INTELLECTUAL PROPERTY
OFFICE OF SINGAPORE

Examination Guidelines for Patent Applications at IPOS

These Guidelines will be updated at regular intervals to take account of developments in Singapore patent law and practice. 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: IPOS_PatentS&E@ipos.gov.sg.

These Guidelines refer to the Singapore Patents Act and Rules in effect immediately before 14th Feb 2014 unless otherwise specified.

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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, Section 29 sets out that the application will be subjected to an examination by an Examiner to determine, *inter alia* —

(i) whether the conditions specified in sections 13 and 25(4) and (5) have been complied with;
(ii) whether the application discloses any additional matter referred to in section 84(1); and
(iii) whether the application discloses any matter extending beyond that disclosed in the application as filed in section 84(2)

taking into consideration all the relevant prior art, if any, that the Examiner is aware of or that has been referred to in the search report or international search report, as the case may be.

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.

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 and amendment.

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 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 would have no material effect upon the way the invention worked, and excluded those which would have been thought to have a material effect.

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. Therefore, variation in "unessential" features of the claimed invention may not be sufficient to take a product or process outside the scope of the protection.

2.14 The purposive construction approach therefore combines a fair degree of protection for the patentee with a reasonable degree of certainty for third parties. Simple examples of variants are derivatives, analogues, fragments and variations involving figures or measurements while more complicated variations of an invention is the replacement of say a single-part device by two separate parts.

2.15 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).

2.16 *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.

2.17 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.

2.18 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.

2.19 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 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.

2.20 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

2.21 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 relevant date.

2.22 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. When dealing with inventive step, unlike novelty, it is permissible to make a "mosaic" out of the relevant documents, but it must be a mosaic which can be put together by an unimaginative man with no inventive capacity."*

2.23 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.

2.24 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

2.25 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.

2.26 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."*

2.27 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."*

2.28 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.

2.29 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 skilled persons in a particular

industry would routinely consider patent specifications 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. "*

2.30 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]*

2.31 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.

2.32 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."*

2.33 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 will 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

2.34 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.

2.35 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 section on "Special meanings").

2.36 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 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 S A 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.

2.37 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.

2.38 When interpreting the words in a claim, one should initially assume that the words take the meanings they would ordinarily have given by the person skilled in the art at the time of the invention. The context of such terms in the specification is then taken into account. If a term is given a special meaning by the author then, this needs to be taken into account. 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?

2.39 For example, if the claim defined "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.

i. Special meanings

2.40 If the description provides a "special meaning" for a particular term then this should be taken into account (*Kirin-Amgen Inc. v Roche Diagnostics GmbH* [2002] RPC 1). Ideally, it should be clear from the claims that a term is defined in such a manner, but this should only be required where the Examiner considers that a person skilled in the art would require such an indication.

2.41 For example, a reference such as the phrase "as hereinbefore defined" can indicate that the term is limited to a previously defined special meaning. This should not be confused with the use of similar phrases in omnibus claims (see section on "Omnibus claims").

2.42 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…".

2.43 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..."

2.44 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

2.45 While the description and claims should be read together 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."*

2.46 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

2.47 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.

2.48 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…"

2.49 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.

2.50 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)

2.51 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.

2.52 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.

2.53 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 clam (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.

2.54 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.

2.55 Sometimes, the preamble may suggest that the claim is directed to a particular category of invention, but this needs to be read in the context of the claim to which it is appended. For example:

1. Compound X wherein R = methyl or ethyl for use in the treatment of pain.
2. Compound X as defined in Claim 1 wherein R is methyl.

In this case, Claim 1 defines a first medical use for compound X. Claim 2 uses the preamble "compound X as defined in Claim 1". This is interpreted as being "Compound X for use in the treatment of pain". Accordingly the claim is not interpreted as the compound *per se*, but rather the first medical use of a preferred embodiment of compound X.

2.56 In the following case:

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

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

2.57 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 to remove specific embodiments. In such cases a clarity objection will probably be required.

2.58 A further consideration will be whether the embodiments remaining after the amendment are novel and inventive. The Examiner should check whether the search of the invention defined by the independent claim has covered these additional embodiments or whether the novelty and inventive step objections that resulted in the amendment still apply to these embodiments.

2.59 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

2.60 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.

2.61 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.

2.62 A combination "**comprising"** components A and B would be likely to have these components as the predominant portion of the combination, and that they would be present in sufficient amount to achieve the desired outcomes of the invention. However, in contrast the term "**includes**" might be taken to mean that there is no requirement that the components are the predominant portion of the combination. In each case the term would need to be construed in view of the specification as a whole (a purposive construction), particularly as it may impact novelty.

2.63 The term "**consisting essentially of**" is generally taken to be equivalent to "**comprising**". The scope of the claim containing this term is construed to include the specified materials or steps and those that do not materially affect the working of the claimed invention.

v. Reference numbers in claims

2.64 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

2.65 "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."

2.66 "…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…."

2.67 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 only 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 use" claims

2.68 A claim to a material or composition for a particular purpose should be construed as a claim to the material or composition suitable for that purpose (*Adhesive Dry Mounting Co Ltd v Trapp and Co* [1910] 27 RPC 341 and *G.E.C's Application* [1943] RPC 60). Thus "… for use…." claims are interpreted as requiring the particular apparatus or material to be suitable for the defined purpose. However first medical use claims are an exception to this rule, and the claim is interpreted as being specifically limited to the defined purpose. If however the compound has been used for a medical purpose previously, then a second medical use format ("Swiss type format") must be used.

2.69 For example, in the following claim the hook must be suitable for fishing. This would preclude, for example, a crane hook:

> "Hook for fishing comprising features X, Y and Z."

2.70 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.

2.71 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.

viii. Product-by-process claims

2.72 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 on "Anticipation of 'for' and 'use' claims" 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.

2.73 When the structure of a product is unknown, and the product cannot adequately be defined in terms of composition, structure, properties or characteristics, a product-by-process claim may be allowable. These claims are in particular relevant for biological products or polymers that cannot be defined in terms of their structure or composition.

2.74 A claim to a product obtained by a process:

"Product X obtained/prepared by process Y"

should be 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 OJEPO 309).

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:

$R_1 – R_2$

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 anticipated in a prior disclosure. 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, Section 29 requires that the Examiner take into account all the relevant prior art that has been referred to in the search report or discovered in the search, **and** that they are "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 search may be performed in such situations, but extensive or original search should be avoided.

3.9 During the course of the examination, the Examiner is also allowed to raise new prior art that has not been identified in the search report or discovered in the search but they are "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 search 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 examination report, and a copy of the document 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 anticipation only arises if it discloses to a notional instructed reader *essential integers* to the invention as claimed.

3.13 The novelty consideration therefore involves a consideration of whether the prior art document discloses all of the features of the claim in question. In general a document will destroy the novelty of a later claim only if it discloses each and every feature specified in that claim. If the claim contains technically equivalent or additional

features, then an objection of obviousness may be 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 appropriate. For example if the invention consisted of a known drug in a package together with instructions for usage, an objection of lack of novelty may be appropriate since the feature of the written instructions do 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 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 construed using the common general knowledge 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 *Insitutut 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 given on 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.

3.27 Disclosures, such as conference proceedings published before the 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 The prior art disclosure must be a single document. Lack of novelty cannot be argued on a mosaic of documents. However 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 *Insitutut 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]."*

F. Implicit disclosure

3.29 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.

3.30 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 - 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 also 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).

3.31 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 the case. In this case a novelty objection cannot be raised to a citation that does not specifically disclose this feature. However an objection of obviousness would be appropriate.

G. "Inherent" disclosure

3.32 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.

3.33 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 provide the claimed invention must be based on sound reasoning.

3.34 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** provide the presently claimed ratio.

3.35 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.

3.36 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.

3.37 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."*

3.38 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 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 in the prior art to work the invention.

H. Errors in citations

3.39 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.

3.40 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 primary document 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 could be taken into account.

3.41 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.

3.42 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.

3.43 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

3.44 A claim lacks novelty if there is a prior art disclosure of something falling within its scope.

3.45 A claim which defines the invention by reference to a range or alternatives will lack novelty if one of these alternatives, or if a single example falling within this range, 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.

3.46 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.

3.47 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 amoxycillin or ampicillin trihydrate was a disclosure of each of the four possible combinations.

J. Anticipation of "for" and "use" claims

3.48 A claim for a new method of using a known apparatus may be regarded as novel. This was established in the UK law 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".*

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

3.50 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.

3.51 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.

3.52 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).

3.53 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.

3.54 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.

3.55 A product-by-process claim will generally be interpreted as a claim to the product *per se*, and not the product as limited by the process steps. 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.

