

Study on the Sufficiency of Disclosure (SCP/22/4)

Standing Committee on the Law of Patents (SCP) Twenty- second session (July 27 to 31, 2015)

Presentation by the Secretariat

Introduction

- Decision of the SCP 21 - to prepare a study on the sufficiency of disclosure
- The study contains the following elements:
 - (i) The enabling disclosure requirement;
 - (ii) Support requirement; and
 - (iii) The written description requirement
- Based on the information provided by Member States, a collection of factual information without analysis or recommendation
- In total, **58 Member States and three regional patent offices** provided their applicable laws (national and regional legislation, court decisions, patent examination manuals and guidelines)
- Scope of the study- information on the main general principles of requirements



THE ENABLING DISCLOSURE REQUIREMENT

The Enabling Disclosure Requirement

- The wording of the relevant provisions in most of the laws is largely similar and reflects Article 29.1 of the TRIPS Agreement:

“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 [...].”

- Examples: An applicant must disclose the invention in a “sufficiently clear and comprehensive manner” (Costa Rica); or in a manner which is “clear enough and complete enough” (Australia); or “sufficiently clear and precise” (Croatia) for the invention to be performed by a person skilled in the relevant art; or a complete specification shall “fully describe the invention and the manner in which it is to be performed” (Zambia); or the specification shall “fully and particularly describe the invention and the methods by which it is to be performed” (Pakistan)

The Enabling Disclosure Requirement

- The substantive elements of the enabling disclosure - a **great amount of similarity** in the laws and the examination guidelines
- Similar elements in both the PCT International Search and Preliminary Examination Guidelines and the examination guidelines of some patent offices
 - E.g. The Manual of Patent Practice of the IP Office of the United Kingdom 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 PCT.

The Enabling Disclosure Requirement

- The purpose of the disclosure requirement - exclusive rights are granted against the disclosure of the invention
- The public disclosure function of the patent system is 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 (e.g., inducing the technology transfer and avoiding a duplicative R&D)

The Enabling Disclosure Requirement

- Responses from Member States on the purpose of the enabling disclosure requirement:
 - 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” (Australia)
 - The 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.” (The United States of America)

The Enabling Disclosure Requirement

Requirements regarding the description

- 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
- 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 laws 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**.

The Enabling Disclosure Requirement

Test for enablement requirement

- In many countries, 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”**
- However, **certain amount of trial and error is generally admissible** in most of the countries
 - E.g., trial and error “to a reasonable extent” or “reasonable number of experiments” is acceptable to comply with the requirement of enabling disclosure
 - “While 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.” (Australia)

The Enabling Disclosure Requirement

Undue burden

- 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**
- Those factors are also found in the PCT International Search and Preliminary Examination Guidelines

The Enabling Disclosure Requirement

National practices on “undue burden”/ “undue experimentation”

- **The United Kingdom:** “[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.”

The Enabling Disclosure Requirement

National practices on “undue burden”/ “undue experimentation”

- **China:** The enabling disclosure requirement is not met when, for e.g. :
 - 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.

The Enabling Disclosure Requirement

The disclosure of essential and well-known features

- In general, 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.
- Details of **well-known ancillary features** neither necessary nor desirable
- However, 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
 - E.g. “[...] 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**” (Singapore)
 - “[...] 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.” (EPO)

The Enabling Disclosure Requirement

The disclosure of essential and well-known features

- In addition, in some offices, it is not required to either state inventions that are not claimed or those extra matters that are unnecessary for carrying out the claimed invention (e.g., Japan)
- 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 (e.g., OAPI)

The Enabling Disclosure Requirement

Provision of examples

- In 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, 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.
 - Denmark: “In these [...] 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.”

The Enabling Disclosure Requirement

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

- In some laws, the enabling disclosure requirement must be assessed on the basis of the “**application as a whole**”, including the description, claims and drawings
- Other laws refer to the “**specification as a whole**” containing the description, claims and drawings.

The Enabling Disclosure Requirement

- Specification must be enabling as of the filing date, not at a later date
- Need to consider:
 - the nature of the invention, the state of the prior art, and the level of skill in the art
- No use of post-filing date references
 - In the United States of America: 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.
 - In Spain, with regards to the date of disclosure of the results of clinical trials: “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.”

