VALIDITY OF BIOTECHNOLOGICAL PATENTS: COMPARISON OF EPO'S, GERMAN AND ENGLISH COURTS' CASE LAW

Saša Bavec

LEK d.d., Verovškova 57, 1526 Ljubljana, SLOVENIA

Received 21-01-2004

Abstract

After the grant "the European patent" becomes a bundle of independent national patents, which are in terms of validity and enforcement subject of national legislation and practice of each member state. When the validity of the patent is determined the questions of novelty, inventive step, industrial applicability, sufficient support of claims by description and the question of "enabling disclosure" are risen. Despite the fact that according to their explanation, the national judges when dealing with patents have the same foundation European Patent Convention, the "results of their work" on the same patent are sometimes totally different. The encouraging thing is that the differences between national legal practice on determination of patent validity have been diminished in last years and that can be a good base for the Community patent, European Community is looking for.

The main purpose of this article is to show the European Patent Office's case law on granting of biotechnological patents and the practice of German and English courts (English and German systems represented two extremes) in the case of determining validity of patents. Further purpose is to highlight the differences in their approaches to the questions of novelty, inventive step, industrial applicability, sufficient support of claims by description, the question of "enabling disclosure" and to find out how these differences reflects on the patents. At the same time the article will touch some of the issues, that were opened due to some specific features biotechnological inventions, like obligatory description of the inventions in written form, distinction between discovery and inventions and question of ethics and morality in the case of "patenting of life".

Introduction

„European patent" becomes after it is granted a bundle of independent national patents. They are in terms of validity and enforcement subject of national legislation and legal practice of each member. The interpretation of common rules of European Patent Convention (EPC) related to the determination of scope of protection is also the matter of national courts to deal with. Interpreting the scope of protection the Court usually opens (in the same or in the separate proceeding)[1] the question of validity of patent. When determining validity the questions of novelty, inventive step, industrial applicability, sufficient support of claims by description and the question of "enabling disclosure" are risen.

National judges explain that when dealing with patents they respect the decisions of EPO, especially of Technical Board of Appeal.[2] EPO states that their practice related to the granting patents relay on the case law of EPC member's national courts. Despite that and the fact that they all have the same foundation (EPC), the "results of their work" on the same patent are sometimes totally different.[3] The main purposes of the patent system is to encourage development and inventiveness, but uncertainty created by unharmonization between national courts and EPO might have an opposite effect. The inventor and the third parties interested in his/her inventions can never be certain if the patent is valid as granted and what is the real scope of its protection.

The main purpose of this article is to show the EPO's case law on granting of biotechnological patents and the practice of German and English courts in the case of determining validity of patents.[4] Further purpose is to highlight the differences in their approaches to the questions of novelty, inventive step, industrial applicability, sufficient support of claims by description, the question of "enabling disclosure" and to find out how these differences reflects on the patents.

The divergence between practices of different EU countries regarding determination of patent validity is seen as a factor that can have crucial impact on success or failure of the proposed Community patent. Contrary to common belief, the differences between German and UK legal practice on determination of patent validity have been diminished in last years as it is evident from this article and that can be a good incentive for the nascent Community patent.

The questions related to the ethics and morality of the patenting that are very often open in the case of biotechnological inventions will not be discussed further in this article, since that is not purpose of this article.[5] The article will not touch the matter of exclusion of plant and animal varieties from patentability by the EPC as well.[6]

Main dilemmas related to patenting of biotechnology

The basic requirements for patentability for biotechnological inventions are the same as for the inventions from the other technological fields. Biotechnology has on some places „ruptured“ the patent system, which has struggled to adjust the application of the system to this new technology.[7] At first, it is very difficult to present a biotechnological invention sufficiently solely by description of its component parts as it can be done with most of other inventions, so it should be defined by functional terms.

Sometimes even that is not enough. In the case of new strains, improved strains and hybridoma cells the deposit of biotechnological material is necessary. This feature has challenged the requirement of patent law for a description of an invention in a written form. Secondly, the traditional distinction made by patent law between a mere discovery and an invention has been challenged, because many of biotechnological inventions are naturally occurring matters like (micro-) organisms, as well as proteins, nucleic acids, polysaccharides and etc. They have already existed in nature for a long time, but they have not been isolated and specified before. In some sense they can be consequently considered as discoveries. Thirdly, despite the fact that patent system has for a long time been formally connected to morality, it was very rarely considered that granting patents has something to do with it. Biotechnology has changed this view and several groups see the patenting of some biotechnological inventions as something immoral and unethical, so they have started actions to ban „patenting of life".

In EU some developments were done in the filed of patents for biotechnological invention by adoption of European Directive on the Legal Protection of Biotechnological Inventions[8] and by its implementation in national patent laws[9] and EPC[10].

Non-paten table matter

Discoveries

According to Article 52(2)a) EPC discoveries are not regarded as paten table inventions. A principle of „industrial applicability" represents the line between discoveries and inventions. Beside a discovery a human technical contribution and ingenuity are necessary to make an invention paten table.

To find a substance freely occurring in nature is mere discovery and therefore unpatentable. However, if the substance found in nature has first to be isolated from its surroundings and a process for obtaining is developed that process is paten table. Moreover, if this substance can be properly characterised by its structure and it is new in the absolute sense of having no previously recognised existence, the substance per se may be paten table. That is a position of EPO evident from the decision in case „RELAXIN"[11].The new Rules 23c(a) and 23e EPC have made this line between discovery and invention even clearer. [12]

Similar position took German Federal Patent Court (BPatG) in the decision "Naturstoffe"[13]. According to their decision, Discovery can be defined as finding something already existing, which has been so far unknown. If it can be transformed into a technical teaching then it can result in a paten table invention. The definition of technicity essentially of the German Supreme Court in the decision „Rote Taube“[14], which is the very leading case in this respect, is as follows (thereby delimiting against discovery): “Technical is a teaching for acting systematically by means of controllable natural forces in order to achieve a result, which can be causally observed.”

