THE QUALITY OF PATENTS ON BIOTECH INVENTIONS:  
THE INTERNATIONAL COOPERATION  
ON THE NON-OBVIOUSNESS STANDARDS

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Abstract. The patent system shall work properly to achieve an appropriate balance of interests between innovators, third parties and the public if it is to serve its purpose of promoting innovation and development. The quality of patents is a crucial aspect of how the patent system operates in order to deliver economic and social policy. However, many granted patents do not reach a sufficient quality standard because of the devaluation of the patent system which is particularly observable within the patentability of biotech inventions. As a result patents are granted for inventions which are not worth of protection.

Even though patent offices make a significant contribution to the proper functioning of the patent system to ensure that the patents they grant meet the standards, their effort is not high enough. Hence, the WIPO took up an international initiative to focus on improving the quality of the patent system, namely of patents granted worldwide.

The aim of this paper is to present the aforementioned issue based on the example of biotech inventions. Particular attention is paid to the assessment of the inventive step, which – firstly – lacks an objective method for verification and – secondly – tends to be too liberal. The subject matter is to submit the issue based on the example of non-obviousness which is, a priori, very difficult to analyze. Due to the complexity of biotech innovations there is a higher probability to grant a patent for a solution which is without merit in comparison to other fields of technology.

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This paper proves that it is possible to objectify the assessment of the inventive step. This could lead to a significant improvement of the patent quality and to greater legal certainty within regional and national patent systems.

**Key words:** Patent quality, biotechnological inventions, non-obviousness, IES/FSTP

**INTRODUCTION**

The development of innovative biotechnology is of great social, health, agricultural, commercial, educational and scientific importance. The preamble to the Directive 98/44\(^1\) indicates that “biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries. The protection of biotechnological inventions will certainly be of fundamental importance for the community’s industrial development”. Patenting of biotechnological inventions remains a matter of huge controversy\(^2\). Patent protection of inventions in this field, however, is necessary due to the necessity to compensate inventors or other authorized entities. Huge amounts of money and time, as well as scientific capabilities are needed to achieve a biotechnological invention\(^3\). Hence, the discussion on the protection of biotechnological inventions shall focus on the establishment of effective and binding mechanisms for granting patents while maintaining the balance of different interests. Granting high quality patents is fundamental to have a well-functioning patent system that promotes innovation, economic growth, healthcare and general welfare.

**GLOBAL PROGRAMS ON THE QUALITY OF PATENTS**

Article 27.1 of the TRIPS Agreement stipulates that patents shall be granted to protect inventions which are “new, involve an inventive step, and are capable of industrial application”. The TRIPS Agreement does not define these three requirements. It is up to each country to implement these requirements according to the national circumstances and level of development.

One of the problems of patent quality is the pending patent backlog. The constant increase of patent applications has led to a growing number of pending applications awaiting a final decision. Hence, on the one hand, the hectic rush of granting a patent leads in some cases to the incomplete and inaccurate testing of the non-obviousness premises. On the other hand, a long-lasting, protracted procedure hampers the proper examination of patentability (the quick procedure may lead to superficial testing. Simultaneously, the lengthy procedure of the granting of a patent might lead to a misunderstanding of the essence of the solution itself.). This situation has prompted various

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2. Representatives of some members of communities/societies argue that the concept of allowing the patenting of biotechnological inventions at its base is wrongly conceived since an invention that uses biological material cannot be patented. Others argue that, although it is theoretically possible to patent a biotechnological invention, it should nevertheless be banned due to the consequences (for the economy, environment etc.). G. Dutfield, ‘Intellectual Property Rights and the Life Science Industries. Past, Present and Future’ (Hackensack/London 2009) 192-.
joint international efforts of patent offices around the world like the Utilisation Implementation Project (UIP)\(^4\) or the so-called Patent Prosecution Highway (PPH)\(^5\).

However, some patents which should not have been granted may exist. In such cases, the interested party may demand a trial to invalidate a complete patent or just some claim which should not be patentable. The reasons for the invalidation of a patent are generally the same as the reasons for the rejection of a patent application.