3.56 An exception here will be where the process steps result in the product possessing unique properties. However such claim style should be avoided and preferably the

product *per se* should be defined, including the unique structural or functional properties. 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.

K. Prior use

3.57 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).

3.58 Prior use according to 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."*

3.59 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.

3.60 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 such 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.

3.61 In *Merrell Dow Pharmaceuticals Inc v N H 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.

3.62 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."

3.63 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.

L. "Whole of contents" novelty

3.65 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.

3.66 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.

3.67 Only PCT applications that have entered the Singapore national phase may 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.

3.68 In the event that a PCT application is cited in a search report as a P, X or E category citation, the IPOS ePatent site ("IP2SG") must be consulted in order to confirm whether the application has entered the national phase in Singapore. In the unlikely 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 note that it may become prior art if it enters the national phase in Singapore and reserve further comment.

3.69 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).

M. Priority dates

3.70 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.

3.71 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.

3.72 During the examination process, the Examiner will generally not investigate the validity of the priority claim. However, the Examiner shall do so when there is a

potential prior art that is published on or after the priority date but before the date of filing of the patent application that is being examined. Hence, 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, EPOLINE and PAIR prior to requesting documents through the Registry.

3.73 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.

N. Exceptions to novelty: grace period

3.74 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.

3.75 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.

3.76 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

3.77 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.

ii. International exhibitions

3.78 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).

3.79 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 ☐

3.80 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 on "The Windsurfing Test").

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 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 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 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 In *Institut Pasteur & Anor v Genelabs Diagnostics & Anor* [2000] SGHC 53, Tay JC stated:

> *"it is not permissible to combine teachings of two or more documents except where one of these directs the reader to study the other."*

4.41 Tay JC also 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."*

4.42 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."

4.43 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."

4.44 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.

4.45 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.

4.46 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).

4.47 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?

4.48 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.

4.49 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.

4.50 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.'"*

4.51 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)

4.52 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"

4.53 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."*

4.54 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.'"*

4.55 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."*

4.56 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."*

4.57 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

4.58 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).*

4.59 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 $5^1/_4$ 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."*

4.60 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.

4.61 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.

4.62 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

4.63 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.

4.64 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]*

4.65 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."

4.66 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]*

4.67 Similarly, in the UK case *Schlumberger Holdings Ltd v Electromagnetic Geoservies 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."*

4.68 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."*

4.69 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.

4.70 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?

4.71 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.

4.72 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"

4.73 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."*

4.74 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

4.75 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).

4.76 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.

4.77 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 β2-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.

4.78 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 ad 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 heard 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."*

4.79 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

4.80 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

4.81 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.

4.82 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".

4.83 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

4.84 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″.

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

4.86 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.

4.87 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.″

4.88 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.

4.89 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."*

4.90 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).

4.91 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.

4.92 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."

4.93 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?

4.94 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?"

4.95 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.

4.96 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).

4.97 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

4.98 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.

4.99 As recently noted in Kitchin 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."*

4.100 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."*

4.101 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]*

4.102 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.

4.103 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.

4.104 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 and numbering of claims (Rule 19(6))

5.5 Rule 19(6) states that the number of claims shall be reasonable in consideration of the nature of the invention claimed and where there are several claims, the claims shall be numbered consecutively in Arabic numerals.

5.6 While the Rule suggests that the number of claims shall be **reasonable**, there is no specific limitation in this regard. In practice this consideration 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(6) 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. 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.

5.8 Notably, the Rule states that where there are **several 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.

5.9 It should also be noted that amendments and corrections comprising marked up changes are generally filed in which claim numbers may be omitted. In such cases, no objection should be taken since it can be reasonably assumed that the clean copies filed prior to grant will meet all formality requirements including numbering.

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

5.10 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.

5.11 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.

5.12 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).

5.13 Issues arising under this Rule are likely to relate to whether the claimed subject matter constitutes an invention. Thus, for example, a claim to a pure business method would probably be objected to on the basis that it is not an invention, rather than whether the invention is defined in terms of technical features. However, 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.

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

5.14 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 by", "wherein the improvement comprises" or similar); 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.

5.15 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.

5.16 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.

5.17 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))

5.18 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.

5.19 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."

5.20 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 (Section 25(4))

5.21 Section 25(4) requires that the specification contain enough information to allow the skilled person to repeat the invention. Commonly known as sufficiency of disclosure or enablement, there is often overlap between this Section and Section 25(5)(c), which states that the claims should be supported by the description and drawings.

5.22 However, as Section 25(4) is a ground for revocation of a patent, unlike Section 25(5)(c) which can only be applied pre-grant, there is a large amount of case law that relates to this Section. Nevertheless, these case laws are also of relevance to issues that arise under Section 25(5)(c). In view of the overlap certain aspects of enablement will be considered alongside support in the discussion on the disclosure of the invention below.

5.23 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 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 lack support in the mean time and can be considered under Section 25(5)(c) (this will become apparent when Section 25(5)(c) is discussed below).

5.24 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.

5.25 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).

5.26 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.

5.27 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).

5.28 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.

5.29 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.

5.30 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.

5.31 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).

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

5.33 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.

5.34 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.

5.35 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.

5.36 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 of lack of patentable subject matter may be more relevant.

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

5.37 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.

5.38 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).

5.39 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

5.40 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.

5.41 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.

5.42 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.

5.43 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).

5.44 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

5.45 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.

5.46 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

5.47 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).

5.48 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.

5.49 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.

5.50 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. However 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

5.51 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".

5.52 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

5.53 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 range of 0%, then only one ingredient is properly defined by the claim (see section on "Compositions with only one ingredient").

(2) Components do not add up to 100%

5.54 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

5.55 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.

5.56 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 claim (see section on "The test for added subject matter").

5.57 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.

5.58 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%.

5.59 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."

5.60 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

5.61 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

5.62 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.

5.63 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.

5.64 More substantive clarity issues arise where there are internal inconsistencies between the claims or between the claims and description and such issues may be more appropriately dealt with under lack of support as they can render the scope of the invention unclear, and will be discussed below.

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

5.65 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).

5.66 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."*

5.67 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.

5.68 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]).

5.69 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

5.70 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."*

5.71 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

5.72 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."*

5.73 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."*

5.74 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."*

5.75 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

5.76 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.

5.77 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]).

5.78 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 an embodiment of how it may be prepared, the specification is generally considered to provide sufficient support for a claim to the compound *per se*.

5.79 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.

5.80 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.

5.81 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

5.82 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.

5.83 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).

5.84 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

5.85 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."

5.86 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.

5.87 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.

5.88 **"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 that 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."*

5.89 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.

5.90 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*).*

5.91 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."

5.92 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

5.93 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."

5.94 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."

5.95 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.

5.96 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

5.97 Patent claims generally define the invention in terms of specific features or function. Specific parameters, such as a physical property, are generally included to distinguish the invention from the prior art. The key consideration with such claims is likely to be relevant for novelty and inventive step assessment – that is whether the claim may be distinguished from prior art that *prima facie* possesses all the features of the invention but does not specifically disclosed the defined parameter.

5.98 However, with respect to support, parametric claims are in effect claims by result and similar considerations will apply. Thus, the specification as filed should disclose at least one means to achieve and/or determine the claimed parameter values, unless a person skilled in the art would know what method to use or all methods would yield the same result.

viii. Reach-through claims

5.99 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.

5.100 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).

5.101 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).

J. Disclosure of the invention

i. Enabling disclosure

5.102 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."*

5.103 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.

5.104 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."

5.105 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.

5.106 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

5.107 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).

5.108 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."*

5.109 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 invention (*Osram Lamp Works Ltd v Pope's Electric Lamp Co Ltd* 34 RPC at page 391).

5.110 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-Synthélabo* [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."

5.111 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.

5.112 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).

5.113 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

5.114 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.

5.115 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).

5.116 The description should not contain material that renders the scope of the invention unclear. Thus, if embodiments are provided that do not fall within the apparent scope of the invention then it should be clear that these are intended for comparative purposes and are not intended to be claimed. Similarly, statements that purport to extend the scope of the claims (such as "the invention should be taken to include modifications….") should be avoided. However, an objection need only be raised if such matter clearly renders the scope of the invention unclear.

5.117 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.

5.118 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

5.119 The description may refer to another document to provide additional background material or further information about the invention, often as an "incorporation by reference." 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.

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.

However, the specification must be sufficient at its date of filing, and any references given in the description should have been published at 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 then the specification may be insufficient. Amendment to incorporate such matter is likely to constitute added matter.

v. Trademarks and industry standards

5.120 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.

