SUFFICIENCY OF DISCLOSURE AT THE INTELLECTUAL PROPERTY OFFICE OF SINGAPORE (IPOS)

1. Introduction

Pursuant to the decision of the thirty-third session of the Standing Committee on the Law of Patents ("SCP"), which was held in Geneva in a hybrid format from December 6 to 9, 2021, Member States and Regional Patent Offices were invited to send to the Secretariat any additional input for the preparation of a study on the sufficiency of disclosure, as proposed in document SCP/31/8 Rev.

Singapore has provided information on our national laws and practices in relation to the requirement of sufficiency of disclosure in the earlier study on sufficiency of disclosure prepared by the Secretariat (document SCP/22/4). The document was discussed at the twenty-second session of the SCP, held in Geneva from July 27 to 31, 2015. Singapore now provides the additional input requested.

The following sections will provide a summary of the general principles set out in document SCP/22/4, before going into the updates to the Singapore Patent Examination Guidelines (the "Guidelines"). It will also discuss the sufficiency of disclosure practice in respective of inorganic and organic chemistry (including pharmaceuticals), microorganisms and artificial intelligence, where each differs from the general principles or deserves special consideration.

2. General Principles

2.1. Sufficiency of Disclosure Requirement

Section 25(4) of Singapore Patents Act 1994 ("SGPA") states that the specification "shall disclose the invention in a manner which is clear and complete for the invention to be performed by a person skilled in the art." This is commonly known as the requirement of sufficiency of disclosure or enablement.

The determination of whether a disclosure is sufficient is highly sensitive to the nature of the invention *(Dien Ghin Electronic (S) Pte Ltd v Khek Tai Ting* (trading as Soon Heng Digitax) [2011] SGHC 36*, Kirin-Amgen Inc v Hoechst Marion Roussel* [2005] RPC 9*)*. Thus, the general approach to determine whether a specification complies with the requirements of Section 25(4) is to identify the invention and what it claimed to enable the skilled person to do, and then ask whether the specification enabled him to do it.

The specification must provide sufficient disclosure across the full scope of the claims. At least one embodiment of the invention or at least one method of performing the invention must be provided in the description, with examples where appropriate, and with reference to the drawings, if any.

The specification does not need to disclose all the details required to work the invention if these would be known or obvious to the skilled person.

Errors in the specification will not result in a lack of sufficiency provided they are obvious errors that the skilled person would have recognised and have known how to correct.

Details of the Guidelines and court decisions relating to the sufficiency of disclosure requirements can be found in document SCP/22/4 on the Sufficiency of Disclosure.

2.2. Support Requirement

When a specification for an invention is considered to lack sufficient disclosure under Section 25(4) of the SGPA, the specification may be irreparable. Specifically, any amendments adding information to cure this deficiency may fail to satisfy the requirements prescribed in Section 84 of the SGPA where amendments of applications and patents are not to include added matter. As such, the Examiner would normally reserve sufficiency objections for instances where the invention cannot be readily enabled even by narrowing the scope of the monopoly claimed.

Hence at pre-grant, it is more common for the objection to be raised under Section 25(5)(c) of the SGPA. Section 25(5)(c) states that the claims should be supported by the description and its consideration often overlaps with the consideration for enablement under Section 25(4). The subsequent discussion on support would make this overlap in consideration between the two requirements more apparent.

In practice, support requirement means that:

(a) the scope of the claims should be justified by the disclosure provided by the description, drawings and sequence listing, and in particular "should not extend to subject matter which, after reading the description, would still not be at the disposal of the person skilled in the art" (*Generics (UK) Ltd v Lundbeck A/S* [2009] RPC 13 at [36]); and

(b) the specification must provide a disclosure that enables the invention to be performed across the breadth of the claims (*Asahi Kasei Kogyo KK's Application* [1991] RPC 485).

Most claims will represent a generalisation of the inventive concept. The extent to which that generalisation is supported will vary from case to case.

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 assessing support is determining whether the skilled person would predict that such variants and equivalents would have the same properties as those specifically described. Notably this may differ between where the invention is in a well-worked art and where the invention is in a new field. In some cases, the scope of terms in a well-worked art may be narrower as there is more certainty as to the types of variants that may be substituted for certain features. In a newer field, it may be less predictable so more flexibility may be given to the drafting. However, if there is insufficient enablement across the full scope then an objection of lack of support may arise.