The definition of the quality of a patent determines the boundaries of “what should deserve protection”. It is “the extent to which patent systems comply with their patentability conditions in a transparent way”\(^6\). Patent quality is determined by three components which mirror the life cycle of a patent and take into account the perspectives of 1) the applicant\(^7\), 2) the patent office, and 3) the users of the patent\(^8\).

Patent quality may be seen objective and mathematical, taking into account every data connected with its granting, exercising and expiry (also invalidation), observable at once from the point of view of each above-mentioned party. The Patent Quality Index\(^9\) was proposed by Kazuyuki Motohashi (Department of Technology Management for Innovation (TMI) University of Tokyo & Research Institute of Economy, Trade and Industry (RIETI)). It includes 1) citation 2) indicator, 3) patent family, 4) patent renewal data, 5) request for opposition, 6) patent litigation data.

However, taking into account the rising number of patents of poor quality, the WIPO (Standing Committee on the Law of Patents (SCP)\(^10\)) proposed a worldwide cooperation on the Patent Quality System. The development of a European Quality System (EQS) provides the basis for continually improving the quality of patents.

Some delegations of countries all over the world proposed work plans for the SCP, inter alia, the delegations of Canada and the United Kingdom:

a. **Technical infrastructure development** – intended to focus on information technology solutions to improve access to information relevant to patentability.

b. **Information exchange on the quality of patents**\(^11\) – intended that patent offices of interested

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\(4\) Within the European Patent Network (EPN).


\(7\) Does the invention, with respect to the solution of the objective problem, constitute a very small improvement for a known technical subject matter, in the sense of an incremental improvement (low degree of inventiveness), or the solution of a previously unsolved problem (high degree of inventiveness)?

\(8\) Depending on the perspective, the term ‘patent quality’ will be perceived differently, additionally in view of the historical, cultural, geographic, technological and other points of view. Discussion on Patent Quality – note from the German Patent and Trademark Office (DPMA); available at: http://www.wipo.int/scp/en/meetings/session_17/quality/germany.pdf.


\(10\) SCP/1/2, paragraph 3; see also A/32/2, Main Program 09, “Development of Industrial Property Law”.

\(11\) However, for offices in countries such as Costa Rica, in which there are few examiners, such quality control becomes a complex issue. Secretariat, ‘Quality of Patents: Comments received from members and observers of the standing committee on the law of patent (SCP)’, SCP/18/INF/2 (Geneva 5.04.2012) Costa Rica, 2.
member states will collect views and experiences from their users relating to the quality of patent office processes and operations and share them with the committee for further consideration.

c. **Process improvement** – intended to identify ways offices can improve their patent granting processes to ensure an appropriate degree of quality, taking into account resources and other constraints as well as flexibilities provided for international agreements.

Members of the WIPO proposed also other instruments, directed especially to the inventive step examinations. Denmark remarked that the examination standards include, as follows, the control of: a/ the search itself; b/ the prior art to be found; c/ the treatment of patent claims; d/ office action\(^\text{12}\). Spain proposed a comparative study of the various methods of the inventive step assessment, as the most controversial and difficult element in relation to the evaluation of patentability\(^\text{13}\). A similar approach was noticed by the National Institute of Industrial Property of France (INPI): “process improvement” should include a reference to improving the quality of searches by analysing prior art and assessing obviousness, or not, of an invention to a person skilled in the art\(^\text{14}\). The Austrian Patent Office remarked that its Quality Management Board examined the trial evaluation which resulted in a circular letter asking the examiners to observe particularly clear argumentation if the criteria of novelty and inventive step are not met\(^\text{15}\).

Apart from these general initiatives undertaken on a global scale particular patent offices work out their own mechanisms intending to guarantee the proper quality of granted patents. One of these mechanisms is a reliable method of assessing the inventive step of the claimed solutions. On the one hand, such a method should provide the verification of the non-obvious requirement in accordance with the normative regulations and technical guidelines. On the other hand, such a method must constitute the most objective possible way of this verification, so that its outcome is not dependable on the experience and knowledge of the engaged expert.

