an improved effect without specifying the degree of improvement and how it could be obtained would be considered insufficient (*Birtcher Medical Systems' Patent* BL O/70/96).
- 5.30 The specification does not need to disclose all the details required to work the invention if these would be known or obvious to the skilled person. In *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] RPC 2, Pumfrey J stated that the straightforward test for sufficiency is whether the specification required the addressee to carry out tests or developments that went beyond routine trials. One approach is to ask whether the skilled person would need to discover something new in order to work the invention (*Edison and Swan Electric Light Co v Holland*, 6 RPC

243 at page 282). It follows that the specification must disclose features that are essential to carry out the invention or provide sufficient detail for the skilled person to work the invention without needing to undertake further invention to do so. These principles were affirmed in *Ng Kok Cheng v Chua Say Tiong* [2001] SGHC 143.

5.31 Some examples of such considerations are as follows:

Reference to an “autoclave” in the specification without specifying the material of which it is made could be insufficient if it is necessary for the invention to work that the autoclave be made of iron rather than the usual enamel type (*Badische Anilin and Soda Fabrik v La Societe etc du Rhone*, 15 RPC 359).

In *Mayne Pharma v Debiopharm and Sanofi-Synthélabo* [2006] EWHC 1123 (Pat), the description related to the preparation of a stable form of oxaliplatin which involved the use of “an effective stabilising amount of a buffering agent selected from oxalic acid or an alkali metal salt thereof”. In this instance, Pumfrey J considered that:

“When one is confronted with a claim which requires ‘an effective stabilising amount’ of a material, it must be possible to design a test which can answer the question ‘Have I used such an amount or not?’. There will always be problems on the edges of claim, but it should in general, be possible to know what the test is. If one cannot identify the test on the basis of the disclosure, then I think that the disclosure is insufficient”.

In this case, the answer to the test was that “you don’t have to add any at all”, and as a consequence the description was found insufficient.

5.32 In *Chiron Corporation v Organon Teknika Ltd* [1994] FSR 202, claims to a vaccine were found invalid as it took the applicants several years after the filing of the application to develop a vaccine. The description was therefore insufficient as it did not provide sufficient information for a skilled person to repeat the invention without invention.

5.33 A specification claiming a surgical suture made of a particular polymer did not disclose the step of drying the polymer and freeing it from undesired monomer.

However, the Court found the patent to be sufficient as these were steps which “the instructed reader desirous of achieving success could be expected, if necessary, to take” (*American Cyanamid v Ethicon* [1979] RPC 265).

- 5.34 Errors in the specification will not result in a lack of sufficiency provided they are **obvious** errors that the skilled person would have recognised and have known how to correct. For example in *Ng Kok Cheng v Chua Say Tiong* [2001] SGHC 143, the Court dealt with such an error in the following manner:

“It was obviously an error to use the word ‘through’ in the claim in such a way that it could be argued that ‘through’ applied to both the main body as well as the auxiliary body where the drawings and the prior art, made it quite clear that such could never have been the intention of the inventor. This error could, however, be readily corrected by the skilled performer in the art in the process of making the invention.”

G. Deposit of Micro-organisms

- 5.35 For inventions that require for their performance the use of micro-organisms which is not available to the public at the date of filing the application, and which cannot 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 specification shall, in relation to the microorganism itself, be treated as disclosing the invention, if one of the conditions set out in sub-paragraph (2) of the Fourth Schedule to the Patents Rules is satisfied.
- 5.36 The Patents Act and the Patents Rules does not provide a definition for the term “micro-organism”. This term is also not defined in the Budapest Treaty (the Treaty on the International Recognition of the Deposit of Micro-organisms for the purposes of patent procedure done at Budapest in 1977). For the purposes of Section 114 Patents Act, Rule 20 and the Fourth Schedule of the Patents Rules, Examiners should regard biological materials that have been successfully accepted for deposit with any international depository authority as defined in the Fourth Schedule of the Patents Rules, as “micro-organisms”.
- 5.37 Section 114 prescribes that the Rules may require that 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 micro-organism; and (b) not to impose or maintain restrictions on the uses to which such samples may be put, except as may be prescribed. A warning is also provided in Section 114(5) that an application for revocation of the patent under Section 80(1)(c) may be made if any of the requirements pertaining to making samples of micro-organisms available in accordance with the Rules ceases to be complied with. Therefore, the applicant or patentee has to be mindful of the requirements relating to availability of the deposited micro-organism during the application of the patent as well as for the duration of the patent, in accordance with Fourth Schedule of the Rules.
- 5.38 Where a deposit was made, Examiners are to check that the name of the international depository authority, the date when the culture was deposited and the accession number of the deposit are provided in the specification of the application.

- 5.39 When an application claims priority to an earlier application and the invention relies upon a deposit for sufficiency purposes, the deposit should have been made not later than the date of filing of that earlier application (T 0107/09 Bristol-Myers Squibb/CD40CR receptor and ligands thereof). Otherwise, priority cannot be claimed for the subject matter where deposit is required in order for the matter to be sufficiently disclosed.
- 5.40 In cases where the biological material used in a process is well known and the process can be adequately described by written description, then as long as the process can be performed in a repeatable manner, even if the final product is a new biological material, a deposit may not be required as long as the product can be prepared without undue burden by a skilled person by following the written description.

H. Claims shall define the matter for which protection is sought (Section 25(5)(a))

- 5.41 Section 25(5)(a) requires that the claim or claims shall define the matter for which the applicant seeks protection. As noted above, Rule 19(7) requires that this is done by using the technical features of the invention which may be expressed in structural, functional or mathematical terms.
- 5.42 The claims should not contain any statements relating, for example, to commercial advantages or other non-technical matter. However, this should be applied narrowly – for example, a definition of a particular property using a comparison with a commercial product would generally not constitute a statement of commercial advantage. For example, a functional definition such as “wherein the antibody binds with pKa greater than (known) antibody X” would not be considered a statement of commercial advantage but rather a reference by which the scope of the claim may be determined.
- 5.43 However, an objection will arise where the claim does not define **any** technical features and instead uses statements of a non-technical nature such as:

“My invention will solve world poverty.”

“My invention is worth a million dollars.”

Such claims are most likely to be filed by applicants who are not represented by an attorney.

- 5.44 This consideration is also related to that of inherent patentability since such claims do not define a technical feature. Where the Examiner considers that the application discloses patentable subject matter but the claims have simply been poorly drafted (such as in the examples above) an objection under Section 25(5)(a) will be appropriate. However, if there is no apparent patentable subject matter in the application then an objection that said application does not relate to an invention may be more relevant.

I. Clarity and conciseness of claims (Section 25(5)(b))

- 5.45 Section 25(5)(b) requires that the claim or claims shall be clear and concise. The test for clarity is whether the skilled person would have difficulty in understanding the language used (*Strix Ltd v Otter Controls Ltd* [1995] RPC 607). The requirement applies to both the claims as a whole and to individual claims.
- 5.46 However, no objection should be raised merely on the basis that a clearer definition could be provided. The key consideration is whether the skilled person together with the surrounding common general knowledge in the art would be able to understand the meaning of the terms. A degree of imprecision is permissible provided it would be clear to the skilled person (*General Tire v Firestone* [1971] RPC 173, upheld on appeal in [1972] RPC 457).
- 5.47 Claims may be considered to be unclear simply due to its wording, such as by the use of relative terms (wide, thin, thick), or unclear antecedents or dependencies and such defects can usually be rectified by simple amendments.

i. Indefinite terms

- 5.48 A degree of indefiniteness is permissible in claims. Indeed, a purposive construction according to the principles discussed in *Catnic* allows for such imprecision in some cases.
- 5.49 The appropriateness of imprecise terms such as “**substantially**”, “**about**”, “**more or less**” and “**approximately**” will depend on the specific circumstances of the case. For example, the definition of a temperature of “about 50 degrees” may be appropriate since in practical terms the person skilled in the art would not expect that precise temperatures could be achieved under standard operating conditions. Where terms such as “about” are used, the degree of variance from the defined value will depend on what the person skilled in the particular art would understand it to mean. In the case of a temperature of about 50 degrees, this might mean 51 or 52 degrees. However, in a definition of about 20K there may be a more significant variance. Conversely, in a feature defined to several decimal points, the degree of variance may be more restricted.
- 5.50 In some cases the use of indefinite terms is objectionable. For example, a definition of a radical having “about 6 carbons” in a chemical compound would be unclear since in the chemical field a more precise definition might be expected. This may be a different consideration in the area of polymers where a product may comprise a mixture of polymers of various lengths.
- 5.51 In general, an objection should only be raised if the use of an indefinite term introduces an ambiguity in the scope of the claim (that is, the skilled person would be unable to reasonably determine the scope of the claim), or if the invention is not clearly distinguished from the prior art with respect to novelty and inventive step (such as where there is only a relatively small difference between the range defined in a claim and a disclosure in the prior art – usually in combination with a consideration of inventive step).
- 5.52 Generalising expressions such as “substantially” may be allowable if it does not render the scope of the claims indeterminate. If the word “substantially” merely indicates that the patentee is not limiting his monopoly to that precisely shown in the drawings and description, then the term may be allowable.

ii. Relative terms

- 5.53 A claim should not use a relative term such as “**thin**”, “**wide**”, “**strong**” and the like unless the term has a well-recognized meaning in the particular art, for example “high-frequency” in relation to an amplifier, and this is the meaning intended.
- 5.54 If a relative term appears in a claim, the Examiner should consider whether the skilled person would be able to determine the scope of the claim either by following a standard disclosed in the description for measuring the degree of that relative term or in view of the common general knowledge in the art. However, even if a standard (for example an ISO-type standard) is provided, this may not provide sufficient clarity since different international standards may exist, or such standards can change over time.

iii. “Preferred” and “optional” definitions

5.55 The terms “**such as**”, “**for example**”, “**preferably**”, “**particularly**” or “**more particularly**” generally will not introduce ambiguity into the claims – the scope of the claim will be set out by the broader definition, with the subsequent narrower terms merely being preferred embodiments that do not limit the scope of the claim. An objection (lack of clarity) should only be raised if the scope of the claim is rendered unclear. For example, if one of the optional features does not fall within the scope of the broader definition then an objection should be taken. For example:

“wherein the colour is a primary colour, preferably red, orange or yellow, more preferably pink”

In this case, the optional features introduce a lack of clarity since the claim defines the colour broadly to be a primary colour but pink (a non-primary colour) is given as an option (a similar issue would arise if pink was provided as a preferred embodiment in an appended claim).

5.56 The term “**and the like**” may cause a lack of clarity in some cases. For example, a definition such as “domestic pets including cats, dogs and the like” could be interpreted in different ways. “and the like” could mean including other domestic pets (e.g. birds, fish, reptiles). However, it could also mean other mammalian domestic pets (e.g. mouse, hamster, horse). These expressions should be objected to **if** they cast doubt on the scope of a claim.

5.57 Terms like “**generally**”, “**typically**”, “**in some cases**” in a claim may be a source of ambiguity as they define the scope in uncertain terms. If the scope of the claim is rendered unclear to the skilled person by using such terms, then an objection should be taken.

5.58 Terms such as “**optionally**”, “**if desired**”, “**when required**” suggest that the component, part or condition to which they relate is optional, not essential. If the term relates to a non-essential element, then it is immaterial to the working of invention, and no objection should be taken. However, if the element is deemed essential, an objection should be made. This is likely an objection of lack of support instead of lack of clarity – the claim does not include an essential feature.

iv. Lack of antecedent

5.59 Lack of antecedent arises where a definition refers to a previously undefined term, for example:

“A device for cracking nuts consisting of a cup shaped base and a striker element, said lever tripping the hammer at timed intervals.”

5.60 In this claim, there are no proper antecedents for “said lever” and “the hammer”. In general, an objection for lack of clarity should be taken when the person skilled in the art would be unable to determine the scope of the claim.

v. Ranges

5.61 The following defects can arise in the use of ranges in a claim:

- (1) 0% to X% of a constituent

A claim must include all of the essential features of an invention and define an operative arrangement. A lower limit of 0% means that the ingredient may or may not be present. Thus, a range comprising 0% should not be permitted if the element is essential to the invention, or if the claim would encompass an inoperative composition of matter for the purpose taught.

Further, in the case of a composition, a claim must define a minimum of two ingredients, at least broadly. If two ingredients are recited, but one of them is defined with a lower limit of 0%, then only one ingredient is properly defined by the claim ([see sub-section vi of Section I in this Chapter](#)).

- (2) Components do not add up to 100%

5.62 In a composition claim comprising ranges (by weight, by volume, etc...), the sum of the lower and/or upper bounds of the ranges for the components must be able to be combined to reach 100%.

- (3) Ranges not specifically disclosed

5.63 When an application includes claims containing a specific limitation with respect to operating conditions, which limitation falls within a broader range disclosed, no objection should be made to the narrow claim solely on the grounds that it is not specifically shown in the description, or that the description does not indicate the significance of the disclosed range.

5.64 For example, an application may disclose a process carried out within certain temperature limits, say between 1000°C and 1500°C. No objection should be made if some claims are directed to the process carried out between 1000°C and 1500°C and others to the process carried out at a temperature falling within a smaller range within

the disclosed range; say between 1200°C and 1300°C. However, should the broader claims fall in view of prior art, the narrower claims would also fall unless it can be shown that by restricting the process to the narrower range, a new and unobvious result is obtained, e.g. a selection invention ([see sub-section viii of Section I in Chapter 4](#)).

- 5.65 In *Auchincloss and another v Agricultural & Veterinary Supplies Ltd. and Others*, [1997] RPC 649, a departure from stated range is not considered to be a variant in the *Catnic* sense; i.e., the applicant is held to the “literal meaning” of their stated range. This was in the case of a claim to a biocidal composition comprising a formulation of a number of ingredients in varying amounts, where each of the ingredients was stated to be used in amounts within the specified ranges.
- 5.66 However, Aldous L.J. in *Lubrizol Corp. v. Esso Petroleum Co. Ltd* [1998] RPC 727 at [748] held that a claim to “at least 1.3 succinic groups” include 1.28 or 1.29 succinic groups. In other words, the claim was not construed as a claim to at least 1.30 succinic groups but to 1.3 rounded. Similarly, Pumfrey J in *Halliburton Energy Services Inc v Smith International (North Sea) Ltd*, [2006] RPC 2, construed a claim to “between 31% and 35% of the total axial force” to mean the number is specified to two significant figures, so including 30.5% to 35.4%, or 30.50% to 35.49%, or 30.500% to 35.499%.
- 5.67 Therefore, the Examiner has to consider how the skilled person would construe a claimed range in the case under examination. This was summarized by Mr David Young QC (sitting as Deputy judge) in *Goldschmidt v EOC Belgium* [2000] EWHC Patents 175 at [91] and [92] as follows:

“The evidence is that pH is generally measured by a pH meter and in an industrial plant to one decimal point. The pH values for each of the Examples in the patent are also recorded to one decimal point. This is to be contrasted with the claimed pH range of from 5 to 8.

I consider that one skilled in the art when viewing a pH range of 5 to 8 would not have read such figures as being 5.0 to 8.0 but would have understood them to be to one significant figure only ... It is also consistent with comparative Example

A4 having a pH of 8.6. In other words when construed purposively, the lower limit pH of 5 is to avoid corrosion problems caused by a pH of below 4.5 and the upper pH limit of 8 is to avoid solidification above a pH of 8.5.”

5.68 Consequently, if the Examiner considers the claimed range to be unclear to the skilled person, a clarity objection should be raised.

vi. Compositions with only one ingredient

5.69 A claim to a composition characterised only by a single ingredient will be interpreted to include the ingredient *per se* – that is without any additional components. This is unlikely to result in an objection of lack of clarity, but it will be a relevant consideration for novelty assessment.

vii. Multiple alternatives

- 5.70 The term “**and/or**” is not always objectionable. The phrase “**A and/or B**” can mean three things: A, B or A+B. As long as each of these conditions is acceptable and the scope of the claim remains clear, then the claim is allowable.
- 5.71 However, if the term appears twice in a claim, such as (A and/or B) and (X and/or Y), there are 9 different conditions that must be verified, and the task becomes more onerous and other issues such as clarity, unity and support may arise. Generally, overuse of the term may call for an objection on the ground that the scope of the claims for which protection is being sought is unclear. This will depend on the specific circumstances of the case and the number of potential alternatives defined.
- 5.72 More substantive clarity issues arise where there are internal inconsistencies between the claims.

viii. Inconsistencies between claims and description

- 5.73 Section 113 prescribes that the extent (scope) of protection conferred is determined in accordance with the claims of the application, as interpreted by the description and any drawings contained in the specification.
- 5.74 Therefore, the description should not contain material that renders the scope of the claimed invention unclear. Thus, if embodiments are provided that do not fall within the apparent scope of the invention then it should be made clear that these are intended for comparative purposes and are not intended to be claimed. Similarly, statements in the description that purport to extend the scope of the claims (such as “the invention should be taken to include modifications...”) should be avoided. For example, when a claim is directed to a compound, then terms such as solvates, metabolites, prodrugs, derivatives and similar terms which are not claimed and which make the boundary of the compound claim unclear, should be removed from the description. This is consistent with the decision in *American Home Products vs Novartis Pharmaceuticals* [2000] EWCA Civ 231, where the Court had construed a claim to rapamycin as encompassing within its scope derivatives of rapamycin in view of a passage in the description. With respect to compounds and formulae which are not claimed, it should be clear from the description that they are not part of the embodiments of the invention. However, removing the unclaimed compounds and formulae from the description may not be necessary if the scope of the compound claim can be clearly determined when it is read together with the description.
- 5.75 In cases where, as a result of amendment, there are specifically described embodiments or statements in the description and drawings which are inconsistent with the claims, a clarity objection to the claims should be raised *if such inconsistency would throw doubt upon the scope of protection sought by the applicant*. It is up to the applicant how this objection (if raised) 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 latter approach may be preferable in a situation where embodiments falling within the claims are partly described with reference to such matter. On the other hand, if the applicant, by way of submissions in

response, can show persuasively that the scope of the claims would be clear to a person skilled in the art, then the objection should be withdrawn.

J. Claims shall be supported by description (Section 25(5)(c))

5.76 Section 25(5)(c) states that the claim or claims shall be supported by the description. In practice, this means that:

- (a) the scope of the claims should be justified by the disclosure provided by the description, drawings and sequence listing, and in particular “**should not extend to subject matter which, after reading the description, would still not be at the disposal of the person skilled in the art**” (*Generics (UK) Ltd v Lundbeck A/S* [2009] RPC 13 at [36]; and
- (b) the specification must provide a disclosure that enables the invention to be performed across the breadth of the claims. (*Asahi Kasei Kogyo KK’s Application* [1991] RPC 485).

5.77 Most claims will represent a generalisation of the inventive concept. The extent to which that generalisation is supported will vary from case to case. Thus, as stated by Lord Hoffmann in *Biogen Inc v Medeva Plc* [1996] UKHL 18:

“... 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 of the same 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: see *May & Baker Ltd v Boots Pure Drug Co Ltd* (1950) 67 RPC 23, 50. 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.”

5.78 Consistent with this approach, an applicant may claim more broadly than the specific embodiments set out in the description, including obvious variants, technical equivalents and the like. One way of approaching this is whether the skilled person would predict that such variants and equivalents would have the same properties as those specifically described. Notably this may differ between where the invention is in a well-worked art and where the invention is in a new field. In some cases the scope of

terms in a well-worked art may be narrower as there is more certainty as to the types of variants that may be substituted for certain features. In a newer field, it may be less predictable so more flexibility may be given to the drafting. However, if there is insufficient enablement across the full scope then an objection of lack of support may arise.

- 5.79 Where the invention relates to a “principle of general application” the claims may be in correspondingly broad terms. The applicant need not show that they have proved its application in every individual instance. On one hand, if the claims include a number of discrete methods or products, the applicant must enable the invention to be performed in respect of each of them. On the other hand, inventions consisting of a single embodiment, such as a single chemical compound, will generally be supported (*Generics (UK) v H Lundbeck A/S* [2009] RPC 13 at [25]).
- 5.80 Particular types of claims will often be more likely to involve a consideration of whether there is sufficient support: broad claims, claims by result, claims in which features are defined by function and reach through claims. While these are dealt with specifically in the Guidelines it should be noted that no special rules exist for such claims and they should be construed as per any other type of claim.

i. Mere coincidence of language is not sufficient

5.81 More than just a mere coincidence of language is needed between the claims and description to meet the requirement that the claims are not broader than justified by the description and drawings. As noted by Aldous J in *Schering Biotech Corp's Application* [1993] RPC 249 at [252]-[253]:

“to decide whether the claims are supported by the description, it is necessary to ascertain what is the invention which is specified in the claims and then compare that with the invention which has been described in the specification. Thereafter the court’s task is to decide whether the invention in the claims is supported by the description. I do not believe 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.”

5.82 Where the subject matter is clearly disclosed in a claim but not elsewhere in the specification it may be permissible to amend the description to incorporate such matter. The key consideration will then be whether the amendment introduces additional matter.

ii. The technical contribution

5.83 In *Biogen Inc v Medeva Plc* [1996] UKHL 18, Lord Hoffmann noted that it is a long-established principle of UK patent law that:

“... the specification must enable the invention to be performed to the full extent of the monopoly claimed. If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms. The patentee need not show that he has proved its application in every individual instance. On the other hand, if the claims include a number of discrete methods or products, the patentee must enable the invention to be performed in respect of each of them.”

He further stated that:

*“the extent of the patent monopoly, as defined by the claims, should correspond to the **technical contribution to the art** in order for it to be supported, or justified.”*

5.84 One means of identifying the technical contribution to the art is to determine what is new and non-obvious (*Generics (UK) Limited and others v H Lundbeck A/S* [2009] UKHL 12; [2009] RPC 13 at [30]). In this case, Lord Walker noted that the terms “inventive concept” and “technical contribution to the art” are not synonymous. In particular he noted that in *Biogen*, Lord Hoffmann used these expressions several times – “inventive concept” in relation to inventive step and “technical contribution in the art”. Lord Walker stated that:

*“‘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.”*

5.85 In *Biogen*, Lord Hoffmann considered there is more than one way in which the breadth of the claim could exceed the technical contribution to the art of the invention (at paragraph 71):

“The patent may claim results which it does not enable, such as making a wide class of products when it enables only one of those products and discloses no principle which would enable others to be made. Or it may claim every way of achieving a result when it enables only one way and it is possible to envisage other ways of achieving that result which makes no use of the invention.”

5.86 Thus, in general lack of support may be a consideration in the following situations:

(1) the description does not provide sufficient enablement across the full scope of the claims. This is likely to be an issue where the claim is so broad as to include a number of alternative products and there is no apparent principle of general application;

(2) the claims encompass other matter that is unconnected to the invention. This was expressed in *Biogen* as:

“it is not whether the claimed invention could deliver the goods, but whether the claims cover other ways in which they might be delivered: ways which owe nothing to the teaching of the patent or any principle which it disclosed.”

(3) the invention is defined in terms of a desired result or known goal, but the invention lies in the particular means by which that goal has been achieved.

(4) there is a serious inconsistency between the claims and description in as much as the claims lack an essential feature of the invention.

iii. The enablement requirement

5.87 A claim will lack support if the description does not provide an enabling disclosure of the claimed invention (*Asahi Kasei Kogyo KK's Application* [1991] RPC 485) – that is, it must provide sufficient information that enables the invention to be performed by the person skilled in the art across the breadth of what is claimed without undue burden of experimentation or the need for further invention.

5.88 A feature in the claims will be sufficiently enabled if, *prima facie*:

The disclosure teaches a principle that the person skilled in the art would need to follow in order to achieve each and every embodiment falling within a claim; and the specification discloses at least one application of the principle and provides sufficient information for the person skilled in the art to perform alternative applications of the principle in a way that, while not explicitly disclosed, would nevertheless be obvious to the person skilled in the art (*Kirin-Amgen Inc. v Hoechst Marion Roussel Ltd*, [2005] RPC 9 at [112]).

5.89 If the invention relates to a single product *per se* the disclosure of one method of making the product provides an enabling disclosure across the full scope of the claim. The applicant is not required to provide all possible methods of making the product (*Generics v Lundbeck* [2009] UKHL 12; [2009] RPC 13 at [80]). For example if the invention relates to a single compound and the specification provides one method of how it may be prepared, the specification is generally considered to provide sufficient support for a claim to the compound *per se*.

5.90 Where the claims relate to a number of discrete processes or products, the consideration is whether the enablement of one of these provides enablement of the others. Where there are different embodiments, each must be sufficiently disclosed and enabled. (*Chiron Corp. and Ors v Murex Diagnostics Ltd and Ors* [1996] RPC 535 at [612-613]). For example, the definition of a “connecting means” may be enabled if the skilled person would reasonably expect the invention to work with any means of connection. However, it would not be necessary in such a case for the specification to show that a broad range of other connectors would work. However, a

broad claim for apparatus for “influencing” substances by means of high frequency electrical energy may not be supported if it includes any kind of influence on any kind of substance (*Esau’s Application* 49 RPC 85). In this situation, the disclosure of a single embodiment will not always satisfy the requirement for an enabling disclosure (see also *Biogen v Medeva* [1996] UKHL 18 at [22]). Whether the skilled person would be required to undertake an undue burden of experimentation in order to achieve the invention may also be a consideration.

5.91 For example, a claimed product comprises two components, each selected from separate vast lists. To perform the invention, the person skilled in the art is required to select a pair of components to achieve particular desirable characteristics in the final product. In this situation, the specification would lack an enabling disclosure where:

- (1) the specification contains little or no guidance on how to select a pair of components which would achieve the desired characteristics in the resulting product; and/or
- (2) the specification provides no information on how the desirable characteristics could be measured or otherwise determined in a product containing any pair of components.

In such cases, performing the invention over the entire scope of the claims may be considered to impose an undue burden on the skilled person. However, by narrowing the scope of the claims to a specific pair of components, the invention may be performed by the skilled person. Nevertheless, care should be taken to ensure that there is basis in the specification as filed for this narrower claim to avoid added matter. If there is no basis for a narrower claim then an objection under Section 25(4) may be more appropriate.

5.92 The following claim was found to be unsupported in *Pottier’s Application* [1967] RPC 170:

“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.”

In this case, the description only showed the treatment of sugar beet seedlings and there was no basis on which the treatment of sugar beet could be applied to other plants generally.

iv. Inconsistencies – essential features

5.93 A lack of support may arise where there is a serious inconsistency between the description and claims. In particular, the claim should include all of the essential features of the invention in order to be supported. These are the features that have a material effect on the way an invention works. A feature may be considered to be essential if:

- (1) it is evident from a reading of the description that a particular feature materially affects the way an invention works;
- (2) the description clearly states that a particular feature is essential;
- (3) the description says or implies, e.g. by its object clause in the Summary of the Invention, that the features are essential to the invention and cannot be omitted from the claims; and
- (4) when a functional clause (e.g. whereby clause) appears in a claim which promises a result to be achieved, then an element required to achieve that result is considered essential.

5.94 Non-essential features are those that have no material effect on the way an invention works. Generally, if there is no working interrelationship, or potential working interrelationship, between a given feature and the other features recited in the claims, then that feature does not usually materially affect the way that the invention works. It is not necessary to set out in the claims all the non-essential elements that may make a combination workable. For example, a claim to an article for conditioning fabrics in a laundry dryer and comprising a flexible woven or non-woven sheet having on it areas of fabric conditioning composition was found to lack support as the description indicated that it was an essential feature of the invention that the material was permeable to air (*Glatt's Application* [1983] RPC 122).

5.95 Similarly, a claim may define a particular method of treating “synthetic resin mouldings” to obtain changes in physical characteristics. If all of the examples described related to thermoplastic resins and the method appeared unsuitable for thermosetting resins, then it may be an essential feature of the invention that thermoplastic resins are used. However, it should be remembered that the applicant does not need to exemplify each and every embodiment they claim – in cases such as this it must be clear that the feature is essential to the invention.

v. Claims by result

5.96 Claims by result generally define the invention in terms of a desired outcome or property. For example:

“Modified protein X having binding activity more than the unmodified protein X.”

5.97 In this case, the inventor may have found a particular way of modifying protein X to produce greater binding activity, but has attempted to claim all modified forms of the protein that exhibit this greater binding activity. Depending on the facts of the case, this may or may not be an allowable type of claim.

5.98 In particular, where a claim defines the invention in terms of desirable results the specification will need to provide enough instruction for the skilled person to make each product and/or work all the processes that are encompassed by the claim, without undue burden or the need for further invention. An objection should not be raised merely on the basis that the claim defines the invention in terms of a desired result. The usual considerations of whether the specification enables the full scope of the claim and whether the claims encompass matter that owes nothing to the teaching of the invention will apply.

5.99 “**All means**” claims may also be allowable if the invention lies in the identification of the problem. In *David Kahn Inc v Conway Stewart & Co Ltd* [1974] RPC at [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.”

5.100 Thus for example, in *No-Fume Ltd v Frank Pitchford Co Ltd* [1935] 52 RPC 231, an “**all means**” claim of the following form was considered supported:

“An ash tray receptacle which without the use of movable parts, retains the smoke arising from objects thrown into it.”

In this case, it was determined that the invention could not be adequately characterised in any other manner. Furthermore the invention could be realised by using dimensions other than those specifically disclosed in the specification, and the skilled person could determine these without any inventive ingenuity.

5.101 In contrast, a claim to the use of **all** vectors producing a certain result may not be supported if the invention is the use of a particular new insert in a vector to produce a polypeptide having a certain activity (*Schering Biotech Corp’s Application* [1993] RPC 249).

5.102 Similarly, in *N V de Bataafsche Petroleum Maatschappij’s Application* [1956] 57 RPC 65, the claim broadly defined that an aqueous dispersion of a bituminous substance forming part of a mixture which penetrated the soil and coagulated therein was “suitably stabilized”. The specification provided no instructions as to how this was achieved and as a consequence the claim was found to lack support. In this case, the Court followed the guidance of Lord Parker in *British United Shoe Machinery Co Ltd v Simon Collier Ltd* 26 RPC 21 at [49]-[50]:

“The problem was simply how to do automatically what could already be done by the skill of the workman. On the other hand, the principle which the inventor applies for the solution of the problem is the capacity of a cam to vary the relative positions of two parts of a machine while the machine is running. Assuming this principle to be new, it might be possible for the inventor, having shown one method of applying it to the solution of the problem, to protect himself during the life of his patent from any other method of applying it for the same purpose, but I do not think that the novelty of the principle applied would enable him to make a valid claim for all means of solving the problem whether the same or a different principle were applied to its solution.”

5.103 Thus, if the problem is known, then the invention cannot lie in identifying the problem. In such cases the claims will need to be limited to the particular features that the inventor has found to solve the problem.

vi. Features defined by function

5.104 Claims will often define one or more elements of a claim in terms of what it **does** rather than what it **is**. The monopoly includes any elements that will achieve this desired result, e.g. “fastening means”, “braking means”. The following claim was found to acceptable in *Lightening Fastener v Colonial Fastener* [1934] 51 RPC 349:

“A machine for making fasteners having means for feeding a tape step by step, means for feeding fastener members into position to be compressed on to said tape, and means for compressing the fastener members thereon.”

5.105 Claims may also define a desired result from the combination of one or more features, often indicated by a “whereby” clause, in which, after the claimed elements are set out, the result flowing from the use of these elements is defined, for example “... whereby the fluid passes from the first tank to the second tank.”

5.106 Claims may broadly define features in terms of their function, even where only one example of the particular feature has been given in the description, provided the skilled person would appreciate that other means could be used for the same function. However, if on a reading of the application it appears that the function must be performed in a specific manner, then the claim may lack support (*American Home Products Corp v Novartis Pharmaceuticals UK Ltd* [2001] RPC 8 at [39]-[43]). In this regard, vague references or general statements in the specification may not be sufficient, particularly if it is not reasonably clear what the alternatives might be or how they might be used.

5.107 Since functional claims are generally broader than claims reciting structural elements, the Examiner should be certain that the claims are neither ambiguous nor unduly broad. The judgment should be made as to the technical contribution made by the invention, and whether the claim goes beyond that contribution.

vii. Parametric claims

- 5.108 Parametric claims comprise definitions of specific parameters, such as directly measurable physical properties or mathematical combinations of several variables in the form of formulae. At first instance, the key consideration for such claims is likely to be novelty ([see Section K in Chapter 3](#)).
- 5.109 With respect to clarity, the consideration for such claims is whether the specified parameters would introduce ambiguity to the scope of the claims to the extent that no meaningful comparison with the prior art can be made. If it is considered unclear to the skilled person which products do indeed possess the parameters required and therefore would fall within the scope of the claims, a lack of clarity objection should be raised. For example, applications in which non-accessible apparatuses are used for measuring the specified parameter(s) are *prima facie* objectionable on grounds of lack of clarity, as no meaningful comparison with the prior art can be made. Such applications might also disguise a lack of novelty. A clarity issue may also arise in the event where the scope of the claimed subject matter might vary when different measurement methods are used for characterizing the specified parameters. In principle, a clear disclosure in the specification of the measurement method is necessary for the unambiguous definition of the parameter, unless a person skilled in the art would know what method to use (e.g. because there is only one method, or because a particular method is commonly used) or all known methods would yield the same result. It is generally considered unnecessary to recite the method of and the means used for the characterization of the specified parameters in the claims; however, such characterization methods and means should be clearly determined by the skilled person when reading the specification as a whole.
- 5.110 Depending on the facts of the case, parametric claims are in effect claims by result which may be subject to lack of support/sufficiency objections. The usual considerations are whether the claims encompass matter that owes nothing to the teachings of the invention in the specification. If it is considered that the skilled person would be faced with undue burden to arrive at the full scope of the claim by following the exemplification given in the specification or procedures common in the art, a lack of support/sufficiency objection should be raised. Admittedly, there is a delicate

balance between the considerations for clarity and lack of support/sufficiency, which have to be assessed based on the facts of each individual case. Objections should not arise merely on the basis that parameters not known in the prior art are used in the claims. In the event it is evident from the specification that the skilled person would face no difficulty in carrying out the characterization disclosed and would be able to establish the exact meaning of the specified parameters (see for example decision T 231/01), use of such parameters would be allowable.

viii. Reach-through claims

5.111 Reach-through claims generally occur where an invention relates to an upstream or platform technology, and the claims are drafted in such a way as to claim future downstream innovations that make use of that technology. The claims are essentially “reaching” through to claim matter that is not actually disclosed in the specification, but may be developed using the invention.

5.112 Reach-through claims have most often arisen in the field of biotechnology. A common situation involved screening techniques and claims of the following type:

1. Purified receptor X having SEQ ID NO 1.
2. Method of screening for inhibitors of receptor X comprising the following steps ...
3. Inhibitors identified by the method of Claim 2.

In this case, Claim 3 is a reach-through claim. This covers any inhibitors that are identified by the screening method, but in most cases the description will enable few, if any, specific inhibitors. This raises two issues:

- (1) if the specification screens libraries of known compounds then the mere identification of a new property of a known compound will not confer novelty on that compound. The claim will lack novelty;
- (2) enablement will only be provided for any specific compounds (or classes of compounds) disclosed in the description. It would otherwise be an undue burden for the skilled person to isolate and characterize all potential compounds, without any effective pointer to their identity. A claim is insufficient if the specification merely constitutes an invitation for the skilled person to perform a research programme (*Eli Lilly v Human Genome Sciences* [2012] EWCA Civ 1185).

5.113 There is no case law from Singapore or Europe that relates specifically to reach through claims, however, there is a consensus that such claims are not allowable as their scope extends beyond what has been disclosed in the description (see, for example, the trilateral report on reach through claims, <http://www.trilateral.net/projects/biotechnology/B3b.pdf>). This practice was also affirmed in the judgment of the US Federal Court of Appeal case *University of Rochester v G.C Searle & Co* 358 F.3d 916 (Fed. Cir. 2004).

K. Disclosure of the invention

i. Enabling disclosure

5.114 The claims play an important role since they define the scope of the monopoly conferred by a patent. However, the grant of an exclusive monopoly to an applicant is in exchange for a full disclosure of the invention and how it may be worked. The importance of a sufficient disclosure and the consequences of insufficiency in revocation were discussed in *Ng Kok Cheng v Chua Say Tiong* [2001] SGHC 143, where the Court referred to the guidance provided by the UK decision of *Biogen Inc. v Medeva plc* [1997] RPC 1 at [47]:

“The requirement of an enabling disclosure in a patent specification is a matter of substance and not form. Its absence should therefore be a ground not only for refusal of the application but also for revocation of the patent after grant.”

5.115 The statutory requirements of proper disclosure are set out in Sections 25(4) and 25(5)(c), which requires that the description of the invention and its operation or use must be in such complete and clear terms as to enable any person skilled in the art or science of the invention or in the art closest to it, to make, construct, compound or use the invention.

5.116 Section 25(4) states that the application “shall disclose the invention in a manner which is clear and complete for the invention to be performed by a person skilled in the art”. This requirement was considered in *Ng Kok Cheng v Chua Say Tiong* [2001] SGHC 143 at [49], where the Court stated that:

“There is one small point here which I should dispose of before dealing with the defendant’s submissions on the merits. This relates to what level of description is required under ss 25(4) and 80(1)(c). The wording requires the specification to disclose the invention ‘clearly and completely’ for it to be performed.

The equivalent English wording is ‘clearly and completely enough’. Mr Kang submitted that the requirement of the UK Act is more lax and that the Singapore requirement is stricter so that the specification must be clear and complete.

I do not agree. Although the word 'enough' does not appear in the Singapore provisions, the phrase 'clear and complete' is not an unqualified one in either of those sections. Instead, it is followed by the words 'for it to be performed by a person skilled in the art'. This is a clear qualification implying that as long as a person skilled in the art would find the wording of the specification sufficient to enable him to make the invention, it does not matter that the specification does not state every single step that has to be followed in order to make the invention. Thus, the clear meaning of the legislation taken as a whole is that it is sufficient if the specification is clear enough and complete enough and absolute clarity and completeness are not required."

5.117 Notably, the approach that absolute clarity and completeness are not required has been followed in *First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd* [2007] SGCA 50 and *Dien Ghin Electronic (S) Pte Ltd v Khek Tai Ting* (trading as Soon Heng Digitax) [2011] SGHC 36.

5.118 The date at which sufficiency has to be judged is the date of filing, not the date of publication (*Biogen Inc. v Medeva plc*). It follows that a specification that is insufficient at the time of filing cannot be made sufficient by subsequent developments in the art.

ii. The role of the skilled person

5.119 The specification is addressed to a non-inventive person of ordinary skill in the art. Therefore, objection should not be raised to any terminology that would be clear in meaning to the skilled person. Moreover, the specification is a technical document that is intended to instruct a skilled person on how to work the invention, and if the specification meets that purpose then no objection should be raised on the basis that it is possible to describe the invention more clearly in a different way (*Schwarzkopf and Ors' Application*, 31 RPC 437).

5.120 The skilled person can include a group or team of such persons. The abilities of the skilled person were stated in *Valensi and another v British Radio Corporation Ltd*, [1973] RPC at page 377:

“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 his is not to be expected to exercise any invention or 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 may be found.”

5.121 If the skilled person comprises a team then different parts of the specification may be addressed to the different skilled addressees, who cooperate to work the invention (*Osram Lamp Works Ltd v Pope's Electric Lamp Co Ltd* 34 RPC at page 391).

5.122 The description should enable the skilled person wishing to achieve success rather than failure to work the invention without an undue expenditure of time and effort and without undue experimentation (*Mayne Pharma v Debiopharm and Sanofi-Synthelabo* [2006] EWHC 1123 (Pat) at [65]). The general principles relating to undue experimentation were stated by Aldous J in *Mentor v Hollister* [1993] RPC 7 as follows:

“The section requires the skilled man to be able to perform the invention but does not lay down the limits as to the time and energy that the skilled person must spend seeking to perform the invention before it is insufficient. Clearly there must

be a limit. The sub-section by using the words, clearly enough and completely enough, contemplates that patent specifications need not set out every detail necessary for performance, but can leave the skilled man to use his skill to perform the invention. In doing so he must seek success. He should not be required to carry out any prolonged research, enquiry or experiment. He may need to carry out the ordinary methods of trial and error, which involve no inventive step and generally are necessary in applying the particular discovery to produce a practical result. In each case, it is a question of fact, depending on the nature of the invention, as to whether the steps needed to perform the invention are ordinary steps of trial and error which a skilled man would realise would be necessary and normal to produce a practical result.”

5.123 The Court in *Institut Pasteur v Genelabs Diagnostics* followed these principles in determining that sufficiency does not require minute, step-by-step directions, and that the skilled person does not need to be told information that would be common general knowledge in the art.

5.124 Insufficiency will not arise merely on the basis that some difficulty is experienced in working the invention. Generally this will be according to acceptable levels of failure in the particular art. However, if the invention is not repeatable or if success is unpredictable then the specification may be insufficient. Nevertheless, it can be assumed that the skilled person should be trying to make the invention work (*Kirin-Amgen Inc v Hoechst Marion Roussel* [2005] RPC 9). Thus, if the skilled person would quickly realise that 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. However, 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 (*Eli Lilly & Co. v Human Genome Sciences Inc* [2008] EWHC 1903 (Pat) [2008] RPC 29).

5.125 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 (*SmithKline Beecham Plc's (Paroxetine Methanesulfonate) Patent*, [2006] RPC 10). However, 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. His common general knowledge forms the background in construing the disclosure, with the patent being construed on similar principles. 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 the skilled person would be able to work the disclosed invention.

iii. Description must be clear

- 5.126 The description should be drafted in language that would be clear to the person skilled in the art. Unnecessary or irrelevant material should be avoided (*Francis' Application* 27 RPC 87). Similarly, discussion of the principles behind the invention and other material such as background calculations are unnecessary unless they are required for a full understanding of the invention. However, no objection should be taken unless the additional discussion is unduly extensive.
- 5.127 As the specification is addressed to a person skilled in the art it is therefore acceptable for a description to use art-specific technical terms. However, the use of these terms must be consistent with the recognised meaning – a different meaning should not be given to a term if it is likely to be unclear to the skilled reader. Nevertheless, the language used in the specification should be readily understandable to the skilled person. Where the invention is difficult to explain, such as where it is so ground breaking that standard nomenclature is not yet available, then some allowance may be given (*Natural Colour Kinematograph Co Ltd v Bioschemes Ltd* 32 RPC 256 at page 269).
- 5.128 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 feature of the invention.
- 5.129 If it becomes necessary for the applicant to restrict the scope of the 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 the 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. An objection based on a lack of support may not be overcome by the addition of further examples or features to the specification since this is prohibited under Section 84, however, an objection to the excessive breadth of the claims may be remedied by restricting the scope of the claims.

iv. Reference to prior art

5.130 The description may refer to another document to provide additional background material or further information about the invention, often as an “incorporation by reference”. Generally, such references will only be an issue where the information disclosed in these documents is essential for a clear and complete disclosure of the invention.

5.131 While prior art may be cited to assist with an understanding of the invention, there is no requirement under the Singapore law that the specification must give details of such documents. Thus, no objection should be raised that prior art cited in, for example, a search report has not been included in the specification.

