SCP/35/5 SUMM
ORIGINAL: ENGLISH
DATE: OCTOBER 3, 2023

Standing Committee on the Law of Patents

Thirty-Fifth Session
Geneva, October 16 to 20, 2023

SUMMARY: FURTHER STUDY ON THE SUFFICIENCY OF DISCLOSURE (PART II)

Document prepared by the Secretariat

I. INTRODUCTION

1. In accordance with the agreements at the thirty-third and thirty-fourth sessions of the Standing Committee on the Law of Patents (SCP), held in a hybrid format from December 6 to 9, 2021 and from September 26 to 30, 2022, respectively, the Secretariat prepared document SCP/35/5, consisting of a Further Study on the Sufficiency of Disclosure (Part II) for discussion at the thirty-fifth session of the SCP. That document addresses the sufficiency of disclosure related to inventions having an experimental nature in unpredictable art, such as chemistry and biotechnology, and of any other areas that deserve special attention, as proposed in document SCP/31/8 Rev, and was based on the information received from Member States and regional patent offices. Since the Further Study on the Sufficiency of Disclosure (Part I) (document SCP/34/5) already addressed the issues pertinent to the sufficiency of disclosure of inventions relating to biological materials, such as microorganisms, this document predominantly focuses on the application of general rules and guidelines to the sufficiency of disclosure of inventions in the field of chemistry, although some examples from the field of biotechnology are also included in the document. This document is a summary of document SCP/35/5.

II. OVERVIEW OF THE SUFFICIENCY OF DISCLOSURE REQUIREMENT

A. Summary of the Sufficiency of Disclosure Requirement

2. The legal provisions regarding the sufficiency of disclosure lay down general requirements that apply to inventions in any technical field. Therefore, Section II.A provides a brief description of the role of the sufficiency of disclosure in the patent system, and an overview of

the general principles of the enabling disclosure requirement, support requirement and written description requirement.

B. Application of the General Principles to Inventions in Specific Technical Fields

3. Oftentimes, the general guidelines prepared by patent offices contain examples about how the substantive requirements are applied to inventions from various technical fields. In addition, some patent offices supplement the general guidance with more detailed and specific guidance on how to apply the general guidelines to the assessment of the sufficiency of disclosure of inventions in a specific technical field, taking into account the special characteristics of these inventions. Case law also provides useful guidance on the application of law in some specific circumstances. Such supplementary information may be considered useful in certain technical fields that can be characterized by its experimental nature, such as chemistry and biotechnology.

III. INVENTIONS RELATING TO CHEMISTRY AND BIOTECHNOLOGY

A. Predictability of the Art and Sufficiency of Disclosure

4. In order to fulfill the sufficiency of disclosure requirement, the “application”, “description” or “specification” must provide sufficient information so that a person skilled in the art can carry out or perform the invention on the basis of the disclosed information, without “undue burden” and/or “any inventive effort” or “undue experimentation”.

5. In some jurisdictions, a similar concept is expressed as “the disclosure must be reproducible without undue burden”. According to the practice of one country, this requires that: (i) the invention is workable (i.e. the technical result or the intended technical effect is achievable); (ii) it is repeatable (i.e., cannot be realized merely by chance); and (iii) it can be realized over the entire scope and with reasonable effort by the person skilled in the art.

6. In general, the term “a person skilled in the art” is understood in a way that he/she possesses the common general knowledge in the art as of the filing date. Accordingly, embodiments (examples) in the application can omit well-known feature or basic steps in the application.

Enabling the full scope of claims – Plausibility/Credibility/Workability

7. In many jurisdictions, one of the general principles well accepted is that the disclosure must be plausible or credible so that the full scope of the claimed invention would work, producing the claimed technical effect. In other words, it should be possible to make a reasonable prediction from the information disclosed in the specification that the claimed invention will work in its full scope. In Europe, the concept of plausibility has arisen from the problem-solution approach and the consideration that only those inventions that made sufficient technical contributions to the art should receive patent grant. Thus, it is an overreaching concept that may touch upon not only the sufficiency of disclosure, but also inventive step or industrial applicability.