The position of the English courts can be deduced from Gale's Patent Application[15] and Genentech Inc's Patent[16]: ”It is trite law that you cannot patent a discovery, but if on the basis of that discovery you can tell people how it can be usefully employed, then a paten table invention may result. A discovery as such is not paten table as an invention under the Act. But when applied to a product or process which, is in the language of 1977 Act, is capable of industrial application, the matter stands differently.”

Methods of treatment of human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body

Beside discoveries also the methods of treatment of human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not regarded as paten table inventions.[17] As the main argument for the exclusion the definition of „industrial applicability“[18] is used.

Brief look into EPO’s practice shows that methods of treatments including surgical step are at all unpatentable[19]. Diagnostic methods are paten table if they are used outside of living human or animal bodies i.e. body tissues or fluids like urine or blood[20]. These exclusions do not apply to products for use in any of these methods[21]. For new products and products for which medical use is described for the first time it is also possible to obtain so called „medical use claims“. So called „second medical use“[22] can be protected only by process claims as a process for the preparation of a medicament or in other words by so called "Swiss type claim" as the use of the therapeutic agent for the manufacture of the medicament.[23]

Similar to EPO's practice also in the German case law only such methods as stipulated in Article 52(4) EPC are excluded from patentability, which are not at all susceptible to industrial application[24].

The present UK position on this issue is the same strongly maintaining the position that methods of medical treatment as such are unpatentable.[25] In the case Bristol-Myers Squibb Co. v Baker Norton Pharmaceutical Inc.[26] the strong comments were made that the treatment exception contained in Article 52(4) EPC shall be narrowly construed to only prevent patent law interfering directly with what a doctor actually does to a patient.

The difference between EPO, UK and German case law lays in the issue of what makes an invention susceptible to industrial application. In Germany already a provision on a product sheet enclosed with a medicament to be put on the market is sufficient. The effect of this difference is evident in the case of so called "second medical use claims" from the decisions of German and English courts in the cases of "Hydropiridine"[27] and Bayer's application[28]. The first has allowed and the second has rejected claim related to use of hydropiridine. The English court strictly follows the decision of Enlarged Board of Appeal in case EISAI/Second medical indication[29] and accept second medical use claims only in the form of so called Swiss claims: ”Use of substance A for *the manufacture of a medicinal product for* the treatment of disease B.”According to German case law the step of manufacturing can be left out of the second medical use claim and German court has allowed the following claim: ”Use of substance A for the treatment of disease B.”

Novelty

One of the requirements of EPC for inventions to be paten table is novelty. The definition in Article 54 EPC said that an invention is novel, if it does not form part of the state of the art. The state of the art comprise everything made available to the public by means of a written or oral description, by use, or in any other way before the date of filing of the respective patent application. Same provisions are included in UK and German Patent Acts as well.

The content of European patent applications as filed, of which the dates of filing are prior to the above mentioned filing date and which were published on or after that date, shall be considered as comprised in the state of the art. Date of filing within the meaning of Article 54 can be also validly claimed priority date of an earlier other application.[30]

By the definition of novelty appears some difference between in EPC, UK and German Patent Acts. According to EPC only earlier European patent applications, but not earlier national patent applications are comprised in the state of the art.[31,32,33]

Novelty destroying prior art

The position of EPO is in case that the invention is partially known from the prior art document that this prior art disclosure can not defeat the novelty of the later patent application if it does not enable persons skilled in the art to apply it without undue burden.[34] In the case NORTH CAROLINA STATE UNIVERSITY/plasmid pTR2030[35] where the prior art document has disclosed some basic principles for the construction and the preparation of plasmid, but the written disclosure was not enabling. At the same time plasmid was not available to the public. In this case EPO has taken position that this prior art document did not contain an enabling disclosure for the preparation of the plasmid in question and therefore it could not be used to defeat novelty.

Decision of German Supreme Court in "Elektrische Steckverbindung"[36] makes clear that the novelty criterion "what is made available to the public" according to definition of prior art in German Patent Act is not bound only to the explicit wording of a prior art teaching, but extends also to anything that is self evident or almost indispensable, supplemented by the skilled person or by what the skilled person readily recognised upon a careful lecture based on his general technical knowledge.

In Van der Lely v. Bamfords[37] the English court said that everything that enables the qualified reader to perceive, understand and be able to practically apply the discovery at once without the necessity of making further experiments can be used for anticipation in the cases determining novelty. The document describing a new substance, but not how it is made and if common knowledge in the industry would not permit a skilled person to select or secure the starting material or intermediate products, can not be regarded as sufficient description of the invention. Such document is not novelty destroying. To satisfy the criteria for anticipation the disclosure in the document must be enabling.[38] In the case Hoechst Celanese Corp. v. BP Chemicals Ltd[39] the court said that the priority document is novelty destroying if it explicitly teaches something within the claim or, as a practical matter, that is what the skilled man would see as teaching.

For the purpose of determination of novelty is not permissible to read two documents together if one does not positively cross-refer to the other.[40] This principle was also mentioned in case Pfizer Ltd's Patent[41] when the difference between interpretation of documents in case of determination novelty and obviousness was discussed.