5.132 However, the specification must be sufficient at its date of filing, and any references given in the description should have been published by the date of filing (*Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] RPC 2). If a reference is unpublished at the time of filing, and the information contained in said reference is necessary for a person skilled in the art to carry out the invention, then the specification may be insufficient. Amendment to incorporate such matter is likely to constitute added matter ([see sub-section ii of Section J in Chapter 7](#)).

v. Trademarks and industry standards

- 5.133 Reference to trademarks should be avoided since it is an indication of origin rather than of composition or content. However, there is likely to be no issue if the properties of a feature are initially described in structural terms and subsequently further characterised by reference to a material by its trade mark. A trademark should be indicated as being such in order to recognise the proprietor's rights.
- 5.134 If a specification refers to a proprietary article or similar material that *prima facie* is not known, then the description should provide sufficient information for the skilled person to obtain or prepare such. Alternatively, the applicant may provide submissions, and if necessary evidence, to show that the skilled person would be able to determine the meaning of the reference.
- 5.135 Nevertheless, trademarks should be avoided in claims as they are indicative of the origin of goods and not a definitive characterisation of the product they contain. In particular the composition of a trademarked product can change over time. The use of a trademark in a claim should only be permitted where the applicant is able to show that its use is unavoidable and does not introduce ambiguity. Similarly, claims defined by an industry standard which could change over time should be objected to under clarity.
- 5.136 However, some judgment may be exercised as to whether an objection is warranted. For example, if the trademark is used in relation to an optional feature, then objection may not be necessary. Similarly if the invention is defined in a manner that clearly sets out the characteristics of a component and an appended claim uses a trademark to characterise a preferred embodiment of that component, it could be assumed that the skilled person would be able to determine the scope of the claim.

L. The abstract

- 5.137 Section 25(3) requires that an application for a patent contain an abstract, and Rule 22 prescribes specific requirements pertaining to the abstract. In particular, the Rule states that the abstract should, *inter alia*, contain a concise summary of the disclosure, said summary indicating the technical field to which the invention belongs, and be drafted in such a way which allows a clear understanding of the technical problem to which the invention relates, the gist of the solution of that problem through the invention, and the principal use or uses of the invention.
- 5.138 Rule 22(9) specifies the intended purpose of the abstract, which is to constitute an efficient instrument for the purposes of searching in the particular technical field, in particular by making it possible to assess whether there is a need to consult the specification of the application itself. The scope of the abstract, and the words used in it, should therefore be selected to ensure that retrieval from electronic databases would be likely when searching similar applications at a later date.
- 5.139 In cases where the abstract submitted by the applicant does not fulfil its purpose, the Examiner is empowered by the Registrar, under Section 25(7), to revise the abstract so that it does. In doing so, he should consider not only the text of the abstract, but also the selection of the figure(s) for publication with it (Rule 22(7)). However, the Examiner should avoid seeking an amendment of the abstract from the applicant, since the abstract does not form part of the specification under examination ([see paragraph 7.62](#)).
- 5.140 The checklist provided in the “WIPO Codes and Guidelines” (Standard ST.12/A) would serve as 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;
- d) 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.

In particular, the content of the abstract should be determined by the new technical disclosure of *the whole specification* rather than by only the inventive concept of the claims.

5.141 Rule 22(5) specifies that the abstract should be as concise as the disclosure permits and should normally not contain more than 150 words.

6. UNITY OF INVENTION

A. Statutory requirements

6.1 Section 25(5)(d) requires that the claims relate to one invention or group of inventions which are so linked as to form a *single inventive concept*.

6.2 Rule 25 further sets out that:

(1) where 2 or more inventions are claimed (whether in separate claims or as alternatives within a single claim), such inventions shall be treated as being so linked as to form a single inventive concept only where there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

(2) In this rule, “special technical features” means those technical features which define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

6.3 Whether or not a particular technical feature makes a “contribution” over the prior art, and therefore constitutes a “special technical feature”, is considered with respect to novelty and inventive step.

6.4 Unity is a ground for refusal under the **Patents Act** but is not a ground for revocation, and as a consequence there is no judicial or hearing guidance from Singapore on this issue. However, the wording of the Singapore law mirrors the wording of PCT Rules 13.1 and 13.2. Guidance for practice in Singapore is therefore taken from Chapter 10 of the PCT International Search and Preliminary Examination Guidelines (“The PCT Guidelines”) (<http://www.wipo.int/export/sites/www/pct/en/texts/pdf/ispe.pdf>).

6.5 There are several administrative considerations that underpin this requirement: the presence of multiple inventions in a granted patent make it more onerous for third parties undertaking searches of the prior art or seeking to determine their freedom to operate; there are additional costs in search and examination without additional fees to cover the cost; and a patent for several inventions could result in additional

complexity in the system (for example multiple infringement/revocation actions in relation to the same patent on different matter and grounds).

B. Approach for determining lack of unity in Singapore

6.6 Most cases under examination in Singapore are national phase filings based on PCT applications. The applicant often requests examination be conducted based on the International Search Report. Given that PCT practice in relation to unity will have been followed, generally the determination provided by the ISA should be directly applicable in Singapore.

6.7 The Singapore Examiner is not bound to follow the ISR, and may disagree with the determination made by the International Examiner (that is, if the ISR raises a lack of unity the Examiner may decide to follow the objection in full, to follow in part or with different reasoning, or to differ). However, the ensuing should be followed:

- (a) A lack of unity should only be raised in the clearest cases when it has not been raised in the ISR or foreign search.
- (b) Any objection of lack of unity should follow the guidance provided in the PCT Guidelines and provide sufficient detail for the applicant to fully understand the basis of the objection.
- (c) Lack of unity is preferably raised *a priori* ([Section C](#) and [sub-section i of Section D](#) in this Chapter).

6.8 The following should be followed when considering *a posteriori* lack of unity:

- (a) Lack of unity is **not** to be raised where the common feature is clearly novel and inventive.
- (b) Lack of unity *a posteriori* is most likely to be a consideration where the common feature is **well known**. This is likely to be where the common feature is disclosed in a manner that suggests it is part of the **common general knowledge** of the person skilled in the art.
- (c) Lack of unity **may** be raised if a feature is not well known, but rather is disclosed in a document that constitutes **public knowledge** – such as a single journal article or patent document. Lack of unity should **not** be raised where a document provides only a generic disclosure of the common feature. In these cases the common feature is not “known” as such.

(d) Generally, lack of unity should **not** be raised where the features are obvious in view of a combination of documents.

6.9 Notably, the PCT Guidelines set out two extremes – situations where the common feature is well known and unity is clearly lacking, and those where there is a novel and inventive feature in common and unity is clearly evident. Between these, the situation is less clear, and rigid rules cannot be applied. Each case should be considered on its merits with the benefit of any doubt being given to the applicant.

6.10 Other guidance as to the level of detail required and the manner in which the inventions are broken down should follow the PCT Guidelines. However, further guidance is given in the sections that follow.

C. General principles

- 6.11 Lack of unity is determined on the basis of the invention(s) as defined by the claims. An application may **describe** a number of different inventions having different inventive concepts, but an objection of lack of unity will only arise if the different inventions are **claimed**. Lack of unity can occur between different claims or within a single claim where said claim contains distinct embodiments which are not linked by a single inventive concept. When considering unity, the description and drawings may be taken into account when interpreting the claims to determine the invention.
- 6.12 Detailed reasons for the objection of lack of unity **must** be given in the report. Chapter 10 of the PCT Guidelines provides general guidance on how to determine whether there is a lack of unity. The examples at 10.20-10.59 provide a framework for certain technology-specific situations.
- 6.13 Lack of unity will be either “*a priori*”, that is, before considering the prior art, or may only become apparent “*a posteriori*” following a search of the prior art. All objections must be drafted following these principles.
- 6.14 The test for unity of invention may start from identifying common or corresponding technical features in the inventions claimed and determining whether the same or corresponding “special technical features” are present in all the claimed inventions.
- 6.15 If there are no common or corresponding technical features, then there is a strong indication that there is a lack of unity *a priori*. When there are common or corresponding technical features, there would be unity if the common or corresponding technical features are considered to be special technical features; on the other hand, if the common or corresponding technical features are not considered to be special technical features, there may be a lack of unity *a priori* or *a posteriori*.
- 6.16 If the common feature is disclosed in a P,X or E-category citation, it cannot be used to support an objection of lack of unity. The common feature must be made available to the public at the priority date of the application in order to support an objection of lack of unity.

- 6.17 In general, the initial consideration will be directed to the independent claims only. However, further consideration of dependent claims which depend on an independent claim may be necessary if the features defined in said independent claim are found in the prior art ([see sub-section ii of Section D in this Chapter](#)).
- 6.18 The following are some scenarios to illustrate whether a lack of unity objection should be raised among dependent claims:
- a) In cases where an independent claim merely defines features that are part of the common general knowledge, and its respective dependent claims additionally define separate inventions, an objection of lack of unity may be raised among the dependent claims.
 - b) In cases where an independent claim is novel and inventive, then an objection of lack of unity should not be raised even when the dependent claims merely define trivial features that would be part of the common general knowledge.
 - c) In cases where an independent claim lacks novelty and/or inventive step and the dependent claims are closely interdependent (that is, they merely define specific embodiments of the invention claimed in the independent claim), then it may be more appropriate to assess novelty and/or inventive step instead of raising an objection of lack of unity to the dependent claims.
- 6.19 It should be noted that this is case dependent and a decision to raise an objection of lack of unity should take into account all circumstances specific to the case in hand ([sub-section iii of Section D in this Chapter](#)).
- 6.20 Alternative forms of an invention may be claimed in a single claim (Markush claims are an example). However, a lack of unity will arise if the alternatives within a claim result in there being no common special technical feature. Broad consideration should be given to the special technical feature – alternatives could be linked by different properties: this could be composition, structure, function or other manner.

D. Assessment of unity of invention

i. Lack of unity *a priori*

6.21 Unity of invention requires that the claims have the same or corresponding “special technical features” that provide the contribution over the prior art. A lack of unity of invention *a priori* should be self-evident and an assessment can be made with little in-depth analysis. A simple example of claims lacking unity *a priori* is as follows:

1. A + X
2. B + Y

6.22 There is a lack of unity *a priori* as there is no common or corresponding technical feature between the two independent claims. Similarly, the following three independent claims lack unity *a priori* as there is no subject matter common or corresponding to all claims:

1. A + X
2. A + Y
3. Y + X

6.23 An objection to lack of unity may be taken by grouping the inventions having a common special technical feature – in this case on the assumption that each of A, X and Y is a special technical feature, the claims are grouped as follows and each group is considered to constitute an invention:

- Invention 1: A + X and A + Y (A is the special technical feature in common);
Invention 2: A + Y and Y + X (Y is the special technical feature in common);
Invention 3: A + X and Y + X (X is the special technical feature in common).

The examination report will be based on the first mentioned invention only.

6.24 In the following example, the two independent claims which have a common feature A may lack unity *a priori* when the common feature A is well known in the art. Before considering the prior art, it is clear that feature A is already disclosed in the state of

the art, and the ‘real’ inventions relate to features X and Y, respectively. An *a priori* lack of unity objection in such a circumstance supported by a reference to a citation may be raised, unless the feature A is so generic in the art that it requires no documentary evidence.

1. A + X

2. A + Y

- 6.25 In some cases the claims may be drafted in a manner that makes it difficult to identify the special technical feature. One approach to dealing with such cases is to **consider the problem** that the application addresses and how the application seeks to solve that problem. The solution will most likely be the **general inventive concept** which can be considered to be the special technical feature, and if this is present in all of the claims then there will be unity ([sub-section v of Section D in this Chapter](#)).
- 6.26 Complex claim sets, chemical intermediates and Markush claims also involve special considerations. These are discussed in later sections.

ii. Lack of unity *a posteriori*

6.27 Unity of invention will be present when the claims all have the same or corresponding “special technical feature” that provides the contribution over the prior art. However, in some cases it may be apparent that the common or corresponding feature does not provide a contribution over the prior art. This will most often occur where a preliminary search identifies documents that disclose the common or corresponding feature. In such cases, an objection to lack of unity may be applicable on the basis that the claims have no common or corresponding technical feature that makes a contribution over the prior art (that is, *a posteriori* – after taking the prior art into account).

6.28 In many cases the lack of unity will be apparent to the Examiner from an initial consideration of the claims, and the key consideration will be as to whether an *a priori* approach is the most appropriate or whether an *a posteriori* approach should be taken. Where an *a posteriori* approach is considered appropriate, an initial search can be carried out to target the matter in common between the claims.

6.29 *A posteriori* lack of unity may be illustrated as follows:

1. A + X
2. A + Y

In the case of independent claims A + X and A + Y which have feature A in common, if it is established after a search that A is not novel or is obvious, there may be a lack of unity *a posteriori*, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art. Each of these groups is taken to be a separate invention.

6.30 However, there will be instances whereby the Examiner discovers, only after a search, that the common feature is **well known** in the art. In such cases, an *a priori* lack of unity objection may be raised. It is noted that the tests for assessing unity, whether *a priori* or *a posteriori*, are meant to assist Examiners in performing the unity assessment and formulating its associated reasoning. When raising a unity objection in the written opinion or in the examination report, the Examiner may specify whether the lack of unity occurs *a priori* or *a posteriori*, although he need not do so.

6.31 The *a posteriori* approach is most applicable in situations where the “real” inventions are unrelated but the manner in which the claims are drafted introduces a common feature that is not essential to each. A simple example of this is the following:

1. Automobile characterised by a new and novel exhaust system.
2. Automobile characterised by a new and novel engine cooling system.

In this case, the “real” inventions relate to the exhaust system and the cooling system respectively. If a search identifies prior art documents that disclose the common feature of the automobile, an objection of lack of unity *a posteriori* may be taken. This is consistent with the policy intention that unity is intended to assist with the efficient administration of the patent system: the two real inventions would require entirely separate searches and examinations, and would be subject to entirely different infringement and revocation actions. On the other hand, if it is determined, whether or not such determination involved a search of the prior art, that the common feature of the automobile is well known, an objection of lack of unity *a priori* may be appropriate.

6.32 Some other examples of these types of situations would be:

1. A batch stirred tank reactor comprising Catalyst X for use in the preparation of compound Z.
2. A batch stirred tank reactor comprising Catalyst Y for use in the preparation of Polymer A.

If Catalyst X and Y and/or compound Z and Polymer A were unrelated, then the only feature in common would be the batch stirred tank reactor. If a search identifies prior art documents that disclose the common feature of the batch stirred tank reactor, then an objection of lack of unity *a posteriori* may be taken. On the other hand, if this type of reactor is well known in the art, then an objection of lack of unity *a priori* may be taken.

6.33 If an independent claim is new and inventive (i.e. a special technical feature is defined in the claim), then it follows that dependent claims will be unified. This will be the case even if the additional features defined in the appended claims are *prima facie*

routine or obvious by themselves or are *prima facie* directed to different inventive concepts. For example, in the following claims, if A + B is found to be novel and inventive and the combination of these features represents a special technical feature, then Claims 2 and 3 will have unity with Claim 1 even if features C and D are well known in the art.

1. A + B
2. A + B + C
3. A + B + D

6.34 If the combination of A + B was not novel, then an *a posteriori* lack of unity could result. In this sort of situation, the decision to raise unity would take into account all circumstances of the case. If, in the opinion of the Examiner, the separate combination with C and D results in different inventions, then a unity objection may be raised. However, if the combination of A + B was known in the art and there was clearly no inventive step in adding either of the features C and D, then the unity objection may be a mere technicality.

6.35 For the combination of A + B, an *a posteriori* lack of unity in view of a combination of documents is generally **not** recommended unless the motivation for combining the documents is absolutely clear. Otherwise raising an objection to a lack of unity may lead the applicant to argue an absence of motivation to combine the documents, which is better dealt with in the inventive step assessment.

iii. Avoid literal or over-technical approaches

6.36 In addition to the actual tests applied in the unity consideration, there is significant variation in the “strictness” of approach applied by Examiners. The PCT Guidelines provide some general examples of where unity may or may not arise, but in practice the unity determination is largely a matter of individual judgment based on the facts of the case. In this regard, the Guidelines set out that:

Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor persisted on the basis of a *narrow, literal or academic approach*. There should be a broad, practical consideration of the degree of interdependence of the alternatives presented, in relation to the state of the art as revealed by the international search or, in accordance with Article 33(6), by any additional document considered to be relevant. If the common matter of the independent claims is well known and the remaining subject matter of each claim differs from that of the others without there being any unifying novel inventive concept common to all, then clearly there is lack of unity of invention. If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then objection of lack of unity does not arise. For determining the action to be taken by the Examiner between these two extremes, rigid rules cannot be given and each case is considered on its merits, the benefit of any doubt being given to the applicant.

6.37 Lack of unity *a posteriori* is particularly open to a “narrow, literal or academic approach” since in theory any novelty or inventive step objection could potentially result in a further objection on lack of unity for any further variations not covered by the novelty/inventive step objection. In such cases each and every further variation could be considered a further invention (in the chemistry area this could amount to thousands of additional inventions). This is clearly not the intention of the unity requirement. If an *a priori* consideration of the claims has determined that the claims have unity, then careful consideration needs to be made as to whether the prior art significantly impacts on that decision.

6.38 Notably, the PCT Guidelines set out two extremes – situations where the common feature is *well known* and unity clearly is lacking and those where there is clearly a novel and inventive feature in common and unity is evident. Between these the situation is less clear, but it could be considered that unity *might* be raised if a feature is not *well known*, but rather is disclosed in a document that might not ordinarily constitute common general knowledge (essentially the feature is public knowledge rather than common general knowledge). Situations where unity would be unlikely to be raised, except in exceptional circumstances, would be where a document provides only a generic disclosure of the feature, or where the features are obvious in view of a combination of documents.

6.39 As noted in the PCT Guidelines the applicant should be given the benefit of doubt. An objection of lack of unity can potentially lead to the applicant filing divisional applications for additional inventions. This can be costly for the applicant, who will need to pay significant additional costs to prosecute these divisional applications.

6.40 Furthermore as set out in the PCT Guidelines, there should be a broad, practical consideration of the degree of interdependence of the alternative inventions. Depending on the specific circumstances of the case, a lack of unity may be “technical”, and the key issue may instead lie in whether the claims are inventive, fully supported or clear in scope. Thus, a practical approach might be to consider inventive step, full support or clarity rather than unity. For example, if an initial consideration of the dependent claims does not identify any feature that would confer inventive step then a “broad brush” approach can be taken under inventive step rather than taking a “technical” objection of lack of unity. Another example would be if the claims have an unduly broad scope and are only partially supported by the disclosure, the Examiner adopting a practical approach may limit the search to the supported subject matter instead of raising a unity objection. More examples are provided below to further illustrate the consideration for lack of unity.

6.41 In some cases the common technical feature may not be readily apparent and can result from different properties of the invention. For example:

1. A polypeptide having activity X comprising SEQ ID No: 1 wherein the sequence possesses mutations at one or more of the positions 4, 19, 143 and 244.

In this case the different point mutations are at quite different and remote positions of the peptide. *Prima facie*, these are different inventions. However, the activity of the peptide may relate to the binding at a particular receptor site. Proteins may adopt a tertiary structure where an active site comprises quite distant amino acids. In this case the mutations may be related to a single binding site where mutations of the amino acids result in changes to the same binding site, which has a technical effect not previously disclosed in the art. This could therefore be the special technical feature the different proteins have in common.

- 6.42 Similarly, if the invention relates to a new property of a related group of articles (some of which are known and some of which are new), then the group will comprise a single inventive concept based on the new property. An *a posteriori* lack of unity does not arise as a result of some of the articles being known. Such situations are likely to arise in the chemical area. For example, if a group of related chemical compounds comprising a number of known compounds as well as a number of unknown compounds is useful in treating a certain disease, then claims to the new use, compositions for the particular use, claims to any novel compounds and methods for the preparation of the novel compounds would constitute a single invention.

iv. Claims that are unduly complex

6.43 Occasionally an application may contain a large number of claims with overlapping scope, which may relate to separate inventions. In some cases the claims may be *unduly* complex or broad in scope. In approaching such cases there may be different strategies that may be employed. Some of the key considerations are as follows.

1. Is there a lack of unity?

6.44 This is likely to be a consideration in combination claims (including methods) where each feature may itself comprise a large number of alternatives such as where the individual features are defined in generic terms.

6.45 The considerations set out in previous sections should be taken into account in the unity determination. Moreover the objection should clearly identify the different inventions. Admittedly this may be difficult if the claim is relatively broad, but must be done in order for the applicant to determine the nature of the amendments that they need to make. Following the guidance of the PCT, the consideration may take into account the description and figures to identify groups of inventions.

2. Is inventive step or novelty the key issue?

6.46 In many cases concerning *a posteriori* lack of unity, the key issue may instead relate to novelty and/or inventive step. In this regard the nature of the citation should be taken into account before raising a lack of unity.

6.47 As discussed in previous sections, whether the common matter is well known is a consideration. Furthermore, whether the broad **inventive concept** or merely a specific embodiment within the scope of the claim is disclosed in the prior art should be taken into account.

3. Are the claims supported?

6.48 Another consideration is whether the claims are in fact supported by the disclosure. The usual considerations of support should be taken into account, such as whether, for example, the inventive concept is a principle of general application which is supported by the description.

6.49 It should be noted that a divisional application filed for any additional invention(s) which were not supported by the description would be invalid. Accordingly unity is clearly not the only issue here. An objection to lack of unity may be raised together with a support objection, with a warning to the applicant against filing a divisional application.

6.50 Example 1:

A method for the diagnosis of prostate cancer comprising the measurement of **one or more** of the 2000 markers shown in Table 1.

In this case, the markers have no significant structural or functional feature in common. The description describes the analysis, identification (using commercial Affymetrix microarrays) and comparison of markers in cancerous and non-cancerous cells. The description states that the up- or down-regulation of a group of 20 markers may be used to determine the presence of prostate cancer.

A literal approach to the claim would be to identify each of the 2000 individual markers, and each and every combination of such as a single invention. This would result in an indeterminate number of inventions. However, a consideration of the specification as a whole indicates that the invention relates to the particular group of markers that can be used to diagnose cancer. In this case, a lack of support could be considered if the specification provides no support for the claim to each and every combination of the named markers being used for this purpose.

Furthermore, a search of the broad inventive concept of fingerprinting the genetic markers produced in prostate cancer cells could be carried out. Any document found by such a search could be used as a novelty and/or inventive step objection (even if the specific markers are not identified since it would be a matter of routine to determine the identity of such markers).

Nevertheless, in case a lack of unity objection is not raised in the first instance, it may still be necessary to raise such an objection once the claims are amended to overcome the other objections such as inventive step/support. In such cases the applicant should be warned in the first instance that there is a potential for lack of unity, but that full consideration is being deferred pending amendment of the claims.

6.51 Example 2:

A method for the diagnosis of prostate cancer comprising the measurement of **one or more** of the (2000) markers shown in Table 1.

As in the above example, the markers have no significant structural or functional feature in common. The description describes the analysis, identification (using commercial Affymetrix microarrays) and comparison of markers in cancerous and non-cancerous cells.

The description states that a group of 20 markers may be used to diagnose lethal prostate cancer. A second group of different markers may be used to diagnose benign prostate disease. A third set of markers may be used to determine the likelihood that chemotherapy will be successful.

In this case a similar approach as taken in Example 1 may be taken to the broad claim on the ground of lack of support. Furthermore a lack of unity may be appropriate, identifying the three inventions as noted above.

v. Combinations of claims of different categories or of interrelated products

6.52 Generally, unity will extend to claims of different categories or of interrelated products related to the same inventive concept, where the claims have corresponding special technical features. The term “interrelated” means different objects that complement each other or work together. Some of the following are examples of where this will be a consideration, and are based on the guidance given in the examples in 10.20-10.59 of the PCT Guidelines.

6.53 Example 1:

In the following example, despite the claims relating to different articles, they relate to the same inventive concept which provides them with unity. Similarly, there may also be unity between different articles provided they are specifically adapted to have a working inter-relationship. For example, the claims are:

1. Plug characterised by feature A.
2. Socket characterised by having an aperture designed to receive feature A.

In this case, the plug and socket interact in operation using the feature A, and are interrelated products. This inventive concept therefore provides unity between the two different articles.

This would also be the case with separate claims directed 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 application. 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 specifically adapted to pierce the container when mounted on it; or a container of chemicals to be sprayed which is specifically 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.

6.54 Example 2:

In most cases, an article or product *per se* will be the special technical feature in common between different aspects of the invention. For instance, in the following example, the compound of Formula X will be the common feature of the claims:

1. A compound of formula X.
2. A herbicidal composition comprising the compound of Formula X as defined in Claim 1, comprising ...
3. A method for preparing the compound of Formula X as defined in claim 1 wherein ...
4. The use of the compound of Formula X as defined in Claim 1 as a herbicide ...

6.55 Example 3:

In the biotechnology area, this may extend to different embodiments related to the same inventive concept even though they are distinct entities. For example, in the case of a gene and protein, claims in a single application may include the protein, the use of the protein, nucleic acids encoding the protein, vectors comprising the nucleic acid, transgenic organisms etc. For example,

1. An Fc binding protein, containing amino acids at positions 35 to 90 of an amino acid sequence described in SEQ ID NO: 1.
2. A polynucleotide, encoding the Fc binding protein according to claim 1.
3. An expression vector, containing the polynucleotide according to claim 2.
4. A transformant obtained by transforming a host with the expression vector according to claim 3.
5. A method for manufacturing an Fc binding protein, comprising culturing the transformant according to claim 4 to produce the Fc binding protein; and recovering the produced Fc binding protein from its culture.

In this case, the protein is the unifying inventive concept. In the case of nucleic acids, unity may exist between the nucleic acid and antisense even though they are different structurally.

6.56 Example 4:

In the case of processes and apparatus, unity will generally rely on the apparatus being “specially adapted” for use in the specific process. In order to be considered as specially adapted, the claim must define the apparatus in a manner that clearly embodies the inventive features of the process.

1. Process of preparing Compound X comprising the steps of:
 - (a) In a first reactor, selectively hydrogenating Compound Y using catalyst Z;
 - (b) In a second reactor, selectively oxidising the product of step (a) using permanganate under elevated pressure of at least 5 atmosphere.
2. Apparatus specially adapted for use in the process of Claim 1.
3. Use of Compound X for ...

If the apparatus has been defined to be specially modified in such a way as to provide the inventive outcomes of the process (automation, operatively linked, catalysts, pressure system, etc.), the apparatus is considered “specially adapted” for use in the process. The claims would have unity in such cases.

However, if the apparatus is defined in a way that merely requires that it is capable of carrying out the process, the claim would not sufficiently embody the inventive concept and an objection of lack of unity may be applicable. Novelty may also be an appropriate consideration in this case since the arrangement of reactor vessels may be interpreted in such a way as to have no distinguishing features over and above the prior art.

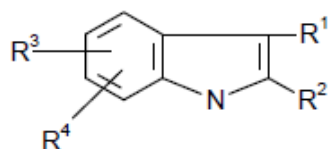
It should also be noted that the construction of claims directed to apparatus “specially adapted” needs to be dealt with on a case-by-case basis ([sub-section vii of Section F in Chapter 2](#)).

vi. Markush claims

- 6.57 A Markush claim is a claim that defines multiple “functionally equivalent” alternative entities for one or more of the features of the invention. This type of claim is mainly encountered in the chemistry field.
- 6.58 Generally, there will be a consistent core structure that provides the activity of a compound. However even relatively straightforward Markush structures might comprise several thousand compounds, while more complex structures have been estimated to include in the order of 10^{61} compounds. By way of reference, the number of actual *known* compounds number in the order of 10^7 .
- 6.59 As previously noted, guidance can be taken from the PCT Guidelines, where the key consideration for unity is whether there is a common or corresponding special technical feature between alternatives. In the case of a Markush structure this requirement is met when the alternatives (that is the compounds defined by the claim) are of a **similar nature**.
- 6.60 The PCT Guidelines also set out that compounds are regarded as being of a *similar nature* where the following criteria are fulfilled:
- (a) all alternatives have a common property or activity, **and**
 - (b) (1) a common structure is present, that is, a significant structural element is shared by all of the alternatives, **or**
 - (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.
- 6.61 In paragraph (b)(1), “significant structural element is shared by all of the alternatives” means that the compounds share a common chemical structure which occupies a large portion of their structures. Where the compounds have only a small portion of their structures in common, the commonly shared structure must constitute a structurally distinctive portion in view of existing prior art, and the common structure must be essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

- 6.62 In paragraph (b)(2), “recognized class of chemical compounds” means that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.
- 6.63 An objection of lack of unity should not be taken only on the basis that the alternatives of a Markush grouping belong to different IPC classes. If at least one Markush alternative is not novel over the prior art, an *a posteriori* lack of unity may be a consideration. However, it should be noted that the mere existence of compound(s) falling within the scope of a claim is not unusual and will rarely result in an objection of lack of unity. This may be an over-technical approach which at its most extreme would result in an objection of lack of unity. When in such cases, a novelty objection will be taken that will generally result in the applicant amending the claim to remove the prior art compound(s). The Examiner should take a broad consideration of the relationship between the alternatives. In these situations the issue may be closely linked to inventive step.
- 6.64 Example 1:

The invention relates to novel compounds of the following formula:



wherein R1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; R2-R4 are methyl, benzyl, or phenyl. The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

In this case, there is a common activity or property and a common structure is present that appears to be essential to the activity. Accordingly, the Markush grouping has unity.

6.65 Example 2:

The following Markush group does not represent a single invention:

A-B-C-D-E

wherein:

A is selected from C1-C10 alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C5-C7 heterocycle having 1-3 heteroatoms selected from O and N;

B is selected from C1-C6 alkyl or alkenyl or alkynyl, amino, sulfoxy, C3-C8 ether or thioether;

C is selected from C5-C8 saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C4-C8 carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.

The key issue here is that the different combinations encompassed by the claim can lead to a large diversity of different compounds having no common structural feature. Furthermore, all of the circumstances of the case should be taken into account. For example, if the specification provides only one specific group of compounds, then there may be an issue of whether the claims are supported and such an objection could be taken instead of, or in addition to, the unity objection.

- 6.66 In chemical cases, a claim directed to a genus expressed as a group consisting of certain specified materials is allowable, provided it is clear from the known nature of the alternative materials or from the prior art that the materials in the group possess at least one property in common which is mainly responsible for their function in the claimed relationship. Therefore, a Markush claim will generally be construed with a generic expression covering a group of two or more different materials (elements, radicals, compounds) as illustrated in the following examples:

“A solvent selected from the group consisting of alcohol, ether and acetone ...”

“A strip of a conductive metal selected from the group consisting of copper, silver and aluminium ...”

6.67 Occasionally, the Markush format may be used in claims directed to subject matter in the mechanical or electrical fields in a manner such as that illustrated in the example below:

“A means for attaching a wall panel to a framework wherein the attaching means is selected from group consisting of nails, rivets and screws ...”

6.68 While an objection should be as detailed as possible, in more extreme cases such as this, there is little benefit in detailing every permutation that falls within the scope of the claim. If there are only a limited number of classes specifically exemplified, then these may be identified in the objection and only a general comment made as to the others. Moreover, the examination should attempt to be of as much benefit as possible to the applicant, as well as avoiding unnecessary or wasted effort through examining embodiments that the applicant ultimately may not pursue. To this end, if the description is directed primarily to one particular group of compounds, then examination should be carried out on that group.

vii. Intermediate and final products

6.69 In some cases claims will be directed towards novel intermediates that are used for the preparation of the final products of the invention. There are special rules that apply in such cases and these are set out in the PCT Guidelines.

6.70 Unity of invention is considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:

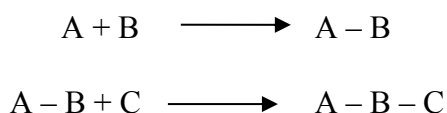
(A) the intermediate and final products have the same essential structural element, in that:

(1) the basic chemical structures of the intermediate and the final products are the same, or

(2) the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product, and

(B) the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separate from it by a small number of intermediates all containing the same essential structural element.

6.71 Unity may exist between different intermediates provided the different intermediates collectively satisfy the above requirements. However, if two different intermediates incorporate a different structural element into the final product, they will not meet the above requirements. A simple example of this is in the following multi-step reaction:



Assuming A, B and C are not relatively simple structural units, the claims are as follows:

1. Compounds having formula A – B – C
2. Compounds having formula A – B
3. Compounds having formula A
4. Compounds having formula C

In this case Claims 1 to 3 would have unity. Compounds of these claims have the same structural element A, and providing this is a relatively significant essential element that is related to the activity of the final compounds, this group of inventions would meet the requirements, taking guidance from the PCT Guidelines.

On the other hand there would not be unity between Claims 3 and 4 since these do not incorporate the same structural element into the final compound. Accordingly, the claims could be divided into two possible groups: Invention 1 comprising Claims 1 to 3, and Invention 2, comprising Claim 1 and Claim 4.

6.72 Other considerations set out in the PCT Guidelines are as follows, but it should be noted that in all cases a pragmatic approach should be adopted as to whether or not a unity objection should be taken:

- (a) The intermediate and final products should not be separated in the process by a known compound (in which case the inventive concept of the intermediate would lie in the preparation of the known intermediate rather than the novel final product).
- (b) It is possible for a compound to be claimed as an intermediate in the preparation of a final product and to also have other uses. The claims could be drafted in that case to define the final products, and/or compositions containing such, their preparation and their use, as well as claims to the novel intermediates and their preparation and use.
- (c) If the intermediate and final products are families of compounds, each intermediate compound must correspond to a compound claimed in the family of the final products. However, some of the final products may have no corresponding compound in the family of the intermediate products so that the two families need not be absolutely congruent.

6.73 The intermediate may have the same use as the final product, or it may have any other use. Any other use of this intermediate may be considered a further invention. Furthermore, the final product should be manufactured directly from the intermediate or from the intermediate *via* a small number of other intermediates having similar structure.

E. Biotechnology examples

6.74 Biosequences can generally be considered using the same principles as used for chemical inventions (for examples point mutations in a protein can be viewed as being analogous to Markush structures), or using the general principles (different categories relating to the same underlying inventive concept). However, there are some circumstances that require further detail.

6.75 One of the issues most often encountered in this technology is how to deal with claims to sequences. There are a number of different circumstances that can arise, and while some guidance may be provided there is still a need to consider the entire circumstances and avoid too technical an approach:

- (1) If a claim is directed to peptides or proteins having a significant structural similarity and the same activity, then there will be a single inventive concept. This can include sequences where there may be mutations at different and remote parts of a molecule. Note that both structure and function are required. If the claims relate to different mutations (such as SNPs) on the same nucleotide and a common function is stated, then the claim will have unity. However, if no function is stated then there *prima facie* will be no unity.
- (2) Nucleotides/Peptides having different sequences will generally not be considered a single invention. This type of situation might arise where screening of a library may identify certain members having desirable activities. Consistent with the principles relating to a Markush grouping, the sequences would need to possess a significant structural homology **and** a common activity. In practice, the sequences would be grouped according to any homology members of the group may possess (including conservative substitution and the like) and an objection of lack of unity taken on the basis of these groupings following the form objection given under Markush groupings.
- (3) Applications may claim different structurally distinct epitopes from a single receptor. If the parent protein is novel, then it may be appropriate to

consider these as a single invention since they relate to the same activity and the same protein. However if the search identifies that epitopes from the same protein having this activity are already known, then the invention may lie in identification of further epitopes and each different sequence would constitute a different invention (*a posteriori*).

- (4) If the only common structural feature of a claim is known then an *a posteriori* lack of unity may be a consideration. However this will only be appropriate where the structural element is known for the same purpose. For example a claim to various sequences having a common catalytic domain may not constitute a single invention if the catalytic domain was previously known for that purpose.

F. ICT examples

6.76 Example 1:

Consider the following claims:

1. Transmitter provided with time axis expander for video signals.
2. Receiver provided with time axis compressor for video signals received.
3. Transmission equipment for video signals comprising a transmitter provided with time axis expander for video signals and a receiver provided with time axis compressor for video signals received.

Here the special technical features are: in claim 1 the time axis expander, and in Claim 2 the time axis compressor, which are **corresponding special technical features**. Unity exists between Claims 1 and 2. Claim 3 includes both special technical features and has unity with Claims 1 and 2. The problem to be solved by these inventions is common, which lies in enabling transmission of video signals through a narrow frequency band.

However, if the transmitter and a receiver were merely *suitable* for the defined purpose then they may be regarded as separate inventions (for example had the claims defined “transmitter/receiver *for use* with a time axis expander for video signals”). Nevertheless, in such cases the objection may relate to novelty (if such transmitters and receivers are known in the art and the claim does not define that they are specially adapted for the particular use), and a simple amendment may be possible to restore unity.

6.77 Example 2:

Consider the following claims:

1. Control circuit A for a d.c. motor.
2. Control circuit B for a d.c. motor.
3. An apparatus including a d.c. motor with control circuit A.
4. An apparatus including a d.c. motor with control circuit B.

Control circuit A is a special technical feature and control circuit B is another unrelated special technical feature. Unity exists between Claims 1 and 3 or between Claims 2 and 4, but not between Claims 1 and 2 or 3 and 4.

G. Search and examination of additional inventions

6.78 Rule 45(1) states that:

If during the preparation of a report under Section 29(1)(a) or (b)³ it appears that an application relates to 2 or more inventions, but they are not so linked as to form a single inventive concept, the search may be restricted to one in relation to the first invention specified in the claims of the application, and the Registrar shall notify the applicant of that fact. Here the first invention means the invention first mentioned in the claims.

6.79 The applicant may pay a fee for a search of the second or subsequent invention(s) to be conducted (Rule 45(2)). This must be done within 2 months of the date of the search report.

6.80 In addition, during the preparation of a search report under Section 29(1)(a) where it is considered there is a lack of unity, there is possibility for a search to be conducted of second (or subsequent) invention(s) in the case that there is **little additional effort** required to undertake such a **search**.

6.81 In such cases, a lack of unity may be raised, but the applicant is informed that the additional invention(s) have been searched as a matter of courtesy. Additional search can be costly in terms of Examiners' effort and costs associated with database and supply of citations. As such, additional search should be limited to where there is little additional cost and effort involved. The approach under the PCT should be followed in determining whether little additional effort is required. For example, if it is a relatively straightforward claim set and the two inventions can be readily searched in a single search statement, then there may little additional work to cover all of the inventions.

6.82 During the preparation of a search and examination report under Section 29(1)(b) where it is considered there is a lack of unity, in exceptional circumstances (e.g. when the inventions are conceptually very close), it is possible to search and examine

³ The corresponding provisions in the *Patents Act* in effect immediately before 14/02/2014 are Section 29(2)(a) and (b), respectively.

second (or subsequent) invention(s) when there is **little additional effort** required to undertake both **search and examination**.

6.83 In such cases, an objection to lack of unity may be raised, but the applicant is informed that the additional invention(s) have been searched and examined as a matter of courtesy. In considering the amount of work involved, the Examiner should take into account the time taken to conduct the examination as well as that needed to perform the search, since even when the analysis involved with regards to the search is negligible, the opposite may be the case for the examination.

6.84 Applicants may address a unity objection as follows:

- (1) Limit the claims to the first invention as specified in the Examiner's report by deleting claims to the second or subsequent invention(s), which can be further pursued by requesting for additional search or filing divisional application(s);
- (2) Amend the claims to include a same special technical feature that joins the claims in a single general inventive concept;
- (3) Provide arguments as to why the claims are unified in compliance with Section 25(5)(d).

6.85 In the event that the applicant files a divisional application, the applicant may request an examination of that divisional application by relying on any search or supplementary search report established for the parent application (if the search for the parent application covers the invention claimed in the divisional application) or alternatively relying on a search report established in another office for that invention (Section 29(1)(c) and Rule 45(3)⁴). Such search or supplementary search reports relied on may include those where the examining office has taken an objection of lack of unity but has undertaken a search of the additional inventions (for example, where

⁴ According to Section 29(1)(c) and Rule 45(3), reliance of search is allowed on (a) any search report or supplementary search report established in the parent application; or (b) where the parent application is an international application for a patent (Singapore) that has entered the national phase in Singapore under Section 86(3), any international search report or international supplementary search report established during the international phase of the parent application; or (c) a search in one corresponding application, corresponding international application or related national phase application.

additional search fees were paid during the International phase of the application).

- 6.86 Pertaining to point (2) above, notably, if as a result of the claim amendments, there is **a shift of the special technical feature** of the invention(s) from that of the first invention searched in the earlier search report, the Examiner is **not** obliged to carry out an additional search for the unsearched subject matter. This is because **even if the claims have been amended such that they are joined by a single inventive concept** by the introduction of a common special technical feature, there would have been no reason for the Examiner to search the specific subject matter of that inventive concept during the initial search. In other words, if the applicant's amendment results in an inventive concept that was not reasonably apparent at the time of the initial search, then additional search and examination would not be carried out because it would result in the search and examination of **two** different inventive concepts.
- 6.87 Pertaining to point (3) above, in particular for a search only case or a search and examination case, if a lack of unity objection has been raised, and subsequently the applicant provides arguments showing that the lack of unity objection is not justified, the Examiner shall carry out an additional search for the subject matter that the Examiner initially did not search based on the incorrect lack of unity objection.
- 6.88 An outstanding lack of unity objection needs to be resolved before the grant of a patent. Pursuant to such a grant, there is no ground for revocation in relation to the patent being for more than one invention.

H. Divisional applications (Section 26(11)/Rule 27)

6.89 According to Section 26(11) and Rule 27, an applicant can file a new application for a patent in respect of any part of the matter contained in the originally filed application, i.e., parent application, where the new application, i.e., divisional application, shall be treated as having, as its date of filing, the date of filing of the earlier application. The said new application must not contain any additional matter extending beyond that disclosed in the original application to satisfy the requirements under Section 84(1).

6.90 The divisional application can be filed at any time after the filing date of the parent application but before all the grant conditions in Section 30 are met for the parent application, or before the parent application has been refused, withdrawn or treated as having been abandoned.

6.91 A divisional application may serve as the original application of a further divisional application. However, the immediate predecessor must be pending at the time the further divisional application is filed. The original application need not be pending in order to file a second (or later) generation divisional application from the first (previous) divisional application.

6.92 Example:

Take the case of application “A” with three inventions described therein. A first divisional application “B” can be filed with two inventions “divided”, or taking basis, from application “A”. A further divisional application “C” can be filed with subject matter divided from the divisional application “B” and relying upon this divisional as its original application. In this case, divisional “C” would have the same filing date as the divisional “B”, which would be the same as the filing date of the application “A”. Hence, if all three applications proceed to grant, they would result in patents that would expire on the same date. However, the time limit for the filing of application “C” is before all the grant conditions in Section 30 are met for divisional “B” or before divisional “B” has been refused, withdrawn or treated as having been abandoned. This time limit is not dependent on the progress of application “A”, which may have been granted before the Examiner makes the requisition to restrict to one invention in divisional application “B”.