8. As it can be seen in many examples, court cases and submissions of Member States cited in SCP/35/5, plausibility or credibility with regard to sufficiency is much scrutinized in the technical fields where the workability of the claimed invention, or the technical effect it is claimed to be produced, is not immediately apparent. In particular, the issue is widely discussed in conjunction with the sufficient level of information that must be provided in the patent application as filed and supportive evidence that may be filed during the patent proceedings. The issue is considered in cases where, for example, the inventive concept of the invention is on a specific

medical use or therapeutical effects of the product claimed. Plausibility is also addressed in relation to sufficient disclosure of compositions that are claimed to have synergistic effects.

B. Generalization of the Inventive Concept in the Claims

9. Many claims represent the inventive concept that generalizes the embodiments described in the patent application. To what extent the generalization can be supported is a case-by-case question. However, some patent offices provide guidance as to the assessment of the description that sufficiently support the claimed invention as well as factors that may be considered for determining the acceptable level of generalization of the claims vis-à-vis the disclosure made in the description. Document SCP/35/5 illustrates examples from the submissions by Member States and guidelines of some patent offices.

C. Undue Burden, Efforts or Experimentation

10. As the sufficient disclosure of inventions in patent applications generally requires them to be carried out, performed or being reproducible without “undue burden, efforts or experimentation”, the interpretation of that phrase is one of the main issues in the determination of the sufficiency of disclosure.

11. The factors to be considered in determining whether the disclosure requires undue experimentation in carrying out the claimed invention, set by each jurisdiction, commonly include: (i) the breadth of the claims; (ii) the nature of the invention; (iii) the common general knowledge of a person skilled in the art; (iv) the amount of information and direction provided in the application (either explicitly or implicitly), including references to prior art; (v) the level of predictability in the art – if a person skilled in the art can anticipate the technical characteristics and effects of the invention easily, he/she may perform the invention with less instructions in the patent application; and (vi) the amount of experimentation required to carry out the claimed invention on the basis of the disclosure. Accordingly, if little is known in the prior art and the art is unpredictable, the applicant may need to explicitly describe in the patent application more details about how to carry out the invention.

12. The state of the art and the general common knowledge, as of the filing date, provide evidence for the degree of predictability in the art, and in turn, relate to the amount of guidance and working examples needed in the application as filed to meet the enabling disclosure. In addition, guidelines of some patent offices touch upon the relevance of experimental evidence to demonstrate the alleged technical effect of the clamed invention particularly in the field of chemistry and biotechnology, since it is more challenging to anticipate the technical effect of chemical compounds, pharmaceutical substance or biotechnological material. Document SCP/35/5 provides practices of some patent offices.

1. Undue burden: quality and quantity of experimentation

13. Even if the person skilled in the art still has to carry out tests in order to achieve the desired result on the basis of the information in the patent specification, this does not conflict with the sufficient disclosure of an invention, as long as such tests do not exceed a reasonable extent in a given case. While it is difficult to precisely define the terms “undue burden”, “undue experiment”, “reasonable” or “inventive” efforts etc., the amount of experiment or burden that would qualify these terms takes into account the quantitative and qualitative aspects of the experiment or burden required. In many countries, the quantity of experimentation required to make and use a claimed chemical compound, such as an extended period of experimentation or excessive amount of expense to carry out the experimentation, is only one factor involved in determining whether the undue experimentation is required.

2. Sufficient amount of guidance provided by the disclosure

14. One of the factors for the determination of the sufficient disclosure is the amount of guidance that a person skilled in the art receives from the disclosure in the specification, i.e., the nature of the direction in which the experimentation should be proceeded by a person skilled in the art.