Determining the anticipation of prior art we usually come across the terms like "person skilled in the art", "sufficiency of disclosure" and "enabling disclosure"[42] which can be defined in very different ways.

Naturally occurring substances

Sometimes it is difficult to decide if the invention is new, especially if it relates to naturally occurring substances. The position of EPO is that the naturally occurring substance can be considered as novel if it is isolated for the first time and it has no previously recognised existence.[43] The same practice is applied in the case of microorganisms. DNA sequence, despite it is contained in known gene library, is not considered as known until the specific hybridisation probes necessary for its isolation and characterisation are known.[44]

German court in the decision "Methonthiole"[45] took the position that mere occurrence of a substance in nature does not defeat its novelty. The novelty of the naturally occurring product resides in the first provision of the isolated product. [46]

UK position can be deduced form the position of the House of Lords in the case Merrell Dow v. Norton[47] where the claim for metabolite of terfenadine, when made outside the human body, was allowed, despite the fact that the metabolite has been produced also prior to the present invention by patients taking pills of terfenadine.

Inventive step

Definition of the state of the art for determination of inventive step

An invention involves an inventive step if it is not obvious, regarding to the state of the art to a person skilled in the art. Other European patent applications that have an earlier priority/application date but are not published before filing date of European patent application in question are not considered to form state of the art[48] for the purpose of deciding whether there has been an inventive step or not.[49]

Requirements for the state of the art necessary to be considered determining inventiveness are in UK and German Patent Acts equivalent to the EPC's definition-state of the art comprise all matter that has been any time before the priority date of the invention in question made available to the public without territorial limitation by written or oral description, by use or in any other way.

Person skilled in the art and the common general knowledge

The EPO's definition of person skilled in the art for the purpose of determination of inventive step is average hypothetical person with general technical background and specific knowledge and expertise in the field of invention. In the case HARVARD/Fusion proteins[50] has EPO defined a person skilled in the art as researcher with university degree or as a team of researchers that works in laboratory practising molecular genetics and genetic engineering techniques, at the time of the origin of the invention. The person skilled in the art was defined in KIRIN-AMGEN/Erythropoietin as a team of three composed of one PhD researcher with several years experience in the aspect of the gene technology or biochemistry under consideration, assisted by two laboratory technicians fully acquainted with the known techniques relevant to that aspect. It is no*t* expected from the person skilled in the art to solve technical problems by doing scientific research in areas not yet explored.[51]

Under the German case law the definition of the person skilled in the art in the field of biotechnology has not been developed yet.[52]

In the UK case Pfizer Ltd's Patent the notional skilled addressee or team would have had relevant but unimaginative expertise and knowledge of most treatments for male erectile dysfunction available at the priority date together with non-inventive expertise in relation to phosphodiestrases. The notional skilled addressee was deemed to have looked at and understood publicly available documents in every language and to have known of public uses in the prior art; he never thought laterally and had no idiosyncratic preferences or dislikes. He never missed the obvious and never saw the inventive. He would have considered the piece of prior art in the light of common general knowledge and might also thought it obvious to supplement the disclosure by consulting other readily accessible publicly available information even in the absence of an express cross reference. In the UK case[53] related to infringement of Amgen's patent

on recombinant human erythropoietin by TKT's GA-erythropoietin the notional skilled addressee would consist of a team of people, including three PhD's with several years' experience in gene technology, molecular biology and cell biology. At least one of these three would have had experience of proteins in general and glycoproteins in particular. The team should also include two laboratory technicians well acquainted with gene technology and biochemical technique.

The UK definition of common general knowledge is evident from decisions in cases Beloit Technologies Inc. v. Valmet Paper Machinery Inc. (No.2)[54] and Raychem Corporation's Patents[55]. The common general knowledge is the technical background of the notional man skilled in the art against which the prior art must be considered. This is not limited to material, which he has memorised and he has in front of his mind. It includes all the material in the field he is working in, which he knows that exists, which he would refer to as a matter of curse if he cannot remember it and which he understands sufficiently reliable to use as a foundation for further work or to help him to understand the pleaded prior art. The fact can not be considered as part of general knowledge just on the basis that the witness is acquainted with it. The mere record of a fact in a document does not make him form a part of common general knowledge. The piece of particular knowledge becomes part of common general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art.

Inventiveness

Biotechnological processes for the preparation of new products are very often analogues and known *per se*. Such processes involve according to EPO an inventive step if the bioprocess results in some new technical effect or if the final product has same different and unexpected properties.[56] New product similar to already known product is considered to involve an inventive step if some surprising and unexpected effects in comparison with the structurally closest known product can be shown.[57] EPO uses for the determination of an inventive step in addition also so called „obvious to try with a reasonable expectation of success" approach. The question used is if the person skilled in the art can before starting the research reasonably predict a successful conclusion of the research project within acceptable time limits.[58] In the case that the approach of solving problem is predictable on the basis of the existing knowledge, but trying to put

the predicted approach in practice the person skilled in the art is faced with unexpected difficulties, then the invention shall be considered as involving inventive step.[59] Invention shall not be considered *a priori* not to involve inventive step merely because of the fact that it consists only from already known elements.[60] Older approach of EPO regarding question of inventiveness was a "problem-and-solution" approach. According to this approach at first the prior art shall be identified, then the technical problem to be solved in reaching the claimed invention shall be formulated and then shall be judged whether the solution is obvious.

The German approach is in line with EPO's "obvious to try" approach. It was said in "Polymerisationsbeschleuniger"[61] that for the question of inventive step it is decisive that a result obtained by the invention could not be expected from the teachings of the pre-published documents.

