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FURTHER STUDY ON THE SUFFICIENCY OF DISCLOSURE (PART II)

Document prepared by the Secretariat

I. INTRODUCTION

1. At the twenty-second session of the Standing Committee on the Law of Patents (SCP), held in Geneva from July 27 to 31, 2015, the Committee discussed a study on the sufficiency of disclosure prepared by the Secretariat (document SCP/22/4). The study addressed the main general principles of the sufficiency of disclosure, with references to relevant national and regional patent laws and practices. It contained the following elements: (i) the enabling disclosure requirement; (ii) the support requirement; and (iii) the written description requirement.

2. At its thirty-third session held in a hybrid format from December 6 to 9, 2021, the Committee agreed that a further study on the sufficiency of disclosure, as proposed in document SCP/31/8 Rev., would be prepared by the Secretariat, based on the information received from Member States and regional patent offices. According to paragraph 11 of document SCP/31/8 Rev., a further study covers inorganic and organic chemistry, including pharmaceuticals, as well as microorganisms, artificial intelligence (AI) and any other technological sector in which the fulfilment of the sufficiency of disclosure deserves special attention. As a non-exhaustive list of topics to be covered, the said paragraph lists the following areas:

- Chemical compounds defined by Markush formula;
- Esters, ethers, salts, N-oxides;
- Stereoisomers (enantiomers, diastereomers, Cis-trans and E-Z isomerism);
- Pro-drugs;

- Compositions and formulations;
- Polymorphic forms and crystalline, co-crystals, hydrates, solvates;
- New use of a known compound;
- Manufacturing process of chemical products;
- Microorganisms (different aspects related to the implementation of the Budapest System);
- Artificial intelligence (AI).

3. Consequently, the Secretariat invited Member States and regional patent offices, through Circular Note C. 9089 dated January 14, 2022, to submit relevant inputs to the International Bureau.

4. Taking into account the information submitted by the Member States and regional patent offices in response to C.9089, the Secretariat prepared document SCP/34/5 entitled “Further Study on the Sufficiency of Disclosure (Part I)”, which was submitted to the thirty-fourth session of the SCP for its discussion. The document covers the issues concerning the sufficiency of disclosure regarding: (i) inventions relating to biological materials, such as microorganisms; and (ii) AI-related inventions (inventions that form the AI technologies and inventions that involve the use of AI). At the same session, the Committee agreed that a second part of the further study on the sufficiency of disclosure will be submitted to the thirty-fifth session of the SCP. It would relate 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., based on the information received from Member States and regional patent offices.

5. Accordingly, the Secretariat invited Member States and regional patent offices, through Circular Note C. 9141 dated December 7, 2022, to submit relevant inputs to the International Bureau. Taking into account the inputs received in response to Circular Notes C.9089 and C.9141, the Secretariat prepared this document, consisting of a Further Study on the Sufficiency of Disclosure (Part II) for discussion at the thirty-fifth session of the SCP.

6. As the further study on the sufficiency of disclosure is built on the earlier study contained in SCP/22/4, they should be read together. In addition, although it could be related/ encompassed in the general issue of disclosure, “clarity and conciseness of claims” (clearly and concisely defining the subject in the claims) are not addressed in this document.

II. OVERVIEW OF THE SUFFICIENCY OF DISCLOSURE REQUIREMENT

A. Summary of the Sufficiency of Disclosure Requirement

7. Similarly to other patentability requirements, the legal provisions regarding the sufficiency of disclosure lay down general requirements that apply to inventions in any technical field. While a couple of supplementary provisions are often found in respect of inventions relating to biological materials, these provisions are applicable to the extent that such inventions cannot otherwise meet the general requirements.¹ Consequently, the general guidance and methodologies for the assessment of the sufficiency of disclosure, which have been developed in each jurisdiction, apply to inventions in all technical fields, including inventions having an experimental nature in unpredictable art, such as chemistry and biotechnology.

8. The sufficiency of disclosure requirement reflects one of the fundamental features of patent law: in exchange for the exclusive rights granted to a patentee on a claimed invention, the right holder must disclose the information relating to the invention to the public. In summary, it is through this requirement that the patent system facilitates the dissemination of and access

¹ See paragraphs 53 to 56 of document SCP/22/4 (Study on the Sufficiency of Disclosure) and paragraphs 19 to 66 of document SCP/34/5 (Further Study on the Sufficiency of Disclosure (Part I)).

to technological information contained in patent applications. Such a public disclosure mechanism is expected to result in the expansion of generally accessible technical knowledge, inducing technology transfer and avoiding duplicative R&D. Another common element in patent laws is that the scope of the claimed invention shall not extend beyond what was disclosed in the application, and what had not been recognized and possessed by the inventor, as of the filing date. This principle forecloses granting patents on speculative inventions.²

9. The general principles of the enabling disclosure requirement, support requirement and written description requirement may be summarized as follows:

- *Enabling disclosure requirement:* Overall, the enabling disclosure requirement requires an applicant to disclose the claimed invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. This means that the assessment of the enabling disclosure requirement is made across the whole scope of the claims. In addition to the information disclosed explicitly or implicitly in a patent application, a person skilled in the art may use the general common knowledge in the art. Based on such information and knowledge, a person skilled in the art should be able to perform or reproduce the claimed invention without undue burden, effort or experimentation. The disclosure must be enabling for a person skilled in the art at the time of the filing date.
- *Support requirement:* In general, the claims shall be fully supported by the description, thereby showing that the applicant only claims subject matter which it had recognized and described in the description on the filing date. 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. Most claims are generalizations from one or more particular embodiments or examples as set forth in the description. In general, the extent of permissible generalization is a matter which has to be established in each particular case in the light of the relevant prior art.
- *Written description requirement:* The written description requirement is a requirement provided under the law of the United States of America. The United States Code, Title 35, Section 112(a) requires that “[t]he specification shall contain a written description of the invention [...]”. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail so that a person skilled in the art can reasonably conclude that the inventor possessed the claimed invention at the time the application was filed.

10. As indicated above, the level of disclosure required closely relates to the determination of a person skilled in the art in each case. It is also evaluated against the scope of the claimed invention and the detailed description of that invention.

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

11. In each country, legal provisions in the applicable law set forth the sufficiency of disclosure requirement. Courts provide judicial interpretation of law, which assists detailed or nuanced understanding of how the legal provisions are applied in each specific case. Taking into account the judicial interpretation of law, some patent offices provide administrative guidelines or manuals that articulate the application of procedural and substantive requirements in various situations that may arise in the course of patent procedures, including examination of patent applications. Such guidelines and manuals facilitate consistent examination of patent applications by patent examiners. If published, they also inform patent applicants, patent

² The earlier study on the sufficiency of disclosure (document SCP/22/4) describes policy objectives, general principles and practices with respect to the enabling disclosure requirement, support requirement and written description requirement in detail.

attorneys and other stakeholders about the applicable laws and practice applied by the national administration.

12. 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.

13. Such supplementary information may be considered useful in certain technical fields that can be characterized by its experimental nature, such as chemistry and biotechnology. In general, physical structures of inventions in these fields are less predictable in terms of their technical effects or their properties (or utilities) in comparison to, for instance, the electronic or mechanical fields. Similarly, functional properties, for instance, does not necessarily guide a person skilled in the art to corresponding physical structures. For example, the technical effects of a chemical compound or a biological material are not always predictable only from its structure, and thus the purported technical effects may need to be verified and confirmed by experimental data. In some cases, it may be possible to define a chemical product or a biological material by its properties, or by a method of preparing such a product, even if its structure has not been fully and clearly defined. In addition, a chemical or biological product with a particular structure could have a number of different and unpredicted properties or utilities, such as a pharmaceutical compound that has different therapeutic effects. In any technical field, inventions in nascent technologies are more challenging to evaluate with regard to the compliance with the sufficiency of disclosure requirement, in view of the lack of well-documented prior art that also determines the level of a person skilled in the relevant art.

14. 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, if applicable.

15. It should be reiterated that the fundamental legal requirements relating to the sufficiency of disclosure are prescribed in the applicable law, and in any technical field, whether an application meets the disclosure requirement is determined by considering each case on its own merits.

III. INVENTIONS RELATING TO CHEMISTRY AND BIOTECHNOLOGY

A. Predictability of the Art and Sufficiency of Disclosure

16. 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”.

17. In some jurisdictions, a similar concept is expressed as “the disclosure must be reproducible without undue burden”.³ According to the submission of Germany, reproducibility must comprise the complete scope for which protection is sought, and the requirement of reproducibility must be fulfilled at the filing date (or priority date).⁴ However, to be reproducible,

³ EPO Case Law of the Boards of Appeal, II.C.6.6.

⁴ Moufang, in: Schulte, *Patentgesetz*, 11th edition 2022, Section 34 marginal number 347 and 355.

it is only necessary to indicate the decisive direction in which a person skilled in the art may work on his/her own accord.⁵ 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

Teva v. Merck Sharp & Dohme⁷ (France)

The case related to an invention concerning medicine. The ruling confirmed that, in order to comply with the sufficiency of disclosure requirement, the pharmacological properties and one or more medical uses must be indicated. The inventor must indicate that the result has been researched and exists, and that tests and experiments tending to demonstrate the claimed medical effect have been carried out. In that case, the examples did not reflect, directly and unambiguously, the claimed medical use. Therefore, the patent application did not reflect, directly and unambiguously, the claimed medical uses and, absent any specific technical training, the person skilled in the art was not in a position to reproduce the invention and was therefore obliged to conduct a full research program.

18. 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. In order to perform/reproduce the claimed invention, the person skilled in the art also uses that knowledge to supplement the information contained within the application. Accordingly, embodiments (examples) in the application can omit well-known feature or basic steps in the application.⁸

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

19. 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.

20. For example, in the United Kingdom, the Court of Appeal in *Regeneron Pharmaceuticals v Genentech* held that, in that case, the specification must make it “plausible” that the invention would work, i.e., be effective to treat the disease, across the claimed scope. The concept of plausibility was summarized by Birss J in *Hospira v Genentech*,⁹ as follows:

“[...] a rule which demanded clinical results could cause real difficulties. On the other hand, if all the patent contains is a mere proposal, then it has not made a contribution to the art in this example [...] Moreover it would be a recipe for abuse if all that was required in order to obtain a patent in this field was a proposal, without any basis, to use drug A to treat disease B. Patent law seeks to address these factors balancing the requirements for sufficiency of disclosure against the rules of novelty and inventive step. But the conventional sufficiency test of asking whether the claimed invention works, does not help. The treatment does work but what if the patent does not say so? For these reasons, the idea of “plausibility” as part of the law of

⁵ BGH, decision of 21 December 1967, ref: Ia ZB 14/66, GRUR 1968, 311 – *Garmachverfahren*.

⁶ Moufang, in: Schulte, *Patentgesetz*, 11th edition 2022, Section 34 marginal number 343.

⁷ High Court of Paris of November 9, 2010; Court of Appeals of Paris of June 30, 2015; Court of Cassation of December 6, 2017.

⁸ See the submission of the United Kingdom.

⁹ *Hospira v Genentech* [2014] EWHC 1094.

sufficiency of disclosure has been developed [...] The term “plausibility” has been coined to characterize what it is that a patent specification must provide in order to be sufficient, short of full clinical proof of efficacy.”

