

INVENTIVE STEP CRITERION FOR PATENTING

SUBMISSION TO WIPO STANDING COMMITTEE ON PATENTS

Prepared by the ICC Commission on Intellectual Property

Summary and highlights

- Definitions of inventive step or non-obviousness
- Principles for assessment of inventive step
- Evaluation of inventive step should not depend on level of invention or field of invention
- Case studies

Inventive Step Criterion for Patenting

With its broad membership including not only intellectual property rights holders but also third parties affected by others' intellectual property rights, ICC understands, and has always supported, the need for a proper balance among different interests. In the field of patents, for example, the system should allow those who innovate and invent to obtain and enforce rights protecting their inventions, but should also ensure that society as a whole benefits, for example from disclosure of inventions and the dissemination of knowledge. In other words, the interests of third parties must be balanced against rights provided to inventors. In the view of ICC, maintaining this balance is necessary for the continued successful operation, and general acceptance, of intellectual property protection systems.

The criteria for patentability are clear. Patents are available for any invention - whether product or process - in any field of technology, provided it is new, involves an inventive step and is capable of industrial application. Only if an innovation meets these criteria, is it entitled to patent protection.

The issue under study in the WIPO Standing Committee on Patents is the criterion of "inventive step", or "non-obviousness"¹. To fulfill this criterion, the invention must not have been obvious to a person skilled in the relevant field of the art at the relevant date of the application, taking into account the state of the art available before that date.

However, there is no common definition or understanding around the world on how this criterion should be applied and TRIPS provides no guidance. The precise manner in which it is applied – for example, with respect to the definition of the person skilled in the art – differs from country to country. It even differs over time within the same country.

For example, in the jurisdictions of the so-called IP5 Offices (EPO, JPO, KIPO, SIPO, USPTO), which account for the vast majority of patents in force in the recent past (see e.g. IP5 Statistics Report 2013²), different definitions exist with respect to the patentability criterion of inventive step.

Definitions of inventive step in the EPC, Japan, Korea, the US and China

The European Patent Convention (EPC) states that: "... *An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art...*" (see Art. 56 EPC).

According to the Japanese Patent Act, where, "... *prior to the filing of the patent application, a person ordinarily skilled in the art of the invention would have been able to easily make the invention... a patent shall not be granted...*" (see Art. 29 (2) Patent Act of Japan).

A nearly identical provision exists under the Republic of Korea Patent Act : "... *where an invention could easily be made prior to the filing of the patent application by a person having ordinary skill in the art to which the invention pertains... no patent shall be granted...*" Article 29 (2) Patent Act of the Republic of Korea.

US current First Inventor to File provisions provide that a: "... *patent... may not be obtained, ... if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains...*" (35 U.S. Code § 103).

¹ The term varies according to jurisdiction. The term "inventive step" is used in the European Patent Convention whereas the term "non-obviousness" is predominantly used in United States patent law.

² Available at: www.fiveipoffices.org/statistics/statisticsreports/2013edition.html

China's Patent Law states: Inventions "... for which patent rights are to be granted shall be ones which are novel, creative and of practical use... Creativity means that, compared with the existing technologies, the invention possesses prominent substantive features and indicates remarkable advancements..." (Art. 22 Patent Law of the People's Republic of China).

While this definition of what involves an inventive step is different from the one of the other four IP5 offices, the current Guidelines for Patent Examination of the State Intellectual Property Office (SIPO) of 2010 (SIPO Guidelines) provide guidance in this respect. According to these guidelines, "... an invention has prominent substantive features means that, having regard to the prior art, it is non-obvious to a person skilled in the art. If the person skilled in the art can obtain the invention just by logical analysis, inference, or limited experimentation on the basis of the prior art, the invention is obvious and therefore has no prominent substantive feature..." (see SIPO Guidelines, Part II, Chapter 4, item 2.2.). Furthermore, "... an invention represents notable progress means that the invention can produce advantageous technical effect as compared with the prior art. For instance, the invention has overcome the defects and deficiencies in the existing technology, or has provided a different technical solution to solve a certain technical problem, or represents a certain new trend of technical development..." (see SIPO Guidelines, Part II, Chapter 4, item 2.3.).

Ultimately, the provisions in all the IP5 jurisdictions explicitly require assessment of inventive step on the following bases, that is:

- a) the prior art³ publicly available before the relevant date of the patent application in the technical field(s) to which the invention pertains, and
- b) the ordinary skills of one skilled in the specific field(s) of the art.

As far as these ordinary skills in the art are concerned, the respective guidelines for patent examination of the IP5 Offices also provide reasonable guidance.

Guidelines for patent examination of the IP5 Offices

According to the Guidelines for Examination of the European Patent Office (EPO Guidelines), the "... term "obvious" means that which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art..." (EPO Guidelines, G, VII, 4.). The person skilled in the art "... should be presumed to be a skilled practitioner in the relevant field of technology, who is possessed of average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date... He should also be presumed to have had access to everything in the "state of the art"... and to have had at his disposal the means and capacity for routine work and experimentation which are normal for the field of technology in question..." (EPO Guidelines, G, VII, 3.).