The English courts have adopted sceptical attitude towards "obvious to try" approach. They have taken a view that, once the desired objective is known, and the standard techniques are applied to test whether a particular route will reach it, it is merely a commercial decision whether to take the chance of success. "Obvious to try" approach was used in Genentech Inc.'s Patent[62]. Lord Hoffman has dismissed the bet on race analogy employed in Genentech Inc.'s Patent as unhelpful and stated that " the question is not what odds were but whether there was an inventive step". To assess a link between inventiveness and "the addition of new idea to the existing stock of knowledge" it is necessary to "include some express or implied reference to the problem which it required invention to overcome". These remarks represent a rejection of the "Genentech" approach.

The classic approach of English court towards the question of inventiveness/obviousness is a four part test formulated for the first time by the Court of Appeal in the case Windsurfing International Inc. v. Tabur Marine[63]:

- first identify the inventive concept in the patent in suit;
- secondly , the court must assume the mantle of an ordinarily skilled person at the priority date and impute to that person what was, at the date, common general knowledge in the art in question;

- thirdly identify what if any differences exist between the matters cited as being known or used, and the alleged invention;

- fourthly ask whether, viewed with no knowledge of the invention, those differences constitute steps which would have been obvious to a person skilled in the art or whether required any degree of invention.

Industrial applicability

To be paten table an invention shall be applicable in industry[64], which means it can be made or used in any kind of industry, including agriculture.[65] The main purpose of this requirement is to exclude the patenting of ideas, which evidently do not achieve the claimed ends, such as machines to produce perpetual motion. The second issue of this requirement is to prevent the patenting of things, processes and scientific information having no known practical application at the priority.[66] For the most of the biotechnological inventions showing the industrial applicability is not a big issue. The problem arises in the case of DNA sequences and genes without known function. Till now EPO has not granted any patent for DNA sequences, fragments of genes or genes themselves without known function. According to EPO that kind of inventions are deemed not to be applicable in industry.[67] According to Jaenichen and Wachenfield[68] the patenting at EPO of DNA sequences like EST's and SNP's will stay questionable until EPO will give some final decisions on this question and design a case law that can be used in support of that kind of patent applications. At the moment EPO's position is that mere possibility to make something in industry (especially in the case of ESTs and SNPs) is not enough to substantiate the industrial applicability. The way how to use an invention in any kind of industry shall be disclosed.[69]

According to UK case law the patents cannot be granted for scientific information for which there are no practical application yet ascertained. Court of Appeal held this in the case Chiron v. Murex Diagnostics[70]. It was stated that claim could not be sustained to an almost infinite number of polypeptides, mostly without any known purpose or use (only some among them would encode the hepatitic C virus or the antigenic determinant to the antibodies produced by exposure to that virus). Probably the same approach will

be used by English court in the case of ESTs and SNPs where the function is not known and where the only utility would be "use as a probe".

Sufficiency of disclosure

An invention must be disclosed in a patent application in a manner sufficiently clear and complete for it to be carried out by person skilled in the art.[71,72]Despite the practice in the field of chemistry where broad claims shall be supported with several examples enabling a person skilled in the art to put in the practice the invention in the whole claimed range, the EPO has allowed very broad biotechnological patent claims even if they were supported only by one working example.[73] As it is evident from the decisions of EPO issued after 1991, the practice regarding the sufficiency of disclosure has changed. In the case SCHERING/Dipeptides[74] EPO said that the decision if only one working example is sufficient should be made on case by case base. The disclosure of only one way of carrying out the invention is sufficient only if it allows a person skilled in the art to carry out the inventions within whole claimed area.[75] Similar position was taken by EPO in the case UNILEVER/Hexagonal liquid crystal gel[76] where Technical Board of Appeal said that the disclosure is sufficient only if it allows a person skilled in the art to carry out the inventions within whole claimed area without doing additional experiments on „inventive level“. The principles set out by last two conventional chemical cases were applied also in the more recent decision in the case GENENTECH/Human t-PA.[77] The depositing biological material is a possibility to support for the disclosure requirement as well.[78]

The German practice in connection with the disclosure requirement is similar to the European practice, although no pertinent case law exists which explicitly indicates the minimum number of examples of practising required for sufficiency of disclosure.[79] There is sufficient and clear disclosure of the invention if, proceeding from the wording and an adequate interpretation, a person skilled in the art is enabled to recognise the nature of the technical teaching and to practice it accordingly. One working example disclosed in application can be sufficient.[80] The sufficiency of disclosure depends on the knowledge of the hypotethical person skilled in the art.[81] For example, in the case of polyclonal antibodies it is necessary for the sufficient disclosure to make available the antigen used for the preparation of antibodies to the public. Microorganisms can be

disclosed sufficiently either by written disclosure or by depositing microorganism.[82] Regarding patenting of plants it is still unclear what is necessary for sufficient disclosure. The case "Tetraploide Kamille"[83] where the question was whether the deposit of propagating material, particularly seeds means sufficient disclosure or not, was unfortunately left undecided. Similar position is in the case of patenting of animals. From "Rote Taube"[84] can be deduced that if a repeatable process for the preparation of animals is disclosed, then also a product claim directed to the animal should be allowed.