Assessment of the inventive step on the example of biotechnological inventions

At first it has to be mentioned that the definition of biotechnological inventions was regulated not in the EPC itself but in the Implementing Regulations to the EPC. According to Rule 26.2 of the Regulations “biotechnological inventions are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used”. Pursuant to Rule 26.1 of the Regulations to the EPC, the Directive 98/44 shall be used as a supplementary means of interpretation to the EPC provisions. However, the Directive 98/44 does not regulate the premises of patentability itself. In other words, the patentability

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\(^{13}\) Secretariat, ‘Quality of Patents: Comments received from members and observers of the standing committee on the law of patent (SCP)’, SCP/17/INF/2 [Geneva 20.10.2012] Spain, 17.


criteria of biotech solutions remain the same as for all other kinds of inventions\textsuperscript{16}. According to the provisions of Art. 52.1 of the EPC European patents shall be granted for any invention, in any field of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. In respect to the non-obviousness requirements the Convention states in Art. 56 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”\textsuperscript{17}. The quality of patents is a key aspect of how the patent system functions. Patent protection can only be provided for inventions that are innovative and worthy of patenting.

According to the Guidelines for Examination of the EPO ‘the term “obvious” means that what 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’\textsuperscript{18}.

In practice, the examination of the non-obviousness of the invention in the European Patent Office - and in the majority of patent offices of European countries- is performed on the basis of the so called “problem - and - solution approach”. This method involves three steps:

1. determining the closest worldwide prior art;
2. establishing the „objective technical problem” that requires a solution;
3. considering whether - in view of the closest state of the art and the identification of the objective technical problem - the solution could have been obvious to a person skilled in the art\textsuperscript{19}.

As far as the first step is concerned it has to be underlined that it may be difficult to identify the prior art of a biotechnological invention because of a really rapid development in this field. That is the reason why it can also be problematic to determine the closest prior art, which means the combination of features contained in the document which best covers the starting point for further work leading to the development of the invention\textsuperscript{20}. However, as the Supreme Court of Poland indicated in the judgment of March 23, 1983 for assessing the inventive step of an invention in question, it is essential to focus on the relationship or on the lack of relationship with the already well-known fields of the application of the prior art. The allegation of obviousness is premature, if 1) there is no prior art having the same or similar features, or 2) there is a prior art solution which, however, exists in another field of knowledge. And it has not been shown that the field of knowledge

\begin{itemize}
\item \textsuperscript{16} Moreover, the WIPO states that ‘the patent offices should grant patents [of biotechnological inventions] for only such inventions that closely, raw (strictly) meet the standards of patentability - namely, novelty, inventive step and industrial applicability’ F. Gurry (ed.), ‘World Intellectual Property Report. The Changing Face of Innovation’ [Geneva 2012] WIPO Economics & Statistics Series, p. 97.
\item \textsuperscript{17} If the state of the art also includes documents within the meaning of Article 54, paragraph 3, (filed but still not published patent applications) these documents shall not be considered in deciding whether there has been an inventive step.
\item \textsuperscript{18} Guidelines for Examination in the European Patent Office (status: 20 June 2012) Part G Chapter VII-3; Case VI SA/Wa 89/08 the District Administrative Court in Warsaw [30 April, 2008] CBOSA http://orzeczenia.nsa.gov.pl/doc/43407C418F.
\item \textsuperscript{19} Guidelines for Examination in the European Patent Office (status: 20 June 2012) Part G Chapter VII-1.
\item \textsuperscript{20} M. du Vall, ‘Prawo patentowe’ (Warsaw 2010) 202.
\end{itemize}
is close enough to the area of the exploitation of the verified invention. Moreover, it is unjustified to identify the obviousness of a theoretical idea underlying the invention with specific technical measures constituting the solution. If, however, the determination of the state of the art seems to be impossible, because the present invention is called a “pioneering invention”, it has also to be assumed that its obviousness is not affected. The prior art, however, should not be interpreted too narrowly, as pointed out in one of the EPO decisions concerning pharmaceutical inventions intended for controlling diseases caused by retroviruses. It has been stated that the closest prior art should not be found among the medical methods of the treatment of this disease but in the biological areas dealing with viruses in general and, especially, with methods of their destruction.