6.93 One consequence of prescribing a divisional application with the filing date of the parent application is that for the purposes of examination, a separate and individual treatment applies when the divisional is examined. There is no need to examine a divisional application with the parent, since the exclusive rights begin with the filing date (which is that of the parent) and end 20 years later on the same date as those of the parent. Of course, the Examiner may find it more efficient to examine the two together.

I. Double patenting (Rule 46(1)(f)⁵)

- 6.94 As set out in Section 80(1)(g), the Registrar may, on the application of any person, by order revoke a patent for an invention on the ground that the patent is one of 2 or more patents for the same invention having the same priority date and filed by the same party or his successor in title. This ground is often referred to as double patenting.
- 6.95 The Examiner is empowered to determine the matter of double patenting (amongst other matters) when conducting an examination or supplementary examination, under Section 2(1) (see definition of “examination” and “supplementary examination”), Rule 2A(1)(d) and Rule 2A(3)(e).
- 6.96 According to Section 2(1), “examination” means an examination conducted by an Examiner in relation to an application for a patent to determine such matters as may be prescribed, and “supplementary examination” means a supplementary examination conducted by an Examiner in relation to an application for a patent to determine sub matters as may be prescribed.
- 6.97 Rule 2A(1)(d) and Rule 2A(3)(e) respectively set out that for the purposes of the definition of “examination” or “supplementary examination” in Section 2(1), the matters to be determined by an Examiner when conducting an examination or supplementary examination in relation to an application for a patent includes:

Whether there is –

- (i) any other application for a patent for the same invention, with the same priority date, filed by the same applicant or his successor in title; and
- (ii) any earlier grant of a patent for the same invention, with the same priority date, to the same applicant or his successor in title.

⁵ In the *Patents Act* with effect immediately before 14/02/2014, Section 30(3)(e) sets out that it is one of the conditions for grant of a patent that a patent application has no double patenting issue.

- 6.98 An Examiner, in determining a positive finding of double patenting, shall notify the Registrar accordingly in his written opinion (Rule 46(1)(f) or Rule 46(1A)(e)). A positive finding of double patenting is considered by the Registrar to be an objection.
- 6.99 If such a positive finding (i.e. an objection) under Patents Rule 46(1)(f) or Rule 46(1A)(e) is left unresolved, it shall be contained in the examination report or the supplementary examination report issued by the Examiner. Consequently, the Registrar shall not issue a notice of eligibility under Section 29A(1). It follows that Section 30(b) would not be satisfied, and hence the patent application would not proceed to grant⁶.
- 6.100 It follows from Rule 2A(1)(d) or Rule 2A(3)(e) that double patenting only applies to the situation where the same applicant (or their successor in title) makes the two applications. If the applications are made by two different applicants, then the applications are allowed to proceed.
- 6.101 It should be noted that double patenting is different from Section 14(3) where a Singapore application which is not published at the time of filing of the application in suit may constitute part of the state of the art for novelty purposes. In the case of Section 14(3), the two applications do not share the same priority date and accordingly one is prior art against the other.
- 6.102 The law applies to both pending applications, as well as granted patents for the same invention. When dealing with co-pending patent applications for the same invention, Examiners should flag any potential double patenting issues to the applicant while continuing with the examination of both applications. It will be up to the applicant how they wish to proceed with the applications in order to avoid double patenting.

⁶ In contrast, under the *Patents Act* with effect immediately before 14/02/2014, when there is double patenting, the Examiner does not raise an objection but should include a note indicating the potential double patenting issue in the written opinion. If the written opinion is otherwise clear, an examination report will issue with the note and the Registrar is also advised of the potential double patenting issue. In other words, under the *Patents Act* with effect immediately before 14/02/2014, the note is not taken to be an unresolved objection but rather an observation. The law did not require the Examiner to examine double patenting under Sections 29(5) and (6), though it is a condition for the application to be granted to have no double patenting issue as per Section 30(3)(e).

- 6.103 Double patenting will apply if two claims are **identical in scope**. In most cases, this will occur if the claims are **coterminous**. This can apply to independent claims where the wording is identical or to dependent claims where the combination of limitations or additional features results in claims having identical scope. Accordingly, Examiners will need to consider both independent and dependent claims in order to determine whether there is a double patenting situation. Double patenting will also apply if the claims use different terminology but are otherwise identical **in substance**. This will include situations where different terminology is used to define the same invention.
- 6.104 Double patenting may apply as well in situations where two claims differ in as much as one contains a specific feature while the other defines a more generic group for the corresponding feature. For example, claim 1 in application “A” and claim 1 of application “B” define identical features, except that claim 1 in application “A” further defines a specific feature and claim 1 in application “B” further defines a more generic group of corresponding feature. An objection of double patenting may arise between applications “A” and “B” in such situations if the specific feature is the only one disclosed in the specification of application “B” and there is no basis for reading the specification as constituting a more generic group. However, if application “B” discloses that there is more than one means of performing a particular step or the specific feature may be selected from a group, then no objection should be taken.
- 6.105 In the case of claims that do not have unity (i.e. they do not share a single inventive concept), they would not be the same invention and double patenting will not occur. Therefore, there should not be double patenting between parent and divisionals if they relate to claims that were objected to for lack of unity in the first place.
- 6.106 Double patenting has yet to be considered by the Singapore Courts but given the similarity in the law some guidance may be taken from UK precedent.
- 6.107 In *Arrow Electric Switches Ltd’s Applications* [1944] 61 RPC 1, the Patents Appeal Tribunal considered a parent application claiming an electric switch **A**. The specification also contained a claim to the switch when operated with an overload device **B** – in essence a claim to **A + B**. The divisional application claimed overload device (**B**). The UK Intellectual Property Office considered that double patenting existed because the patent to **B** *per se* would encompass its use with device **A** – thus including **A + B**

(that is, a claim to the item *per se* is a claim to the item in *all* environments), even if not explicitly defined. They sought that the applicants include a disclaimer in the divisional application to avoid overlap.

6.108 On appeal, Morton J questioned the logic of this approach. Taken to its full extent, the claim to **A** *per se* in one would always include within its scope the combination of **A** + **B**, and a claim to **B** *per se* in the other would always include within its scope the combination of **A** + **B**. As a consequence, the divided patent to **B** *per se* would *always* need a disclaimer, regardless of whether or not the parent application contained a claim to the combination of **A** + **B**. If for any reason the parent patent to **A** *per se* was subsequently made void, the patentee would then have no protection at all over the use of **A** + **B** in combination because they had disclaimed it.

6.109 The subsequent UK Patents Act 1977 codified the exclusion to double patenting, as did the Singapore Act. Moreover, the UK Act forbids double patenting for UK national applications and those originating under the EPC and designating the UK. Several decisions have considered the term “same invention” in relation to these provisions which can provide guidance as to the application of the double patent provision in Singapore.

6.110 In *Marley Roof Tile Co. Ltd. 's Patent* [1994] RPC 231, the Court of Appeal found that a claim to a product will conflict with a claim to the same product as produced by a specific process. This is consistent with the approach that a product-by-process claim is indistinguishable from a claim directed to the product *per se* (and made by a different process).

6.111 Several other relevant hearings decisions have issued from the UK Intellectual Property Office. In general, the approach is taken that an objection of double patenting will arise where the claims explicitly include all of the same features (that is they are coterminous, including where the claims are dependent as well as independent), but also where the claims differ in wording but not in substance.

6.112 *Kimberley-Clark Worldwide Inc.* BL O/279/04 involved a situation wherein (in short) a European patent covered **A** + **B**, while the UK patent covered only **A**. In accordance with the UK examination guidelines, the hearing officer noted that some overlap of

claims was allowable. In this case, he considered it useful to consider whether the integer **B** was an invention in its own right – since the conclusion could then be readily reached that the two patents were for different inventions. Furthermore, he noted that the European patent had been amended to remove claims to **A** in isolation as a result of opposition proceedings and had been allowed to proceed with claims to the combination. He considered this highly persuasive since the patent would not have been allowed to proceed had it still been to the same invention.

6.113 In *SeeReal Technologies SA* BL O/261/12, the hearing officer noted that the fact that a claimed invention in a second patent could have been included as a dependent claim in the first patent does not automatically mean there is double patenting. An absence of plurality does not necessarily mean the presence of conflict. Applying this to the case in hand, the hearing officer considered there was a feature that made a substantial difference between some of the objectionable claims and therefore they constituted different inventions. A second difference between the claims was considered implicit since this was the only way described to carry out the particular feature.

6.114 The permissible degree of overlap was also considered in *Optinose AS* BL O/026/12, wherein the hearing officer stated:

“But even if the divisional application has a claim that falls clearly within the scope of a claim in the parent then it is not necessarily fatal to the divisional application. This is clear from Arrow Electric Switches Ltd’s Applications and Kimberley-Clark Worldwide Inc’s Patent. However, if the two claims are coterminous or the like, in Maag, if in substance they relate to the same invention then there would be conflict.”

In this case, the hearing officer considered the claim of the parent patent included method **A**, method **B** and various combinations of the two (these being the various methods disclosed in the specification, but were not specifically defined in the claims). The divisional was limited specifically to method **B**. The hearing officer therefore concluded that there was no double patenting because the claims were not coterminous, nor did they in substance relate to the same invention. However, this may be considered on a case by case basis. For example, if a claim clearly defined a

method using **A or B** and the divisional application claims were identical but limited only to the method using **B**, an objection may be appropriate since the scope of the divisional is identical to one of the alternatives in the first granted patent.

7. AMENDMENTS AND CORRECTIONS

A. Statutory requirements

7.1 Note: Amendments and Corrections are dealt with under different sections of the Patents Act.

7.2 **Amendment** of an application or amendment of the specification of a patent must comply with the requirements of Section 84. Section 84(2) requires that pre-grant amendments do not result in the application disclosing any matter extending beyond that disclosed in the application as filed. Section 84(3) requires that post-grant amendments do not result in the specification disclosing any additional matter or extend the protection conferred by the patent. The same principles apply for deciding whether a new application filed under Section 20(3), Section 26(11) or Section 47(4) of this Act or an application for which a filing date has been secured upon satisfying the conditions referred to in Section 26 (1)(a), (b) and (c)(ii) discloses any added matter as well. Section 84(1) requires that if an application filed under Section 20(3), Section 26(11) or Section 47(4) of this Act discloses matter extending beyond the earlier application made under this Act as filed, the application shall not be allowed to proceed unless it is amended to exclude that matter. Section 84(1)(A) requires that if an application having made a Section 17(2) priority declaration contains a incorporation by reference statement to an earlier relevant application under Section 26(1)(c)(ii) and the description of the invention later filed under Section 26(7)(b) discloses matter extending beyond the earlier relevant application, the application shall not be allowed to proceed unless it is amended to exclude that matter.

7.3 In contrast, correction of an application or the specification of a patent or of any document filed in connection therewith is governed by Section 107. In short, **correction** is the alteration of a document so that it may better express the intention the drafter had at the time of drafting, including where an agent drafting a document has misconstrued his given instructions. Once it has been established that the change is indeed a correction, the question of whether subject matter is added or the protection conferred is extended is not a relevant consideration.

- 7.4 It is important that Examiners examine the correct specification of the application, and accordingly all relevant amendments or corrections must be identified and taken into account during examination. This will include any amendments made (PCT Article 19 and 34) or rectifications authorized (PCT Rule 91) in the international phase, as well as any amendments or corrections made by the applicant during the national prosecution.
- 7.5 A pre-grant amendment, once accepted, takes effect from the date the amendment was filed, whereas an amendment of the specification of a patent post-grant, once allowed, shall have effect and be deemed always to have had effect from the date of grant of the patent (Section 38(3)). A correction, once accepted, takes effect from the date of filing, as if the error has never been made in the first place.
- 7.6 How amendments made (PCT Article 19 and 34) and rectifications authorized (PCT Rule 91) in the international phase should be dealt with during the national phase are discussed in detail in later sections.

B. General power to amend before grant

7.7 Section 31 sets out that:

- (1) Subject to subsections (2), (3) and (4), the applicant may, of his own volition or otherwise, amend the application or the specification thereof.
- (2) The applicant shall not be entitled to amend the application or specification unless —
 - (a) he has made a request to do so to the Registrar —
 - (i) in the prescribed manner; and
 - (ii) within the prescribed period; and
 - (b) the request is accompanied by the prescribed documents.
- (3) The applicant may only amend the application or specification in accordance with the prescribed conditions and subject to section 84.
- (4) If the applicant fails to comply with any requirement under subsection (2) or (3), the Registrar shall —
 - (a) refuse the applicant's request to amend the application or specification; and
 - (b) inform the applicant of the refusal.

7.8 Pre-grant amendments under Section 31 shall be made within the prescribed time frames according to Rule 49 and in the prescribed manner according to Rule 48.

i. General process for amendments before grant

7.9 Rule 49 sets out the time frames within which that an applicant may make different types of pre-grant amendments:

- (1) The applicant may, of his own volition, amend the request for the grant of a patent at any time before payment of the fee for the grant of the patent.
- (2) Subject to paragraph (3), the applicant may, unless the Registrar otherwise requires, of his own volition, amend the description, claims, drawings and abstract at any time before payment of the fee for the grant of a patent.
- (3) Subject to section 29B(2), an amendment shall not be made under paragraph (2) —
 - (a) at any time after the filing of a request for a search report under section 29(1)(a) and before the receipt of that report by the applicant;
 - (b) at any time after the filing of a request for a search and examination report under section 29(1)(b), unless the amendment is contained in a response filed under rule 46(3) in respect of that report;
 - (c) at any time after the filing of a request for an examination report under section 29(1)(c) or (3), unless the amendment is contained in a response filed under rule 46(3) in respect of that report;
 - (d) at any time after the filing of a request for a supplementary examination report under section 29(1)(d), unless the amendment is contained in a response filed under rule 46(3) in respect of that report; or
 - (e) at any time after a request for a review under section 29B(1) is made.

7.10 Taking a search and examination request as an example, amendments to the application (that is, description, claims, any drawings and abstract) can only be made either prior to or at the filing of the request or during a response to the Examiner's written opinion under Rule 46(3). In other words, apart from at the time of filing the response, there is no other opportunity for the applicant to make amendments to the application during the period after the filing of the request and before payment of the fee for the grant of a patent, unless the Registrar requires such amendments.

7.11 The identification of the afore-mentioned different types of pre-grant amendments can be facilitated by an understanding of the governing rules and prescribed forms used for their filing as follows:

- Applications for amendment of the request for the grant of a patent on Patents Form 1 or applications for amendment of the description, claims, drawings and abstract prior to or at the filing of a request for a search or any type of examination should be made on Patents Form 13 (Rule 48(1)).
- Amendments to the specification (that is, description, claims and any drawings) in response to a written opinion should be made on Patents Form 13A (Rule 46(3)).
- Amendments to to the specification (that is, description, claims and any drawings) at the time of requesting for an examination review should be made on Patents Form 13 (Rule 46A(3)).
- Within the prescribed period of putting the application in order for grant, the applicant is required to provide clean copies of the specification including the amended pages, but these clean copies are not forwarded for checking by the Examiner. Only amendments in order to comply with the formal requirements made on Patents Form 13 are allowed to be introduced at this stage (Rule 47(6)).

7.12 Formality requirements would be checked by the Registry prior to forwarding the application to the Examiners, so the Examiners need not routinely check these details. However, if the Examiner notices that the application may not fulfil the formality requirements, the matter should be referred to the Registry.

ii. Amendments made in response to written opinions (Rule 46(3))

- 7.13 For a search and examination request or an examination only request, Section 29(9) provides that an applicant may respond to at least one written opinion that has been issued under Section 29(7), and subject to Section 84, amend the specification of the application. Rule 46(3) states that the response to the written opinion may contain written submissions on the Examiner's opinion, an amendment of the specification of the application or both.
- 7.14 Given the time frames associated with the examination process, it is foreseeable that there may be several rounds of communication between the Examiner and the applicant. When the deadline for issuing the examination report is approaching and the applicant still fails to resolve all the issues with the application, it will be at the discretion of the Examiner whether to issue a further written opinion according to Rule 46(6). Factors that may be taken into account at this juncture would include: whether sufficient time remains for the applicant to respond, which generally depends on the nature of the outstanding issues, and whether sufficient time remains for the Examiner to draw up an examination report. However, if the prosecution of the case has reached a stalemate and is unlikely to progress further, where Section 29(7) applies and the Examiner has already issued at least one written opinion before, the Examiner may issue an adverse examination report rather than issue a further opinion. In such circumstances, the Examiners should discuss the case with a Senior Examiner.
- 7.15 Under Rule 46(7), an Examiner's further opinion or report need not take into account any response filed by the applicant after the Examiner has commenced drawing up the opinion or report.
- 7.16 For a supplementary examination request, Section 29(8) mandates that the Examiner issue the applicant **only one** written opinion. An applicant's written submissions to the written opinion and/or amendments to the specification under section 29(9) will be forwarded to the Examiner for consideration, and subsequent establishment of a supplementary examination report. If the Examiner considers that the written submissions and/or amendments do not overcome the objections, an adverse examination report will be established.

7.17 Rule 46(3) sets out that, in all the types of examination requests aforementioned, amendments to the specification (that is, the description, the claims and any drawings) in response to the written opinion issued by the Examiner should be made on Patents Form 13A. The amendments filed may be in response to the issues raised by the Examiner, and may include other amendments that are not in response to the Examiner's objections.

C. Allowability of pre-grant amendments (Section 84(2))

7.18 Pre-grant amendments (Section 84(2)):

(2) No amendment of an application for a patent shall be allowed under section 31 if it results in the application disclosing any matter extending beyond that disclosed in the application as filed.

7.19 Section 84(2) requires that no added matter beyond that disclosed in the application as filed is to be incorporated into the application during any pre-grant amendments ([see sub-section i of Section J in this Chapter](#)). This consideration applies to amendments made of the applicant's own volition, amendments made by the applicant in response to a written opinion, or amendments required by the Registrar. The test and considerations for added subject matter are discussed in later sections.

7.20 There is no *pre-grant* restriction on the applicants broadening the scope of their claims provided the amendment does not include matter extending beyond that disclosed in the application as filed. That is, if the disclosure in the specification as filed is broader than the claims as filed, the applicant may make amendments before grant to bring the claims into alignment with the specification.

D. General power to amend after grant (Section 38)

7.21 Section 38 sets out that:

- (a) Subject to this section and section 84, the Registrar 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.
- (b) No such amendment shall be allowed under this section where there are pending before the court or the Registrar proceedings in which the validity of the patent may be put in issue.
- (c) 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.
- (d) A person may give notice to the Registrar of his opposition to an application under this section by the proprietor of a patent, and if he does so the Registrar shall notify the proprietor and consider the opposition in deciding whether to grant the application.

7.22 The Examiner should refer to [Section E in this Chapter](#) to determine whether such amendments are allowable. As compared to pre-grant amendments, post-grant amendments have the further restriction that the scope of the claims cannot be broadened.

i. General process for amendments after grant (Rule 52)

- 7.23 An application to the Registrar for leave to amend the specification of a patent following grant (i.e., post-grant amendment) may be filed by the proprietor of the patent using Patents Form 17.
- 7.24 If the Registrar is satisfied that the application may be allowed, the application and the reasons for proposed amendment are advertised for opposition. Interested parties have 2 months to oppose the proposed amendment. If the proposed amendments are opposed, the proprietor may, within 2 months, file a counter-statement setting out fully the grounds upon which the opposition is resisted, if he wishes to continue with the request for amendment. In the event of such an opposition, the Registrar may refer the matter to an Examiner for an opinion on whether the amendment is allowable, taking into account the application for leave to amend, together with the notice of opposition, the accompanying statement setting out fully the facts upon which the opponent relies and any counter-statement, where applicable.
- 7.25 If no opposition is filed within the prescribed period, or the opposition filed is not accompanied by the said required statement and the Registrar is satisfied with the reasons for the proposed amendment, the amendment of the patent will be allowed.

E. Allowability of post-grant amendments (Section 84(3))

7.26 Post-grant amendments (Section 84(3)):

(3) No amendment of the specification of a patent shall be allowed under section 38(1), 81 or 83 if it —

- (a) results in the specification disclosing any additional matter; or
- (b) extends the protection conferred by the patent.

7.27 Guidance on the assessment of post-grant amendments have been provided in two recent Singapore High Court decisions: *Ship's Equipment Centre v Fuji Trading* [2015] SGHC 159 and *Warner Lambert v Novartis* [2016] SGHC 106.

7.28 For the determination of condition **(a) whether the proposed amendment discloses additional matter**, the same test that applies for pre-grant amendments as set down in the UK case *Bonzel and Schneider (Europe) AG v Intervention Ltd* [1991] RPC 553 applies essentially for post-grant amendments. The *Bonzel* test was accordingly followed in *Ship's Equipment Centre v Fuji Trading* and *Warner Lambert v Novartis*.

7.29 The proposed amendment was from a method of treatment claim to a Swiss-style claim in *Warner Lambert v Novartis*. Specifically, the granted claims were directed towards methods of treating pain by administering a therapeutically effective amount of the disclosed compound. The proprietor proposed to amend the granted claims to claims directed to the use of the same compound to prepare a medicament (i.e. the therapeutically effective amount of the disclosed compound) for treating pain. Following the *Bonzel* test, George Wei J concluded the amendment does not disclose any “added matter”, taking into account the skilled addressee would appreciate that the Swiss-style claims were conceived to protect specific medical indications.

7.30 After considering condition (a), it is then necessary to determine condition **(b) whether the proposed amendment extends the protection conferred by the patent**. The crux of the inquiry is whether the ambit of the protection conferred by the patent will be extended by the proposed amendment. As such, it is important not to be unnecessarily side-tracked by the change in the category or subject matter of the claims in the patent. For example, it would be permissible to reformulate an apparatus

claim by way of amendment to a claim covering only a use of the product, if the result is to cut down the scope of protection. In this sense, the decision as to whether the scope of protection has been extended cannot be decided on a formalistic basis (see *Ship's Equipment Centre v Fuji Trading* and *Warner Lambert v Novartis*).

7.31 A good test is to ask whether something that fell outside the scope of the [granted] claims (properly interpreted) and hence not an infringing act on its own now falls within the [proposed amended] claims such that it becomes an infringing act (“the Infringement Test”) (Terrell on the Law of Patents at para 15-41, Richard Miller *et al*, Sweet & Maxwell, 17th Ed, 2011). In properly applying the test, a “purposive approach” should first be applied to construing the patent claims. It is then necessary to compare **the totality of protection** established by the patent before and after the amendment, and not the scope of protection within the wording of each single claim as granted. For example, the extension of the scope of an individual claim *per se* is not objectionable, if it does not result in the extension of the protection of the patent (see *Warner Lambert v Novartis* and *Ship's Equipment Centre v Fuji Trading*).

7.32 Based on these considerations, George Wei J concluded that the amendment has broadened the scope of protection to include manufacture of a medicament, which represents a shift away from the granted claims directed to the method of treatment, and hence fails condition (b).

“Whilst broadly connected by the same final objective (of treating pain), the granted claims and the amended claims are targeted at different activities — the latter covers the making of the compound for the purposes of administration (to treat pain) whereas the former covers only the follow-on act of administration of the compound to treat pain.”

7.33 Apart from the requirements under Section 84(3), the proposed amendments must also satisfy the requirements under Sections 25(5)(b) and (c) of the Patents Act, i.e., **the [amended] claim or claims must be ‘clear and concise’ and ‘supported by the description’**. These are the “base-line criteria” that any claim amendments must satisfy as set out in *Trek Technology (Singapore) Pte Ltd v FE Global Electronics Pte Ltd and others and other suits* [2005] 3 SLR(R) 389, as affirmed in *Ship's Equipment Centre v Fuji Trading* and *Warner Lambert v Novartis*.

7.34 The Registry issued a Circular No. 1/2016 on 30 June 2016 which takes effect from its issuance date and applies to all pending and future requests. In addition to the requirements under Section 84(3), it is made clear in the Circular that any post-grant amendments under Section 38 will also be assessed based on the following criteria:

- (1) Whether relevant matters are sufficiently disclosed;
- (2) Whether there was any unreasonable delay in seeking amendments; and
- (3) Whether the patentee has gained an unfair advantage obtained by delaying amendments which are known to be needed.

7.35 As required by criterion (1) of the Circular, any application for post-grant amendment should set out fully the reason(s) for amendments, including the circumstances leading to the amendments and any evidence in support thereof to facilitate the assessment. As such, relevant matters, i.e. the reason(s) for amendments, should be disclosed to the extent that said disclosure would be sufficient for the Examiner to establish a *prima facie* case of allowability for the proposed amendments. In the situation where the Examiner deems that the evidence in support of the reason(s) for amendment is not sufficient, a request may be made, via the Registry of Patents, for the applicant to provide further evidence.

7.36 Guidance for consideration of criterion (2) Whether there was any unreasonable delay in seeking amendments may be found in *Warner Lambert v Novartis* [2016] SGHC 106 at 101-104:

“First and foremost, for the delay to be considered undue, the period of the delay need not be long provided that there is no plausible explanation for the delay.”

“Second, a delay may not be held against the applicant if it is able to provide a reasonable explanation for the delay.”

“Third, the appropriate juncture to question whether the amending party has been guilty of an unreasonable delay is the time it was first made aware of the need to amend.”

7.37 Guidance for consideration of criterion (3), whether the patentee has gained an unfair advantage obtained by delaying amendments which are known to be needed, may also be found in *Warner Lambert v Novartis* [2016] SGHC 106 at 117-121.

F. Consideration of PCT amendments in the national phase (Section 86(6))

7.38 Amendments during the international phase of PCT applications may be made under Article 19 or, if the applicant demands Chapter II examination, Article 34. In most cases these will need to be taken into account during the national prosecution. They will always be superseded by amendments made to the same claim(s) in the national phase by using Patents Form 13 or Patents Form 13A, where applicable.

7.39 The provisions relating to the manner in which such amendments are dealt with in the national phase are set out in Section 86(6) as follows:

(6) Where, during the international phase, the application is amended in accordance with the Patent Co-operation Treaty, the amendment shall be treated as made under this Act if, and shall be disregarded unless –

(a) when the prescribed period expires, where –

(i) the amendment is not in English; and

(ii) if any copy of the amendment has been communicated to the Registry in accordance with the Treaty, that copy is in a language other than English, an English translation of the amendment has been filed at the Registry; or

(b) where the applicant expressly requests the Registrar to proceed earlier with the national phase of the application, there is filed at the Registry –

(i) a copy of the amendment, if none has been communicated to the Registry in accordance with the Treaty; and

(ii) an English translation of the amendment, if –

(A) the amendment is not in English; and

(B) where any copy of the amendment has been communicated to the Registry in accordance with the Treaty, that copy is in a language other than English.

7.40 In most cases, the Registry will process Article 19 and 34 amendments communicated from International Bureau and translations thereof in accordance with the Rules, and

the application received from the Registry should have all the necessary documents. As such, the Examiners need not routinely check these details. However, if the Examiner discovers any irregularity in the documentation that may affect the scope of the application (e.g. if there is doubt over whether any Article 19 and 34 amendments have been made in the international phase), then the Examiner may, after checking the available databases such as Patentscope and the EP Register, refer the matter to the Registry.

- 7.41 Where the amendments made under the PCT are in a foreign language, the applicant shall file at the Registry an English translation of the amendments accompanied by a copy of a verification document upon entry into the national phase or request the International Bureau to send an English translation of the amendments under the PCT to the Registry after entry into the national phase. If the Registry does not receive the required translation at filing, a notice is issued under Rule 86(6) and the applicant is given 2 months to provide a translation. If the Registry considers that the translation filed at the Registry is inaccurate, a notice is issued and the applicant is given 2 months to provide another translation. In the event that any prescribed requirement for the English translation filed at the Registry has not been met, the amendments under the PCT will be disregarded and the application will proceed in its unamended form.
- 7.42 Where the applicant expressly requests a PCT application to enter the national phase early, the applicant shall file at the Registry a copy of the amendments, if no such amendments have been communicated to the Registry. The applicant shall also file at the Registry an English translation, if the amendments filed at the Registry are in a foreign language or amendments in a foreign language are communicated to the Registry. In the event that any prescribed requirement for the English translation filed at the Registry has not been met, the amendments under the PCT will be disregarded and the application will proceed in its unamended form.
- 7.43 The Examiner should refer to [Section G in this Chapter](#) to determine whether the Article 19 and 34 amendments are allowable.

G. Allowability of PCT amendments in the national phase

7.44 When amendments are made under the PCT, a consideration is given at that stage as to the allowability of the amendments. These are set out in the PCT Guidelines at 20.09. Notably, the considerations are analogous to the considerations made under the Singapore law:

20.09 The examiner makes sure that amendments filed do not add to the content of the application as filed, thus violating Article 19(2) or 34(2)(b). Furthermore, they must not itself cause the international application as amended to be objectionable under the PCT; for example, the amendment should not introduce obscurity. The examiner should consider as acceptable restriction of the scope of the claims or amendments that improve the clarity of the description or amendments to the claims in a manner clearly desirable, without changing their subject matter content or scope.

7.45 If the International Authority has considered an amendment to add subject matter, this will be indicated in Box I of the International Report on Patentability II (IPRP II). It should be noted that a consideration of the allowability of amendments in the international phase is done only if the application has demanded Chapter II examination. This will include a consideration of both Article 19 and Article 34 amendments filed before expiry of the prescribed time limit. The opinion of the International Authority is not binding, and Examiners are not bound to follow it if they disagree. However, if the Examiner considers that the amendments are in fact allowable, they generally should review the search to ensure that the matter of the amendments is adequately searched.

7.46 If the applicant has not demanded Chapter II examination and has made Article 19 amendments, then there will have been no examination of these amendments during the international phase. Accordingly, Article 19 amendments will need to be checked carefully to ensure that they are allowable.

7.47 It should also be noted that practices differ between international authorities as to what constitutes added matter. For example, intermediate generalizations may not be

recognized by all authorities. As a consequence, Examiners will need to consider whether all amendments made during the international phase of the application meet Singapore requirements.

- 7.48 In the event that amendments are considered to incorporate added matter, then this should be indicated at Box I.3, with a detailed explanation provided in a supplemental box.

H. Added matter in divisional applications (Section 84(1))

7.49 Divisional applications that are filed in respect of matter disclosed in an earlier application and claim the filing date of the earlier application under Section 20(3), Section 26(11) or Section 47(4) could possibly introduce added matter, that is, matter extending beyond that disclosed in the earlier application.

7.50 The provisions relating to the manner in which such divisional applications that have introduced added matter are dealt with are set out in Section 84(1) as follows:

(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 made under this Act or in the application made under the United Kingdom Patents Act 1977 or the application under the European Patent Convention designating the United Kingdom filed at the European Patent Office from which the filing date and right of priority is sought to be derived, as filed, or the application for the patent, as filed, may be filed under section 20(3) or 47(4) or section 116(6) of the Patents Act (Cap. 221, 1995 Ed.), or as mentioned in section 26(11), but shall not be allowed to proceed unless it is amended so as to exclude the additional matter.

7.51 In deciding whether a divisional application comprises additional matter, the Examiner should take into account the same test and considerations that apply for added subject matter in application and patent specifications discussed in the previous sections.

I. Added matter in applications having declared a priority due to later filed description (Section 84(1A))

7.52 According to Section 26(1), an applicant for a patent can secure a date of filing at the earliest time when the documents filed at the Registry to initiate the application satisfy the following conditions: (a) the documents indicate that a patent is sought; (b) the documents identify the applicant; and (c) the documents contain something which is or appears to be a description of the invention sought. In the event where the application contains a priority declaration under Section 17(2), the description of the invention sought in condition (c) may be substituted by:

- (A) a reference to an earlier relevant application specified in the declaration under section 17(2) made in or in connection with the application;
- (B) such information on the earlier relevant application as may be prescribed; and
- (C) a statement that the description of the invention for which the patent is sought is incorporated in the application by reference to, and is completely contained in, the earlier relevant application, as filed.

7.53 In such an event, within the prescribed period after the filing, the applicant is required under Section 26(7) to file: (a) a written notice confirming the above statement (C); (b) the description of the invention for which the patent is sought; and (c) other prescribed documents in relation to the application. Failing to do so will cause the application to be treated as having been abandoned according to Section 26(12).

7.54 The afore-mentioned later filed description under Section 26(7)(b) could possibly introduce added matter, that is, matter extending beyond that disclosed in the earlier relevant application as specified in the Section 17(2) declaration. Such applications shall not be allowed to proceed unless amended so as to exclude the additional matter.

7.55 In deciding whether such applications having made a Section 17(2) priority declaration would introduce additional matter due to the later filed descriptions, the Examiner should take into account the same test and considerations that apply for added subject matter in patent applications and patent specifications as discussed in the previous sections.

J. The test for added subject matter

7.56 In *FE Global Electronics Pte Ltd and others v Trek Technology (Singapore) Pte Ltd* [2006] 1 SLR 874 at [24], *Martek Biosciences Corp v Cargill International Trading Pte Ltd* [2011] 4 SLR 429 at [81], and *Main-Line Corporate Holdings Ltd v DBS Bank Ltd* [2012] 4 SLR 147 at [73], the Singapore Courts have followed the test set down in the UK case *Bonzel and Schneider (Europe) AG v Intervention Ltd* [1991] RPC 553. The Court in *Novartis AG and another v Ranbaxy (Malaysia) Sdn Bhd* [2012] SGHC 253 at [8] followed a further elaboration of this test as provided in *European Central Bank v Document Security Systems Incorporated* [2007] EWHC 600 at [97]-[102].

7.57 The Court in *Bonzel* set down that in order to determine whether an amendment to the description had the result that a patent as granted disclosed matter which extended beyond that disclosed in the application a three-step test is applied —

- (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.

7.58 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 implicitly** (emphasis added).

7.59 In *European Central Bank*, the *Bonzel* test was further elaborated as follows:

“97. A number of points emerge from [the Bonzel] formulation which have a particular bearing on the present case and merit a little elaboration. First, it requires the Court to construe both the original application and specification to determine what they disclose. For this purpose the claims form part of the disclosure ... though clearly not everything which falls within the scope of the claims is necessarily disclosed.

98. *Second, it is the Court which must carry out the exercise and it must do so through the eyes of the skilled addressee. Such a person will approach the documents with the benefit of the common general knowledge.*

99. *Third, the two disclosures must be compared to see whether any subject matter relevant to the invention has been added. This comparison is a strict one. Subject matter will be added unless it is clearly and unambiguously disclosed in the application as filed.*

100. *Fourth, it is appropriate to consider what has been disclosed both expressly and implicitly. Thus the addition of a reference to that which the skilled person would take for granted does not matter: DSM NV's Patent [2001] R.P.C. 25 at [195]-[202]. On the other hand, it is to be emphasised that this is not an obviousness test. A patentee is not permitted to add matter by amendment which would have been obvious to the skilled person from the application.*

101. *Fifth, the issue is whether subject matter relevant to the invention has been added. In case G1/93, Advanced Semiconductor Products, the Enlarged Board of Appeal of the EPO stated (at paragraph [9] of its reasons) that the idea underlying Art. 123(2) is that an applicant **should not be allowed to improve his position by adding subject matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application.** At paragraph [16] it explained that whether an added feature which limits the scope of protection is contrary to Art 123(2) must be determined from all the circumstances. **If it provides a technical contribution to the subject matter of the claimed invention then it would give an unwarranted advantage to the patentee. If, on the other hand, the feature merely excludes protection for part of the subject matter of the claimed invention as covered by the application as filed, the adding of such a feature cannot reasonably be considered to give any unwarranted advantage to the applicant. Nor does it adversely affect the interests of third parties.***

*102. Sixth, it is important to **avoid hindsight**. Care must be taken to consider the disclosure of the application through the eyes of a skilled person who has not seen the amended specification and consequently does not know what he is looking for. This is particularly important where the subject matter is said to be implicitly disclosed in the original specification.”*

i. Basis of the consideration: *the application as filed*

- 7.60 The Examiner must construe the document through the eyes of the person skilled in the art and with the benefit of the common general knowledge of such a person. As with the construction of any document, Examiners should take a purposive approach to construction.
- 7.61 Notably the legislation sets out that consideration of post-grant amendments is done on the “specification” rather than the “application” as is set out in the legislation for pre-grant amendments (the application includes both the specification and the abstract as per Section 25(3)). However, the same consideration applies to both pre- and post-grant amendments: that is, the whole of the description, any drawings and claims may be considered. The comparison is done between the specification as filed and the specification as proposed to be amended.
- 7.62 The abstract is not taken into account when determining what the application disclosed at filing (*Abbott Laboratories Ltd. v Medinol Ltd* [2010] EWHC 2865 (Pat)). The purpose of the abstract is to provide technical information about the invention (Section 25(7)). The abstract should therefore be consistent with the specification. If it is, then it adds nothing in the way of disclosure. If it is not, then it is incorrect. Examiners should therefore disregard the content of the abstract in determining whether an amendment adds matter.
- 7.63 Similarly, a priority document does not form part of the application, and any matter disclosed in the priority document but omitted from the specification as filed may not be subsequently added. For example, if figures, sequence listings or the like are disclosed in the priority documents but omitted from the application, the applicant may not rely on the priority document as a basis for amending the application (see T 260/85 *Coaxial Connector* and VEB Kombinat Walzlager [1987] RPC 405).
- 7.64 In cases where a listing of biological sequences was included after the date of filing of the original application, the determination of the allowability of such a sequence listing will be decided depending on the facts of the case.

ii. Incorporation by reference

7.65 The specification may refer to another document, which should be unambiguously identified and should have been published at the date of filing the Singapore application in question, to provide additional background material or further information about the invention, often as an “incorporation by reference” ([see subsection iv of Section K in Chapter 5](#)). However, the specification must provide a clear and complete disclosure of the invention at the date of filing ([see Section K in Chapter 5](#)). Incorporation by reference of an entire document without indication of the specific features to be incorporated generally will not be permitted. For analogous reasons, features which have not been included in the specification as originally filed but are only described in the document incorporated by reference may subsequently be introduced into the claims of the application by way of amendment as essential features of the invention **only under particular conditions** (see T6/84 *Amendment of claims* and T 689/90 *Event detector*).

7.66 In the case of T6/84, it was considered that the structural features that were included into the main claim by way of amendment were indeed those which unequivocally formed part of the specification and the amendment is thus acceptable. The originally filed Claim 1 had the following wording:

“1. A process for catalytic dewaxing a waxy hydrocarbon oil which comprises contacting said oil with a catalyst at dewaxing conditions, characterised in that the catalyst is synthetic offretite.”

7.67 The text in the original description which identified the features disclosed by reference was worded:

“Synthetic offretite is a well-defined zeolite, with a known X-ray diffraction pattern and a proposed crystal structure ... The synthetic offretite useful in the present invention and its method of preparation are disclosed in Canadian patent 934130 ...”

7.68 It is thus clear that the catalyst “synthetic offretite” referred to in the characterising portion of the main claim as originally filed was an identified material, and that further characterising parameters of such material were stated in the specification as originally filed to be set out in the cross-referenced Canadian patent.

- 7.69 The further characterising parameters of such synthetic offretite that were incorporated into the main claim from the Canadian patent during the amendment were the mole ratio of the oxides contained in synthetic offretite and the X-ray powder diffraction pattern. The Board considered that such parameters were already implicitly present in the main claim, and the amendment simply defined in greater detail the synthetic offretite. In other words, the amendment simply introduced that which was already an essential feature of the invention as described and claimed in the specification as originally filed.
- 7.70 However, the Board also cautioned that all the essential structural features thus disclosed which belong together must be incorporated into the claim during the amendment; **it is not permissible to single out a particular essential structural feature.**
- 7.71 It was further established by the Board in T 689/90 that incorporating information by reference is permissible **only if** the description of the application as filed leaves a skilled reader in no doubt that:
- (a) protection is or may be sought for features which are only disclosed in the reference document;
 - (b) the features contribute to achieving the technical aim of the invention and are thus comprised in the solution of the underlying technical problem of the invention;
 - (c) the features, implicitly, clearly belong to the description of the invention contained in the application as filed; and
 - (d) such features are precisely defined and identifiable within the total technical information within the reference document.
- 7.72 The determination of whether an amendment that sought to incorporate matter from the reference document introduces added matter should take into account all circumstances of the case.

iii. Comparing disclosures: clearly and unambiguously disclosed

7.73 Some EPO decisions have adopted a “novelty test” when assessing the allowability of amendments. These decisions may provide useful guidance when considering whether a document provides a clear and unambiguous disclosure of matter proposed to be incorporated by an amendment. For example, as set out in the “Lead Alloys” decision T 0201/83:

“The test for compliance with Article 123(2) EPC is basically a novelty test, i.e. no new subject-matter must be generated by the amendment. Normally the test for novelty calls for an inquiry whether or not a document, or article in use, contains sufficient information so that the person skilled in the art could derive the subject-matter in question from it directly and unambiguously, including any features implicit therein ... When this maxim is applied to patent applications in order to test the propriety of proposed amendments, the first condition must be that the feature of the amendment should be contained within the same document or would have to come from the relevant background art to be incorporated in that disclosure in consequence of Rule 27(1)(d) EPC. It is, nevertheless, also the view of the Board that the requirement is not satisfied unless the skilled man could directly recognise the same as a combination of features available from the document.”

7.74 The third step set out in *Bonzel* has been acknowledged as being substantially the same test as that applied in this case (CIPA Guide to the Patents Act, Seventh Edition at 76.18).

7.75 The “novelty test” is applied only to the matter which is added by the amendment. That is to say, the matter disclosed in specification after amendment is compared with the matter disclosed in the specification as filed in order to determine the subject matter generated by the amendment. If the subject matter generated by the amendment would constitute a novelty-destroying disclosure for a hypothetical claim whereas the original matter would not, then the amendment would not be allowable.

7.76 For example, in EPO decision T 194/84 the invention involved the use of natural cellulosic fibres in the electrode of a storage battery cell. An amendment was proposed to broaden the claim to the use of cellulosic fibres in general. The applicant argued that the amendment was allowable as the original application could be cited against the novelty of a more generic claim to cellulose fibres. However, the Court noted that the consideration should be based on the difference in matter between the specification prior to amendment and the specification after amendment, in this case the use of non-natural cellulosic fibres. Thus the original matter would not constitute a novelty-destroying disclosure against a hypothetical claim to the use of non-natural cellulose, and accordingly the amendment was not allowable.

iv. Express and implicit disclosures

- 7.77 The Examiner must consider what has been disclosed both explicitly and implicitly. The addition of matter to that the person skilled in the art would take for granted or consider implicit would generally be allowable (*DSM NV's Patent* [2001] RPC 25 at [195]-[202]). For example, an amendment is made to explicitly include a feature that the skilled person would consider an intrinsic part of the invention would probably be allowable.
- 7.78 A simple example of this type would be an amendment to include the term “wheels” in a specification relating to a bicycle incorporating a new steering assembly would be allowable.
- 7.79 In *Keith's Application* BL O/455/99, the Comptroller stated that matter is only implicitly disclosed if the person skilled in the art would inevitably consider that such matter was included in the application:

“In his judgment, Aldous, J stated in terms that the test for added subject-matter is a strict one and that in order to be acceptable the matter in question must be ‘clearly and unambiguously disclosed [in the application as filed] either explicitly or implicitly’. I believe that is clear as it stands, but in the face of Mr Keith's argument to the contrary, I confirm that I interpret the expression ‘disclosed ... implicitly’ as meaning that the skilled addressee would recognise that the matter in question, though not actually mentioned, must inevitably be present.”