Where the invention relates to a "principle of general application" the claims may be in correspondingly broad terms. The applicant need not show that they have proved its application in every individual instance. On one hand, if the claims include a number of discrete methods or products, the applicant must enable the invention to be performed in respect of each of them. On the other hand, inventions consisting of a single embodiment,

such as a single chemical compound, will generally be supported (*Generics (UK) v H Lundbeck A/S* [2009] RPC 13 at [25]).

Details of the Guidelines and court decisions relating to the support requirements can be found in document SCP/22/4 Study on the Sufficiency of Disclosure.

3. Recent Updates in the Guidelines with respect to the Support Requirements

There are certain claim types which are more likely to involve a consideration of whether there is sufficient support: broad claims, claims by result, claims in which features are defined by function, parametric claims and reach-through claims etc. These are dealt with specifically in the Guidelines. In particular, updates in the Guidelines in 2017 have elaborated on the consideration for parametric claims as follows -

> Depending on the facts of the case, parametric claims are in effect claims by result which may be subject to lack of support/sufficiency objections. The usual considerations are whether the claims encompass matter that owes nothing to the teachings of the invention in the specification. If it is considered that the skilled person would be faced with undue burden to arrive at the full scope of the claim by following the exemplification given in the specification or procedures common in the art, a lack of support/sufficiency objection should be raised. Admittedly, there is a delicate balance between the considerations for clarity and lack of support/sufficiency, which have to be assessed based on the facts of each individual case. Objections should not arise merely on the basis that parameters not known in the prior art are used in the claims. In the event 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 specified parameters (see for example decision T 231/01), use of such parameters would be allowable.

It should be noted that while the Guidelines dealt specifically with the considerations for these group of claims, no special rules exist for such claims and they should be construed as per any other type of claim.

4. Sufficiency of Disclosure with respect to Specific Technology Sections

4.1 Inorganic and Organic Chemistry (including Pharmaceuticals)

Inventions pertaining to inorganic and organic chemistry follow the general principle in enabling disclosure requirements where the specification must provide sufficient disclosure across the full scope of the claims (*Chiron Corp. v Murex Diagnostics Ltd* [1996] RPC 535).

However, the specification does not need to disclose all the details required to work the invention if these would be known or obvious to the skilled person. For example, when a claim relates to a single compound *per se*, the disclosure of one method of making the compound may provide sufficient disclosure across the full scope of the claim and the applicant is not required to provide all possible methods of making the product (*Generics (UK) Limited and others v H Lundbeck A/S* [2009] RPC 13).

If the invention is unpredictable in nature, then more detail may be required so that no undue burden will be imposed on the person skilled in the art. For example, when the specification claims for a synergistic combination of two components, each selected from separate vast lists, the specification must contain sufficient guidance on how to select this a pair of

components to achieve the desired characteristic in the resulting product or on how the desirable characteristics could be measured.

To determine if the specification has disclosed all features that are essential to carry out the invention, a straightforward test is to determine if the specification requires the addressee to carry out tests or developments that went beyond routine trials (*Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] RPC 2). In addition, the person skilled in the art should be able to identify the tests or developments on the basis of the disclosure (*Mayne Pharma v Debiopharm and Sanofi-Synthélabo* [2006] EWHC 1123 (Pat)). As considered by Justice Puffrey in *Mayne Pharma v Debiopharm and Sanofi-Synthélabo* [2006] EWHC 1123 (Pat),

> "*When one is confronted with a claim which requires 'an effective stabilising amount' of a material, it must be possible to design a test which can answer the question 'Have I used such an amount or not?'. There will always be problems on the edges of claim, but it should in general, be possible to know what the test is. If one cannot identify the test on the basis of the disclosure, then I think that the disclosure is insufficient*".

4.2 Microorganisms

Inventions involving microorganisms follow the general principles in enabling disclosure requirements. This includes that the specification should provide sufficient information of the microorganisms required for the performance of the inventions to the person skilled in the art to work the invention.