[*Hospira v Genentech* [2014] EWHC 1094]

21. Recently, the Enlarged Board of Appeal (EBA) considered in G 2/21 admissibility of post-published evidence and the notion of “plausibility” in the context of inventive step.¹⁰ Although being outside the scope of the point of law referred to the EBA, it also analyzed the case law of the Boards of Appeal with respect to the similar issues that had arisen in the determination of the sufficiency of disclosure, particularly with regard to inventions concerning second medical use, where a new therapeutic effect of a known substance is usually claimed. The EBA arrived at the intermediate conclusion that the scope of reliance on post-published evidence is much narrower under sufficiency of disclosure (Article 83 EPC) compared to the situation under inventive step (Article 56 EPC). In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, the proof of a claimed therapeutic effect has to be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved. A lack in that respect cannot be remedied by post-published evidence.

22. As it can be seen in many examples, court cases and submissions of Member States cited in this document, 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 (Section III.C), supportive evidence that may be filed during the patent proceedings (Section III.D), particularly in cases where the inventive concept of the invention is on a specific medical use or therapeutical effects of the product claimed (Section III.G). Plausible disclosure of compositions is addressed in Section III.L.

B. Generalization of the Inventive Concept in the Claims

23. 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. In general, an applicant may claim broader scope than the specific embodiments in the description, such as obvious variants and technical equivalents.

24. The submission of Singapore notes that 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 it may depend on, *inter alia*, whether the invention is in a well-known technical art or in a new field. For example, as the scope of terms in a well-known art may be more precisely defined, there is more certainty as to the types of variants that may substitute the embodiment described.

¹⁰ <https://www.epo.org/en/boards-of-appeal/decisions/g210002ex1>. The order issued by the Enlarged Board of Appeal reads as follows:

1. Evidence submitted by a patent applicant or proprietor to prove a technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date.
2. A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention.

25. On the similar note, the Examination Guidelines of the Japan Patent Office (JPO)¹¹ state that claims may recite an invention based on expansion or generalization of one or more specific examples in the description. However, the maximum extent to which the claims may be generalized without going beyond the disclosure in the description depends on the technical field in which the invention pertains. For example, in the technical fields where it is difficult to understand the relationship between the structure of the invention and its function, characteristics etc., the maximum extent to which the claims can generalize the specific examples in the description tends to be narrower.

Example from the Examination Guidelines of the JPO

Compounds activating R receptor¹²

[Claim 1] A compound having activity of activating R receptor.

[Overview of the description] The applicant found R receptor and a method of screening compounds having activity of activating R receptor. The series of steps include a screening step which is conducted to detect the presence of such activity and a method of detecting the compound having the activity of activating R receptor is defined in the description. As examples of the claimed invention, chemical structures of new compounds X, Y, and Z and a method of producing them are described, together with the supportive experimental data. However, there is no description with respect to the chemical structures and production methods of other compounds.

[Overview of reason for refusal]

Claim 1 covers any compound having the activity of activating R receptor, while the description merely indicates compounds X, Y and Z only. According to the common general knowledge at the time of filing, it was difficult to understand the specific compound that can activate the new receptor. From the description and the common general knowledge, it is difficult to understand other compounds that have the activity of activating R receptor. Thus, it would be necessary for a person skilled in the art to synthesize, screen and examine the activities of a myriad of compounds by trial and error to enable the invention claimed in claim 1, which is beyond the extent to which such a person should be reasonably expected. Therefore, the description of the invention is not clearly and sufficiently stated so as to enable a person skilled in the art to carry out the invention claimed in claim 1. Furthermore, since the description does not provide any grounds for expanding or generalizing the claim beyond these specific compounds, the invention claimed in claim 1 exceeds the extent of disclosure in the description.

26. Similarly, the submission of Germany states that the generalization must not go so far as to mention only those terms which merely circumscribe the problem of the underlying invention, without an apparent causal connection between the means used and the success sought. This would be an obstacle to a technical progress, leaving the skilled person unable to achieve the result expected from the invention.¹³ The same applies if success does not occur with some reliability, but only under favorable circumstances, or if the goal cannot be achieved with a statistically acceptable probability, i.e. if the error rate is too high.¹⁴ Likewise, general indications of ranges of physical properties going beyond the teaching disclosed in the application must not be overly generalized so that protection would be extended to hypothetically claimed broad ranges exceeding the contribution to the art by the invention.¹⁵

¹¹ Examination Guidelines, Japan Patent Office, Part II, Chapter 2, Section 2.2.2.

¹² Examination Handbook for Patent and Utility Model in Japan, Annex A, Description Requirement Case 2.

¹³ BGH, decision of 19 July 1984, ref: X ZB 18/83, GRUR 1985, 31 – *Acrylfasern*.

¹⁴ Moufang, in: Schulte, *Patentgesetz*, 11th edition 2022, Section 34 marginal number 346.

¹⁵ BGH, judgement of 25 February 2010, ref: Xa ZR 100/05, GRUR 2010, 414 – *Thermoplastische Zusammensetzung*.

27. Regarding the extent to which the claims may be generalized, the Industrial Property Office of the Czech Republic requires a limitation of the scope of claims in proportion to the scope documented in the examples, where the claimed scope of protection is clearly disproportionate in view of the evidence found in the examples. The Office understands the notion of “proportionately” as an adjustment of the scope of protection to what has been demonstrated in the examples and at the same time supported by the arguments in the descriptive part of the patent specification. If the applicant limits the scope proportionately or explain why such limitation request by the Office is unjustified, the Office should reconsider its position.¹⁶

C. Undue Burden, Efforts or Experimentation

28. 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.

29. 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.¹⁷

30. As it can be deduced from the non-exhaustive factors indicated in the previous paragraph, 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.¹⁸ If a person skilled in the art can easily anticipate the effect of the invention and how to make and use it from the state of the art and common general knowledge, less detail may be required in the patent application.

Example in the Patent Examination Guidelines of the Intellectual Property Office of Singapore (IPOS)

A claimed product comprises two components, each selected from separate vast lists. To perform the invention, the person skilled in the art is required to select a pair of components to achieve particular desirable characteristics in the final product. In this situation, the specification would lack an enabling disclosure where:

(i) the specification contains little or no guidance on how is claimed, the specification must contain sufficient guidance on how to select that pair of components to achieve the desired characteristic in the resulting product; and/or

(ii) the specification provides no information on how the desirable characteristics could be measured or otherwise determined in a product containing any pair of composition.

In such cases, performing the invention over the entire scope of the claims may be considered to impose an undue burden on the skilled person. However, by narrowing the scope of the claims to a specific pair of components, the invention may be performed by the skilled person.

¹⁶ The submission of the Czech Republic.

¹⁷ See, for example, the submissions of Singapore and Spain as well as the USPTO's MPEP §2064.01(a).

¹⁸ See, for example, the submission of Singapore to SCP/35.

Nevertheless, care should be taken to ensure that there is a basis in the specification as filed for such a narrower claim to avoid added matter.¹⁹

31. 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 needed in the application as filed to meet the enabling disclosure. Thus, the state of the art is also related to the sufficient amount of working examples required in the application. According to the Manual of Patent Examination Procedures (MPEP) of the United States Patent and Trademark Office (USPTO), in the field of chemistry generally, the well-known unpredictability of chemical reactions would alone be enough to raise a reasonable doubt as to the legitimacy of a broad statement as enabling support for a claim, particularly where the statement is, on the face of it, contrary to generally accepted scientific principles.²⁰ In the same token, the guidelines of the JPO note that, generally, medicinal invention belongs to a technical field where it is relatively difficult to understand how to make and use a product on the basis of their structures or names. Hence, normally one or more representative examples are necessary for the description to be stated such that a person skilled in the art can carry out the invention, unless a person skilled in the art can manufacture or obtain the compound, etc. and can also use the compound, etc. for the medicinal use in light of the common general knowledge as of the filing.²¹

32. To the extent available under the applicable law, the applicant may be able to prove its claim of enablement with additional information, the submission of which after filing a patent application may be accepted in some jurisdictions.²² In general, since it is more challenging to anticipate the technical effect of chemical compounds or biotechnological material, providing experimental evidence to demonstrate the alleged technical effect of the claimed invention may facilitate meeting the sufficiency of disclosure requirements. However, a caution should be given to the fact that the “state of the art” evolves overtime. Areas that are currently regarded as “unpredictable art” would become more and more predictable, as the very science that created them also finds its way to measure, qualify and describe them, as has been done in the evolution of science.²³

1. Undue burden: quality and quantity of experimentation

33. 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.²⁴

34. 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 the invention, 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. Issues relating to disclosure of processes for producing chemical products are addressed in Section III.E.

¹⁹ Paragraph 5.99 of the Patent Examination Guidelines of the Intellectual Property Office of Singapore (IPOS).

²⁰ MPEP §2164.03, referring to *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971).

²¹ Application Examples of Specific Technical Fields, JPO, in Chapter 3.

²² See Section III.D.1. in this document.

²³ Submission of Trinidad and Tobago.

²⁴ BGH, decision of 21 December 1967, ref: Ia ZB 14/66, GRUR 1968, 311 – *Garnachverfahren*; BGH, judgement of 21 November 1975, ref: X ZR 29/75, GRUR 1976, 213 – *Brillengestelle*.

2. Sufficient amount of guidance provided by the disclosure

35. One of the factors considered 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. For example, in *In re Colianni*, the court of the United States of America ruled that “an extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance.”²⁵ Similarly, in *Mayne Pharma v Debiopharm and Sanofi-Synthélabo*, a person skilled in the art should be able to identify the test or development on the basis of the disclosure.²⁶

Mayne Pharma v Debiopharm and Sanofi-Synthélabo [2006] EWHC 1123 (Pat)

As considered by Justice Puffrey:

“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”.

36. The sufficient amount of guidance or direction in the specification can mean that the description does not necessarily contain indications of how to achieve all conceivable variants covered by a functional definition²⁷ or the 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-enabling²⁸. Referring to case law, the USPTO’s MPEP²⁹ clarifies situations where working examples should be included in a patent application, and in particular in applications in unpredictable art. Even in unpredictable arts, a disclosure of every operable species is not required. However, in applications directed to inventions in arts where the results are unpredictable, such as most chemical reactions and physiological activity, the disclosure of a single species usually does not provide an adequate basis to support generic claims. This is because in art areas having a high degree of uncertainty (i.e. the unpredictable arts), it is not reasonably predictable from the disclosure of one species, what other species will work. Proof of enablement may be required for other members of the claimed genus.

Cases in France and Spain relating to lack of sufficient working examples

The ruling in *Virbac v. Merial* in France³⁰, which related to a patent dispute with respect to a chemical compound, states that it is not necessary under the law to always provide specific examples. The failure to do so, in and of itself, cannot result in a patent being declared null and void. In this case, the absence of examples is only one aspect of the description’s insufficiency, which prevents the person skilled in the art from carrying out the invention with her or his general knowledge. In order to reproduce the invention in this case, a person skilled in the art would have to carry out a full research program, which requires an excessive effort beyond being permissible.