- 7.80 It is not sufficient that the added matter was one of several possibilities that could be derived from the original disclosure. This approach is consistent with the approach in a novelty consideration, where a feature may only be considered inherent if the working of the invention would inevitably provide that result.
- 7.81 It must be noted that this is not an obviousness consideration. Amendments incorporating matter which would have been **obvious** to the person skilled in the art from the application are **not** allowable. For example, in *Flexible Direction Indicators Ltd's Application* [1994] RPC 207 the invention related to a traffic bollard

characterised by its flexibility. The specification originally disclosed that the bollard was made from a compound of two polymers. The applicants sought an amendment to include the use of a single polymer, arguing that it would be obvious to the skilled person that it could provide the desired flexibility. Aldous J noted in this case that the consideration of whether the matter extends beyond the original disclosure “*is concerned with what is disclosed, not with that which the skilled reader might think could be substituted or what had been omitted*”.

v. Matter which extends beyond the original disclosure

7.82 The reference in Section 84(2) to “*any matter extending beyond that disclosed in the application as filed*” refers to matter directly in relation to the invention.

7.83 The underlying principle of whether matter relevant to the invention has been added is that an applicant should not be allowed to improve their position by adding subject matter not disclosed in the application as filed. A key consideration 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.*” (Jacob J in *Richardson-Vicks Inc. 's Patent* [1995] RPC 568).

7.84 One approach taken by the Courts has been:

“If it provides a technical contribution to the subject matter of the claimed invention then it would give an unwarranted advantage to the patentee. If, on the other hand, the feature merely excludes protection for part of the subject matter of the claimed invention as covered by the application as filed, the adding of such a feature cannot reasonably be considered to give any unwarranted advantage to the applicant.(European Central Bank v Document Security Systems Incorporated at [101]).”

7.85 The addition of prior art information or other material not directly related to the invention would generally be considered an allowable amendment. However, if the amendment changes the way in which the person skilled in the art would understand the invention from what was originally indicated or changes the nature of the problem to be solved, then it may not be allowable.

7.86 For example, inclusion of prior art which shows the invention possesses certain advantages will be allowable only if the advantage would have been apparent to a person skilled in the art in possession of that prior art (*Palmaz's European Patents (UK)* [1999] RPC 47).

vi. Data submitted after the filing date

- 7.87 Under Singapore Patents Act, the specification of an application or a patent cannot be amended in a manner which would result in added subject matter. Therefore, if experimental data is to form part of the specification, it should be included at the date of filing.
- 7.88 The Applicant may submit data or evidence after the date of filing in order to address objections (e.g. an inventive step, sufficiency or industrial applicability objection) raised by the Examiner. Whether the data or evidence will be admitted depends on the technological field and individual case. Usually, as long as support could be found in the original disclosure (no new teaching), the submitted data may be considered by the Examiner.
- 7.89 Generally, in the assessment of sufficiency, the applicant cannot rely on data or evidence submitted after the filing date itself to establish sufficiency of disclosure and overcome a sufficiency objection.
- 7.90 When assessing inventive step, advantages in association with the invention (e.g. substantiated by experimental data) that are not disclosed in the specification as filed but submitted after the filing date may be considered by the Examiner. However, if the data or evidence submitted after the filing date provides new teaching, e.g. a selection invention for which support cannot be found in the application as filed, then it would not be allowable to claim a specific compound/composition by merely providing its advantages at a later stage.

vii. Intermediate generalisation

7.91 The claims form part of the disclosure but as noted in *European Central Bank* not everything which falls within the scope of the claims is necessarily disclosed.

7.92 For example, amendments may limit the scope of a claim by the introduction of one or more features from the description or claims, but add matter through what is known as “intermediate generalisation”. This was described by Pumfrey J in *Palmas’s European Patents (UK)* [1999] RPC 47 in the following way:

“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’.”

7.93 The applicability of intermediate generalisations in Singapore has been specifically addressed by the Singapore Courts. Most recently, Lee Seiu Kin J in *Novartis AG and another v Ranbaxy (Malaysia) Sdn Bhd* [2012] SGHC 253 noted that the concept is firmly entrenched as part of the UK law, but noted that “*the policy-oriented rules applicable in England by virtue of the European Patent Convention should not be unthinkingly adopted in Singapore without an examination of its compatibility with the local statutory regime*”. At [39] he went on to state:

“I am of the view that the principle of intermediate generalization appears to be subsumed under the test of added matter. This is because the question which the test of intermediate generalization seeks to answer is simply whether a person skilled in the art would learn something new which has not hitherto been disclosed in the patent specifications ... the ‘right question is whether the proposed amendment would result in the specification disclosing additional matter’ ... This is precisely the test which the court has to apply under s 84(3) of the Act.”

7.94 An intermediate generalisation will add matter if the person skilled in the art is presented with information that they could not have derived from the application as originally filed. This will occur where a particular feature that is present in only one embodiment (or in only a limited number of the embodiments) is imported into the broader invention as a defining feature of the invention, without importing the other features of the embodiment(s). Unless the application suggests that this feature has a broader significance, then it may be taken to constitute an impermissible intermediate generalisation (see for example, *Datacard Corp. v Eagle Technologies Ltd.* [2011] RPC 17).

7.95 For example, in *Teva UK Ltd v Merck & Co. Inc.* [2010] FSR 17, the Court found that an amendment of a claim to limit a formulation to a particular pH range was not allowable on the basis that:

“given the paucity of the disclosure about pH generally, the only disclosure that the skilled person would take out of the application as filed for combinations of dorzolamide and timolol would be gellan gum at pH 5.5 to 6.0 and HEC at pH 6. To claim a range of pH 5.5 to 6.0 for dorzolamide irrespective of viscosifier amounts to an impermissible intermediate generalisation.”

7.96 An intermediate generalisation may also occur by the deletion of matter to place emphasis on certain features. For example, in the decision of the Court of Appeals in *Merck & Co Inc’s Patents* [2004] FSR 16, the applicant sought to limit the claim to a single pill comprising 70 mg of alendronate by deleting other tablet dosages and combinations. This amendment was considered to place particular emphasis on this specific dosage form, when no such importance was indicated in the application as filed, and as a consequence the amendment was not allowable.

7.97 In contrast, in *Novartis*, an amendment to a claim to limit the scope specific formulations comprising valsartan in free form as the only active agent, and where the composition comprised 2-10% of crospovidone (a disintegrant used widely in pharmaceuticals) was found to be allowable. The Court found that both these features had been clearly and unambiguously disclosed in the application as filed, including in examples of preferred embodiments and specific examples. Moreover, on the question

of whether the limitation of the claims constituted an impermissible intermediate generalisation, since the claim did not include other components which were described in “typical” compositions of the invention, the Court considered that nothing turned on this point. The omitted components were considered to have no inventive significance to the person skilled in the art since they were merely coloring and film coating agents that had no effect on the performance of the invention.

viii. Generic disclosure as a basis for amendment to a specific feature

7.98 If a generic term can be regarded as applying only to a **limited number** of alternatives then amendment to one of those alternatives may be allowable. This would be restriction of subject matter rather than addition of subject matter.

7.99 For example, disclosure of a pump for use with a fluid would be contemplated as being used for liquid or gas. Restriction to one of these alternatives would probably be permissible.

7.100 However, this will depend on the facts of the case. In *Noxell Ltd's Application* BL O/137/92, the hearing officer did not allow amendment to limit the term layer to “non-peelable layer” despite submissions from the applicant that “layer” included peelable and non-peelable.

ix. Addition and deletion of features

- 7.101 Addition or deletion of text, particularly when it relates to the features of the invention, can result in a specification including additional matter. Disclaimers are a similar amendment that can result in the addition of matter. Disclaimers are separately dealt with below. Care should be taken during examination whenever such changes are made, and similar considerations will apply in relation to divisional applications.
- 7.102 Deletion of a feature will often result in a broadening of the scope of a claim, but prior to acceptance the key consideration will be whether it results in a disclosure of added matter that was not in the specification as filed. In *Protoned's Application* [1983] F.S.R. 110 the invention involved the use of a gas spring and a mechanical compression spring to adjust the seat and back of a chair. An amendment to change the definition of a “mechanical compression spring” to a “mechanical spring” was refused as it resulted in the application disclosing added matter inasmuch as it included the use of mechanical springs not referred to in the specification as filed.
- 7.103 An amendment which deletes or adds features may be allowable provided the invention is disclosed in the application when read as a whole. In particular, if the feature that has been deleted would be understood by the skilled person to be *arbitrary or unnecessary* then its deletion may be allowable. However, deletion of a feature from a claim will not be allowable if the original specification is construed as teaching that the feature is essential (see for example the “AMP/ Coaxial connector” decision T 0260/85).
- 7.104 Similarly, in *Glatt's Application* [1983] RPC 122, the application as filed described an article for conditioning fabrics in a laundry dryer which comprised a flexible woven or non-woven air-permeable web. Amendment to omit the feature of air-permeability was not allowed as this was considered to be an essential feature of the invention.
- 7.105 *Raychem Ltd's Application* [1986] RPC 547, dealt with divisional applications in which a cross-linking step from the parent application was omitted from the claims of the divisional applications. This step was held by the Patent Court to be an essential feature of the invention described, and therefore claims to an intermediate product

without the cross-linking step were considered to constitute additional matter. In the corresponding European applications, claims in which the intermediate was limited to containing cross-linkable groups, thereby incorporating the inventive concept, were found allowable.

7.106 In International *Playtex Corporation's Application* [1969] RPC 362, the omission of a feature that was essential to fulfil the purpose of the invention was not allowable. In particular, the specification as filed stated that the object of the invention was to design a brassiere with maximum resistance to riding over derived from its built-in differential stretch patterns. The applicant sought to replace this text with one referring to “a triangular insert” based on a feature defined in the claims (“a triangular piece of stretchable fabric”), but the Court considered that this was not an allowable amendment.

7.107 There may also be situations where an invention is claimed in a different manner but is still the same inventive concept. In *Southco Inc. v Dzus Fastener Europe Ltd* [1990] RPC 587 at [616], Aldous J:

“There is no definition in the Act of what is meant by the word ‘matter’ and I believe that this word is wide enough to cover both structural features of the mechanism and inventive concepts ... 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 ...”

7.108 If a claim does not define a particular feature, it does not necessarily follow that this feature must be absent. As a consequence, amendment of a claim to specifically define the absence of a feature could in fact lead to additional matter (T 170/87 “SULZER/ Hot gas cooler”).

x. Ranges

7.109 Amendments to the ranges shall be allowed if the amended range is clearly and unambiguously disclosed in the application either explicitly or implicitly. If the specification as filed merely discloses a range in general, and the applicant later on amends to a narrower range to overcome a piece of prior art, such amendment may not introduce added matter as long as there was support within the specification as filed demonstrating to the person skilled in the art there was clear justification to claiming the narrower range. However, such amendment may still face an inventive step objection.

xi. Disclaimers

7.110 Applicants will often use disclaimers as a means to overcome novelty and inventive step objections during amendments. These are generally in the form of a proviso or similar statement excluding specific embodiments or groups from the original claim.

7.111 Amendments to incorporate disclaimers will generally be allowable if the matter remaining in the claim following amendment is clearly disclosed.

7.112 Of particular concern in this regard are so-called “undisclosed” disclaimers. An undisclosed disclaimer is one that is not disclosed *as such* in the original specification or the subject matter excluded by it is not disclosed in the original specification.

7.113 Whether or not the incorporation of an undisclosed disclaimer is to be considered as added matter depends on the circumstances of the individual case. Generally, an undisclosed disclaimer is not allowable if:

- (i) it is used to exclude embodiments that do not work or in order to address an objection of lack of sufficiency;
- (ii) it makes a technical contribution.

7.114 If the incorporation of an undisclosed disclaimer, although limiting the subject-matter claimed in the original application, provides a technical contribution to the working of the invention thereby giving an unwarranted advantage to the applicant, it would be considered to constitute added matter (see G1/93 “Advanced Semiconductor Products”).

7.115 Examples of an “undisclosed” disclaimer that makes a technical contribution and may be subjected to an added matter objection include:

- (1) one that excludes a feature, the exclusion of which makes a technical contribution to the working of the invention;
- (2) one that leads to a selection invention of compounds or sub-classes of compounds not disclosed in the application as filed or otherwise derivable therefrom; or
- (3) an intermediate generalization, which is not explicitly mentioned or implicitly disclosed in the application as filed.

7.116 If, on the other hand, the incorporated disclaimer merely excludes part of the subject-matter from the originally claimed invention, which does not provide any unwarranted advantage to the applicant or adversely affect the interests of third parties relying on the content of the original application, it would be allowable (see G1/93 “Advanced Semiconductor Products”).

7.117 In particular, the EPO Enlarged Board of Appeal set out several specific criteria under which an undisclosed disclaimer would be considered **allowable** in G1/03 “Disclaimer/PPG” and G2/03 “Disclaimer/Genetic Systems”. When applied to the Singapore context, this would be set up as follows:

- (a) Avoiding a document cited under section 14(3): namely, a conflicting Singapore patent application published after the priority date.

Different applicants may be entitled to different aspects of an invention based on their respective priority dates and the matter in each claim. A disclaimer in this situation merely reflects the respective rights of each applicant in this regard.

- (b) Avoiding an accidental anticipation in an unrelated field that the person skilled in the art would never take into consideration because it relates to an unrelated field or the skilled person would not consider the subject matter helpful to the invention.

This is typical in the area of chemistry, where searches of claims to a broad chemical class useful for a particular treatment will uncover prior art compounds having a different unrelated use. Thus a disclaimer to exclude one or more specific compounds would be allowable.

- (c) Avoiding subject matter that is excluded from patentability, including inventions that are considered non-industrially applicable such as methods of treatment of the human body, or inventions that are considered offensive, immoral or anti-social.

For example, where a particular treatment could be used for medical treatment but also for cosmetic, non-medical treatments, a disclaimer to exclude the medical treatment would generally be allowable ([see Section C in Chapter 8](#)).

K. Corrections (Section 107)

7.118 Examiners will generally only be dealing with corrections to the specification, and as a consequence this section provides procedural guidance only in that regard.

7.119 Section 107 sets out the law in relation to corrections of errors:

- (1) The Registrar may, subject to any provision of the 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.
- (2) Where the Registrar is requested to correct such an error or mistake, any person may in accordance with the rules give the Registrar notice of opposition to the request and the Registrar shall determine the matter.

7.120 Rule 91 provides for some of the procedural matters associated with Section 107. A request to correct an error should be made on Form CM4⁷.

7.121 Once corrected, a document is deemed always to have been in the state in which it is after the correction. Corrections are not subject to the same considerations of allowability as set out in Section 84 that apply to amendments. As a consequence, a correction can potentially result in the specification disclosing added matter or the protection conferred by the claims being extended (*Rock Shing Industrial Ltd v Braun AG* BL O/138/94). The implications of such changes for the public and potential competitors are quite significant, and care should be taken to ensure that all relevant considerations are taken into account. Importantly if a specification is being corrected, care should be taken to ensure that the changes are in the nature of a correction. However, once this has been established there is no impediment in relation to the allowability of the changes.

7.122 Generally, replacement sheets for rectifications of obvious errors in an international application authorized by the competent International Authority are deemed to be part of the international application as originally filed (PCT Rule 91) and will be taken into

⁷ The prescribed form under the Patents Rules in effect immediately before 14/02/2014 is Form 23.

account accordingly during examination. Only in the rare case when it is found that such rectifications would not have been authorized under Rule 91 if IPOS had been the competent authority, and the applicant is given an opportunity to make observations on the intention to disregard the rectification within a reasonable time limit under the circumstances, the Examiner may disregard a rectification authorized under the PCT (PCT rule 91.3f).

i. The “two-step test”

7.123 Rule 91(2) sets out the requirements for a correction as follows:

Where such a request relates to a specification, no correction shall be made therein unless the correction is obvious in the sense that it is immediately evident that nothing else would have been intended other than what is offered as the correction.

7.124 Notably this provision applies only to corrections that are made to the **specification**. The assumption is therefore that correction of other documents, including the abstract are not subject to the same requirement that the error be obvious and it be immediately evident that nothing else would have been intended. Nevertheless, evidence may be required in order to establish that an error has occurred.

7.125 The consideration under Rule 91(2) essentially consists of **a two-step test** (*Dukhovskoi’s Application* [1985] RPC 8):

- (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?

7.126 It must be obvious **on the face of the document** that there is an error. This encompasses relatively clear errors such as missing pages and the like. However, the consideration is through the eyes of the skilled addressee, and as a consequence their knowledge and their understanding of the document must be taken into account. Thus, while an error in a cited document may not be readily apparent to a casual reader, it may be apparent to the person skilled in the art that the cited document is incorrect. Similarly, the skilled person may have regard to references (such as standard textbooks) in order to confirm that the document is indeed an error.

7.127 The requirement that the correction be “**immediately evident**” is a strict requirement – the skilled person would understand that nothing other than the proposed correction was intended. Arguments to the extent that the correction “on balance of probabilities” would be the “most likely” solution to the skilled reader should be rejected.

- 7.128 In some cases it will be readily apparent on the face of the document what the correction should be. However, in the case of cited prior art or numerical data, the correction may not be readily apparent. There is no restriction on the person skilled in the art having regard to other documents in order to determine what was intended. This can include other documents filed with the application, such as the foreign language application in the case of a translated document and the priority document, even if filed later than the original application (see *Dukhovskoi's Application* [1985] RPC 8). However, a discrepancy between documents does not necessarily establish that there is an error – this could be indicative of an error of judgment on the part of the drafter (see *Tragen's Application* BL O/96/90).
- 7.129 If the specification makes technical and linguistic sense, then it will not be immediately evident that this would not have been what was originally intended. It follows that it cannot be determined with certainty that the proposed correction would have been intended. It is unlikely in such circumstances that the matter can be dealt with as the correction under Section 107.
- 7.130 Depending on the circumstances of the case, evidence is to be provided by the applicant to address some of the threshold questions. This may include evidence as to why it would be obvious to the person skilled in the art that there is an error and why the correction would be understood to be original intention.
- 7.131 The two-step test set out in *Dukhovskoi's Application* [1985] RPC 8 has been adopted in *Application for correction of a patent by Genpharm International Inc and Objection thereto by Lonza Biologics Tuas Pte Ltd* [2014] SGIPOS 9.
- 7.132 In this case, the corrections to the title of Table 17 to change “affinity” to “avidity” were considered allowable by the hearing officer based on the evidence. The other corrections of general references to “affinity” to read “avidity” throughout the specification were not allowed as either the evidence did not establish that the skilled person would consider it clear that there was an error, or the evidence showed that the skilled person would consider two corrections were feasible.
- 7.133 In order to meet the requirements of the first step, it must be apparent on the face of the document that there is an error. The standard of proof in this regard is the balance

of probabilities; i.e., whether on the balance of probabilities the reader would conclude that there was an error (see *R. v the Comptroller-General of Patents ex parte Celltech Ltd* [1991] RPC 475). This consideration is made through the eyes of the skilled addressee, the common general knowledge in the art and the skilled person's understanding of the document.

- 7.134 Once it has been determined that there is an error, the rectification must be “immediately evident” (see *Dukhovskoi's Application* [1985] RPC 8). This is a strict requirement – the skilled person must understand that nothing other than the proposed correction was intended. The standard in this respect is not “on balance of probabilities” or whether the proposed correction is the “most likely” solution to the skilled reader – there must be only one feasible correction. To that end, if several alternative corrections may be envisaged, then the rectification cannot be considered immediately evident. For example, if the document already makes technical and linguistic sense, generally it is not possible to conclude that there is an error and that there is only one feasible rectification for the said error (see *R. v the Comptroller-General of Patents ex parte Celltech Ltd* [1991] RPC 475).
- 7.135 The Opponent also argued that the applicant had knowingly and intentionally chosen to delay the corrections in order to exploit the time delay that the proceedings would cause and the corrections should therefore not be allowed. However, the hearing officer considered that there was no apparent discretion for the Registrar to take such matters into account when determining whether the corrections are allowable under Section 107 and Rule 91.
- 7.136 The corresponding UK provision has been interpreted as having no restriction on who may request correction. This would in theory allow the Examiner to make corrections during the examination process (with authorisation from the attorney). However, in practice Examiners should only note the error in the written opinion if it is of a significant enough nature. If a significant error is discovered late in the process, such as at the point of establishing the written opinion, then the Examiner may contact the attorney to discuss the matter. Because the Examiner is working with electronic documents, handwritten amendments may not be appropriate, and in most cases the applicant will need to file replacement pages.

7.137 In clear cases (such as where a page has been omitted), the Examiner should indicate in the report that correction of the specification under Section 107 will be required. In general, a request for a correction will be required if matter has been omitted or deleted – such as in the case of a missing page or an error in a chemical structure – and the information cannot otherwise be gleaned from the specification as filed. However, amendment may be the appropriate course of action if the missing information can be ascertained from the specification as filed (that is, no additional matter results from the amendment).

ii. Errors in translations

- 7.138 In the absence of clear evidence to the contrary, the Examiner should generally assume that the translations of the application and amendments are accurate.
- 7.139 However, if there are obvious errors or omissions in the translated document (e.g. missing pages or text), then the Examiner should interpret the document by using available translation tools or in consultation with an Examiner with the appropriate language skills. The Examiner should raise the issue in Box I, under “Additional observations”, of the written opinion, with an explanatory comment. In such cases, the applicant may request to correct the error.
- 7.140 If the error in the translations is to the extent that it may influence the scope of search and/or examination, the Examiner may consult a Senior Examiner, and subsequently refer the matter to the Registry.

8. PATENTABLE SUBJECT MATTER AND INDUSTRIAL APPLICABILITY

A. Statutory requirements

8.1 Section 13(1) of the *Act* states as follows:

Subject to subsection (2), a patentable invention is one that satisfies the following conditions:

- (a) the invention is new;
- (b) it involves an inventive step; and
- (c) it is capable of industrial application.

Section 13(1) contains the word “invention”. Therefore, the subject matter of a patent application must be for an invention – with the assessment of whether the invention is *patentable* involving a consideration *inter alia* of whether the subject matter is new, involves an inventive step and is capable of industrial application.

8.2 The primary focus of the inquiry under Section 13 should be on the criteria of novelty, inventive step and industrial application. In most cases, a finding that the claims do not fulfil any one or more of the three requirements of novelty, inventive step and industrial application would be a sufficient basis for an objection under Section 13. Examiners should begin by properly construing the claims and identifying the claimed inventive concept ([Chapter 2](#) and [Section F in Chapter 4](#)). The Examiner then proceeds to consider the specific conditions set out in Section 13(1), including novelty, inventive step and industrial application.

8.3 If there is a residual issue that the claims may relate to subject matter which is not an “invention”, a separate analysis of the claimed subject matter should be undertaken. In determining whether or not the claims define an “invention”, the Examiner should take into account the substance rather than the form of the claims in order to identify the actual contribution which is made by the claimed subject matter, having regard to the problem to be solved, how the claimed subject matter works, and what its

advantages are. Regard should also be given to the person skilled in the art and the common general knowledge he possesses.

- 8.4 The identification of the “actual contribution” referred to here is the second step in the *Aerotel/Macrossan* test in *Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1* [2007] RPC 7 (*Aerotel/Macrossan*). The critical factors for the Examiner to consider when identifying the actual contribution can be found at [43] of *Aerotel/Macrossan*;

“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.”

- 8.5 An objection should be raised if the actual contribution lies solely in subject matter that is not an “invention” (for example, if the actual contribution falls within any of the areas described in sub-sections i, ii, iii, iv or v of this Section in this Chapter).
- 8.6 In considering the actual contribution of claims directed to computer-implemented inventions (CIIs), Examiners should determine the extent to which the computer (or other technical features) contributes to the invention defined in the claims. For such CIIs, it must be established that said computer (or other technical features), as defined in the claims, is integral to the invention in order for the actual contribution to comprise said computer (or technical features).
- 8.7 For example, claims relating to a computer-implemented business method would be considered an invention if the various technical features (e.g. servers, databases, user devices etc.) interact with the steps of the business method (i) to a material extent; and (ii) in such a manner as to address a specific problem. As an example of what is meant by “material extent”, a claim may recite known hardware components for implementing a business method, but if the overall combination of the hardware provides, for example, a more secure environment for performing transactions, then the hardware would be regarded to interact with the business method to a material

extent to address a specific problem. The actual contribution, in this case, is likely to be the use of that combination of hardware for the business method, which would be considered an invention. However, if the technical features recited in the claim are such that they are no more than the workings of a standard operating system, in particular, the use of a generic computer or computer system to perform a pure business method, then such an interaction would not be considered to be a material extent and it is apparent that no specific problem is solved. The actual contribution is likely to be the business method, and the claimed subject matter would not be considered an “invention” by merely including the term “computer-implemented” or a similar *generic* term in the claims.

- 8.8 The following sub-sections provide some guidance as to what “subject matter” are not considered to be “inventions”. These are presented in view of the local jurisprudence and also in view of the public policy considerations, including maintaining consistency with international patent norms. Generally, major jurisdictions including the US, Europe, the UK and Australia preclude mental, intellectual, aesthetic and abstract matters from being patentable. The following sub-sections should not be considered to be exhaustive as to what “subject matter” are not considered to be “inventions”.

i. Discoveries

8.9 The Singapore Court of Appeal has drawn a distinction between discovery and invention in *Merck & Co Inc v. Pharmaforte Singapore Pte Ltd* [2000] SGCA 39 at [63], referencing *Lane Fox v. Kensington & Knightsbridge Electric Lighting Co* [1892] 3 Ch 424:

“In this regard, we must also point out that the fact that a discovery is made does not mean there is an invention. The latter does not necessarily follow from the former. This distinction was brought out by Lindley LJ in Lane Fox (supra) at page 429 where he said:

‘An invention is not the same thing as a discovery. When Volta discovered the effect of an electric current from his battery on a frog’s leg he made a great discovery, but no patentable invention. Again, a man who discovers that a known machine can produce effects which no one before him knew could be produced by it, may make a great and useful discovery; but if he does no more, his discovery is not a patentable invention: ... He has added nothing but knowledge to what previously existed. A patentee must do something more; he must make some addition, not only to knowledge, but to previously known inventions, and must so use his knowledge and ingenuity as to produce either a new and useful thing or result, or a new and useful method of producing an old thing or result.’”

8.10 From the above quotation that was referenced by the Singapore Court of Appeal, it is clear that discoveries are not inventions. As Section 13(1) of the Patents Act provides for the grant of patents for inventions, discoveries are not patent eligible subject matter under Section 13(1) of the Patents Act.

8.11 The difference between invention and discovery can be unclear. Many inventions are based on a discovery, but there must be “something more” to constitute an invention. The discovery of a particular property of a material will add to the stock of knowledge in relation to that particular substance. However, if that property results in the application of that substance in a new use then it may constitute an invention.

- 8.12 For example, the mere isolation of a naturally occurring material or microorganism without a specific use would represent a mere discovery. However if a new use of that material or microorganism is found, then the use could be claimed, as well as the new isolated material or microorganism. Nevertheless, if the material or microorganism *per se* is not clearly distinguished from the prior art naturally occurring material or microorganisms, then an objection will be raised under novelty.
- 8.13 Likewise, a claim directed at a process that occurs in nature is not new unless it is clearly distinguishable from the natural process. For example, a method of growing a plant with a particular trait comprising selection and breeding steps would be considered as directed to a naturally occurring process and lack novelty, despite the selection and breeding being performed by man. However, it may be possible to claim the process of selection if the claimed process comprises technical steps that clearly distinguishes the process from the natural process.
- 8.14 Similarly, the synthesis of a new compound would not constitute an invention in patent law, as it would represent no more than a chemical curiosity. However if the compound could be used in an industrial process or a new and useful property was discovered then it would constitute an invention. In *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9, the invention related to the production of erythropoietin by recombinant DNA technology. In this case, erythropoietin had been a particularly elusive goal because it had been difficult to obtain sufficient quantities to carry out the necessary research. The prior art disclosed the N-terminal sequence of erythropoietin (with two incorrect base residues). The application in question claimed a DNA sequence, a recombinant polypeptide and a process of making the polypeptide. The Court considered that the invention did not lie in the DNA sequence – this was considered to provide information only – or the polypeptide, but the invention was in the process of making recombinant erythropoietin.

ii. Scientific theories and mathematical methods

- 8.15 A scientific theory or a mathematical method *per se* is not an invention, but if an application of the principle results in a new material or process, then the resulting product may be considered an invention.
- 8.16 For example, the theory of relativity would not be an invention, but a Global Positioning System that makes use of the theory of relativity to more accurately locate the user would constitute an invention.
- 8.17 The implementation of a theory or principle does not require an inventive step if the theory or principle is inventive. Thus, in *Hickton's Patent Syndicate v Patent & Machine Improvements Co.* [1909] 26 RPC 339, Fletcher Moulton LJ stated:
- “In my opinion invention may lie in the idea and it may lie in the way in which it is carried out, and it may lie in the combination of the two; but if there is invention in the idea plus the way of carrying it out, then it is good subject matter for letters patent.”*
- 8.18 This approach has been followed in *Genentech's Patent* [1989] RPC 147 and *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9.
- 8.19 However, if the claimed matter merely constitutes a statement of the principle underlying a known process then it will not be an invention. In such cases an objection under inventive step should be considered since the mere elucidation of the principle is not inventive.

iii. Aesthetic creations: literary, dramatic, musical or artistic works

- 8.20 A purely aesthetic creation (including written works, photographs, paintings, sculptures, music, speeches, or other artistic works) is not an invention. This includes not only the idea or mental aspects of the creation, but also any physical representation of the work.
- 8.21 However, there may be certain instances where the actual contribution is more than the mere aesthetic creation. For example a design on a surface would likely constitute a purely aesthetic creation if the design was merely decorative. However, if the actual contribution of the claimed subject matter is the achievement of improved non-slip properties as a result of the design, then the design may constitute an invention.
- 8.22 Similarly, a particular colour may be considered an invention provided the selection of said colour addresses a specific problem that is not merely aesthetic. For example, a blue squash ball was considered patentable since the colour improved its visibility (*ITS Runner Ltd's Application* [1979] RPC 318).

iv. Schemes, rules or methods for performing a mental act, playing a game or doing business

8.23 Methods that are considered mental acts or schemes are generally not inventions. These include teaching methods (such as a method of learning a language or reading), methods of mental arithmetic, methods of memorising things or methods of designing a product.

8.24 This practice is applied narrowly – for example, in *Halliburton Energy Services Inc v. Smith International (North Sea) Ltd* [2005] EWHC 1623, the Court found that claims to a method of designing a drill bit were sufficiently broad to also encompass the purely intellectual content of a design process, and hence the claims were deemed to be directed to a mental act. However, the Court considered that this deficiency was a matter of form and could have been overcome by the inclusion of a manufacturing step.

v. Presentation of information

- 8.25 Any invention which is characterised solely by the content of the information is not an invention, even if a physical apparatus is involved in the presentation. In *Townsend's Application* [2004] EWHC 482 (Pat), claims relating to an advent calendar with an additional indicium on each door were found not to be an invention. Laddie J held that the exclusion does not only apply to the expression of information but also to the provision of information.
- 8.26 The key consideration in such cases is whether the actual contribution is the presentation of the information as such.
- a. For example, a gaming machine having product names rather than conventional symbols would represent mere presentation of information (*Ebrahim Shahin's Application* BL O/149/95).
 - b. A claim defining the choice of how and where to present information would not be an invention since this still relates to the presentation of information (*Autonomy Corp Ltd v. Comptroller General of Patents, Trade Marks & Designs* [2008] EWHC 146 (Pat)).
 - c. A newspaper layout designed such that folding the paper did not hinder reading was found to be an invention (*Cooper's Application* [1902] 19 RPC 53), as was a ticket on which information was presented in such a way that it was not lost when the ticket was torn (*Fishburn's Application* [1940] 57 RPC 245).
 - d. An instructional speech course in which text was highlighted in a particular way to indicate stress and rhythm was not considered an invention (*Dixon's Application* [1978] RPC 687).
 - e. A claim to a known product such as a pharmaceutical which is characterised by the instructions on the package will not generally be allowed, since the contribution lies solely in the presentation of information ([see paragraph 8.179](#)).

- f. Claims to software that are characterised only by *source code*, and not by any technical features, is unlikely to be considered an invention on the basis that the actual contribution would be a mere presentation of information.

B. Industrial applicability

8.27 Section 16(1) states that an invention is considered industrially applicable if it can be made or used in any kind of industry.

8.28 “Industry” is understood in its broadest sense and includes any useful and practical activity as distinct from intellectual or aesthetic activity. In general there must be something in which a new and useful effect, be it creation or alteration, may be observed. It need not be an article or substance nor necessarily involve a manufacturing process, but it must be useful in practical affairs. In *Chiron Corp v Murex Diagnostics Ltd* [1996] RPC 535, industrial application was taken to carry the connotation of trade or manufacture in its widest sense and whether or not for profit.

i. Subject matter contrary to established physical laws

- 8.29 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. In considering whether an invention operates in a manner which is clearly contrary to well-established physical laws, the Examiner should consider the material present on the balance of probabilities. If there is substantial doubt about an issue of fact which could lead to patentability, 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 (*Blacklight Power Inc. v The Comptroller-General of Patents* [2009] RPC 6). In such a case the application should be allowed to proceed.
- 8.30 It should 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. An alternative or additional objection may be that the specification is not complete enough to allow the invention to be performed under Section 25(4).

C. Methods of medical treatment

8.31 Methods of medical treatment are a specific exclusion under industrial applicability. The exclusion only applies to methods that are therapy or surgery, as well as diagnostic methods practised on the human or animal body, as set out in Section 16(2):

“An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.”

8.32 Section 16(2) is primarily intended to ensure that medical or veterinary practitioners are not hindered from properly exercising their professional skills by patent rights. This is consistent with G 05/83 EISAI/*Second medical use OJEPO 1985, 64*, which highlights that

“The intention of Article 52(4) EPC ... is only to free from restraint non-commercial and non-industrial medical and veterinary activities.”

8.33 Section 16(2) corresponds to Article 52(4) EPC 1973, which states that “Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application ...” and similarly to Section 4(2) of the UK Patents Act prior to the 2004 amendments. In Singapore, the general approach is set out in *Bristol-Myers Squibb v Baker Norton Pharmaceuticals Inc* [1999] RPC 253 by Jacob J at [51]:

“A like approach is indicated in Plant Genetic Systems/Plant Cells (EPO [1995] 545, T0356/93 OJ). There is also the limited purpose of the exception to be considered. It is not so broad as to stop doctors using whatever they feel they need to treat patients. If that were the purpose then one would not allow patents for medicines or medical implements at all. The purpose of the limitation is much narrower, merely to keep patent law from interfering directly with what the doctor actually does to the patient. Patent monopolies are permitted to control

what he administers to, or the implements he uses on, the patient. The thinking behind the exception is not particularly rational: if one accepts that a patent monopoly is a fair price to pay for the extra research incentive, then there is no reason to suppose that that would not apply also to methods of treatment. It is noteworthy that in the US any such exception has gone, and yet no-one, so far as I know, suggests that its removal has caused any trouble.”

i. Therapy

- 8.34 Therapy refers to any treatment designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the human or animal body (T 24/91 THOMPSON/*Cornea* OJEPO 1995, 512; T 58/87 SALMINEN/*Pigs III* [1989] EPOR 125; T 1599/09 COVIDIEN).
- 8.35 The following methods will generally constitute methods of therapy, and Examiners should have particular regard to such claims (*Unilever (Davis's) Application* [1983] RPC 21):
- (i) Preventative treatment, including vaccination of healthy individuals;
 - (ii) Methods to alleviate disease symptoms;
 - (iii) Curative treatment; and
 - (iv) Veterinary treatment of a diseased or injured animal, including prophylactic and immunotherapeutic treatment.
- 8.36 The key consideration here is if it is possible to establish a direct link between the treatment and the disease being cured, prevented or alleviated (*Commonwealth Scientific and Industrial Research Organization's Application* BL O/248/04; *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104). If a link can be established then a method falls within the “treatment by therapy”.
- 8.37 In addition, any medical treatment of a disease, ailment, injury or disability, i.e. anything that is ailing a patient and for which a doctor or veterinarian would be consulted would generally be regarded as therapy. This may be a Western trained doctor/therapist or a Traditional Chinese Medical physician. Similarly prophylactic or preventative treatments by such practitioners may be regarded as constituting therapy for the purposes of Section 16(2).
- 8.38 However, whether a medical practitioner or a veterinarian performs the method is not the only consideration. As long as the treatment cures, prevents or alleviates a disease, the treatment would constitute a method of therapy whether the treatment is performed by the patient (such as the administration of a medicament), by an automated system (see T 1599/09), or by a farmer (such as treatment of farm animals, see T 116/85

WELLCOME/*Pigs I* OJEPO 1989, 13). This is also consistent with the Board of Appeal decision in T 245/87 SIEMENS/*Flow measurement* OJEPO 1989, 171 a method of stimulating a limb during blood collection in order to facilitate the flow of blood, where the Board noted that:

“The need for a medical practitioner to perform a measure on the human body or supervise such an operation is not the sole criterion by which a method step has to be assessed with regard to the exclusion of subject-matter from patenting under Art. 52(4) EPC. The purpose and inevitable effect of the step at issue are much more important.”

8.39 In this regard, it is more important for the Examiner to consider the purpose and inevitable effects of the invention. The Board of Appeal further noted that:

“If the claimed subject-matter is actually confined to operating an apparatus for performing a method with the technical aim of facilitating blood flow towards a blood extraction point, the operating method has no therapeutic purpose or effect and, therefore, is not excluded from patentability.”

8.40 On the other hand, if a method has no therapeutic purpose or effect, then the mere fact that an invention may be carried out by a medical practitioner does not render it incapable of industrial application. For example, in *Schering A.G.’s Application* [1971] RPC 337 it was held that claims that are directed solely to non-therapeutic medical treatments will be generally accepted.

8.41 A method claim would also fall under the prohibition of Section 16(2) even if it contains only one step that defines a therapeutic activity. For instance, including a step of “administering a substance for prophylactic reasons” in a method claim would likely render the method claim incapable of industrial application (see G 01/04 *Diagnostic methods* OJEPO 2006, 334).

ii. Claims to both therapeutic and non-therapeutic methods

8.42 In some cases a claim can be construed to include both therapeutic and non-therapeutic methods, as exemplified by the following claim:

“A method for inhibiting the coagulation of blood by contacting the blood with a carrier containing compounds X and Y.”

This claim could be construed as including a method of treating the blood in a patient as part of a therapeutic method, and a method of treating stored blood in a tube, which is not a method of medical treatment. In such cases, the claim should be carefully construed to determine its scope.

8.43 Therapeutic and non-therapeutic effects of a claimed method must be clearly distinguishable. If the non-therapeutic effect is inseparable from the therapeutic effect, or if it is merely a secondary consequence of the therapy, then regardless of any disclaimer or a purely formal rewording of the claim, the invention is not capable of industrial application under Section 16(2). Both the UK Courts and the EPO have held that if a claim encompasses a use comprising a non-therapeutic element that is associated with a therapeutic element and that latter element is an essential part of the claimed method, the claim is non-patentable. For example, in T 290/86 ICI/*Cleaning Plaque* OJEPO 1992, 414 a claim directed to a cosmetic method for the removal of plaque from teeth, was considered to also have a therapeutic benefit in preventing tooth decay and gum disease:

“... the claimed use of a lanthanum-containing composition for cleaning plaque and/or stains from human teeth ... will always inevitably have a therapeutic effect (at least in the prophylactic sense) as well as a cosmetic effect. Thus the invention as here claimed is not directed solely to a cosmetic effect, but is also necessarily defining ‘a treatment of the human body by therapy’ as well.”

If the effects are separable, then the existence of a possible therapeutic use should not prevent cosmetic or other non-therapeutic methods from being industrially applicable under Section 16(2) provided the therapeutic use is not part of the claim.

- 8.44 Generally, disclaimers to exclude methods of treatment by therapy are allowable. However, where a disclaimer is employed there must be support in the specification for such non-therapeutic methods or else the amendment will constitute added matter (G 01/03 PPG/*Disclaimer* OJEPO 2004, 413; G 02/10 SCRIPPS/*Disclaimer* OJEPO 2012, 376). In *ICI (Richardson's) Application* [1981] FSR 609, a claim to a method of producing an anti-oestrogenic effect in a human and, which excluded any method of treatment by therapy was rejected since the specification did not describe any application of the method other than in the treatment of breast cancer or infertility. Any disclaimer needs to exclude all possible therapeutic methods, not merely those disclosed in the specification, and the scope of the remaining monopoly should be clear. For example, the term “cosmetic” in a claim to a method of treatment is generally acceptable as a sufficient limitation, as long as there is support in the specification for such non-therapeutic method in the application as filed (T 144/83 DU PONT/*Appetite suppressant* OJEPO 1986, 30). If there is no such support from the application as filed, then the amended claim will constitute added matter. However, if it is unambiguously clear from the specification that the claims relate only to non-therapeutic methods, then no amendment is required.
- 8.45 The Examiner should take care, where the claim has been limited to exclude therapeutic methods, to require amendment of the description, so that all references to a therapeutic effect are removed. It should be clear from both the claims and the description that therapeutic methods do not fall within the scope of the invention.

iii. Surgery

8.46 Surgery refers to the treatment or manipulation of the body using manual, instrumental and/or robotic surgical techniques.

8.47 A broader interpretation of the definition of “methods of surgery” was considered in T 35/99 GEORGETOWN UNIVERSITY/*Pericardial access* OJEPO 2000, 447 where it was held that any surgical activity, irrespective of whether it is carried out alone or in combination with other medical or non-medical procedures should be excluded:

*“In contrast to procedures whose end result is the death of the living being ‘under treatment’, either deliberately or incidentally (eg the slaughter of animals or methods for measuring biological functions of an animal which comprise the sacrificing of said animal, cf. T 182/90 SEE-SHELL/Blood flow OJEPO 1994 – **not excluded**), those physical interventions on the human or animal body which, whatever their specific purpose, give priority to maintaining the life or health of the body on which they are performed, are ‘in their nature’ methods for treatment by surgery within the meaning of Article 52(4) EPC.”* (emphasis added in bold terms)

8.48 However, in G 01/07 MEDI-PHYSICS/*Treatment by surgery* OJEPO 2011, 134, the Enlarged Board of Appeal held that given the continuous advances in medical procedures, a more narrow interpretation of what is encompassed by “method of surgery” should be given, in which the purpose of the method should be irrelevant and a surgical method is defined by the nature of the method, namely the level of surgical skill required and health risks involved. Specifically, in G 01/07 paragraph 3.4.2.3 it is stated that:

“... thus any definition of the term ‘treatment by surgery’ must cover the kind of interventions which represent the core of the medical profession’s activities, i.e. the kind of interventions for which their members are specifically trained and for which they assume a particular responsibility.”