Similarly, the SIPO Guidelines state: "... Whether or not an invention involves an inventive step shall be evaluated on the basis of the knowledge and capability of the person skilled in the art. The person skilled in the art refers to a fictional "person" who is presumed to be aware of all the common technical knowledge and have access to all the technologies existing before the filing date or the priority date in the technical field to which the invention pertains, and have capacity to apply all the routine experimental means before that date. However, he is not presumed to have creativity. If the technical problem to be solved impels that person to seek technical means in other technical field, he should also be presumed to have access to the relevant prior art, common technical knowledge, and routine experimental means in the other technical field before the filing date or the priority date. The purpose of establishing such a concept is to unify the

³ There is a lack of a common understanding in these offices of what constitutes prior art illustrated by, for example, the divergences regarding the scope and effects of a grace period and the treatment of conflicting applications. However, a detailed analysis of these issues is outside the scope of the present paper.

standard of examination and to avoid subjectivity as far as possible..." (see SIPO Guidelines, Part II, Chapter 4, item 2.4.).

Similar considerations are made in the Manual of Patent Examination Procedure (MPEP) of the U.S. Patent and Trademark Office (USPTO): "... *Any obviousness rejection should include... an indication of the level of ordinary skill... The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (1) "type of problems encountered in the art;" (2) "prior art solutions to those problems;" (3) "rapidity with which innovations are made;" (4) "sophistication of the technology; and" (5) "educational level of active workers in the field"...*" (see MPEP, Chapter 2141, II, C)

Similarly, according to the Korean Patent Examination Guidelines (KIPO Guidelines), a "... *person skilled in the art to which the invention pertains... refers to a hypothetical person who has common general knowledge in the art to which the claimed invention pertains and the ability to use ordinary technical means for research and development (including experiment, analysis, and manufacture); who has the ability to exercise ordinary creativity in selecting materials and changing designs; and who is able to comprehend based on his/her own knowledge all technical matters regarding the state of the art in the field to which a claimed invention pertains at the time of filing a patent application. In addition, an expert in the technical field is one able to comprehend based on his/her own knowledge all technical matters in the technological field relevant to a problem to be solved by the claimed invention...*" (see KIPO Guidelines, Part III, Chapter 3, Section 3.2). A very similar definition is given in the Japanese Guidelines for Patent Examination (see JPO Guidelines, Chapter 2, Section 2.2 (2)).

It can be seen from these guidelines that all IP5 offices apparently base the decision on inventive step on the knowledge of a fictional person skilled in the art who is presumed to

- a) be aware of all information that was available to the public in the technical field(s) of the invention on the day before the relevant date of the patent application, and
- b) have the capacity to apply all the routine means in the technical field(s) of the invention on that specific day.

ICC welcomes this general convergence in the principles applied by the IP5 offices and agrees with these. ICC further notes the following:

- a) Inventive step should be established based on the relevant prior art, namely the information that was available to the public in the technical field(s) of the invention on the day before the relevant date of the patent application.
- b) Neither the legal requirements for inventive step nor any other basic criteria make any distinction between different levels of invention – for example between "incremental" and "radical" or "breakthrough" inventions. Hence, any claim should be judged against the same basic principle, namely the question: what would one ordinarily skilled in the specific field have done on the relevant day? With such an approach, improper assessment in hindsight can be avoided. In any case, assessment should not depend on subjective determinations of whether an invention is "radical", "incremental" or otherwise.
- c) While ordinary skill clearly depends on the specific field of technology, the principles of evaluation of inventive step should not depend on the subject matter, *i.e.* the same basic rules should be applied irrespective of the field of the invention.

To the extent that genuine concerns about patent quality exist, they relate to the whole range of technology. If a claim fails to meet the fundamental criteria set out above, a patent should not be granted. Where a patent has wrongly been granted, offices and courts should continue correcting

those errors; all as part of international efforts to ensure that an appropriate balance is achieved between all entities affected by patents.

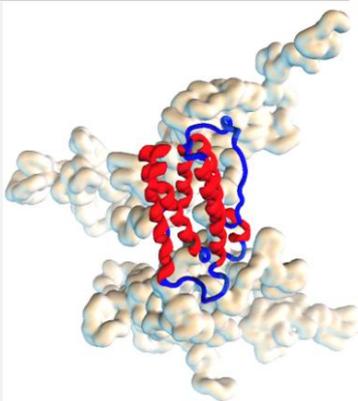
- d) The use of criteria extraneous to the above basic rules for the determination of inventive step creates uncertainty and lack of predictability both at the national and the international level, especially when patent applications are filed in several jurisdictions.

The case studies below illustrate the socio-economic importance of inventions which, in hindsight, only represent incremental technological advances.

