

Standing Committee on the Law of Patents

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FURTHER STUDY ON INVENTIVE STEP (PART II)

Document prepared by the Secretariat

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 inventive step prepared by the Secretariat (document SCP/22/3). The study addressed the definition of a person skilled in the art, methodologies employed for evaluating inventive step and the level of the inventive step. At its twenty-seventh session, held in Geneva from December 11 to 15, 2017, the SCP agreed that the Secretariat would prepare a further study on inventive step, giving a particular attention to the topics suggested in paragraph 8 of document SCP/24/3 (Proposal by the Delegation of Spain). Paragraph 8, of document SCP/24/3, lists the following topics that may be included in a study or studies by the Secretariat: (i) common general knowledge: its combination with the state of the art; (ii) combination: juxtaposition vs synergic effects; (iii) the danger of hindsight analysis; (iv) secondary indicia; (v) selection inventions; (vi) problem invention; and (vii) the assessment of inventive step in the chemical sector (Markush claims, enantiomers. etc.).

2. Consequently, the Secretariat invited Member States and Regional Patent Offices, through its Note C. 8728, dated February 9, 2018,¹ to submit to the International Bureau examination guidelines and manuals, as well as summaries of the most important case law or interpretive decisions concerning the suggested topics for the preparation of such a study.

¹ The information submitted by Member States and regional offices is available in full on the website of the SCP electronic forum at: http://www.wipo.int/scp/en/meetings/session_28/comments_received.html.

3. Taking into account the information submitted by the Member States and Regional Patent Offices in response to Note C.8728,² the Secretariat prepared the first part of a further study on inventive step, which was submitted to the twenty-eighth session (document SCP/28/4). The Further Study on Inventive Step (Part I) focuses on the topics (i) to (iii) referred to in paragraph 1, above. At the said session, the Committee agreed that the Secretariat would prepare a Further Study on Inventive Step (Part II) giving a particular attention to the topics suggested in paragraph 8 of document SCP/24/3.

4. This document contains the Further Study on Inventive Step (Part II), which focuses on the topics (iv) to (vi) referred to in paragraph 1, above, namely, secondary indicia, selection inventions and problem inventions. In preparing this document, the Secretariat took into account the information submitted by the Member States and Regional Patent Offices in response to Note C.8728.

5. Part II of the Further Study on Inventive Step is built on the earlier studies contained in SCP/22/3 and SCP/28/4, and therefore, they should be read together for the comprehensive understanding of the topic.

SECONDARY INDICIA

General characters of secondary indicia

6. In principle, an assessment of obviousness involves a question as to whether the claimed invention as a whole would have been obvious, having regard to the prior art as a whole. The Determination of obviousness is dependent on the facts of each case. It is based on the entire record, with due consideration to all factual information and secondary evidence.³

7. In determining whether a claimed invention is obvious or not, a number of issues should be considered. The UK court, for example, developed a non-exhaustive list of relevant questions in *Haberman v Jackal* when assessing existence or lack of inventive step, as follows:

- (a) What was the problem which the patented development addressed?
- (b) How long had that problem existed?
- (c) How significant was the problem seen to be?
- (d) How widely known was the problem and how many were likely to be seeking a solution?
- (e) What prior art would have been likely to be known to all or most of those who would have been expected to be involved in finding a solution?
- (f) What other solutions were put forward in the period leading up to the publication of the patentee's development?
- (g) To what extent were there factors which would have held back the exploitation of the solution even if it was technically obvious?

² The information submitted by Member States and regional offices is available in full on the website of the SCP electronic forum at: http://www.wipo.int/scp/en/meetings/session_28/comments_received.html.

³ Manual of Patent Examination Practice (MPEP), 2142, United States Patent and Trademark Office (USPTO).

- (h) How well had the patentee's development been received?
- (i) To what extent could it be shown that the whole or much of the commercial success was due to the technical merits of the development?⁴

Some of the questions in the Haberman list may not be answerable before grant of a patent application or without evidence.

8. Similarly, a number of countries have developed a number of secondary indicators that may be taken into account for the assessment of inventive step. Secondary indicia themselves can neither establish the existence of inventive step nor replace the inventive step assessment methodology established in each jurisdiction.⁵ According to the established case law of the Boards of Appeal of the European Patent Office (EPO), a mere investigation for indications of the presence of inventive step is no substitute for the technically skilled assessment of the invention *vis-à-vis* the state of the art pursuant to Article 56 of the European Patent Convention (EPC) concerning inventive step.

9. Where such indications are present, the overall picture of the state of the art and consideration of all significant factors may show that inventive step is involved, but this need not necessarily always be the case.⁶ The EPO Boards of Appeal clarified that secondary indicia of this kind are only of importance in cases of doubt, i.e. when objective evaluation of the prior art teachings has yet to provide a clear picture.⁷ Therefore, as its name suggests, the secondary indicia are merely auxiliary considerations in the assessment of inventive step. To put it differently, they may merely in individual cases give an incentive to particularly critically consider the obviousness of inventions.⁸

10. Consequently, the mere fact that an applicant (or a patentee) submitted secondary evidence does not mean that the evidence is dispositive of the obviousness.⁹ Such secondary evidence can only be a persuasive evidence to support the inventive step on the case-by-case basis, when the claimed invention is assessed against the prior art and general common knowledge.¹⁰ In other words, the weight to be given to those secondary indicators is made on the case-by-case basis, by assessing a piece of factual evidence more convincing than another piece of factual evidence that offers in opposition to it.¹¹

11. The objective evidence of non-obviousness must be commensurate in scope with the claimed invention which the evidence is offered to support.¹² For example, while an unexpected technical effect may be regarded as an indication of inventive step under the EPO practice, it must derive from the subject-matter as claimed, not merely from some additional features which are mentioned only in the description. The unexpected effect must be based on the characterizing features of the invention, in combination with the known features of the claim. Similarly, according to the practice in Japan, the examiner may consider commercial success and the fact that the invention had been desired to achieve for a long time as a secondary

⁴ *Haberman v Jackal* [1999] FSR 685 (at 699 to 701).

⁵ See, for example, the submission of Germany to SCP/28.

⁶ T 24/81, OJ 1983, 133 and T 55/86.

⁷ T 645/94, T 284/96, T 71/98, T 323/99, T 877/99.

⁸ Submission of Germany to SCP/22.

⁹ MPEP, 2141.

¹⁰ Submission of Germany to SCP/29.

¹¹ MPEP, 2142.

¹² See, for example, MPEP, 716.02(d).

consideration for supporting the existence of an inventive step. This applies only if the examiner is convinced that these facts are not derived from other factors, such as sales promotion techniques or advertisements, but from the technical features of the claimed inventions on the basis of the applicant's arguments and evidences.¹³

12. Generally speaking, there are several secondary indicators that are used in more than one jurisdiction. They include:

- the claimed invention solves a long felt need, or overcome previous failed attempt by others;¹⁴
- the claimed invention has a particular commercial success or shows a significant economic importance;¹⁵
- the claimed invention is copied by others in preference to the prior art or market competitors sought commercial implementation of the claimed invention (for example, seeking licenses);¹⁶
- the prior art "teaches away" a person skilled in the art from the claimed invention, or the inventor overcomes a technical prejudice;¹⁷
- the claimed invention produces unexpected technical effects, results or advantages;¹⁸
- the claimed invention overcomes technical difficulties not solved by other means¹⁹ or is particularly complex and not readily carried out²⁰;
- the claimed invention offers a surprisingly simple solution or a surprisingly simpler low-cost way of manufacture;²¹
- the originality of the solution brought by the claimed invention, which departs from the beaten path and opens a new path.²²

13. While detailed information about the practice of some countries and regional patent offices are described in the Annex of this document, the following paragraphs provide further general information about some of those indicators that are used in some jurisdictions.

