

Standing Committee on the Law of Patents

Twenty-Second Session
Geneva, July 27 to 31, 2015

STUDY ON THE SUFFICIENCY OF DISCLOSURE

Document prepared by the Secretariat

INTRODUCTION

1. At its twenty-first session, held from November 3 to 7, 2014, the Standing Committee on the Law of Patents (SCP) confirmed that, in accordance with the agreement made at its twentieth session, a study on the sufficiency of disclosure would be prepared by the Secretariat and be submitted to the twenty-second session of the SCP. The Committee agreed that the study would contain the following elements: (i) the enabling disclosure requirement; (ii) support requirement; and (iii) the written description requirement. The Committee also agreed that the study would be based on the information provided by Member States, and would be a collection of factual information without analysis or recommendation.

2. Pursuant to the above decision, the Secretariat invited Member States and Regional Patent Offices, through Note C. 8403, dated December 15, 2014, to submit information to the International Bureau on the requirements of the sufficiency of disclosure, as indicated above. In total, 58 Member States and three regional patent offices provided their applicable laws in relation to the requirement of sufficiency of disclosure.¹ Taking into account the submitted information, the Secretariat prepared a study on the sufficiency of disclosure, which is contained in this document.²

¹ The information received from Member States and the Regional Patent Offices is available on the website of the SCP electronic forum at: <http://www.wipo.int/scp/en/meetings/>.

² The information received included national and regional legislation, court decisions, patent examination manuals and guidelines. They were generally referred to as “applicable law” where the precision of the type of the legal source was not necessary. As regards the patent examination manuals and guidelines, while they are used intensively throughout the document, they do not constitute substantive rulemaking and hence do not have the force and effect of law. In general, such manuals and guidelines are simply designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law.

3. As mandated by the Committee, the document focuses on the listed three requirements. By doing so, the document provides information on their main general principles, and does not provide information on how these three requirements are applied in the specific areas of technology (e.g., chemistry). Furthermore, this document does not address other formal and substantive requirements which are related to the sufficiency of disclosure but nevertheless are not within the mandated scope of the study, such as, the requirements regarding the manner and order of drafting the description or drawings, or requirements relating to kinds of claims, clarity of claims, interpretation of claims, etc.

THE ENABLING DISCLOSURE REQUIREMENT

4. In general, the wording of the relevant provisions in most of the laws is largely similar and reflects Article 29.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which states:

“Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art [...].”

5. For example, the following wordings for this requirement are found in the applicable laws:

- the specification shall include “a description of the manner of performing the invention, as to enable the skilled person to perform said invention”;³
- an applicant must disclose the invention in a “sufficiently clear and comprehensive manner”;⁴ or in a manner which is “clear enough and complete enough”⁵ or “sufficiently clear and precise”⁶ for the invention to be performed by a person skilled in the relevant art;
- a complete specification shall “fully describe the invention and the manner in which it is to be performed”;⁷ or
- “the specification shall fully and particularly describe the invention and the methods by which it is to be performed”.⁸

6. In the United States of America, Title 35 of the United States Code, Section 112(a) states “[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same [...]”.⁹ In sum, the applicable laws use the adjectives “clear”, “comprehensive”, “complete”, “full”, “concise”, “precise”, or “exact” in order to characterize the nature of the disclosure, and at the same time, clarify that the disclosure is required to the extent that a person skilled in the art can carry out or perform the claimed invention.

7. As regards the substantive elements of the enabling disclosure, a great amount of similarity of the laws and office practices in the examination guidelines was observed. In addition, similar explanations and examples are found in the PCT International Search and Preliminary Examination Guidelines and the examination guidelines of some patent offices. At

³ Section 12(a) of the Israel Patent Law.

⁴ Article 6.4 of Law No.6867 of Costa Rica.

⁵ Section 40 of the Patents Act 1990 of Australia.

⁶ Article 20 of the Patent Act of Croatia.

⁷ Section 14 of the Patent Act of Zambia.

⁸ Chapter IV of the Pakistan Patents Ordinance 2000.

⁹ Section 112(a), Title 35, of the United States Code.

least one office examination guidelines states that the provision on enabling disclosure is intended to have, as nearly as practicable, the same effect as the corresponding provisions of, *inter alia*, the Patent Cooperation Treaty.¹⁰

8. In general, in relation to the purpose of the disclosure requirement, patent holders are given exclusive rights to prevent others from commercial exploitation of the patented inventions and, in return for such rights, they are required to disclose information relating to the invention. This public disclosure function of the patent system is considered as one of the important rationales of the patent system and one of the pillars that justifies the system. It is through the disclosure requirement that the patent system facilitates the dissemination of information and access to technological knowledge contained in the patent application. This results in the expansion of public stocks of technical knowledge and an increase in the overall social benefits, for example, inducing the technology transfer and avoiding a duplicative R&D.

9. The above stated rationale was also highlighted in the administrative guidelines of some Member States, noting that the enabling disclosure requirement “reflects a fundamental principle of international patent law that, in exchange for the exclusive rights given to the patentee, the patentee must share with the public the information necessary to make and use the invention”¹¹ or “[t]he purpose of the enablement requirement is to ensure that the specification sufficiently describes an invention in such terms that one skilled in the art can make and use the claimed invention and that the invention is communicated to the interested public in a meaningful way.”¹² In Israel, the requirement for sufficiency of disclosure, in general, was explained to be intended to “ensure that on the effective date the inventor indeed had possession of the claimed invention and to ensure the right of the interested public to know the scope of the invention and the manner and means of performing it. This allows exploiting the invention after patent expiration or under a license given by the patentee as well as preventing discouragement research in the relevant field”.¹³

Requirements regarding the description

10. The description part of a patent application discloses the invention, clarifies the technical field in which it lies with regard to the prior art, and provides indications allowing a person skilled in the art to carry out the invention.

11. The requirements regarding the manner and order of drafting the description may differ from one country to another. In general, as regards the manner of drafting the description, the requirements under many applicable laws, in general, are that the contents of the description shall be clear and definite and without any ambiguity, vagueness or self-contradiction.¹⁴ Any such error may result in non-compliance with, *inter alia*, the enablement requirement.

¹⁰ See Section 14.58 of the Manual of Patent Practice of the Intellectual Property Office of the United Kingdom.

¹¹ Section 2.11.3A of the Patent Manual of Practice and Procedure of the IP Office of Australia.

¹² Chapter 2164 of the Manual of Patent Examining Procedure of the United States Patent and Trademark Office (USPTO).

¹³ Hughes Aircraft Company vs. The State of Israel, CA 345/87, (2.7.1990); (Akerstein et al. vs. Alumim et al., CA 21/83 (31.12.1983).

¹⁴ Paragraph 4.22 of the PCT International Search and Preliminary Examination Guidelines captures a number of common elements regarding such requirements found under the various laws: “The description should be clear and straightforward with avoidance of unnecessary technical jargon. In general, only such technical terms, signs and symbols should be used as are generally accepted in the art. Little known or specially formulated technical terms may be allowed, provided that they are adequately defined and that there is no generally recognized equivalent. This discretion may be extended to foreign terms when there is no equivalent in the language of the international application. Terms already having an established meaning must not be used to mean something different as this is likely to cause confusion. There may be circumstances where a term may legitimately be borrowed from an analogous art. Terminology and signs should be consistent throughout the international application.”