5.121 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.

5.122 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.

5.123 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.

6. UNITY OF INVENTION

A. Statutory requirements

6.1 Section 25(5)(d) requires that the claims relate to one invention or group of invention 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 Unity is a ground for refusal under the revised **Patent Act** but is not a ground of 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/pct/en/texts/pdf/ispe.pdf#page=75).

6.4 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

6.5 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, the determination provided by the ISA should be directly applicable in Singapore.

6.6 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*, with a detailed discussion including the special technical features.

6.7 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. Objections of this type are likely to be rare.

(d) Lack of unity should **not** be raised where a document provides only a generic disclosure of the common feature, or where the features are obvious in view of a combination of documents (that is, where the lack of unity is raised in view of an obviousness objection). In these cases the common feature is not "known" as such.

6.8 In cases where the first 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 first claim), then inventive step is most likely the issue in the dependent claims. Unity should be considered based on the above guidance.

6.9 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. 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 In general, the initial consideration will be directed to the independent claims only. However further consideration of dependent claims may be necessary if the special technical feature is found in the prior art (see *a posteriori* lack of unity). However, claims will almost always have alternatives defined for each feature (Markush claims are an example), but a lack of unity will only arise if the combinations 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. Approaches to assessing unity of invention

i. Lack of unity *a priori*

6.15 Unity of invention requires that the claims have "special technical features" in common that provide the contribution over the prior art. In most cases these features will be self-evident and an assessment of *a priori* unity can be made with little in-depth analysis. A simple example of claims having unity is as follows:

1. A+X
2. A+Y

Unity is present provided feature A is **new** since the claims have the novel feature A in common. Feature A would be considered the special technical feature.

6.16 This contrasts to the following situation having claims that do not have unity:

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

These claims lack unity since there is no feature in common between all of the claims.

6.17 A lack of unity would be taken grouping the inventions having a common special technical feature – in this case the inventions could be grouped as:

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.

6.18 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 (see section on "Combinations of different categories of claims").

6.19 Complex claim sets, chemical intermediates and Markush claims also involve special considerations. These are discussed in later sections.

ii. Lack of unity *a posteriori*

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

6.21 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.

6.22 The PCT Guidelines state that 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" [emphasis added]. Notably the common feature must be *well known*. Any objection should be supported by reference to a citation unless the feature is so generic in the art that it requires no documentary evidence.

6.23 By "known" it can be assumed that the feature must be publicly known in the art at the priority date of the application. Thus, 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. Such matter was not publicly known at the priority date of the application.

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

1. A+X
2. A+Y

If a search of the prior art establishes that feature A is **well known** in the art then there is no special technical feature that is common to all of the claims. Each of these groups is taken to be a separate invention.

6.25 This 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. The common feature of the automobile is well known. Consistent with the policy intention that unity is intended to assist with the efficient administration of the patent system an objection of lack of unity *a posteriori* could be taken: the two real inventions would require entirely separate searches and examinations, and would be subject to entirely different infringement and revocation actions.

6.26 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 tank reactor. However this type of reactor is well known in the art, and as a consequence this is not a special technical feature.

6.27 A broad consideration should be given to the determination of lack of unity. 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, 9, 13 and 24.

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 relate to a single binding site at which mutation of the amino acids can result in changes to the binding at the site. This could therefore be the technical feature the different proteins have in common.

6.28 Similarly, if the invention relates to a new property of a related group of articles (some of which are known and some 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.

6.29 If an independent claim is new and inventive and a special technical feature unifies the matter 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. For example in the following claims, if A+B has found to be novel and inventive and the combination of these feature 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

6.30 However, 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 should

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.

iii. Avoid literal or over-technical approaches

6.32 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 in 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.

6.33 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.

6.34 Notably, the 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.

6.35 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.

6.36 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.

iv. Additional fees for search of additional inventions (Rule 45)

6.37 Rule 45(1) states that:

> If during the preparation of a report under Section 29(2)(*a*) or (*b*) 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 [emphasis added].

6.38 However 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.

6.39 In addition, there is possibility for search of a second (or subsequent) invention provided there is **little additional effort** required to undertake such a search. 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 searching can be costly in terms of Examiners' time, database costs and supply of citations and should only be done where there is **minimal** 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.

v. Examination procedure with respect to unity (Rule 45)

6.40 No examination of an additional invention should be undertaken even if it has been searched. The applicant must file a divisional and request an examination (Rule 45(3)). The applicant may rely on any search or supplementary search report established for the parent application or may alternatively rely on a search established in another office for that invention (see rules in relation to divisional applications).

6.41 This will include examination requests where the examining office has taken an objection of lack of unity but has undertaken a search and/or examination of the additional inventions (for example, where additional fees were paid during the International Search phase of the application). Examination must be carried out on the "first invention" with the objection specifying the invention in the report.

6.42 Applicants may respond to a unity objection as follows:

(1) Limit the claims to the first invention as specified in the Examiner's report
(2) File divisional application(s) for the second or subsequent inventions
(3) Amend the claims to include a common special technical feature that joins the claims in a single general inventive concept
(4) Provide arguments as to why the claims comply with Section 25(5)

6.43 Under the existing "self-assessment" legislation, it is required that 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.

6.44 Under the new Patents Act, should an impasse be reached between the Examiner and the applicant regarding the unity issue, according to Section 29A(3), the Registrar shall issue the applicant with a notice of intention to refuse the application for a patent. The applicant may within a prescribed period according to Section 29A(4) apply for a review of the examination report. However, should the applicant fail to apply for a review, then the application for a patent shall be refused.

6.45 For a search and examination case, if a lack of unity objection has been raised, and

subsequently the applicant provides comments 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.

vi. Claims that are unduly complex

6.46 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?

6.47 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.

6.48 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 that the applicant can identify 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?

6.49 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.

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

3. Are the claims supported?

6.51 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.

6.52 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 issue here and should be avoided.

6.53 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 innumerable 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 since the specification provides no support for the claim to each and every one 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).

6.54 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.

vii. Combinations of different categories of claims

6.55 Generally, unity will extend to claims of different categories related to the same inventive concept. 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.

6.56 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 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. 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 adapted to pierce the container when mounted on it; or a container of chemicals to be sprayed which is adapted to be mounted on a carrier, and such a carrier specially adapted for receiving the container; or to a new form of cable and to a sheath stripper particularly adapted to deal with this cable.

6.57 Example 2:

In this example, the application is directed to the treatment of Disease X by inhibition of Receptor Y by known Receptor Y antagonists. A search indicates that treatment of Disease X by this pathway is new and inventive. The specification discloses two

preferred known Receptor Y antagonists: Compound A and Compound B. These two compounds belong to two different chemical classes and have no structural similarity. The claims define the following:

1. Use of Receptor Y antagonists for the preparation of a medicament for the treatment of disease X.
2. Use according to Claim 1wherein the Receptor Y antagonist is Compound A.
3. Use according to Claim 1wherein the Receptor Y antagonist is Compound B.

In this case, the claims will be unified even though Compounds A and B are chemically distinct and have no structural similarity. The inventive concept in this case is that Disease X may be treated by inhibition of Receptor Y. Compounds A and B are simply specific Receptor Y inhibitors.

However, if a document disclosing the inventive concept had been found during the search - for example if a citation disclosed that Disease X could be treated targeting Receptor Y – then the special technical feature would no longer lie in such concept and an *a posteriori* lack of unity might be appropriate.

6.58 Example 3

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...

6.59 Example 4:

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.

6.60 Example 5:

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 ...

In this case, the apparatus has been "specially adapted" for use in the process and it can therefore be read into the claims that the apparatus is configured in such a way as to specifically provide the inventive outcomes of the process (automation, operatively linked, catalysts, pressure system, etc). 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 (for example "apparatus for use in the process of Claim 1"), 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.

viii. Markush claims

6.61 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.

6.62 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}.

6.63 The key consideration for unity as stated in the PCT Guidelines is whether there is a common 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**.

6.64 The PCT Guidelines 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.

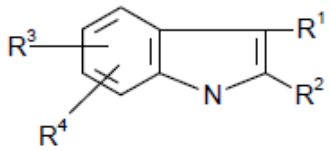
6.65 In paragraph (b)(1), "significant structural element is shared by all of the alternatives" means that the compounds share a common chemical structure which occupies a large portion of their structures. Where the compounds have only a small portion of their structures in common, the commonly shared 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.

6.66 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.

6.67 An objection of lack of unity should not be taken 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, *a posteriori* lack of unity may be a consideration. However, it should be noted that the mere existence of prior art compounds 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.

6.68 Example1:

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.

6.69 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.

6.70 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..."

