*Science and Engineering Ethics (2005) **11**, XX-XX*

Ethics and Patentability in Biotechnology*

Rafał Witek
Witek, Twardowska, Śnieżko, Patent Attorneys, Wrocław, Poland

Keywords: **PLEASE ADD A FEW KEYWORDS**

ABSTRACT: *The systems of patent rights in force in Europe today, both at the level of national law and on the regional level, contain general clauses prohibiting the patenting of inventions whose publication and exploitation would be contrary to "ordre public" or morality. Recent years have brought frequent discussion about limiting the possibility of patent protection for biotechnological inventions for ethical reasons. This is undoubtedly a result of the dynamic development in this field in the last several years. Human genome sequencing, the first successful cloning of mammals, and the progress in human stem cell research present humanity with many new questions of an ethical nature. Directive 98/44 of the European Parliament and of the Council of July 6, 1998, on the Legal Protection of Biotechnological Inventions created a new basis for patent protection in this field of technology. Based on the European experience to now, however, it must be said that patent law is not the right place to legislate the consequences of the morality of an invention.*

The systems of patent rights in force in Europe today, both at the level of national law and on the regional level (the Munich Convention), contain general clauses prohibiting the patenting of inventions whose publication and exploitation would be contrary to "ordre public" or morality (see below).

Polish Industrial Property Law:

Article 29
1. Patents shall not be granted for:
(i) inventions whose exploitation would be contrary to public order or morality; the exploitation shall not be deemed to be so contrary merely because it is prohibited by law, (...)

***** An earlier version of this paper was presented at an international conference, "The Ethics of Intellectual Property Rights and Patents," held in Warsaw, Poland on 23-24 April, 2004.

Address for correspondence: Rafał Witek, Witek, Twardowska, Śnieżko, Patent Attorneys, ul. Rudolfa Weigla 12, 53-114 Wrocław, Poland; email: witek@wtspatent.pl.

Munich Convention:

Article 53 Exceptions to patentability
European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; (...)

This legacy was introduced into the Munich Convention with reference to earlier, analogous regulations in the legal systems of many European countries, whose representatives created the basis for a unified, pan-European system of patent law in the 1960s and '70s.[1] In British law, the roots of the prohibition of patenting an invention whose application would be "contrary to law or morality" goes back to the Statute of Monopolies of 1624. It was recognized that, as patents were granted in the name of the Crown, protecting an invention of doubtful morals may unfavorably reflect upon the Crown's dignity. It must be emphasized that this statute was invoked very rarely in practice, but it was e.g. the reason why birth control devices were first denied patent protection. In the justification of refusing the patenting of such an invention in 1927 it was stated that, "I express no opinion whether the use of these articles is consistent with morality … these are not articles for which … the Crown can be expected to exercise its discretion."[2]

In short, the history of the United Kingdom in relation to the granting of patents involving moral issues is one of very little activity, with "morality" being largely equated with "sexual morality". A similar approach is observed in the practice of German, French, and Dutch patent offices. In these countries, traditional practice acted against two classes of patent applications: those in which the patent specification itself could be seen to be plainly indecent, and those in which the exercise of the instructions in the specification would be likely to breach the peace or induce immoral or criminal activity. When drawing up the Munich Convention, the question of forbidding the patenting of inventions whose application would be "contrary to law or morality" was not the subject of lively discussion. It was recognized that placing an analogous provision in the Munich Convention reflected established legal principles of the countries who would be parties to the convention and it would be in accordance with their higher goal, i.e. the attempt to develop the basis for a unified and harmonized European patent law.

It was first the explosive advances in the biological sciences in the second half of the twentieth century, and the controversies they incited with regard to their ethical aspects, that sparked intense discussion on the moral dimensions of the patenting of biotechnological inventions. One manifestation of this discussion were attempts to limit the patenting of such inventions on the basis of article 53(a) of the European Patent Convention (EPC) or national counterparts of this regulation. Initially, the patenting of transgenic organisms raised the most doubts, opponents claiming there

represented a threat to the environment. Inventions involving the instrumental treatment of experimental animals also invoked strong opposition.

A certain Polish patent application involved, among other things, a method for producing a transgenic non-human mammal by introducing, by means of the invention, a genetic expression system into the fertilized egg or embryo cell of a non-human mammal such that the expression system is incorporated into the germ-line of the mammal and then the resulting fertilized egg or embryo is developed in an adult female of the non-human mammal. The transgenic animal has not been claimed as such.