8.49 For example, if a claim is directed to a method of introducing an agent (e.g. a pharmaceutical or contrast agent) it is the health risk of the invasive procedure that

should be assessed. Even if the procedure is not physically performed by a medical professional, if it is risky enough to be the responsibility of a medical professional, it may be sufficient to be considered a method of surgery. On the other hand, if the procedure is a minor intervention which did not imply substantial health risks when carried out by said qualified paramedical professional with due care and skill, then it may not be considered to be a surgical method (T 663/02 PRINCE).

- 8.50 In a subsequent decision, T 1695/07 TRANSONIC SYSTEMS, it was considered that the term “medical profession” should not be limited to medical doctors and physicians and it should cover all health care providers. In this case, it was deemed that the claimed process comprised steps that qualified as a surgical method due to the substantial health risk associated with them, even if performed by paramedical support staff. Consequently, the level of medical skill needed to perform a method and the health risks involved in the procedure should be used by the Examiner as a guide to determine if that method constitutes a “method of surgery”.
- 8.51 If a method does not require medical skills or knowledge, such as, for example, a method for cosmetic ear-piercing, or a method of tattooing the body, then it would not be considered a method of surgery. Another example is that while the setting of bones is carried out by medical practitioners and thus considered to be surgical in nature, the making and applying a plaster cast is usually performed by a technician and so would not be regarded as surgery. In any case, as aforementioned, the Examiner should always take into consideration that even if the procedure is performed by a technician, if it is of such a risky nature that it falls under the responsibility of a medical doctor, it would still be a method of treatment by surgery.
- 8.52 In addition, a method claim can fall under the exclusion even if it comprises just one feature defining a physical activity or action that constitutes a method of surgery (G 01/07 paragraph 4.3.2). In T 2187/10 Z-KAT independent method claim 1 was confirmed to be not allowable on the grounds of it being a method of treatment of the human or animal body by surgery due to the step of “... performing the surgical procedure ...”. In this regard, even if a disclaimer is used to omit the surgical step, the claims still need to adequately define the invention. As such, if the omitted surgical

step is an essential feature of the invention then disclaiming or omitting this from the claim should be objected to as lacking support.

8.53 Some examples of “surgical methods” include:

- (i) Catheterization, endoscopy, incision, excision or centesis (T 182/90 SEE-SHELL/*Blood flow* OJEPO 1994, 641);
- (ii) “Closed surgery” (see T 182/90), such as setting of broken bones or relocating dislocated joints;
- (iii) Implantation of an embryo which requires the intervention of a surgeon or a veterinary surgeon (*Occidental Petroleum’s Application* BL O/35/84);
- (iv) Dental surgery (T 429/12 DENTAL VISION);
- (v) Any implantation or insertion of devices by surgical means (*Allen’s Application* BL O/59/92);
- (vi) Insertion of devices into respiratory cavities (with and without incision) (T 05/04 CAMTECH); and
- (vii) Puncture/injections such as lumbar punctures to deliver epidural injections, venipunctures (T 1075/06 FENWAL).

8.54 On the other hand, a method that is not itself surgical but is useful during surgery by providing, for example, real-time feedback and enable a surgeon to decide on the course of action to be taken during a surgical intervention, should not be considered a method of surgery (see G 01/07). Additionally, claims to methods involving the internal operation of implanted devices, or the interaction between the implanted device and an external user or system, should not be considered a surgical method insofar as the method only concerns the operation of the device, if:

- (a) there is no functional link to the effects produced by the device on the body (see T 245/87); or
- (b) they are not related to the actual implantation of the device (T 09/04 KONONKLIJKE PHILIPS ELECTRONICS and T 1102/02 MAQUET CRITICAL CARE).

8.55 Additionally, claims directed to a technical method for improving the performance of a pacemaker without a surgical implantation step, would normally not be considered a

method of surgery. Some examples of procedures generally not considered as “surgical methods” under Section 16(2):

- (i) Simple injection methods, either for taking blood samples or introducing compositions (see T 663/02);
- (ii) Cosmetic ear-piercing, or methods of tattooing the body, which does not represent the core of the medical profession’s activities and does not pose substantial health risks (see G1/07 para 3.4.2.3);
- (iii) Methods to measure, make and apply a plaster cast or attaching exoprostheses to the skin using an adhesive (T 635/08 DOW CORNING FRANCE);
- (iv) Methods of making artificial limbs; and
- (v) Methods carried out on a dead body or interventions that result in the death of the subject (e.g. sacrifice of laboratory animals) (see T 35/99).

8.56 It is important to keep in mind that, while a method might not be considered as “surgery”, the said method could be a procedure that falls under the definition of “therapy” or “diagnosis”. In such cases, the method would still not be considered to be capable of industrial application under Section 16(2).

8.57 In general, any operation on the body which requires the skills or knowledge of a surgeon or other medical practitioner is regarded as surgery, whether or not it is therapeutic. In *Unilever (Davis’s) Application*, Falconer J. stated, as follows:

“[S]urgery can be curative of the disease or diseased conditions, or prophylactic, that is, preventive of diseased conditions, as for example, where an appendix or tonsils may be removed before any diseased condition starts up, and surgery may even be cosmetic without being curative or preventive. So that the subsection it seems to me is saying that any method of surgical treatment whether it is curative, prophylactic or cosmetic, is not patentable.” (obiter)

8.58 As stated in G 01/07 “... the meaning of the term ‘treatment by surgery’ is not to be interpreted as being confined to surgical methods pursuing a therapeutic purpose”. The Technical Board of Appeal has followed G 01/07 in the recent T 1213/10 SONY

where a method of measuring *in vivo* enzymatic activity which included a surgical step of using a “penetration device” (e.g. an endoscope) to introduce a substrate to an organ in the body was excluded for being a method of surgery despite the Applicant’s argument that the method was carried out for analytical rather than therapeutic purpose.

8.59 Therefore, any methods of surgery, even for non-therapeutic purposes would be considered to be not capable of industrial application under Section 16(2).

iv. Some specific examples of therapeutic/surgical and non-therapeutic/surgical methods

Cosmetic treatments

8.60 Purely cosmetic treatments of the skin and hair are considered patentable inventions. For example a cosmetic treatment for strengthening hair was considered patentable (*Joos v Commissioner of Patents* [1972] 126 CLR 611, 619). Similarly, a method of reducing normal hair loss by administration of a composition defined by its active ingredients was considered a patentable non-therapeutic method once the claims were restricted to it being carried out as a cosmetic treatment (T 453/95 REDKEN).

8.61 Similarly, in *Virulite's Application* BL O/058/10:

“A method of cosmetically treating a superficial area of mammalian skin around, above or below an eye by reducing or alleviating or removing or diminishing wrinkles that occur as a result of natural aging, the method comprising irradiating the skin ...”

was considered to be a cosmetic method for removing wrinkles by phototherapy, and was allowed as the removal of wrinkles caused by ageing had no apparent therapeutic benefits.

8.62 In T 383/03 GENERAL HOSPITAL/*Hair removal method* OJEPO 2005, 159 it was also held that a method to remove body hair was non-therapeutic as the excess of body hair is not considered to be a condition that causes pain or discomfort and is directed to an aesthetic purpose, which is clearly distinguishable from a therapeutic purpose. Thus, an application containing claims directed to a purely cosmetic treatment by administration of a chemical product may be considered industrially applicable (see also T 144/83).

8.63 In contrast, a cosmetic treatment that has a therapeutic effect is considered a method of therapy. For example, the use of a composition for the local treatment of comedones (blackheads) was generally regarded as a cosmetic method of non-medical body hygiene. However, when applied for the treatment of acne this might be regarded

as a method of therapy (T 36/83 ROUSSEL-UCLAF/*Thenoyl peroxide* OJEPO 1986, 295). In T 36/83, the Technical Board of Appeal considered that the cosmetic and therapeutic compositions were similar and consequently a cosmetic use may result in an incidental therapeutic effect. Nonetheless, they considered that the following claim was allowable as it was sufficiently limited to the cosmetic use of the compound:

“Use as a cosmetic product of thenoyl peroxide.”

The description expressly disclosed two very different properties of a compound used in the treatment of comedones, i.e. its anti-bacterial and its hygienic action. The application showed that pharmaceutical and cosmetic preparations could have very similar, if not identical, forms. The distinction was clearly set out in the description as filed. The Board decided that the cosmetic application of a product, which also had a therapeutic use, was patentable, since the Applicants had only claimed in respect of “use as a cosmetic product”. The use of the term “cosmetic” was held to be sufficiently precise, although the cosmetic treatment according to the application might also incidentally involve a medical treatment.

8.64 Therefore, methods of a purely cosmetic nature, which are not invasive to the human body and that do not have a therapeutic purpose are usually allowable, such as, for example, methods for: deodorization, decoration, or beautification. Nevertheless, a cosmetic method comprising one or more surgical steps may be considered to be a method of surgery.

Protection of the skin

- 8.65 Methods of protecting the skin by simply blocking UV radiation are not considered to be therapeutic, but where a method produces physiological effects then it is considered to be a non-patentable therapeutic method. For example, in T 1077/93, the EPO Technical Board considered that claims directed to the use of the cupric complex of 3,5-Diisopropyl salicylic acid (CuDIPS) as a cosmetic product for the protection of human epidermis against ultraviolet radiation, had also to take into consideration the mechanism by which CuDIPS acted. The Board then concluded that at least part of the protective effects did not derive from a simple filtering at the level of the skin surface, but rather from an interaction with the cellular mechanisms in the epidermis, with the purpose of preventing a pathological state (erythema); therefore the process is considered to be a method of therapy.

Methods of hygiene, including treatment of parasites

- 8.66 Methods of hygiene will generally be capable of industrial application even though they may ultimately prevent the occurrence of diseases. However, methods of treating or preventing infestation of parasites, including the treatment of head lice, will generally be regarded as methods of therapy. For example, treatment of parasites residing on the skin of a human or animal is considered to be therapy (see T 116/85):

“A method for the control of ectoparasitic infestations of pigs comprising the application to a localised area of the pig’s body surface of a pesticidal composition.”

The Technical Board of Appeal considered that the invention was directed to the treatment of permanent ectoparasites based on the experimental evidence of the description of the patent application, and held that since permanent ectoparasites cause direct harm to the infested host, the control or eradication of permanent ectoparasites is a therapeutic treatment of the animal body. Consequently, the treatment of, for example, head lice, is considered therapeutic.

- 8.67 This is further supported in *Ciba-Geigy’s Application* BL O/35/85, a method of controlling parasitic helminths by the use of an anthelmintic composition was considered a disease requiring medical treatment of the animal and that such treatment, whether curative or preventative, constituted therapy even if the host animal is unaffected and that it is only the parasites that are being killed. Accordingly, the Hearing Officer held that the claims in question were not allowable. Nevertheless, the Examiner should always assess if there is a direct link between the treatment and the condition to be treated or prevented.
- 8.68 For example, in *Commonwealth Scientific & Industrial Research Organization’s Application* BL O/248/04 it was held that a method for reducing parasitic infestations by destroying the hair follicles in the skin of sheep was allowable since it was not directly linked to a disease state.
- 8.69 To fall within the exclusion of being a method of therapy, there should be a direct link between the treatment and the condition to be treated or prevented.

Treatment of stock animals

- 8.70 The treatment of stock animals in order to improve the quality of meat or increase the production of milk, eggs or the like would not be regarded as therapy, even if the substances concerned may have therapeutic benefits. However, in such cases the claims should clearly be limited to the non-therapeutic aspects. For example, in T 774/89 BAYER, the EPO Technical Board allowed claims directed at medication to increase milk production in cows since the benefits of administering the medication were not linked to the health of the cow. To establish its decision, the Board assessed if a non-therapeutic method would be expected to show an improvement on the normal condition of the subject, rather than just return an animal to a normal, healthy condition.
- 8.71 However, if the industrial benefit (e.g. an increase in meat yield) is a result from improved health through a therapeutic treatment, then it may not be allowable. For example, in T 780/89 BAYER/*Immunostimulant* OJEPO 1994, 797 claims directed to the use of compounds for immunostimulation or stimulating the animal body's own defences were considered to constitute therapy even with the Applicant arguing that immunostimulation merely increased meat production.
- 8.72 This was further confirmed in T 438/91 MEIJI/*Feeds* [1999] EPOR 333, wherein the step of feeding said animals had the effects of (a) remedying scours (via treatment with bifidobacteria included in the feed) and of (b) weight increase of the animals being bred. However, since (a) and (b) cannot be separated, the Technical Board of Appeal considered the claimed method to relate to a method of therapy or prophylactic treatment of domestic animals and thus not allowable.

Oral care

- 8.73 Methods for the removal of dental plaque, or preventing the formation of plaque are considered to be therapeutic and thus not allowed as all such methods have the effect of treating or preventing dental caries (*Oral Health Products (Halsteads) Application* [1977] RPC 612; *Lee Pharmaceuticals' Applications* [1975] RPC 51). The inherent therapeutic effect of removing plaque cannot be separated from the purely cosmetic effect of improved appearance of the teeth, and so restriction of such a claim to a cosmetic method is not possible (see T 290/86).
- 8.74 Non-patentable oral care method claims are those that may include, for example, references to antiseptic action, treatment of abscess, gumboil, gingivitis, inflammation of gums, mouth ulcers, periodontitis, pyorrhoea, periodontal disease, sensitivity, stomatitis and thrush.
- 8.75 However, in T 675/11 COLGATE-PALMOLIVE the Technical Board of Appeal considered that the “for use in the treatment of halitosis” of the claimed dentrifice composition was not a method of treatment by therapy as only in extreme cases it can be considered a disease, such as, for example, chronic halitoses.

Pain, addiction and fatigue

- 8.76 The relief of pain is considered to be therapeutic, even where the pain has no pathological cause. In the case of T 81/84 RORER/*Dysmenorrhoea* OJEPO 1988, 202, the claim:

“A method for relieving the discomfort of a human female attendant to menstruation, which method comprises administering thereto an effective amount of an amidino-urea of the general formula: X.”

was considered a therapeutic method; it was stated that irrespective of the origin of pain, discomfort or incapacity, its relief, by the administration of an appropriate agent, is to be construed as “therapy” or “therapeutic use”.

- 8.77 However, a method to reduce discomfort by cooling (T 385/09 LELY ENTERPRISES), and a method to reduce the perception of fatigue in healthy individuals (T 469/94 MIT) have been considered non-therapeutic since it is not comparable with the relief of pain, discomfort or incapacity.
- 8.78 Methods of treatment of addiction or withdrawal symptoms are considered to be therapeutic.

Obesity, appetite suppression and weight reduction

8.79 Treatment of obesity is generally considered to be therapeutic. However, methods of weight reduction for purely cosmetic reasons are not considered therapeutic and hence are industrially applicable under Section 16(2). Claims to such methods must be drafted to clearly relate to cosmetic weight loss only – for example the following would be allowable:

- A claim limited to a purely cosmetic purpose, such as “A method of improving the body appearance ...” (see T 144/83 DU PONT/ Appetite suppressant OJEPO 1986, 30).
- A claim limited to healthy subjects, such as “A method of improving the skeletal muscle performance of healthy subjects ...” (T 1230/05 BIOENERGY).

Contraception, abortion and fertility treatment

- 8.80 In general, methods of contraception are allowed since pregnancy is not an illness or disorder (*Schering A.G.'s Application*; T 74/93 BRITISH TECHNOLOGY GROUP/*Contraceptive method* OJEPO 1995, 712) but may be excluded under Section 16(2) if the method contains a therapeutic element.
- 8.81 For example, a contraceptive method using one active ingredient with concomitant treatment to reduce its ill effects by using a second agent would not be allowable (T 820/92 GENERAL HOSPITAL/*Contraceptive method* OJEPO 1995, 113). In this case, even though the use of an oral contraceptive constituted a non-therapeutic method, the Technical Board of Appeal considered that the claimed concentrations of the hormone content in the oral contraceptive were specifically selected at low levels in order to prevent or reduce the likely pathological side effects of the contraceptive. Consequently, the Board held that the claim is intrinsically indistinguishable from the non-therapeutic contraceptive method since the prevention of side effects is considered to be a therapeutic method.
- 8.82 Claims to methods of abortion, termination of pregnancy or induction of labour are not allowable regardless of the reasons for treatment (*UpJohn (Kirton's) Application* [1976] RPC 324). Moreover, methods to prevent or cure any diseases that may occur during pregnancy, but which are not inherently linked to the pregnancy itself, may still be considered therapeutic.
- 8.83 Methods of infertility treatment, including methods of *in vitro* fertilisation, are considered to be therapeutic. Implantation of an *in vitro* fertilised embryo would generally involve a surgical process (see *Occidental Petroleum's Application*) and therefore would not be industrially applicable under Section 16(2).

Methods relating to implanted devices

- 8.84 Methods relating to implants and the like may be patentable provided the claimed method does not relate to any therapeutic effect. For example, if the invention were to a method of monitoring the performance of the implanted device without any changes being made to the output signal then the method would be considered non-therapeutic (T 789/96 ELA MEDICAL/*Therapeutic method* OJEPO 2002, 364). Similarly, a method for measuring the flow of a drug from an implant, and which did not control the flow of the drug, was also held to be non-therapeutic (see T 245/87 SIEMENS/*Flow measurement* OJEPO 1989, 171).
- 8.85 On the other hand, a method of optimising an artificial respiration system while the system is in use was considered by the EPO Technical Board in T 1680/08 BÖHM to be indistinguishably linked to the therapeutic use of the respiration system in keeping the patient alive and consequently the claim was not allowable.
- 8.86 In addition, a method of operating a pacemaker in which its output to the heart was adjusted was deemed a method of treatment by therapy (T 82/93 TELETRONICS/*Cardiac pacing* OJEPO 1996, 274). In this case, the Applicant's argument that this was a "technical operation performed on a technical object" was considered irrelevant.

Treatments performed outside the body

- 8.87 In general, a therapeutic treatment of the human or animal body is not capable of industrial application under Section 16(2) even if the actual treatment takes place outside the body.
- 8.88 Examples of such treatments include blood dialysis where the blood is returned to the same body after treatment (*Calmic Engineering's Application* [1973] RPC 684 and *Shultz's application* BL O/174/86); it is necessary that the blood is returned to the same body for this to be considered to be a method of therapy. Therefore, treatment of blood for storage in a blood bank is not regarded as therapeutic treatment.
- 8.89 Similarly, methods for treating samples that have been extracted from the human body (e.g. blood, urine, skin, hair, cells or tissue) and methods for gathering data by analysing such samples are generally not considered to be therapeutic, unless the process is performed on the presumption that the samples are to be returned to the same body (see T 1075/06 FENWAL). For example, in T 794/06 GAMBRO LUNDIA it was argued that a method of preparing a dialysis solution carried out while the patient was connected to the dialysis system was not therapeutic since the dialysis solution was never in contact with the patient's blood.

v. **Diagnosis**

8.90 Section 16(2) excludes methods of diagnosis practised on the human or animal body. Diagnosis includes methods identifying a disease state, but also includes methods identifying the absence of such a disease state (T 807/98 ST JUDE).

8.91 The process of diagnosis involves four steps leading towards identification of a condition (see G 01/04):

- (1) The examination and collection of data;
- (2) Comparison of the data with normal values;
- (3) Recording any deviation from the norm; and finally,
- (4) Attributing the deviation to a particular clinical picture.

8.92 This is a narrow interpretation – only methods comprising all four of these steps and which will lead to the identification of a clinical state will be excluded from industrial applicability. Such interpretation is consistent to that of the earlier decision T 385/86 BRUKER/*Non-invasive measurement* OJEPO 1988, 308 where a method of determining temperature and pH by magnetic resonance imaging that included a step of taking a sample, or determining internal temperature or pH, without leading to the identification of a pathological condition and thereby was not considered to be a method of diagnosis (see also *Bio-Digital Sciences' Application* [1973] RPC 668).

What does “practised on the body” involve?

- 8.93 Section 16(2) requires that a diagnostic method be carried out on a living human or animal body. Therefore, if the diagnostic method is not carried out on a living human or animal body, but on a dead body, for example to determine the cause of death, said method would not be objectionable (e.g. performing an autopsy).
- 8.94 The criterion “practiced on the human or animal body” is to be considered only in respect of method steps of a technical nature (G 01/04). Section 16(2) does not require a specific type and intensity of interaction with the human or animal body. The criterion “practiced on the human or animal body” is satisfied as long as the step of technical nature (usually the examination and data collection step) implies any interaction with the human or animal body, necessitating the presence of the latter.
- 8.95 When deciding whether a claim defines a method of diagnosis practised on the human or animal body, the Examiner may use a simplified test. First, the Examiner should consider whether the method includes a technical step, i.e. a measurement or examination step (explicitly or implicitly), and a deductive step of determining the disease or deriving a clinical picture (corresponding to steps (1) and (4) above). If this is the case, then the second question is whether the technical step is “practised on the body” – the simple test for this is whether the patient has to be present during this step. If the answer to both questions is “yes”, an objection should be made.
- 8.96 In this regard, the Enlarged Board of Appeal in G 01/04 also noted that:
- “if ... some or all of the method steps of a technical nature ... are carried out by a device without implying any interaction with the human or animal body, for instance by using a specific software program, these steps may not be considered to satisfy the criterion ‘practised on the human or animal body’, because their performance does not necessitate the presence of the latter.”*
- 8.97 Therefore, if a claim to a diagnostic method includes new and inventive technical steps that are all carried out separately from the body, for example, by being carrying out *in vitro* on a sample of tissue obtained from the body, it will be capable of industrial application. For example, in T 666/05 UNIVERSITY OF UTAH, claims

defining methods for diagnosing a predisposition for breast cancer by detecting a mutation in the BRCA1 gene in a tissue sample from the subject was allowable since the technical steps of the claimed methods are performed on an *in vitro* tissue sample. Nonetheless, such claims should still be examined to determine whether they fall under the definition of a method of therapy or surgery.

- 8.98 Additional, intermediate steps which relate to, for example, the preparation or adjustment of a device for data collection, may be introduced into a diagnostic method claim for completeness. However, since these intermediate steps are not part of steps (1) to (4) as described above, which are necessary for making the diagnosis, they are ignored when assessing the diagnostic character of the method. Thus, even when the performance of such intermediate technical steps do not require the presence of the human or animal body, it would still not overcome a diagnostic method claim that was in the first place not allowable (see T 1197/02 THE AUSTRALIAN NATIONAL UNIVERSITY and T 143/04 BETH ISRAEL HOSPITAL ASSOCIATION).

Who performs the method?

- 8.99 The question of whether a claimed method is excluded under Section 16(2) depends on whether it falls within the definition of a “method of diagnosis”, and whether it is “practised on the human or animal body”. It does not depend on who performs the method, or if a medical or veterinary practitioner is required.
- 8.100 In general, a method is “practised on the human or animal body” if it involves any interaction that requires the presence of the subject. Consequently, as long as the subject’s presence is required, it will be considered as being “practised in the human or animal body”.
- 8.101 In this regard, G 01/04 states that:

“... whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC should neither depend on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practised by medicinal or nonmedicinal support staff, the patient himself or herself or an automated system.”

Identification of a condition and/or disease to be diagnosed

- 8.102 A diagnostic method requires a deductive step (4) that must involve the identification of a “condition”. For example, a method of measuring temperature using magnetic resonance would be allowable as there is no condition to be diagnosed (see T 385/86).
- 8.103 Notably the omission of such a step from the claim may overcome an objection under Section 16(2), but may result in a support objection under Section 25(5)(c) if an essential feature of the invention is not defined. For example, in decision T 143/04 the claims as originally filed were directed to a method of diagnosing Alzheimer’s disease. The Applicant amended the claims to include only the examination phase and remove the references to a comparison and diagnosis. However, the EPO Technical Board did not allow this amendment because the invention as filed is not an independent data collection method, but a method of diagnosis that included those data collection steps. In addition, it was held that as long as the method can be used to diagnose a disease, whether the method is reliable is an irrelevant consideration (paragraph 3.4 of T 143/04).
- 8.104 There may be cases where it is apparent from the description that a claimed method is in fact a method of diagnosis, even if the words of the claim do not specify a specific disease. For example, in T 125/02 AEROCRINE the measurement of nitrogen monoxide levels in exhaled air was used to identify “impaired respiratory function”; and the description indicated that the method allowed particular course of treatment to be selected, and so the claimed method was considered to encompass all the steps leading to a diagnosis.
- 8.105 In some cases, the method may be useful in diagnosing a disease but does not provide sufficient information in itself to enable a diagnosis. Thus, a method should not be considered a method of diagnosis if it merely determines the general health and well-being of an individual and is not intended to determine a pathological condition.
- 8.106 For example, methods such as fitness tests and the like would be considered patentable. Similarly, if a method is merely for data acquisition or processing and it only provides intermediate results that may be of diagnostic significance, it could be patentable as long as no actual diagnosis can be obtained. However, care must be

taken in such cases since if the application indicates that the claimed method of data acquisition or processing is an integral part of a method of diagnosis, there may be support issues when the said data collection/processing method is claimed as an independent method (see paragraph 2 of T 143/04).

8.107 Examples of techniques that may be allowable include:

- (i) Methods of imaging using CT scanning (see T 09/04 KONONKLIJKE PHILIPS ELECTRONICS);
- (ii) Methods of measuring a parameter in a sample, such as blood glucose (T 330/03 ABBOTT LABORATORIES);
- (iii) Methods of assessing tissue viability by measuring total haemoglobin, oxygen saturation and hydration (T 41/04 NATIONAL RESEARCH COUNCIL OF CANADA)
- (iv) Methods of determining ear temperature (T 1255/06 EXERGEN CORPORATION);
- (v) Methods of imaging an artery in a patient using magnetic resonance imaging (see T 663/02 PRINCE); and
- (vi) Methods of detecting regional variations in oxygen uptake from the lungs (T 990/03 MEDI-PHYSICS INC.).

8.108 Although these are *prima facie* allowable methods, if the method encompasses attribution of the result to a clinical condition or disease, then it may still be considered a diagnostic method.

D. Medical use

i. First medical use

8.109 Whilst methods of treatment are excluded from patentability by virtue of Section 16(2), there is some relief for innovators wishing to patent substances or compositions used in methods of medical treatment. This is specifically provided in Section 16(3), which states that:

Subsection (2) shall not prevent a product consisting of a substance or composition from being treated as capable of industrial application merely because it is invented for use in any such method.

8.110 Section 16(3) is further supplemented by Section 14(7) which states that a known substance or composition for use in a method of treatment excluded by Section 16(2) will be new if the use of the substance or composition in any such method does not form part of the state of the art. Consequently, known substances or compositions which have not been used previously for medical purposes may be claimed in the form of a first medical use claim.

8.111 First (and second) medical use claims are often filed for new substances or compositions that have medical uses, in anticipation of any unforeseen prior disclosure of the claimed substance or composition that are found only after grant. Known substances or compositions not previously used for medical purposes may also be claimed in the form of a first (and/or second) medical use.

Forms of claim

8.112 A claim to the first medical use of a new or known substance or composition may broadly claim any therapeutic use. Examples of suitably drafted claims include:

- (i) Compound X for use in therapy.
- (ii) Compound X for use as a medicament.

8.113 It is clear that no single drug is suitable for treating all diseases. However, this broad form of first medical use claim is allowable on condition that there is support for at least one medical use of the substance or composition claimed. The permissibility of this broad form of first medical use claim was deliberated by the Technical Board of Appeal (T 128/82 HOFFMAN-LA ROCHE/*Pyrrrolidine-derivatives* OJEPO 1984, 164). It was decided that claims which did not state the specific therapeutic purpose were allowable if the substance or composition in question had not been previously used for any form of therapy, even if the specification only indicated one therapeutic use. It was further agreed that an inventor who for the first time discovered the use of a new or known compound for therapy should be duly given this broad form of protection.

8.114 First medical use claims may also be drafted in the form of a specific medical use claim and be worded in the form:

- (iii) Compound X for use in the treatment of disease Y.

Both broad and specific first medical use claims are anticipated by any prior medical use of the compound. Essentially, regardless of the claim wording, be it in the form of either examples (i)-(iii), first medical use claims will lack novelty in view of earlier known use of the compound for any therapeutic purpose.

8.115 This differs from the UK and European patent practice, whereby specific medical use claims, in the form of example (iii), are only anticipated by the use of X for the specific treatment of disease Y. This is because, following the implementation of EPC 2000, such claims are regarded by UK IPO and EPO as limited to the specific medical

uses claimed. In other words, in proceedings before the UK IPO and EPO, claims of this form are anticipated only when the use of X for the specific purpose of treating disease Y is disclosed.

8.116 Inappropriate first medical use claims include:

(iv) Compound X when used in therapy.

The claim of example (iv) is interpreted as a method of medical treatment and would not be capable of industrial application.

(v) Compound X for treating disease Y / Compound X for the treatment of disease Y.

The claim of example (v) lacks clarity. It is unclear if the claim is directed to compound X as “suitable for” treating disease Y or whether the intention is to limit compound X to the medical use of treating disease Y. In this scenario, the Examiner is to adopt the broader interpretation, wherein “for” is interpreted as “suitable for”. Accordingly, any disclosure of compound X, regardless of therapeutic inference would anticipate the claim of example (v) if the compound disclosed is in a form which would be suitable for the claimed use. For example, a disclosure of compound X used as a moisturizing agent, will anticipate a claim drafted in the form of (v) wherein disease Y is eczema.

8.117 In general, Section 16(3) is not relevant to substances or compositions that are not used in a method prohibited by Section 16(2). The meanings given to “surgery”, “therapy” and “diagnosis” in Section 16(2) is applied equally to Section 16(3). Therefore, Section 16(3) does not apply to substances or compositions that are used purely for cosmetic purposes since purely cosmetic methods are not considered as methods of treatment of the human or animal body by surgery or therapy or of diagnosis. Moreover, known substances or compositions drafted as a first medical use claim do not fall under the remit of Section 16(3) if there is no genuine prophylactic or therapeutic effect beyond, for example, the maintenance of a healthy diet (T 135/98 NORSK HYDRO [2004] EPOR 14).

8.118 A known substance or composition used as an inactive carrier or excipient for use in therapy cannot be protected by a first medical use claim. In order for a first medical use of a known substance or composition to be claimed, the substance or composition must be present as an active agent in a medicine. In T 1758/07 BIOTEC PHARMACON, a disclosure concerning the use of acid-hydrolysed yeast materials for improving the palatability of animal feed and the palatability of oral medicaments for administration to animals was considered to not anticipate a first medical use claim for the same composition. This was because the yeast hydrolysate in the prior art document was not used as an active agent for therapy of a disease but was instead used as an inactive carrier or excipient for a therapeutic agent. Even though this decision was made in relation to novelty, the same basis may be applied in determining the admissibility of an inactive carrier or excipient in the form of a first (or second) medical use claim. For this reason, an inactive carrier or excipient for a therapeutic agent cannot be claimed in the form of a medical use claim and the claim would lack support if claimed as such.

Novelty and inventive step assessment of first medical use claims

- 8.119 Any disclosure of the claimed substance or composition as a therapeutic agent will anticipate a first medical use of the substance or composition. However, in some instances, it is not necessary for the compound to have been isolated in the prior disclosure if, by carrying out the methods of the earlier disclosure, the compound would have been inevitably made. Specifically, in *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76, 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 because of prior use but because it was the inevitable result of carrying out the instructions as taught in the earlier terfenadine patent.
- 8.120 Actual therapeutic use of the claimed substance or composition must be indicated in non-patent documents for it to be considered an enabling disclosure. Disclosure of experiments in non-patent documents demonstrating an activity which would make the substance or composition a suitable candidate for use in therapy or disclosure of *in vitro* testing for such a use is not considered as an anticipatory document unless actual therapeutic use can be inferred from the document (implicit disclosure). This document may of course serve as a basis for an obviousness objection under inventive step.
- 8.121 However, when the application contains only *in vitro* experimental data and the only difference between the application and the prior art document is the assertion of a therapeutic use, then the Examiner may still object to the claim for lacking novelty since there was no new technical feature provided in the application that confers novelty to the claim (T 1031/00 SEPRACOR INC.).
- 8.122 A statement indicating the therapeutic uses of the claimed substance or composition in a patent document without accompanying clinical data may be cited for novelty. This statement is considered to anticipate the first medical use of the claimed substance or composition and the onus is on the Applicant to challenge whether such a document constitutes an enabling disclosure. As discussed in T 1001/01 SMITHKLINE BEECHAM:

“... it is common practice that a patent literature document, in order to be an enabling disclosure of a medical indication for pharmaceutically active compounds ... does not necessarily need to include either clinical tests (Phase I, II or even III) or in vivo human assays.”

8.123 As medical use claims are limited to the intentional treatment of a disease, the disclosure that the substance or composition of interest has previously been administered or ingested would not anticipate a first medical use claim if there was nothing in the prior art documents to indicate any therapeutic benefits even though this may have inherently occurred.

Support for first medical use claims

- 8.124 First medical use claims must be supported by evidence of the likely efficacy of the substance or composition in therapy. However, the Applicant is entitled to a broad form of claim (such as in examples (i) and (ii)) in the case of a substance or composition, wherein its use in medicine is previously unknown. Therefore, it is unlikely a first medical use claim will lack support as long as the Applicant provides credible evidence of the efficacy of the claimed substance or composition for use in the treatment of any one, if not more diseases. For a first medical use claim drafted in form of example (iii): “Compound X for use in the treatment of disease Y”, support has to be provided for the specified use.
- 8.125 This requirement of support for known substances or compounds is based on the decision of the Patents Court in *Prendergast’s Applications* [2000] RPC 446. Although this case law is pertaining to support for “Swiss-type” claims, it remains nonetheless relevant to first medical use claims. It was held in *Prendergast’s Applications* that since the distinguishing feature of the “Swiss-type” claim from the prior art is its intended use, this use must in turn, be supported by credible evidence.
- 8.126 This requirement of support is also mandatory for new and inventive substances or compositions. This view was held by the Hearing Officer in *F. Hoffman - La Roche’s Application* BL O/192/04:

“Support is needed for claims to the use of compounds for therapy, regardless of whether the compounds are themselves new or inventive.”

- 8.127 The form of evidence is not critical. *In vivo*, *in vitro* and *in silico* modelling data may prove sufficient if it is considered a credible form of support of its efficacy in a medical use. However, the level of evidence provided will be decided upon a case-by-case basis as it may also be dependent upon the state of the art in relation to a particular application. In *F. Hoffman-La Roche’s Application* BL O/192/04, homology comparisons of the claimed polypeptide were used to determine biological activity by reference to a polypeptide of known activity. It was concluded that although the description provided support for the function of the Npt2B polypeptide in its native

state, this support cannot be read across to the claimed polypeptide in an isolated, non-naturally occurring environment. The Hearing Officer was of the view that it is unlikely the Npt2B polypeptide will retain its native state structure when isolated in 99% pure form and hence it was also unlikely that the polypeptide retained its function as a sodium phosphate transporter. Moreover, in the absence of any evidence demonstrating the efficacy of the isolated polypeptide in a non-naturally occurring environment, the claims relating to the therapeutic uses of the isolated form of Npt2B polypeptide were considered to lack support.

8.128 The evidence in support of first medical use claims must be provided in the application as filed. The absence of this would result in the first medical use as being no more than mere speculation. In such instances, the Examiner is required to inform the Applicant of the lack of support for the claimed first medical use. This objection cannot be overcome by later-filed data.

8.129 Moreover, if the application claims priority from an earlier application and there is no evidence in that earlier application of the therapeutic use of the claimed substance or composition, then claims relating to the medical use of the substance or composition would not be entitled to a priority date based upon the earlier application.

ii. Second medical use

8.130 Second or subsequent medical uses of a substance or composition may only be claimed in the form of “Swiss-type” claims. This form of claim, first allowed by the Swiss Patent Office in response to a lack of provision in the legislation for the protection of second medical uses of a substance or composition, were also deemed allowable by the Enlarged Board of Appeal in G 05/83, and subsequently by the Patents Court in *John Wyeth’s and Schering’s Applications* [1985] RPC 545. As stated in G 05/83:

“... it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case where the process of manufacture as such does not differ from known processes using the same active ingredient.”

8.131 “Swiss-type” claims are regarded as purpose limited process claims whereby the claim is directed to the use of the substance for the manufacture of a medicament for a specified medical use. Hence, “Swiss-type” claims are not restricted to second or subsequent medical uses of a substance or composition and can be used even when the first medical use of a compound is not previously known.

8.132 This practice of using a “Swiss-type” claim format for second medical uses differs from that of UK and Europe. Since the implementation of the EPC 2000, Applicants within contracting member states have been able to protect inventions relating to second and subsequent medical uses through a more direct claim form: “substance X for use in the treatment of disease Y”. However, without similar provisions in the Singapore legislation, such claims cannot be construed as providing the same limitations of being specifically directed to the treatment of disease Y in Singapore.

8.133 Normally, “for” is interpreted as “suitable for”. However, in a “Swiss-type” claim, “for” is interpreted as “suitable and intended for” treatment of the indication specified. In *Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Ors (Rev 1)* [2015] EWHC 72, Arnold J. (citing *Actavis v Merck* and Birss J. in *Hospira UK Ltd v*

Genentech Inc.), noted that a “Swiss-type” claim is directed at the manufacturer and that the intention of the manufacturer in the production of the pharmaceutical product is key.

8.134 Second medical use claims can only derive novelty from their intended use if the use is in a method of treatment excluded under Section 16(2). This means that “Swiss-type” claims are not allowable for the new use of a known substance in a non-medical method. In *Commonwealth Scientific & Industrial Research Organization’s Application* BL O/248/04, the method of follicle ablation on sheep was considered as a method of maintaining hygiene, even though the consequence of wool removal results in a reduction of conditions favourable for balanitis and blowfly strike occurrence. However, this reduction of favourable conditions was not directly linked to a therapeutic activity of follicle ablation. Therefore, the method was considered a non-therapeutic method and consequently was not entitled to protection in the form of a “Swiss-type” claim.

8.135 An application may include both “Swiss-type” claims and non-therapeutic claims (e.g. use of the compound for cosmetic purposes) on condition that the therapeutic and non-therapeutic methods are supported and distinct. As stated by the Hearing Officer in *Commonwealth Scientific & Industrial Research Organization’s Application* BL O/248/04:

“... an application may include both claims to the second medical use of a compound for therapeutic purposes, and claims to non-therapeutic methods of using the compound, providing the therapeutic and non-therapeutic methods are distinguishable and both methods are fully supported by the application as filed. On the other hand, if the therapeutic and non-therapeutic aspects cannot be distinguished, or if the non-therapeutic effect is merely a secondary consequence of the therapy, then the invention is unpatentable, regardless of the wording used ...”

8.136 Although the Enlarged Board of Appeal in G 05/83, referred only to “therapeutic” methods, second medical use claims may be used to protect the use of a known substance or composition in any method excluded under Section 16(2) of the Patents

Act, on condition that the specified medical use is new and inventive. In T 655/92 NYCOMED/*Contrast agent for NMR imaging* OJEPO 1998, 17, a “Swiss-type” claim was allowed for the use of a known compound, previously used as a medicament, as a reagent in a diagnostic method performed on the human body. The allowed claim reads:

“Use of a magnetically responsive material for the manufacture of a diagnostic contrast agent for use in a method of in vivo nuclear magnetic resonance imaging of a subject, said agent comprising particles of a matrix material having a diameter of up to 10 micrometres and having enclosed therein a said magnetically responsive material the magnetic responsiveness of which is such that said particles are magnetically localisable and such that said particles in said nuclear resonance imaging of said subject cause relaxation time changes resulting in a visualisable ‘black hole’ contrast effect.”

8.137 The following are examples of suitably drafted second medical use claims:

- (vi) Use of compound X in the manufacture of a medicament for the treatment of disease Y.
- (vii) Use of compound X in the manufacture of a pharmaceutical composition for treating disease Y.

8.138 Unsuitably drafted second medical use claims include, but are not limited to:

- (viii) Use of compound X for the treatment of disease Y.
- (ix) Compound X for use in the treatment of medical condition Y.

Claim (viii) is interpreted as a method of medical treatment and would lack industrial application.

Claim (ix) is consistent with current second medical use forms accepted by UK IPO and EPO. However, under present Singapore practice, it is construed as a claim to a first medical use and accordingly, the claim lacks novelty if compound X is a known medicament as the specific use is not considered to be limiting. Nonetheless, if a previous medical use is not known then such claims are allowable, provided that there is evidence in the specification supporting the claimed use.

8.139 T 1075/09 LABORATOIRES SERONO provides a further example of suitably and unsuitably drafted “Swiss-type” claims. In T 1075/09, a claim to the combined use of two hormones was drafted in a way such that one of the hormones was interpreted as a second medical use while the other, as a therapeutic method. The claim in question relates to the new use of luteinising hormone (LH) and included the phrase “wherein folliculogenesis is induced by the administration of follicle stimulating hormone (FSH)”. This phrase was considered as a method of administering follicle stimulating hormone and so the claim was interpreted as encompassing a method of medical treatment. On the other hand, the claim “The use of FSH and LH in the production of a medicament for inducing paucifolliculogenesis or unifolliculogenesis ... wherein the FSH is for inducing folliculogenesis and the LH is to be administered subsequent to FSH ...” was found to be allowable. Thus, the wording of claims relating to combined treatments needs to be checked to ensure that a method of treatment by therapy is not included in the scope of the claims.

8.140 Another example of a Swiss-type claim that is not properly formatted is seen in BGH/Carvedilol II [2006] X ZR 236/01. The claim reads:

“Use of carvedilol for the production of a medicament for the reduction of mortality ... wherein the medicament is administered in starting dosage of ...”

The phrase “wherein the medicament is administered” was considered a therapeutic procedure for the treatment of the human body and thus was not considered a proper “Swiss-type” claim.

A suitable rectification would be to replace the phrase “wherein the medicament is administered” with “wherein the medicament is to be administered” such as in the claim below:

- (x) Use of a compound X in the manufacture of a medicament for the treatment of disease Y wherein the medicament is to be administered at a daily dosage of Z mg.

Novelty and inventive step assessment of second medical use claims

8.141 As in the case of a first medical use claim, a disclosure of an activity that merely suggests that a substance or composition can be used for the claimed therapy, or that discloses *in vitro* testing for such a use in a non-patent document would not anticipate a second medical use claim for the same proposed medical use, if the document did not explicitly or implicitly disclose the use of the substance or composition for the claimed therapy. Mere assertion or assumption of a therapeutic use of a compound based upon *in vitro* testing is not sufficient to destroy the novelty of the claim. This is primarily because the disclosure in the non-patent document may not be enabling, and moreover, following the directions in the document would not necessarily infringe a claim to a therapeutic use. Nonetheless, such documents would form the basis of a strong inventive step argument. Summarizing the disclosure requirement, Lord Hoffmann in *SmithKline Beecham's (Paroxetine Methanesulfonate) Patent* [2006] RPC 10, stated:

“Anticipation requires prior disclosure of subject-matter which, when performed, must necessarily infringe the patented invention.”