Test for enablement requirement

12. In many countries, the relevant provisions state that in order to fulfill the requirement for an enabling disclosure, the “application”, “description” or “specification” must provide sufficient information so that the person skilled in the art can, on the basis of the information disclosed in the application as filed and the common general knowledge in the art, perform the invention without “undue burden” and/or “any inventive effort” or “undue experimentation”.¹⁵

13. However, while a person skilled in the art, using his common general knowledge, should be able to carry out the invention without undue burden, certain amount of trial and error is generally admissible in most of the countries. For example, some laws state that trial and error “to a reasonable extent” or “reasonable number of experiments” is acceptable to comply with the requirement of enabling disclosure.¹⁶ In this regard, in the submission of Australia, it is also explained that “[w]hile it is acceptable that the skilled person would need to use a reasonable amount of trial and error, there must be either adequate instructions in the specification, or basis in the common general knowledge in the art, to lead the skilled addressee towards success, through evaluation of initial failures.”

Undue burden

General description

14. While the terms “undue burden”, “any inventive effort” or “undue experimentation” may be interpreted differently in various jurisdictions, generally, the factors to be considered in determining whether undue experimentation is needed to carry out the claimed invention include:

- (i) the breadth of the claims;
- (ii) the nature of the invention;
- (iii) the general knowledge of a person skilled in the art;
- (iv) the level of predictability in the art;
- (v) the amount of direction provided in the application, including references to prior art; and
- (vi) the amount of experimentation required to carry out the claimed invention on the basis of the disclosure.

15. Those factors are also found in the PCT International Search and Preliminary Examination Guidelines which provide the below explanation in relation to each factor.¹⁷

16. The breadth of the claims is relevant to the determination of undue experimentation, since a person skilled in the art must be able to carry out the entire scope of the claimed invention. For example, the applicant is not entitled to claim everything within the scope of the invention, if

¹⁵ See, for example, Article 34 of Law 17-97 of Morocco; Section 2.11.3A of the Patent Manual of Practice and Procedure of the IP Office of Australia; and Case Law of the Boards of Appeal of the EPO: T 629/05 and T 79/08.

¹⁶ For example, in Japan, if a person skilled in the art who intends to work the invention would have to make trials and errors, beyond the reasonably-expected extent, such explanation of the invention should be deemed insufficient (Examination Guidelines Chapter I, Section 3.2).

¹⁷ Paragraph 5.47 of the PCT International Search and Preliminary Examination Guidelines.

the application only discloses how to carry out part of the claimed invention. However, even in unpredictable arts, it is not necessary to provide examples covering every possible variation within the scope of a claim. Representative examples together with an explanation of how these can be applied to the scope of the claim as a whole will ordinarily be sufficient if a person skilled in the art could carry out the claimed invention without undue experimentation.

17. The subject matter to which the claimed invention pertains is essential to determine the general knowledge of a person skilled in the art and the state of the art. For example, if the selection of the values for various parameters is a matter of routine for a person skilled in the art, such a selection may not be considered as requiring undue experimentation.

18. “The amount of direction provided in the application” refers to the information explicitly or implicitly contained in the description, claims and drawings, including working examples and references to other applications or documents. The more about the nature of the invention is known in the prior art by a person skilled in the art and the more the art is predictable, the less information in the application itself is needed in order to carry out the claimed invention. For example, there is predictability in the art if a person skilled in the art can readily anticipate the effect of a feature of the claimed invention.

19. In addition to the time and expenses needed for carrying out the experimentation, the character of the experimentation, for example, whether it constitutes merely routine work or goes beyond such routine, is also considered.¹⁸

National practices

20. Some countries’ case law and examination guidelines provided further insight on the test of enabling disclosure applied and how the terms “undue burden”, “any inventive effort” or “undue experimentation” should be interpreted in those respective countries.

21. For example, in Australia, in order to comply with the enablement requirement, the complete specification must provide sufficient information to enable the skilled person to perform the invention over the whole width of the claims, without undue burden or the need for further invention. The test for “a clear enough and complete enough disclosure” was provided by Lord Hoffmann as follows: “[w]hether the specification is sufficient or not is highly sensitive to the nature of the invention. The first step is to identify the invention and decide what it claims to enable the skilled person to do. Then one can ask whether the specification enables them to do it.”¹⁹

22. In relation to “undue burden”, section 2.11.3.4A of the Patent Manual of Practice and Procedure of the IP Australia states: “[i]n considering whether performing the invention would constitute an undue burden, regard should be had to the nature of the invention, and the abilities of the person skilled in the art in which the invention has been made. The question can then be asked whether the specification requires the skilled addressee to carry out tests or developments that go beyond the routine. Where it is prima facie apparent that the skilled addressee, seeking to perform the claimed invention following the directions in the complete specification, would take considerably longer than would be typically expected in the art given the nature of the invention, and/or that inventive ingenuity would be required, this would constitute an undue burden.”

¹⁸ Paragraphs 5.48-5, *Ibid.*

¹⁹ Subsection 40(2)(a) of the Patents Act of Australia requires that a complete specification must “(a) disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art;” See *Kirin-Amgen Inc v Hoechst Marion Roussel* [2004] UKHL 46; [2005] RPC 9 at [103].

23. In the United States of America, the standard for determining whether the specification meets the enablement requirement was stated in the Supreme Court decision of *Mineral Separation v. Hyde* according to which the central inquiry in determining whether a claim is enabled is whether that experimentation is “undue or unreasonable”. Whether the experimentation is “undue” is determined by several factors, which include: (i) the breadth of the claims; (ii) the nature of the invention; (iii) the state of the prior art; (iv) the level of one of ordinary skill; (v) the level of predictability in the art; (vi) the amount of direction provided by the inventor; (vii) the existence of working examples; and (viii) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Section 2164.01 of the Manual of Patent Examining Procedure (MPEP) of the United States Patent and Trademark Office (USPTO) further notes that “[i]t is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner’s analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole.”

24. The general principles relating to undue experimentation in the United Kingdom were stated as follows: “[t]he 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.”²⁰

25. According to case law in France, disclosure is insufficient if it does not allow a person skilled in the art to carry out the subject matter of the invention or arrive at the expected result using his professional knowledge alone and by carrying out simple operations that do not involve excessive difficulty. Insufficiency of disclosure can thus be recognized when the description is imprecise, ambiguous or contains errors.²¹ Also a disclosure is insufficient when approximative elements that make reading insufficient for a person skilled in the art to carry out the invention or when the described invention cannot be carried out technically by a person skilled in the art²² because the fundamental characteristic required to carry out that invention were affected.

26. French case law recognizes, however, that when evaluating sufficiency of disclosure, it is necessary to take into account not only essential technical information mentioned in the text of the patent application but also secondary information which can be deduced therefrom and

²⁰ Aldous J in *Mentor v Hollister* [1993] RPC 7. In addition, in *Eli Lilly & Co. v Human Genome Sciences Inc* the court stated that 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).

²¹ However, the Court of Cassation in France, in its decision of March 22, 2005, found that an error in the description of a traditional production method (mascara brush) did not nullify the patent on the grounds of insufficiency of disclosure since a person skilled in the art was easily able to rectify the error (N° de pourvoi: 03-16532, March 22, 2005).

²² See the decision of the Appeal Court of Paris, 4th Division B, of May 20, 2005, in which the Judge nullified Claim No.1 of a patent for insufficiency of disclosure on the grounds that it did not indicate certain technical conditions that were essential to carry out the invention by a person skilled in the art.

which a person skilled in the art can find himself when reading prior art documents.²³ Drawing from prior art can therefore mitigate apparent insufficiency of disclosure.