English courts in general follow the decisions of Technical Board of Appeal in GENENTECH I/Polypeptide expression and EXXON/Fuel oils. It is fundamental to the validity of a patent that it not merely discloses novel process or process, but that the disclosure is also enabling.[85,86] The invention is disclosed sufficiently if it can be performed by the person skilled in the art, even only single embodiment of the invention is disclosed in the patent application. In the case Biogen v. Medeva Lord Hoffman has introduced another concept of sufficiency that is called by Neuberger J in Kirin-Amgen Inc v. Transkaryotic Therapies Inc as "Biogen insufficiency". If the claim is cast more widely than the teaching justifies, the claim will be "Biogen insufficient"; if the claim on the face of it appears to be cast narrowly enough, it may nonetheless be classically insufficient if the teaching of the specification is not enabling.[87,88] The observation of Lord Hoffman in Biogen v. Medeva was that: “There is more than on way in which the breadth of a claim may exceed the technical contribution to the art embodied in the invention. The patent may claim results, which it does not enable, such as making a wide class of products when it enables only one of those products and discloses no principle, which would enable others to be made. Or it may claim every way of achieving a result when it enables only one way and it is possible to envisage other ways of achieving that result which make no use of the invention. ... The claimed invention is too broad. Its excessive breadth is due, not to the ability of the teaching to produce all promised results, but to the fact that the same results could be produced by different means.”

The decision in Biogen v. Medeva somehow altered the interpretation of section 14 (5) (c) of UK Patents Act that support of claims by description is not necessary only for a valid patent application, but can be also a ground for revocation of the patent.[89]

This decision may also suggest that the House of Lords is unhappy with the impossibility of invalidating a granted claim on the ground that it lacks support.[90]

Claims (Clarity, Support by description)

The matter for which the protection is sought shall be defined by claims. They shall be clear, concise and supported by the description.[91] The claims because of their function to define the scope of protection shall be clear to ensure the sufficient degree of legal certainty to third parties. The claims must be supported in their breadth by the description so that the claimed invention can be performed in its entire scope.[92] In general, technical features shall define an invention, in the case of biotechnological inventions also functional terms are allowed. It is important that the definitions in a description and claims are not contrary to each other. In the case GENENTECH/Human t-PA EPO took the position that technical features described and defined in the description as key features shall be the same as those used for a definition of the invention in the claims.

The aspect concerned by requirements for the sufficient disclosure and support of claims by description are closely interrelated although they are directed to different parts of patent application-to ensure that the patent monopoly should be justified by actual technical contribution of the invention to the art.[93] For determination if the claims are sufficiently supported the whole patent application including description and drawings should be considered.[94] Very broad claims are not *a priori* considered as unacceptable despite the fact that the description does not contain sufficient information to assume that all claimed substances have also claimed technical effect. In case that inventive step is grounded by technical effect the question of sufficient support can be solved within the scope of Article 56 EPC.[95]

The sufficient support of claims by description is necessary only for a valid patent application., However, the insufficient support of claims can not be a ground for revocation of the patent neither in Germany, nor in UK. Third parties can rise objections on this issue only during the prosecution in third party observations. Cases Biogen v. Medeva and American Home Products show that English courts find "Biogen insufficiency" as a tool to deal with the issue of insufficient support of claims as well. There is lack of relevant German case law on this issue.[96] The decision 16 W (pat)

64/88[97] of German Federal Patent Court could be used as an indication what the practice of German courts on the issue of insufficient support of claims could look like. In this case the court did not allow broad claim for type II restriction endonuclease, characterised solely by the palindromic recognition sequence and the cleavage site, since the patent did not provide any teaching which would enable the finding of further enzymes having the same specificity. The court allowed a product-by-process claim limited by reciting the microbial source of the enzyme.

Conclusion

Looking to the practice of EPO, English and German courts in relation to the validity issue of biotechnological patents[98] we can say that they are not any more as "miles and miles apart" as they were in the early eighties when the modern biotechnology has "boomed". Differences between practices were in the comparison made in this article identified only in the cases of definition of prior art, definition of industrial applicability that reflects in different practice in the case of "second medical indications", approach to the determination of inventiveness[99] and that the insufficient support of claims can be used through "Biogen insufficiency" as a ground for invalidation of patent. First two differences would probably disappear in the near future with the amendments to the EPC as decided on a diplomatic conference held in Munich in November 2000.[100] The last difference according to authors is the result of the fact that EPO and German patent court deal solely with issues related to the validity of patents and English courts usually at the same time deal with the infringement issues as well.

The English court can during the infringement proceeding see to what kind of conclusions and to what kind of interpretation of the scope of claims the wording of patent specification and granted claims lead. According to authors this kind of approach gives to the court possibility to look on the validity issue from different points of view.[101] The EPO and German patent court are through the legal proceedings enabled to look at patent specification and claims in the case of validity issue only on the ground of common decisions of the infringement courts.[102] According to authors the UK legal system gives to the courts possibility to approach the case from a variety of perspectives and to take in*to* account different points of view. This is especially important in the

cases where it is difficult to determine the contribution of the invention to common knowledge and the justified scope of granted monopoly, as it is usually the case with biotechnological inventions.

From the article one can conclude that the patent, which passes trough Technical Board of Appeal at EPC, would be very likely recognised as valid also under UK and German jurisdiction at least regarding novelty, inventive step and industrial applicability. German decisions on sufficient disclosure would probably be in line with EPO practice. By the attempts of the applicants to extend the scope of protection beyond the literal meaning of claims and beyond the contribution of their invention to the common knowledge the English courts could find, when determining infring*e*ment, lack of the sufficient disclosure of the invention in the whole claimed area or lack of support of claims by disclosure.

Acknowledgements

I would like to thank to my mentors prof.dr. Peter Raspor and prof.dr.Bojan Pretnar for their help during the preparation of this paper and for their useful comments and suggestions. At the same time I would like to thank to dr. Andreas Oser, who unselfishly shared with me his experiences on the field of patents.

