

REQUIREMENTS FOR INVENTIVE STEP AND SUFFICIENCY OF DISCLOSURE AT IPOS

1. INVENTIVE STEP

1.1. National Legislation

Singapore Patents Act 1994 (SPA) Section 13(1)(b) states that a patentable invention is one that involves an inventive step.

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).

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

(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.

1.2. Patent Examination Guidelines (the Guidelines) and Court Decisions

1.2.1. The definition of a person skilled in the art

In inventive step assessment, any piece of prior art must be viewed through the eyes of the person skilled in the art at the priority date. A significant issue in examination is the use of hindsight or *ex post facto* analysis. The Examiner should attempt to place himself 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.

Chapter 2 of the Guidelines elaborates the definition of a person skilled in the art when dealing with construction of the specification and claims. The same definition is applicable to assessment of the inventive step. The notional skilled 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.

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.”

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.

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.

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.

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. In most cases an assertion that certain information forms part of common general knowledge should be supported by documentary evidence. 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 Ipcor* [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.

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. 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.

Further information can be found in paragraphs 2.21-2.33 of the [Examination Guidelines for Patent Applications at IPO](#).

1.2.2. Methodologies employed for evaluating the inventive step

The test set out in *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 (the Windsurfing test) 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.

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.”

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.

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” as set out in Section 14(2) and use such a term in the objection.

Examiners may also use the modified Windsurfing test i.e. the Pozzoli approach when formulating an inventive step objection, although this modified test has not formally been adopted by the Singapore Courts. The Pozzoli approach was elaborated upon by Jacob LJ in *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588. In any case the differences are essentially in form rather than substance.

Further information can be found in paragraphs 4.18-4.24 of the [Examination Guidelines for Patent Applications at IPOS](#).

1.2.3. Having regard to the prior art, the level of inventiveness (obviousness) to meet the inventive step requirement

Wherever possible, the principles of the Windsurfing test should be followed in examination. 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.’”

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.

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.”

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).

“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). 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”

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.”

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”.

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.”*

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.

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)”.*

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.”

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.”

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."

Furthermore, 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)

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".

Further information can be found in paragraphs 4.4-4.24 and 4.38-4.101 of the [Examination Guidelines for Patent Applications at IPO](#).

2. SUFFICIENCY OF DISCLOSURE

2.1. National Legislation

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.

Enabling disclosure requirement is set out in Section 25(4) which states 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.

Support requirement is set out in Section 25(5)(c) which states that the claim or claims shall be supported by the description.

Besides the above provisions, Subsection 25(5)(a) requires that the claim or claims shall define the matter for which the applicant seeks protection. Subsection 25(5)(b) requires that the claim or claims shall be clear and concise. Rule 19 expands upon these formality and substantive requirements.

2.2. Patent Examination Guidelines (the Guidelines) and Court Decisions

2.2.1. Enabling disclosure requirement

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. Section 25(4) requires that the specification contain

enough information to allow the skilled person to repeat the invention. 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.”

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.

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).

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 meantime and can be considered under Section 25(5)(c).

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.

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).

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.

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).

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. The Court also stated at [49] 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.”

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.

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.

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).

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.”

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).

The skilled person can include a group or team of such persons. 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).

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.”

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.

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).

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.

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. 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.

Further information can be found in paragraphs 5.21-5.32, 5.76-5.81 and 5.102-5.113 of the [Examination Guidelines for Patent Applications at IPOS](#).

2.2.2. Support requirement

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).

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.”*

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.

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]).

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.

The Guidelines also provide guidance on how to deal with various cases relating to the support requirement, e.g. whether mere coincidence of language between the claims and description is sufficient, whether the breadth of the claim could exceed the technical contribution to the art of the invention, overlapping of the enablement requirement and the

support requirement, inconsistency between the claims and description, claims by result, features defined by function, parametric claims and reach-through claims.

Further information can be found in paragraphs 5.56-5.101 of the [Examination Guidelines for Patent Applications at IPOS](#).