27. In Germany, “only what can be “directly and unambiguously” derived from the originally filed documents forms part of the disclosure of the patent application, not however any further knowledge at which the skilled person may arrive based on his common general knowledge or by modifying the disclosed teaching.”²⁴

28. In Singapore, 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.

29. In addition, examination guidelines of some offices provide examples where the enabling disclosure requirement, as provided in the respective country, would not be met. For example, in China, the Guidelines for Patent Examination provide the following examples:²⁵ (i) the description sets forth only a task and/or an assumption, or simply expresses a wish and/or a result, providing no technical means that a person skilled in the art can implement; (ii) the description sets forth a technical means, but the means is so ambiguous and vague that a person skilled in the art cannot concretely implement it according to the contents of the description; (iii) the description sets forth a technical means, but a person skilled in the art cannot solve the technical problem of the invention or utility model by adopting said means; (iv) the subject matter of an application is a technical solution consisting of several technical means, but one of the means cannot be implemented by a person skilled in the art according to the contents of the description; and (v) the description sets forth a concrete technical solution but without experimental evidence, while the solution can only be established upon confirmation by experimental results. For example, in general, the invention of a new use for a known compound requires experimental evidence in the description to validate the new use and effects thereof: otherwise, the requirement of enablement cannot be met.

30. In Japan, a non-compliance with the enablement requirement is found in the following cases: (i) improper statement of modes for carrying out the invention; and (ii) part of claims not supported by a mode for carrying out the invention.²⁶

The disclosure of essential and well-known features

31. In general, according to the practice of many of the patent offices, in order to meet the requirement of the enabling disclosure, the description shall indicate at least one way for the skilled person to carry out the invention, using examples where appropriate and referring to the drawings, if any.²⁷ Since the application is addressed to the person skilled in the art, it is neither necessary nor desirable that details of well-known ancillary features should be given, but the description must disclose any feature essential for carrying out the invention in sufficient details to render it apparent to the skilled person how to put the invention into practice without undue burden or experimentation and without needing inventive skill.²⁸

²³

Ibid.

²⁴

German Federal Court of Justice, 8 July 2010 - Xa ZR 124/07 – Fälschungssicheres Dokument - GRUR 2010, 910.

²⁵

Section 2.1.3, Chapter 2, Part II of the Guidelines for Patent Examination.

²⁶

Section 3.2.2, Chapter I of the Examination Guidelines.

²⁷

In some countries, the term “mode for carrying out the invention” is used. See, e.g., Japan.

²⁸

See, e.g., the submission from Singapore: “[...] 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 [...] absolute clarity and completeness are not required”. See also Part F, Chapter III-5.2 of the Guidelines for Examination of the EPO:

[Footnote continued on next page]

32. In addition, some office examination guidelines further clarify that along with well-known ancillary features, it is neither required to state inventions that are not claimed nor those extra matters that are unnecessary for carrying out the claimed invention.²⁹ It is also unnecessary that the description provides all the details needed for producing the invention on a commercial basis and reveal indications for the practical execution of the invention, i.e. execution of industrial know-how. The description needs only to contain indications necessary for carrying out the invention.³⁰

33. Any embodiment of the invention, as defined in the broadest claim, must be capable of being realized on the basis of the disclosure. This implies in particular that an objection of insufficiency could be raised against the subject matter of any claim, independent or dependent.

Provision of examples

34. In general, according to practices of many patent offices, a provision of a single example may be sufficient to satisfy the requirements of enabling disclosure. However, where the claims are broad, it is more likely that the specification will need to give a number of examples, or describe alternative embodiments or variations, extending over the whole scope of the claims. However, in some cases, even broad claims can be substantiated by a limited number of examples. As explained in the submission of Denmark, a “single example may suffice, but where the claims cover a broad field, the application should not usually be regarded as satisfying the requirements unless the description gives a number of examples or describes alternative embodiments or variations extending over the area protected by the claims. However, regard must be given to the facts and evidence of the particular case. There are some instances where even a very broad field is sufficiently exemplified by a limited number of examples or even one example. In these latter cases the application must contain, in addition to the examples, sufficient information to allow the person skilled in the art, using his common general knowledge, to perform the invention over the whole area claimed without undue burden and without needing inventive skill.”^{31,32}

[Footnote continued from previous page]

“[...] the specification does not need to describe all the details of the operations to be carried out by the person skilled in the art on the basis of the instructions given, if these details are well-known and clear from the definition of the class of the claims or on the basis of common general knowledge.”

²⁹ See, e.g., Examination Guidelines Chapter I, Section 3.2 of the Japan Patent Office.

³⁰ See, e.g., the submission from the African Intellectual Property Organization (OAPI). In this regard, Section 14.71 of the Manual of Patent Practice of the Intellectual Property Office of the United Kingdom states: “In *Mentor Corporation v Hollister Inc.* [1993] RPC 7 (at page 17 lines 4-14) it was accepted that it was enough that the patent allowed a “workable prototype” to be arrived at with comparative ease [...] and the requirement was not to produce a “successful commercial product”. Similarly, the fact that a specification does not refer to a step which may well be useful for the purpose of being able to reproduce consistently reliable products of commercial quality and range does not render the disclosure incomplete provided that the directions in the specification lead to a product which has “patent utility”, i.e. is suitable for and fulfils the purpose for which the specification states it is intended [...].”

³¹ The response further clarifies that, in this context, the “whole area claimed” is to be understood as substantially any embodiment falling within the ambit of a claim, even though a limited amount of trial and error may be permissible, e.g., in an unexplored field or when there are many technical difficulties. See also Part F, Chapter III-1.1 of the Guidelines for Examination of the EPO.

³² Similarly, Section 2.11.3.4 A of the Patent Manual of Practice and Procedure of IP Australia states “[a] specification that provides a single example of the invention may satisfy the requirements of a clear enough and complete enough disclosure, but only where the skilled person can extend the teaching of the specification to produce the invention across the full width of the claims, without undue burden, or the need for further invention. However, where the claims are broad, it is more likely that the specification will need to give a number of examples, or describe alternative embodiments or variations, extending over the whole scope of the claims. This ensures that the monopoly extends to that which could reasonably be said to be disclosed and no further.”

35. In this regard, the Examination Guidelines of the Japan Patent Office states that, in cases where it is possible to explain the invention so as to enable a person skilled in the art to carry out the invention based on the statements of the description and drawings, as well as the common general knowledge as of the filing, neither embodiments nor working examples are necessary.³³ In China, the examination guidelines explain that: “the number of embodiments shall be determined in accordance with the nature of the invention, the technical field to which the invention pertains, the state of the prior art and the claimed extent of patent protection”.³⁴

Assessment on the basis of the application/specification as a whole

36. As regards the part of the application relevant for assessing the enablement disclosure requirement, some laws state that the enabling disclosure requirement must be assessed on the basis of the “application as a whole”, including the description, claims and drawings,³⁵ while other laws refer to the “specification as a whole” containing the description, claims and drawings.³⁶

Specification must be enabling as of the filing date

37. The requirement that the specification shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art must be satisfied at the time of filing the specification. In other words, the disclosure must be enabling for a person skilled in the art at the time of the filing date, and not at a later time, for example, at the time of the search and examination. In general, if the disclosure is seriously insufficient, such a deficiency cannot be cured subsequently by adding further examples or features, as a patent application cannot be amended in a way that it contains subject-matter which extends beyond the disclosure in the application as filed.³⁷

38. In general, whether the specification would have been enabling as of the filing date involves consideration of the nature of the invention, the state of the prior art, and the level of skill in the art. The initial inquiry is into the nature of the invention, i.e., the subject matter to which the claimed invention pertains. The nature of the invention becomes the backdrop to determine the state of the art and the level of skill possessed by one skilled in the art.