¹³ JPO Examination Guidelines, Part III, Chapter 2, Section 2 (Inventive Step), 3.3.

¹⁴ For example, Australia, Bulgaria, China, Croatia, France, Germany, Israel, Norway, Republic of Korea, Singapore, Slovakia, Spain, United Kingdom, United States of America, African Regional Intellectual Property Office (ARIPO), Eurasian Patent office (EAPO) and EPO. See also the Andean Patent Examination Manual and Patent Examination Manual for Central America and the Dominican Republic.

¹⁵ For example, Australia, Austria, Bulgaria, China, Croatia, Germany, Israel, Japan, Norway, Republic of Korea, Singapore, Spain, United Kingdom, United States of America, ARIPO, EPO and EAPO.

¹⁶ For example, Australia, United States of America and EPO.

¹⁷ For example, China, France, Germany, Israel, Norway, Republic of Korea, Singapore, Slovakia, Spain, United Kingdom, United States of America, EPO and EAPO. See also the Andean Patent Examination Manual and Patent Examination Manual for Central America and the Dominican Republic.

¹⁸ For example, Australia, China, Israel, Norway, Spain, United States of America, ARIPO and EPO. See also the Andean Patent Examination Manual and Patent Examination Manual for Central America and the Dominican Republic.

¹⁹ For example, Australia and Germany.

²⁰ For example, EAPO.

²¹ For example, Germany, Israel, Spain, EAPO and EPO. See also the Andean Patent Examination Manual and Patent Examination Manual for Central America and the Dominican Republic.

²² For example, EAPO. See also the Andean Patent Examination Manual and Patent Examination Manual for Central America and the Dominican Republic.

14. The “secondary” or auxiliary character of the secondary indicia is well described in case law and guidelines of some jurisdictions. For example, in *Elconnex Pty Ltd v Gerard Industries Pty Ltd (1992) AIPC*, the court acknowledged that the length of the prior perceived problem’s existence, can be indicative of the existence of an inventive step in overcoming this problem. However, while these “matters are of importance ... they are not conclusive [...]”. In a case of doubt the existence of a long felt want and immediate imitation might well persuade a court [...]. But in the end one has to come to the question whether or not the claimed invention is obvious.”

15. In the guidelines of some other jurisdictions, however, those same indicia, for example solving a long felt need, are simply included in a list of factors to be applied in assessing the inventive step, or in a list of factors that may be used for the positive determination of inventive step. In those cases, the “secondary” nature of the indicia cannot necessarily be readily asserted.

Solving a long-felt needs and failure of others

16. Where the invention solves a technical problem which has been attempting to be solved for a long time, or otherwise fulfils a long-felt need, this may be regarded as an indication of inventive step in certain jurisdiction. This indication is closely linked to the positive indication of the time factor and age of the cited documents to demonstrate that the problem or need has indeed existed for a long period without solution.

17. The age of documents known long before the filing date might only be an indication of an inventive step if a need for the solution of an unsolved problem had existed for the entire period between the date of the documents and that of the invention.²³ Similarly, in the United States of America, the long-felt need must have been a persistent one that has been recognized by those of ordinary skill in the relevant art, and the claimed invention is the first one to satisfy that need.²⁴

18. The long period of time to be considered is the period between the time the problem became apparent and the date of filing of the patent application providing a solution.²⁵ The exact duration of such period that is accepted as sufficiently “long” depends on each case under each circumstance.

19. If only one individual skilled person identified a long-felt need, it is not sufficient to demonstrate the existence of inventive step. In general, only if various and repeated attempts to deal with the relevant problem could be identified, would such a long-felt need could be established. For example, in Germany, if the expert community has already been trying to find a solution for a long time, or has accepted disadvantages that the invention avoids, this circumstance may be indicative of inventive step.

20. According to the UK case law, if the inventor has solved a long-recognized problem by means which others could have used but did not, then there may be an inventive step (*Minnesota Mining and Manufacturing Co v Rennicks (UK) Ltd [1992] RPC 331*).²⁶ However, if the inventor has solved a long-standing problem by using, in a conventional way, materials or techniques that have only recently become available, the invention is not inventive. In addition,

²³ T 79/82 and T 295/94.

²⁴ MPEP, 716.04.

²⁵ T 478/91. See also the practices of France, Germany and the United States of America.

²⁶ In *Chiron Corp v Organon Teknika Ltd [1994] FSR 202* a claim to a polypeptide comprising an antigenic determinant of the hepatitis C virus was found to be non-obvious because despite the attempts of numerous research groups over a 10-year period to identify the agent responsible for Non-A, Non-B Hepatitis, the patentees succeeded in a unique fashion by adopting a known technique which would not have been obvious to try in the circumstances.

the Examination Guideline for Singapore Intellectual Property Office (SIPO) clarifies that if a product has not been made from a particular material or by a particular process for reason of cost, and the material or process becomes cheaper or the market value of the product increases, it is unlikely that the invention will be considered as having an inventive step.

21. In some countries, the aspect of whether others have previously attempted but failed to achieve what the claimed invention achieved may be a secondary indication in support of inventive step.²⁷ In this regard, the courts in Australia held that if a problem has been the subject of previous failed attempts to solve it,²⁸ or the solution was complex and laborious, involving “a good deal of trial and error, with dead ends” and is not routine,²⁹ then an inventive step is likely.

Commercial success

22. The fact that the claimed invention has been commercially successful may be a relevant consideration for the assessment of inventive step in some jurisdictions. However, commercial success alone is not to be regarded as indicative of inventive step.³⁰ In some countries, evidence of immediate commercial success when coupled with evidence of long-felt want is of relevance.³¹ A person who is asserting commercial success to support non-obviousness bears the burden of proof that such success directly derived from the technical features of the invention and not from other influences such as selling techniques, advertisement,³² or other business events extraneous to the merits of the claimed invention.³³ In one country, the economic success of a product can only be used as an indication of inventive step to the extent that it is based on technical causes.³⁴

23. In *ex parte* proceedings before the United States Patent and Trademark Office (USPTO), an applicant must show that the claimed features were responsible for the commercial success of an article if the evidence of non-obviousness is to be accorded substantial weight.³⁵ In addition, to be pertinent to the issue of non-obviousness, the commercial success of devices falling within the claims of the patent must flow from the functions and advantages disclosed or inherent in the description in the specification.³⁶

24. In T 110/92, the EPO Board of Appeal did not dispute that the heating assembly according to claim 1 might have been a commercial success. However, such a commercial success alone, with the technically relevant examination of the claimed subject-matter leading to a

²⁷ See the practices of Spain, the United States of America and the Andean Patent Examination Manual and Patent Examination Manual for Central America and the Dominican Republic.

²⁸ *Technograph Printed Circuits Limited v Mills and Rockley (Electronics) Limited* [1972] RPC 346 at 353.

²⁹ *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411.

³⁰ The courts of Australia stated that while commercial success cannot be conclusive by itself, it is “a material matter” that must be weighted “by reference to all the surrounding circumstances” (*Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) CLR 228 at 239) and that commercial success was “a valuable weight in favor of the patent” on a case-by-case basis (*General Tire & Rubber Company v Firestone Tyre and Rubber Company Ltd* [1972] RPC 457 at 503).