8.142 However, patent documents which disclose the substance or composition for treatment of the claimed disease, but without providing actual clinical data may still be cited as a prior art for novelty. This is because even if the document does not disclose actual clinical use, by following the directions in the document, the skilled person would still infringe the patent. Similar to first medical use, the onus is on the Applicant to challenge whether the disclosure in the prior art document constitutes an enabling disclosure.

8.143 Likewise, experimental data demonstrating the efficacy of the treatment for the claimed ailment using the substance or composition on animals would constitute anticipation of the medical use claim. If, on the other hand, and as pointed out in T 715/03 PFIZER, the document does not indicate the use of the substance or composition for the treatment of the claimed disease, but merely mentions the completion of Phase I or commencement of Phase II trials, without providing any results on therapeutic efficacy, then this will not necessarily constitute evidence of

therapeutic use. This is because Phase I trials merely assess the safety of the drug and Phase II trials indicate the efficacy of the drug but not necessarily its therapeutic effect. Nevertheless, this would again be a strong basis for an argument under inventive step. However, the Examiner should consider such disclosure on a case-by-case basis, taking into account the intention of the trials and what is known regarding the substance or the composition under trial before making a decision on whether a novelty or an inventive step objection is warranted.

8.144 In the case whereby the substance or composition has been used to treat a related condition, the inventiveness of the claim may be questioned. However, T 913/94 EISAI/*Medicament for gastritis* [2001] EPOR 362 stated that even if the diseases have a common origin, causative factors or mechanism, this may not necessarily mean that the claim lacks inventiveness. If the severity of the symptoms of the disease indicated in the prior art document is greater than the claimed disease, this would strongly imply that the same agent will similarly be effective for the latter condition. More often than not, these cases may need to be individually dealt with by the Examiner on a case-by-case basis.

8.145 For a new use of a known substance or composition to be recognized as inventive, the specification needs to provide reasons not previously known or recognised as to why the claimed substance or composition is likely to be effective for the new use. It was stated in *Teva v Astrazeneca* [2014] EWHC 2873:

“Where, as here, a patent is sought in relation to a new use of an existing drug or combination of drugs, patent protection will only be justified if the patentee discloses sound reasons, not recognised or known before, for thinking that new use will be effective to secure the object for which it is put forward.”

8.146 Typically, the answer to the final question of the Windsurfing test determines the inventiveness of new medical uses of known substances or composition. The question may be along the lines of: Is it obvious to try to use the said substance or composition for the claimed purpose? In this instance, obviousness is only found where it is considered as obvious to try with a reasonable or fair expectation of success. This is particularly so in the area of pharmaceuticals and biotechnology as a means of

minimizing deterrence to research. The Court of Appeal in *MedImmune v Novartis* [2010] EWCA Civ 1234, [2013] RPC 27 provides some guidance on this:

“Whether a route has a reasonable or fair prospect of success will depend upon all the circumstances including an ability rationally to predict a successful outcome, how long the project may take, the extent to which the field is unexplored, the complexity or otherwise of any unnecessary experiments, whether such experiments can be performed by routine means and whether the skilled person will have to make a series of correct decisions along the way.”

Although this case did not relate to medical use claims, this approach was validated by the Court of Appeal in *Regeneron Pharmaceuticals v Genentech* [2013] EWCA Civ 93 in relation to a second medical use claim.

The new use

Treatment of a new disease or condition

8.147 Typically, a second medical use claim is used to protect the use of a substance or composition in the treatment of a different disease. An example of this would be aspirin, which was originally used as an antipyretic and analgesic, and was subsequently found to be useful as an anticoagulant, and later as an anti-stroke medication and an anti-ischaemic. Hence, a claim based on a new medical use of a known substance or composition may claim novelty in the form of a “Swiss-type” claim. Guidance on evaluating novelty for this form of claims may be taken from the decision in *Schering A.G.’s Application* [1985] RPC 553:

“... a second pharmaceutical use invention, which is also referred to as the second medical indication, that is to say an invention based on the discovery that a drug already known for a particular medical activity (or activities) has another useful medical activity unconnected with the first and which had not previously been expected.”

8.148 In a scenario where the new use is the treatment of a specific form of a disease, the novelty of such a second medical use claim may vary depending on the facts of the case. In most cases, a general disclosure of a class of diseases, does not anticipate a claim to a specific disease within that class. Nonetheless, a novelty objection may be made in instances where the prior art document discloses a class of diseases which appear to encompass the specific disease claimed, and either the specific disease is referred to in the prior art document as being treatable with the claimed substance or it may be reasonably implied that the prior art document does disclose the treatment of the specific disease. The onus will be on the Applicant to argue whether the prior art document constitutes an enabling disclosure for the specific disease claimed. In T 1001/01, a “Swiss-type” claim to adenocarcinoma of the ovary was judged as novel over the prior art document which disclosed experimental data employing a metastatic reticulum cell sarcoma arising from the ovary of a C57BL/6 mouse. The Technical Board of Appeal was convinced by the Appellant’s arguments and evidence that the preclinical model using metastatic reticulum cell sarcoma could not serve as a model

for adenocarcinoma of the ovary which is of epithelial origin and has a glandular growth pattern. Additionally, the Board reasoned that the skilled person would be able to distinguish when an ovarian cancer is an adenocarcinoma of the ovary and therefore the novelty of the claim over the prior art document was acknowledged.

New mode and dosage of administration

- 8.149 The mode of administration may play a critical role in a medical treatment and can serve as a distinguishing feature over the prior art documents. In T 51/93 SERONO, the administration of human chorionic gonadotrophin in the treatment of male sexual disorders or infertility by a subcutaneous route was considered to confer novelty over the prior art documents which disclosed administration via an intramuscular route. In this case, the Applicant demonstrated that the subcutaneous route provided the advantages of reduced nerve lesions and the option of self-administration. Nevertheless, it should be noted that the claim must be appropriately drafted such that the claimed mode of administration is directed at the manufacturer and not at the medical practitioner. If the claim is drafted such that it is deemed to be directed to a medical practitioner then it will be considered as a medical method of treatment and thus lack industrial application. Although second medical use claims may be defined in part by their modes of administration, defining the use in these terms alone (e.g. for enteral administration) without further specifying any actual therapy, is not considered to define a new medical use and so in such cases, the claim would be construed as a substance or composition “suitable for” such a use (T 1278/12 N.V. Nutricia).
- 8.150 Second medical use claims which are distinguished from the prior art documents by the dosage regime used are allowable, on the condition that the claimed dosage regime is novel and inventive. In *Actavis v Merck* [2008] RPC 26, the dispute centered around the second medical use of finasteride at a new daily dosage of about 0.05 mg to 1.0 mg for the treatment of androgenic alopecia. Finasteride was a known drug for treating prostate conditions and had been previously proposed as a treatment for androgenic alopecia at a dosage of at least 5 mg. Thus, the new feature in the claim was a lowered dosage of finasteride for the treatment of androgenic alopecia. In this case, the Court of Appeal overturned the decision of the Patents Court in *Actavis v Merck* [2007] EWHC 1311 and held that a second medical use claim in the form of a new dosage regime was allowable. Additionally, after much deliberation, Jacob LJ acceded to Merck’s argument that based on the state of knowledge of the skilled person at the priority date of the document, it would not have been obvious to the skilled person to reduce the dosage range for the treatment of androgenic alopecia.

8.151 However, in most cases, a new dosage regime is generally presumed as lacking inventiveness unless there is a clear technical prejudice pointing away from the claimed dosage regime. Therefore, typically, such dosage regimes will be considered obvious as investigation of dosage regime is regarded to be a routine practice in the art. This point was highlighted in *Actavis v Merck* [2008] EWCA Civ 444:

“Only in an unusual case such as the present (where ... treatment for the condition with the substance had ceased to be worth investigating with any dosage regime) could specifying a dosage regime as part of the therapeutic use confer validity on an otherwise invalid claim.”

New patient group

8.152 A second medical use claim may, for novelty and inventive step purposes, rely solely on the patient group to be treated. This is despite the known association of the claimed substance or composition and the disease to be treated.

8.153 The new patient group must consist of a distinctly different group of patients from those treated in the prior art. Furthermore, there must be a functional relationship between the particular physiological or pathological status of this group of patients and the therapeutic or pharmacological effect achieved. Guidance is provided by the Technical Board of Appeal in T 233/96 MEDCO RESEARCH:

(1) The new patient group must be clearly distinct from the patient group treated in the prior art and these 2 groups must not overlap;

(2) The distinction must not be arbitrary and must be based on a functional relationship between the physiological or pathological characteristics of the new group and the therapeutic effect.

An example of a non-overlap of the new patient group with the known patient group would include the therapeutic application of a vaccine known for the treatment of sero-negative pigs, to a new and different class of the same animal, sero-positive pigs in T 19/86 DUPHAR/Pigs II OJEPO 1989, 24. As stated by the Board of Appeal:

“... Such a new use is not only valuable in cases where a novel area of therapeutic use, i.e. a novel medical indication, is provided but also in those cases where a novel class of animals, which previously did not respond to a medicament, is cured or protected against a disease. The question whether a new therapeutic use is in accordance with the decision Gr 05/83 should not be answered exclusively on the basis of the ailment to be cured but also on the basis of the subject (in the present case the new group of pigs) to be treated.”

8.154 A second medical use claim directed to the use of a substance or composition in the manufacture of a medicament for the treatment of a disease in a specific patient group will not be considered novel if the same substance or composition has already been

used to treat the same group of patients, amongst others. Mere discovery that a treatment is particularly effective in one sub-group of patients does not render a claim novel if it is explicitly or inherently implied from the prior art documents that the same substance has been used to treat the same disease in this patient group. The identification of this sub-group of patients is considered a mere discovery of an advantage to an already known treatment. For example, in *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [1999] RPC 253, it was decided that new information of an advantage or how a treatment worked did not constitute an invention if this information did not lead to a new use. This decision was upheld in the Court of Appeal in *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 253.

New mechanism or technical effect

8.155 Second medical use claims distinguished solely by a different mechanism of action or technical effect, but used for the same therapeutic purpose as the prior art will lack novelty. The mere discovery of how a treatment works is inconsequential.

8.156 This interpretation is based by the decision of the Patents Court in the earlier discussed *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [1999] RPC 253. As stated by Jacob J:

“All you have is more information about the old use. In due course no doubt more information about the exact mode of action of Taxol will emerge. No-one could obtain a patent for its use simply by adding ‘for’ at the end of the claim and then adding newly discovered details of the exact mode of action.”

8.157 This conclusion was followed by the Patents Court in *El-Tawil v The Comptroller General of Patents* [2012] EWHC 185 where the decision of the Hearing Officer in the rejection of claims relating to a mechanism of action of a known treatment was upheld. Furthermore in *Actavis UK Ltd v Jassen Pharmaceutica NV* [2008] EWHC 1422, a second medical use claim relating to the use of an agent for potentiating the effects of blood pressure reducing agents having adrenergic and/or vasodilating activity was concluded as merely providing more information about the mechanism of action of a known treatment. It was stated:

“I think that all that is done here is to explain why the results that would be obtained with compound 84 are as good as they are.”

8.158 The newly discovered mechanism or technical effect is insufficient on its own in conferring novelty to a second medical use claim. As stated by Floyd J in *Actavis UK Ltd v Jassen Pharmaceutica NV* [2008] EWHC 1422:

“In my judgement, merely explaining the mechanism which underlies a use already described in the prior art cannot, without more, give rise to novelty.”

Hence, the discovery of a new technical effect has to be associated with some other

feature of the treatment which is clearly distinguishable over the prior art document such as a new therapeutic use, patient group or clinical situation in order to fulfil novelty.

8.159 A claim defined in mechanistic terms does not necessarily mean that the claims are unclear. In *Regeneron Pharmaceuticals Inc. and Bayer Pharma AG v Genentech Inc.* [2013] EWCA Civ 93, the phrase “non-neoplastic disease or disorder characterised by undesirable excessive neovascularisation” was deliberated. Floyd J held that there was no difficulty in identifying treatable diseases characterised by undesirable excessive neo-vascularisation. It was stated:

“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.”

8.160 Examiners should therefore consider such claims on a case-by-case basis and in relation to what is generally known about the mechanism of action being claimed and its relationship with specific medical conditions. Nevertheless, even if the condition to be treated defined in mechanistic terms is considered to be clear, the Examiner should ensure that such claims are supported and that there is a clear indication that all conditions which fall under the scope of such a mechanism would in fact be treatable by the claimed composition.

New advantage to known use

8.161 Claiming an unexpected advantage to a known treatment is not considered as a new therapeutic use, although it may form the basis of such a use. In *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [1999] RPC 253, the invention lay in the unexpected discovery that a shorter infusion time of Taxol of 3 hours versus a 24 hour period led to a lessening of neutropenia (white blood cell count). The court found that the Applicant was simply seeking to protect new information (i.e. lessening of neutropenia) regarding the known use of Taxol for treating the same disease over the same infusion duration. As stated by Jacob J:

“... there is a big difference between new information that a prior proposal previously thought unworkable in fact works and new information to the effect that a prior proposal has an additional advantage.”

Level of efficacy of treatment

- 8.162 Generally, the sole feature of an improved level of efficacy over an existing treatment will not confer novelty to the claim. Moreover, lack of clarity may be raised as the claim is defined in terms of a desired outcome. In T 315/98 STERLING/ S(+) ibuprofen, 2000, the “hastened onset” of pain relief was not considered to be a new medical use when the substance was already known for its analgesic properties. The fact that the prior art document did not expressly mention hastened onset did not automatically establish novelty of the claimed use. Both the patent in suit and prior art document referred to the same racemate of ibuprofen as a basis for comparing the pharmacological activity of the S(+)enantiomer. Additionally, both referred to pharmacological activity in the form of analgesic response. Hence, it was held that the reference in the prior art document to S(+)ibuprofen in higher concentrations reaching the site of action more quickly with a higher activity means nothing else than hastened onset of analgesia. Accordingly, it was concluded that the pharmacological effect of S(+)ibuprofen as claimed was disclosed in the prior art document.
- 8.163 Claims defining a level of efficacy of treatment were also discussed in *Hospira v Genentech* [2015] EWHC 1796. The patent claimed the use of an antibody in combination with a taxoid to treat breast cancer wherein the clinical benefit was measured by time to disease progression, which is one of several parameters used generally to determine the efficiency of anti-cancer treatments. It should be noted though for this case, the claimed level of efficacy of treatment was not critical for the establishment of novelty as it could not be established from the prior art documents that this combination of drugs had been used to treat cancer. Thus, the patent was in fact, revoked on grounds of inventive step. However, in general, if a claim defines a level of efficacy and the prior art documents disclose the actual treatment with the same agent for the same purpose applied in the same manner, it would be reasonable to assume that the efficacy achieved in the prior art documents would be similar if not the same as that of the application in question.

Co-administration

- 8.164 It is common to combine two or more known substances or compounds for use as a medicament. Such compositions comprising two or more agents for the treatment of a disease may claim novelty in the form of a second medical use claim on condition that the stated combination has not previously been used for the specified disease or condition. In *Actavis UK Ltd v Janssen Pharmaceutica NV* [2008] EWHC 1422, the use of one stereoisomer of blood pressure drug, nebivolol, to potentiate the blood-pressure reducing effects of other agents, including one of its other stereoisomers, was anticipated by the use of a racemic mixture for the treatment of hypertension.
- 8.165 The inventiveness of claims of this type will require determining whether the claim relates to a single or a plurality of inventions. If the two (or more) components simply perform their usual function in the body and there is no synergy between them, then the claim would be considered as relating to two separate inventions and there is no inventiveness in combining them. This practice finds support in the judgement by the House of Lords in *SABAF v MFI Furniture Centres* [2005] RPC 10 whereby the judge held that the design was obvious, involving essentially only the collocation of two known features. Evidence of this synergistic effect must be provided at the time of filing; any evidence provided post-filing cannot be used to demonstrate inventiveness in this situation. As stated in *Glaxo Group's Patent* [2004] RPC 43:

“If a synergistic effect is to be relied on, it must be possessed by everything covered by the claim, and it must be described in the specification. No effect is described in the present specification that is not the natural prediction from the properties of the two components of the combination.”

- 8.166 Moreover, evidence of unexpected synergy between the claimed components does not render a combination inventive if this combination was obvious to the skilled person. In particular, if it is known to combine two categories of active agent, it is unlikely that the substitution of a newer, more effective agent of one or other category in the combined preparation be considered as inventive. The patents in both *Glaxo Group's Patent* [2004] RPC 43 and *Richardson-Vicks' Patent* [1995] RPC 568 were revoked on these grounds.

- 8.167 If the synergy of the combined components is no greater than the equivalent prior art combination, then this synergy does not equate to evidence of inventiveness in this combination. In T 492/99 NIPRO, it was determined that there was no advantage of the combined anti-inflammatory agent claimed in the main request over the state of the art and therefore it was held that the claim in question did not involve an inventive step.
- 8.168 However, in *Schering-Plough Ltd v Norbrook Laboratories Ltd* [2005] EWHC 2532, even though the combination was *prima facie* obvious, inventiveness was acknowledged because technical prejudice pointed away from the combination in question. The inventive concept was the use of a long-acting anti-microbial with an anti-inflammatory in a combination therapy. Combination products are single products designed to administer two therapeutic agents in the same dose whilst in concurrent therapy, the two drugs are administered separately but at the same time. The common general knowledge consisted of (i) a combination treatment of a short-acting anti-microbial with an anti-inflammatory, and (ii) a concurrent therapy of long-acting anti-microbial and an anti-inflammatory. In view of this, the idea of combining the two products was *prima facie* obvious. However, the underlying issue was whether this combination therapy retained the long-acting effect of the anti-microbial after administration which forms the basis of the technical prejudice. On the basis of expert evidence, the High Court was satisfied that the data in the patent showed that the long-acting antimicrobial effect of Norbrook's long-acting oxytetracycline product was retained when formulated together with flunixin in a single product and that this was an unexpected benefit.

Use in treatments performed outside the body

8.169 Therapeutic treatments such as dialysis where blood or tissue is treated outside of the body and thereafter returned to the patient are considered to be methods of treatment by therapy and therefore unpatentable. It therefore follows that an invention relating to the use of a known substance or composition for such an *ex vivo* treatment could be protected under a second medical use claim. For example, in T 2003/08 EDWARDS LIFESCIENCES, a “Swiss-type” claim directed the use of an agent for treating a pathological condition by removal of immunoglobulins from plasma *ex vivo* before reinfusion was allowed.

Support for second medical use claims

8.170 Second medical use claims have to be supported by adequate evidence in the specification as filed that it is (or at least likely to be) effective for the specified use. The second medical use claims in *Hoerrmann's Application* [1996] RPC 341 and *McManus's Application* [1994] FSR 558 were rejected for this reason. As stated by the Hearing Officer in *Hoerrmann's Application* [1996] RPC 341:

"... unless there is some indication in the description of applications of this type of tests, however rudimentary, demonstrating that the invention has been carried out in an effective manner then the application must fail for lack of support for the invention claimed."

8.171 The mere assertion that tests had been carried out is insufficient. In *Consultant Suppliers Ltd's Application* [1996] RPC 348, a mere statement in the specification that the claimed invention has been tested in the absence of any details of this test was deemed to lack support. Similarly, in *Prendergast's Applications* [2000] RPC 446, it was stated that full, detailed, rigorous and conclusive testing of a drug for its ability to treat a condition is not necessary but there must be at least some evidence that it would in fact work. 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. As stated by the Patents Court:

"... where you have a claim for the use of a known active ingredient in the preparation of a medicament for the treatment of a particular condition, the specification must provide, by way of description, enough material to enable the relevantly skilled man to say this medicament does treat the condition alleged ... pure assertion is insufficient."

8.172 Similar to a first medical use claim, support for a second medical use claim must be found in the specification as filed. As such, an objection to a lack of support cannot be overcome by later-filed evidence. As stated in T 0609/02 SALK INSTITUTE FOR BIOLOGICAL STUDIES:

“Sufficiency of disclosure must be satisfied at the effective date of the patent, ie on the basis of the information in the patent application together with the common general knowledge then available to the skilled person. Acknowledging sufficiency of disclosure on the basis of relevant technical information produced only after this date would lead to granting a patent for a technical teaching which was achieved, and, thus, for an invention which was made, at a date later than the effective date of the patent.”

It was further added by the Technical Board of Appeal in T 0609/02:

“Once this evidence is available from the patent application, then post-published (so-called) expert evidence (if any) may be taken into account, but only to back-up the findings in the patent application in relation to the use of the ingredient as a pharmaceutical, and not to establish sufficiency of disclosure on their own.”

8.173 In *Commonwealth Scientific & Industrial Research Organization’s Application* BL O/248/04, the application was not considered to have provided support for the treatment of both the diseases, blowfly strike and balanitis in sheep and related animals, as claimed. The tests included in the application relates solely to blowfly strike with no data provided to demonstrate that balanitis may be treated by a similar method. Thus, the “Swiss-type” claims relating to balanitis were deemed unsupported by the description as filed.

8.174 However, if the evidence in the application shows an effect on a common underlying mechanism behind a broader class of diseases, then a correspondingly broad claim may be considered to be supported. In *American Home Products v Novartis* [2001] RPC 8, Aldous LJ states:

“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 either 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.”

8.175 Further guidance may be found in *Agency for Science, Technology and Research’s Application* BL O/221/13 and *G W Pharma’s Application* BL O/237/12. Although not drafted as a “Swiss-type” form of second medical use claim, the decision in *Agency for Science, Technology and Research’s Application* in terms of support for second medical claim is still relevant. In *Agency for Science, Technology and Research’s Application*, it was held that experimental data performed solely on breast cancer cells made it plausible that the claimed agents could treat any cancer characterised by the over-expression of a particular protein called VHZ. On consideration of information presented, the Hearing Officer concluded that it was credible that at the priority date the skilled addressee could have expected from reading the application that anti-VHZ agents could be used to treat not only breast cancer but the other claimed cancers.

8.176 On the other hand, in *G W Pharma’s Application* BL O/237/12, there was no teaching in the application that the provided *in vitro* evidence was related to the mechanism underlying prostate cancer, which was the claimed use. Moreover, in view of the state of the art, there was no teaching that suggested any correlation existed between the provided *in vitro* evidence and prostate cancer. Accordingly, the claims were concluded to lack support.

Kit of parts/Set of instructions

8.177 Combined preparations of individual components may be protected as a kit of parts, provided that the components form a functional combination through a purpose directed application. Such claims may be defined in terms of simultaneous or sequential administration or at particular time intervals. Claims in this form was discussed in T 09/81 ASTA/*Cytostatic combination* OJEPO 1983, 372, where the invention related to a combined preparation containing an oxazaphosphorin cytostatic agent and the sodium salt of 2-mercapto-ethane-sulphonic acid as therapeutic active ingredients. The co-administration of sodium 2-mercapto-ethane-sulphonate ceased the severe side effects caused by cytostatic agents. Individually, these two components were known medicaments, however these two components had never been used together to provide a joint effect and were also unknown as a single composition. The claim in question read:

“Products containing an oxazaphosphorin cytostatic agent and the sodium salt of 2-mercapto-ethane-sulphonic acid as a combined preparation for simultaneous, separate or sequential use in cytostatic therapy.”

8.178 As indicated in the claim, the components were not necessarily present as a single composition, and as such the components may be used separately or sequentially. It was held by the EPO Board of Appeal that the combined preparation of an oxazaphosphorin cytostatic agent and the sodium salt of 2-mercapto-ethane-sulphonic acid was novel and inventive but needed to be drafted specifying its purpose in the form of a medical use claim in order to distinguish it from a medical kit, collection or package containing the two agents together for their known independent uses. Hence, such claims are allowable provided that the pack is stated to be for the method in which the invention resides and that the pack is novel and not obvious for any other application.

8.179 A claim to a pack containing a known substance with instructions describing the new use would normally be construed as directed to a pack containing the known substance since instructions are not considered to make a technical contribution to the claim.

8.180 However, in the case where the actual contribution resides beyond mere instructions, the claim may be patentable. For this, the claim must define the functional relationship between integers in the kit that necessarily provides the invention. In *Organon Laboratories' Application* [1970] RPC 574; [1970] FSR 419, a claim in relation to a pack containing two types of contraceptive pills arranged in a distinct order with instructions for its use was granted under the old UK law (1949 Act). Although packs containing contraceptive pills in a given order were known, the claim was allowed on the basis that the particular order of arranging the pills in this case was novel and not obvious from the prior art as it was based on a new and inventive method of contraception.

iii. Devices

8.181 Claims to a medical device are allowed on the condition that it is novel and inventive. However, it is not possible to claim the first or second medical use of devices. Contrary to substances or compositions in Section 16(3) and Section 14(7) of the *Patents Act*, which can derive novelty from a novel use in a therapeutic method, there is no equivalent provision in the *Patents Act* for medical devices. As such, when the device *per se* is known, the use of the device in relation to a new medical indication would not render the claim novel. “Swiss-type” claims relating to a new use of known surgical apparatus were disallowed in T 775/97 EXPANDABLE GRAFTS/*Surgical device* [2002] EPOR 24, T 227/91 CODMAN/*Second surgical use* OJEPO 1994, 491, and in *National Research & Development Corporation’s Application* BL O/117/85.

8.182 In T 2003/08 EDWARDS LIFESCIENCES, a “Swiss-type” claim relating to the use of a substance in the manufacture of a column for removing immunoglobulin from the blood *ex vivo* before re-infusing the blood back to the patient was allowed. The claim in question reads:

“Use of a specific ligand for human immunoglobulin in the manufacture of a column having said ligand coupled thereto for the treatment of a patient suffering from dilated cardiomyopathy, said treatment comprising passing plasma of the patient over the column under conditions which effect the binding of said specific ligand to immunoglobulin in the patient’s plasma, thereby removing a significant portion of the immunoglobulin from the patient’s plasma, and reinfusing the plasma to the patient.”

In this decision, several factors were recognised: namely the blood was in a closed circuit connected with the body and thus was considered as a part of the body; the column and ligand were brought into contact with a part of the body, namely blood, and hence was regarded as administered to the patient’s body; the ligand was consumed during use and hence was regarded as a chemical entity; and lastly, the column was not instrumental in achieving the therapeutic effect and thus was regarded as merely a carrier for the ligand. Hence, it was held that the means for achieving the treatment lies in that of the ligand and not the column that holds it. Since the ligand

was undeniably a chemical entity, it was also considered a substance or composition. As such, the invention herein lies not in the device (column) *per se* but in the compound (ligand) and thus, the “Swiss-type” claim was allowed.

E. Morality

8.183 Section 13(2) states that inventions which would encourage offensive, immoral or anti-social behaviour if published or exploited are not patentable.

8.184 The intention of Section 13(2) 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. However, it should be noted that the test relates to public perceptions – moral beliefs differ between individuals and care should be taken by Examiners to avoid applying their personal beliefs during examination. As a consequence, any objection under 13(2) should be referred to a Senior Examiner for discussion.

8.185 Section 13(3) states that for the purposes of Section 13(2), behaviour shall not be regarded as offensive, immoral or antisocial only because it is prohibited by any law in force in Singapore. Thus, a law may prohibit the use of an invention in Singapore, but this does not necessarily exclude it from patentability under Section 13(2). For example, the product could be manufactured in Singapore for export to a country where such prohibitions do not apply. Generally, it would be useful to consider the reason(s) behind any relevant legal prohibition in Singapore, in order to determine whether a Section 13(2) objection should be raised.

8.186 If an invention can be exploited legally albeit in accordance with stringent legal regulations, then an objection under Section 13(2) should generally not apply. For example, a pistol could be used inappropriately, but otherwise may have legitimate uses. In such cases no objection is raised under Section 13(2).

8.187 Section 27(3) states that the Registrar 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 antisocial behaviour. While the Examiner is not required to specifically look for such material in an application, where he becomes aware of such matter, he should discuss this with a Senior Examiner and inform Registry. Where this provision is used, the specification will contain a statement at the place where this has been applied that “certain matter

has been suppressed from publication under Section 27(3)". Where a specification is so riddled with offending material that publication of any text does not make sense, then the whole specification may be suppressed from publication. It should be noted that any matter that has been omitted from publication under Section 27(3) will also be closed to public inspection.

8.188 Section 33 deals with information prejudicial to defence of Singapore or safety of the public. According to Section 33(1):

Where an application for a patent is filed in the Registry (whether under this Act or any treaty or international convention to which Singapore is a party) and it appears to the Registrar that the application contains information of a description notified to him by the Minister as being information the publication of which might be prejudicial to the defence of Singapore, the Registrar shall give directions prohibiting or restricting the publication of that information or its communication to any specified person or description of persons.

Section 33(2) states that:

If it appears to the Registrar 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 3 months from the end of a period prescribed for the purposes of section 27.

8.189 Generally, a technology that is of exclusively military application (such as reactive vehicle armor) is more likely to be considered prejudicial to national security than a technology that is capable of more general application but also has military application (such as a rocket propulsion engine).

8.190 Where the specification describes a technology that is designed or has the capacity to cause death, bodily harm, an epidemic, or substantial damage to properties, or which in the Examiner's opinion may potentially be relevant under Section 33, he should discuss the application with a Senior Examiner and if necessary refer the application

to Patent Registry for further advice. An objection under Section 13(2) may also be considered in such cases.

8.191 Biological agents and toxins are regulated under the Biological Toxins and Agents (BATA) Act (Cap. 24A) in Singapore. Biological agents are classified under the First to Fourth Schedules and toxins are listed in the Fifth Schedule. The Schedules can be downloaded from the Ministry of Health website at: https://www.moh.gov.sg/content/moh_web/biosafety.html, and is updated from time to time. Generally, biological agents contained in the First and Second Schedules, as well as the toxins listed in the Fifth Schedule are perceived to have greater potential for bioterrorism and/or to cause diseases; and transportation of any agents or toxins listed in these Schedules within Singapore by mail or public transportation is prohibited. Therefore, Examiners should exercise care when examining applications relating to these biological agents and toxins, as well as technologies concerning their transportation. If in doubt, the Examiner should refer to a Senior Examiner for discussion.

i. Methods of human cloning, generation of human embryos and human stem cell lines

8.192 The prohibition of human reproductive cloning was codified into law as the Human Cloning and Other Prohibited Practices Act (HCOPPA) in Singapore as it is almost unanimous from the international community, local scientific and religious groups as well as our general public that reproductive cloning of human beings is abhorrent and should not be allowed under any circumstances. Therefore objections under Section 13(2) should be made over such inventions.

8.193 The Bioethics Advisory Committee (BAC) issued a report in 2001 stating that (at paragraph 39, page 31):

“There is consensus from all sectors in opposing reproductive cloning. The BAC is of the view that the implantation of a human embryo created by any cloning technology in a womb, known as reproductive cloning, or any other treatment of a human embryo intended to result in its development into a viable infant, should be prohibited. There are strong public policy reasons for this position. These include: (a) the view that human reproductive cloning goes against moral ideas that holds that a human being is not to be treated as a means to an end, but only as an end. This translates into the fear that a whole human being may be brought into existence for a utilitarian purpose; (b) that the social and legal implications of reproductive cloning are very serious, including issues of identity and responsibility; and (c) the fear that it will result in a reduction in biodiversity.”

8.194 Following the BAC report, the HCOPPA was enacted and it came into force in Singapore on 1st October 2004. In the Second Reading of the Bill as it then was, the Senior Minister of State & Health (Dr Balaji Sadasivan) said that:

“There will be no unanimous view on this subject and my Ministry recognises and respects the diversity of views. But in the area of human reproductive cloning, there is almost unanimous agreement from the international community, local scientific and religious groups as well as our general public that reproductive cloning of human beings is abhorrent and should not be allowed under any circumstances.”

8.195 When dealing with applications involving human embryos and cloning, Examiners should consider raising a Section 13(2) objection when the invention encompasses performance of an act that is one of the “Prohibited Practices” in Part III of the HCOPPA.

8.196 Acts that are prohibited by the HCOPPA include:

- (i) placing a human embryo clone in the body of a human or the body of an animal even if the human embryo clone did not survive or could not have survived;
- (ii) development of any human embryo that is created by a process other than fertilisation of a human egg by human sperm, for a period of more than 14 days (excluding any period when the development of the embryo is suspended);
- (iii) development of any human embryo outside the body of a woman for a period of more than 14 days (excluding any period when the development of the embryo is suspended);
- (iv) removal of any human embryo from the body of a woman for the purpose of collecting a viable human embryo;
- (v) placing any human embryo in a non-human animal;
- (vi) placing any human embryo in the body of a human other than in a woman’s reproductive tract;
- (vii) placing any animal embryo in the body of a human for any period of gestation;
- (viii) placing any prohibited embryo in the body of a woman;
- (ix) the import into Singapore or export out of Singapore of any prohibited embryos; and
- (x) commercial trading in human eggs, human sperm and human embryos.

A prohibited embryo as defined in Section 2(1) of the HCOPPA, includes among others, any human embryo that has been developing outside the body of a woman for a period of more than 14 days (excluding any period when the development of the embryo is suspended) and any human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo.

8.197 Generally, methods of generating human embryonic stem cell lines from human blastocysts will not be objected under Section 13(2) since human blastocysts are less than 14 days old post fertilization. Methods of producing human stem cell lines from adult tissues are normally also allowed. The patenting of parthenote-derived human embryonic stem cell lines was recently considered by the Australian Patent Office (*International Stem Cell Corporation* [2016] APO52) and the European Court of Justice (*International Stem Cell Corporation v Comptroller General of Patents, Designs and Trademarks* [2014], C-364/13), and the decision was a blastocyst formed via parthenogenic activation of an unfertilized human oocyte cannot develop into a human being, and therefore are also allowable. Accordingly, such inventions will likely not attract a Section 13(2) objection in Singapore. However, Examiners should still consider the facts of the case when examining such inventions.

8.198 The Human Biomedical Research Act (HBRA) 2015 prohibits certain kinds of human biomedical research activities as a result of ethics concerns. Examiners should consider raising a Section 13(2) objection when the invention fall within “Prohibited human biomedical research” in Section 30 and the Third Schedule of the HBRA.

8.199 The Third Schedule of the HBRA prohibits:

- (i) human biomedical research involving the development of particular types of human-animal combination embryos beyond 14 days or the appearance of the primitive streak, whichever is earlier (these particular types are cytoplasmic hybrid embryos; human-animal combination embryos created by the incorporation of human stem cells including induced pluripotent stem cells; and human animal combination embryos created *in vitro* by using human gametes and animal gametes; or one human pronucleus and one animal pronucleus);
- (ii) human biomedical research involving the implantation of any human-animal combination embryo into the uterus of an animal or a human;
- (iii) human biomedical research involving the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brains of living great apes (whether prenatal or postnatal); and
- (iv) human biomedical research involving the breeding of animals which have

had any kind of pluripotent stem cells (including induced pluripotent stem cells) introduced into them.

There are strong ethics reasons for prohibiting such research and therefore, when Examiners encounter applications involving any of the above prohibited research, he should discuss the application with a Senior Examiner and generally consider raising a Section 13(2) objection.

8.200 In addition, any claim which encompasses a human would be objected to under Section 13(2). This is consistent with the patent practice in other major jurisdictions.

ii. Genetically modified organisms

8.201 Inventions relating to transgenic plants and transgenic non-human animals generally do not raise ethics alarms in Singapore. As acknowledged in paragraph 14 of the Bioethics Advisory Committee's (BAC) Consultation Paper on Human-Animal Combinations for Biomedical Research:

"... transgenic animals are already widely used in research. Besides enabling scientists to understand the causes of diseases, and to develop more effective treatment for these diseases, they have also been used to test the safety of new products and vaccines and to study the possibility of producing organs for transplantation that will not be rejected. As transgenic animals are not thought to raise any new ethical difficulties, they are not considered further in this Consultation Paper."

8.202 This appears to be the case even if the genome of such transgenic non-human animals contains human genes. The Bioethics Advisory Committee's Ethics Guidelines for Human Biomedical Research (June 2015) stated that:

"Transgenic animals are animals in which the genome has been modified to include human genes. They have been widely used in laboratory research into the understanding and treatment of diseases for many years. In its Human-Animal Combinations Report and in preparing these Guidelines, the BAC has not explicitly considered transgenic animals but insofar as these Guidelines are relevant they should apply. However, to the extent that research involves the use of transgenic mice or other small mammals in laboratory conditions, and subject to observance of provisions for laboratory animal welfare, the BAC does not foresee any ethical difficulty in the continued use of such animals."

8.203 Therefore, in the absence of laws prohibiting the creation of such transgenic non-human animals coupled with the scientific and medical benefits arising from such research involving the use of these transgenic non-human animals, mere offence to a section of the public, in the sense that that section of the public considers such

inventions distasteful, is not enough for Section 13(2) to apply. Section 13(2) will apply only if the general public would regard the grant of patent rights for such inventions as abhorrent.

- 8.204 In contrast to the ethics position on the germline genetic modification of non-human animals, the position is less clear with regards to germline genetic modification of humans. There have been recent international deliberations on germline editing of genes in humans for the treatment of serious genetic diseases. In the Ethics Guidelines for Human Biomedical Research (June 2015), it was acknowledged that such germline genetic interventions are still at the experimental stage and there is insufficient knowledge to assess the potential long term consequences of such interventions. Accordingly, when the invention encompasses germline genetic modification of humans, the case should be discussed with a Senior Examiner.
- 8.205 Inventions relating to genetic manipulations that can cause public safety concerns or serious environmental hazards should also be discussed with a Senior Examiner. If it is determined that publication of the invention may be prejudicial to public safety under Section 33(2) of the Patents Act, the Examiner should inform and consult Patents Registry for further advice. An objection under Section 13(2) may also be warranted in such situations.

9. SUPPLEMENTARY EXAMINATION

A. Overview of supplementary examination

9.1 This chapter of the Guidelines refers to the Singapore Patents Act and Rules with effect from 14th Feb 2014. Note: for the purpose of conciseness, the expression “corresponding or related application” is used hereinafter to refer to:

- (a) the corresponding application; or
- (b) the corresponding international application; or
- (c) the related national phase application.

The term “PCT application” refers to the international phase of an international application for a patent (Singapore) that has entered the national phase in Singapore under Section 86(3).

9.2 Under Section 29(1)(d) applicants may rely on the prosecution of certain foreign or international applications for supplementary examination of a patent application in Singapore. The basic requirements that make an application suitable for supplementary examination process are:

- There are **final** results of search and examination as to the substance of a corresponding or related application, or the PCT application; and
- Each claim in the Singapore application is **related** to one or more claims in the corresponding or related application, or the PCT application, as the case may be; and
- According to the final results each claim of the Singapore application appears to satisfy the criteria of novelty, inventive step (or non-obviousness) and industrial applicability (or utility).

9.3 The determination of whether a foreign or international application can be used for initiating a supplementary examination is performed by the Registry at filing, so Examiners should not routinely check these details. However if the Examiner notices that the application may not fulfil the requirements of being corresponding or related

then they should refer the matter to the Registry.

- 9.4 Supplementary examination considers only a limited number of prescribed matters under Rule 2A(3). The presumption is that the quality of the examination carried out in the foreign offices is such that little or no additional examination is required on the application in Singapore. There is no statutory mechanism by which an Examiner may raise new citations or objections if they become aware of them.
- 9.5 If the foreign report has a negative indication against a claim for novelty, inventive step or industrial applicability, then that claim cannot be used for initiating a supplementary examination. There is no action available to the applicant to amend and/or make submissions in order to use any claim that has a negative indication for initiating a supplementary examination, regardless of how trivial an amendment is required. The applicant in such cases can only rely upon claims for which there are positive indications.
- 9.6 In contrast, it is possible to further limit the scope of a claim for which there is a positive indication by adding further provisos or additional features that are supported in the specification. The assumption here is that the positive indication applies to all matter within the scope of the claim.
- 9.7 Furthermore, the reference in the Patents Act and Rules to there being a positive indication in relation to novelty, inventive step and industrial applicability is restricted to the consideration (and as a consequence the law and practices) in the foreign offices. Thus, in theory at least, the outcome of the foreign search and examination could be inconsistent with the Singapore law and practices.
- 9.8 As there is no legislative basis on which an Examiner can raise new objections, they should strictly apply the existing legislative requirements, and in particular ensure that the final results filed in support of the supplementary examination request clearly establish that the claims are novel, inventive and industrially applicable **across the full scope of the claims**.

9.9 For example, if the final results indicate that a search and examination has not been carried out across the full scope of the claims because, for example, of clarity or support issues, then a supplementary examination can only be requested by relying on those claims that have been examined and given a positive opinion. In such cases the applicant may file an amendment to limit to those claims qualified for the supplementary examination either before requesting the examination or in response to an adverse written opinion.

B. General process

9.10 The general process for supplementary examination is as follows:

- The Registry checks that the request for supplementary examination has been made within the prescribed period.
- The Registry checks that the prescribed documents to meet the requirements of Section 29(1)(d) have been filed.
- If the request and the prescribed documents have been filed and met the prescribed requirements, the Registry will forward the application to the Examiner (Rule 42A(3)).
- The Examiner determines whether the application meets the prescribed requirements under Section 29(1)(d) and Rule 2A(3) and advises the Registrar accordingly (through establishment of either a written opinion or an examination report).
- Where a matter is raised in a written opinion, the Registrar will forward the written opinion to the applicant and invite them to address the matter within 3 months of the date of the invitation (Rule 46(4A)).
- The applicant has **one** opportunity to respond to an adverse written opinion by filing written submissions and/or amendments. These are forwarded to the Examiner for consideration and subsequent establishment of a supplementary examination report.
- If the Examiner establishes a supplementary examination report with no unresolved objections, the Registrar will issue a notice of eligibility to proceed to the grant of a patent (Section 29A(1)). The applicant will then have 2 months to meet the requirements for the grant of the patent (Section 30).
- If there are unresolved objections in the supplementary examination report the Registrar will issue a notice of intention to refuse the application (Section 29A(3)). The applicant will then have 2 months from the date of the Registrar's letter to request an examination review (Rule 46A(2)). If the applicant does not request an examination review within the prescribed period, the application is refused.

C. Requirements under Section 29(1)(d)

9.11 Section 29(1)(d) sets out the requirements that an applicant shall comply with at the time of request in order to proceed with a supplementary examination. At filing the Registry will only ensure that:

- The applicant has filed a request for supplementary examination using Patents Form 12A (Rule 42A(1)); and
- The applicant has filed the **prescribed documents** (Rule 42A(2)).

9.12 The Registry will not consider the substance of the documents and their compliance with prescribed requirements. This is left for the Examiner to determine.

9.13 Thus for example, Registry will consider whether a claim correspondence table has been filed but generally will not consider the contents of the table to determine whether the claims are indeed related. Similarly, Registry will consider whether a set of final results have been filed but generally will not determine whether the final results relied on clearly establish that all claims of the application are novel, inventive and industrially applicable. If, for example, the Examiner subsequently finds that the final results have not provided a positive indication on an independent claim but have indicated that a dependent claim is allowable, the Examiner will issue a written opinion, thereby allowing the applicant to amend claims to incorporate the allowed dependent claim into the independent claim during supplementary examination.