15. The sufficient amount of guidance or direction in the specification can mean that the description does not necessarily need to contain indications of how to achieve all conceivable variants covered by a functional definition. Similarly, absence of working examples (an example based on work actually performed or experiments conducted that yielded actual results) will not by itself render the invention non-enabling. Document SCP/35/5 describes examples from the submissions of some Member States, guidelines of some patent offices and case law on the level of guidance that should be provided by patent applicants to meet the sufficiency of disclosure requirement.

Reasonable trial and routine experiment

16. Since a person skilled in the art may need to carry out a reasonable level of experimentation, a reasonable amount of trial and error by a person skilled in the art is not considered an “undue burden”. As the test is not merely quantitative, in many countries, a considerable amount of experimentation is permissible, provided that it is merely a routine experiment. Document SCP/35/5 outlines practices and a court case on this matter from some countries.

Errors and lack of certain information

17. In addition, even if certain information for making and using the claimed invention is missing or inaccurately presented in the specification, it does not necessarily mean that the disclosure is insufficient. The submissions of some Member States illustrate cases where the application as filed contained inaccurate information, certain information is missing from the application or some specific variants indicated in the application are not available or are unusable. Depending on the specific circumstance of each of these cases, a person skilled in the art might be able to compensate such errors or omissions with his/her common general knowledge, and subsequently could carry out the claimed invention without undue burden.

Enabling the full scope of claims without undue burden

18. Jurisprudence and guidelines of many countries state that the disclosure must enable the “full scope” of the claimed invention without undue experimentation.

Sufficient disclosure of inventions defined by parametric claims

19. If an essential feature of the invention is expressed by a parametric definition, the question is whether the parameter is so defined that a person skilled in the art, based on the disclosure in the specification and the common general knowledge, could identify the technical measures leading to the claimed invention and thus carry out the invention. Such parameters may be directly measurable physical properties or mathematical combination of several variables in the form of formulae.

20. With respect to the sufficiency of disclosure, in general, the consideration is whether the parametric definition would make a person skilled in the art to face undue burden in arriving at the full scope of the claim by following exemplification given in the specification or procedures common in the art. If it is evident from the specification that the skilled person would face no difficulty in carrying out the characterization disclosed and would be able to establish the exact

meaning of the specific parameters, use of such parameters would be allowed, even if the parameter not known in the prior art are used in the claim.

Prophetic examples

21. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. Following the case law, an example of the claimed invention can be either “working” or “prophetic” in the United States of America. According to the guidelines of the United States Patent and Trademark Office (USPTO), the claims, however, should be drafted in a manner that assists readers in differentiating between actual working examples and prophetic examples, i.e., prophetic examples should not be described using the past tense, but rather in future or present tense.

D. Supportive Evidence and Data

22. Since it is more challenging to anticipate the technical effect of chemical compounds or biotechnological material, applications in these fields are more frequently required to provide experimental data or evidence, such as the results of tests or trials, together with the parameters of such experimentation. As the burden of proving that the application sufficiently discloses the claimed invention is on the applicant, many patent offices allow applicants to submit evidence to demonstrate that such disclosure was sufficiently made in the patent application as filed. For example, additional evidence is generally accepted during the substantive examination phase, provided that it is intended exclusively to confirm the information already contained in the application as initially filed.

Evidence obtained after the filing date

23. Recognizing the challenges that applicants in, for example, chemistry, pharmaceutical or life science fields may face in having sufficient data and evidence at hand as of the filing date, some offices allow applicants to rely on evidence that had not been public, or experimental data that had not been obtained, before the filing date of the patent application to demonstrate sufficiency of disclosure. The treatment of such evidence obtained by the applicant after the filing date of the application is not the same among jurisdictions. However, what is common in all jurisdictions is that such evidence obtained after the filing date cannot be utilized to render an insufficient disclosure in a patent application sufficient. It is used merely to back up the disclosure in the application as filed.