References and Notes

1. Validity questions are usually not challenged on the Court's own motion, but a corresponding counter-claim has to be raised in the litigation proceedings. In the UK court can deal with patent infringement and validity issues in the same proceeding. In Germany only the Patent Office and Federal Patent Court-"Bundespatentgericht" can revoke or invalidate a patent. The infringement courts (District Court-"Landgericht" and Court of Appeal-"Oberlandesgericht") are bound by the decision to grant a patent and do not deal with validity issues. The Federal Supreme Court-"Bundesgerichtshof" as the last and final instance deals with both-patent infringement and patent validity.
2. Statement of Lord Hoffmann in the case of "Merrill Dow v. Norton", *R.P.C.* **1996**, 76.
3. In "Biogen v. Medeva", *R.P.C.* **1997**, 1. In the House of Lords revoked a UK patent which had been upheld after careful and long deliberation by Board of Appeal (T296/93, "BIOGEN/Hepatitis B", *E.P.O.R.* **1996**, 1.); similar did the German Supreme Court in the case "Inkrustierinhibitoren", *GRUR* **2000**, 591; differences are evident from the decisions of German and English Courts on the infringement in the so called "Epilady" ("Improver v Remington", *F.S.R.* **1990**, 181; "Epilady VIII", *GRUR Int.* **1993**, 242) as well.
4. The practices of German and English courts represent two legal extremes in the European region and the practices of other national courts in Europe are considered to be somewhere between those two extremes.
5. The opinion of the authors is that the patent system is not the right place to solve the issue of morality and ethics of biotechnology as such and to make assessments on this topic (S. Bavec P. Raspor,

Proceedings of the Workshop-Expert Meeting ICCS Ljubljana, 21-24 February 2001- "Biotechnological Intellectual Property at Universities-scientific, technological, economic, legal and ethical aspects", 28-36). The opinions on this issue are different (see also P. Drahos, *E.I.P.R.* **1999**, 441-449).

6. The exclusion is of "administrative nature" and it was mainly included into EPC with purpose to avoid problems with the double protection in the states where a protection of plant varieties through the system provided by Union for the Protection of New Plant Varieties of Plants is possible. For more about this issue see J. V. Funder, *E.I.P.R.* **1999**, 551-577; R. Nott, *E.I.P.R.* **1999**, 33-37; G1/98, "NOVARTIS/Transgenic plant", *E.P.O.R.* **1999**, 123.
7. A. McInerney, *E.I.P.R.* **1998**, 14-21.
8. EU directive 98/44/ECC.
9. The implementation of the Directive into national laws is still a question, since it was fully implemented only by some countries. For example, there is still a debate in Germany with the possibility that provisions of the Directive may be adopted more narrowly (especially: limitation of the scope of protection by the function disclosed in the patent). If so, there is the danger that biotechnological inventions will be judged in a different manner and the differences between the countries within EU will appear again.
10. Implementation of New Rules 23b-e EPC on September 1, 1999.
11. "RELAXIN", *O.J. EPO* **1995**, 388.
12. Generally, it is now consensus that claiming a DNA sequence without disclosing the associated function is considered as a mere discovery and not as a technical teaching.
13. „Naturstoffe", *GRUR* **1978**, 238.
14. „Rote Taube", *GRUR* **1969**, 672.
15. "Gale's Patent Application", *R.P.C.* **1991**, 305 (C.A.).
16. "Genentech Inc's Patent", *R.P.C.* **1987**, 553.
17. Article 52(4) EPC; K. Goldbach, H. Vogelsang-Wenke, F. -J. Zimmer, *Protection of Biotechnological Matter under European and German Law*; VCH Verlaggesellschaft, Weinheim, FRG, VCH Publishers, New York, USA, 1997: "The intention of underlying said exclusion from patentability is to ensure that no one who wants to use the above methods as a part of the medical treatment of humans and animals is prevented there from by patents."
18. An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture (Article 57 EPC).
19. "T116/85, WELLCOME/Pigs I", *O.J. EPO*, **1989**, 13; "T182/90, SEE-SHELL/Blood flow", *O.J. EPO* **1994**, 641; From decisions of EPO it can be concluded that EPO considers method as excluded from patentability, as soon as it has any therapeutical application irrespective of whether, it may additionally have a non-therapeutical application. However, if the therapeutic and the non-therapeutic (e.g. cosmetic) use can be separated and the claim wording is li1mited to the non-therapeutic use, the subject matter is paten table, see e.g. "T36/83, ", *O.J. EPO* **1986**, 295.).
20. "T385/86, BRUKER/Non-invasive measurement" *O.J. EPO* **1988**, 308.
21. Decision of Enlarged Board of Appeal in case "G5/83, EISAI/Second medical indication", *O.J. E PO* **1985**, 64.
22. Further medical applications of the substance that is already known as a medicament.
23. However, with the revision of the EPC as decided at the Munich diplomatic conference in November 2000, a product-type claim will be allowed in the future even for second medical uses; then the claim wording has to specify the newly found therapeutic use and this will be considered as a scope limiting feature.
24. "Hydro pyridine", *GRUR* **1983**, 729.
25. A. Faros, *E.I.P.R.* **2001**, 79-85.
26. "Bristol-Myers Squibb Co. v Baker Norton Pharmaceutical Inc.", *R.P.C.* **1999,** 253.
27. n.24 above.
28. "Bayer's application", *R.P.C.* 11 **1984.**
29. n.21 above.
30. Issues concerning the legal aspect of novelty related to so called "grace period" and "voluntary disclosure" are not dealt with here.