In Spain, Decision No. 00122/2008 of May 16, 2008 ruled by the Madrid Provincial High Court (Division 28) related to the dispute between Diffusion Bactériologie du Var, S.A. and International Microbio S.A./Biomérieux España, S.A. regarding the Spanish patent

²⁵ *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977), referred to in MPEP §2164.06.

²⁶ See the submission of Singapore.

²⁷ See the submission of Germany.

²⁸ MPEP §21164.02.

²⁹ MPEP §21164.02 and §21164.03.

³⁰ High Court of Paris, February 13, 2014.

No. ES2024687T and the European patent No. EP311541 relating to mycoplasma. Insufficiency of disclosure was one of the grounds alleged in seeking invalidation of the patent. The judge concluded that the patent did not fulfill the sufficiency of disclosure, because a person skilled in the art would need to conduct excessive experimentation due to the lack of the information necessary to carry out the only example contained in the description. It was shown that more than 900 experiments had to be performed to do so. The Court concluded that the patent did not fulfill the sufficiency of disclosure requirement.

Reasonable trial and routine experiment

37. Furthermore, 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”.³¹ 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.³² For example, referring to *In re Wands*, the USPTO’s MPEP states that in the chemical arts, the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed. If a very difficult and time consuming assay is needed to identify a compound within the scope of a claim, then it could be considered as a great quantity of experimentation in the overall analysis of whether it is undue experimentation or not. At the same time, time and difficulty of experiments are not determinative if they are merely routine, and the quantity of examples is only one factor that must be considered before reaching the final conclusion that undue experimentation would be required.³³

Shionogi and AstraZeneca v. Biogaran (France)

The ruling in *Shionogi and AstraZeneca v. Biogaran*³⁴ states that the sufficiency of disclosure requirement is met when the description indicates the means that make it possible for the person skilled in the art, equipped with the appropriate knowledge, to carry out or implement the invention by making a reasonable effort of analysis, for example through routine tests. The person skilled in the art can always supplement the information provided in the application with their own knowledge.

Errors and lack of certain information

38. 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. For example, the submission of the United Kingdom states that obvious mistakes that could be spotted and corrected by a person skilled in the art are enabling disclosure.

39. In some particular cases (for example, claims relating to a combination of ranges or Markush claims), the scope of the claim might encompass a large number of alternatives, some of which correspond to non-working embodiments. According to the decision of the Enlarged Board of Appeal of the EPO (G 1/03), in such cases, the presence of non-working embodiments in the claim is of no harm, provided that the specification contains sufficient information on the relevant criteria to identify the working embodiments within the claimed alternatives.³⁵ The

³¹ See, for example, the submissions of France, Singapore, Spain and the United Kingdom.

³² See, for example, the submission of the United Kingdom.

³³ MPEP §21164.06, referring to *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

³⁴ High Court of Paris of February 9, 2018.

³⁵ See also a decision in Germany (BGH, decision of 9 October 1990, ref: X ZB 13/89, GRUR 1991, 518 – *Polyesterfäden*) and the submission of Singapore to SCP/35, explaining the case where the specification is not

[Footnote continued on next page]

same applies if some specific variants indicated in the application are not available or are unusable, but can be replaced by other variants, which by knowledge of the skilled person have the same effect.³⁶ In addition, deviations that may occur during the attempted reproduction of the invention are insignificant, if the skilled person recognizes that the result obtained is identical to the promised result of the claimed invention.³⁷

*Aristo Pharma Iberia S.L. v. Simbec Ibérica S.L.*³⁸ (Spain)

In this case, the court ruled that the patent fulfilled the sufficiency of disclosure requirement, even if it did not explicitly contained certain information.

The plaintiff requested invalidation of Spanish patent No. ES2380229, alleging insufficiency of disclosure. Claim 1 of the patent related to the composition in the form of a matrix that includes two ingredients: the active principle (ebastine) and one or more non-ionic surfactants. It was alleged that, despite use of the word “includes” in the claim, the patent offered not a single example of the matrix composition that contained ingredients other than ebastine and the non-ionic surfactant. It was also alleged that extremely broad ranges of ebastine and non-ionic surfactant were claimed, i.e., between 10 % and 90 %.

The Court however affirmed that the skilled person testing the sufficiency of disclosure could compensate the errors and omission of information in the patent by drawings or common general knowledge, provided it did not entail inventiveness on the side of the person skilled in the art. It ruled that the answer to the question as to whether a person skilled in the art could easily work the full scope of the claims, without undue effort or inventive capacity, was affirmative. It stated that the fact that the word “includes” meant that other ingredients could be added to the composition did not prevent the skilled person from working the invention, to the full extent of the first claim, without undue effort: the common general knowledge of the skilled person enabled him/her to determine what other ingredients might hypothetically be added. Regarding the breadth of the ranges, the Court noted that the description in the patent provided numerous examples of how the invention could be worked, enabling the skilled person to prepare the composition claimed without any need of inventive capacity. The Court therefore concluded that the patent fulfilled the sufficiency of disclosure requirement.

Enabling the full scope of claims without undue burden

40. As ruled in *Aristo Pharma Iberia S.L. v. Simbec Ibérica S.L.* above, jurisprudence and guidelines of many countries state that the disclosure must enable the full scope of the claimed invention without undue experimentation. For example, the submission of the Czech Republic notes that applicants should choose embodiments described in the description to cover the claimed scope of protection.

Sufficient disclosure of inventions defined by parametric claims

41. 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. With respect to the sufficiency of disclosure, in general, the

considered to be insufficient for the claim which is expressed in terms broad enough to include both the working and failed methods.

³⁶ Moufang, in: Schulte, *Patentgesetz*, 11th edition 2022, Section 34 marginal number 345.

³⁷ Moufang, in: Schulte, *Patentgesetz*, 11th edition 2022, Section 34 marginal number 376 and 392.

³⁸ Decision No. 77/2018, February 13, 2018, Barcelona Commercial Court (Division 4).

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.³⁹ 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.⁴⁰

T 1583/17 (Use of coated films / Taghleef), Decision of the Technical Board of Appeal, EPO, February 24, 2021

The invention concerned the use of coated films. Claim 1 reads:

“1. A use of a film comprising a substrate of plastic film (1) manufactured by extrusion with a thickness comprising between 10 and 40 mym to which is added by coating a liquid base dispersion of aliphatic polyurethane (2), which contains between 30% and 100% solids depending on the degree of soft touch required, the thickness of said coating, when dry, being comprised between 0.2 and 5 mym, in the lamination of printed matter.”

As regards determining the thickness of the coating, it was undisputed that neither Claim 1 nor the description indicated a method to be used for this, and it was also undisputed that different methods, which might produce different results, were available to the skilled person. Recalling the case law, the Board observed that the mere fact that a claim was unclear or its scope ambiguous did not automatically mean that the invention it defined was not sufficiently disclosed.

In this case, as the claimed invention was not restricted to thicknesses measured by a particular method, the skilled person was free to use any suitable method. The selection of a suitable method did not involve an undue burden since measuring the thickness of a coating or of a layer in general was an absolute standard procedure for which many commonly known methods were available. The Board observed that the invention would possibly not be sufficiently disclosed if it could only be carried out with coatings having a thickness measurable only with a specific, yet undisclosed method. The Board stressed that no specific degree of soft touch was required according to the claimed subject-matter. The Board concluded that no evidence on file showed that the absolute thickness of the coating, and thus the selection of a method for measuring the thickness, were critical for carrying out the invention, i.e., for producing a coating having a thickness in the claimed range and a certain degree of soft touch. Accordingly, the Board ruled that the sufficiency of disclosure is met.

Prophetic examples

42. In the United States of America, an example of the claimed invention can be either “working” or “prophetic.” According to MPEP,⁴¹ a prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. This comes from the case law that an applicant needs not have actually reduced the invention to practice prior to filing.⁴² 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

³⁹ Examination Guidelines of IPOS, paragraph 5.118.

⁴⁰ *Idem*.

⁴¹ MPEP §21164.02, IV,

⁴² In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The court held that “The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it.” 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting In re Chilowsky, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)).

future or present tense. The USPTO states that it is a best practice to label examples as prophetic or otherwise separate them from working examples to avoid ambiguities, since such presentation will help a reader easily distinguish these examples and will enhance the public's ability to rely on the patent disclosure.⁴³ The courts have further cautioned that the presence of prophetic examples alone should not be the basis for asserting that a specification is not enabling. Rather, a lack of operative embodiments and undue experimentation should be determinative considerations.⁴⁴

D. Supportive Evidence and Data

43. 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 to demonstrate the alleged technical effect in the application as filed. For example, it would be more difficult for a person skilled in the art to predict a pharmacological effect of a new or known chemical compound to be used in the treatment of a specific disease without any supporting data or other evidence.⁴⁵

44. For example, according to the submission of Cuba, with respect to chemicals and pharmaceuticals, experimental evidence based on testing or trials must be provided to demonstrate particular properties or activities, together with detailed information on testing parameters. Simply stating the use of an invention to be effective does not count as evidence.

45. Under the first-to-file system, filing a patent application as soon as possible may be critical. At the same time, sufficiently complete disclosure of the claimed invention in the application as filed is vital, since the applicant cannot add new matter to the specification.

*Aventis Pharma, S.A., May & Baker Ltd and Sanofi-Aventis, S.A. v. Hospira Productos Farmacéuticos y Hospitalarios, S.L.*⁴⁶ (Spain)

As a counterclaim, annulment of Spanish patents Nos. ES2096091T7, ES2248070, ES2114620 and ES2163076 relating to new antitumor compositions was sought. Insufficiency of disclosure was alleged for each of the patents. Notably, the Court asserted that "insufficiency of disclosure cannot be remedied after the application is filed by adding examples or explanations during the patent examination process, which amounts to a broadening of scope and thus grounds for refusal". Partial annulment was ordered, invalidating some of the claims.

46. 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, in Brazil, additional evidence is accepted during the substantive examination phase, provided that it is intended exclusively to complement the information already contained in the application as initially filed.⁴⁷

Evidence obtained after the filing date

47. Recognizing the challenges that applicants in, for example, chemistry, or the pharmaceutical and 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,

⁴³ Federal Register Notice 86 FR 35074 by the USPTO, Properly Presenting Prophetic and Working Examples in a Patent Application, July 1, 2021.

⁴⁴ *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984), referred to in MPEP §2164.02.

⁴⁵ The submission of Türkiye.

⁴⁶ Decision No. 289/2012 of November 6, 2012, Granada Commercial Court No. 1.

⁴⁷ Patent Application Examination Guidelines, Block I, paragraph 3.89 (INPI Resolution No. 124 of December 4, 2013), INPI Brazil.

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.

48. In the United Kingdom, the so-called post-published evidence is generally allowed to establish that the disclosure in the patent application was sufficient at the filing date (for example, the disclosure of the invention as filed indeed achieved the alleged technical effect (such as for use in treating a certain disease) of the claimed invention). However, it cannot be used to render an insufficient disclosure in a patent application sufficient, i.e., the post-published evidence cannot be used to remedy the insufficient disclosure of the invention in the application.⁴⁸

49. In Australia, a question as to whether post-filing experimental data is admissible was addressed in the recent decision.