The Enabling Disclosure Requirement

Specification must be enabling to a person skilled in the art

- The requirement is evaluated in relation to a person skilled in the art
- 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
- In many countries, the person skilled in the art - the same for the evaluation of sufficiency of disclosure and the inventive step requirement
 - In India, the Intellectual Property Appellate Board: 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”
- 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 specialty

The Enabling Disclosure Requirement

Availability of starting materials

- In general, the starting materials essential to making the claimed invention though not cited in the claim must be adequately disclosed:
- For example:
 - **The United States of America:** 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
 - **Australia:** 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
 - **China:** 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

The Enabling Disclosure Requirement

Trademarks and trade names

- In some countries, 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
- Reason: the use of trademarks may not provide an enabling disclosure as the composition of the trademarked article may change over time or the manufacturer may discontinue making it
- In some countries: if such a word is used, 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, in some countries, where such words have become internationally accepted as standard descriptive terms and have acquired a precise meaning, they may be allowed without further identification of the product to which they relate (e.g., Argentina, Croatia, the United Kingdom)

The Enabling Disclosure Requirement

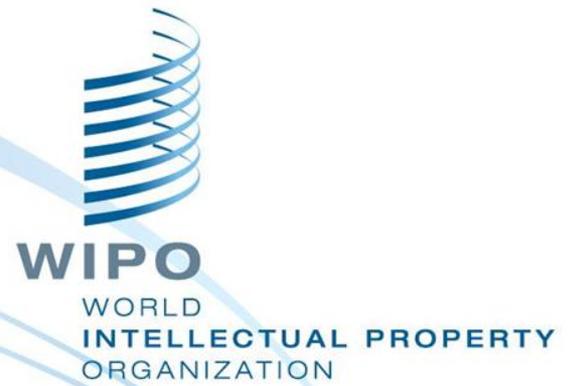
Disclosure of biological material

- Deposit of such material with an authorized institution
- Depository institution: any institutions recognized under the Budapest Treaty or any other recognized depository institutions
- 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.
 - Other variations: e.g., 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.
 - 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
- The invention is disclosed when an application contains:
 - information on the characteristics of the deposited biological material as is available to the applicant
 - the name of the depository institution and
 - the accession number of the deposit

The Enabling Disclosure Requirement

Fundamental insufficiency

- Two instances:
 - where the successful performance of the invention is dependent on chance
 - where successful performance of the invention is inherently impossible because it would be contrary to well-established physical laws



SUPPORT REQUIREMENT

Support Requirement

- **Claims** which define the matter for which protection is sought **shall be fully supported by the description**
- The meaning of the term “the claims shall be fully supported by the description” is largely similar in most jurisdictions:
 - 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 the contribution to the art

Support Requirement

- In Japan, the purpose of this requirement was explained in an IP 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.”
- In Australia, the court explained that the support for the claims means that “[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.”

Support Requirement

- In many offices, 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**
- The **mere coincidence of wording** in the claim and the description **does not mean** that the claim is necessarily supported by the description

Support Requirement

Methodologies for examination on the compliance with the support requirement

Example: Patent Manual of Practice and Procedure of IP Australia:

To determine whether the specification complies with the support requirement, examiners should:

- (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.

Support Requirement

Generalization and its extent

- Many offices' examination guidelines focus on the concept of generalization:
 - 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 to be established in each particular case in the light of the relevant prior art
 - 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-** 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

Support Requirement

- In many patent offices, a claim in a generic form 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
- If the information is insufficient- 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
- Notably, to illustrate the question of support, some patent offices' examination guidelines provide the similar examples
 - “a synthetic resin mouldings to obtain changes in characteristics”, “plant seedlings” (e.g., China, Croatia, EPO, PCT)

Support Requirement

The question of support is illustrated by the following examples:

EPO and PCT:

- a claim not being consistent with the disclosure, for instance, due to contradictions between the elements contained in the claims and the description; and
- 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

Japan:

- the matter neither stated nor implied in the detailed explanation of an invention is stated in the claims;
- 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; and
- 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

Support Requirement

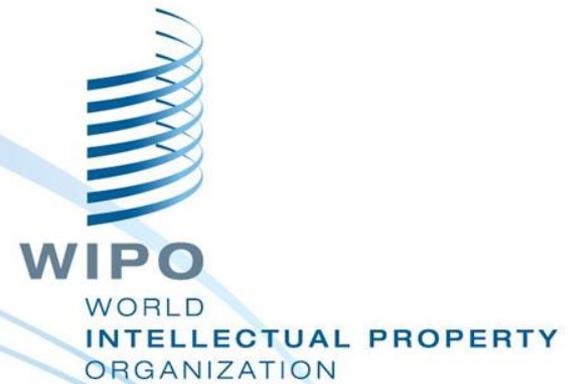
Whole contents of the description together with any drawings to be taken into account

- 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.”
- Each of the claims (independent and dependent 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
 - 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

Support Requirement

The enabling disclosure requirement and the support requirement

- Compliance with the enabling disclosure requirement and the support requirement are determined **independently**
- If 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.**



The Written Description Requirement

The Written Description Requirement

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

The 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, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention

The Written Description Requirement

Policy objectives:

- To clearly convey the information that an applicant has invented the subject matter which is claimed
- To put the public in possession of what the applicant claims as the invention

(Chapter 2163(I) of the MPEP of the USPTO)

The Written Description Requirement

The “written description” question arises in the context of:

- an original claim which is not supported by the disclosure of an application as filed
- the specification as originally filed does not support claims not originally filed in the application
- the interference context, where the issue is whether a specification provides support for a claim corresponding to a count in an interference

The Written Description Requirement

Steps to determine whether the written description requirement is met:

- 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

Thank You