³³ Chapter I, Section 3.2.1 of the Examination Guidelines of the Japan Patent Office.

³⁴ Examination Guidelines Part II, Chapter II, Section 2.2.6.

³⁵ The submission from the Russian Federation states that “the requirement of sufficiency of disclosure in the application covers the description, claims and drawings [...]”. The submission from Australia states both “section 40(2)(a) [the enabling disclosure] and sec 40(3) [the support requirement] require the specification to provide an enabling disclosure of the claimed invention. Under sec 40(2)(a), the clear enough and complete enough (enabling) disclosure must be found in the complete specification. In contrast, for section 40(3), the enabling disclosure supporting the claims must be found in the body of the specification (the description and any drawings and sequence listing).” The German Federal Court of Justice stated that the patent claim did not have to contain the indications necessary for the skilled person to carry out the protected teaching but it was sufficient that they result from the content of the patent specification as a whole (German Federal Court of Justice, 1 October 2002 - X ZR 112/99 - Kupplungsvorrichtung II - GRUR 2003, 223). The submission from the EPO states that the “disclosure does not have to be contained completely in the description. Other parts of the application, i.e. the claims and the drawings may also contribute to the disclosure”. Further, in T 32/84 (OJ 1986, 9) it was pointed out that the fact that certain elements of an invention essential to its operation were not referred to explicitly either in the claims, or in the relevant portion of the description nor shown in the drawing of the invention as claimed did not necessarily mean that the application did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art as required by Art. 83 EPC 1973.

³⁶ See, e.g., Section 14.60 of the Manual of Patent Practice of the Intellectual Property Office of the United Kingdom.

³⁷ Therefore, in such circumstances, the application normally is refused. If, however, the deficiency arises only in respect of some embodiments of the invention and not others, it could be remedied by restricting the claims to correspond to the sufficiently described embodiments only, the description of the remaining embodiments being deleted. See, e.g., Part F, Chapter III-2 of the Guidelines for Examination of the EPO.

39. The state of the prior art is what one skilled in the art would have known, at the time the application was filed, about the subject matter to which the claimed invention pertains. In general, the relevant art should be defined in terms of the problem to be solved rather than in terms of, for example, the technology area, industry or trade for which the invention is used.³⁸ The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement.

40. The state of the art for a given technology is not static in time. It is entirely possible that a disclosure which would not have been enabled if filed on January 2, 1990 might be enabled if the same disclosure had been filed on January 2, 1996. Therefore, the state of the art must be evaluated for each application based on its filing date.³⁹ A specification that is insufficient at the time of filing cannot be made sufficient by subsequent developments in the art.

41. In general, an examiner should not use post-filing date references to demonstrate that a patent is not enabled. The court in the United States of America stated that exceptions to this rule could occur if a later-dated reference provides evidence of what one skilled in the art would have known on or before the effective filing date of the patent application.⁴⁰

42. In Spain, with regards to the date of disclosure of the results of clinical trials, the Madrid Provincial Court stated that in European law, "it is not always necessary for the results of clinical trials to be given on the [filing] date; what is required, however, is that the patent/application supplies certain information relating to a direct effect of the claimed compound on a metabolic process specifically implicated in the disease. Provided this information is available in the patent/application, evidence published at a later date may be taken into account to support the description in the patent application."⁴¹

Specification must be enabling to a person skilled in the art

43. Under the enabling disclosure requirement, the applicant shall disclose the invention in a manner as provided in the applicable law so that a person skilled in the art could carry it out. In other words, this requirement is evaluated in relation to a person skilled in the art.

44. In general, the term "a person skilled in the art" refers to an ordinary skilled person who has good knowledge and specialization in the relevant field but who is not necessarily an expert in the field.⁴² This allows for a simplified description since it can be assumed that the reader will be an informed reader having the background knowledge which makes it unnecessary to describe every basic detail of the invention.

45. In many countries, the person skilled in the art who acts as a reference for the evaluation of sufficiency of disclosure is the same hypothetical person who is selected to assess the inventive step requirement.⁴³

³⁸ See, e.g., section 2164.05(a) Manual of Patent Examining Procedure of the USPTO.

³⁹ Ibid.

⁴⁰ In re Hogan, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977). Ibid.

⁴¹ Janssen Pharmaceutica NV-Janssen-Cilag, S.A. vs. Teva Genéricos Española, S.L., the Madrid Provincial Court (Division 28, decision 194/09 of December 16, 2009).

⁴² For example, in Japan, the enabling disclosure should be directed to a "person who has ability to use ordinary technical means for research and development (including comprehension of document, experimentation, analysis and manufacture) and to exercise ordinary creativity in the art (a person skilled in the art) to which the invention pertains" (Examination Guidelines Chapter I, Section 3.2).

⁴³ The skilled person has the same level of skill for assessing inventive step and sufficiency of disclosure, according to practice of, e.g., the following patent offices: France, Morocco, Norway and Israel. For information with regard to the definition of a person skilled in the art for the purposes of the inventive step requirement, see document SCP/22/3.

46. However, some offices clarify that, for the purposes of sufficient disclosure, a person skilled in the art has a patent specification in front of him/her and is seeking to make a patent work. For example, the Manual of Patent Practice of the Intellectual Property Office of the United Kingdom explains that “[...] although the phrase “person skilled in the art” is construed in the same way when considering sufficiency and inventive step, for the purposes of [the sufficiency of disclosure requirement] the skilled person is seeking to make the patent work and does so with the common general knowledge at the time the patent was filed. In contrast to the situation for inventive step purposes, the skilled worker has the patent in front of them, and thus is “trying to carry out the invention and achieve success,...not searching for a solution in ignorance of it.” [...]. This can be significant in determining the nature and skills of the skilled person (or team), as they need not be the same for both inventive step and sufficiency purposes”.⁴⁴ In India, the Intellectual Property Appellate Board pointed out the differences in the words used in the provisions of the enablement requirement and the inventive step requirement noting that Section 64(1)(h) (relating to an enablement requirement) uses the term “a person with an average skill and average knowledge”, while Section 2(1)(ja) (inventive step) refers to “a person skilled in the art”.⁴⁵

47. The person skilled in the art should be able to carry out the invention on the basis of teachings in the statements of the description and the drawings and by virtue of his/her general knowledge as of the filing date.⁴⁶ The description should be sufficiently clear and complete for a person skilled in the art and contain all the necessary information for performing the invention. In this regard, the submission from Singapore notes: “[t]he 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”.⁴⁷

48. The relative skill of those in the art refers to the skill level of those in the art in the technological field to which the claimed invention pertains. In general, where different arts are involved in the invention, the specification is enabling if it enables persons skilled in each art to carry out the aspect of the invention applicable to their speciality.⁴⁸

⁴⁴ Section 014 of the Manual of Patent Practice of the Intellectual Property Office of the United Kingdom. See also the submission from the EPO which stated that while the skilled person has the same level of skill for assessing inventive step and the sufficiency of disclosure, in the latter case the skilled person is aware of the content of the patent application.

⁴⁵ Specifically, the Board stated: “[i]n fact it is clear that in the context of enablement, the person to whom the complete specifications are addressed is a person “who has average skill and average knowledge.” Neither of these attributes has been assigned by the Act to the person to whom the invention should be non-obvious. We are not called upon in this case to decide the person who is enabled. We are only pointing out to the difference in the words used in the Act. We do not intend to visualise a person who has super skills, but we do not think we should make this person skilled in the art to be incapable of carrying out anything but basic instructions. The Act makes a distinction between the person skilled in the art (the obviousness person) and the person who has average skill (enablement man).” (See *Enercon, vs. Aloys Wobben*, (Order No. 123 of 2013) (Paragraphs 30 and 32).