BASF Corporation [2019] APO 34 (July 19, 2019) (Australia)

The case related to two patent applications concerning synergistic fungicidal or insecticidal mixtures. During prosecution, the applicant provided post-filing experimental data, demonstrating synergistic effect of some of the claimed mixtures. The examiner, however, maintained that the applications were not enabling, because in the absence of experimental data evidencing the synergy in the application as filed, the claimed invention is not plausible. The Applicant requested to be heard before the Patent Office. Regarding the post-filing experimental data, the Delegate referred to the passage from the *Warner-Lambert* decision by the UK Court⁴⁹:

“This does not mean that subsequent data is never admissible in a dispute about sufficiency, but the purpose for which it is admitted is strictly limited. Where the asserted therapeutic effect is plausible in the light of the disclosure in the patent, subsequent data may sometimes be admissible either to confirm that or else to refute a challenger’s contention that it does not actually work . . . it cannot be a substitute for sufficient disclosure in the specification.”

As part of the hearing submission, the applicant submitted an expert declaration stating that the information provided in the application as filed would make it likely that the synergistic effect would be observed in the various combination of mixtures claimed. The Delegate found the post-filing experimental data admissible as it related to the plausibility of a person skilled in the art understanding the application as filed. The application was thus found to comply with the requirement of the sufficiency of disclosure.

50. In general, a number of decisions made by the Boards of Appeal of the EPO indicate that sufficiency of disclosure must, in principle, exist at the effective date of a patent, while post-published evidence may be used as evidence that the invention as disclosed is reproducible without undue burden only under certain circumstances.⁵⁰ For example, in the absence of any tangible proof in the patent specification that the claimed concept can be put into practice, post-published documents can be used as evidence whether the invention merely disclosed at a general conceptual level was indeed reproducible without undue burden at the relevant filing date (T 994/95 and T 157/03). In T 1262/04, the Board considered that this principle applied at least to cases such as the one at issue, where the technical teaching as disclosed in the application was credible.

⁴⁸ The submission of the United Kingdom.

⁴⁹ *Warner-Lambert Company LLC v Generics (UK) Ltd [2018] UKSC 56.*

⁵⁰ EPO Case Law of the Boards of Appeal, II.C.6.8.

51. However, as addressed in T 609/02, if the specification provides no more than a vague indication of a possible medical use for a chemical compound yet to be identified, later more detailed evidence cannot be used to remedy the fundamental insufficiency of disclosure of such subject matter. Similarly, in relation to the applications regarding the use of the compound(s) as a pharmaceutical, post-published evidence may be taken into account, only to back up the findings in the application (T 609/02, T 950/13). The Boards consistently rule that sufficiency of disclosure must, in principle, be shown to exist at the effective date of a patent, and evidence cannot be used to cure the insufficiency of disclosure. Reference is made to Section III.A.1 regarding the decision of the Enlarged Board of Appeal of the EPO (G 2/21) on the admissibility of post-published evidence and the notion of “plausibility” in the context of inventive step.

Decision of the Technical Board of Appeal, EPO, T 609/02 (AP-1 complex/SALK INSTITUTE), October 27, 2004

Against European patent with the title “methods mediated by the proto-oncogenic protein complex AP-1”, oppositions were filed. The Opposition Division decided that enabling disclosure was not provided in relation to claim 6 and maintained the patent for the rest of the claims. The Appellant appealed against the decision of the Opposition Division.

The Board reviewed Claim 6, which claims the use of a certain steroid hormone or steroid hormone analogue as identified by the method of claims 1 to 5, for the preparation of a pharmaceutical for the treatment of AP-1 stimulated tumor formation, arthritis, asthma, allergies and rashes. The patent specification provides no evidence at all relating to the invention in claim 6.

The appellant provided post-published evidence showing that steroid hormones needed to carry out the use according to claim 6 were later structurally identified, and that they, indeed, have an effect on AP-1 stimulated transcription. Based on the disclosures of these post-published documents, the Appellant argued that, by carrying out the claimed invention, one would necessarily obtain pharmaceutical compositions. It also claimed that the post-published results had been obtained by following the teachings of the patent in suit.

The Board, however, did not share that opinion. It stressed that sufficiency of disclosure must be satisfied at the effective date of the patent, i.e., on the basis of the information in the patent application together with the common general knowledge then available to the skilled person. In its opinion, acknowledging sufficiency of disclosure on the basis of relevant technical information produced only after that date would lead to granting a patent for a technical teaching which was achieved, and, thus, for an invention which was made, at a date later than the effective date of the patent. It noted that the general principle that the extent of monopoly conferred by a patent should correspond to, and be justified by, the technical contribution to the art, has to be kept in mind.

In this case, the Board considered that the patent concerned needs to provide some information in the form of, for example, experimental tests, to show that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease concerned: this mechanism being either known from the prior art or demonstrated in the patent *per se*. Once such evidence is available from the patent application, then post-published so-called expert evidence may be taken into account, but only to back up the findings in the patent application in relation to the use of the ingredient as a pharmaceutical, and not to establish sufficiency of disclosure on their own.

Accordingly, the Board denied the sufficiency of disclosure in relation to claim 6.

52. In China, Section 3.5.1 of the Patent Examination Guidelines (Notice No. 391), implemented on January 15, 2021, sets out the principle applicable to the examination of supplementary experimental data. The determination of whether the description is sufficiently disclosed shall be subject to the contents recorded in the original description and the claims. The examiner shall examine the supplementary experimental data submitted by the applicant after the filing date for the purpose of fulfilling the requirements of inventive step⁵¹ and sufficiency of disclosure⁵². The technical effects demonstrated by the supplementary experimental data shall be those that a person skilled in the art can obtain from the contents disclosed in the patent application as filed.

53. A hypothetical example provided in of the Guidelines is a case where an application as filed claims compound A with a detailed description of how to prepare that compound, the hypotensive effect of the compound, and the method to measure such effect. However, no experimental data was disclosed in the application as filed. In order to prove that the specification completely disclosed the claimed invention, the applicant submitted data regarding the hypotensive effect of compound A. For those skilled in the art, based on the information disclosed in the application as filed, the hypotensive effect of compound A has been disclosed and the technical effect proved by the supplementary experimental data can be obtained from the content disclosed in the application as filed. In that case, the supplementary experimental data filed after the filing date should be considered.

54. In the United States of America, the applicant may submit factual affidavits under 37 CFR 1.132 or cite references to show what one skilled in the art knew at the time of filing the application. A declaration or affidavit is, itself, evidence that must be considered. All the evidence on record, including the specification, any new evidence supplied by the applicant, and any evidence and scientific reasoning previously presented in the rejection is weighed for the determination of enablement.

55. To overcome a *prima facie* case of lack of enablement, the applicant must present an argument and/or evidence that the disclosure would have enabled one of ordinary skill in the art to make and use the claimed invention at the time of filing. This does not preclude the applicant from providing a declaration after the filing date which demonstrates that the claimed invention works. However, the steps, materials, and conditions used in the experiments of the declaration with those disclosed in the application are carefully compared by the examiner to make sure that they are commensurate in scope, i.e., the experiments used the guidance in the specification as filed and what was well known to one of skill in the art at the time of filing. Such a showing also must be commensurate with the scope of the claimed invention, i.e., it must reasonably enable the full scope of the claimed invention.⁵³

56. The MPEP of the USPTO also provides guidance as to whether examiners may use post-publication evidence to reject patent applications.⁵⁴ According to MPEP, in general, the examiner should not use post-filing date references to demonstrate that a patent is not enabled. 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. The MPEP refers to *In re Wright*,⁵⁵ where the court found that an article published five years after the filing date of the application adequately supported the examiner's position that the physiological activity of certain viruses was sufficiently unpredictable so that a person skilled in the art would not have believed that the success with one virus and one animal could be extrapolated successfully to all viruses with all living organisms. Accordingly, the court held

⁵¹ Article 22(3) of the Patent Law of China.

⁵² Article 26(3) of the Patent Law of China.

⁵³ MPEP §2164.05, USPTO.

⁵⁴ MPEP §2164.05(a), last paragraph, USPTO.

⁵⁵ 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513-14 (Fed. Cir. 1993).

that the applicant's earlier-filed claims not limited to the specific virus or the specific animal were non-enabled.

57. On the plausibility or credibility of the claimed invention disclosed, Section III.A.1. provides explanations on its concept and some examples. Reference is also made to sufficient disclosure of inventions relating to medical use (Section III.G) and compositions and mixtures of compounds (Section III.L).

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

58. 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 for producing chemical products, in particular, manufacturing processes of chemical or biological inventions.⁵⁶ In general, as long as the specification discloses at least one method for carrying out the entire scope of the claimed invention, the sufficiency of the disclosure is met.⁵⁷

59. The Examination Manual of Thailand⁵⁸ notes that, regardless of a process for preparing a substance or any other process, the description shall describe the raw materials, procedures and processing conditions adopted in the process. If necessary, the effect of the process on the property of the title substance shall be described in such a manner that a person skilled in the art is able to carry out the process of the described invention in order to solve technical problems in accordance with the invention's objective. As for the raw materials used in the process, the components, their properties, and the manufacturing process shall be described in such a manner that a person skilled in the art can carry it out.

60. The submission of Portugal indicates that it is necessary to describe the process for obtaining the chemical compound and its experimental conditions, such as temperature, pressure, reagents, start and intermediate materials, chemical reactions, etc. Similarly, the submission of the Czech Republic notes that it is not enough to describe the process only in theory, and that process parameters such as temperature, pressure, yield, etc. need to be specified. Likewise, in the submission of Türkiye, it is recommended that applicants demonstrate all the production steps if a new chemical compound is synthesized. To illustrate, it is essential to demonstrate the necessary reactions, process parameters, such as operating temperature and pressure, the catalyst that is used for the reaction.

61. The Examination Guidelines of KIPO⁵⁹ explains that due to unexpected reactions that may be observed in chemistry, in addition to the structure of a chemical substance, a process for producing that substance should be disclosed so as to reproduce a chemical substance without undue burden (except where a person skilled in the art can easily understand the chemical reaction, based on the disclosure in the specification and the common general knowledge).⁶⁰ To perform the invention, the description should disclose information about starting materials, conditions and parameters necessary to manufacture the invention as well as a result of an experiment directly carried out under the conditions in accordance with those of the embodiments.

⁵⁶ For example, Cuba, the Czech Republic, Germany, Japan, the Republic of Korea, the Russian Federation, Thailand, Türkiye, and the EPO.

⁵⁷ For example, submissions of Colombia and Germany,

⁵⁸ Patent and Petty Patent Examination Manual, B.E. 2562 (2019), Chapter 5.

⁵⁹ Guidelines for Examination (2021.12), KIPO.

⁶⁰ Supreme court decision 2000Hu2958, 2003Hu1550, 2005Hu1417.

62. The Examination Guidelines of the JPO⁶¹ note that an invention of a process producing a product consists of three factors, i.e., (i) a starting material; (ii) process steps ; and (iii) a final product. Accordingly, these three factors must be, in principle, stated in such a manner that a person skilled in the art can produce the product based on the disclosure in the application and the common general knowledge at the time of the filing. The Guidelines thus clarify that even if a statement of quantitative values such as manufacturing conditions is not included in the application, it satisfies the sufficiency of disclosure requirement if a person skilled in the art, based on the information contained in the application and the common general knowledge, can carry out the claimed invention. In the same line, the submission of Germany also states that in applying the general principle of the sufficiency of disclosure requirement, that requirement is met even if concrete sizes, quantities or dimensions have to be determined first or if further experiments or tests need to be carried out, provided that these do not exceed the usual (undue) extent and do not require inventive reasoning.