The second step aims at fixing the technical problem requiring a solution. In order to complete this task it is necessary to study the application, the closest prior art, and the difference - in terms of either structural or functional features - between the claimed invention and the closest prior art. The differing parts of the compared solutions are called the “distinguishing features”. The identification of the technical effect resulting from the distinguishing feature leads eventually to the formulation of the technical problem.

Within the third step, it has to be answered whether an expert might have come to the solution of the applied invention. If so, the invention does not have the attribute of non-obviousness.

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23 Decision T 91/98, the Enlarged Board of Appeal EPO [29 May, 2001]: Decision T 91/98, the Enlarged Board of Appeal EPO [29 May, 2001] 12: ‘As there is a practical impossibility for a pharmaceutical formulation against a given agent to be produced before this agent is identified, the fact that the claimed formulations were the first of the kind undoubtedly reflects the celerity with which the Appellants searched for a remedy against the diseases caused by the retroviruses. Yet, it is not a convincing proof of the inventive step because, in such a situation, the inventive step rather depends on the state of the art on retroviruses, which may or may not point out in an obvious manner to a way in which these viruses can be eliminated. In the Board’s view, the ordinary skilled person would have looked in the literature for any known substances reported to have an effect on retroviruses because of the new and urgent need for a medicament against them’.
26 At the beginning of the patenting of biotechnological inventions the requirements for qualifications were very highly placed. Only few top performers were involved in biotech and, therefore, the assessment of biotechnological inventions could often be accused of non-obviousness. The notion is right that a high-end specialist will draw conclusions that some solutions are obvious, and the average expert will be careful in using such with similar issues and solutions. Decision T 791/96 the Enlarged Board of Appeal EPO [15 November, 1999]: ‘the technical circumstances of the case should be investigated from the point of view of the skilled person, avoiding any ex-post facto analysis. In the board’s judgment, the skilled person would not have been in the position to carry out the analysis of the situation that Dr. Davison made in his declaration. This is, because differently from Dr Davison, who was undisputedly a highly skilled virologist, the skilled person for the purpose of Article 56 EPC, when dealing - like in the present case - with a relatively unexplored technical area, adopts a cautious attitude and is unable to arrive at what later turns out to be the correct conclusion unless there is solid evidence pointing to this conclusion and only filling minor gaps in existing knowledge is needed (decisions the Enlarged Board of Appeal EPO cases: T 223/92, T 886/91, T 455/91). The latter was the case, for example, in the technical circumstances of decision T 386/94 (supra), where the skilled person’s only task was to complete, by applying known techniques, the work of cloning and expressing a DNA encoding chamois, whose characterization had already reached an advanced stage. If, however, the determination of the state of the art seems to be impossible, because the present invention is called a “pioneering invention”, it has also to be assumed that its obviousness is not affected. The prior art, however, should not be interpreted too narrowly, as pointed out in one of the EPO decisions concerning pharmaceutical inventions intended for controlling diseases caused by retroviruses. It has been stated that the closest prior art should not be found among the medical methods of the treatment of this disease but in the biological areas dealing with viruses in general and, especially, with methods of their destruction.

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and, thus, is not patentable. This model is called the “could - would approach”\textsuperscript{27}. It is not essential whether the „skilled person could have arrived at the invention by adapting or modifying the closest prior art, but whether he would have done so because the prior art incited him to do so in hope of solving the objective technical problem or in expectation of some improvement or advantage”\textsuperscript{28}.

The European Patent Office did not accept the Anglo-Saxon approach called “obvious to try”. The “obvious to try method” means that it would be obvious to a skilled person that, in order to achieve a specific solution, it is essential to attempt a concrete method. However, if the invention is a variant or an alternative of this solution, it does not preclude its non-obviousness, even though the attempt to obtain the solution was obvious. Nevertheless, there is the obviousness when the solution and the attempt to obtain the solution with the use of a specific method were the most preferred ones. Hence, the solution was closely related to the expectation of success\textsuperscript{29}.

The decisions of the EPO clearly marked a boundary between “obvious to try” and “expectation of success”\textsuperscript{30}. It has been accepted in the EPO practice that even a parallel research by several groups of scientists does not exclude the non-obviousness of the invention as long as the method was not the most preferable one”. However, this interpretation is considered useful only if the invention was the result of the application of predictable methods\textsuperscript{31}.