The Polish Patent Office (PPO) acting in the first instance refused to grant a patent to that part of the invention. In its decision, the PPO stated that, "(…) A realization of the method of the claim would violate the public order in the sense of Article 12.3 of the Polish Patent Law. The introduction of a transgenic organism into the natural environment could result in an infringement upon the ecological balance, the results of which would be difficult to estimate. (…)".

In the opinion of the applicant, the PPO statement expressed in the official decision did not lead to the definite conclusion that the exploitation of the claimed method would seriously prejudice the environment and, as such, was only a supposition. However, the applicant's appeal was not recognized by the Board of Appeal, and the official decision of the PPO was upheld.

A similar question was discussed by the Board of Appeal of the European Patent Office (EPO) in a case resulting in the decision T 356/93.[3] The subject of the invention was plants and seed resistant to a certain class of herbicides, thanks to which they could be selectively protected against weeds and fungi. This was achieved through a stabile integration into the genome of the plants of heterogenic DNA which encoded a protein capable of inactivating or neutralizing the herbicides. In this regard, the question considered in view of article 53(a) involved determining whether the use of the devices stipulated is harmful to the environment or whether it is connected with an inappropriate or destructive application of the biotechnology of plants.

The Board's opinion was: "refusal of a European patent on the strength of article 53(a) based on the fact that use of the patented invention may seriously threaten the environment assumes that the threat to the environment is sufficiently investigated at the moment of issuing the decision by the EPO refusing the patent grant."

In this case, the Commission stated that the documents supplied by the opponent contained basic proofs of the possibility of a threat connected with the genetically engineered plants applied for which did not lead to the definitive conclusion that the use of any of these stipulated objects may seriously endanger the environment. For this reason, the Commission recapitulated that article 53(a) of the EPC did not present an obstacle to granting a patent in this specific case.

As can be seen from the examples cited above, application of the prohibition of patenting inventions whose exploitation would contrary to the "*ordre public*" as they pertain to biotechnological inventions is not uniform and gives rise to serious problems of interpretation. In fact, patent examiners are not trained to make moral judgements over technology or its use.

Conclusions essential for the development of European legal doctrine were expressed in the decision T 19/90 (onco-mouse/Harvard),[4] in which the Commission maintained that in the case in question, which contained genetic manipulations on animals consisting of the insertion of activated oncogenes, they were unquestionably forced to the necessity of considering the exclusions from article 53(a) of the EPC with reference to the question of patentability. As this was not accomplished at the level of the first instance, the Commission sent the case for investigation to the department of research with the task of giving exact consideration to the suffering of the animals and the possible risk to the environment on the one hand, and the usefulness to humanity on the other before deciding to grant or deny a patent on the invention. The renewed investigation resulted in the granting of the patent (OJ EPO 1992, 588). The opinion expressed in this verdict quickly found a permanent place in European patent law (compare Art. 6.2 (d) below) and, in the wave of the harmonization of Polish law with European law which was a required part of the obligations accepted by Poland in connection with accession to the EU, this decision also became the source of the provision contained in article 93(3) 2. 4 of the Polish Industrial Property Law.[5]

Article 6 Directive	**T 19/90**
„2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable: (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”	„5. (…)The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention’s usefulness to mankind on the other.”

Recent years have brought frequent discussion about limiting the possibility of patent protection for biotechnological inventions for ethical reasons. This is undoubtedly a result of the dynamic development in this field in the last several years. Human genome sequencing, the first successful cloning of mammals, and the progress in human stem cell research present humanity with many new questions of an ethical nature. The general guideline following from decision T 19/90 requiring a comparison of the benefits and threats proved to be too imprecise. European patent law underwent sudden specification regarding biotechnological inventions. Directive 98/44 of the European Parliament and of the Council of July 6, 1998, on the Legal Protection of Biotechnological Inventions[6] created a new basis for patent protection in this field of technology. Of greater interest are the provisions of Article 6.2 of the Directive, which defines a series of examples of inventions whose commercial exploitation is apparently deemed to be contrary to morality.

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
   (a) processes for cloning human beings;
   (b) processes for modifying the germ line genetic identity of human beings;
   (c) uses of human embryos for industrial or commercial purposes;
   (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

It soon turned out, though, that these regulations were also insufficient. The legislator was not in a position to foresee the particular, subsequent questions which would appear in the course of biotechnological advances. Moreover, the more precise legal barriers became, the more rapidly they were rendered out-of-date. An example of this is the case of the progress in stem cell research, where already 4 years later, in May 2002, the European Group on Ethics in Science and New Technologies of the European Commission suggested that the provisions involving patents in this field demanded further updating.[7,8] One may also come to this conclusion when analyzing the decision taken in the case of patent application EP 695 351,[9] which contained several controversial theses which went beyond the hitherto existing interpretation of the EPC and the suggestions contained in the Directive. In addition, the introduction of specific regulations does not always go hand in hand with facilitating the application of enacted law. We have to deal with such a situation in, for example, the problems in the interpretation of the concept "industrial application" contained in Art.5.3 of the Directive regulating the principles of gene patenting.[10]