63. In the Russian Federation, in accordance with the requirements set forth by the Requirements for Materials of Patent Applications for Inventions, approved by the Order of the Ministry of Economic Development of Russia No. 316 of May 25, 2016 (Requirements), the description section of the patent application comprises two subsections, titled "Invention Essence Disclosure" and "Invention Implementation", where the applicant shall disclose necessary data about the invention and the way a person skilled in the art may make it. The second subsection of the description shall contain data on how an invention could have been made by a person skilled in the art, bearing in mind the invention's purpose and confirming its capability to achieve the technical result, by providing a detailed description of at least one example of the invention with reference to drawings, if any. This data shall include end materials obtained from experiments, tests or assessments accepted in related technology, or theoretical justifications based on scientific knowledge.

64. The requirements also specify precise information that shall be provided in the application for various types of subject matter related to chemistry, pharmaceuticals and biotechnology, such as substance, composition, method, application, strain, etc. In general, for an invention relating to a chemical compound with an established structure, a structural formula, proven by known methods, physical and chemical constants, the method to obtain the compound and the invention feasibility for the indicated purpose shall be described. Information to be described in the application for other specific types of compounds, compositions or methods of obtaining chemical compounds will be provided later in this document.

65. In Lithuania and the Russian Federation, the accepted practice is that, for describing a method for the preparation of a new group of compounds defined by a general structural formula, examples of how the compounds of the group can be obtained using this method must be given. In case where the group consists of radicals of different chemical nature, then, such examples should be given in a way that it sufficiently confirms the capability of obtaining the compounds with these different radicals. With respect to inventions related to methods of obtaining chemical compounds with undefined structure or mixtures of undefined compositions and characteristics, information allowing to distinguish these compounds from others must be provided. Such information includes data on initial reagents for obtaining compounds/mixtures and confirmation of the suitability of these compounds/mixtures for the intended use.

1. Starting material

66. One of the issues relating to the sufficient disclosure of chemical processes is the appropriate disclosure of the starting materials or apparatus that is necessary for manufacturing the claimed invention. The courts in the United States of America made clear that if a particular apparatus or certain chemicals are required to make a compound or practice a chemical

⁶¹ Examination Guidelines of the JPO, Part II, Chapter 1, Section 1.3.

process, the application must provide sufficient disclosure of the apparatus if it is not readily available.⁶² Further, the MPEP of the USPTO specifically note the importance of a starting material when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening.⁶³

67. On the starting material, the submission of Germany notes that the disclosure of a chemical substance is not sufficient if its formula and the manufacturing process are specified, but the skilled person does not know how to obtain the necessary starting materials and intermediate products. Information that can only be found through extensive research cannot be attributed to the expertise of the skilled person. Therefore, the disclosure in the application as filed must not only cover the substance of the intermediate product, but also its further processing into the final product, if this is not familiar to the skilled person. If an intermediate is formed only temporarily in a reaction mixture, no substance claim can be addressed thereon if no way for its isolation is disclosed.⁶⁴

Bayer A.G. v. Rasfer S.A. (Spain)⁶⁵

The case related to disclosure of a manufacturing process, where appropriate disclosure of the starting substance was lacking. It considered the validity of patent No. ES505138, pertaining to a procedure for the manufacture of ciprofloxacin and enrofloxacin.

Insufficiency of disclosure was one of the grounds alleged in seeking invalidation of the patent. It was argued that “the patent does not contain all the information necessary to enable a person skilled in the art concerned, at the time of filing, to obtain the starting substance required for the procedure (fluorquinolonic acid), which was not available at that time”. According to the description in the patent, ciprofloxacin and enrofloxacin could be obtained through the process patented, but the Markush formula used was incomplete, leaving the skilled person unable to obtain ciprofloxacin and enrofloxacin.

No example was provided in the description of an experimental process for synthesizing quinolonic compounds. The court held that the suggestion that fluorquinolonic acid could simply be formulated on the basis of patent No. ES0478047 was insufficient. It was concluded that, in failing to provide sufficient information on the starting substance, the patent did not fulfill the sufficiency of disclosure requirement.

2. Intermediate compounds

68. In general, an intermediate is a substance formed during an intermediate step of a chain of multiple chemical reactions between reactants that eventually lead to a final compound. After it is created in an 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.

69. In Lithuania and the Russian Federation, if the invention is an intermediate compound, the description must also show the capability of processing it into a known final product or the capability of obtaining a new end product with a specific purpose or biologically active properties.⁶⁶ In the United States of America, in accordance with *In re Breslow*, for unstable

⁶² *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971) and *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981), referred to in MPEP 2164.01(b), USPTO.

⁶³ MPEP §2164.01(b), USPTO.

⁶⁴ Moufang, in: Schulte, *Patentgesetz*, 11th edition 2022, Section 34 marginal number 429.

⁶⁵ Decision No. 00090/1999, March 1, 1999, Barcelona Provincial High Court (Division 15).

⁶⁶ The Submission of Lithuania to SCP/35. The submission of Germany to SCP/34 notes that if an intermediate is formed only temporarily in a reaction mixture, no substance claim can be addressed thereon if no way for its isolation is disclosed.

and transitory chemical intermediates, the applicant is not required to teach how to make the claimed product in stable, permanent or isolatable form, despite the general “how to make” requirement. The submission of Brazil notes that as the claims relating to intermediaries are necessarily chemical compound claims, the guidelines regarding chemical compounds also apply to intermediaries.⁶⁷

F. How to Use the Invention

70. 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. Depending on the nature of the claimed invention, how to use the invention can be obvious to a person skilled in the art without any explicit indication in the specification. 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.

71. For example, the MPEP of the USPTO states that it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. If one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy the sufficiency of disclosure.⁶⁸

72. Going in the similar direction, the patent examination manual of Thailand⁶⁹ as well as the guidelines of Lithuania and the Russian Federation⁷⁰ also highlights the relevance of disclosing a “method for using a chemical product invention” and information on the use of an invention if it is a “new compound with a defined structure”, respectively.

73. The MPEP of the USPTO states that when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for non-enablement based on lack of the disclosure related to “how to use”.⁷¹ On the other hand, if multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.

74. However, there are other cases where a compound or composition claim is limited by a particular use (for example, a compound limited to a specific use of treating a particular disease). In these cases, the MPEP clarifies that enablement of such claim should be evaluated based on that limitation.⁷² Indeed, these cases, particularly those that are limited to therapeutic use, attracted the submissions of Member States on their practices relating to sufficiency of disclosure.

G. Disclosure of Inventions Related to Medical Use

75. If a new use of a known compound is found (e.g., compound X used for painting is found to be suitable for solidifying cement) and claimed, unless a person skilled in the art can readily

⁶⁷ Reference is made to Item 206 of the INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208 of December 27, 2017).

⁶⁸ MPEP §2164.01(c).

⁶⁹ Patent and Petty Patent Examination Manual, B.E. 2562 (2019).

⁷⁰ See the submissions of Lithuania and the Russian Federation, respectively.

⁷¹ MPEP §2164.01(c).

⁷² *Idem*.

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 (e.g., showing certain experimental data indicating that compound X has a technical effect of solidifying cement). Admittedly, demonstrating suitability for therapeutic use would be much more complex than measuring and showing the solidity of cement. Therefore, 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 – in other words, how the general rules and principles apply to inventions that are used for medical purposes.

76. The submission of Portugal states that where the therapeutic effect, such as the treatment of a specific disease, is claimed, the patent application must make such therapeutic effect plausible to fulfill the requirement of sufficiency of disclosure. A mere statement about the therapeutic effect in the application is not sufficient: the application must provide information to show that the claimed compound has direct effect on the mechanism involved, which must be known from the prior art or demonstrated in the patent application as such. The information to be provided includes tests or any kind of data to the extent that they clearly and unambiguously reflect the therapeutic effect.

Ethypharm v. AstraZeneca (France)

The ruling in *Ethypharm v. AstraZeneca*⁷³ confirms that a patent for a medicine must contain an indication of its pharmacological properties relating to medical use. However, there is no requirement, for the purpose of sufficiency of disclosure, to demonstrate those pharmacological properties or result, provided that they have been sought and claimed. Nor is it necessary, for the purpose of the sufficiency of disclosure, to demonstrate the existence of a technical effect resulting from tests or experiments that prove the product's "real" effectiveness.

77. Some submissions from the Member States⁷⁴ also highlighted the relevance of technical data that attest and give support to the claimed medical use, or evidence showing that the compound can be used for treatment of a specific disease, to sufficient disclosure of inventions that pertain new medical use.

78. With respect to medical use claims, the practice of the EPO is that the patent application must either provide suitable evidence for the claimed therapeutic effect or this effect must be derivable from the prior art or common general knowledge. In other words, there is no automatism: a mere fact that a claim addresses a specific therapeutic use of a certain compound does not necessarily mean that evidence for the claimed therapeutic effect must always be provided.

79. The submission of Germany further clarifies various scenarios and circumstances that may be involved in each specific case of medical use inventions. According to the practice in Germany, sufficient disclosure of a claimed use requires that the new effect, function or purpose has been originally shown. If use for a therapeutic purpose is claimed, the invention must be disclosed so clearly and comprehensively that the skilled person does not perceive it as mere speculation and the claimed use seems at least plausible. This does not necessarily require experimental data or even clinical trials. In the absence of data, a scientific reason should be given to support the claimed pharmaceutical effect or it should be derivable from general expert knowledge.⁷⁵

⁷³ High Court of Paris of June 23, 2017.

⁷⁴ See, for examples, the submissions of Brazil, the Czech Republic, Lithuania, the Russian Federation and Türkiye.

⁷⁵ Moufang, in: Schulte, *Patentgesetz*, 11th edition 2022, Section 34 marginal number 422.

80. Furthermore, advantages and valuable properties should be disclosed originally. This is indispensable particularly if the invention acquires its actual meaning only through the mention of advantages and functional properties, i.e., if the advantages constitute the essence of the invention. The addition of advantages and valuable properties to the description of the application may be permissible in rare exceptional cases, e.g., if the advantages are not originally mentioned in the application, but the skilled person is able to recognize them from the overall content of the original disclosure even without their explicit mention.⁷⁶ With respect to functional properties, functional statements require original disclosure under the same conditions as benefits and valuable properties. A subsequent submission of efficacy claims relating to these valuable properties may also be permissible in exceptional cases.⁷⁷

81. In Japan, according to its guidelines, the results of pharmacological studies are usually required for supporting the medicinal use.⁷⁸ They are required for the purpose of confirming the pharmacological effects of the compound etc. that are claimed as a medicinal invention. Therefore, in principle, all of the following information should be made sufficiently clear as the results of the pharmacological study:

- which compound etc. is applied to what pharmacological testing system,
- what results are obtained, and
- what relevance the pharmacological testing system has with the medicinal use of the claimed medicinal invention.