24. Document SCP/35/5 provides information about acceptability of evidence obtained after the filing date in some countries from guidelines of patent offices and jurisprudence. This issue is also closely related to the plausibility or credibility of the claimed invention disclosed, particularly, but not limited to, sufficient disclosure of inventions relating to medical use or compositions and mixtures of compounds.

E. How to Make the Claimed Invention – Chemical Process for Producing a Product

25. As the mere physical structure of inventions regarding chemical compounds or biological materials does not necessarily teach a person skilled in the art on how to make, or how to use, these inventions, many submissions of Member States touched upon the qualitative and quantitative disclosure relating to chemical processes, in particular, manufacturing processes of chemical or biological inventions. The submissions of some Member States and the guidance given by some patent offices are illustrated in document SCP/35/5.

1. Starting material

26. Regarding the sufficient disclosure of chemical processes, one of the issues raised in the submissions of some Member States and guidelines of some patent offices is the importance of the starting materials or apparatus that is necessary for manufacturing the claimed invention. The same applies to a starting material when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. Following the general principle of the sufficiency of disclosure requirement, the level of required disclosure of starting material depends on whether a person skilled in the art would know, without undue efforts, how to obtain the necessary starting materials to produce the final product.

2. Intermediate compounds

27. In general, an intermediate is a substance formed during an intermediate step of a chain of multiple chemical reactions between reactants that lead to a final compound. After the intermediate is created in the intermediate step, it is consumed in a later step in the chemical reaction process. Intermediaries may be highly reactive and short-lived, losing their identity in the entire chemical reaction process, i.e., they do not appear in the overall chemical equation. Document SCP/35/5 presents information received from some Member States regarding sufficient disclosure of intermediates.

F. How to Use the Invention

28. For a person skilled in the art to carry out the claimed invention, the specification should teach that person not only how to make the invention, but also how to use the invention. In the field of chemistry where the structure or formula of a compound does not necessarily teach the usage of the compound, at least one particular technically significant use of the compound would be necessary to meet the sufficiency of disclosure. However, following the general principle of the sufficiency of disclosure requirement, if a person skilled in the art, based on his/her knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate method of use without undue experimentation, this would be sufficient to satisfy the sufficiency of disclosure. The guidelines of some patent offices in this regard are illustrated in document SCP/35/5.

G. Disclosure of Inventions Related to Medical Use

29. In some cases, a compound or composition claim is limited by its particular use. If a new use of a known compound is found and claimed, unless a person skilled in the art can readily predict the new use, the specification is required to sufficiently disclose the invention to the point that the compound is indeed credibly usable for the new kind of usage. As demonstrating suitability for therapeutic use would be complex, it is not surprising that one of the main questions relating to sufficient disclosure of medical inventions is the extent to which new and inventive therapeutic application should be disclosed in the patent application as filed.

30. Practices of some patent offices as well as jurisprudence of some Member States regarding the sufficient disclosure of compounds or compositions characterized by its therapeutic use are described in document SCP/35/5. At the higher conceptual level, they commonly note that the disclosure in the specification as filed must make it plausible or credible that the compound or composition will be effective for the claimed therapeutic use. To demonstrate such plausibility or credibility, they highlight the relevance of technical data or pharmacological studies that attest and give support to the claimed therapeutic use. Any evidence showing that the compound or composition can be used for the treatment of a specific disease may play a significant role in justifying sufficient disclosure of the invention that pertains to such new therapeutic use.

31. At the same time, the necessity of technical data, pharmacological study or evidence depends on to what extent a scientific reason for supporting the claimed therapeutic use can be established in the absence of such data, study or evidence, from the viewpoint of a person skilled in the art and his/her undue experimentation. Therefore, various scenarios and circumstances that may be involved in each specific case of medical use inventions may need to be taken into account. Accordingly, the issues discussed in other parts of document SCP/35/5, such as the concept and examples of plausible/credible disclosure, qualitative and quantitative disclosure required to meet sufficiency, and evidence and information that are required to support sufficiency, are particularly relevant to the sufficient disclosure of inventions relating to medical use.