³¹ Guidelines for Examination in the EPO, Part G, Chapter VII, 10.3. See also the practices of Spain and ARIPO.

³² See, for example, the practices of China, Germany, Japan, the Republic of Korea, Singapore, Spain, ARIPO and EPO.

³³ *In re Mageli*, 470 F.2d1380, 176 USPQ 305 (CCPA 1973).

³⁴ *BGH, Xa ZR 22/06 (2009) – Dreinahtschlauchfolienbeutel*, GRUR 2010, 44; *BGH, X ZR 104/90 (1993) – Meßventil*, GRUR 1994, 36.

³⁵ However, in *Demaco Corp. v. F. VonLangsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (*Fed. Cir. 1988*), in civil litigation, a patentee does not have to prove that the commercial success is not due to other factors. “A requirement for proof of the negative of all imaginable contributing factors would be unfairly burdensome, and contrary to the ordinary rules of evidence.”

³⁶ MPEP, 716.03(b).

negative result, could not be regarded as forming the basis for an indication of inventive step, even if the Board were convinced that the success derived from technical features of the heating assembly and not from other causes such as those of a commercial nature.

25. In another case in the UK, although claim 1 covered the products which had enjoyed commercial success, it also covered other products which could never do so and no features which might ensure the success were recited in Claim 1. The court held that all matter within the scope of the claim must include the features contributing to the commercial success of the invention.³⁷

26. In Spain, in *ECLI: ES:JMB:2012:1265*,³⁸ the patentee argued that the patented product, SEROQUEL PROLONG, was one of the 20 best-selling drugs in the world, and that its sales in Spain had surged by 42% in the previous fiscal year. In addition, the patentee demonstrated the surprising effect of the claimed invention where it provides a better side effect profile, especially at high doses. Those two secondary indicia were taken into consideration by the court, which declared that the claimed invention was novel and involved inventive step. That decision was appealed to an appeal court (*ECLI: ES:APB:2013:11696*).³⁹ The second instance judges declared the patent invalid because of lack of inventive step. As to the indicator of commercial success, while the court recognized the commercial success of the patented product, since that alone cannot be considered as indicative of inventive step, it still lacks other additional data that sufficiently demonstrate the inventiveness of the claimed invention. Regarding the indicator of a surprising effect, the court held that the lower side effect was not an unexpected effect from the prior art.

27. Since most patents are prosecuted early in the development of an invention, applicants may have difficulty in demonstrating commercial success at the early stage of patent prosecution. However, this may be a relevant consideration regarding inventive step later in the office procedure or during the litigation stage.

Copied by others and market competition

28. Somewhat closely related to commercial success of a claimed invention, extent of copying by others or competitors' behaviors in the market is considered as one of the factors that may be taken into account in some jurisdictions. In *Meyers Taylor Pty Ltd v Vicarr Industries Ltd (1977) CLR 228 at 239*, the High Court of Australia pointed to the copying of a claimed invention as demonstrative of a "public need which is relevant to the question of obviousness", although it cannot be conclusive evidence by itself. Similarly, in the United States of America, evidence that competitors in the marketplace are copying the invention instead of using the prior art may be presented by applicants, often during litigation. More than the mere fact of copying is necessary to make that action significant, since copying may be attributable to other factors, such as a lack of concern for patent property or contempt for the patentee's ability to enforce the patent.⁴⁰

29. In T 915/00, the Board of Appeal of the EPO held that commercial implementation, market competitors' efforts to obtain licensing and the recognition of the inventor's merits by the scientific community constituted further convincing secondary indicia for the presence of inventive step. These factors may result in a positive decision on inventive step, but need not

³⁷ *Tetra Molectric Ltd v Japan Imports Ltd*, [1976] RPC 547.

³⁸ *ECLI: ES:JMB:2012:1265: Commercial Court of Barcelona, Section 2. Appeal No. 523/2011; Ruling No. 202/2012, 09/07/2012*

³⁹ *ECLI: ES:APB:2013:11696: Provincial Court of Barcelona, Section 15. Appeal No. 687/2012; Ruling No. 367/2013, 22/10/2013.*

⁴⁰ MPEP, 716.06.

necessarily do so. In T 812/92, shortly before the filing date of the contested patent, one of the patent proprietor's competitors offered a customer a technical apparatus without reducing to practice the advantageous technical solution according to the invention. The Board held that this might be an indication that an inventive step was involved. In T 252/06, the Board confirmed the presence of inventive step *inter alia* on the grounds that the proprietor's competitors had used the patent's teaching and had filed applications relating to it.

Overcoming technical prejudice, skepticism by experts and teaching away

30. According to the practices of some countries, inventiveness can sometimes be established by demonstrating that a known prejudice, i.e., a widely held but incorrect opinion of a technical fact, needs to be overcome.⁴¹ A prejudice in any particular field relates to an opinion or preconceived idea widely or universally held by experts in that field. Similarly, in some countries, expressions of disbelief or skepticism by experts constitute strong evidence of non-obviousness.⁴²

31. The existence of such prejudice is normally demonstrated by reference to the literature or to encyclopedias published before the priority date. According to French courts, the prejudice, technical in nature, does not need to be formulated explicitly as such, neither in the patent nor in the prior documents.

32. In this regard, the Examination Guidelines for Patent Applications at IPOS explains that an examiner should consider what the skilled person would consider doing, but also what the skilled person would be prejudiced against doing. An invention may be regarded as non-obvious if it goes against the generally accepted views and practices in the art.⁴³ Examples where this may be a determining factor include: (i) if the common general knowledge was such that the skilled person did not perceive a problem with the prior art; (ii) if certain materials or techniques would be considered by the skilled person as unsuitable for a particular purpose and the inventor has found that this prejudice is not well-founded; (iii) if a certain step in a method or component in an apparatus was considered essential, but the inventor has found that it may be omitted.

33. In order to establish that the inventor overcame the technical prejudice, the burden is on the patentee (or patent applicant) to demonstrate, for example, by reference to suitable technical literature that the alleged prejudice really existed.⁴⁴ Generally speaking, established EPO Board of Appeal case law is very strict when it comes to recognizing the existence of a prejudice. A solution put forward as overcoming a prejudice must clash with the prevailing teaching of experts in the field, i.e., their unanimous experience and notions, rather than merely cite its rejection by individual specialists or firms.⁴⁵ The Board in T 1989/08 observed that this meant the standard of proof was almost as high as that required for common general knowledge in the art.

34. In some countries, where the prior art or common general knowledge teaches away from the claimed solution, an inventive step may be not denied, except where the prior art is readily identifiable as erroneous and correctable by the skilled addressee.⁴⁶

⁴¹ T119/82, OJ 1984, 217; T48/86.

⁴² MPEP, 716.05. In *In re Dow Chemical Co*, the court held that "the skepticism of an expert, expressed before these inventors proved him wrong, is entitled to fair evidentiary weight.

⁴³ *Dyson Appliances Ltd v Hoover Ltd* [2001] RPC 26.

⁴⁴ T 60/82, T 631/89, T 695/90, T 1212/01.

⁴⁵ See also the practice in Singapore where the prejudice must be sufficiently widespread for it to be attributed to the person skilled in the art.

⁴⁶ See the practices of Australia, the Republic of Korea and the United States of America.