⁴⁶ The Court of Cassation of France, in its ruling of November 13, 2013, confirmed that “an invention is sufficiently disclosed when a person skilled in the art can perform the invention by reading the description and using his normal professional, theoretical and practical knowledge” (Cour de Cassation. *Pourvoir no P 12-14.803*. R 12-15.449).

⁴⁷ *Schwarzkopf and Ors’ Application*, 31 RPC 437 cited in the submission from Singapore.

⁴⁸ For example, in *Ex parte Zechnall*, 194 USPQ 461 (Bd. App. 1973), the Board stated “appellants’ disclosure must be held sufficient if it would enable a person skilled in the electronic computer art, in cooperation with a person skilled in the fuel injection art, to make and use appellants’ invention.” 194 USPQ at 461.

Availability of starting materials

49. One issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In general, the starting materials essential to making the claimed invention though not cited in the claim must be adequately disclosed. For example, the court in the United States of America made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process.⁴⁹

50. Similarly, in Australia, section 2.11.3.13 of the Patent Manual of Practice and Procedure of Australia states that the starting materials of a chemical process, or ingredients of chemical compositions, must be known compounds. Alternatively, a method of preparation of those compounds from known materials should be either disclosed in the specification or otherwise evident.⁵⁰ Likewise, in China, the examination guidelines state that the description of a chemical product invention shall describe at least one preparation method and disclose the raw materials, procedures, conditions and specially adapted equipment used for carrying out the method so as to make it possible for a person skilled in the art to carry it out. As for the raw materials used in the process, the component, property, manufacturing process or source of it shall be described in such a manner that a person skilled in the art can obtain it.⁵¹

Trademarks and trade names

51. In some countries, the examination guidelines specify that the use of trademarks or trade names or similar words to refer to materials or articles is not recommended insofar as such words merely denote origin or where they may relate to a range of different products.⁵² This is because identification of a feature that is required to perform the claimed invention by way of a trademark or trade name, may not be sufficient to provide an enabling disclosure of the invention as the composition of the trademarked article may change over time or the manufacturer may discontinue making it.⁵³ In general, where the use of a trademark introduces uncertainty in relation to the performance of the invention, the enabling disclosure requirement is not met.⁵⁴

52. Some offices' examination guidelines specify that if such a word is used, in order to satisfy the requirement of the enabling disclosure, the product must be sufficiently identified, without reliance upon the word, to enable the invention to be carried out by a skilled person at the date of filing. However, where such words have become internationally accepted as standard

⁴⁹ In re Ghiron, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), and In re Howarth, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

⁵⁰ Section 2.11.3.13 of the Patent Manual of Practice and Procedure of IP Australia further states that "[a] statement in the specification that a compound is obtainable, or otherwise known, should generally be accepted. Reference to a compound by a trade name or by another commercial identification, whilst possibly unsatisfactory in other respects, may be considered as a *prima facie* indication that the compound is known." Examination Guidelines Part II, chapter 10, Sections 3.1(2) and 3.2(2).

⁵¹ See, e.g., Argentina, Australia, Chile, China, Croatia and the EPO. In general, it is to be noted that a trademark is used to identify the source of origin of a good, not its properties.

⁵² E.g., the Section 14.100 of the Manual of Patent Practice of the Intellectual Property Office of the United Kingdom states that "a trade mark should preferably not be used in a specification since it is an indication of origin rather than of composition or content and on that account cannot properly be used to describe an article."

⁵³ In the United States of America, the court in *In re Coleman*, recognized that where a specification recites a trademark or trade name, there is some possibility that the specific materials disclosed may be removed from the market or that the trademark or trade name may be applied to significantly different products. However, where the risk is small and the occurrence of the event of nonenablement is too remote and speculative, a rejection under the first paragraph of 35 U.S.C 112 cannot be supported.

descriptive terms and have acquired a precise meaning, in some countries, they may be allowed without further identification of the product to which they relate.^{55,56}

Disclosure of biological material

53. Where the application refers to biological material which cannot otherwise be sufficiently disclosed in the written application to meet the enabling disclosure requirements, as provided under the applicable law, the deposit of such material with an authorized institution is taken into consideration when determining whether those requirements have been met. The deposit is considered part of the description to the extent that the requirements regarding sufficiency of disclosure cannot otherwise be complied with.

54. With regard to the depositary institution, some applicable laws make a specific reference to any institutions recognized under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure of April 28, 1977,⁵⁷ and/or any other recognized depositary institutions.⁵⁸

55. As regards the timing of the deposit, in most countries the deposit has to be made at the latest on the filing date of the application or where a right of priority is claimed, the date of filing of the priority application.⁵⁹ However, some variations to this rule are found in some laws. For example, in the United States of America, a deposit may be made at any time before filing the application for patent or during pendency of the application for patent.⁶⁰ In Paraguay, the deposit shall be made no later than 60 days from the filing date of the application or where a right of priority is claimed, the date of filing of the priority application.⁶¹

56. The invention referring to biological material is regarded as disclosed when an application contains information on the characteristics of the deposited biological material as is available to the applicant, the name of the depositary institution and the accession number of the deposit.

Fundamental insufficiency

57. Occasionally, applications with fundamental insufficiency, in the sense that they cannot be carried out by a person skilled in the art, are filed. There is then a failure to satisfy the enabling disclosure requirements which is essentially irreparable. In general, some examination manuals described two instances deserving special mention. The first case is where the successful performance of the invention is dependent on chance. That is to say, a skilled person, in following the instructions for carrying out the invention, finds either that the alleged results of the invention are not reproducible or that success in obtaining these results is achieved in a totally

⁵⁵ See, e.g., Argentina, Croatia, the United Kingdom and the EPO.

⁵⁶ In Switzerland, the use of marks is acceptable in the description if no disadvantage attributed to cited products (Guidelines for substantial examination of national patents in the Swiss Federal Institute of Intellectual Property, section 8.2). In the United States of America, a trademark or trade name may be used in a patent application to identify an article or product if: "(A) its meaning is established by an accompanying definition in the specification which is sufficiently descriptive, enabling, precise and definite such that a claim including the trademark or trade name complies with the requirements of 35 U.S.C. 112, or (B) its meaning is well-known to one skilled in the relevant art and is satisfactorily defined in the literature." (The Manual of Patent Examining Procedure (MPEP) of the USPTO, chapter 608.01(v)).

⁵⁷ See, e.g., Austria, Bulgaria, Croatia, Guatemala, Mexico and Spain.

⁵⁸ See, e.g., Mexico and the EAPO.

⁵⁹ See, e.g., Australia, Argentina, Austria, Bulgaria, Croatia, Guatemala, Mexico, and Spain.

⁶⁰ When the original deposit is made after the effective filing date of an application for a patent, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed. See 37 CFR 1.804.

⁶¹ Article 16, Law no.1.630/2000.

unreliable way. An example where this may arise is a microbiological process involving mutations. Such a case should be distinguished from one where repeated success is assured even though accompanied by a proportion of failures, as can arise, for example, in the manufacture of small magnetic cores or electronic components. In this latter case, provided the satisfactory parts can be readily sorted by a non-destructive testing procedure, no objection arises under the enabling disclosure requirement. The second case is where successful performance of the invention is inherently impossible because it would be contrary to well-established physical laws. This applies, for example, to a perpetual motion machine.⁶²

SUPPORT REQUIREMENT

58. The important aspect of the disclosure requirement in patent law is that claims which define the matter for which protection is sought shall be fully supported by the description.