82. In principle, the results of pharmacological study should be described with quantitative data, but when the results cannot be described with quantitative data due to the nature of the pharmacological testing system, an objective description equivalent to quantitative data may be accepted. An objective description equivalent to the quantitative data is, for example, description of the objective results of observation obtained by a medical doctor. Furthermore, a clinical study, an animal experiment, and an in-vitro study are employed as the pharmacological testing system.

83. In the United Kingdom, for patents relating to a second medical use of a known substance or composition, the specification as filed must make it plausible that the substance or composition will be effective for the claimed use or uses – if not, the disclosure in the patent will be insufficient. A claim to a class of products said to possess a useful activity must be based upon the identification of a common principle (a principle of general application) which permits a reasonable prediction to be made that substantially all the claimed products do indeed share that activity. It is not permissible to bypass that requirement simply by adding a functional limitation that restricts the scope of the claim to all products which “work”.⁷⁹

84. There is a three-step test established for the above determination, i.e., (i) identify what falls within the scope of the claimed class; (ii) identify what it means to say that the invention works; and (iii) determine whether it is possible to make a reasonable prediction that the invention will work for substantially everything falling within the scope of the claim.⁸⁰ In the United Kingdom, there are three types of insufficiency objection that have been established in the case law. Firstly, a classical inefficiency relates the situation where a lack of disclosure prevents a person skilled in the art from performing the invention without exercising inventiveness or undue burden of research. The second type is insufficiency due to the excessively broad scope of the claims. The third type is insufficiency due to the ambiguity of the

⁷⁶ Moufang, in: Schulte, *Patentgesetz*, 11th edition 2022, Section 34 marginal number 323 et seq.

⁷⁷ Moufang, in: Schulte, *Patentgesetz*, 11th edition 2022, Section 34 marginal number 325.

⁷⁸ Examination Guidelines, Part II, Chapter 1, Section 1 Enablement Requirement 3.1(1)(iii), JPO and Application Examples of the Specific Technical Fields, Chapter 3, JPO. Referring to the Guidelines for Examination (2021.12), KIPO, the submission of the Republic of Korea also notes the disclosure of an example of a trial represented with pharmacological data, etc. or a description that sufficiently replaces such trial.

⁷⁹ Novartis AG v Johnson & Johnson [2009] EWHC (Pat) 1671.

⁸⁰ Fibrogen v Akebia Therapeutics Inc.[2021] EWCA Civ 1279.

specification. The guidelines of the UKIPO well cover case law relating to second medical use inventions for all these types of insufficiency.

85. Reference is made to the explanation about the concept and examples of plausible/credible disclosure in Section III.A. The extent of qualitative and quantitative disclosure is addressed in Section III.C. Issues relating to evidence and information that support sufficiency are discussed in Section III.D.

In vitro/in vivo

86. 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.

87. The submission of Brazil notes that results from *in vitro* tests may provide clues to a new therapeutic use. However, these data are often not confirmed *in vivo*, due to i.e., pharmacokinetic aspects to the behavior of the drug within the body. Thus, it is not always possible to extrapolate the results of the *in vitro* tests to a practical therapeutic use, unless additional information is provided by the applicant clearly demonstrates such equivalence of effect. In the case of studies carried out on animals, it is essential that the adopted models could be extrapolated to humans or animals to be treated.

88. Likewise, the submission of Portugal notes that it is sufficient to show pharmaceutical effect *in vitro* if, for a person skilled in the art, there is a clear and accepted establish the relationship between shown physical activities and disease, i.e., the effect directly and unambiguously reflects the therapeutic application.

89. In the United States of America, the relationship between *in vitro* or *in vivo* animal model assays and a disclosed or a claimed method of use is considered in relation to the issue of the presence or absence of working examples.⁸¹ An *in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a “working example”, if that example “correlates” with a disclosed or claimed method invention. If there is no correlation, the examples do not constitute “working examples.” The “correlation” with the claimed/disclosed method of use is also dependent on the state of the prior art. In other words, if the art is such that a particular model is recognized as correlating to a specific condition, it should be accepted as correlating, unless evidence points otherwise. Even with such evidence, the evidence for and against correlation must be carefully weighed from the viewpoint of a person skilled in the art.

H. Markush formula – Claiming Numerous Alternatives

90. A “Markush” claim recites a list of alternatively usable members in one claim.⁸² 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.⁸³ 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

⁸¹ MPEP 2164.02 II, also referring to *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995), (reversing a USPTO decision based on finding that *in vitro* data did not support *in vivo* applications).

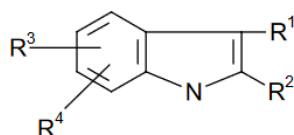
⁸² MPEP, §2117.

⁸³ *Ex parte Markush*, 1925 Dec. Comm’r Pat. 126, 127 (1924).

inventions involving pure mechanical features or process steps can also be claimed in the Markush style.⁸⁴

91. In general, alternatives in a Markush claim may be recited as “X selected from the group consisting of a, b and c”: for example, “A metal selected from the group consisting of copper, gold and iron”. 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 R¹ is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy and methyl; R²–R⁴ are methyl, benzyl or phenyl.

92. If properly used, a Markush claim assists a person skilled in the art to grasp the entire scope of alternatives in a single claim, instead of reading and analyzing many claims that define each alternative. In addition, the Markush style of claiming allows the patent drafter to group together the alternatives that do not have otherwise a well-defined generic name. In general, a Markush claim format is accepted in many countries, provided that it meets the various requirements, such as the unity of invention, the clarity and conciseness of the claims, the support requirement and the enabling disclosure requirement. In a way, these requirements work together, although they are distinct requirements.

93. In certain circumstances, 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 supported by the description, or the working examples and other information described in the specification allow a person skilled in the art, with the common general knowledge to carry out the entire scope of the claims. At the higher level, 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, where the claims cover a very broad scope.

94. 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 Section III.C (Undue Burden, Efforts or Experimentation) in this document suggests, to meet the requirement, a person skilled in the art must receive a sufficient amount of (explicit or implicit) guidance from the specification to carry out the claimed invention. The clarification that a person skilled in the art may still need to exercise due efforts or experimentation to carry out the invention suggests that working examples of each and every alternatives in the claims are not required in the description: what is required is representative embodiments in the specification, which encompasses the claimed scope.⁸⁵ 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.⁸⁶

⁸⁴ MPEP §2117.

⁸⁵ See the submissions of Germany, Mexico, Portugal and Türkiye.

⁸⁶ See the submission of Germany, referring to Moufang, in: Schulte, *Patentgesetz*, 11th edition 2022, Section 34 marginal number 388.

95. 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.

96. In the United Kingdom, like in other countries,⁸⁷ case law established that the entire scope of the claim must be sufficiently disclosed in the specification. This principle in relation to a Markush claim was considered in *Pharmacia Corporation and Others v Merck & Co Inc.*, where it was held:

“Where the claimed invention is to a class of compounds, the same principle applies and, as was made clear by the House of Lords in *Biogen*, is that the disclosure in the specification must enable the invention to be performed to the full extent of the monopoly claimed. Thus if the invention is a selection of certain compounds, in order to secure an advantage or avoid some disadvantage, not only must the specification contain sufficient information on how to make the compounds, it must also describe the advantage or how to avoid the disadvantage. Further the compounds monopolised by the claim must all have that advantage or avoid the disadvantage. The same principle applies where the claim is to a class of compounds. To be sufficient, the specification must identify the characteristics of the class and a method of manufacture. Further all the claimed compounds must in substance have the characteristics of the class.”

Pharmacia v Merck [2002] RPC 775 (at paragraph 56)

Accordingly, while only one example will be needed in the case of a single compound claimed, if the claim encompasses a generic class, or is in a Markush formula, it is likely that multiple examples will be required.⁸⁸ For chemical compounds defined by Markush formula, to meet the sufficiency of disclosure requirement, the specification must identify: (i) the characteristics of that class (all of the compounds claimed must fall within that class); and (ii) a method of manufacture of the class.⁸⁹

97. The submission of Brazil notes that theoretically, the compounds defined by a particular Markush formula may have similar activities. However, it is not possible to extrapolate the new use of a single compound to the range of compounds foreseen in the general formula, unless technical data are presented proving the equivalence of effect. Only the use of the compounds that are effectively demonstrated in the description can meet the sufficiency.

98. The Examination Guidelines of the JPO provides a hypothetical example in this regard, as below.

Examination Guidelines of JPO, Part II, Chapter I, Section 1, 5.1

The description fails to comply with the enablement requirement when a claim includes alternatives written with the Markush grouping, only a part of which is stated in the description, and there is a well-founded reason to find that a person skilled in the art would be unable to carry out the rest of the alternatives even when taking into account the statements in the description and drawings as well as the common general knowledge at the time of filing. It

⁸⁷ See Section II.C(2) in this document.

⁸⁸ See Examining patent applications relating to chemical inventions, UKIPO, paragraphs 107 to 109.

⁸⁹ See the submission of the United Kingdom.

should be noted that methods of experimentation and analysis may be included in the common general knowledge at the time of filing.

Example

The claimed subject matter is a method for manufacturing para-nitrosubstituted benzene by nitrating a starting compound of substituted benzene, wherein a substituent group (X) is recited in an alternative form as CH₃, OH, or COOH. The description only states, as a working example, a case where the starting compound is toluene, i.e., X is CH₃. If a rational reasoning can be established that such a method is inappropriate when the starting compound is benzoic acid, i.e., X is COOH, in view of the technical fact that, for example, considerable difference in the orientation between CH₃ and COOH exists, the statement in the description does not satisfy the enablement requirement.

99. Another aspect that is raised by the submissions of 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.⁹⁰ 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.

100. Applying the general principle of the sufficiency of disclosure, in general, if part of the variants in the invention is incapable of being performed by a person skilled in the art, the relevant claims must be deleted, and the specification must be worded so that the remaining claims are supported by the description. However, the practice in the EPO⁹¹ and in Germany⁹² is that in some cases, particular circumstances of each case are taken into account. For example, in case of Markush claims, where the scope of the claims 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 presence of non-working embodiments, however, does not harm, so long as the specification contains sufficient information for a person skilled in the art to distinguish working and non-working embodiments (see also Section II.C(2) explaining that lack of information in the specification as such does not necessarily raise insufficiency).

101. The submissions of some Member States that provided ample information on this topic are reproduced, below.

Brazil

102. All possible substitutes claimed in the Markush formula must be clearly and precisely based on the description. Generic and undefined terms, such as “aryl”, “heteroaryl”, “alkyl”, “alkoxy”, “cycloalkyl”, “inferior alkyl”, “substituted”, etc., are not allowed. Such expressions are imprecise, since they do not define important characteristics of the substituent, such as carbon chain size, number and nature of heteroatoms, presence or absence of branches in the carbon chain, among others. The sufficiency of disclosure by means of a Markush formula is only satisfied if the information described in the patent application allows the reproduction of each invention by a person skilled in the art. In the case of compounds defined by a Markush formula, it cannot be predicted or extrapolated that compounds with substituents belonging to

⁹⁰ See the submissions of, for example, Brazil, Cuba, Lithuania, Mexico, the Russian Federation and the United Kingdom.

⁹¹ See the submission of the EPO.

⁹² See footnote 35.

different chemical classes can be obtained by the same preparation method, since the nature of the reactions involved in the synthesis is different.