Unexpected technical effect, result or advantages

35. In some jurisdiction, an unexpected technical effect or result may be regarded as an indication of inventive step.

36. The unexpected effect must be based on the characterizing features of the invention, in combination with the known features of the claim. It cannot be based merely on features which are, in combination, already comprised in the prior art. Therefore, an unexpected bonus effect does not confer inventiveness on an obvious solution. If it is obvious for the skilled person to combine prior art teachings in order to solve an essential part of the problem, the presence of even an unexpected extra effect allowing another part of the problem to be solved at the same time does not in principle imply the presence of inventive step.⁴⁷

37. Similarly, according to the US case law, in general, if a claimed invention achieved a greater than expected result, it can be an evidentiary factor pertinent to the legal conclusion of non-obviousness of the claims at issue.⁴⁸ Since a greater than additive effect can either be expected or unexpected, applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage.⁴⁹ Evidence of the (i) presence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, (ii) presence of an unexpected property in the claimed invention not possessed by the prior art, or (iii) absence of property which a claimed invention would have been expected to possess based on the teachings of the prior art, may be indicative of non-obviousness.⁵⁰

38. The Examination Guidelines for the China Intellectual Property Office (CNIPA) explain that the unexpected technical effect means that, as compared with the prior art, the technical effect of the invention represents a “qualitative” change, that is, new performance, or represents a “quantitative” change which is unexpected. Such a qualitative or quantitative change cannot be expected or inferred by the person skilled in the art in advance.

39. If, having regard to the state of the art, it would already have been obvious for a skilled person to arrive at something falling within the terms of a claim, for example, due to a lack of alternatives thereby creating a “one-way street” situation, the unexpected effect is merely a bonus effect which does not confer inventiveness on the claimed subject-matter.⁵¹ If the skilled person would have to choose from a range of possibilities, there is no one-way street situation and the unexpected effect may very well lead to the recognition of an inventive step.

40. According to the established jurisprudence of the EPO, a surprising effect (advantageous effect or feature) demonstrated in a comparative test can be taken as an indication of inventive step. If comparative tests are chosen to demonstrate an inventive step on the basis of an improved effect, the nature of the comparison with the closest state of the art must be such that the alleged advantage or effect is convincingly shown to have its origin in the distinguishing feature of the invention compared with the closest state of the art.⁵² Alleged but unsupported advantages cannot be taken into consideration in respect of the determination of the problem underlying the invention.⁵³

⁴⁷ T170/06.

⁴⁸ MPEP 716.02(a).

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*

⁵¹ T 231/97 and T 192/82. See also the practices of Australia and the ARIPO.

⁵² T 197/86, OJ 1989, 371; T 234/03; T 378/03.

⁵³ T 20/81, OJ 1982, 217; T 561/94.

41. In some jurisdictions, even if the invention is the result of a foreseeable worsening of the prior art, the result of a non-functional modification of the prior art or a mere choice from a host of possible solutions, an inventive step might be present if such modification or choice is accompanied by an unexpected advantage.⁵⁴

Practical difficulties to overcome

42. In Australia, where the solution may be obvious, but there were practical difficulties in implementing this, and the overcoming of the difficulties require an inventive ingenuity, then this can give rise to an inventive step. In contrast, if “any problems of design ... [relating to the implementation of the solution] ... would be easily solved by anyone skilled in the art ... the combination must be held to have been obvious.”⁵⁵ Similarly, in Germany, among other factors, the nature, scope and effects of difficulties which may arise along the path to the solution to be followed, the risk that such difficulties make attaining the goal considerably more difficult, or the goal unattainable, as well as the time, cost and efforts of the work required to solve the problem must be taken into account.⁵⁶

Surprisingly simple solution

43. In Germany, the court held that the fact that, before the filing date or priority date, no skilled person had found the solution for producing a (known) mass article in a new, simpler and cheaper way, which was disclosed in the application, justified the assumption that an inventive step was involved, although there has long been a need for a solution.⁵⁷ Similarly, in accordance with the case law of the EPO, in a technical field of commercial importance to which considerable attention is directed, the simplicity of a proposed solution may indicate an inventive step. The difficulty of developing a simple solution without sacrificing quality may therefore indicate an inventive step.⁵⁸ This did however presuppose the absence in the prior art of anything that hinted at the proposed solution.

SELECTION INVENTIONS

General issues

44. In general, a selection invention may involve, for example, the selection of individual elements, sub-sets or sub-ranges, which are within the larger set or range in the prior art but have not been specifically disclosed in the prior art. The Examination Guidelines for the EPO states that “the subject matter of selection invention differs from the closest prior art in that it represents selected subsets or subranges”. Similarly, according to the Patent Examination Guidelines for the Korean Intellectual Property Office (KIPO), a selection invention is an invention involving selection of species from a genus disclosed in a prior art reference, including a selection of matter which is not directly disclosed in the prior art reference as an essential element.⁵⁹

⁵⁴ T 72/95 and T 939/92. See also the practices of Singapore and the United Kingdom and the section “selection inventions” in this document.

⁵⁵ *Tetra Molectric Ltd v Japan Imports Ltd* [1976] RPC 541, 581.

⁵⁶ BGH, X ZR 27/04 (2007) – *Stahlblech*, GRUR 2008, 145; (12) BGH, X ZR 141/10 (2013) – *PNGase F*, IBRRS 2014, 0612; (13) BGH, X ZR 148/11 (2016) – *Zöliakiediagnoseverfahren*, GRUR 2016, 1027.

⁵⁷ BGH, I ZR 156/54 (1957) – *Polstersessel*, GRUR 1957, 543.

⁵⁸ T 106/84, OJ 1985, 132; T 229/85, OJ 1987, 237; T 9/86, OJ 1988, 12; T 29/87, T 44/87, T 528/89, T 73/95.

⁵⁹ The Examination Guidelines for Patent and Utility Model in Japan states that “a selection invention is an invention that belongs to a technical field where an effect, which would be yielded by a structure of an article, is difficult to predict and fulfills the following items (i) or (ii): (i) an invention (b) which is selected from invention (a) expressed in a broader concept in publication, etc. and which is expressed in a narrower concept

45. Although more generically defined prior art may exist, selection inventions may be held patentable, based on the patentability analysis case-by-case. Generally speaking, this is because if all species within a known genus is held unpatentable, researchers might have less incentive to research into further improvement in the generally known technical area. Under certain circumstances, such as where a sub-set or sub-group of a known broader range has a surprising advantage that was not readily expected by the previously known broader range, patent protection of such sub-set or sub-range may be justified with a view to properly incentivize R&D that contributes to further technological advancement. In this regard, there needs to be a balance between encouraging innovation from a known area and avoiding patent protection for obvious and common-sense selections from the known area.

46. Selection inventions may be present in any technical field: there is no limitation found in terms of the technical field of inventions. However, in practice, it appears that the examples of selection inventions are primarily found in the field of chemistry and biotechnology. For example, a selection invention may involve a particular group of compounds having certain advantageous properties that are not possessed by the known wide class of compounds, or a selection of a particular range of numerical factor (such as temperature) that defines and limits the conditions applies to a known chemical process. It may also reside in a selection from the alternative compounds set forth in a Markush grouping. This may be due to the experimental and unpredictable nature of research outcomes in these technical fields, since whether the claimed invention is obvious or not is also considered in the context of, among other considerations, the degree of predictability of the claimed invention vis-à-vis the prior art by a person skilled in the art.⁶⁰

47. Since the assessment of inventive step in the chemical sector is one of the topics suggested in paragraph 8 of document SCP/24/3 (Proposal by the Delegation of Spain), descriptions regarding selection inventions in the chemistry sector, including examples in that field, will be provided in a separate document to be submitted to the SCP in a subsequent SCP session. This document therefore provides the general description regarding the assessment of inventive step relating to selection inventions.