59. The meaning of the term “the claims shall be fully supported by the description” is largely similar in most jurisdictions. In general, the term means that there must be a basis in the description for the subject matter of every claim and that the scope of the claims must not be broader than is justified by the description and drawings.⁶³ The examination guidelines of some offices also add that the scope of the claims must not be broader than is justified by “the contribution to the art”.⁶⁴

60. In Japan, the purpose of this requirement was explained in an Intellectual Property High Court Decision: “the claimed inventions should not exceed the scope stated in the detailed explanation of the invention. To state in a claim an invention that is not stated in the detailed explanation of the invention means to seek a patent protection for an invention which is not disclosed to the public. Article 36(6)(i) is intended to prevent this happening.”⁶⁵ In Australia, the court explained that the support for the claims means that “[...] the definitions in the claims [i.e. the claimed invention] should essentially correspond to the scope of the invention as disclosed in the description. In other words, [...] the claims 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.”⁶⁶

⁶² If the claims for such a machine are directed to its function, and not merely to its structure, an objection arises not only in relation to the sufficiency of disclosure requirement but also in relation to the requirement of industrial application. See, e.g., paragraph 4.13 of the PCT International Search and Preliminary Examination Guidelines and Part F, Chapter III-3 of the Guidelines for examination of the EPO.

⁶³ See, e.g., Paragraph 4.6.11 of Manual for the Examination of Patent Applications for Inventions in the Industrial Property Offices of the Countries of the Andean Community (Andean Patent Manual). In China, the claim shall be supported by the description means that “the technical solution for which protection is sought in each of the claims shall be a solution that a person skilled in the art can reach directly or by generalization from the contents sufficiently disclosed in the description, and shall not go beyond the scope of the contents disclosed in the description” (Part II, Chapter 2, Section 3.2.1 of the Guidelines for Patent Examination of The State Intellectual Property Office of the People’s Republic of China). In the United States of America “the scope of the claims must bear a reasonable correlation to the scope of the enablement provided by the specification to persons of ordinary skill in the art” (Paragraph 112, Title 35 of the United States Code).

⁶⁴ See, e.g., Section 2.11.7.1A of the Patent Manual of Practice and Procedure of the IP Australia; Chapter 6 of the Patent Examination Guidelines in Croatia and Chapter IV-6.1 of the Guidelines for Examination of the EPO. In this regard, the Patent Manual of Practice and Procedure of the IP Australia explains: “An inventor’s contribution to the art lies in what is added to the state of the art as a result of the inventive concept disclosed in the specification, i.e. how far forward has the inventive concept carried the state of the art? One way of identifying the contribution to the art is to determine what is disclosed that is new to the art and not obvious. [...] In effect, the sec 40(3) requirement that the scope of the claims must not be broader than is justified by the inventor’s contribution to the art requires that the claims must be restricted to products and/or processes disclosed in the specification that are novel, inventive and enabled by that disclosure.”

⁶⁵ Intellectual Property High Court Decision dated November 11, 2005, (Hei 17 (Gyo-Ke), No. 10042, cited in Examination Guidelines Chapter I, Section 2.2.1.1 of the JPO.

⁶⁶ Generics (UK) Ltd v H Lundbeck A/S [2009] RPC 13 at [36], affirming T 409/01, Australia.

61. According to the practice of many offices, as a general rule, a claim is regarded as supported by the description unless there are well-founded reasons for believing that the person skilled in the art would be unable, on the basis of the information given in the application as filed, to extend the particular teaching of the description to the whole of the field claimed by using routine methods of experimentation or analysis. Support must, however, relate to the features of the claimed invention: vague statements or assertions having no technical or other relevant content provide no basis. Typically, an examiner raises an objection of lack of support only if there are well-founded reasons. Where an objection is raised, the reasons, where possible, should be supported specifically by a published document.⁶⁷

62. Further, some examination guidelines note that the mere coincidence of wording in the claim and the description does not mean that the claim is necessarily supported by the description.⁶⁸

63. According to the decisions of the Boards of Appeal of the EPO, the skilled person, when considering a claim, should try, building up rather than tearing down, to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of the patent. In addition, each claim should be read giving the words the meaning and scope which they normally have in the relevant art, unless in particular cases the description gives the words a special meaning, by explicit definition or otherwise.⁶⁹

64. The applicant is not required to restrict the claims to the specific embodiments described, but the scope of the claims must be properly supported by the matter disclosed in the body of the specification.⁷⁰

Consideration of support

65. Some patent offices' examination guidelines provide specific methodologies for examination on the compliance with the support requirement. For example, in Australia, the Patent Manual of Practice and Procedure explains that "the proper construction of the specification and claims is fundamental to the consideration of whether the claimed invention is supported by the matter disclosed in the specification. Each application should be assessed on its own merits based on a proper construction of the specification and the facts of the case."⁷¹ It further states that in order to determine whether the specification complies with the support requirement, examiners should:

⁶⁷ See, e.g., Chapter 6 of the Patent Examination Guidelines in Croatia and Part F, Chapter IV-6.3 of the Guidelines for Examination of the EPO. In this regard, the response from the Russian Federations states: "[...] any objection by the examiner concerning, in particular, non-conformity with the requirement of sufficiency of disclosure of the invention [...] must be supported by technical arguments with references to technical literature. References to technical literature are not required only if the arguments of the examiner are based on common knowledge in a specific field of art."

⁶⁸ In this regard, Section 2.11.7.1A of the Patent Manual of Practice and Procedure of the IP Australia explains that "[t]he mere mention in the description of features appearing in the claims is not necessarily sufficient support. The word 'support' means more than just coincidence of language and requires the disclosure to be the base which supports grant of a monopoly of the width claimed. (Schering Biotech Corp.'s Application [1993] RPC 249 at 252-253)". In addition, Part II, Chapter 2, Section 3.2.1 of the Guidelines for Patent Examination of China explains that "[h]owever, that the technical solution in a claim has the same wording as that in the description does not mean the claim is necessarily supported by the description. It is only when the technical solution as defined in a claim can be reached directly or by generalization by a person skilled in the art from the contents sufficiently disclosed in the description that the claim defining that technical solution can be regarded as having support in the description."

⁶⁹ See, e.g., the decisions of the Boards of Appeal of the EPO: T311/93, T1321/04.

⁷⁰ See, e.g., the examination guidelines of patent offices of the United Kingdom and Australia.

⁷¹ Section 2.11.7.1A of the Patent Manual of Practice and Procedure of the IP Australia.

- (i) construe the claims;
- (ii) compare the claimed invention with the matter disclosed in the body of the specification (i.e. the description, together with any drawings and sequence listing); and
- (iii) determine whether, on the balance of probabilities, the specification satisfies the following criteria:
 - (a) the body of the specification must contain an enabling disclosure, i.e. it must disclose the claimed invention in a way which will enable it to be performed by a person skilled in the art without undue burden, or the need for further invention; and
 - (b) the extent of the patent monopoly as defined in the claims must not be broader than is justified by the extent of the description, drawings, sequence listing and the contribution to the art.

