

Standing Committee on the Law of Patents

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STUDY ON THE SUFFICIENCY OF DISCLOSURE: SUMMARY

Document prepared by the Secretariat

INTRODUCTION

1. In accordance with the decision made at the twenty-first session of the Standing Committee on the Law of Patents (SCP), held in Geneva from November 3 to 7, 2014, document SCP/22/4 contains a study on the sufficiency of disclosure prepared by the Secretariat. In particular, it contains the following three elements: (i) the enabling disclosure requirement; (ii) the support requirement; and (iii) the written description requirement.

THE ENABLING DISCLOSURE REQUIREMENT

2. 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 [...].”

3. As regards the substantive elements of the enabling disclosure or support requirements, 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.

4. 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; patent holders 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 applications. 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.

Requirements regarding the description

5. 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. Any such error may result in non-compliance with, *inter alia*, the enablement requirement.

Test for enablement requirement

6. In many countries, the test for fulfilling the requirements for an enabling disclosure is that 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”.

7. 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 by such person is generally admissible to comply with the enablement requirement in most of the countries.

Undue burden

8. 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.

9. 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 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.

10. 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.

11. “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.

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

13. Some countries’ case law and the 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.¹

The disclosure of essential and well-known features

14. 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. 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 be given, but the description must disclose any feature essential for carrying out the invention in sufficient detail 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.

Provision of examples

15. In general, according to the practice 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, regard must be given to the facts and evidence of the particular case. In some cases, even broad claims can be substantiated by limited number of examples.

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

16. 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, while other laws refer to the “specification as a whole” containing the description, claims and drawings.

¹ For details, see document SCP/22/4.

Specification must be enabling as of the filing date

17. 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.²

18. 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.

19. 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.

20. The state of the art for a given technology is not static in time. Therefore, the state of the art must be evaluated for each application based on its filing date. A specification that is insufficient at the time of filing cannot be made sufficient by subsequent developments in the art.

21. In general, an examiner should not use post-filing date references to demonstrate that a patent is not enabled.

Specification must be enabling to a person skilled in the art

22. 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.

23. In general, the term “person skilled in the art” refers to an average skilled person who has good knowledge and specialization in the relevant field but who is not necessarily an expert in the field. 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.

24. 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. 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. In addition, in one country, it was clarified that in comparison with the person skilled in the art for the purposes of the inventive step, in the context of enablement requirement, the person to whom the specification is addressed is a person who has an “average skill and average knowledge”.

² 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.

25. 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. 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.

Availability of starting materials

26. 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 must be adequately disclosed.

Trademarks and trade names

27. In general, where the use of trademarks or trade names introduces uncertainty in relation to the performance of the invention, the enabling disclosure requirement is not met. 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. 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.

Disclosure of biological material

28. Where the application refers to biological material which cannot otherwise be sufficiently disclosed in the written application to meet the enabling disclosure requirement, as provided under the applicable law, the deposit of such material with an authorized institution is taken into consideration when determining whether such requirement has 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.

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

30. 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.

SUPPORT REQUIREMENT

31. 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.

32. 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 and by the contribution to the art.

33. Some submissions have explained the purpose of this requirement as follows: “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. [The support requirement] is intended to prevent this happening”, or “[...] 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.”

34. 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, the 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.

35. 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.

Generalization and its extent

36. In explaining the support requirement as provided in the law, 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. 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.

37. According to the practice 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 it is of broad scope, provided there is a 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.

Relationship of claims to disclosure

38. 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.

39. 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 sets 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 that is not 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.

40. 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.

The enabling disclosure requirement and the support requirement

41. 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 concerning the relationship of the claims to the disclosure and the enabling disclosure requirement.

WRITTEN DESCRIPTION REQUIREMENT

42. 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.

43. The written description requirement has several policy objectives. As stated in Chapter 2163(l) of the Manual of Patent Examining Procedure of the United States Patent and Trademark Office (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. Further, the written description requirement promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent’s term.

44. 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. However, a showing of possession alone does not cure the lack of a written description.

45. 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 paragraph 132, Title 35 of the United States Code. 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.

46. To determine the adequacy of a 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 the 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 the applicant was in possession of the claimed invention as a whole at the time the application was filed.

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