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Conclusions

Let us try to answer the following questions: What is the real intention of the attempts to limit the patenting of biotechnological inventions, and can this intention be achieved

by the route chosen in Europe? It seems that the goal of the European legislator is to control technological development and exclude certain regions from its scope as untouchable on ethical grounds. For fear that uncontrolled biotechnological development may encroach upon areas regarded until now as sacred, the attempt is undertaken to regulate the development of biotechnology by limiting the possibilities of patenting a certain kind of invention. Why exactly were patents selected? Patents are traditional instruments which are particularly eagerly employed in this economic sector. The high costs of research and implementation in biotechnology, especially medical, as well as the relatively long time necessary to introduce a new product to the market imply that a return on investment attractive to investors can be assured by the monopoly a patent provides. Biotechnological start-ups encourage potential investors by presenting their patent portfolios, which are intended to represent the security of future profits. Technology transfer from the scientific environment to the industrial is most often connected with a transfer of exclusive rights. The phenomena described are neither new nor peculiar to the biotechnological branch, but rather result from practical solutions based on similar principles of development in the pharmaceutical industry.

Therefore, it may also appear that by limiting the patenting of inventions that arouse moral controversy one may regulate the direction of biotechnological development. Based on the European experience until the present however, it must be said that patent law is not the right place to legislate the consequences of the morality of an invention. One may present several arguments testifying to the validity of this thesis:[11]

1. patent office staff are not prepared to issue opinions on the morality of technology or its exploitation;
2. a patent right does not define the scope of application of the patented invention by the owner, nor is it permission to use the patented technology, but it is merely the right allowing the patent owner to forbid other persons from using the invention;
3. society's ideas of what is morally appropriate changes rather more quickly than legislative adjustments in patent law (e.g. stem cells);
4. if society wishes to control the use of some technological advance, that control should not be limited to what is patentable.

Also, concerns that the patenting of inventions vital to human development may cause excessive limitations on access to their application cease to be justified when we consider the institution of compulsory licensing currently existing in most patent systems. One must add that patents are not the only possibility of monopolizing the commercial application of biotechnological inventions. In the case of data bases containing, for example, the results of the human genome sequencing project, one can gain broad and effective protection by way of the protection by *sui generis* rights,[12] while the only circumstance of protecting the commercial exploitation of the data bases is substantial investment.[13,14]

In summary one may state that the attempt which has been undertaken within the realm of patent law to settle the fundamental questions of ethics in regard to advances in the biological sciences is a false and ineffective solution.

REFERENCES

1. Edward Armitage, Ivor Davis, "Patents and Morality in Perspective", Common Law Institute of Intellectual Property, London 1994
2. A and H's Application 44 RPC 298
3. T 356/93 OJ EPO 1995, 545
4. T 19/90 OJ EPO 1990, 476, see also: OJ EPO 1989, 451 and OJ EPO 1992, 588
5. Published: Polish Journal of Laws No 119/2003, text 1117
6. O.J. 1998 L213/13
7. http://europa.eu.int/comm/european_group_ethics/index_en.htm
8. Krauß J., Engelhard M.: Patente im Zusammenhang mit der menschlichen Stammzellforschung - ethische Aspekte und Übersicht über den Status der Diskussion in Europa und Deutschland GRUR 2003 Heft 12 985
9. Zwicker J. Mittelungen der deutschen Patentanwälte 94. Jg/2003 Seite 502
10. Jeanichen H., L. McDonell L., Haley Jr., "From Clones to Claims", Heymans 2002
11. G. Kamsatra et al. Patents on Biotechnological Inventions: The E.C. Directive, London, Sweet & Maxwell, 2002
12. Strowel, E. Derclaye *Droit d'auteur et numérique: logiciels, bases de données et multimédia, droit belge, européen et comparé*, Bruylant, Bruxelles, 2001, 488 p.
13. E. Derclaye "What is a database? A critical analysis of the definition of a database in the European Database Directive and suggestions for an international definition" [2002] 5 *JWIP* 6, p. 981-1011.
14. E. Derclaye "Do sections 3 and 3A of the CDPA violate the Database Directive? A closer look at the definition of a database in the UK and its compatibility with European law" [2002] 10 *EIPR* 466-479.