In cases where the microorganism or biological material used in a process is well known and the process is adequately described by written description, the specification is considered to be sufficient as long as the written description allows the skilled person in the art to perform the process in a repeatable manner and prepare the product without undue burden, even if the final product is a new biological material.

In inventions where their microorganisms or biological materials are not available to the public at the date of filing the application, and which cannot be described in the specification in such a manner as to enable the invention to be performed by a person skilled in the art, the specification would have to satisfy the conditions set out in Rule 20 of the Singapore Patent Rules ("SGPR") and sub-paragraph (2) of the Fourth Schedule to SGPR.

Rule 20 of the SGPR states that the Fourth Schedule to SGPR shall have effect in relation to certain applications for patents, and granted patents, for inventions which require for their performance the use of microorganisms.

The Fourth Schedule stipulates that for inventions that require for their performance the use of microorganisms which is not available to the public at the date of filing the application, and which cannot be described in the specification in such a manner as to enable the invention to be performed by a person skilled in the art, the specification shall, in relation to the microorganism itself, be treated as disclosing the invention, if one of the conditions set out in sub-paragraph (2) of the Fourth Schedule is satisfied.

The conditions referred to in sub-paragraph (2) of the Fourth Schedule are:

(a) a condition that —

(i) not later than the date of filing of the application, a culture of the microorganism has been deposited with any international depositary authority which is able to furnish a sample of the microorganism; and
(ii) the name of the international depositary authority, the date when the culture was deposited and the accession number of the deposit are given in the specification of the application; and

(b) a condition, in the case of an international application for a patent (Singapore) which is treated, by virtue of section 85 as a patent under the SGPA, or, as the case may be, an application for a patent under the SGPA, that the corresponding provisions of the Implementing Regulations to the Patent Co-operation Treaty have been complied with,

and where a new deposit is made under paragraph 4, a further condition that the applicant or proprietor makes a new deposit in accordance with that paragraph.

As such, the above conditions of sub-paragraph (2) would require a deposit of the microorganism to be made in cases where the microorganism cannot be adequately described by written description in a manner to enable the skilled person in the art to arrive at the microorganism.

Section 114 of the SGPA emphasises the availability of samples of microorganisms to the public and states that provision may be made by rules prescribing the circumstances in which the specification of an application for a patent, or of a patent, for an invention which requires for its performance the use of a microorganism is to be treated as disclosing the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art. Section 114 further prescribes in sub-paragraph (2) that the SGPR may require the applicant or patentee —

(a) to take such steps as may be prescribed for the purposes of making available to the public samples of the microorganism; and
(b) not to impose or maintain restrictions on the uses to which such samples may be put, except as may be prescribed.

A word of warning is also provided in Section 114(5) that an application for revocation of the patent under Section 80(1)(c) of the SGPA may be made if any of the requirements pertaining to making samples of microorganisms available in accordance with the SGPR ceases to be complied with. It is stated in Section 80(1)(c) that the Registrar may, on the application of any person, by order revoke a patent for an invention on the ground of the specification of the patent does not disclose the invention clearly and completely for it to be performed by a person skilled in the art. It is therefore important that the applicant or patentee is mindful of the requirements relating to availability of the deposited microorganism during the application of the patent as well as for the duration of the patent, in accordance with Fourth Schedule.

When an application claims priority to an earlier application and the invention relies upon a deposit for sufficiency purposes, the deposit should have been made not later than the date of filing of that earlier application *(*T 0107/09 Bristol-Myers Squibb/CD40CR receptor and ligands thereof). Otherwise, priority cannot be claimed for the subject matter where a deposit is required in order for the matter to be considered sufficiently disclosed.

4.3 Artificial Intelligence

Inventions pertaining to artificial intelligence follow the general principles in enabling disclosure requirements. While there is no principle specifically highlighting inventions pertaining to artificial intelligence, the developments in this field is being observed for any potential impact on the examination practices.

5. Closing

Further information can be found in para. 5.23-5.40, 5.84-5.87, 5.97-5.99,5.116-5.118, and 5.122-5.126 of the Examination Guidelines for Patent Applications at IPOS (updated Oct 2021) (https://go.gov.sg/patentexaminationguide).