Assessment of inventive step

48. The information collected from some jurisdictions seem to indicate that there are no special rules designed for the analysis of inventive step regarding selection inventions, i.e., the general principle of inventive step analysis in each jurisdiction applies. However, administrative guidelines and case law of some countries provide a guidance as to how to apply such general principle to selection inventions.

embraced within the broader concept, wherein novelty of the invention (b) it not denied by the invention (a) expressed in the broader concept of publications etc.; (ii) an invention (b) which is selected from invention (a) expressed by multiple choices.”

⁶⁰ See *Eisai Co. v. Dr. Reddy's labs, Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (“To the extent an art is unpredictable, as the chemical arts often are, KSR’s focus on these ‘identified, predictable solutions’ may present a difficult hurdle because potential solutions are less likely to be genuinely predictable”).

49. In some countries, in general, the following elements appear to be often considered in assessing the inventive step of selection inventions:

- (i) whether a special technical effect, characteristics or advantage is achieved by the selection invention, in comparison to the prior art;
- (ii) such special technical effect, characteristics or advantage is unexpected, or unpredictable from the prior art, by a person skilled in the art.

In some jurisdictions, it is also clarified that if the effect is of the same kind (or qualitatively same), the unexpected effect achieved by the selection invention should be in a quantitatively prominent degree or of technical significance.⁶¹

50. Against this backdrop, a mere arbitrary selection,⁶² a mere choice from alternatives,⁶³ a selection based on routine trial and error,⁶⁴ a selection applying usual technical design procedures by a person skilled in the art,⁶⁵ a selection based on mere extrapolation from prior art⁶⁶ are generally regarded as non-obvious selection among a number of known possibilities.

51. The determination as to what the prior art reference and the common general knowledge expressly or implicitly teach a person skilled in the art to select the claimed invention is important in the assessment of inventive step regarding selection inventions. Therefore, whether the prior art as a whole teaches a person skilled in the art toward the particular selection, or whether it teaches away from the selection, is a relevant factor in, for example, Australia. Similarly, if a claimed invention follows inevitably from developments in the prior art in such a way that a person skilled in the art would naturally be led to make the claimed selection (one-way street), it is not considered as involving inventive step.⁶⁷ Likewise, the size of the prior art class from which a selection was made may be relevant to the question of obviousness, according to the case law of the United Kingdom.

52. In countries where an unexpected technical effect, characteristics or advantage achieved by a selection invention is considered as an important factor to demonstrate its inventiveness, it is often stated that such effect, characteristics or advantage should be clearly identified, or otherwise made plausible, in the application at the time of filing date.⁶⁸ However, in general, evidence to provide support for justification of the unexpected technical effect, characteristics or advantage made plausible by the specification may be submitted by the applicant even after the filing date. Some of the secondary indicia described earlier in this document may be particularly relevant to selection inventions.

53. Moreover, it is generally considered that the unexpected effect or advantages achieved by the selection invention must apply to the entire range as claimed, and not to part of the claimed range alone.⁶⁹

⁶¹ See, for example, the practices of China, Japan, the Republic of Korea and the United Kingdom.

⁶² See, for example, the practices of Germany, UK and Singapore.

⁶³ See, for example, the practices of China, Germany and the EPO.

⁶⁴ See, for example, the practices of China and the EPO.

⁶⁵ *Ibid.*

⁶⁶ *Ibid.*

⁶⁷ See, for example, the practices of Singapore, United Kingdom and the EPO.

⁶⁸ See, for example, the practices of Singapore, the Republic of Korea and the United Kingdom.

⁶⁹ See, for example, the practices of Norway, Singapore, the Republic of Korea, the United Kingdom, the United States of America and the EPO. See also the Andean Patent Examination Manual and Patent Examination Manual for Central America and the Dominican Republic.

54. In the United States of America, obviousness of selection inventions is analyzed no different than other inventions, applying *Graham* factors. As far as selection inventions are concerned, the Manual of Patent Examination Procedures (MPEP) provides that examiners should make findings as to (i) the structure of the claimed invention and the prior art; (ii) physical or chemical properties and utilities disclosed in the prior art and any problems alleged to be addressed by the prior art genus; (iii) the predictability of the technology; and (iv) the number of species encompassed by the genus.

55. Furthermore, while examiners should consider all relevant prior art teachings, the MPEP guides the examiners to consider the following non-exhaustive aspects, when present: (i) the size of the prior art genus; (ii) whether the prior art reference expressly teaches a particular reason to select the claimed species or subgenus or teaches away from the claimed species or subgenus; (iii) the teachings of structural similarity and differences (any teachings of a “typical,” “preferred,” or “optimum” species or subgenus within the disclosed genus); (iv) the properties and utilities of the structurally similar prior art species or subgenus; and (v) the predictability of the technology.

56. Following the general principle, the ultimate determination of patentability of selection invention in the United States of America is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence.⁷⁰ The evidence may be included in the specification as filed, accompanying the application on filing, or by provided in affidavits or declarations in the timely manner at some other point during the prosecution. As to selection inventions, such evidence may be that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. It may also include the criticality of the selection made from genus.

57. The following paragraphs provide the practices of some countries.

Australia⁷¹

58. In *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd (1980) 144 CLR 253 at 293*, it was said that “In the case of a combination patent the invention will lie in the selection of integers, a process which will necessarily involve rejection of other possible integers. The prior existence of publications revealing those integers, as separate items, and other possible integers does not of itself make an alleged invention obvious. It is the selection of the integers out of, perhaps many possibilities, which must be shown to be obvious.” Where a solution is one of several alternatives, and there is not special inducement or reason for claiming that solution, and there is a surprising or unexpected advantage, then the solution is not obvious, as the skilled addressee would not be “directly led to the invention”.⁷²

59. Conversely, where the person skilled in the art would have adopted the particular solution, or chosen the particular selection, on the basis of a special inducement, and there is no practical difficulty in implementing the particular solution, or in producing the selection claimed, the claim lacks an inventive step. This is because the claimed solution is said to be “lying in the way ... [of] the ordinary route”.⁷³ A special inducement occurs where the prior art teaches towards the solution, when the common general knowledge teaches towards the solution, or teaches away from the other solutions; or when the other solutions are impractical. It is not necessary to show that success is certain or ‘clearly predictable’.

⁷⁰ MPEP, 2142.

⁷¹ See the submission by Australia for SCP/28.

⁷² *Aktiebolaget Hassle v Alphapharm Pty Ltd [2002] HCA 59; (2002) 212 CLR 411.*

⁷³ *Elconnex Pty Ltd v Gerard Industries Pty Ltd 105 ALR 247 at 262.*

China⁷⁴

60. In determining the inventive step of a selection invention, the main factor to be considered is whether the selection can bring about unexpected technical effect. Conversely, selection inventions do not involve an inventive step in the following cases:

- (i) the invention consists merely in choosing among a number of known possibilities, or merely in choosing from a number of equally likely alternatives, and the selected solution does not produce any unexpected effect;
- (ii) the invention resides in the choice of particular dimensions, temperature ranges, or other parameters from a limited range of possibilities, while such choice can be made by the person skilled in the art through normal design procedures and does not produce any unexpected technical effect;
- (iii) the invention can be arrived at merely by a simple extrapolation in a straightforward way from the known art.