6.71 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..."

6.72 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.

ix. Intermediate and final products

6.73 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.

6.74 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.

6.75 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:

$$A + B \longrightarrow A - B$$

$$A - B + C \longrightarrow A - B - C$$

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 given in 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, or Invention 2, comprising Claim 1 and Claim 4.

6.76 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.

6.77 The intermediate may also have the same use as the final product, but it must not 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

6.78 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.

6.79 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 will be no unity. Whether the claim defines a patentable invention will be a separate consideration in this case.

(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 *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

6.80 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 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, had the transmitter and a receiver been 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"). However, 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.

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

6.82 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, wherein 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).

6.83 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(c) are met for the parent application or before the parent application has been refused, withdrawn or treated as having been abandoned. Under Rule 47, there is no time limit to put an application in order and therefore, there is unlimited time in order to file a divisional which is only limited by the end of prosecution of the parent application. For the purposes of the discussion relating to unity, all unity issues under search and examination must have been resolved in order for an application to fulfil the grant requirements.

6.84 Therefore, 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 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.

Example:

6.85 Take the case of a "first-filed original" application "A" with three subject matters described. A "first divisional" application "B" can be filed with two subject matters divided from application "A". A "further divisional" application "C" can be filed with subject matter divided from the divisional application "B" and citing this divisional as its original application. In this case, divisional "C" would have the same filing date as the divisional B which is 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 the issue date of the divisional "B" or the expiry date of the time to reinstate it. This time limit is not dependent on application "A", which may have issued before the Examiner makes the requisition to restrict to one subject matter in divisional application "B".

6.86 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 and so alter regular practice.

H. Double patenting (Section 30(3)(e))

6.87 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, or 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. An objection of double patenting may arise in such situations if the specific feature is the only one disclosed in the specification and there is no basis for reading the specification as constituting a more generic group. However, if there is more than one means of performing the particular step or the feature may be selected from a group, then no objection should be taken.

6.88 Section 30 states that the Registrar shall grant a patent provided certain conditions have been met. These include Section 30(3)(e), which requires that there is —

(i) no other application for a patent for the same invention having the same priority date filed by the same applicant or his successor in title; and

(ii) no earlier grant of a patent for the same invention having the same priority date to the same applicant or his successor in title.

6.89 It follows that this provision 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.

6.90 It should be noted that this provision is different to Section 14(3) where a Singapore application which is not published at the time of filing of the first application constitutes 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.

6.91 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. Under the current Act, a note is included in the opinion. If the opinion is otherwise clear, an examination report will issue with the note and the Registrar is also advised of the potential double patenting issue. Under the new Act, an adverse opinion will be issued and it will be up to the applicant how they wish to proceed with the applications in order to avoid double patenting.

6.92 In the case of claims that do not have unity (i.e. they do not share a single general 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.

6.93 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.

6.94 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.

6.95 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.

6.96 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.

6.97 *Turner & Newall's Patent* [1984] RPC 49: in this case the applicant had concurrent UK and EP applications. The applicant sought to amend the UK application to include only omnibus claims since such claims were not allowed in EP applications but were allowed in UK patents. These were considered the same invention as the EP application, even though there was an additional drawing in the UK patent that had been omitted from the EP patent and it could therefore be argued that there was a difference in scope.

6.98 Similarly in *Maag Gear's Patent* [1985] RPC 532, it was determined that the claims of the two patents do not need to define the invention in identical terms and that mere differences in scope such as limitation to an omnibus claim will not avoid double patenting. In this case, the claim of the European patent included an additional definition of certain "pad geometry". Even though this feature was absent in the UK claims, the *only* embodiment described and exemplified in the specification related to such pad geometry, and as a consequence the hearing officer considered the UK patent directed to the same invention.

6.99 In *Marley's Patent* [1994] RPC 231, the Court of Appeal held that the interpretation of the provision is such that overlap in the protection provided by each patent is sufficient for revocation – so that if one patent covers a different invention in addition to the same invention, the provision will still apply. The Court also 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 the product *per se* (and made by a different process).

6.100 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 their scope does not differ in substance.

6.101 *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. However, he noted that the European patent had been amended to remove claims to **A** in isolation as a result of opposition proceedings, but 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.

6.102 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 able to be 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 – that is, two claims could be in the same application because they relate to the same inventive concept, but they may still constitute two different inventions. 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 a different invention. However, in the case of a "system" claim in one patent and a "method" claim in the other, the hearing officer considered that they were "two sides of the same coin" in that they defined the invention in different ways, but the invention was the same. A second difference between the claims was considered implicit since this was the only way described to carry out the particular feature.

6.103 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."*

6.104 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.

6.105 Similarly in *Intel Corporation* BL O/281/12, the hearing officer took submissions from the applicant to the effect that merely replacing a generic feature of the UK claims by an embodiment of that feature will not overcome double patenting, but that adding a new essential feature to the UK claims may overcome conflict. Referring to *Marley's Patent* and *SeeReal Technologies*, he considered that the applicant's arguments were consistent with these decisions. Thus the test for conflict is not whether the two applications define the same inventive concept, but rather whether they define the same invention.

7. AMENDMENTS AND CORRECTIONS

A. Statutory requirements

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

7.2 **Amendment** of an application or of the specification of a patent must comply with the requirements of Section 84. That is, the amendment cannot add subject matter or, in the case of a patent, extend the protection conferred. The amendment must fall within what the person skilled in the art would understand the specification as filed to have disclosed.

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 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 set of application, and accordingly all relevant amendments must be identified and taken into account during examination. This will include any amendments made under the PCT (Article 19 and 34), as well as any amendments or corrections made by the applicant in the national prosecution.

7.5 An amendment, once accepted, takes effect from the date the amendment was filed. A correction, once accepted, takes effect from the date of filing as if the error has never been made in the first place.

B. Amendments before grant (Rule 48)

7.6 Amendments to the request and specification prior to grant should be made on Patents Form 13. The reason for the amendment should be provided by the applicant.

7.7 A copy of pages incorporating the amendments must be filed with the request to amend. Changes will be indicated striking through any text, figure or other matter that is to be deleted, and by underlining any replacement matter. Prior to grant the applicant will provide clean copies of pages incorporating the amendments (note: the clean copies are not forwarded for checking by the Examiner).

7.8 Formalities should be checked by the Registry prior to the file being sent to the S&E unit, so Examiners will not routinely need to ensure that the correct form has been used and all required information has been provided, if any.

7.9 Amendments that generally are dealt with by Registry and require no consideration by the Examiner include:

(1) Changes to the applicant's name, address or address for service
(2) Change of priority details

7.10 If it appears that amendments of these types have been overlooked, a note advising the Registry of the amendment should be included with the case when the opinion or report is returned to Registry.

C. General power to amend before grant (Section 31)

7.11 Section 31 sets out that:

(1) If it appears to an Examiner during the examination of an application that —

(a) the conditions specified in sections 13 and 25(4) and (5) have not been complied with; or

(b) the application discloses —

(i) any additional matter referred to in section 84(1); or

(ii) any matter extending beyond that disclosed in the application for the patent as filed,

the Examiner shall give the applicant at least one written opinion to that effect, and the Registrar shall, upon receiving the written opinion, send the applicant a notification and a copy of the written opinion.

(2) The applicant shall, before the examination report is issued, have the right —

(a) to respond in the prescribed manner to the written opinion within any prescribed period; and

(b) subject to section 84, to amend in the prescribed manner the specification of the application in accordance with the prescribed conditions.

(3) Notwithstanding subsection (1), during any period prescribed for the purposes of this subsection, the applicant may, in accordance with the prescribed conditions and subject to section 84, amend the application of his own volition.

7.12 Section 31 mandates that the applicant be provided with at least one opportunity to respond to issues with the application. This response may be in the nature of written arguments disputing the Examiner's objections, or it may be amendments to the application. Given the time frames associated with the examination process, it may be feasible that several opinions could issue. However, if there are outstanding issues and the final deadline for the examination report is too near or the prosecution of the case has reached a stalemate and is unlikely to progress further, the Examiner may

issue the examination report rather than issue a further opinion. In such circumstances the Examiners should discuss the case with their Senior Examiner.

7.13 Section 31 also allows applicants to amend the application of their own volition within prescribed time frames (see section on "Time for making amendments before grant"). These time frames are provided in Rule 49 (see the following section).

D. Time for making amendments before grant (Rule 49)

7.14 Rule 49 sets out that:

> (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) 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, except that any such application for amendment shall not be made –
>
> (a) after filing of the request for a search report referred to in section 29(2)(a) and before receipt of that report by the applicant;
>
> (b) after filing of the request for a search and examination report referred to in section 29(2)(b) and before receipt of that report by the applicant; or
>
> (c) after filing of the request for an examination report referred to in section 29(2)(c)(i), (d)(i) or (e)(i) or (4) and before receipt of that report by the applicant.