103. The description must present detailed information on the reactions and conditions involved in the manufacturing processes, including concrete examples of the production of at least one representative compound for each chemical class encompassed in the different substituents provided for in the formula. In short, the description should present examples that clearly teach how the different substituents foreseen in the Markush formula can be incorporated into the general basic structure. In cases where the person skilled in the art cannot carry out the invention as claimed, or where this represents an undue effort of experimentation, the generic claims should be restricted to the embodiments mentioned in the patent application description.

Cuba

104. For patent applications claiming a particular chemical compound or group of chemical compounds, under a Markush claim, for instance, the following elements must be included to meet the sufficiency of disclosure requirements:

- examples of how most of the different compounds claimed to result from structural variations, including at least one but possibly several compounds representative of the variety possible, can be derived from the general formula;
- the procedures for obtaining each of those compounds;
- physio-chemical characterization: melting point and infrared (IR) absorption spectrum, nuclear magnetic resonance or mass spectrum;
- experimental tests demonstrating the property or activity claimed: if a pharmacological activity is claimed for a Markush group of compounds, it must be demonstrated that the activity can be achieved using all of the compounds offered as examples.

105. The examples of manufacturing processes must include all the operations to be performed, in the order required, with the conditions and raw materials necessary to perform them and precise indications of the reagents to be used and relative quantities needed. These requirements must also be met for new forms of known compounds, possibly including a selection of the compounds under a Markush claim, new polymorphic forms, isomers, solvates, hydrates, salts, ethers, esters, nitrogen oxides, prodrugs or metabolites. Merely referring to the definition of a derivative based on previously established knowledge does not provide a sufficient basis for testing an invention.

Czech Republic

106. Not every compound that would fall under the Markush claim can be described as embodiments in the description. However, in case of a certain often wide range of substituents, it is not possible to meet the enabling disclosure requirement if only one substituent is described in the examples. Similarly, in the case of a component content range in the composition, if component contents approaching only one extreme range were given in the examples, it does not meet the enabling disclosure requirement.

107. Where the claimed scope of protection is clearly disproportionate in view of the evidence in the examples, the Industrial Property Office of the Czech Republic (hereinafter referred to as 'Office') requires a limitation of the scope of claims in proportion to the scope documented in the examples. We understand the notion 'proportionately' as an adjustment of the scope of protection to what has been demonstrated in the examples and at the same time supported by

the arguments in the descriptive part of the patent specification. If the applicant limits the scope proportionately or explain why such a request is unjustified, the Office should reconsider its opposition. On the other hand, the clarity of the subject-matter also needs to be examined. If a group, e.g., alkyl without defining the number of carbon atoms, is claimed in the application, as well as in the description, but only methyl is given in the example, then the objection to the non-sufficiency of disclosure, and thus requirement for restriction of the scope of protection, is appropriate.

108. Reference is made to Section III.C for examples of some factors that may be relevant to the determination of sufficient disclosure of Markush claims.

I. Stereoisomers

109. 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). Structural isomers are a type of isomers in which molecules with the same molecular formula have different bonding patterns and atomic organization. Stereoisomers have the same bond structure, but the geometrical positioning of atoms and functional groups in space differs.

110. 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 (racemate), which contains equal parts of (+) and (-) enantiomers. Enantiomer members often have different chemical reactions with other enantiomer substances. 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.

111. With respect to sufficient disclosure of inventions regarding stereoisomers and enantiomers, only a few Member States submitted specific information relating to these inventions.

112. According to the submission of Brazil, the clear and sufficient description of the stereoisomer in its pure form resides in the characterization of the absolute configuration of its chiral center at the time of filing the patent application. Analytical techniques such as circular dichroism (CD), nuclear magnetic resonance (NMR) (with or without addition of chiral shift reagent), circular birefringence, optical rotatory scattering, chromatography (with chiral column), polarimetry and single crystal X-ray diffraction can be used for the characterization of the claimed enantiomer/atropisomer/diastereoisomer. The parameters of the process for obtaining the stereoisomer, either by asymmetric synthesis or by the purification process after the synthesis of the compound, must be specified in the description, in order to guarantee its reproducibility by a person skilled in the art. Due to the possibility of racemization of chiral compounds during the synthesis process, it is important that the description reveals the reagents used (especially in the chiral center formation step), the reaction conditions, and the isolation and purification methods of the stereoisomer obtained by said process. The description must also describe the eventual enantiomeric excess obtained and the analysis method used for its measurement.

113. In its practice, stereoisomers must be defined using the official nomenclature IUPAC or other system that unambiguously identifies them. The use of the generic expression "its stereoisomers" in claims referring to a compound *per se* is not sufficient to identify the

stereoisomers in a clear and precise way. If the patent description sufficiently describes this subject matter, the claim may be reformulated to better define the claimed matter.

114. The Submission of the Czech Republic notes that if protection is desired for a particular stereoisomeric form, its specific preparation/testing is required, including evidence of its advantage over other forms. Similarly, the submission of Türkiye states that if the invention relates to the pure form of enantiomer, sufficient experimental data should be provided, showing how the enantiomer is isolated from the racemic mixture. It is recommended to compare the invention with the prior art and explain the differences between the prior art and the claimed invention. If there is further technical effect, the alleged technical effect should be supported with experimental data.

J. Prodrugs

115. A prodrug⁹³ 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 moiety before, during, after absorption, or within specific target tissue, depending upon the purpose of prodrug strategy.

116. The submission of Brazil states that substantive analysis of patent applications claiming prodrugs follows the same guidelines applied to chemical compounds in general. The submission of the EPO noted that prodrugs and metabolites are examined in a similar manner and are a form of a functional definition of a product. A lack of clarity objection may apply if their chemical structure is not well defined.

117. According to the submission of the United Kingdom with respect to prodrugs and metabolites etc., if a class of new compounds is well defined and the functional groups which may be readily derivatized are similarly clear, then esters, ethers, salts and N-oxides may well be deemed enabled (e.g. where acids or alcohols are clearly defined and can be readily produced given the information in the application as filed then simple esters and ethers are likely to be deemed supported). Where the sites of derivatization are not self-evident, then these functional groups are likely to be regarded as not enabled in the absence of relevant synthetic examples. Similarly, enantiomers or other isomers (though frequently not regioisomers) are likely to be supported (i.e. a claim need not be limited to one particular isomer) where it is clear that the synthesis/syntheses will allow access to all isomers. Where a technical prejudice exists in the art to obtaining a particular isomer then an application claiming that isomer must be enabled i.e. that technical prejudice must be overcome (c.f. *Generics v Lundbeck*). Undisclosed prodrugs are by their nature not likely to be enabled unless the metabolic pathway of the compounds of the invention is either disclosed or well understood according to the common general knowledge.

K. Polymorph Forms and Crystalline

118. According to the submission of the EPO, 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 same criteria are applied to

⁹³ Mari Minn, Assessment of disclosure in European Prodrug Patent Claims, *Chicago-Kent Journal of Intellectual Property*, Volume 18, Issue 3, pages 429-449; Rakesh K. Tekade (ed.), *The Future of Pharmaceutical Product Development and Research* (2020), Chapter 6 (Prodrug design for improving the biopharmaceutical properties of therapeutic drugs).

examine the sufficiency of disclosure of either polymorph forms and crystals or any other parametric definition.

119. In line with the above, submissions of some Member States relating to the specific information on this subject focus on the importance of identifying physical and chemical characterization of polymorph forms through appropriate techniques as well as disclosure of the process for obtaining the polymorph form, together with the essential steps, parameters and conditions. The subsequent paragraphs provide practices of some countries.

Brazil

120. The identification of a crystalline form⁹⁴ is done by means of physical-chemical parameters that define its structure. Crystal definition merely by designations such as, for example, alpha or beta form, form I or II, does not clearly and precisely define the crystalline form. For an adequate definition and characterization of the crystalline form, the description must contain, on the filing date, the identification data obtained by physicochemical characterization techniques for solids, such as those exemplified below, or by validated alternative techniques that better identify it:

- (i) Single Crystal X-Ray Diffraction (Single Crystal XRD);
- (ii) X-Ray Powder Diffraction (XRPD);
- (iii) Solid State Carbon-13 Nuclear Magnetic Resonance Spectroscopy (13C NMR);
- (iv) IR Spectroscopy;
- (v) Raman Spectroscopy;
- (vi) Electron Microscopy;
- (vii) Thermal Analysis, such as Differential Scanning Calorimetry (DSC) or Thermogravimetric Analysis (TGA); and
- (viii) Differential Thermal Analysis (DTA).

121. The single-crystal XRD analysis is considered to be sufficient for the perfect characterization of the crystal structure of the solid. If single-crystal XRD data are not available, the XRD technique using the powder method with indexing must be used, associated with other methods of physical-chemical characterization of solids, provided that the set of techniques is sufficient for the unambiguous identification of the crystalline form.

122. More advanced solid characterization techniques not provided for in the Guidelines will be evaluated as to their pertinence for the identification of the claimed crystalline solid. In the absence of crystalline solid characterization data, it will be considered that the description does not clearly and sufficiently describe the claimed subject matter. The presentation of any characterization data of the claimed solid will not be allowed after the filing date, as it would be considered an extrapolation of the originally filed subject matter.

123. The parameters of the process for obtaining the crystalline form must be specified in the description in order to guarantee its reproducibility by a person skilled in the art. Essential parameters of the preparation process may be, for example, the type of solvent and its concentration, rates of addition of solvent(s), heating and cooling rates, description of the method of obtaining seeds eventually used in the crystallization process and other parameters that may be considered critical. The claimed crystalline form is considered part of the preparation process: for the process to be considered sufficiently enabling, the polymorph obtained by such a process must be properly characterized in the description.

⁹⁴ Sufficiency of disclosure related to polymorphs is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2013 to 2016 (INPI Resolution No.124 of December 4, 2013) and INPI Guidelines for Examination of Patent Applications – Chemistry, Item 4.1 (INPI Resolution No.208 of December 27, 2017).

124. In some crystalline solids, the solvent may be incorporated into the compound crystalline network in stoichiometric or non-stoichiometric proportions. These molecular adducts are called solvates, also known as pseudopolymorphs. When the water is the crystallization solvent, the resulting solid is called hydrate. Clathrates are inclusion compounds in which a guest molecule is entrapped in a cavity of the host molecule or the host molecule network (e.g., cyclodextrin inclusion complexes). In general, solvates, clathrates, and co-crystals have the following common characteristics: (i) all of them are formed by at least two molecules; (ii) all of them may have different crystalline forms; and (iii) all of them may have different characteristics according to the structure and constituents of the crystal.

125. For a clear and sufficient description of a solvate, clathrate, crystalline or co-crystal complex,⁹⁵ chemical identification of the molecule and stoichiometry is mandatory, which can be determined by using TGA techniques, Karl Fischer or other validated techniques that provide such information. In addition, the use of the generic expressions “and its solvates”, “and its hydrates”, “and its clathrates” and/or “and its co-crystals” in claims, referring to a compound *per se*, does not clearly and precisely identify the solvate, hydrate, clathrate and co-crystal derivatives, and are therefore not accepted.