Germany⁷⁵

61. An inventive step of the selection may be that a specifically selected range has valuable characteristics in comparison to the known range, e.g., has a previously unknown or superior effect which the skilled person would not have expected. On the other hand, an arbitrary choice made at will cannot as a rule substantiate an inventive step,⁷⁶ which applies both to the selection from a larger range and to the selection of one of several alternatives.⁷⁷ Further, the generalizing indication of a range of values cannot be regarded as inventive, if the selection of individual values from the uniformly claimed range were obvious to the skilled person through prior art.⁷⁸ Moreover, the selection of one of several alternatives to the solution of the technical problem, which the skilled person can recognize having regard to the state of the art, cannot be regarded as being based on an inventive step merely because, from the point of view of the average skilled person, other solutions appear more suitable or advantageous.⁷⁹

62. For the question of obviousness of alternative solutions, the secondary criterion of an “appropriate expectation of success” can be used.⁸⁰

Japan⁸¹

63. When effects of a selection invention fulfill all of the following items (i) to (iii), the examiner determines that the selection invention involves an inventive step:

- (i) the effect of the selection invention is an advantageous effect which is not stated in prior art documents, etc.;
- (ii) the selection invention yields an effect which is different from, or identical but prominently superior to an effect yielded by an invention expressed in a broader concept or multiple choices;

⁷⁴ Guidelines on Examination of Patents, Part II, Chapter 4, 4.3.

⁷⁵ See the submission by Germany for SCP/28.

⁷⁶ *BGH, X ZR 56/03 (2007) – Injizierbarer Mikroschaum, GRUR 2008, 56.*

⁷⁷ *BGH, X ZR 7/00 (2003) – Blasenfreie Gummibahn I, GRUR 2004, 47.*

⁷⁸ *BGH, X ZR 100/10 (2013) – Laser-Feinabtastung, IBRRS 2014, 0122.*

⁷⁹ *BGH, X ZR 49/94 (1996) – Rauchgasklappe, GRUR 1996, 857.*

⁸⁰ *BGH X, ZR 50/09 (2012) – Ebastin, IBRRS 2012, 1491; BGH, X ZR 98/09 (2012) – Calcipotriol-Monohydrat, GRUR 2012, 803.*

⁸¹ Examination Guidelines for Patent and Utility model in Japan, Part II, Chapter II, Section 4, 7.2.

- (iii) the effect of the selection invention cannot be predicted by a person skilled in the art from the state of the art.

Example: Compounds expressed by a certain general formula have been known to have insecticidal property. A claimed invention is included in the general formula. However, the claimed invention is based on a finding that a certain specific compound, which is not specifically well-known about its insecticidal property, is remarkably less poisonous to human beings than the other compounds expressed by the general formula, and is conceived by selecting the specific compound as an active ingredient of an insecticide. There is no evidence from which the compound is predictable. In this case, the claimed invention involves an inventive step as a selection invention.

64. Similarly, where the difference between the claimed invention and the prior art may reside in the limitation of numerical range, the invention may involve an inventive step if: (i) the effect of the claimed invention, which is not disclosed in the prior art, is advantageous within a limited range of numerical values; (ii) the effect of the claimed invention is different in nature from the effect yielded by the prior art, or remarkably superior although it is the same as the effect of the prior art; and (iii) the effect is not one which can be predicted by a person skilled in the art from the state of the art as of filing. An advantageous effect is a prominent one, if it exists in an overall range of the numerical value.

65. In addition, where a difference between the claimed invention and the primary cited prior art lies only in the presence or absence of a numerical limitation and where a common problem exists, a remarkable quantitative difference of the effect must exist outside and inside the boundary of the numerical limitations in order to demonstrate a distinctive advantageous effect as critical significance of the numerical limitation. However, even if a difference between the claimed invention and the primary cited prior art lies only in presence or absence of a numerical limitation, where a problem is not common and an advantageous effect is different in nature, it is not required that the numerical limitation has the critical significance.

Republic of Korea⁸²

66. Selection of an optimized means through experimentation from publicly known technology is not considered involving inventive step, because selecting the best or suitable means from publicly known technology comes within the scope of an exercise of ordinary creativity of a person skilled in the art. However, if a selection invention achieves advantageous effect in comparison with a prior art reference, the inventive step of the selection invention can be acknowledged. In that case, all specific means included in the selection invention should have advantageous effects qualitatively different or qualitatively the same but quantitatively prominent.

67. The description of the selection invention should precisely explain that the invention achieves an advantageous effect in comparison with the prior art reference, and needs not provide experimental materials to confirm the prominence of the effect. Nevertheless, regarding selection inventions in the pharmaceutical field, at least, its pharmacological effect should be stated as clearly as possible for skilled person in the art to recognize it as the effect of a selection invention.

68. If the invention is rejected because of the effect is doubted, the applicant can assert the effect concretely by submitting materials relating to experimental comparisons.

⁸² KIPO Patent Examination Guidelines, 6.4.1.

Republic of Moldova⁸³

69. In relation to selection inventions, an invention shall be considered as involving an inventive step if it: (i) represents a selection in a process of particular technical parameters covered within a known range, producing unexpected effects in the operation of the process or the properties of the resulting product; or (ii) represents a selection from a very large group of compounds having unexpected advantages. Conversely, a selection invention shall not be considered as involving an inventive step if: (i) it can be arrived at a problem in the field of chemistry or biology consisting in a selection of a particular case from amongst a plurality of previously protected components, provided that such selected case would not lead to special qualities or results in comparison with those of the plurality of components from which it was selected; or (ii) the solution of the problem relates to the selection of a corresponding known material and/or to the making of certain constructive changes according to rules known by itself.

Spain⁸⁴

70. Non-obvious selection or choice from a range of known possibilities (such as within particular operating conditions (e.g. temperature and pressure) or within a known scale) may involve an inventive step, if such selection has unexpected effects on the performance of the process or on the properties of the resulting product. In ECLI: ES:APM:2013:4725, the court ruled that what is expected of the selection patent is that it should yield a real substantive change, or a different effect.⁸⁵

United Kingdom⁸⁶ and Singapore⁸⁷

71. According to the practice in the United Kingdom, if it is clear from the prior art that taking a step from the prior art is likely to lead to success, there may be an invention if that is only one of many courses possible, and there is no reason to infer from the prior art that this one is more likely than the others to be profitable. In *Bayer AG (Batz's) European Application [1982] RPC 321*, carbonless copying paper was characterized by microcapsules made of a particular polymer, which was already known for forming coatings on textiles, leather, wool and metal. Even if these were thought to be neighboring fields, there was no reason to expect that improved results would be obtained by the use of this material (as the results of comparative experiments showed they were), and thus it was not obvious to select it from the enormous number possible.

72. When faced with claims that may relate to a selection invention, the *prima facie* inventive step objection should be raised using the Windsurfing/Pozzoli approach, unless the selection is so clear-cut as to make this unnecessary. If the inventiveness may lie in a selection invention, the question to be asked is whether the invention makes a hitherto unknown technical contribution or is merely an arbitrary selection.⁸⁸ If it is merely an arbitrary selection, then the invention is obvious.