7.15 Under the existing Rules amendments must not be requested during the period from when the request for search and/or examination report is made and receipt of that report. This is primarily for practical reasons, since amendments may change the scope of the search and examination, and lead to additional effort by the Examiner. Requests to amend made during this period should not be taken into account, and a note advising the applicant of this should be included in the report.

E. PCT amendments in the national phase (Section 86(6))

7.16 Amendments during the international phase of PCT applications will generally 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 examination process.

7.17 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.

7.18 In most cases, the Registry will process PCT amendments and translations in accordance with the Rules and the application sent for examination has all necessary

documentation.

7.19 The Registry will generally receive Article 19 and 34 amendments from the International Bureau. If the amendments are not received by the Registry from the International Bureau (or from the applicant), the amendments will be disregarded and the specification in its unamended form will form the basis for examination. This should be indicated in Box I of the written opinion, with an explanatory comment under "Additional observations".

7.20 Where the application and amendments are in a foreign language, the applicant must provide a translation of these documents at filing. If the Registry does not receive these at filing, a notice is issued and the applicant is given 2 months to provide such translations. In the event that translations of the amendments are not filed, the application will proceed in the unamended form.

7.21 If the applicant enters the national phase early, then they will need to provide a copy of the application and any amendments made under the PCT. Translations of any amendments in a foreign language will be required. If these are not received then the application will proceed in its unamended form.

F. Responses to written opinions (Rule 46(7))

7.22 The applicant's response to the written opinion may include amendments in response to issues raised by the Examiner, but can include other amendments that are not in response to the Examiner's objections.

7.23 If a further submission to a same written opinion is made after the Examiner has commenced preparation of a further written opinion or report, the Examiner need not take into account such further submissions according to Rule 46(7).

7.24 If an applicant makes a partial response and requests a further written opinion, then the Examiner may do so provided sufficient time remains. However, there is no provision under the Patents Act for such a request, and it will be at the discretion of the Examiner whether to issue a further written opinion. Factors that may be taken into account include the nature of the outstanding issues and whether the partial response has progressed prosecution of the case. In this situation the Examiners should discuss the case with their Senior Examiner.

G. Amendments following grant (Rule 52)

7.25 An amendment following grant (i.e., post-grant amendment) should be made on Patents Form 17.

7.26 A copy of pages incorporating the amendments should be filed with the request to amend. Changes should be indicated striking through any text, figure or other matter that is to be deleted, and by underlining any replacement matter.

7.27 The application and the reasons for amendment are advertised for opposition. Interested parties have 2 months to oppose the amendment. If a notice of opposition is filed, the Registrar may refer the matter to an Examiner for an opinion on whether the amendment is allowable under Section 84(3). The Examiner will take into account the application for leave to amend together with the notice of opposition, the accompanying statement and any counter-statement, during examination.

7.28 If no opposition is filed and the Registrar is satisfied with the reasons for amendment, the amendment will be allowed.

H. Allowability of amendments (Section 84)

7.29 Pre-grant (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.

7.30 Post-grant (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.

7.31 Section 84(2) requires that no added matter relating to the invention is incorporated into the application. This consideration applies to amendments made in response to a written opinion and an amendment made of the applicant's own volition.

7.32 Pre-grant amendment requires that the amendment does not result in the application disclosing any matter extending beyond that disclosed in the application as filed (see following section on "Basis of the consideration: the application as filed").

7.33 Post-grant amendment has the further restriction that the scope of the claims cannot be broadened. Thus 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 amend before grant to bring the claims into alignment with the description.

I. The test for added subject matter

7.34 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].

7.35 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.

7.36 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).

7.37 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 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*

7.38 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.

7.39 Notably the legislative 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.

7.40 A priority document does not form part of the application, and matter disclosed in the priority document but omitted from the specification as filed may not be subsequently added. 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.

7.41 Similarly, 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.

7.42 Note: the abstract is part of the application, though not part of the specification. In *ARMCO Inc's Application* BL O/84/85 the Hearing Officer accepted that matter present in an abstract filed on the date of filing could be considered to be part of the disclosure of the application. However, this approach is not to be followed.

ii. Comparing disclosures: clearly and unambiguously disclosed

7.43 Some EPO decisions have adopted a "novelty test" when assessing the allowability of amendments. 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."*

7.44 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). EPO decisions may therefore provide useful guidance when considering whether a document provides a clear and unambiguous disclosure of matter proposed to be incorporated by an amendment.

7.45 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.

7.46 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.

iii. Express and implicit disclosures

7.47 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.

7.48 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.

7.49 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."*

7.50 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.

7.51 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"*.

iv. Matter which extends beyond the original disclosure

7.52 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.

7.53 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).

7.54 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])."*

7.55 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.

7.56 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).

v. Data submitted after the filing date

7.57 Under Singapore Patents Act, a patent specification 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.

7.58 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. Generally, as long as support could be found in the original disclosure (no new teaching), the submitted data may be considered by the Examiner.

7.59 Generally, in sufficiency assessment, the applicant cannot rely on data or evidence submitted after the filing date itself to establish sufficiency of disclosure and overcome a sufficiency objection.

7.60 Generally, 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 filed, then it would not be allowable to claim a specific compound/composition by merely providing its advantages at a later stage.

vi. Intermediate generalisation

7.61 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.

7.62 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 *Palmaz'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'."*

7.63 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 (malasia) 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."*

7.64 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).

7.65 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."*

7.66 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.

7.67 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.

vii. Generic disclosure as a basis for amendment to a specific feature

7.68 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.

7.69 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.

7.70 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.

viii. Addition and deletion of features

7.71 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.

7.72 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.

7.73 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).

7.74 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.

7.75 *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.

7.76 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.

7.77 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 …"*

7.78 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").

ix. Ranges

7.79 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.

x. Disclaimers

7.80 Applicants will often use disclaimers as a means to circumvent novelty and inventive step objections. These are generally in the form of a proviso or similar statement excluding specific embodiments or groups from the claim.

7.81 Amendments to incorporate disclaimers will generally be allowable if the matter remaining in the claim following amendment is clearly disclosed.

7.82 Of particular concern in this regard are so-called "undisclosed" disclaimers. These are disclaimers that are not supported by the description as originally filed, and that as a consequence appear to result in the application including added matter. The EPO Enlarged Board of Appeal set out the 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 each claims. 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 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 be allowable.

7.83 When putting a disclaimer, the invention shall still be enabled to a person skilled in the art equipped with common general knowledge. Conversely, disclaimers should not be used to exclude embodiments that do not work or in order to address an objection of lack of sufficiency.

7.84 A disclaimer that makes a technical contribution (for example one that excludes a feature, the exclusion of which makes a technical contribution to the working of the invention) would not be allowable. If a disclaimer (e.g. disclaiming an embodiment that is positively exemplified) is made in order to overcome a prior art in a related field, an objection may be raised under added matter, support, or inventive step.

xi. Allowability of PCT amendments in the national phase

7.85 When amendments are made in 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 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.*

7.86 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 only done if the application has demanded Chapter II examination. This will include a consideration of both Article 19 and Article 34 amendments. 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 should review the search to ensure that the matter of the amendments is adequately searched.

7.87 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.

7.88 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.

7.89 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.

J. Corrections (Section 107)

7.90 Examiners will generally only be dealing with corrections to the specification, and as a consequence this section provides procedural guidance only in that regard.

7.91 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.

7.92 Rule 91 provides for some of the procedural matters associated with Section 107. A request to correct an error should be made on Form 23 (or Form CM4 under the 2012 Patent Amendments and consequential Rule changes). Where the correction relates to a specification or abstract, the request should be filed together with document showing the proposed corrections using strikethrough to indicate deletion and underlining to indicate replacement.

7.93 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.

7.94 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.

7.95 Notably this provision applies only to corrections that are made to **specifications**. 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.

7.96 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?

7.97 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.

7.98 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.

7.99 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. However, 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).

7.100 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.

7.101 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.

7.102 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.

7.103 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).

8. PATENTABLE SUBJECT MATTER AND INDUSTRIAL APPLICABILITY

A. Statutory requirements

8.1 The Singapore legislation does not provide a definition for an "invention" and provides only limited specific exclusions to patentability (e.g., non-industrially applicable inventions, methods of medical treatment, etc.). The precise boundaries of patentability in Singapore are therefore relatively unclear and have yet to be considered in the Courts.