Colombia

126. For a polymorph to be deemed sufficiently described, the application shall contain a sufficient description of at least one process to obtain the seed crystal or first polymorph, including all the essential steps and experimental conditions so that a person with average skill in the field can use the method and obtain the claimed polymorphs. In addition, description of the polymorph should be made, using techniques available for such purpose. They include:

- (i) the 2-Theta values of the single-crystal XRD pattern and corresponding figure or the 2-Theta values of the XRPD pattern and corresponding figure; and
- (ii) other technical data to characterize a given polymorph, as obtained by thermal analysis methods (e.g., DSC, DTA, TGA and Hot Stage Microscopy (HSM)) or spectroscopic methods (e.g., Raman, IR and ¹³C NMR).

127. XRD provides a complete supramolecular description of the crystal structure from a “near perfect” single-crystal sample, and data for calculating or predicting the diffraction pattern obtained from the powder of such material, thus providing a suitable technique for characterizing the crystal structure of a solid compound (polymorph). If a given polymorph has been characterized using this technique, a description of other techniques serving the same purpose will be optional. Should single-crystal XRD data not be provided, XRPD data should be provided, which is an important analytical tool for differentiating crystalline forms, as it provides a “fingerprint” of the crystal lattice. XRPD data must also be provided in the initial application along with the other technical data to characterize a given polymorph as indicated in the previous paragraph.

⁹⁵ The compliance with sufficient disclosure related to solvates, clathrates and co-crystals is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.16 (INPI Resolution No.124 of December 4, 2013) and INPI Guidelines for Examination of Patent Applications – Chemistry, Item 5 (INPI Resolution No.208 of December 27, 2017). If the claimed invention is a solvate, the instructions contained in the Chemical Compound Item of INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208 of December 27, 2017), and in the INPI Patent Application Examination Guidelines, Block II (INPI Resolution No. 169 of July 15, 2016) must be consulted. If the claimed invention is a crystalline form, it must be characterized by the techniques described in the Polymorph Item of INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208 of December 27, 2017) and in the INPI Patent Application Examination Guidelines, Block II (INPI Resolution No. 169 of July 15, 2016).

128. It is important that figures relating to the diffractograms of each polymorph are presented, where the scanning region should be from 0° to 40° 2-Theta for organic compounds (small molecules) and from 0° to more than 50° 2-Theta (for example, up to 90°, up to 120°, or up to 150°) for inorganic compounds, as appropriate. It is suggested that each diffractogram show the relative intensities (Y-axis) according to the 2-Theta angles (X-axis) in their respective data tables. It is suggested that the diffractogram show the most relevant relative intensities to characterize the polymorph.

129. As with other inventions, for polymorphs, the description must disclose the technical problem confronting existing forms in the prior art and the solution provided by the polymorph in the application, which must be supported by evidence establishing that the problem has been solved.

130. The description shall be considered insufficient to describe the polymorph where it does not clearly describe the preparation procedure of the claimed polymorph, it does not include all the preparation processes disclosed in the application, including the seeding of crystals, the preparation of seed crystals is not described, or the essential parameters employed in such processes are omitted.

Cuba

131. When the subject matter of the invention is polymorph form, an X-ray powder diffractogram is also required, together with the results of two of the following additional tests: Raman spectroscopy; a solid-state NMR; electron microscopy; differential scanning calorimetry (DSC); thermo-gravimetry analysis (TGA); differential thermal analysis (DTA); purity testing, or a single-crystal X-ray diffractogram.

Czech Republic

132. For polymorphic forms, crystalline forms and co-crystals, their preparation/testing is required as well as proof of preference over other forms (amorphous, other crystalline), including indication of spectrum/peak measurement parameters (wavelength, radiation source used, etc.). Likewise, for inventions regarding the hydrate/solvate form, disclosure of their preparation/ testing as well as demonstration of their benefits are required.

Mexico

133. in the case of polymorphs, there is a lack of descriptive sufficiency when: (i) the application does not give a clear description of the methods used to measure the values of the parameters that identify the claimed polymorph; (ii) the preparation processes described in the application are identical to those described in the state of the art but it is claimed that the polymorph is different; or (iii) all of the preparation processes described obtain the claimed polymorph through crystallization using seed crystals but the seed crystal preparation processes are not described.

Türkiye

134. To comply with the sufficiency of disclosure requirements for inventions related to polymorphic forms, it is recommended to present the analytic results such as XRD, which characterizes the polymorph. Applicants are also suggested to demonstrate the production method of new polymorphic form. Technical effect should be discussed in detail in the description of invention.

L. Compositions and Formulations

135. From the submissions of several Member States, issues surrounding the disclosure of compositions appear to be clarity of composition claims, i.e., how to define a composition in the claims in a clear and concise manner. Although clarity of claim is a requirement that is distinct from the sufficient disclosure requirement, inherent insufficiency may arise if the claims are too ambiguous.

136. Regarding pharmaceutical composition, according to the guidelines of the UKIPO,⁹⁶ composition claims of the form “a pharmaceutical composition containing compound X together with a diluent, excipient or carrier” are considered to be clear – X being a medically active compound which characterizes the composition, and the diluent, excipient or carrier being any material suitable for the purpose and being selectable by knowledge of the art or by non-inventive experiment. There is no requirement for the diluent, excipient or carrier to be further characterized. However, the Technical Board of Appeal considered that a claim to the active ingredient “with an auxiliary substance or substances” was so broad as to be meaningless, and this could not distinguish the claim from the prior art.⁹⁷

137. In addition, the guidelines of the UKIPO also note that terms such as “therapeutically effective amount” of an active ingredient are generally considered to be clear.⁹⁸ However, if such a term is used to distinguish the composition from the prior art, this is open to objection unless the specification teaches how this is tested, or there is a standard test in the art (T 151/01 INSITE VISION). The Board of Appeal in T 1635/09⁹⁹ (PDF, 203 KB) held that if a composition claim is defined in terms of parameters which require testing to determine its scope, then it may be objectionable on grounds of clarity if it could be defined without the need for such tests, particularly where the tests may be burdensome and/or ethically questionable.

138. The submission of Brazil to SCP/35 notes that while a pharmaceutical composition is usually defined by its constituents, it may be defined by mixed characteristics, in order to encompass characteristics of physical form or application, provided that they are defined qualitatively and/or quantitatively by their constituents in the description. If the quantitative definition is essential, it is mandatory. Compositions defined solely by their use, form of administration, or mechanism of action are not precise and therefore not accepted.

139. Furthermore, the submission of Brazil states that the clarity of claims may arise where combination of compounds are claimed. The cases discussed are:

- Combination comprising compounds defined by Markush formula;
e.g., *Combination characterized by comprising a compound as defined by the general formula (I) in association with compound A.*
- Combinations comprising one or more classes of chemical compounds
e.g., *Pesticidal combination characterized by comprising a pyrethroid compound and an X enzyme inhibitor compound.*

Defining the compounds of the pharmaceutical combination by their chemical class or by their mechanism of action in a generic way, without specifying which is(are)

⁹⁶ Examining Guidelines for Patent Applications relating to Medical Inventions in the Intellectual Property Office, paragraph 238, UKIPO.

⁹⁷ T 80/96 LONZA/L-Carnitine OJEPO 2000, 50

⁹⁸ Examining Guidelines for Patent Applications relating to Medical Inventions in the Intellectual Property Office, paragraph 239, UKIPO.

⁹⁹ T 1635/09 BAYER SCHERING/Composition for contraception OJEPO 2011, 542.

the exact compound(s) comprised in the combination, is not sufficient to clearly define the subject matter to be protected

- Combinations optionally comprising other active ingredients
e.g., *Combination characterized by comprising compound A and B and, optionally, other active ingredients.*

Special attention should be paid to the clarity and accuracy of the wording of the combination claim, as the mere mention of the term “and optionally other active ingredients” is not sufficient to clearly define the claimed subject matter.

- Combinations in which compounds are in separate forms
In patent applications relating to combinations in which the compounds are in separate forms, the description must present evidence that such combinations are obtainable in the form of a “product for simultaneous application”, even if such product is claimed by means of a kit.¹⁰⁰

140. In the practice of the EPO, for compositions comprising many components in various proportions, an approach similar to that adopted for any claim comprising many alternatives is followed.¹⁰¹ Similarly, the submission of Cuba notes that when the subject matter of an invention consists of a mixture of compounds, such as compositions or combinations, and their quantities are expressed as ranges, examples of mixtures representative of the ranges claimed need to be presented.

141. According to the practice in Lithuania and the Russian Federation regarding composition inventions (mixture, solution, etc.), the examples provided in the description must indicate the ingredients included in the composition, their characteristics and their quantitative composition. The method of obtaining the composition must be described, and if its ingredient is a new substance, the method of obtaining it must also be described. In the presented examples, the amount of each ingredient must be indicated in such a unit value that is within the limits specified in the interval of the claims of the invention (maintaining the quantitative ratio of all ingredients in the claims of the invention in percent (by mass or volume), and the sum of all the ingredients indicated in the example must be equal to 100%).

142. In relation to pharmaceutical compositions, the Technical Board of Appeal of the EPO pointed out in T 1616/09 that, for the purpose of the enabling disclosure, the level of disclosure in the application which is required for claims directed to pharmaceutical compositions or kits is not the same as the level of disclosure required for medical use claim.¹⁰²

143. For claims directed to pharmaceutical compositions or kits, it is in principle sufficient that the application provides information which allows the skilled person to produce the composition or kit, and that there are no substantiated doubts that it could indeed be used in therapy. This was contrasted with the requirement for second-medical-use claims, where it is required not only that the composition itself is disclosed in an enabling way but also that its suitability for the claimed treatment is plausibly disclosed in the application.

144. Referring to this decision of the Board of Appeal, the guidelines of the UKIPO¹⁰³ note that if it is considered implausible that the composition could possibly have any therapeutic benefit (either because of toxicity or lack of any plausible activity), an objection of insufficiency may

¹⁰⁰ Guidelines of Examination of Patent Applications, Block II, Paragraph 7.11, INPI Brazil.

¹⁰¹ Guidelines for Examination in the European Patent Office, B-VIII, 3.1 and B-VIII, 3.2, EPO.

¹⁰² Case Law of the Boards of Appeal, II.C.7.2.3, EPO.

¹⁰³ Examining Guidelines for Patent Applications relating to Medical Inventions in the Intellectual Property Office, paragraph 240, UKIPO.

arise. If it is considered inherently implausible that it could have any useful properties at all, it may also be objected on the grounds of lack of industrial applicability.

145. The guidelines of the UKIPO also cites another case where the Hearing Officer refused a group of applications relating to compositions comprising ultra-low doses of antibodies on grounds of both sufficiency and industrial applicability, as it was considered implausible that the compositions (in which a single dose would be statistically unlikely to contain any antibody molecules) could have any therapeutic effect.¹⁰⁴ However, on appeal, the Patents Court held¹⁰⁵ that the application did provide plausible evidence of activity (if a claimed effect can be established to be plausible by evidence provided in the application, there is no need to identify a plausible basis according to the conventional scientific view), and the decision was overturned.

[End of document]

¹⁰⁴ Epshtein's Applications BL O/508/15, cited in *Idem*.

¹⁰⁵ Epshtein's Applications [2016] EWHC 1511; [2017] RPC 11.