66. In this regard, the Examination Guidelines of Japan Patent Office states that:

- “(1) [a] determination on whether the statement of a claim complies with the [support requirement] shall be made based on comparison and review of the claimed invention and the invention stated in the detailed explanation of the invention. This comparison and review shall be conducted by studying what is stated in the detailed explanation of the invention, on the basis of the claimed invention. The judgment should be done while taking care not to be too restrictive on the scope of claims by the specific examples stated in the detailed explanation of the invention.
- (2) In performing the comparison and review, a substantial correspondence between the claimed invention and the invention stated in the detailed explanation of the invention shall be examined, regardless of the consistency of expressions in the claims and the detailed explanation of the invention. If the consistency of expressions were sufficient to comply with Article 36(6)(i), it could result in granting a patent on subject matter which has not substantially been disclosed to the public, and thus would not meet the purpose of that provision.
- (3) Examination for the substantial correspondence relationship is performed by looking into whether or not the claimed invention exceeds the scope stated in the detailed explanation of the invention in such a way that a person skilled in the art [...] could recognize that a problem to be solved by the invention would be actually solved. In case determining that the claimed invention exceeds the scope stated in the detailed explanation of the invention in such a way that a person skilled in the art could recognize that a problem to be solved by the invention would be actually solved, the claimed invention and the invention stated in the detailed explanation of the invention are not corresponding with each other and the application doesn't comply with the [support] requirement [...].”

Generalization and its extent

67. In explaining the support requirement as provided in their laws, many offices' examination guidelines focus on the concept of generalization. In particular, it is explained that most claims are generalizations from one or more particular embodiments or examples as set forth in the description. In general, the extent of generalization permissible is a matter which has to be

established in each particular case in the light of the relevant prior art. Thus, an invention which opens up a whole new field is entitled to more generality in the claims than one which is concerned with advances in a known technology.⁷² An appropriate claim is one which is not so broad that it goes beyond the invention nor yet so narrow as to deprive the applicant of a just reward for the disclosure of his invention. The applicant should be allowed to claim all obvious modifications of, equivalents to and uses of what he has described. In particular, if it is reasonable to predict that all the variants covered by the claims have the properties or uses the applicant ascribes to them in the description, he should be allowed to draw his claims accordingly.^{73,74}

68. According to the practices of many patent offices, a claim in generic form, i.e., relating to a whole class, for example, of materials or machines, may be acceptable even if of broad scope, if there is fair support in the description and there is no reason to suppose that the invention cannot be carried out through the whole of the field claimed.⁷⁵ Where the information given appears insufficient to enable a person skilled in the art to carry out though the whole of the field claimed, the applicant is invited to establish that the invention can in fact be readily applied on the basis of the information given in the description over the whole field claimed or, failing this, to restrict the claim to accord with the description.

69. Notably, to illustrate the question of support, some patent offices' examination guidelines provide the following similar examples:⁷⁶

- (i) a claim relates to a specified method of treating "a synthetic resin mouldings to obtain changes in characteristics", if the examples described in the description relate only to thermoplastic resins, and the applicant cannot establish that this method is also applicable to thermosetting resins, then the applicant shall restrict the claim to thermoplastic resins; and

⁷² See, e.g., Part II, Chapter 2, Section 3.2.1 of the Guidelines for Patent Examination of The State Intellectual Property Office of the People's Republic of China; Section 6 of the Examination guidelines of the State Intellectual Property Office of Croatia; Section 14.143 of the Manual of Patent Practice of the Intellectual Property Office of the United Kingdom; Part F, Chapter IV-6 of the Guidelines for Examination of the EPO. In this regard, the submission from Singapore stated: "[...] 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."

⁷³ Ibid.

⁷⁴ The German Federal Court of Justice, while noting that it is not necessary to describe the invention in every detail, stated that, "[h]owever, generalisation must not go so far as to only state the problem and the result to be achieved. This is to prevent that IP rights are granted that cover all other ways and means to achieve the same result, which would be an obstacle to technical progress." Moreover, scope and legal certainty of the IP right would not be clear. (German Federal Court of Justice (cf. BGH, Blatt für PMZ 1985, p. 28, p. 29 - Acrylfasern -)).

⁷⁵ Lord Hoffmann stated 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 [...]. 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."

⁷⁶ These examples are found in Part II, Chapter 2, Section 3.2.1 of the Guidelines for Patent Examination of The State Intellectual Property Office of the People's Republic of China, Chapter 6 of the Patent Examination Guidelines in Croatia, the Guidelines for examination of the EPO, Part F-IV, 6.3, as well as paragraph 5.53 of the PCT International Search and Preliminary Examination Guidelines.

- (ii) a claim relates to a process for treating all kinds of "plant seedlings" by subjecting them to a controlled cold shock so as to produce specified results, whereas the description discloses the process applied to one kind of plant only. Since it is well-known that plants vary widely in their properties, there are well-founded reasons for believing that the process is not applicable to all plant seedlings. Unless the applicant can provide convincing evidence that the process is nevertheless generally applicable, he must restrict his claim to the particular kind of plant referred to in the description. A mere assertion that the process is applicable to all plant seedlings is not sufficient.

Relationship of claims to disclosure

70. The claimed invention must be fully supported by the description and drawings, thereby showing that the applicant only claims subject matter which he had recognized and described on the filing date.

71. In general, the claims are not consistent and not commensurate with the description and drawings if, after reading the application, the claimed invention is still not at the disposal of a person skilled in the art, because an essential element for the function or operation of the invention is missing from the claim. To exemplify, the PCT International Search and Preliminary Examination Guidelines set forth the following examples which are also found in other examination guidelines:

- (i) a claim that relates to improved fuel oil compositions which have a given desired property. The description provides support for one way of obtaining fuel oils having this property, which is by the presence of defined amounts of a certain additive. No other ways of obtaining fuel oils having the desired property are disclosed. If the claim makes no mention of the additive, the claim is not fully supported by the description;
- (ii) a claim not being consistent with the disclosure, for instance, due to contradictions between the elements contained in the claims and the description; and
- (iii) having regard to the description and the drawings, the scope of the claims covers an area which was not recognized by the applicant, for example, mere speculation of possibilities that have not been explored yet.⁷⁷

72. Additionally, other examples of non-compliance with the support requirement were provided in the examination guidelines of some offices. For example, the Examination Guidelines of the Japan Patent Office states that the types that do not comply with the support requirement are:

- (i) the matter neither stated nor implied in the detailed explanation of an invention is stated in the claims;
- (ii) terms used in the claims and those used in the detailed explanation of the invention are inconsistent and as a result, the relation between the claims and the detailed explanation of the invention is unclear; and⁷⁸

⁷⁷ See, e.g., Guidelines for Examination of the EPO, F-IV, 6.3 and paragraph 5.5 of the PCT International Search and Preliminary Examination Guidelines.

⁷⁸ Examples of (i) are: 1. A claim has a numerical limitation while any specific numerical value is neither stated nor implied in the detailed explanation of the invention; 2. A claim solely states an invention using an ultrasonic motor while the detailed explanation of the invention states only the invention using a D.C. motor

[Footnote continued on next page]

- (iii) the content disclosed in the detailed explanation of the invention can neither be expanded nor generalized to the scope of the claimed invention even in light of the common general knowledge as of the filing.