8.2 The Singapore Patents Act 1994 came into force on 23 February 1995. This mirrored the UK Patents Act 1977, and provided a non-exhaustive list of subject matter that was not considered inventions *as such*.

8.3 Section 13(2) provided as follows:

> It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of -
>
> (a) a discovery, scientific theory or mathematical method;
> (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
> (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
> (d) the presentation of information;
>
> but the forgoing provisions shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or an application for a patent relates to that thing as such.

8.4 Section 13(2) was repealed in 1996 shortly after Singapore joined the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). At the time, the list of excluded subject matter was thought to be inconsistent with our obligations under the TRIPS Agreement. This has been

argued by some to have removed any requirement of inherent patentability or for inventions to involve some technical feature in order to constitute an invention.

8.5 However, the Act has to be read in combination with the *Patent Rules* and Rule 19 requires the specification to identify the "**technical field**" and the "**technical problem**" to which the invention relates and the claims are to define the invention in terms of "**technical features**":

(5) The description shall first state the title of the invention as appearing in the request and shall —

specify the **technical field** to which the invention relates; ...

disclose the invention as claimed in such terms that the **technical problem**, even if not expressly stated as such, and its solution can be understood, and shall state the advantageous effects, if any, of the invention with reference to the background art; …

(7) 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.

(8) Claims shall be written —

in 2 parts, the first part consisting of a statement indicating those **technical features** of the invention which are necessary in connection with the definition of the claimed subject-matter and which, in combination, appear to be part of the prior art and the second part preceded by the words "characterised in that", "characterised by", "wherein the improvement comprises", or other words to the same effect, followed by a statement stating concisely the **technical features** which, in combination with the features stated in the first part, define the matter for which protection is sought; or in a single statement containing a recitation of a combination of several elements or steps, or a single element or step, which defines the matter for which protection is sought.

(9) 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.

8.6 Accordingly, in view of the requirements set down in Rule 19, it is a requirement that an invention comprises a "technical" feature. Furthermore, the Singapore Court of Appeal has indicated that there is a distinction between discovery and invention (*Merck & Co Inc v Pharmaforte Singapore Pte Ltd* [1999] SGHC 323).

8.7 The following sections provide guidance on some subject matter that may not be patentable. However, if an Examiner is unsure they should discuss the case with a Senior Examiner. External Examiners should contact the Registry to arrange for an IPOS Senior to contact them for discussions.

i. Discoveries

8.8 The Singapore Court of Appeal has indicated that there is indeed an inherent patentability requirement by drawing a distinction between discovery and invention (*Merck & Co Inc v Pharmaforte Singapore Pte Ltd* [1999] SGHC 323 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."*

8.9 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 The difference between invention and discovery can be unclear. Many inventions are based on a discovery but this does not mean that a discovery will necessarily 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.

8.11 For example, the isolation of a naturally occurring material or microorganism 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. In this case 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 rather than patentability.

8.12 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 and a recombinant polypeptide. The Court considered that the invention did not lie in the DNA sequence – this was considered to provide information only – but there was patentable subject matter in the isolation and the process of making erythropoietin.

ii. Scientific theories and mathematical methods

8.13 A scientific theory or a mathematical method *per se* is not patentable subject matter, but if an application of the principle results in a new material or process, then the resulting product may be patented.

8.14 For example, the theory of relativity would not be patentable, but a Global Positioning System that makes use of the theory of relativity to more accurately locate the user would be patentable subject matter.

8.15 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."*

8.16 This approach has been followed in *Genentech's Patent* [1989] RPC 147 and *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9.

8.17 However, if the claimed matter merely constitutes a statement of the principle underlying a known process then it will not be patentable subject matter. In such cases an objection under inventive step should be considered since the mere elucidation of the principle underpinning an invention is not inventive.

iii. Aesthetic creations: literary, dramatic, musical or artistic works

8.18 A purely aesthetic creation is not patentable subject matter (including written works, photographs, paintings, sculptures, music, speeches, or other artistic works). This includes not only the idea or mental aspects of the creation, but also any physical representation of the work.

8.19 However, if there is some technical aspect to the creation then it may constitute patentable subject matter. For example a design on a surface would likely constitute a purely aesthetic creation if the design was merely decorative. However if the design were of a nature that served a technical function, such as providing improved non-slip properties as a result of the design, then it may constitute an invention.

8.20 Similarly, a particular colour may confer patentability. 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

8.21 Methods that are considered mental acts or schemes are generally not patentable. 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.

8.22 This practice is applied narrowly – for example, a claim to a method that is capable of being carried out mentally (but uses a computer) may not be considered to constitute a mental act. This follows *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2005] EWHC 1623, where it was argued that a computer implemented method of designing a drill bit was not a mental act merely because it was capable of being carried out mentally. This differed from the approach taken in a similar later case (*Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] RPC 2) where the Court found that the claims defined a mental act. However, in the latter case the claims were not limited to a computer-implemented method. It should also be noted that the Court considered that this deficiency was a matter of form and could have been overcome by inclusion of a manufacturing step.

v. Presentation of information

8.23 Any invention which is characterised solely by the content of the information is not patentable, even if physical apparatus is involved in the presentation. In *Townsend's Application* [2004] EWHC 482 (Pat), an invention relating to an advent calendar with an additional indicium on each door was found non-patentable. Laddie J held that the exclusion does not only apply to the expression of the information but also to the provision of information.

8.24 The key consideration in such cases is whether the presentation of the information serves a practical function. 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). A claim defining the choice of how and where to present information would be excluded since this still relates to the presentation of information (*Autonomy Corp Ltd v Comptroller General of Patents, Trade Marks & Designs* [2008] EWHC 146 (Pat)). If the invention makes a "technical" contribution then it may be patentable subject matter. Thus a newspaper layout designed such that folding the paper did not hinder reading was found patentable (*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). However an instructional speech course in which text was highlighted in a particular way to indicate stress and rhythm was considered unpatentable (*Dixon's Application* [1978] RPC 687).

8.25 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.

B. Industrial applicability

8.26 Section 16(1) states that an invention is considered industrially applicable if it can be made or used in any kind of industry.

8.27 "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

8.28 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.

8.29 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

8.30 Methods of medical treatment are a specific exclusion under industrial applicability. Section 16 is relevant for patent applications relating to medical inventions:

8.31 Section 16(2) sets out that:

(2) An invention of a method of treatment of the human or animal body by therapy or surgery or of diagnosis performed on the human or animal body shall not be taken to be capable of industrial application.

8.32 Section 16(3) sets out that:

(3) Section 16(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.

8.33 Section 16(2) is primarily intended to ensure that medical or veterinary practitioners are not hindered by patent rights from properly exercising their professional skills (T 245/87 SIEMENS/Flow measurement OJEPO 1989, 171). Notably, Section 16(2) corresponds with 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 [50] - [51]:

> *"50. Nor do I accept that on his construction the claim amounts to merely to a method of treatment. It is to the manufacture of the medicines to be used in that treatment. I am reinforced in that view by the consideration that the Article 54(4) provision about methods of treatment is an exception to patentability and as an exception should be construed narrowly…*
>
> *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."

8.34 It should be noted that not all methods of treatments of the human or animal body are excluded by Section 16(2) (*Schering A. G.'s Application* [1971] RPC 337). In particular, the exclusion only applies to methods that are **therapy, surgery or diagnosis and** that are performed **on** the human or animal body. If the claimed invention does not impact in this manner it is unlikely to fall within the exclusion.

8.35 Section 16(3) essentially codifies that a substance or composition is considered industrially applicable even if its intended purpose is for use in a method of treatment excluded by Section 16(2).

8.36 Section 14(7) provides that a known substance or composition for use in a method of treatment excluded by Section 16(2) will be new if this use does not form part of the state of the art.

8.37 Section 14(7) sets out that:

(7) In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

8.38 Thus a "first medical use" of a known compound may be claimed, or in the case of a substance or composition that is previously known for a medical use, a different "second medical use" may be claimed.

8.39 Proper "first medical use" claims may have the following wording:

(1) Compound X for use in therapy
(2) Compound X for use as a medicament
(3) Compound X for use in the treatment of medical condition Y
(4) Compound X for use as an antibiotic
(5) The use of compound X in the manufacture of a medicament for the treatment of medical condition Y (Typical form of Swiss-type claim)

8.40 Inappropriate "first medical use" claims include, but are not limited to:

(1) The use of compound X in therapy
(2) The use of compound X as a medicament/pharmaceutical
(3) The use of compound X in the treatment of medical condition Y
(4) Compound X when used to treat medical condition Y
(5) A method of treating ….
(6) A compound X when used …

8.41 These claims are not allowable since they are construed as methods of medical treatment, which are not industrially applicable (Section 16(2)). Where appropriate, amendment to acceptable medical use claims format should be sought for claims of these types.