73. In *Generics [UK] LTD (t/a Mylan) v Yeda Research and Development co. LTD & Anor [2013] EWCA Civ 925*, the Court of Appeal came to the position that a selection from the prior art which is purely arbitrary and cannot be justified by some useful technical property is likely to

⁸³ See the submission by the Republic of Moldova for SCP/28.

⁸⁴ See the submission by Spain for SCP/28.

⁸⁵ ECLI: ES:APM:2013:4725: Provincial Court of Madrid, Section 28. Ruling No. 71/2013, Date of Ruling: 04/03/2013, Appeal No. 708/2012.

⁸⁶ Manual of Patent Practice, 3.88, 3.89, 3.91, 3.91.1, 3.92 and 3.93.

⁸⁷ Examination Guidelines for Patent Applications at IPOS, 4.83, 4.85 and 4.88,

⁸⁸ Approach used by the Court of Appeal in *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd [2010] RPC 9*.

be held to be obvious, because it does not make a real technical advance. Furthermore, it states that a technical effect which is not rendered plausible by the patent specification may not be taken into account in assessing inventive step. The Court also noted that if the alleged contribution is a technical effect which is not common to substantially everything covered by a claim, it cannot be used for the purposes of judging obviousness. In such circumstances, the claim must either be restricted to the subject matter which makes the technical contribution, or a different contribution common to the whole claim must be found.

74. Although the size of the class from which a member or members have been chosen is not relevant to the question of novelty of a selection invention, it may be relevant to the question of obviousness (*Du Pont de Nemours & c (Witsiepe's) Application*, [1982] FSR 303 at page 310). In addition, the technical significance of the parameters by which the product or process is selected should be considered.

75. The unknown technical effect (i.e. advantage gained or disadvantage avoided) relied upon to justify a selection invention should be clearly identified or otherwise made plausible (e.g. discernible from tests provided in the application), in the specification at the time of filing. Later-filed evidence may be used to provide support for the presence of such an effect or the fact that it is common to everything claimed, but unexpected bonus effects not described in the specification cannot form the basis of a valid claim to a selection invention.⁸⁹ If there is no statement of advantage in the specification at the time of filing, it may not be added later, since in the context of synergy, whether or not the advantage was demonstrated "by experiments conducted after the date of the patent cannot help show obviousness or non-obviousness ... and it would be quite wrong for later-acquired knowledge to be used to justify the amended claim."⁹⁰

76. However, the later evidence that shows the non-existence of technical property or effect that was relied upon in the specification as filed is admissible, because such evidence is simply defining what the invention is, and is not determining existence or lack of inventive step.⁹¹

77. Similar to the UK practice, in Singapore, if the invention is one of many possible alternatives, and there is no indication in the prior art that any particular alternative is more advantageous than another then the invention may be considered non-obvious. In order to be considered non-obvious, (i) the selection must not be arbitrary but must be justified by a hitherto unknown technical effect; and (ii) a technical effect which justifies the selection of the claimed group must be one which can be fairly assumed to be produced by substantially all the selected members.

78. The administrative guidelines of Singapore states that regarding selection inventions, the technical effect can only be taken into account if it can be accepted as having been indicated in the specification as filed. Later-filed evidence may be used to provide support for justification of unknown technical effect or of the application of unexpected technical effect to the entire range as claimed. However, unexpected bonus effects not described in the specification cannot form the basis of a valid claim to a selection invention.

United States of America⁹²

79. The patentability of a claim to a specific compound, species, or subgenus embraced by a prior art genus should be analyzed no differently than any other claim for purposes of 35 U.S.C. 103 (non-obviousness requirement), which should be analyzed upon the facts of the

⁸⁹ See *Glaxo Group Ltd's Patent [2004] RPC 43*.

⁹⁰ Stated by Jacob J. in *Richardson-Vicks Inc.'s Patent [1995] RPC 568 at 581*.

⁹¹ *Generics [UK] LTD (t/a Mylan) v Yeda Research and Development co. LTD & Anor [2013] EWCA Civ 925*.

⁹² MPEP, 2144.05 and 2144.08

particular case in view of the totality of the circumstances. The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness.

80. According to MPEP, a proper obviousness analysis involves a three-step process. First, examiners should establish a *prima facie* case of unpatentability considering the *Graham* factors. In the case of a prior art reference disclosing a genus, examiners should make findings as to: (i) the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus; (ii) any physical or chemical properties and utilities disclosed for the genus, as well as any suggested limitations on the usefulness of the genus, and any problems alleged to be addressed by the genus; (iii) the predictability of the technology; and (iv) the number of species encompassed by the genus taking into consideration all of the variables possible.

81. Once the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus are identified, examiners should compare it to the claimed species or subgenus to determine the differences. He/she should determine whether it would have been obvious to one of ordinary skill in the relevant art to make the claimed invention as a whole, i.e., to select the claimed species or subgenus from the disclosed prior art genus. Examiners should consider all relevant prior art teachings, including the following non-exhaustive aspects, where present:

- the size of the prior art genus;
- whether the prior art reference expressly teaches a particular reason to select the claimed species or subgenus or teaches away from the claimed species or subgenus;
- the teachings of structural similarity and differences (any teachings of a “typical,” “preferred,” or “optimum” species or subgenus within the disclosed genus);
- the properties and utilities of the structurally similar prior art species or subgenus;
- the predictability of the technology.

One of those aspects alone cannot support an obviousness rejection.

82. With respect to numerical ranges, in the case where the claimed ranges overlap or lie inside ranges disclosed by the prior art, a *prima facie* case of obviousness exists. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating such concentration or temperature is critical. For example, the court states that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”⁹³ However, applicants can rebut a *prima facie* case of obviousness by showing the criticality of the range or by showing that the prior art, in any material respect, teaches away from the claimed invention.

83. As to rebuttal evidence, the general rules also apply to selection inventions.⁹⁴ If a *prima facie* case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the *prima facie* case. When timely presented,

⁹³ *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

⁹⁴ See, in particular, MPEP 716.01 and 2145.

affidavits or declarations containing evidence, including evidence of “secondary considerations”, as described above, may be taken into account. Thus, with respect to selection invention, the rebuttal evidence may include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. It may also include the criticality of the selected range.

84. The evidence may be included in the specification as filed, accompanying the application on filing, or by provided in the timely manner at some other point during the prosecution. The weight to be given to any objective evidence is made on a case-by-case basis.⁹⁵ The legal standard of “a preponderance of evidence” requires the evidence to be more convincing than the evidence which is offered in opposition to it. The objective evidence of non-obviousness must be commensurate in scope with the claimed invention which the evidence is offered to support.⁹⁶ For example, the showing of unexpected results must be reviewed to see if such results occur over the entire claimed range.

Andean Community, Central America and the Dominican Republic⁹⁷

85. In case of selection inventions, for example, a sub-group of compounds selected from the more general and broader scope of compounds previously disclosed, inventive step is present if all the compounds in the subgroup have a technical effect or property not described in the prior art, which are also unexpected. In that case, all selected members of the subgroup of compounds should exhibit such unexpected technical effect or property. Office personnel should make explicit findings on the similarities and differences between the closest prior art and the claimed species or subgenus, including findings relating to similarity of structure, properties and utilities.

European Patent Office⁹⁸

86. If a claimed invention represents selected sub-sets or sub-ranges of the closest prior art and such selection is connected to a particular technical effect, and if no hints exist leading the skilled person to that selection, then an inventive step is accepted. The technical effect occurring within the selected range may also be the same effect as attained with the broader known range, but it should be to an unexpected degree. For inventive step, it has to be considered whether the skilled person would have made the selection or would have chosen the overlapping range in the hope of solving the underlying technical problem or in expectation of some improvement or advantage. If the answer is negative, then the claimed matter involves an inventive step.