An assessment of the evidence of non-obviousness is particularly difficult in the examination of inventions relating to biological material isolated from the environment. Initially, the examination concerned the non-obviousness of both: the features of the invention as such and the way of its acquisition. A combination of those two aspects – biological material and its isolation method – may render the whole solution non-obvious, although the substance as such was already present in nature\textsuperscript{32}. Regarding relaxin, the search of a substance occurring in nature is only a non-patentable discovery, but when a naturally occurring substance must first be isolated from the environment in the way it is designed for, it is patentable. Furthermore, if the substance can only be properly characterized, either by its structure, or by way of receipt, or by other features, and is ‘new’ in the sense that its existence has not been known before, it may be patentable as the same substance as

\textsuperscript{27} M. du Vall, ‘Prawo patentowe’ (Warsaw 2010) 203.
\textsuperscript{28} See T 2/83
\textsuperscript{29} In re Dow Chemical, 5 USPQ 2d 1529 (Fed. Cir. 198); as well K. Bozevic, ‘Patenting DNA – obviousness rejections’ [December 1992] JPTOS. Guidelines for Examination in the European Patent Office (status: 20 June 2012) Part G Chapter VII-5; See as well H. Zakowska – Henzler, ‘Wynalazek biotechnologiczny: przedmiot patentu’ (Warsaw 2006) 183. However, in the case of biotechnological inventions, most of them will not meet those requirements. Typically for the invention, the biological material is a component based on biological processes or genetic engineering, or the invention is an isolated, purely biological material that does not meet the test “obvious to try”.
\textsuperscript{30} Decision T 386/94, the Enlarged Board of Appeal EPO [11 January, 1996]: ‘the person skilled in the art would attempt any one of these undertakings with a reasonable expectation of success. (…) Furthermore, it was argued that if, at a given point in time, two groups started on the same project, it might be that both were driven by the hope to succeed. If, however, as many as four groups simultaneously started on the same project, it must be that, in view of the existing knowledge, there was a reasonable expectation of success.’
\textsuperscript{31} Decision T 737/96, the Enlarged Board of Appeal EPO [9 March, 2000]: ‘as for the expectation of success, the board is of the opinion that in the present case it is not appropriate to attempt to evaluate the expectation of success of a random technique such as mutagenesis when results depend on chance events’.
such”33. In support of this case the Opposition Division of the EPO indicated that the essence of the invention does not consist in the fact that the isolating DNA encoding human relaxin, the substance which was not produced by conventional methods but by the patentee, provided the public with the substance (containing hormone, gene) which was not previously known34.35 However, due to the development of molecular biology and recombinant DNA techniques, the substances present in the environment were obtained using well-known and common methods. Hence, the study of the non-obviousness of inventions by a method of obtaining relaxin with the above-mentioned well-known and/or common method may not be justified anymore.

As a result from the rules accepted in the EPO, the assessment of the non-obviousness of an invention has been significantly liberalized, and the inventive step of many inventions is very low. According to some significant voices of the doctrine, the assessment of the inventive step of biotechnological inventions is actually illusive36.

All of the above mentioned weak points of the “problem – solution approach” contribute to the process of the trivialization of patents which was noticed already some years ago in the EPO, not only in regard to biotechnological inventions but also in other fields of technology. The EPO representatives are aware of the fact that too many weak, trivial patents have been granted which may lead to a hypertrophy of intellectual property rights37.

Also in the opinion of the European Union authorities there is a concern that a spiraling demand for patents can result in an increased granting of low quality patents38. In "An Industrial Property Rights Strategy for Europe” the European Commission states “it is vital that patents are awarded only where a true inventive contribution is made. The granting of poor quality patent rights has a negative effect on the economic and legal uncertainty”39.

Last – but not least – also the courts expressed their opinion on the fulfillment of the non-obviousness requirements. The supreme courts of Germany and the United States have issued judgments in which they seem to seek to identify a specific "unit of measurement" of non-obviousness, so that the method of the verification of non-obviousness can be more standardized and objective.