9.14 If the prescribed documents appear to have been filed, the Registrar will forward the application to the Examiner for supplementary examination (Section 29(6)).

i. Prescribed documents for a corresponding or related Application

9.15 The applicant must file the following prescribed documents in support of the request for a supplementary examination (Rule 42A(2)(a)):

EITHER:

- (d) A copy of the patent granted by the patent office in question, which is duly certified by that office or which is otherwise acceptable to the Registrar. If the patent is not in English then an English translation must **also** be provided; **AND**
- (e) A claim correspondence table showing how the claims of the Singapore application are related to one or more claims of the corresponding or related application, as the case may be, which has been subject to examination for novelty, inventive step and industrial applicability.

OR,

All of the following:

- (f) Other documents, to the satisfaction of the Registrar, setting out the final results of the search and examination. If the document is not in English then an English translation must **also** be provided; **AND**
- (g) A copy of the claims referred to in the final results; **AND**
- (h) A claim correspondence table showing how the claims of the Singapore application are related to one or more claims of the corresponding or related application, as the case may be, which has been subject to examination for novelty, inventive step and industrial applicability.

9.16 In this case the final results of search and examination may be on either a corresponding application or a related national phase application filed in a **prescribed office** or a corresponding international application which has a search and examination conducted by **any International Searching Authority (ISA)** or a further examination conducted by **any International Preliminary Examining Authority (IPEA)**.

ii. Prescribed documents for a PCT Application

- 9.17 Where the Singapore application is a PCT application designating Singapore that has entered the national phase in Singapore under Section 86(3), the applicant may rely upon the International Preliminary Report on Patentability (IPRP) (Rule 42A(2)(b)). The applicant must provide a copy of the IPRP. If the IPRP is not in English, a translation must **also** be provided.
- 9.18 A claim correspondence table is also required, showing how the claims of the application are related to one or more claims of the PCT application which have been subject to examination and given a positive indication for novelty, inventive step and industrial applicability.
- 9.19 If a translation of any document or part of a document is required then this should be accompanied by a verification of the translation.

iii. Certified copies

- 9.20 The applicant may provide a “certified” copy of a granted patent. This may be a copy of the granted patent which is accompanied by a signed certificate from the prescribed office confirming that it is a true copy of the granted patent.
- 9.21 Alternatively the applicant may provide a copy of the granted patent which has been downloaded from the website of the prescribed office or from another source such as ESPACENET (<http://www.espacenet.com/>). In this case the document must be certified to the Registrar’s satisfaction.
- 9.22 A declaration by the person who downloaded the submitted copy will be sufficient in this regard. Examiners may assume that the Registry has checked this requirement, but if there is a clear issue they may contact the Registry for clarification.

iv. Translations

- 9.23 If a translation of any document or part of a document is required then this should be accompanied by a declaration by the translator that:
- (i) States the document being translated; **AND**
 - (j) Verifies that the translation corresponds to the original text of the document or part; **AND**
 - (k) States the name of the translator and contains a statement that he/she is well versed in English and the relevant foreign language.
- 9.24 Examiners may assume that the translation is accurate and should not routinely check the veracity of the document.
- 9.25 However, if there are clear errors or omissions in the document (for example, missing pages or text), then the Examiner may check the document using available translation tools or in consultation with an Examiner with appropriate language skills. The Examiner should raise the issue as a note in the written opinion. In such cases the applicant may make an amendment to correct the error.
- 9.26 If the error or omission is present in the original document then there is no legislative mechanism to address the issue, unless it results in a deficiency in one of the examined areas (support, claim relatedness, morality, methods of medical treatment or diagnosis, double patenting or added matter). The Examiner may include a note in an adverse written opinion bringing the error to the attention of the applicant. It may be possible to amend the specification and claims to address such issues, but careful consideration of the amendments will be required to ensure they meet the requirements of claim relatedness and the like.

v. Prescribed offices

9.27 The definition of prescribed offices is given in Rule 41 as follows:

- Australia
- Canada (in respect of applications for a Canadian patent filed in the English language)
- Japan
- New Zealand
- Republic of Korea
- United Kingdom
- United States of America
- European Patent Office (in respect of applications for a European patent filed in the English language)

9.28 Japanese and Korean applications may be relied upon provided an English translation has been filed. However in the case of corresponding or related Canadian or European applications, these must have been filed **in English**.

9.29 For example, the final results of a European application that was filed in French or German **cannot** be used as a basis for supplementary examination. The English translations of foreign language claims that are published at the grant of European patents **do not** satisfy the requirements of Rule 41.

9.30 The language requirements will generally be checked by the Registry at filing of the request for supplementary examination. If during the examination the Examiner considers that the corresponding or related application does not meet the language requirements they would advise the Registry.

vi. Final results

9.31 As set out in section 29(1)(d)(i), supplementary examination may be based on the **final results** of a search and examination on:

- a **corresponding** application; or
- a **corresponding international** application; or
- a **related national phase** application; or
- a **PCT** application.

9.32 Section 2(1) sets out the definitions for the different foreign or international applications on which a supplementary examination may be based. These are discussed in later sections.

9.33 The applicant may rely on the final results for **corresponding or related applications in a prescribed office**. According to Rule 42A(2)(a)(i), there is no specific format for these final results, but they must clearly state the claims in question and give a positive indication in relation to novelty, inventive step and industrial applicability.

9.34 The indication must be across the full scope of the claim. If the foreign report indicates that the search and examination has been limited or truncated in any way then the applicant will need to restrict their claims to the matter for which a search and examination has been carried out and a positive indication provided.

9.35 Examples of suitable final results include:

- A notice of intent to grant stating that specific claims are allowable.
- An examination report stating that certain claims are novel, inventive and industrially applicable.
- A notice of refusal stating that certain claims are novel, inventive and industrially applicable, but that the application is refused on other grounds.

9.36 Rule 42A(4) codifies that in the case of a **corresponding international application** the IPRP in the international phase (that is IPRP Chapter I or Chapter II) is the final result. In the case of a **PCT application**, Rule 42A(2)(b) codifies that the IPRP is the

final result. If subsequent examinations have been done on the PCT application during its national phase in one or more countries, these are not taken into account in the supplementary examination – the IPRP is still considered the final result and no additional citations or objections should be raised.

- 9.37 In the case of an application relying on an IPRP Chapter I, the Examiner should verify whether the applicant has made any amendments under Article 19 of the PCT since these amendments will not be enclosed with the IPRP Chapter I report. The allowability of such amendments shall be considered in accordance with the practices set out in Section 9J of these Guidelines.
- 9.38 Similarly to the above considerations in relation to corresponding or related applications in a prescribed office, the positive indication must be across the full scope of the claims under consideration.

D. Corresponding applications

9.39 According to Section 2(1), **corresponding applications** are those which are filed or treated as filed in one of the prescribed offices and:

- The Singapore application claims priority from the corresponding application under Section 17; or
- The corresponding application claims priority from the Singapore application; or
- The corresponding application and the Singapore application (under Section 17) share at least one **priority document** in common that forms the basis for a **priority claim** in both applications.

9.40 If one of these conditions is met the final results of a search and examination in the prescribed office may be used as the basis for supplementary examination.

9.41 In its simplest form, a corresponding application refers to the following 3 scenarios (1)(a)-(1)(c) (refer to Diagrams in Section 9J of these Guidelines):

- (1)(a): The Singapore application validly claims priority under Section 17 (also under Paris Convention) from the prescribed office application being used as the basis for the supplementary examination request. **[See Diagram 1]**
- (1)(b): The prescribed office application being used as the basis for the supplementary examination request validly claims priority under Paris Convention from the Singapore application. **[See Diagram 2]**
- (1)(c): The Singapore application validly claims priority under Section 17 from an earlier application filed in a Convention country and the prescribed office application being used as the basis for the supplementary examination request also validly claims priority under Paris Convention or validly claims domestic priority from said earlier Convention country application. In other words, the Singapore application and the prescribed office application share at least one priority document in common that forms the basis for a priority claim in both applications. **[See Diagram 3]**

i. Corresponding applications: Divisional applications

- 9.42 Divisional applications filed in Singapore are not regarded to make a priority claim to the parent application. Generally, a divisional application filed in Singapore is taken to adopt the filing date of the parent application as its filing date under Section 26(11) rather than making a priority claim in the sense of Section 17 to that application. Where the parent application in Singapore has a priority claim, the divisional application would generally inherit priority claims by filing a declaration of priority(s) under Section 17(2) unless the applicant purposely gives up the priority claim or claim fewer priorities. In comparison, where the parent application in Singapore is a first application having no priority claim under Section 17(2), the Singapore divisional application is taken to “adopt” the filing date of the parent application as its filing date rather than making a priority claim to that application. Therefore, the presence of a priority claim by the parent application in Singapore to an earlier filed application impacts on whether or not the divisional application would be considered a corresponding application as defined in Section 2(1).
- 9.43 In the case of divisional applications filed with a prescribed patent office, such applications are regarded in the spirit of the Paris Convention since the definition of corresponding applications under Section 2(1) does not delimit priority claims made by applications filed with any of the prescribed patent offices. Divisional applications are considered to preserve an earlier filing date comprising the filing date of the parent application as well as the benefit of the right of priority, if any. Therefore it is accepted that a divisional application filed with any of the prescribed patent offices makes a priority claim to its parent application.
- 9.44 The following scenarios (1)(d)-(1)(l) presented in Section 9J of these Guidelines provide examples in relation to divisional applications. **[See Diagrams 4-12]**

ii. Corresponding applications: PCT national phase applications

9.45 The Singapore application and the prescribed office application referred to in the definition of **corresponding applications** under Section 2(1) also include PCT application that has entered the national phase in Singapore or the prescribed office, respectively. Based on the requirements as elaborated above, in the following scenarios (1)(m)-(1)(t) presented in Section 9J of these Guidelines, the final results in the prescribed office may be used as the basis for a supplementary examination of the Singapore application. **[See Diagrams 13-20]**

E. Related national phase applications

9.46 According to Section 2(1), a **related national phase application** meets the following criteria:

- There is a national phase application in one of the countries and jurisdictions the offices of which are the prescribed offices **and** in Singapore based on the same PCT application (including a divisional application filed in accordance with section 26(11) which derived its filing date from the PCT application); and
- The PCT application **makes no earlier priority claim** (that is the PCT application was the first application for the invention).

9.47 In this case the applicant may rely upon the final results of the prosecution of a related national phase application in a prescribed patent office. Notably the original PCT application need not necessarily be filed in a prescribed office – that is it may have been filed in any Receiving Office and the international search and/or examination may have been conducted by any ISA or IPEA. However the related national phase application derived from that PCT application and used for initiating a supplementary examination must be a national phase entry in a prescribed patent office.

9.48 In the following scenarios (2)(a) and (2)(b) presented in Section 9J of these Guidelines, the final results in the prescribed office may be used as the basis for a supplementary examination of the Singapore national phase application and any divisionals derived therefrom. **[See Diagrams 21-22]**

9.49 However, in the following scenarios (2)(c) and (2)(d) presented in Section 9J of these Guidelines, the final results of the examination of a divisional application in the prescribed office **cannot** be used as the basis for a supplementary examination of any of the applications in Singapore since said divisional application does not meet the criteria of being a related national phase application according to Section 2(1). **[See Diagrams 23-24]**

F. Corresponding international applications

9.50 According to Section 2(1), a **corresponding international application** is a PCT application that:

- (l) is an international application from which the Singapore application derived its priority under Section 17; or
- (m) is an international application which claims priority to the Singapore application; or
- (n) is an international application claiming priority from an application in a convention country that also forms the basis of a priority claim in a Singapore application.

9.51 The corresponding international application need not have entered the national phase in Singapore. For example, a supplementary examination may be requested for a Singapore application that shares a common priority document with a PCT application that has not entered the national phase in Singapore.

9.52 Rule 42A(4) codifies that in the case of a corresponding international application, the IPRP in the international phase (that is IPRP Chapter I or Chapter II) is the final result. If subsequent examinations have been done on the PCT application during its national phase in one or more countries, these are not taken into account in the supplementary examination – the IPRP is still the final result.

9.53 In its simplest form, a corresponding international application refers to the following 3 scenarios (3)(a)-(3)(c) presented in Section 9J of these Guidelines. **[See Diagrams 25-27]**

9.54 The following scenarios 3(d) and 3(e) presented in Section 9J of these Guidelines involve divisional applications. **[See Diagrams 28 and 29]**

G. PCT applications entering the national phase in Singapore

9.55 According to Section 29(1)(d)(i)(B), where the Singapore application is a PCT application for a patent (Singapore) that has entered the national phase in Singapore under section 86(3), the final results of search and examination in the international phase may be used as the basis for supplementary examination. **[See Diagram 30]**

9.56 Rule 42A(2)(b) codifies that in the case of a PCT application, the IPRP in the international phase (that is IPRP Chapter I or Chapter II) is the final result. If subsequent examinations have been done on the PCT application during its national phase in one or more countries, these are not taken into account in the supplementary examination – the IPRP is still the final result.

H. Grounds for examination

9.57 During supplementary examination **only** the following grounds are subject to examination according to Rule 2A(3):

- Support
- Relatedness of claims
- Morality
- Methods of medical treatment or diagnosis
- Double patenting
- No added matter

9.58 It should be noted that there is no provision for consideration of other grounds, including unity, clarity, patentable subject matter and sufficiency. As a consequence it may be possible for the applicant to rely upon final results which have negative indications in relation to these grounds, but a positive determination in relation to novelty, inventive step and industrial applicability. For example, there is no requirement that the claims be directed to a single invention. Thus, if the claims lack unity but additional fees have been paid for a search and examination of the second and subsequent inventions resulting in the final results, then a supplementary examination may be carried out.

9.59 As there is no statutory mechanism by which an Examiner can raise new objections in relation to other matters, e.g. clarity, there is no room for the applicant to make submissions in order to argue against such objection given in the final results and/or amend to overcome such objection.

9.60 Although there is no provision for consideration of clarity in supplementary examination, it may be deliberated whether the support requirement has been met in the meantime wherein the applicant will have **one** opportunity to respond to the objection raised, if any.

9.61 However, a clarity objection in the final results may nevertheless be referred to by the Examiner in order to determine how the claims were construed and which claims were

examined that formed the basis of the positive indication given in the final results. If the foreign report clearly indicates that the search and examination has been limited or truncated in any way due to the clarity objection, then the applicant should amend the claims to the matter for which a search and examination has been carried out and a positive indication is provided. The consideration is a **strict** one – the final results relied upon must **clearly** establish that a positive indication is given **across the full scope** of the claims.

- 9.62 For example, in cases where the foreign office Examiner examined and gave a positive indication towards the claim “Device comprising X, Y1 and Z” but not “Device comprising X, Y and Z” based on his interpretation, the applicant may amend the claim in the Singapore application from Y to Y1 either prior to requesting supplementary examination or in response to an adverse written opinion.
- 9.63 In comparison, in cases where the foreign office Examiner did not provide any reasoning for the clarity objection and/or provide any indication as to the extent to which the claims were examined, the Examiner should issue an adverse written opinion indicating it cannot be clearly established that a positive indication in relation to novelty, inventive step and industrial applicability is given across the full scope of the claims. Assuming that the applicant makes an amendment and there is no added matter as a result of the amendment, since there has been no indication of the extent of examination carried out in the foreign report, it is considered that none of the possible amendments would be justified to be entitled to the positive indication given in the foreign report. In such cases, the foreign report cannot be used as the basis for a supplementary examination request and the applicant may consider requesting for an examination under the local or mixed route instead.
- 9.64 The considerations in relation to support, morality, methods of medical treatment or diagnosis, double patenting and added matter are the same as those for applications undergoing other routes of examination and practices as set out in the relevant section should be followed. Examination of claim relatedness is specifically dealt with in the following section.

i. Claim relatedness

9.65 Examination of claim relatedness is set out in Rule 2A(3)(b) as follows:

- (b) whether, at the time the prescribed documents referred to in section 29(1)(d) are filed, each claim in the application in suit is related to at least one claim which —
 - (i) is set out in the prescribed documents relating to the corresponding application, corresponding international application or related national phase application referred to in section 29(1)(d), or to the application in suit during its international phase; and
 - (ii) has been examined to determine whether the claim appears to satisfy the criteria of novelty, inventive step (or non-obviousness) and industrial applicability (or utility);

9.66 The meaning of claim relatedness is given in Section 2(4) which states that:

“For the purposes of this Act —

- (a) a claim is related to another claim if —
 - (i) the 2 claims are identical; or
 - (ii) each limitation in the second claim —
 - (A) is identical to a limitation in the first claim; or
 - (B) differs from a limitation in the first claim only in expression but not in content; and
- (b) more than one claim may be related to a single claim.”

9.67 The consideration in examination is therefore essentially two-fold:

- Are all the claims of the Singapore application identical to the claims of the corresponding, related application or PCT application or do they differ only in expression but not in limitation or does each claim at least contain all the limitations in a claim in the corresponding, related application or PCT application?
- Have the claims of the corresponding, related application or PCT application been examined to determine whether they appear to satisfy the criteria of

novelty, inventive step and industrial applicability?

Are the claims related?

- 9.68 **The first consideration** will be relatively straightforward where the claims of the Singapore application and the corresponding, related application or PCT application are identical.
- 9.69 The requirement that each limitation in the claims differs only in expression but not in content means that the claims do not need to be identical in wording provided each limitation in the claims defines the same subject matter.
- 9.70 For example, a claim defining a method of manufacturing an article would not be related to a claim to using the article in a particular environment. However a claim to a method of using an article may be related to a claim defining the same article **when used** in the particular method.
- 9.71 Care should therefore be taken to ensure that the claims are directed to the same subject matter. This will include cases where there may be differences in how claims are construed – for example some offices consider preambles and definitions of purpose to limit the scope of claims. Where the Examiner is aware of the differences in claim construction, or where the documents in support of the request suggest a particular construction has been taken that is not consistent with the Singapore practice, then an objection would be raised that the claims are *prima facie* not related.
- 9.72 Section 2(4)(b) states that more than one claim may be related to a single claim. This suggests that a number of claims of different scope of the Singapore application may be related to a single claim of the corresponding, related application or PCT application (and *vice versa*).
- 9.73 Thus, one or more claims of the Singapore application may be related to a single claim of the corresponding, related or PCT application – the key consideration being that the Singapore claims are entirely within the scope of those claims. It follows that the claims of the Singapore application may be of a narrower scope than the claims of the corresponding, related application or PCT application. For example, the Singapore

claims may include an additional proviso or define a subset of the invention defined in those claims. The Singapore claims may be amended to be further limited by an additional feature that is supported in the specification. However the Singapore claims may not be broader in scope than those of the corresponding, related application or PCT application.

- 9.74 Any objections to claim relatedness raised should be supported with reasoning in a written opinion. The applicant may remedy the lack of claim relatedness by making amendments and/or making submissions in rebuttal. However, any amendments made must be fully supported by the original application, that is, there is no added matter.

Is there a positive indication for the claims?

- 9.75 **The second consideration** is whether the claims of the corresponding, related application or PCT application have been examined to determine whether they appear to satisfy the criteria of novelty, inventive step and industrial applicability. There is no statutory basis on which new citations or objections can be raised in relation to these requirements – the assumption is that these requirements have been determined to be satisfied in the final results provided by the applicant.
- 9.76 The consideration is therefore a strict one – the final results relied upon must clearly establish that these criteria are met **across the full scope** of the claims.
- 9.77 A positive indication must be made in the final results for the claims that are used as the basis for a supplementary examination. When requesting for a supplementary examination, the applicant **cannot** amend the claims to address the negative indication, nor can they make submissions arguing the objection. If a negative indication has been given against the related claims for novelty, inventive step or industrial applicability then there is no remedy available for the applicant to use these claims for initiating a supplementary examination.
- 9.78 Where the applicant relies on final results comprising references to P or E documents, said final results may or may not be considered to be a positive indication. In the case of P documents being cited, the Examiner should first check the foreign report for an indication of the validity of the priority claim of the corresponding or related

application. If the foreign report indicates that said priority claim appears to be invalid or that the priority claim could not be verified, references to P documents should be taken as a *prima facie* negative indication since verifying the priority claim is not among the grounds for supplementary examination. An objection would then be raised that the claims do not appear to satisfy the criteria of novelty, inventive step and industrial applicability.

- 9.79 If the foreign report affirms the validity of the priority claim, the Examiner should then proceed to check the origin of the cited P documents and their respective priority dates. In the case where a cited P document has an earlier priority date than the Singapore application **and** is itself a Singapore application or an international application designating Singapore that has entered the Singapore national phase, the cited P document in the final results should be taken as a negative indication since said reference is relevant for novelty under Section 14(3). An objection would be raised that the claims do not appear to satisfy the criteria of novelty, inventive step and industrial applicability. In the case where the cited P document is an international application designating Singapore that has **not** entered the Singapore national phase at the time of establishment of the supplementary examination report, the Examiner may proceed to issue a positive supplementary examination report. However, said examination report should include a statement that the positive indication is conditional, provided that the P document does not later enter the Singapore national phase. If it is subsequently found out that the P document has indeed entered the Singapore national phase, Section 81 may be invoked.
- 9.80 Otherwise, references to P documents may be disregarded and the final results may be taken to be a positive indication despite P documents being raised.
- 9.81 For final results comprising references to E documents, the Examiner should check if any of the cited E documents are international applications designating Singapore that have entered the Singapore national phase. A check of the priority date of the E document may also be necessary since the E document may have an earlier priority date than the corresponding or related application. If the cited E document has entered the Singapore national phase and has an earlier priority date, the cited E document in the final results should be taken as a negative indication. In the case where the cited E

document is an international application designating Singapore that has **not** entered the Singapore national phase at the time of establishment of the supplementary examination report, the Examiner should similarly issue a positive supplementary examination report comprising a conditional statement as detailed above.

- 9.82 Examiners should not review the positive indications given in the final results to ensure the corresponding, related application or PCT application used as the basis complies with the Singapore law and practice. Thus, there may be differences in law and practice between the prescribed office or ISA/IPEA in question and Singapore but there is no statutory mechanism by which new citations or objections may be raised. For example, Singapore examines inventive step according to the “Windsurfing test” while many other offices adopt different tests. There may be instances where a different outcome could be obtained using different tests, but no objection can be taken. The same will apply in industrial applicability, but here there is a basis for raising objection if the claims define a method of medical treatment or diagnosis.

ii. Medical use claims

9.83 Pharmaceutical applications require specific considerations and care should be taken where claims include first medical use or Swiss-style formats:

- First medical use claims are not related to method of medical treatment claims. As a consequence if the invention lies in the first medical use of a known compound and the claims of corresponding, related application or PCT application are method of medical treatment claims (for example an Australian or US application), then an objection will be taken that the claims are not related. The treatment steps are a limitation in a method of medical treatment claim. A first medical use claim does not include such treatment steps.
- Similarly, Swiss-style claims are not related to method of medical treatment claims. Swiss-style claims define a method of preparing a pharmaceutical which is intended for a particular treatment – in effect a purpose-limited process of preparing the pharmaceutical. This is different subject matter to a method of medical treatment.
- Swiss-style claims are not related to European-style second medical use claims. EPO allows second medical use claims in a format corresponding to a Singapore first medical use claim – that is substance X for use in treatment of Y and in effect a purpose-limited product claim. As noted above the Swiss-style claims are limited by the preparation of a medicament and in effect a purpose-limited process claim. As these two claims have different claim limitations, they are considered not related.

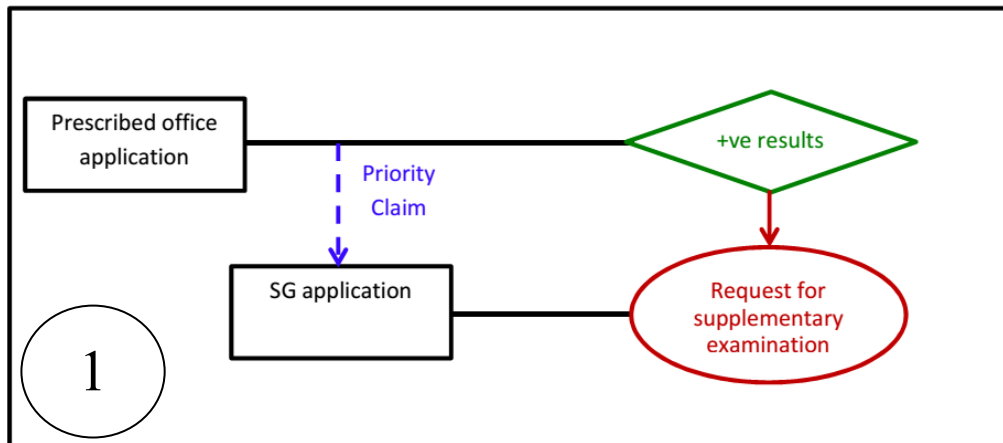
I. Responding to written opinions

- 9.84 As set out in Section 29(8), where the Examiner raises one or more matters in a written opinion, the applicant will have **only one** opportunity to respond. They may make amendments to overcome any deficiencies in the specification and/or make submissions in rebuttal.
- 9.85 The response must be filed within 3 months of the Registrar's letter forwarding the written opinion. If no response is filed within the prescribed period, the written opinion is taken to be the supplementary examination report.
- 9.86 If the Examiner considers that the submissions and/or amendments do not overcome the objections, an adverse examination report will be established. The Registrar will then issue a notice of intention to refuse the application under Section 29A(3). The options for the applicant at that stage are to request an examination review (Rule 46A(2)) or to file a divisional application.
- 9.87 An applicant may withdraw the request for supplementary examination and file a request for search and examination or examination, but the withdrawal of the request for supplementary examination must be done before the establishment of the supplementary examination report. The request for search and examination or examination must be filed within 36 months from the earliest priority date (Rule 43(1)).
- 9.88 Supplementary examination may be requested within 54 months from the earliest priority date (Rule 43(3)), and if the 36-month period in which the request for search and examination or examination may be filed has expired, the applicant may consider requesting an extension of time to request for search and examination or examination. The applicant may also file a divisional application in such cases.

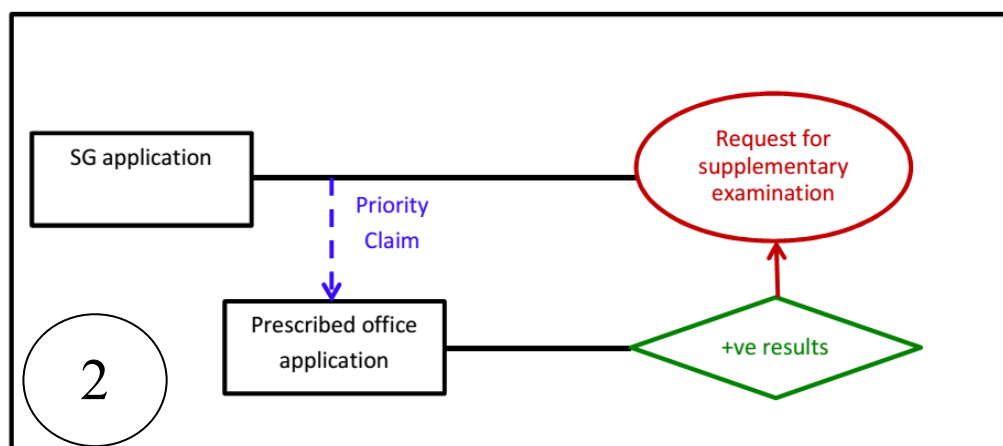
J. Annex

i. Corresponding applications

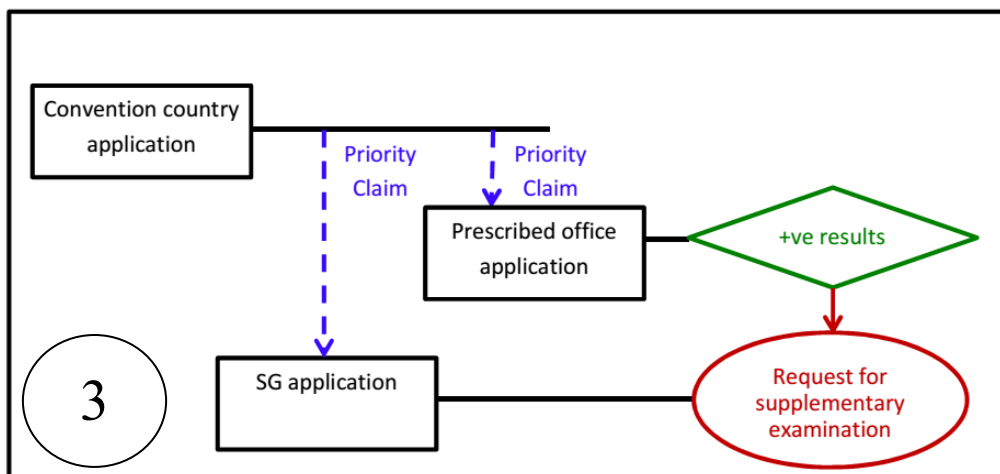
9.89 **Scenario (1)(a):** The Singapore application validly claims priority under Section 17 (also under Paris Convention) from the prescribed office application being used as the basis for the supplementary examination request.



9.90 **Scenario (1)(b):** The prescribed office application being used as the basis for the supplementary examination request validly claims priority under Paris Convention from the Singapore application.

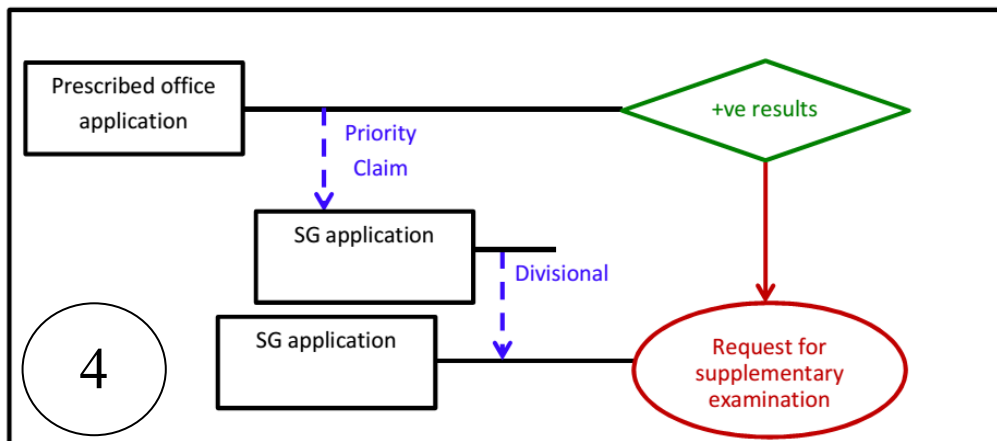


9.91 **Scenario (1)(c):** The Singapore application validly claims priority under Section 17 from an earlier application filed in a Convention country and the prescribed office application being used as the basis for the supplementary examination request also validly claims priority under Paris Convention or domestic priority from said earlier Convention country application. In other words, the Singapore application and the prescribed office application share at least one priority document in common that forms the basis for a priority claim in both applications.

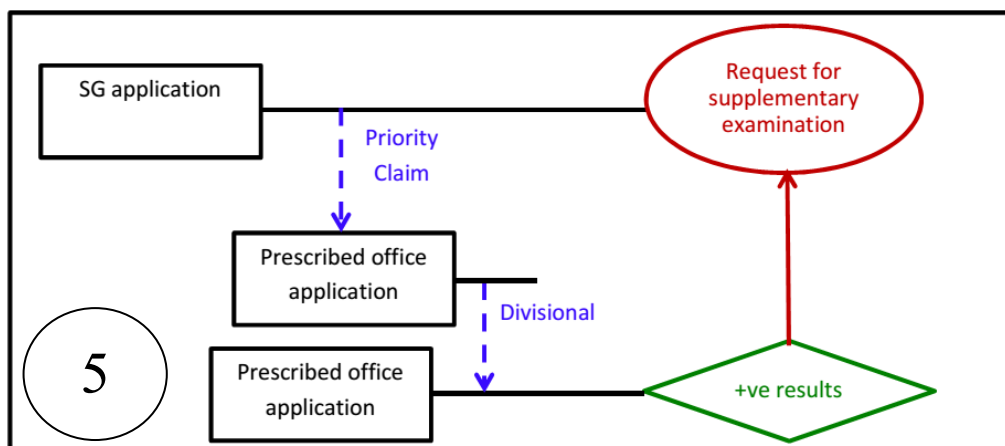


i(a). Corresponding applications: Divisional applications

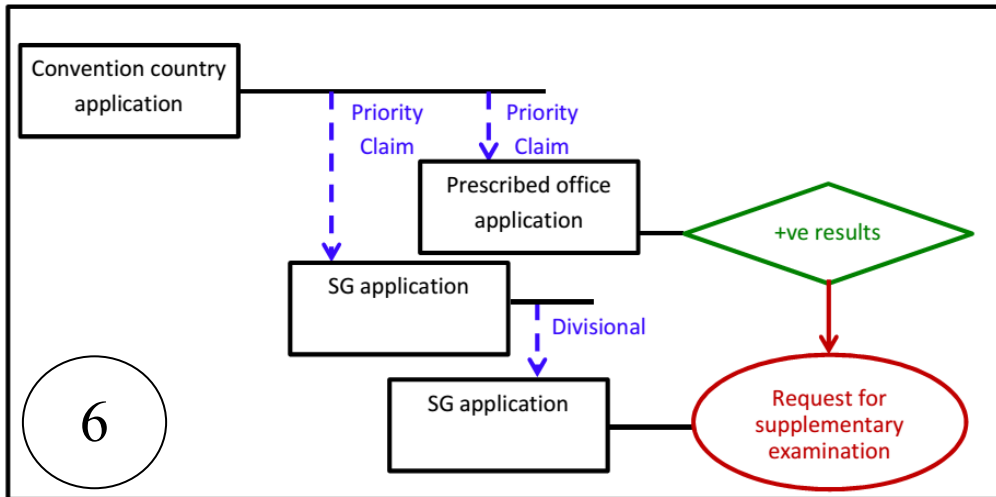
9.92 **Scenario (1)(d):** The Singapore application is a divisional application of the Singapore application referred to in (1)(a) above, and said divisional application validly claims priority under Section 17 from the prescribed office application being used as the basis for the supplementary examination request.



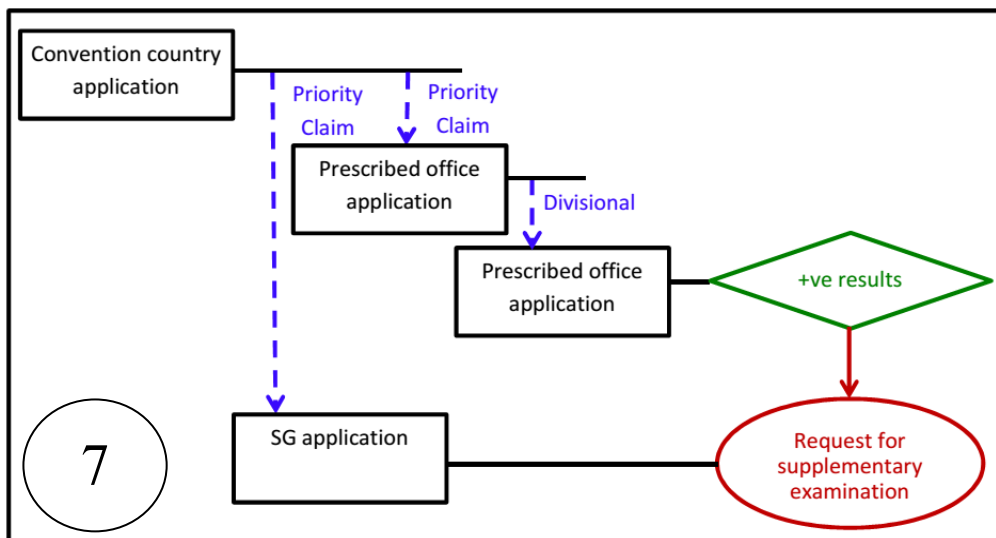
9.93 **Scenario (1)(e):** The prescribed office application being used as the basis for the supplementary examination request is a divisional application of the prescribed office application referred to in (1)(b) above, and said divisional application validly claims priority under Paris Convention from the Singapore application.



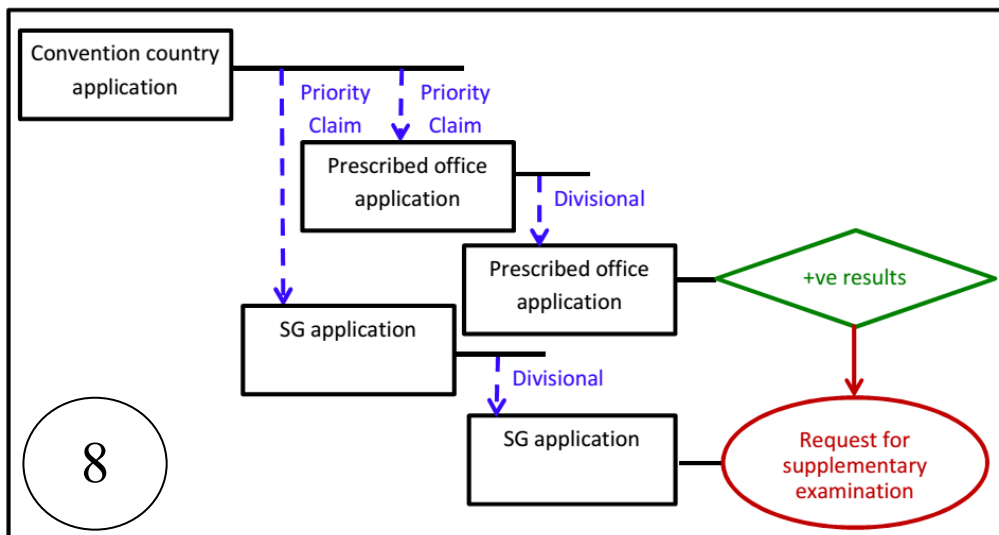
9.94 **Scenario (1)(f):** The Singapore application is a divisional application of the Singapore application referred to in (1)(c) above, and said divisional application validly claims priority under Section 17 from said earlier Convention country application, and the prescribed office application being used as the basis for the supplementary examination request also validly claims priority under Paris Convention or domestic priority from said earlier Convention country application.



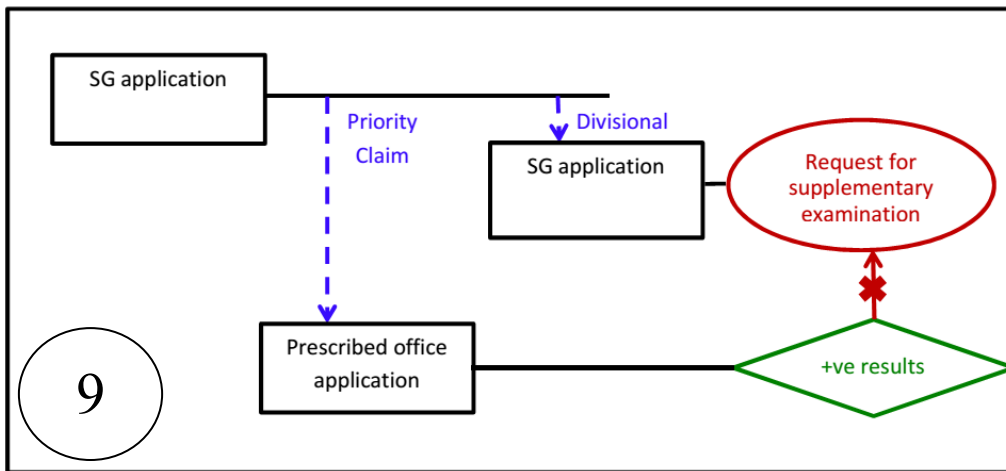
9.95 **Scenario (1)(g):** An application is filed in a Convention country. Applications are subsequently filed both in Singapore validly claiming priority under Section 17 from said earlier Convention country application and in a prescribed office validly claiming priority under Paris Convention or domestic priority from said earlier Convention country application. The prescribed office application being used as the basis for the supplementary examination request is a divisional application of the parent prescribed office application and also validly claims priority from said earlier Convention country application.



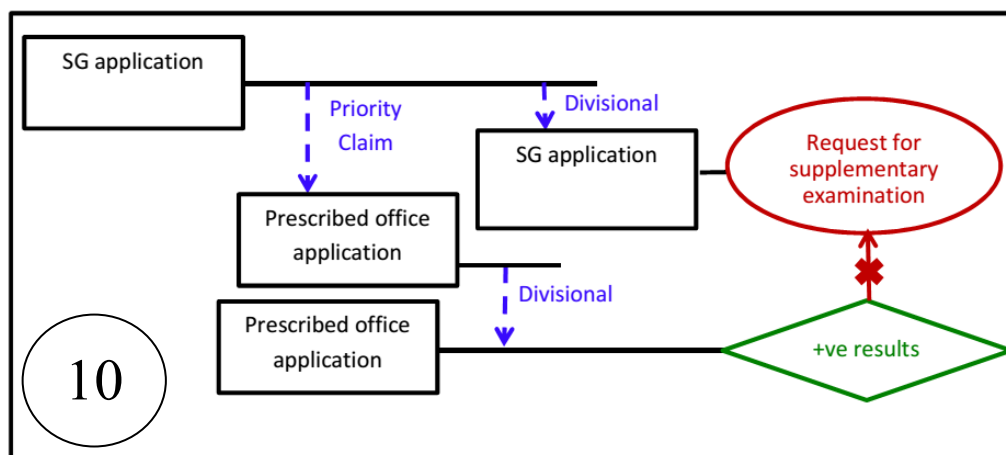
9.96 **Scenario (1)(h):** An application is filed in a Convention country. Applications are subsequently filed both in Singapore validly claiming priority under Section 17 from said earlier Convention country application and in a prescribed office validly claiming priority under Paris Convention or domestic priority from said earlier Convention country application. The Singapore application is a divisional application of the parent Singapore application and validly claims priority under Section 17 from said earlier Convention country application. The prescribed office application being used as the basis for the supplementary examination request is a divisional application of the parent prescribed office application and also validly claims priority from said earlier Convention country application under Paris Convention.