73. Some offices' examination guidelines state that functional features may be included in the claims provided that a skilled person would have no difficulty in providing some means of performing this function without exercising inventive skill. This could be the case even where only one example of the feature has been given in the description, if the skilled reader would appreciate that other means could be used for the same function. For example, "terminal position detecting means" in a claim might be supported by a single example comprising a limit switch, it being evident to the skilled person that e.g. a photoelectric cell or a strain gauge could be used instead. In general, however, if the entire contents of the application are such as to convey the impression that a function is to be carried out in a particular way, with no intimation that alternative means are envisaged, and a claim is formulated in such a way as to embrace other means, or all means, of performing the function, then an objection arises. Furthermore, it may not be sufficient if the description merely states in vague terms that other means may be adopted, if it is not reasonably clear what they might be or how they might be used.⁷⁹

Whole contents of the description to be taken into account

74. In general, when determining whether a claim is supported by the description, the whole contents of the description, together with any drawings shall be taken into account.⁸⁰ As explained in the submission from China "[...] the examiner shall take into account the whole contents of the description, rather than merely the contents in the part of specific mode for carry out the invention [...]. If other parts of the description also include contents concerning embodiments or examples, and it can be established the generalization of the claim is appropriate viewed from the whole contents of the description, then the claim shall be considered to have support in the description."⁸¹

75. For the claims including both independent and dependent claims or different kinds of claims, each of the claims shall be examined as to whether it is supported by the description. If an independent claim is supported by the description, that does not mean its dependent claims are necessarily supported by the description. Similarly, if a process claim is supported by the description, that does not mean a product claim covering a product obtained by such process is necessarily supported by the description.⁸²

Amendments

76. Where there is any serious inconsistency between the claims and description, amendments to remove this will be required. For example, the description may state, or may imply, that a certain technical feature not mentioned in the claims is essential to the performance of the invention. In such a case, the claims should normally be amended to

[Footnote continued from previous page]

and it neither states nor implies anything about using an ultrasonic motor. Example of (ii): It is unclear whether the "data processing means" of a word processor stated in the claims corresponds to the "means for changing the size of characters" in the detailed explanation of the invention, or corresponds to the "means for changing line spacing" in the detailed explanation of the invention, or both of them. (Examination Guidelines Chapter I, Section 2.2.1.3.)

⁷⁹ See, e.g., Section 14.156 of the Manual of Patent Practice of the Intellectual Property Office of the United Kingdom; Section 6.5 of Chapter IV, Part F of the Guidelines for Examination of the EPO; and paragraph 5.56 of the PCT International Search and Preliminary Examination Guidelines.

⁸⁰ Some laws also refer to the sequence listing. See, e.g., the supra footnote 35 in relation to Australia.

⁸¹ See, e.g., Part II, Chapter 2, Section 3.2.1 of the Guidelines for Patent Examination of China.

⁸² Ibid.

include this feature. If however the applicant can show convincingly that it would be clear to a person skilled in the art that the description was incorrect in suggesting that the feature in question was essential, and if the claim which implies (by omission) that the feature is not essential was present on the date of filing, amendment of the description may be allowed instead.⁸³

77. Where certain subject matter is clearly disclosed in a claim of the application as filed, but is not mentioned anywhere in the description, it is generally permissible to amend the description so that it includes this subject matter.^{84,85}

The enabling disclosure requirement and the support requirement

78. In general, compliance with the enabling disclosure requirement and the requirement for support for the claims in the disclosure are determined independently. In some cases, where the claim is too broad to be supported by the description and drawings, the disclosure may also be insufficient to enable a person skilled in the art to carry out the claimed invention over the whole of the broad field claimed. Thus there may be non-compliance with both the requirement of support and the enabling disclosure requirement.

WRITTEN DESCRIPTION REQUIREMENT

79. The written description requirement is a requirement which is provided under the law of the United States of America. Section 112(a), Title 35, of the United States Code requires that “[t]he specification shall contain a written description of the invention [...]”. While Section 112(a) also relates to the enabling disclosure requirement, the written description requirement considered to be separate and distinct from the enablement requirement.⁸⁶

80. The written description requirement has several policy objectives. As stated in Chapter 2163(l) of the MPEP of the USPTO, the essential goal of this requirement is “to clearly convey the information that an applicant has invented the subject matter which is claimed.” Another objective is to put the public in possession of what the applicant claims as the invention.⁸⁷ Further, the written description requirement promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent

⁸³ See, e.g., Section 14.144 of the Manual of Patent Practice of the Intellectual Property Office of the United Kingdom.

⁸⁴ See, e.g., Part II, Chapter 2, Section 3.2.1 of the Guidelines for Patent Examination of China; Paragraph 4.6.11 of the Andean Patent Manual (which further clarifies that such modification does not imply a broadening if the initial claims had been filed together with the description); and Section 14.145 of the Manual of Patent Practice of the Intellectual Property Office of the United Kingdom (which further clarifies that when however original claims filed later than the filing date of the application contain matter not present in the description, such matter will need to be deleted).

⁸⁵ As regards the consequences of non-compliance with the support requirement, in some jurisdictions, the lack of support is a ground for opposition and invalidation (e.g., Australia). In some other countries, it is a ground for invalidation (e.g., China, Ecuador, Ghana, Japan and Mexico).

⁸⁶ See e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written description requirement); In *re Curtis*, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) (“conclusive evidence of a claim’s enablement is not equally conclusive of that claim’s satisfactory written description”) cited in chapter 2163 of the Manual of Patent Examining Procedure (MPEP) of the USPTO.

⁸⁷ “The ‘written description’ requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.” (*Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005)).

specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

81. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed. However, a showing of possession alone does not cure the lack of a written description.⁸⁸

82. A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not supported by the disclosure of an application as filed. Further, much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in these cases is most often phrased as whether the original application provides adequate support for the claims at issue or whether the amendment to the specification incorporates "new matter" in violation of Section 132, Title 35 of the United States Code.⁸⁹ The "written description" question similarly arises in the interference context, where the issue is whether a specification provides support for a claim corresponding to a count in an interference.⁹⁰

83. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including: (i) either by describing of an actual reduction to practice; (ii) or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete; (iii) or by describing, distinguishing, identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

84. A specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of certain biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 et seq.⁹¹

85. The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed; however, with respect to newly added or amended claims,

⁸⁸ Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 969-70, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002).

⁸⁹ Section 132, Title 35 of the United States Code states "(a) Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention." See Chapter 2163(I) of the MPEP.

⁹⁰ An interference is a contest under 35 U.S.C. 135(a) between an application and either another application or a patent. An interference is declared to assist the Director of the USPTO in determining priority, that is, which party first invented the commonly claimed invention within the meaning of 35 U.S.C. 102(g)(1). Once an interference has been suggested under 37 CFR 41.202, the examiner refers the suggested interference to the Board of Patent Appeals and Interferences (Board). An administrative patent judge declares the interference, which is then administered at the Board. A panel of Board members enters final judgment on questions of priority and patentability arising in an interference. "Count" means the Board's description of the interfering subject matter that sets the scope of admissible proofs on priority. Where there is more than one count, each count must describe a patentably distinct invention. (See Chapter 2301 of the MPEP).

⁹¹ Ibid.

applicant should show support in the original disclosure for the new or amended claims.⁹² Consequently, rejection of an original claim for lack of written description should be rare. The compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis.

86. To determine the adequacy of the written description requirement, the USPTO examiners follow the following steps: (i) for each claim determine the scope of the claim; (ii) review the entire application to understand how applicant provides support for the claimed invention including each element and/or step; and (iii) determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention as a whole at the time the application was filed.⁹³

87. The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed [...] and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification.⁹⁴

[End of document]

⁹² See Chapters 714.02 and 2163.06 of the MPEP (“Applicant should ... specifically point out the support for any amendments made to the disclosure.”); and Chapter 2163.04 of the MPEP (“If applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.”) cited in Chapter 2163(II) of the MPEP.

⁹³ Ibid.
⁹⁴ Ibid.