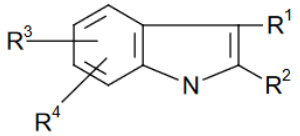
In vitro/in vivo

32. For inventions to be used for medical treatments (regardless of a new substance or a known substance), *in vitro* or *in vivo* tests are usually carried out to test therapeutic effects. The question regarding to what extent these test results must be disclosed in the specification to meet the sufficiency of disclosure is generally a matter related to the credibility or plausibility of the alleged therapeutic effect being produced by the claimed invention and any evidence supporting the claimed effect. Document SCP/35/5 describes practices and guidelines of some patent offices.

H. Markush formula – Claiming Numerous Alternatives

33. A “Markush” claim recites a list of alternatively usable members in one claim. Typically, a Markush claim covers a list of alternatives from which a selection is to be made. It is named after *Ex parte Markush* in the United States of America. The listing of specified alternatives within a Markush claim is referred to as a Markush group or Markush grouping. A Markush grouping is frequently used for defining inventions in metallurgy, chemistry and biology, such as a chemical formula having a common structural element to be covered in one claim, although inventions involving pure mechanical features or process steps can also be claimed in the Markush style. Where the Markush claim defines a group of chemical compounds by a chemical formula, it may be expressed as follows:

Claim 1. A compound of the formula:



wherein R^1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy and methyl; R^2–R^4 are methyl, benzyl or phenyl.

34. A Markush claim format is accepted in many countries. If properly used, a Markush claim assists a person skilled in the art to grasp the entire scope of alternatives in a single claim. In certain circumstances, however, the scope of the claim defined by alternatives in a Markush group may be so expansive that a person skilled in the art would not be able to determine that all alternative compounds covered by the claim are sufficiently disclosed. In general, the issues arising from the sufficient disclosure relating to Markush claims are akin to the questions about the required level of disclosure in the specification in cases where the claims cover a very broad scope.

35. From the general principle of the sufficiency of disclosure requirement, the mere fact that the scope of claims is very broad, or the claims contain a massive number of alternatives, does

not automatically lead to lack of sufficient disclosure. As a person skilled in the art may still need to exercise due efforts or experimentation to carry out the invention, working examples of each and every alternative in the Markush claims are not necessarily required. Representative embodiments in the specification that encompasses the full scope of the Markush claim would be sufficient. For example, an implicit description of alternative substances claimed is sufficient, if it is clear to the skilled person which substances are specifically meant from the general description or representative examples in the specification.

36. As to the sufficiency of disclosure of chemical inventions, for example, if a Markush group includes compounds with radicals of different nature, or covers different chemical classes, what can be considered as sufficient and reasonable amount of guidance in the disclosure may be more extensive than the guidance required for carrying out a claim covering, for instance, a single chemical class. However, whether representative embodiments are indeed sufficient or not depends on the determination of the person skilled in the art, the state of the art and the common general knowledge as well as what could be regarded as undue efforts for a person skilled in the art under each specific circumstances.

37. Another aspect that is raised by the submissions of some Member States on this topic is that the sufficiently representative working example(s) on manufacturing process(es) for obtaining the entire scope of the claimed compounds defined in the Markush formula is(are) necessary. Again, whether the working examples and other information disclosed in the specification are sufficiently representing the entire Markush claim or not depends on the extent to which a person skilled in the art can extrapolate such examples and information to other alternatives covered in the claims.

38. Where the scope of a Markush claim encompasses a large number of alternatives, some of them may correspond to non-working embodiments with regard to the technical effects alleged in the specification. The practice of some offices is that so long as the specification contains sufficient information for a person skilled in the art to distinguish working and non-working embodiments, the presence of non-working embodiments does not affect the sufficiency. Document SCP/35/5 also includes additional information provided by some Member States on this topic.