87. The unexpected technical effect must apply to the entire range as claimed. If it occurs in only part of the claimed range, the claimed subject-matter does not solve the specific problem to which the effect relates.

⁹⁵ MPEP, 2041.

⁹⁶ MPEP, 716.02(d).

⁹⁷ The Andean Patent Examination Manual and Patent Examination Manual for Central America and the Dominican Republic.

⁹⁸ Examination Guidelines for the EPO, Part G, Chapter VII, 12. See also the Guidelines for Examination at ARIPO, Section 3.7.15 and the submission of Norway to SCP/28.

88. The Examination Guidelines for the EPO provides the following examples as obvious and non-inventive selection among a number of known possibilities:

- (i) The invention consists merely in choosing from a number of equally likely alternatives;
- (ii) The invention resides in the choice of particular dimensions, temperature ranges or other parameters from a limited range of possibilities, and it is clear that these parameters could be arrived at by routine trial and error or by the application of normal design procedures;
- (iii) The invention can be arrived at merely by a simple extrapolation in a straightforward way from the known art;
- (iv) The invention consists merely in selecting particular chemical compounds or compositions (including alloys) from a broad field;
- (v) The invention follows inevitably from developments in the prior art, in such a way that there was no choice between several possibilities (the “one-way street” situation).

PROBLEM INVENTION

89. The concept of the “problem inventions” appears to be prevalent in the jurisdictions where the identification of the problem constitutes one of the steps in the analysis of inventive step.⁹⁹ The concept relates to the situations where the technical contribution of the invention lies in the identification of a problem, the solution being obvious once the problem is identified but not being obvious from the prior art alone.

90. With regard to such inventions, the body of case law has been developed by the EPO. In T 2/83, the Board of Appeal stated that “the discovery of an unrecognized problem may in certain circumstances give rise to patentable subject-matter in spite of the fact that the claimed solution is retrospectively trivial and in itself obvious”.¹⁰⁰ According to the Board, the question regarding the inventive step was not whether the skilled man could have made such modification but whether he would have done so in expectation of some improvement or advantage. The outcome of the modification was not predictable and the claimed modification involved an inventive step on that basis. It also concluded that those considerations were conditional on the fact that the deficiency of the prior art product was not in the state of the art at the priority date of the application.¹⁰¹

91. In a more recent decision, the Board confirmed that the formulation of a hitherto unrecognized problem may in certain circumstances give rise to a patentable subject matter.¹⁰²

⁹⁹ For example, one of the essential steps in the problem-solution approach is establishing the “objective technical problem” to be solved by the invention. See document SCP/22/3.

¹⁰⁰ T 2/83, OJ 1984, 265; See also T 225/84, EPO Case Law of the Boards of Appeal, Part I, Chapter D, 9.10.

¹⁰¹ T 2/83, paragraph 8.

¹⁰² T 1641/009, 22 July 2014. In this case, the Board also stated: “Since the identification of the problem is not obvious, the solution to the problem cannot be obvious either, even if it retrospectively appears to be trivial in view of the identified problem”. para 3.2.6 and 3.2.7.

92. In other cases relating to the problem inventions, the Boards of Appeal clarified that:

- The posing of a new problem did not represent a contribution to the inventive merits of the solution if it could have been posed by the average person skilled in the art.¹⁰³
- It has to be taken into consideration that it is the normal task of the skilled person to be constantly occupied with the elimination of deficiencies, the overcoming of drawbacks and the achievement of improvements of known devices and/or products.¹⁰⁴
- To address a problem simply by looking for ways of overcoming difficulties arising in the course of routine work did not constitute inventiveness.^{105, 106}

93. In addition, in another case, the Board emphasized that the appreciation of conventional technical problems which formed the basis of the normal activities of the notional person skilled in the art, such as the removal of shortcomings, the optimization of parameters or the saving of energy or time, could not involve an inventive step.¹⁰⁷ The appreciation of a technical problem could thus only contribute to the inventive step in very exceptional circumstances. However, if an applicant nevertheless wished to rely on an assertion that the inventive activity resided in the recognition of a technical problem to which the solution was admittedly obvious, then the minimum requirement to be met was that this technical problem be clearly and unambiguously disclosed in the application as filed.¹⁰⁸

94. In Australia, the inventive step can arise where: the problem was known, the cause of the problem was unknown at the priority date, and the inventor has identified the cause of problem, i.e., the “real nature” of the problem.¹⁰⁹ According to *Wellcome Foundation Pty Ltd v VR Laboratories*,¹¹⁰ “the perception of the true nature of the problem was the inventive step which, once taken, revealed that straightforward experiments will provide the solution”. Thus, if an inventive step lies in the identification of the true nature of the problem, it is irrelevant whether there is any subsequent inventive step in providing a solution to the problem.¹¹¹ In *Winner & Anor v Ammar Holdings Pty Ltd*, it was held that where the invention lies in identifying the true nature of the problem, that must be clear from the specification.¹¹² The court also held that if the nature of the problem would be obvious to the skilled addressee, then an inventive step cannot lie in the discovery of the problem.¹¹³ Furthermore, if the prior art discusses the nature of the problem, then no inventiveness can lie in the alleged discovery of the problem.¹¹⁴

¹⁰³ T 109/82, OJ 1984, 473.

¹⁰⁴ T 15/81, OJ 1982, 2; T 195/84, OJ 1986, 121.

¹⁰⁵ T 532/88.

¹⁰⁶ Following this case law, the Boards held in T 630/92, T 798/92, T 578/92, T 610/95, T 805/97 and T 1417/05 that the posing of the problem could not confer any inventive merit on the claimed subject-matter. Inventive step was however acknowledged in T 135/94, T 540/93 (pet doors) and T 1236/03 on the ground (also) that the posing of the problem was not obvious. See EPO Case Law of the Boards of Appeal, Part I, Chapter D, 9.10.

¹⁰⁷ T 971/92.

¹⁰⁸ T 43/97, T 1417/05.

¹⁰⁹ Section 2.5.3.6 ‘Invention in Identifying the ‘Real Nature’ of the Problem’, The Manual of Practice of Procedure.

¹¹⁰ *Wellcome Foundation Pty Ltd v VR Laboratories (Aust) Pty Ltd (1981) 148 CLR 262 at 281 (Aickin J)*.

¹¹¹ Section 2.5.3.6 ‘Invention in Identifying the ‘Real Nature’ of the Problem’, The Manual of Practice of Procedure.

¹¹² *Winner & Anor v Ammar Holdings Pty Ltd* 24 IPR 137 at 141.

¹¹³ *Ibid*, IPR 273 at 295.

¹¹⁴ Section 2.5.3.6 ‘Invention in Identifying the ‘Real Nature’ of the Problem’, The Manual of Practice of Procedure.

95. In the United Kingdom, the UKIPO Manual of Patent Practice states that “[...] if a newly arisen problem is solved by the use of available resources in an obvious way, then there is no inventive step (unless the inventor has been the first to identify the problem). But if the inventor has solved a long-recognized problem by means which others could have used but did not, then there may be an inventive step.”¹¹⁵

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¹¹⁵ *Minnesota Mining and Manufacturing Co v Rennicks* (UK) Ltd [1992] RPC 331, cited in Section 3.47 of the UKIPO Manual of Patent Practice.