Better treatment of hepatitis C through incremental but patentable innovation

In the pharmaceutical sector, the majority of progress occurs through incremental innovations. These have a range of significant benefits, especially higher therapeutic efficiency, including through improved dosing options. Dosing options play a crucial role for biotherapeutic medicines such as interferon alpha (IFN α), the active ingredient in most hepatitis C drugs. Worldwide, some 150 million people are chronically infected with the hepatitis C virus, of which more than 350,000 are estimated to die from related liver diseases each year. While IFN α became the treatment of choice, its molecular structure poses two important challenges in terms of positive response rates. First, the substance is rapidly absorbed, metabolized and cleared via the kidney. Second, IFN α is widely distributed throughout the body, preventing concentration of the drug at the desired target site of the liver. As a result, the IFN α achieves only a low cure rate of some 40 per cent, requiring at the same time a high dosing frequency of 3-7 times weekly. To address these shortcomings, researchers modified the molecule of IFN α by attaching a polyethylene glycol chain through a process termed “pegylation”. In 2001, Roche, the Swiss pharmaceutical company, launched PEGASYS®, a form of pegylated interferon, which was patented in more than 80 countries, incl. US, JP, Member States of the EPC, China and Brazil, despite prior art already disclosing pegylated interferons by providing a specific branch-type pegylation resulting in unexpected and superior pharmacokinetic properties. It is absorbed at a sustained rate and, displays a much slower rate of renal clearance, thereby assuring adequate drug serum concentrations and hence sufficient antiviral activity for considerably longer periods of time. In addition, it shows a restricted distribution in the blood with increased concentration in the liver. As a consequence, PEGASYS® permits a markedly less complex dosing regimen of once a week, while obtaining an improved efficacy rate of some 56 per cent. The modified molecule has led to substantial improvements across a broad range of patient populations, in particular difficult-to-treat patients such as those with cirrhosis or HIV.

Figure 1: High-resolution image of PEGASYS® *Source: IFPMA (2013)*



Source: IFPMA (2013) Incremental innovation. Adapting to patient needs. Geneva.

Overcoming obviousness rejections to obtain small wind turbine patent

Global climate change, one of the world's largest challenges, requires the development of a wide variety of new technologies. However, environmentally sound technologies often involve the combination of pre-existing technologies, *i.e.*, of more than one piece of prior art. This can pose difficulties in meeting the inventive step or non-obviousness requirement. Therefore patent claims need to capture the integration of several technologies in order to avoid obviousness rejection, as the following example illustrates.

Renewable Devices Swift Turbines Ltd. (Swift), a Scottish energy products and solutions company, developed a wind turbine that considerably reduces the operating noise, which has been the major obstacle to the adoption of turbines in densely populated areas. The Swift's turbine design addresses the problem in a number of ways (Figure 2).

First, the wind turbine comprises a circular diffuser (21) that rings the turbine blades. Thus, when it reaches the ends of the blades, the airflow contacts the diffuser and proceeds in a circumferential path instead of flowing off the ends of blades. Second, the turbine contains a furling device (50) with tailfins (53, 54). When the airflow exceeds a certain speed, the furling device rotates the rotor to maintain the direction of the airflow in line with the turbine's rotational axis. Moreover, in excessively high winds, the turbine rotor can be rotated out of the airflow altogether, thereby minimizing the vibrations of the turbine assembly components. Third, the Swift turbine comprises a mounting structure that includes a rubber core to absorb vibrations before they spread upward to the moving parts of the turbine assembly.

The US Patent & Trademark Office considered Swift's patent claim as a combination of known elements, rejecting it as obvious over two prior art patents, one of which disclosed a rotor, blades and a diffuser and another that taught an aerofoil diffuser. According to the patent examiner, it would have been obvious to combine the aerofoil diffuser with the rotor blades and diffuser to obtain a reduced noise level.

Swift successfully overcame this rejection by highlighting deficiencies in the cited prior art as well as by using a number of non-obviousness arguments. For instance, the company argued that the prior art taught away⁴ from attaching a large mass to the ends of rotor blades, that the degree of noise reduction was an unexpected result and that competing designs had failed to achieve comparable noise reduction. Finally, Swift submitted audiovisual evidence of its quiet turbine in action.

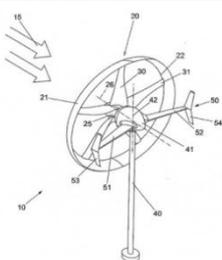


Figure 2: Swift's wind turbine (US Patent No 7,550,864) *Source: Lane (2011)*

Sources: Kim, HE (2011) The role of the patent system in stimulating innovation and technology transfer for climate change. Including aspects of licensing and competition law. Nomos, Baden-Baden; Lane E (2011) Clean Tech Intellectual Property. OUP.

⁴ Technical term in patent law to describe the solution to a problem in a way that excludes a particular alternative to solving that problem addressed by a later invention.



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