I. Stereoisomers

39. Isomers are molecules with identical chemical formulae, but having distinct structures, i.e., a different sequence of bonding or different special arrangements. Isomers do not necessarily share the same properties. Two main forms of isomerism are structural isomerism (or constitutional isomerism) and stereoisomerism (or spatial isomerism). Stereoisomers have the same bond structure, but the geometrical positioning of atoms and functional groups in space differs. Enantiomers is one of stereoisomers that are mirror images of each other, such as left and right hands having a mirror image along one axis. In general, enantiomers have identical chemical and physical properties except for their ability to rotate plane-polarized light (+/−) by equal amounts but in opposite directions. Chemical synthesis of enantiomeric substances produces racemic mixture, which contains equal parts of (+) and (-) enantiomers. Since many biological molecules are enantiomers, in medicines, it is not rare that one of the enantiomers have desired pharmacological property, while the other enantiomer is less active, inactive, or sometimes having adverse effects.

40. With respect to sufficient disclosure of inventions regarding stereoisomers and enantiomers, only a few Member States submitted specific information relating to these inventions. They address, for example, sufficient description of the characterization and configuration of stereoisomers, parameters of processes for obtaining stereoisomers, experimental data showing, for example, a process of isolation of an enantiomer from the racemic mixture, and evidence of the advantage of the claimed stereoisomer or enantiomer over

other forms. Document SCP/35/5 provides more information on this subject, based on these submissions.

J. Prodrugs

41. A prodrug is a pharmacologically inactive substance that must go through a chemical or enzymatic transformation to become effective inside the body. The therapeutic rationale behind prodrugs is to enhance the properties of the parent drug once metabolized in the body. Although prodrugs have the advantages of overcoming bioavailability issues associated with parent drugs, they have been considered to have less therapeutic activity than the parent drug. The prodrug must release active drug and cross-linked promoiety before, during and after absorption, or within specific target tissue, depending upon the purpose of prodrug strategy.

42. Only a few Member States submitted specific information relating to sufficient disclosure of prodrug inventions. One Member State stated that substantive analysis of patent applications claiming prodrugs followed the same guidelines applied to chemical compounds in general. A few submissions pointed to the functional definition of prodrugs and metabolites in patent claims, and the submission of the United Kingdom elaborated on its practice regarding prodrugs and metabolites, which are provided in document SCP/35/5.

K. Polymorph Forms and Crystallines

43. In general, polymorph forms and crystals are typically defined by their chemical composition and/or parameters (X-ray diffraction, solid state infrared (IR), Nuclear Magnetic Resonance (NMR) etc.). Accordingly, the submissions of some Member States on this topic primarily focus on the importance of identifying physical and chemical characterization of polymorph forms through appropriate techniques, including the Single Crystal X-Ray Diffraction (Single Crystal XRD) and X-Ray Powder Diffraction (XRPD). Some submissions also put emphasis on the disclosure of the process for obtaining the polymorph form, together with the essential steps, parameters and conditions. Other issues addressed include disclosure of the technical problem of the prior art form and the solution provided by the polymorph form as well as chemical identification of a solvate, clathrate, crystalline or co-crystal complex for clear and sufficient disclosure of these inventions. Further information on the practices of some Member States is provided in document SCP/35/5.

L. Compositions and Formulations

44. From the submissions of some Member States and guidelines of some patent offices, one of the main issues surrounding the disclosure of compositions appear to be how to define a composition in the claims in a clear and concise manner. Although clarity of claims is a requirement that is distinct from the sufficient disclosure requirement, inherent insufficiency may arise if the claims are too ambiguous. Clarity of the expressions such as “a pharmaceutical composition containing compound X together with a diluent, excipient or carrier”, “therapeutically effective amount” of an active ingredient, an active ingredient “with an auxiliary substance or substances” are discussed in these submissions and guidelines. Other issues relating to sufficient disclosure of composition claims are those defined in terms of parameters, or solely by their use, form of administration, or mechanism of action. Document SCP/35/5 indicates practices of some countries.

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