8.42 The following forms of "second medical use" claims are allowable:

(1) The use of compound X in the manufacture of a medicament for the treatment of medical condition Y - Typical form of Swiss-type claim.
(2) The use of compound X for the manufacture of a medicament for the therapeutic and/or prophylactic treatment of medical condition Y
(3) The use of compound X in the manufacture of an anti-Y agent in a package together with instructions for its use in the treatment of medical condition Y
(4) The use of compound X in the preparation of an anti-Y agent in ready-to-use drug form for treating or preventing medical condition Y

8.43 The following types of claim are not interpreted as "second medical use" claims:

(1) Compound X for use in the treatment of medical condition Y – this type of claim is consistent with current European "second medical use" claim practice. 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 already a known medicament..

(2) The use of compound X in the treatment of disease Y – Unpatentable method of medical treatment.

(3) A process for the manufacture of a medicament for use in the treatment of medical condition Y, characterised by the use of substance X. – worded as a method claim, but does not define any of the steps of the method.

i. Definition of therapy

8.44 Therapy refers to any treatment which is 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). The following methods will generally constitute non-patentable methods of therapy, therefore 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
(iv) Veterinary treatment of a diseased or injured animal.

8.45 In general, 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 may be regarded as therapy. This may be a Western trained doctor 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).

8.46 However, if a method has no therapeutic purpose or effect, then the fact that it may be carried out by a doctor does not render it incapable of industrial application. For example, in T 245/87 SIEMENS/Flow measurement OJEPO 1989, 171, the invention related to a method of stimulating a limb during blood collection in order to facilitate the flow of blood. The Board of Appeal 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.*
>
> *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. "

8.47 Conversely, methods for treating diseases in farm animals are excluded even if the method may routinely be carried out by the farmer rather than the veterinarian (T 116/85 WELLCOME/Pigs OJEPO 1989, 13).

ii. Claims to both therapeutic and non-therapeutic methods

8.48 In some cases a claim can be construed to include both patentable and non-patentable therapeutic methods. For example, the following claim could be construed as including a method of treating the blood in a patient as part of a non-patentable therapeutic method and also a patentable method of treating stored blood in a tube:

> "A method for inhibiting the coagulation of blood by contacting the blood with a carrier containing compounds X and Y."

8.49 In such cases the claim should be carefully construed to determine its scope. If the claims are construed as including non-patentable methods then amendment of the claims will be required to clearly limit the claims to patentable methods. Alternatively, the specification could be amended to clarify that therapeutic methods do not form part of the invention. If it is unambiguously clear from the specification that the claims relate only to patentable methods, then no amendment is required.

8.50 Disclaimers to exclude non-industrially applicable methods of treatment by therapy or surgery, or diagnosis practised on the human or animal body, are generally allowable. Any disclaimer needs to exclude therapeutic methods and leave the scope of the remaining claims clear. The term "cosmetic" in a claim to a method of treatment is generally acceptable as a sufficient limitation. 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.

8.51 However, the 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, the invention is not industrially applicable under Section 16(2). For example, it is not possible to claim a cosmetic method for the removal of plaque from teeth because the inherent therapeutic effect of removing plaque cannot be separated from the purely cosmetic effect of improving appearance of the teeth. However, 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) – some treatments may be therapeutic or cosmetic depending on the subject being treated.

iii. Some specific examples of therapeutic and non-therapeutic methods

Cosmetic treatments

8.52 Purely cosmetic treatments of the skin and hair are considered patentable inventions. For example a cosmetic treatment for strengthening hair and was considered patentable (*Joos v Commissioner of Patents* [1972] 126 CLR 611, 619). Similarly, a method of reducing normal hair loss was considered patentable once the claims were restricted to where it was carried out as a cosmetic treatment (T 453/95 REDKEN). The claim defined the application of a composition comprising a chelating agent as principal active ingredient:

> "A **cosmetic method** for reducing normal average daily hair loss characterized by periodically distributing onto the scalp of a person subject to hair loss, a composition having as the principal active ingredient an ingredient consisting essentially of a sufficient amount of active chelating agent to chelate at least 0.3 milligrams of divalent calcium per millilitre of composition, and leaving the composition in contact with the scalp for at least eight hours"

8.53 Methods of protecting the skin by simply blocking UV radiation are not considered to be therapy, but where a method produces physiological effects then it is considered to be a non-patentable therapeutic method.

Methods of hygiene, including treatment of parasites

8.54 Methods of hygiene will generally be patentable 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.

8.55 To fall with the exclusion of therapy, there must be a direct link between the treatment and the condition to be treated or prevented. For example, a method for reducing parasitic infestations by destroying the hair follicles in the skin of sheep was found patentable since it was not directly linked to a disease state (*Commonwealth Scientific & Industrial Research Organization's Application* B LO/248/04).

8.56 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 therapeutic as well (T 36/83 ROUSSEL-UCLAF/Thenoyl peroxide OJEPO 1986, 295). In this case the Board of Appeal considered that the cosmetic and therapeutic compositions were similar and as a consequence a cosmetic use may result in an incidental therapeutic effect. However, 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."

8.57 It should be noted here that the “use as” format of the claim would have been interpreted as defining a method of medical use had the claim been interpreted to include a medical effect.

Pain and addiction

8.58 The relief of pain is considered to be therapeutic, even where the pain has no pathological cause (T 81/84 RORER/Dysmenorrhoea OJEPO 1988, 202). 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 Perception of fatigue/MIT 1997) have been considered non-therapeutic.

8.59 Methods of treatment of addiction or withdrawal symptoms are considered to be therapeutic. This includes methods that assist to stop smoking.

Obesity and weight reduction

8.60 Treatment of obesity is generally considered be therapeutic. However, methods of weight reduction for purely cosmetic reasons are not considered therapeutic and hence are industrially applicable under Section 16(2) (T 144/83 DU PONT/Appetite suppressant OJEPO 1986, 30). Claims to such methods must be drafted in such a manner as to clearly relate to cosmetic weight loss only – for example the following would be allowable:

"A method of improving the body appearance..." (limited to a cosmetic method – see T 144/83 DU PONT).

"A method of improving the skeletal muscle performance of healthy subjects..." (limited to use with healthy patients – see T 1230/05 BIOENERGY).

Contraception, abortion and fertility treatment

8.61 Claims to methods of abortion, termination of pregnancy or induction of labour are not industrially applicable regardless of the reasons for treatment (*UpJohn (Kirton's) Application* [1976] RPC 324).

8.62 Methods of contraception are patentable since pregnancy is not an illness or disorder (*Schering's Application* [1971] RPC 337), but may be excluded under Section 16(2) if the method contains a therapeutic element. 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 patentable (T 820/92 GENERAL HOSPITAL/Contraceptive method OJEPO 1995, 113).

8.63 Methods of treating infertility, including methods of *in vitro* fertilisation, are considered to be therapeutic. Implantation of an *in vitro* fertilised embryo would generally involve a surgical process and therefore would not be industrially applicable under Section 16(2).

Methods relating to implanted devices

8.64 Methods relating to implants and the like may be patentable provided the claimed method does not relate to any therapeutic effect.

8.65 For example, if an invention involved regulating the output signal of an implant device and the way in which it regulated the heart rhythm, then the method would be considered therapeutic. However, if the invention was a method of monitoring the performance of the device without any changes being made to the output signal then the method would be considered patentable. Similarly, a method for measuring the flow of a drug from an implant would be patentable provided the method did not actually control the flow of the drug.

Treatments performed outside the body

8.66 A therapeutic treatment of the human or animal body may be non-industrially applicable under Section 16(2), even if the actual treatment takes place outside the body. Examples of such treatments include blood dialysis where the blood is returned to the same body after treatment. However, treatment of blood for storage in a blood bank is not regarded as therapeutic treatment.

Treatment of stock animals

8.67 The treatment of stock animals in order to improve their meat or increase production of milk, eggs or the like is not regarded as therapy even if the substances concerned may have therapeutic benefits. The claims should clearly be limited to the non-therapeutic aspects.