31. Lack of novelty can be challenged in national nullity proceedings based on earlier national rights, see Article 139 (2) EPC) .
32. According to German Patent Act 1981 the state of the art comprises also:
33. national patent applications as originally filed with the German Patent Office (GPO),
34. European patent applications if the application claims protection for Germany, unless the European patent application originated from an international patent application and the conditions specified in Article 158 (2) EPC are not satisfied, and
35. International patent applications under Patent Cooperation Treaty as originally filed with the Receiving Office, if the GPO is the Designated Office for the application.
36. According to UK Patents Act 1977 the state of the art shall comprise also the matter contained in application for another patent which was published on or after the priority date of the invention, if:
37. that matter was contained in the application for that other patent both as filed and as published; and
38. the priority date of that matter is earlier than that of the invention.
39. "T81/87, COLLABORATIVE/Preprorennin", *O.J. EPO* **1990**, 250.
40. "T576/91-Plasmid pTR2030/NORTH CAROLINA STATE UNIVERSITY", not published.
41. "Elektrische Steckverbindung", *GRUR* **1995**, 330.
42. "Van der Lely v. Bamfords", *R.P.C.* **1963**, 61.
43. "Asahi KK's Application", *R.P.C.* **1991**, 485. (H.L.)
44. "Hoechst Celanese Corp. v. BP Chemicals Ltd", *F.S.R.*. **1998**, 586.
45. W. R. Cornish, *Intellectual Property*; Sweet & Maxwell, London, UK, 1996, pp 156.
46. "Pfizer Ltd's Patent", *F.S.R.*. **2001**, 16.
47. These terms will be defined later in this article.
48. n.11 above.
49. „T301/87, BIOGEN/Alpha-interferons", *O.J. EPO* **1990**, 335; „T412/93, KIRIN-AMGEN/Erythropoietin", *E.P.O.R.*. **1995**, 629.
50. "Methonthiole", *GRUR* **1978**, 702.
51. n.13 above.
52. "Merrell Dow v. Norton", *R.P.C.* **1996**, 76.
53. as defined for determination of novelty.
54. Article 56 EPC.
55. „T60/89, HARVARD/Fusion proteins", *O.J. EPO* **1992**, 268.
56. „T500/91, BIOGEN/Alpha-interferon II", *E.P.O.R.*. **1995**, 69.
57. K. Goldbach, H. Vogelsang-Wenke, F.-J. Zimmer, *Protection of Biotechnological Matter under European and German Law*; VCH Verlaggesellschaft, Weinheim, FRG, VCH Publishers, New York, USA, 1997, pp 56; In the case ″Thrombocyte counting″ (″Thrombocyte counting″, *GRUR* **1986**, 372), the German Supreme Court held that the ″averaged skilled person″ can also be understood to include several experts in the field of the invention. The averaged skilled person must not display above average, special knowledge.
58. "KIRIN-AMGEN Inc v. TRANSKARYOTIC THERAPIES Inc", unpublished decision of English Patent Court dated 11 April **2001**.
59. "Beloit Technologies Inc. v. Valmet Paper Machinery Inc. (No.2)", *R.P.C.* **1997**, 489.
60. „Raychem Corporation's Patents", *R.P.C.* **1999**, 497.
61. „T119/82, EXXON/Gelation", *O.J. EPO* **1984**, 217.
62. „T164/83, EISAI/Antihistamines", *O.J. EPO* **1987**, 149.
63. „T296/93, BIOGEN INC/HBV antigen production", *O.J. EPO* **1995**, 627.
64. „T932/92, GENENTECH/Human t-PA", not published.
65. n.50 above.
66. "Polymerisationsbeschleuniger", *GRUR* **1965**, 138.
67. "Genentech Inc.'s Patent", *R.P.C.* **1989**, 613.
68. "Windsurfing International Inc. v. Tabur Marine", *R.P.C.* **1963**, 59.
69. Article 52(1) EPC.
70. Article 57 EPC.
71. W. R. Cornish, *Intellectual Property*; Sweet & Maxwell, London, UK, 1996, pp 175-176