35 In this context, as indicated by the Administrative Court in Warsaw in judgment of March 30, 2009 on a patent: ‘The preparation of biologically active collagen from the skins of salmon, invention which is a compilation of a number of measures must be assessed globally, the defense of lack obviousness brought to such invention shall be the whole solution, not just its individual components, and the combination of known resources in a new way can provide a new and non-obvious’. Case VI SA/Wa 1837/08, the Polish District Administrative Court in Warsaw [30 March, 2009].
38 Communication from the Commission to the European Parliament and the Council - Enhancing the patent system in Europe, COM/2007/0165 final, 3.1
The German Federal Court of Justice in its judgment of 2008 (case Gegenstandsträger) decided that the solution is non-obvious, if the inventor made more than one independent thought (Ge-dankenschritt), starting from the prior art to find a solution of the problem. In addition, the court also used the term “number of mental steps of thought”\(^{40}\).

The US Supreme Court (USSC) indicated in its judgment of 2007 (case KSR\(^{41}\)) that the assessment of non-obviousness necessarily involves a verification of the amount of creativity in the examined solution. The idea of the amount of creativity was developed in the subsequent rulings Mayo vs. Prometheus\(^{42}\), Assn for Molecular Pathology vs. Myriad\(^{43}\) and Wildtangent vs. Ultracemical\(^{44}\), where the USSC expressed the absolute need of at least one inventive concept underlying the invention so that it can be accepted as non-obvious.

The presented rulings confirm the necessity to objectify the evaluation of the non-obviousness of inventions and represent attempts to achieve the quality of a patent by reference to concepts and quantitative and qualitative measures. Thus, it seems to be the most reasonable way to test the non-obviousness of inventions by mathematical and rational means, rather than solely based on legal language. An example of a method which applies mathematical and logical methods to the legal evaluation is the IES/FSTP method.

THE INNOVATION EXPERT SYSTEM

The Innovative Expert System (IES) allows to effectively analyze and assess the interrelations between the patent application in question and its prior art documents. The technical teachings from both – the patent application and the prior art documents – are presented and structured in a manner which was unknown before with the help of an IES.

An IES is able to analyze basically every technical teaching which is used to denote the functional description of any procedure solving a given problem of whatsoever type, not only the problems described in patents or solely technical issues.

IES is subject to pending patent applications.

CONCLUSION

Patents of the highest quality are the key to reach the objectives of patent protection, that is to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of the producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.

\(^{40}\) Case Gegenstandsträger, BGH X ZR 84/06, the German Supreme Court [22 April, 2008].
\(^{41}\) Case KSR International Co. vs. Telex Inc. et al., [30 April, 2007]; available at: https://www.eff.org/sites/default/files/filenode/ksr_v_telex/KSR_vs._Telexflex_Opinion.pdf
\(^{43}\) Case Association for Molecular Pathology, et. al. vs. Myriad Genetics, Inc., et. al. [27 April 2012].
\(^{44}\) Case Wildtangent Inc. vs. Ultracemical, LLC [22 June].
A highly problematic issue is the subjective and discretionary examination of the requirement of “inventive step”. Moreover, this requirement is subject to an increasing liberalization of interpretation and examination of the prerequisites in question, which is particularly observable for the example of biotechnological inventions. The verification of the non-obviousness in this area, but also in other fields of technology, needs necessarily to be refined. It seems that there is a wrong and unwelcome practice of patent offices to resign from the assessment of non-obviousness in cases of patents about inventions relating to biological material isolated from its environment.

Consequently, such inventions are patented only after examining the prerequisite of novelty. The Innovation Expert System and the FSTP-Test seem to provide a reliable and highly developed means of assessment of the inventive step. Thanks to this system the above mentioned prerequisite can be verified in an objective, precise and worldwide uniform way. This can be an important tool in the management of patent quality.

Abbreviations

EPC - the Convention on the Grant of European Patents
EPO – European Patent Office
Regulation to EPC - Implementing Regulations to the Convention on the Grant of European Patents
TRIPS Agreement - Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April, 1994
WIPO – World Intellectual Property Organization

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du M. Vall, ‘Prawo patentowe’ (Warsaw 2010) 202