8.68 However, if the benefit is a consequence of a therapeutic treatment, for example eradication of an internal parasite that provides weight gain, then such a method is not considered to be industrially applicable under Section 16(2).

iv. Claims for packs or kits of medicines

8.69 Claims directed to kits of active ingredients may be patentable provided the defined kit is purpose limited (T 09/81 ASTA/Cytostatic combination OJEPO 1983, 372). Thus the claim must be in a first or second-medical use format, or defined in such a way that there is a functional relationship between the integers in the kit that necessarily provides the invention (see for example, *Organon Laboratories Ltd.'s Application* [1970] RPC 574) in which the invention lay in arranging the pills in a particular order on a card). A claim which is characterised by a set of instructions to carry out the treatment will not be patentable since the contribution to the art is merely a presentation of written information.

v. Surgery

8.70 Surgery refers to the treatment or manipulation of the body using operative manual, instrumental and/or robotic techniques.

8.71 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.

8.72 Claims to methods of surgery should be objected to regardless of their purpose. To decide on whether a claim refers to a surgical method, the claim should be assessed on its technical features, and not on the intention of the person using the method. Surgery is not only limited to therapeutic surgery. Therefore, a method of surgery for cosmetic purposes is also considered non-industrially applicable under Section 16(2).

8.73 Excluded surgical methods embraced any physical interventions performed on the body in which maintaining the life and health of the subject was of paramount importance. It is to be noted that interventions which result in the death of the subject (e.g. slaughter of farm animals or sacrifice of laboratory animals) are not considered surgery.

8.74 Surgery includes, but not limited to methods such as:

(i) Endoscopy;
(ii) Excision;
(iii) Catheterization;
(iv) Cutting the body;
(v) "Closed surgery", such as setting of broken bones or relocating dislocated joints;
(vi) Embryo implantation that requires the intervention of a surgeon or a veterinary surgeon;
(vii) Dental surgery;
(viii) Any implanting or insertion of devices by surgical means;
(ix) Insertion of devices into respiratory cavities (without incision); and
(x) Puncture/injections that require specialist medical skills, such as lumbar

punctures to deliver epidural injections.

The examples mentioned above are unpatentable as they are not industrially applicable under Section 16(2).

8.75 On the other hand, the following procedures are generally not considered as "surgery", and therefore, are not excluded from industrial applicability under Section 16(2):

(i) Simple injection methods, either for taking blood samples or introducing compositions;
(ii) Method that does not require medical skills or knowledge, such as cosmetic ear-piercing, or a method of tattooing the body;
(iii) Method to measure, make and apply a plaster cast;
(iv) Method of making artificial limbs;
(v) Method involving the internal operation of implanted devices, or the interaction between the implanted device and an external user or system, if they do not relate to the implantation of the device and do not impact on the body. The fact that the device needs to have been implanted by surgical means prior to performing the claimed method does not render the claim non-industrially applicable;
(vi) A method carried out on a dead body; and
(vii) Interventions which result in the death of the subject (e.g. sacrifice of laboratory animals).

8.76 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". If such cases arise then it will not be industrially applicable under Section 16(2) either.

vi. Diagnosis

8.77 Section 16(2) relates to methods of diagnosis practiced on the human or animal body.

8.78 Diagnosis includes the identification of a disease state, but also includes methods identifying the absence of such a disease state.

8.79 The process of diagnosis involves four steps leading towards identification of a condition (G 01/04 Diagnostic Methods [2006] 5 OJEPO 334, [2006] EPOR 15):

(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.

8.80 This is a narrow consideration – only methods comprising all four of these steps will be excluded from industrial applicability under Section 16(2).

8.81 In general the key consideration will involve the first collection step (1) since this is most likely to be the one performed on the human or animal body in an excluded diagnostic method. In general if the test requires the presence of the patient it will be considered as being practiced on the human or animal body. However a claim to an *in vitro* diagnostic method carried out on a sample taken from the body will be allowable provided the claim clearly does not include the collection step.

8.82 Furthermore, a diagnostic method requires a deductive step (4). Notably the omission of such a step from the claim may overcome an objection under Section 16(2), but may result in an objection under Section 25(5)(c) if an essential feature of the invention is not defined. However, in some cases the method may be useful in diagnosing a disease but will not provide sufficient information itself to enable a diagnosis. This will include techniques such as: a method of imaging using CT scanning (T 09/04 KONONKLIJKE PHILIPS ELECTRONICS), a method of measuring blood glucose (T 330/03 ABBOTT LABORATORIES) and a method of assessing tissue viability by measuring total haemoglobin, oxygen saturation and hydration (T 41/04 NATIONAL RESEARCH COUNCIL OF CANADA).

8.83 The intermediate analytic steps (2) and (3) may be considered implicit in any diagnostic method. As a consequence even if a claim does not include these steps, if steps (1) and (4) are present, then the claim would not be allowable.

8.84 A method is not 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. For example, methods such as fitness tests and the like would be considered patentable.

8.85 The claim does not necessarily specify that a particular disease is diagnosed, this may be implicit if the specification indicates that by following a particular method then that particular disease may be diagnosed. However, the narrow interpretation of diagnosis requires that a method 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 BRUKER/Non-invasive measurement OJEPO 1988, 308).

8.86 Section 16(2) requires that a diagnostic method be carried out on a living human or animal body. A method carried out on a dead body, for example to determine the cause of death, would not be objectionable.

8.87 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 "practiced on the human or animal body". It is not dependent on who carries out the method, or whether a physician needs to be present.

8.88 *In vivo* methods of testing pharmacological efficacy or toxicity of drugs, or experimental methods of investigating diseases in animals are not considered to be methods of diagnosis as defined in Section 16(2). However, such claims should be examined carefully to determine whether they fall under the definition of a method of therapy or surgery.

8.89 In Singapore, it is not a consideration under Section 16(2) whether a method would cause suffering to an animal.

D. Morality

8.90 Section 13(2) states that inventions which would encourage offensive, immoral or anti-social behaviour if published or exploited are not patentable.

8.91 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.

8.92 Inventions may have offensive uses – for example, a weapon could be used inappropriately – but otherwise may have legitimate uses. In such cases no objection is raised under Section 13(2). However, if the specification explicitly refers to offensive uses of an invention, then the specification should be amended to remove these references.

8.93 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 on the basis of Section 13(2). For example, the product could be manufactured in Singapore for export to a country where such prohibitions do not apply.

i. Human cloning

8.94 The prohibition of human reproductive cloning was codified into law (that is, the Human Cloning and Other Prohibited Practices Act) 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.

8.95 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."*

8.96 Following the BAC report, the Human Cloning and Other Prohibited Practices Act 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."*

ii. Patentability of genes, genetic material and embryos

8.97 The issue of morality under Section 13(2) should be considered when assessing inventions relating to genes.

8.98 In *Howard Florey Institute [Relaxin], V8/94 Relaxin, OJ EPO 6/1995*, the invention is directed to mRNA isolated from tissue taken from pregnant women with consent. The Opposition Division of the EPO held that DNA is not "life", but a chemical substance which carries genetic information and can be used as an intermediate in the production of proteins which may be medically useful. The patenting of a single human gene therefore has nothing to do with the patenting of human life – even if every gene in the human genome was cloned (and possibly patented), it would be impossible to reconstitute a human being from the sum of its genes. Thus where the subject matter involves genes *per se*, the Examiner should proceed to assess whether it meets the section 13(1) requirements. A Section 13(2) issue does not arise.

8.99 Inventions relating to transgenic and/or chimeric animals should be assessed accordingly. In Singapore, paragraph 14 of the BAC's Consultation Paper on Human-Animal Combinations for Biomedical Research, acknowledged that:

> *"...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. "*

8.100 In the absence of local laws prohibiting the creation of such transgenic non-human mammals coupled with the scientific and medical benefits arising from such research involving the use of these transgenic non-human mammals, mere offence to a section of the public, in the sense that that section of the public would consider the invention 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 or where the public need protection from the publication or exploitation of the inventions. Inventions involving transgenic animals generally do not attract a Section 13(2) objection. Similarly, a chimera is an animal or a human whose body contains cells or tissues from another animal or human. Thus a person with a pig heart valve transplant is, strictly speaking, a chimera. Chimeras are usually created in research by introducing human cells such as stem cells into an animal, or an animal embryo or foetus. Only in the clearest cases should Section 13(2) be invoked if the general public would regard the invention as abhorrent or from which the public need protection.

8.101 The use of the human embryos for commercial or industrial purposes is not patentable under the UK Patents Act Schedule A2 and European Directive 98/44/EC. However, there are no specific provisions governing the patentability of human embryos and their products in Singapore patent law. The use of human embryos is governed under the Singapore Human Cloning and other Prohibited Practices Act which prohibits the use of human embryos after 14 days of its fertilisation. Methods for generating human embryonic stem cell lines as well as methods where human blastocysts (an early stage of the embryo) are generated from fertilised human oocytes should therefore not run foul with the Human Cloning and Other Prohibited Practices Act. However, such inventions will be considered on a case by case basis.