72. H.-R. Jaenichen, J. Wachenfeld, Biopharm Patent Forum: Global patent strategy briefings-Spring series, 1999, London .
73. Working Party of the Trade Committee OECD, "Intellectual property practices in the field of biotechnology", 1999; TD/TC/WP(98)15/FINAL:1-27-document can be found on the world wide web at http://www.oecd.org/ech/tradedoc/htm/ .
74. Mere assumptions mentioned in the patent application are not sufficient.
75. „Chiron v. Murex Diagnostics", *F.S.R.*. **1996**, 153 (C.A.).
76. Article 83 EPC.
77. "T694/92, MYCOGEN/Modifying plant cells", *E.P.O.R.*. **1998**, 114.
78. "T292/85, GENENTECH I/Polypeptide expression", *O.J. EPO* **1989**, 275.
79. „T548/91, SCHERING/Dipeptides", *E.P.O.R.*. **1995**, 327.
80. „T409/91, EXXON/Fuel oils", *E.P.O.R.*. **1994**, 149.
81. „T435/91, UNILEVER/Hexagonal liquid crystal gel", *E.P.O.R.*. **1995**, 314.
82. In the case "T19/90, Onco-mouse/HARVARD". *O.J. EPO* **1990**, 476 the claims covered all non-human mammalian animals, but the invention was only described with examples performed on mice. However, the Board held that the mere fact that the claim is broad is not in itself a ground to assume insufficient disclosure, unless the EPO has convincing arguments against the scope of the invention as claimed. Recent development on this case is that the Board has limited the claim to cover rodents only.
83. This possibility is based on Rule 28 of EPC and corresponding national regulations.
84. K. Goldbach, H. Vogelsang-Wenke, F.-J. Zimmer, *Protection of Biotechnological Matter under European and German Law*; VCH Verlaggesellschaft, Weinheim, FRG, VCH Publishers, New York, USA, 1997, pp 49.
85. Contribution of German Patent Office to the document Intellectual Property Practice in the Field of Biotechnology prepared by OECD (see n.68 above)
86. „Isolierglasscheibenrandfugenfüllvorrichtung", *GRUR* **1984**, 272.
87. 82. "Tollwutvirus", *GRUR* **1987**, 231; "Bäckerhefe", *GRUR* **1975**, 430.
88. "Tetraploide Kamille", *GRUR* **1993**, 651.
89. "Rote Taube", *GRUR* **1969**, 672.
90. n.38 above.
91. "Valensi v. British Radio Corporation", *R.P.C.* **1973**, 337. (C.A.): "The hypothetical addressee is not a person of exceptional skill and knowledge, ... he is not to be expected to exercise any invention nor any prolonged research, enquiry or experiment. He must, however, be prepared to display a reasonable degree of skill and common knowledge of art in making trials and to correct obvious errors in the specification if a means of correcting them can readily be found."
92. Lord Hoffman in "Biogen v. Medeva", *R.P.C.* **1997**, 1.
93. The decision Biogen v. Medeva was followed by the Court of Appeal in "American Home Products", *IP&T* **2000**, 1308 (the case is known also as "Rapamycin case") as well. In his judgement Aldous LJ said:" There is a difference between on the one hand specification which requires the skilled person to use his skill and application to perform the invention and, on the other, a specification which requires the skilled person to go to the expense and labour of trying to ascertain whether some products has the required properties. When carrying out the former the skilled person trying to perform invention, whereas the latter requires him to go further and to carry out research to ascertain how the invention is to be performed. If the latter is required the specification would appear to be insufficient."
94. Prior Biogen v. Medeva the non-compliance with section 14 (5) (c) was not a ground of revocation. Court of Appeal in "Chiron v. Murex", *F.S.R.*. **1996**, 153 referred to this issue, but held "that it was not necessary to decide the exact nature of such overlap".
95. Report of British AIPPI Group in AIPPI Yearbook 1998/V Group reports Q 142: "Breath of Claims, Support by Disclosure and Scope of Protection of Patents", AIPPI, 1998, pp 115-120.
96. Article 84 EPC.
97. "T659/93, ELF ATOCHEM S.A./-", not published.
98. n.75 above.
99. "T1055/92, AMPEX CORPORATION/Clarity", *O.J. EPO* **1995**, 214.
100. "T939/92, AGREVO/Triazoles", *O.J. EPO* **1996**, 309.

101. K. Goldbach, H. Vogelsang-Wenke, F.-J. Zimmer, *Protection of Biotechnological Matter under European and German Law*; VCH Verlaggesellschaft, Weinheim, FRG, VCH Publishers, New York, USA, 1997, pp 175.
102. "16 W (pat) 64/88", BPatGE 32, 174.
103. In the case of EPO its practice related to granting patents is considered.
104. The results of different approaches are almost the same.
105. According to the proposal the national patent application shall be considered also by EPO as prior art as it was already case in UK and Germany. The direct claims to second medical use will be allowed.
106. In this case courts can see directly on their decisions on particular infringement case to what kind of interpretation of scope of claims the specification and claim's wording lead, so they can look at the patent during the determination of validity also from the standpoint how the claims and specification were understood during the infringement proceeding.
107. They lack the information on the issue how the infringement court would understand the particular patent specification and how on its ground the breadth of patent claims would be interpreted.

Povzetek

Po podelitvi postane "Evropski patent" šopek neodvisnih nacionalnih patentov, ki so z vidika svoje veljavnosti predmet nacionalne zakonodaje in pravne prakse vsake izmed držav članic Evropske patentne konvencije. Ko sodišča odločajo o veljavnosti patenta, ponavadi odprejo tudi vprašanje novosti, inventivnosti, industrijske uporabljivosti, zadostne podpore patentnih zahtevkov z samim opisom izuma in tako imenovano vprašanje "enabling disclosure". Kljub temu, da naj bi nacionalni sodniki pri svojem delu izhajali iz Evropske patentne konvencije, so občasno "rezultati njihovega dela" na istem patentu popolnoma različni.Ohrabrujoče pa je dejstvo, da se razlike med nacionalnimi pravnimi praksami v primeru določanja veljavnosti patentov v zadnjih letih zmanjšujejo, kar predstavlja dobro osnovo za takoimenovani "Community patent", ki ga želi upeljati Evropska skupnost.

Poglavitni namen tega članka je prikazati prakso Evropskega patentnega urada v primeru podeljevanja biotehnoloških patentov in prakso nemških in angleških sodišč (angleški in nemški sistem predstavljata dva ekstrema) v primeru določanja veljavnosti patentov. Nadalje je namen članka osvetliti razlike v njihovih pristopih do vprašanja novosti, inventivnosti, industrijske uporabljivosti, zadostne podpore patentnih zahtevkov z samim opisom izuma in do tako imenovanega vprašanja "enabling disclosure" in ugotoviti, kako se razlike v pristopih odražajo na patentih. Istočasno se članek dotika nekaterih problemov, kot so obvezen opis izuma v pisni obliki, razlika med odkritjem in izumom ter vprašanje etike in morale v primeru takoimenovanega "patentiranja življenja", ki so se odprli v patentnem sistemu spričo nekaterih specifičnih lastnosti biotehnoloških izumov.