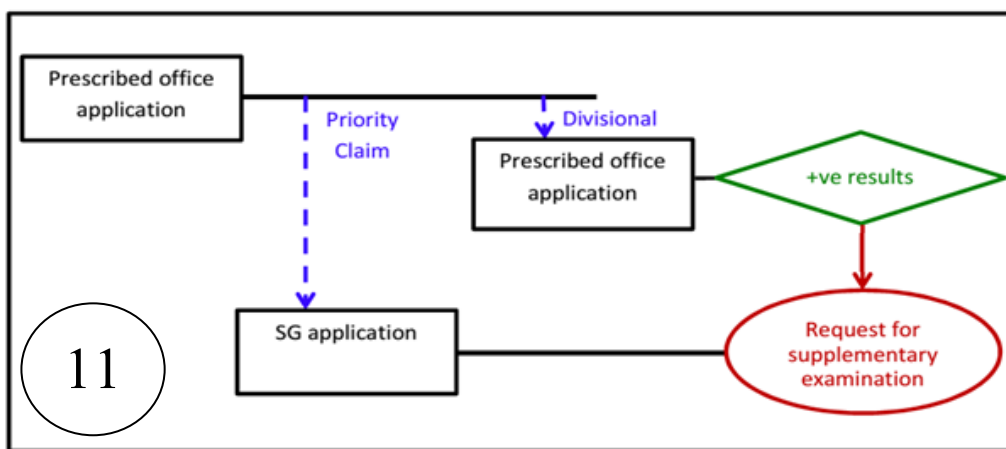
9.97 **Scenario (1)(i):** An application is filed in Singapore with no priority claim and an application is subsequently filed in a prescribed office validly claiming priority from said earlier Singapore application under Paris Convention. The Singapore application is a divisional application of said earlier Singapore application. The Singapore divisional application in this case is taken to adopt the filing date of the parent application as its filing date rather than making a priority claim to that application. The prescribed office application and the Singapore divisional application are therefore not corresponding applications.



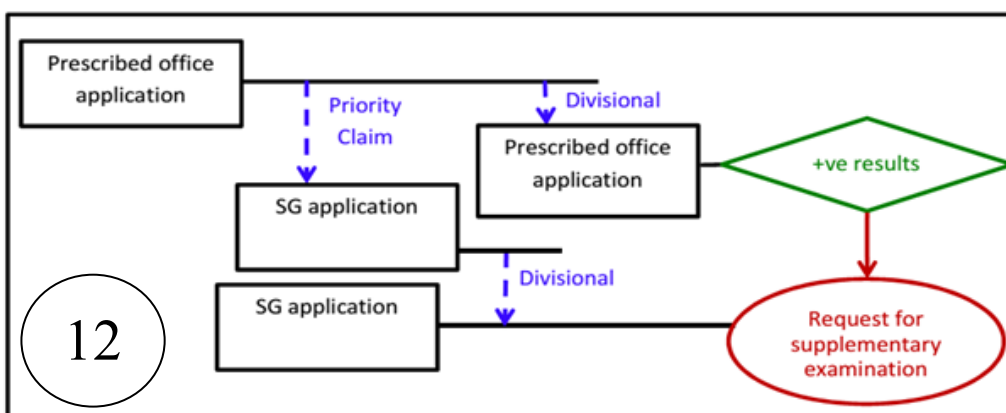
9.98 **Scenario (1)(j):** Similarly, the prescribed office application is a divisional application of the prescribed office application referred to in (1)(i) above, the final results of the prescribed office divisional application may not be used as the basis for a supplementary examination for the Singapore divisional application.



9.99 **Scenario (1)(k):** An application is filed in a prescribed office with no priority claim and an application is subsequently filed in Singapore validly claiming priority from said earlier prescribed office application under Paris Convention. The prescribed office application is a divisional application of the parent application in the prescribed office. The prescribed office divisional application preserves an earlier filing date comprising the filing date of the parent application as well as the benefit of the right of priority, if any. Said divisional application is regarded to make a priority claim to its parent application. The Singapore divisional application and the prescribed office application are thus corresponding applications.

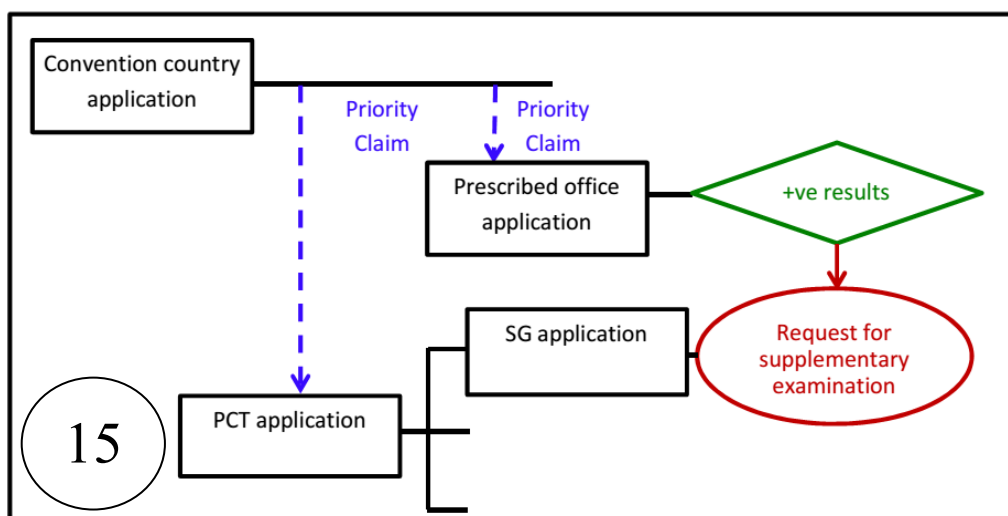
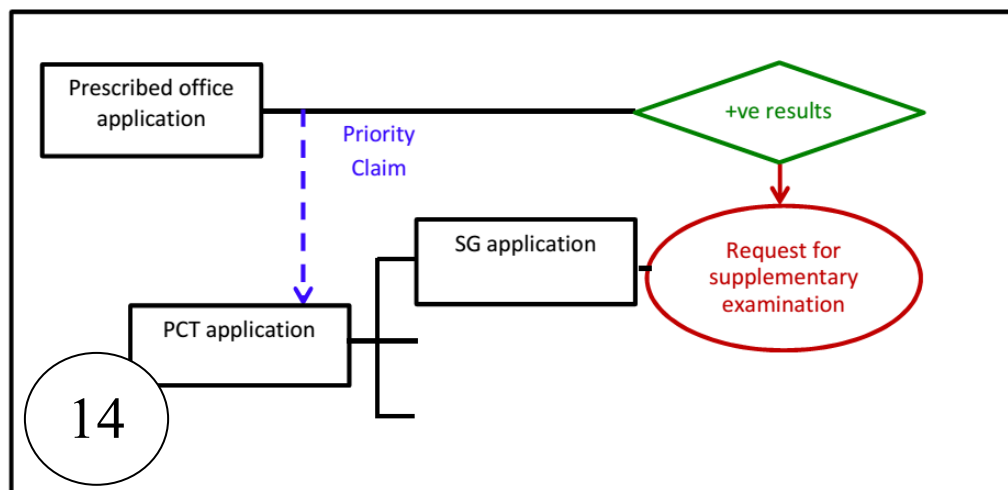
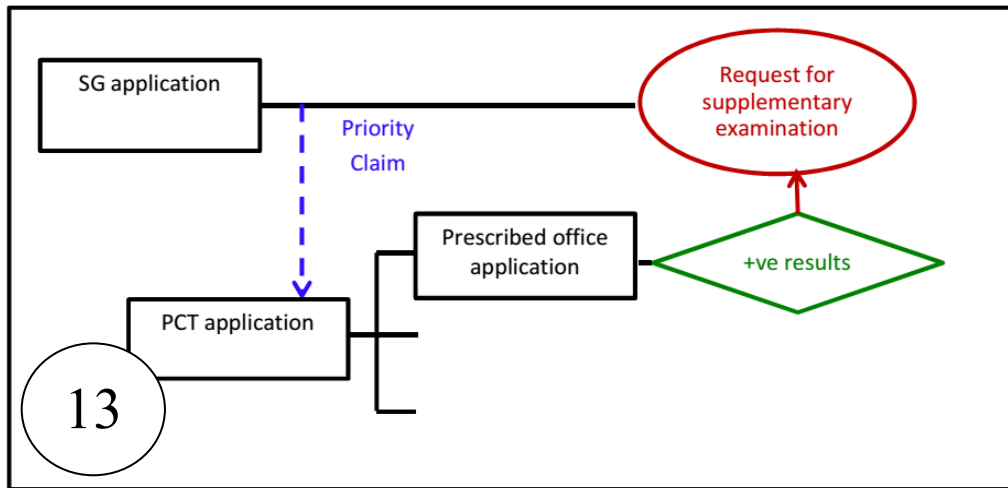


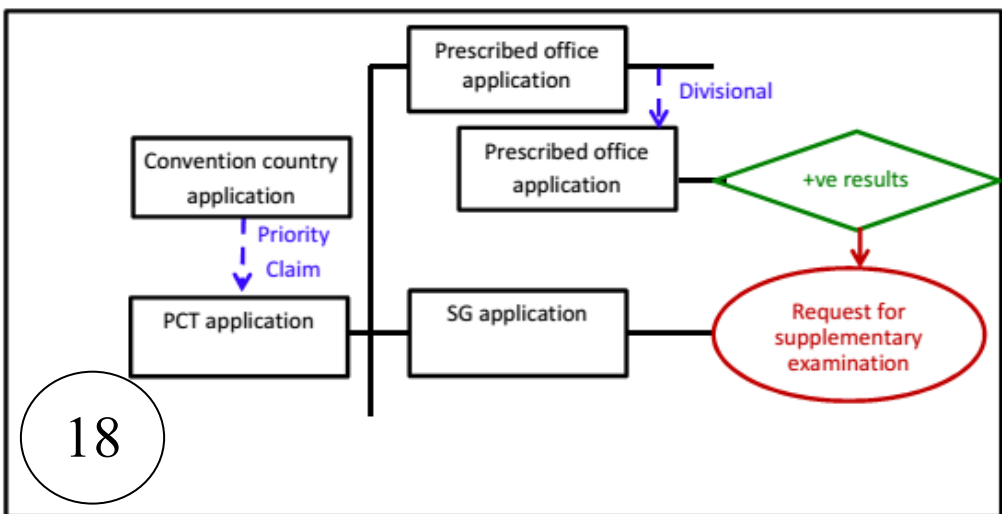
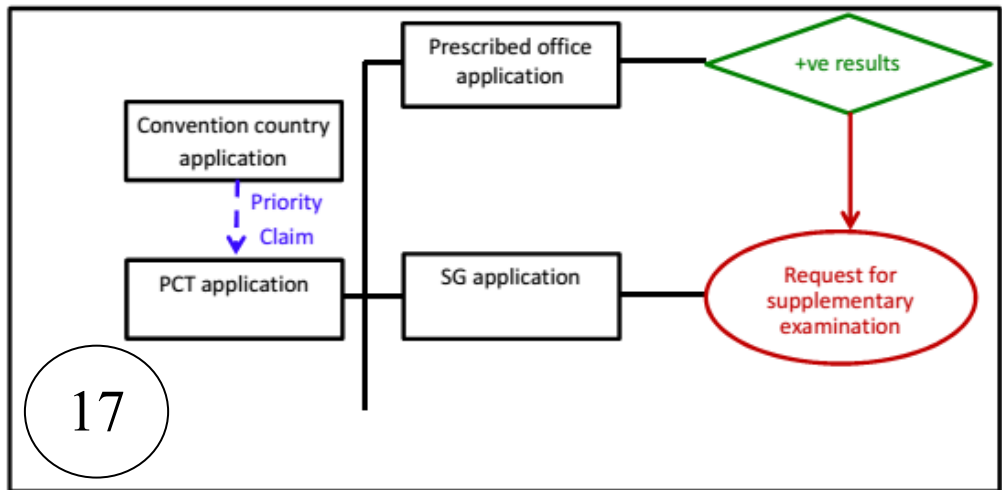
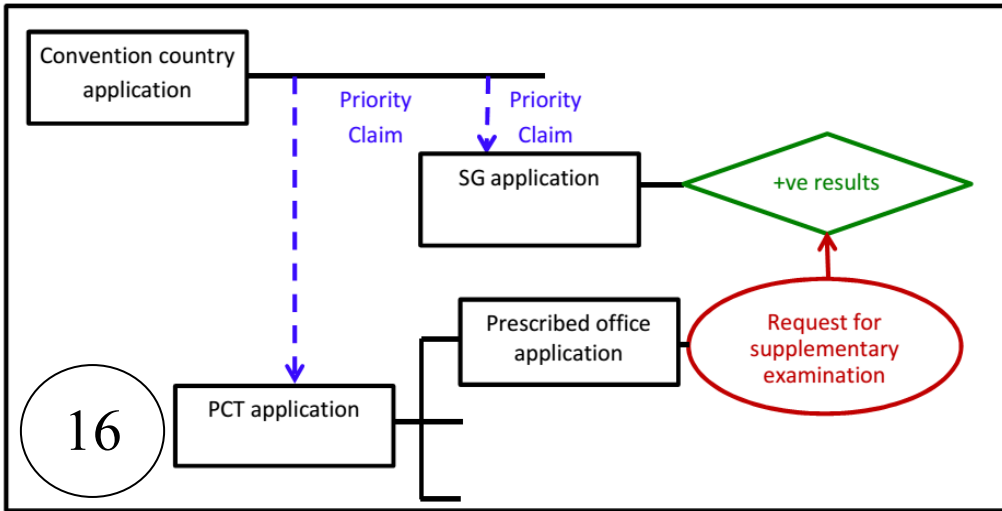
9.100 **Scenario (1)(l):** Similarly, the Singapore application is a divisional application of the Singapore application referred to in (1)(k) above, the final results of the prescribed office divisional application may be used as the basis for a supplementary examination for the Singapore divisional application.

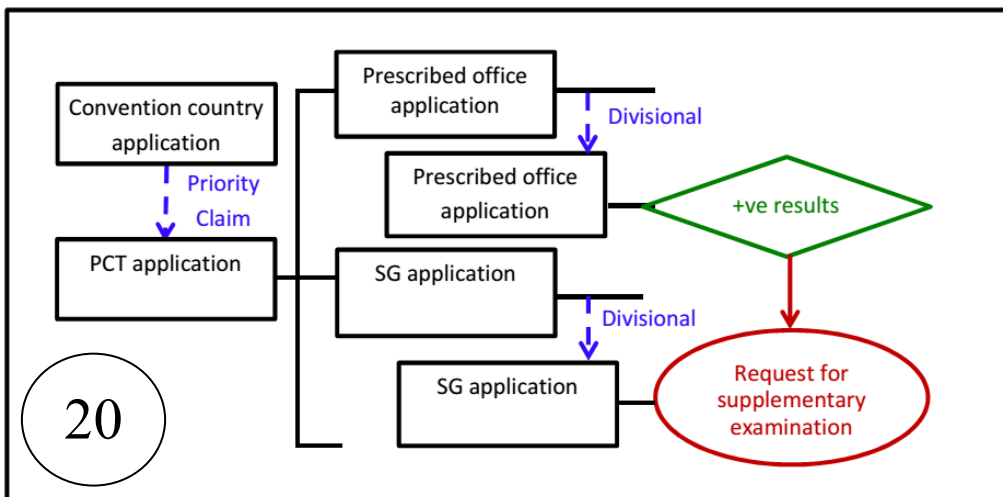
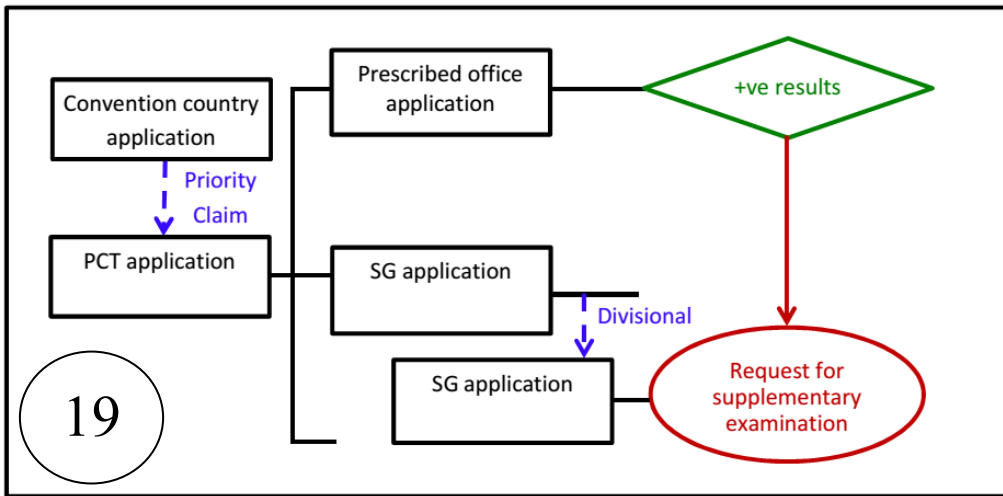


i(b). Corresponding applications: PCT national phase applications

9.101 Scenario (1)(m)-(1)(t):

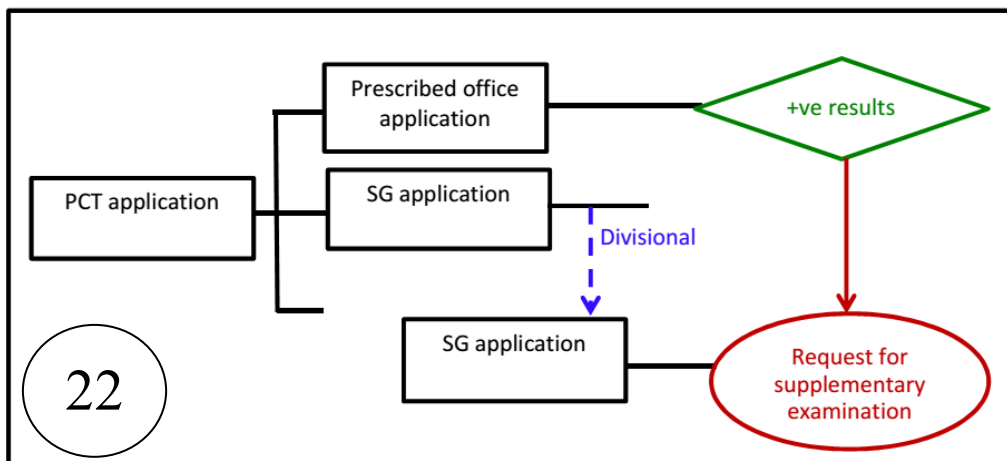
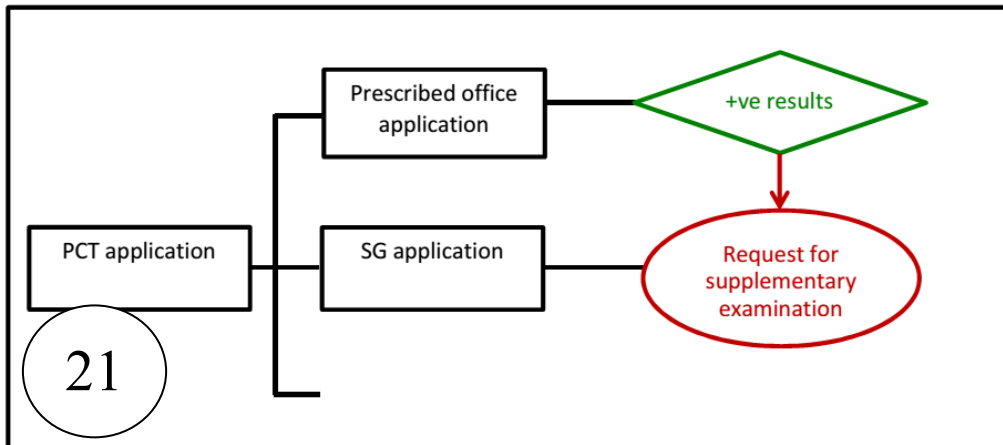




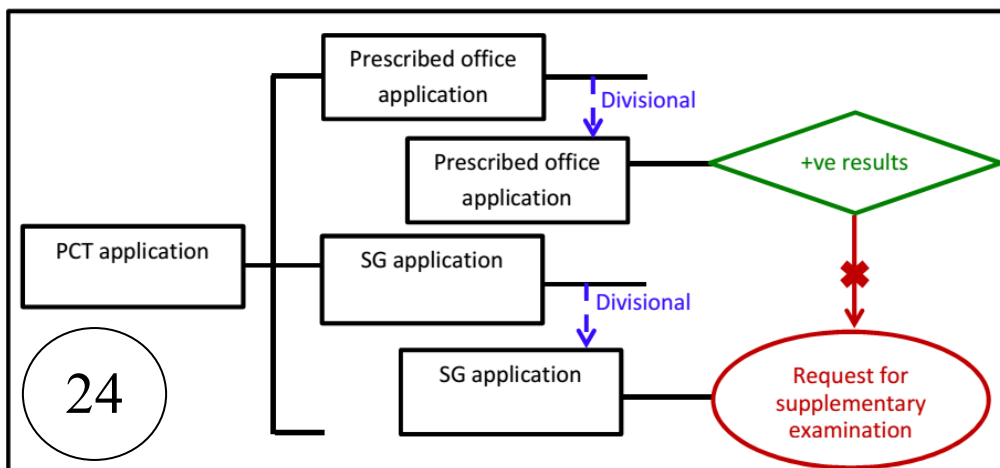
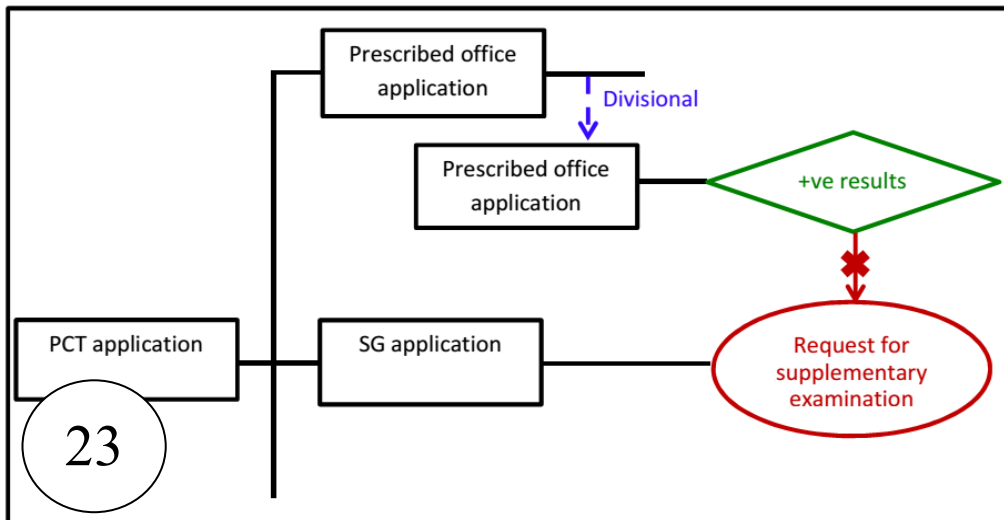


ii. Related national phase applications

9.103 **Scenario (2)(a) and (b):** The following scenarios illustrate how the final results in the prescribed office may be used as the basis for a supplementary examination of the Singapore national phase application and any divisionals derived therefrom.

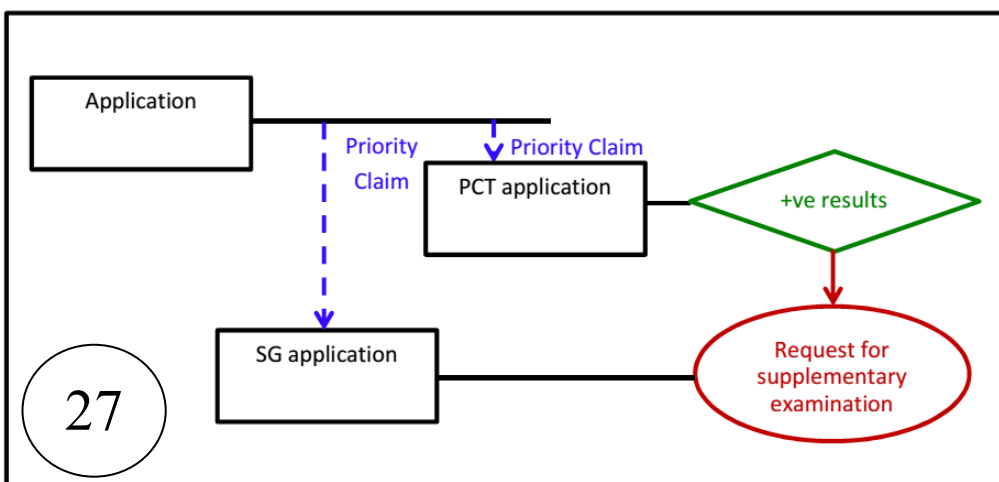
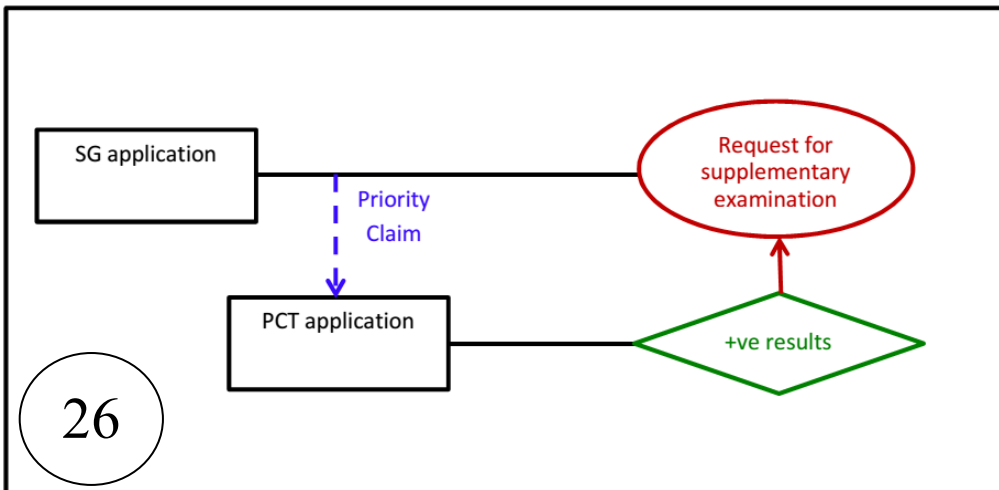
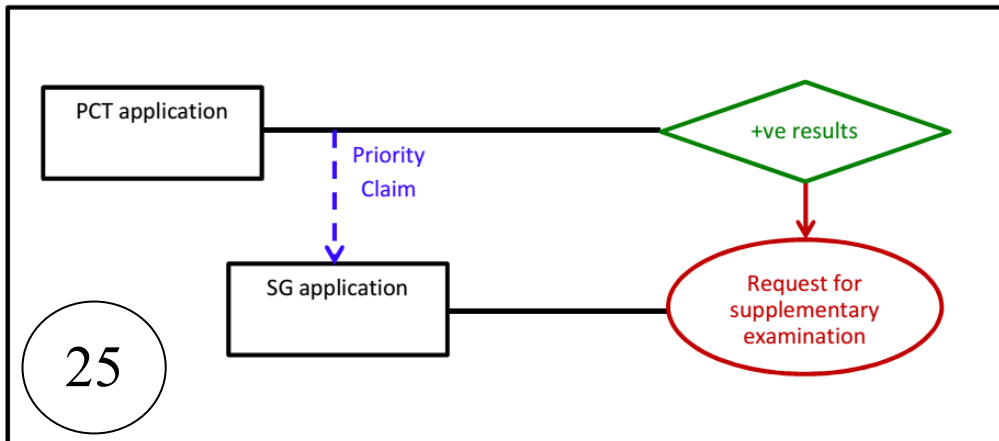


9.104 **Scenario (2)(c) and (d):** However, the final results of the examination of a divisional application in the prescribed office cannot be used as the basis for a supplementary examination of any of the applications in Singapore since said divisional application is not a related national phase application.

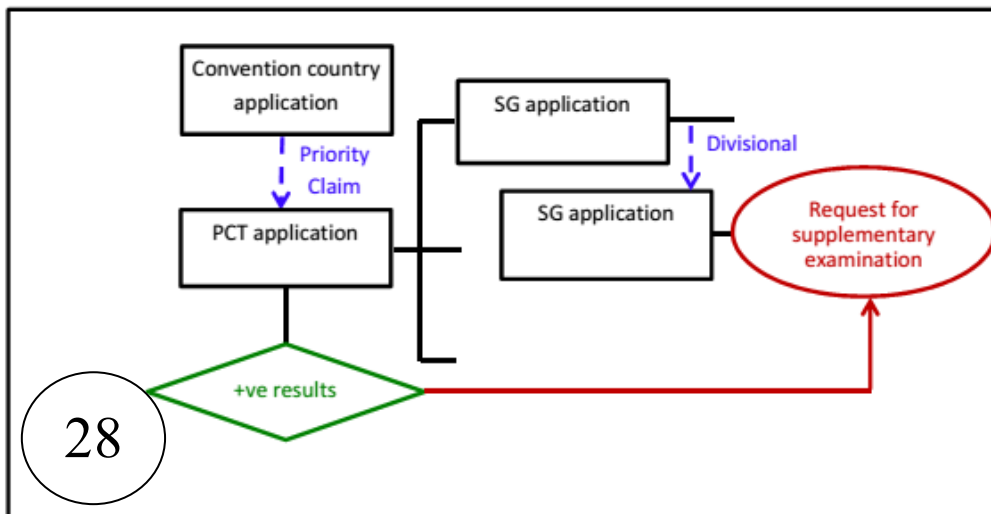


iii. Corresponding international applications

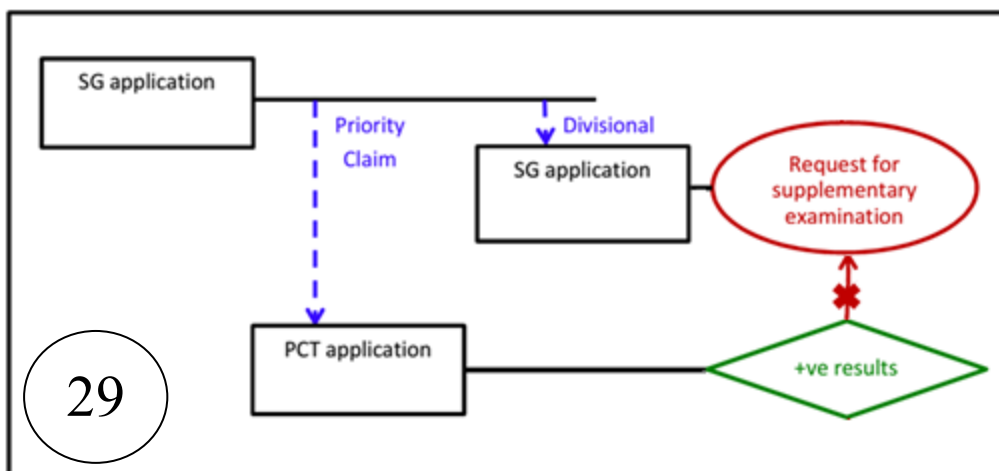
9.105 Scenario (3)(a)-(3)(c):



9.106 **Scenario (3)(d):** The final results of the PCT application may be used as the basis for a supplementary examination of the Singapore application. An application is filed in a Convention country and a PCT application is subsequently filed validly claiming priority from said earlier Convention country application under Paris Convention. For the Singapore application which is a divisional application of the Singapore national phase application in this case, the PCT application will be a corresponding international application as they share a common priority document (i.e. the convention country application).

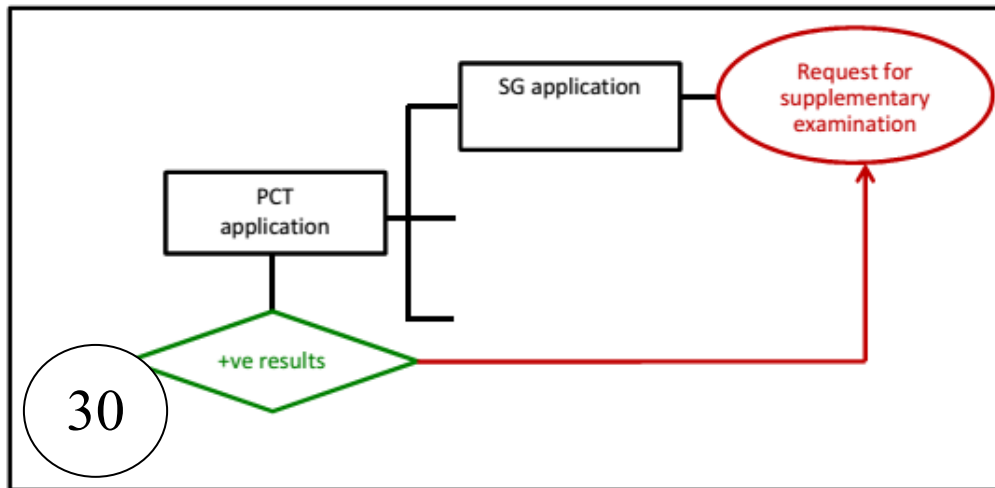


9.108 **Scenario (3)(e):** The final results of the PCT application may be used as the basis for a supplementary examination of the Singapore application. An application is filed in Singapore with no priority claim and a PCT application is subsequently filed validly claiming priority from said earlier Singapore application under Paris Convention. The Singapore application is a divisional application of said earlier Singapore application. The Singapore divisional application in this case is taken to adopt the filing date of the parent application as its filing date rather than making a priority claim to that application. The PCT application and the Singapore divisional application are therefore not corresponding applications.



iv. PCT application entering the national phase in Singapore

9.109 **Scenario (4):** Where the Singapore application is a PCT application for a patent (Singapore) that has entered the national phase in Singapore under section 86(3), the final results of search and examination in the international phase may be used as the basis for supplementary examination.



10. EXAMINATION REVIEW

A. Overview of examination review

10.1 For the purpose of conciseness, unless otherwise specified, the term “examination report” is used hereinafter in Chapter 10 to refer to:

- (a) an examination report issued under section 29(4); or
- (b) a search and examination report issued under section 29(5); or
- (c) a supplementary examination report issued under section 29(6).

10.2 Section 29A(3) prescribes that where an examination report contains one or more unresolved objections, the Registrar shall issue to the applicant a notice of intention to refuse the application. In such a case, the applicant may, in accordance with Section 29B(1), apply for a review of the examination report within the prescribed period under Section 29A(4)(a). If the applicant fails to apply for a review of the examination report, the application shall be refused, in accordance with Section 29A(4)(b).

10.3 Under Section 29B(1), a request for a review of an examination report shall be made by filing:

- (a) the prescribed form for the request within the prescribed period; and
- (b) written submissions to overcome the unresolved objections in the examination report.

10.4 At the time the request for a review of the examination report is made, the applicant may also, according to Section 29B(2), amend the specification of the application in the prescribed manner to overcome the unresolved objections in the examination report. Such amendments are subject to the conditions prescribed in Section 84.

10.5 The examination review process, under Section 29B, is predicated on the assumption that the applicant has exhausted all available means to overcome the objections raised by the Examiner during examination or during supplementary examination, and provides the applicant with a final opportunity to address any unresolved objections.

During the examination review, matters relating to the examination report under review would generally be decided by a different and, if possible, a more senior Examiner. The examination review process is intended to provide an option for the applicant to continue the prosecution of an application that has been the subject of an adverse examination report. If the examination review report maintains that the application should be refused, an appeal may be made to the Courts.

B. General process

10.6 The general process for an examination review is as follows:

- The Registry shall check that the request for an examination review has been made within the prescribed period and that the required forms have been filed. The request for a review of the examination report should be made **within 2 months** after the date of the Registrar's letter forwarding to the applicant the notice under Section 29A(3) (Rule 46A(2)), by filing the prescribed Patents Form 12B (Rule 46A(1)). Written submissions to overcome the unresolved objections in the examination report should also be filed in order to meet the requirements of Section 29B(1). Optionally, the applicant may, at the time the request is made, subject to Section 84, amend the specification of the application to overcome one or more unresolved objections in the examination report (Section 29B(2) and Rule 46A(3) and (4)).
- If the necessary requirements are met Registry then forwards the application to an Examiner to perform the examination review. Generally, the Examiner performing the examination review will be different from the Examiner who established the examination report.
- Upon completing the examination review, the Examiner prepares an examination review report (Section 29B(3) and Section 29B(4)) which is forwarded to the Registrar.
- Upon receiving the examination review report, the Registrar sends the applicant a copy of that report (Section 29B(5)(a)). If the Registrar is satisfied by the examination review report that there is no unresolved objection, the Registrar will proceed to issue to the applicant a notice of eligibility to proceed to the grant of a patent (Section 29B(5)(b)(i)). If the Registrar is satisfied by the examination review report that there are one or more unresolved objections, the Registrar will proceed to issue to the applicant a notice of refusal of the application (Section 29B(5)(b)(ii)).
- In accordance with Section 29B, there is **no** opportunity for the applicant to respond to an adverse examination review report which contains one or more unresolved objections.

- If a notice of eligibility to proceed to the grant of a patent has been issued, the applicant will have 2 months to meet the requirements for the grant of the patent under Section 30(a) and (c) (Section 29B(5A)(a) and Rule 47(2)). If the applicant fails to comply with those requirements within the prescribed period, the application shall be treated as abandoned (Section 29B(5A)(b)).
- If a notice of refusal of the application has otherwise been issued, that refusal shall take effect upon the expiry of 2 months after the date of the Registrar's letter forwarding the notice (Section 29B(6), Rule 46A(5)).

C. Unresolved objections

- 10.7 Section 29B refers to “unresolved objections” in relation to the adverse examination report subject to an examination review. While there is no explicit definition for “unresolved objections” in the Act or the Rules, Rule 46(1) and Rule 46(1A) do explicitly prescribe the adverse opinions that an Examiner should notify the Registrar of in his written opinion during an examination or a supplementary examination respectively. Adverse opinions relating to any of the prescribed matters in Rule 46(1) or Rule 46(1A) would be regarded by the Registry to be “objections” for the purposes of an examination or a supplementary examination. When the applicant has exhausted all available means to overcome the objections during the examination or during the supplementary examination, these outstanding objections become unresolved objections in the examination report.
- 10.8 Hence, for an examination report issued under Section 29(4) or a search and examination report issued under Section 29(5), an unresolved objection would mean an opinion in relation to any the following matters stated in Rule 46(1)(a)-(f):
- (a) the description, claims, or drawings are so unclear, or the claims are so inadequately supported by the description, that no meaningful opinion can be formed on —
 - (i) the novelty or inventive step of the claimed invention; or
 - (ii) whether the claimed invention is capable of industrial application;
 - (b) the invention defined in any claim —
 - (i) does not appear novel;
 - (ii) does not appear to involve an inventive step; or
 - (iii) does not appear to be capable of industrial application;
 - (c) the conditions specified in sections 13 and 25(4) and (5) have not been complied with;
 - (d) the application discloses any additional matter referred to in section 84(1) or (1A) or any matter referred to in section 84(2);

- (e) a claim relates to an invention in respect of which no search has been completed, and the Examiner has decided not to carry out the examination in respect of that claim; or
- (f) there is —
 - (i) any other application for a patent for the same invention, with the same priority date, filed by the same applicant or his successor in title; or
 - (ii) any earlier grant of a patent for the same invention, with the same priority date, to the same applicant or his successor in title.

10.9 For a supplementary examination report issued under Section 29(6), an unresolved objection would mean an opinion on any the following matters stated in Rule 46(1A)(a)-(f):

- (a) any claim in the application is not supported by the description of the invention;
- (b) at the time the prescribed documents referred to in section 29(1)(d) are filed, any claim in the application in suit is not related to at least one claim which —
 - (i) is set out in the prescribed documents relating to the corresponding application, corresponding international application or related national phase application referred to in section 29(1)(d), or to the application in suit during its international phase; and
 - (ii) has been examined to determine whether the claim appears to satisfy the criteria of novelty, inventive step (or non-obviousness) and industrial applicability (or utility);
- (c) the invention is an invention referred to in section 13(2) that is not patentable;
- (d) the invention is an invention referred to in section 16(2) that is not to be taken to be capable of industrial application;
- (e) there is —
 - (i) any other application for a patent for the same invention, with the same priority date, filed by the same applicant or his successor in title; or

- (ii) any earlier grant of a patent for the same invention, with the same priority date, to the same applicant or his successor in title; or
- (f) the application discloses any additional matter referred to in section 84(1) or (1A) or any matter referred to in section 84(2).

D. Examination review report

10.10 Section 29B(4) provides that:

The examination review report shall specify —

- (a) whether the Examiner agrees or disagrees with the examination report, search and examination report or supplementary examination report, as the case may be;
- (b) where the applicant has amended the specification of the application under subsection (2), whether each unresolved objection in the examination report, search and examination report or supplementary examination report, as the case may be, has been overcome in the amended specification; **and**
- (c) the reasons for the Examiner's decision under paragraph (a) and, where applicable, paragraph (b).

10.11 Thus, according to Section 29B(4)(a), the Examiner is required to review the examination report and specify whether he agrees or disagrees with the examination report. In arriving at his decision, the Examiner should take into account the written submissions filed by the applicant under Section 29B(1)(b), and consider whether or not said submissions overcome the unresolved objections in the examination report. The Examiner may also consider any other relevant documents on record, including earlier written opinions for the application and responses to the written opinions filed by the applicant so as to obtain a clearer idea of the proceedings that led to the adverse examination report, but should note that this is a review of the examination report and not a review of the previous written opinions.

10.12 With respect to the written submissions filed under Section 29B(1)(b), applicants are advised to clearly identify the outstanding unresolved objections, and where applicable the relevant claims, in the examination report that are intended for consideration, and to provide relevant and well substantiated arguments for said consideration. This would place the Examiner in a better position to review the examination report.

- 10.13 It is noted that Section 29B(4)(a) does not limit the Examiner to specify whether he agrees or disagrees with only the unresolved objections in the examination report, and hence the Examiner may disagree in the sense that he considers an objection that should have been raised in the examination report was not raised. This may result from, for example, a different construction of the claims during the examination review. Hence, an examination review report may comprise unresolved objections, which were not previously raised in the earlier examination report, on any of the grounds stated in Rule 46(1) (for the review of an examination report or a search and examination report) or in Rule 46(1A) (for the review of a supplementary examination report).
- 10.14 For the purposes of an examination review, the Examiner is not expected to actively perform further searches for additional prior art documents in order to demonstrate that a claim, which was acknowledged to be novel and inventive in the earlier examination report, would lack novelty and/or inventive step. The basis of consideration for novelty and inventive step during the examination review should only be with respect to those documents that are connected with the search and examination history of the file at IPOS.
- 10.15 Where there are amendments to the specification filed under Section 29B(2), the Examiner should also specify, according to Section 29B(4)(b), whether each unresolved objection in the examination report has been overcome in the amended specification.
- 10.16 During consideration of said amendments, the Examiner should also take into account the written submissions filed by the applicant in relation to the amendments. Any other relevant documents on record may also be considered. Applicants are advised to provide relevant and well substantiated arguments detailing how the amendments would overcome the unresolved objections in the examination report under review.
- 10.17 According to Section 29B(4)(c), the Examiner should specify reasons for his decision. To the extent possible, the examination review report should address all issues concerning the examination report under review, and the reasons provided should clearly set out how the Examiner had arrived at his decision with respect to each issue.

It is worthwhile to note that the examination review report may potentially serve as a useful reference in the event that a subsequent appeal is filed at the Courts for an application that has been refused by the Registrar in view of an adverse examination review report.