IPR-Helpdesk is a constituent part of the IP Awareness and Enforcement: Modular Based Actions for SMEs project which is co-financed by the CIP Programme, DG Enterprise and Industry of the European Commission

The protection of biotechnological inventions in Europe

Last updated in June 2006

Biotechnological inventions are playing an ever more important role in life today.

The development of new medical products for the treatment of asthma and diabetes, the use of gene therapy in the fight against illness, and the manufacture of genetically modified plants and animals are only some examples which emphasize that biotechnology now probably influences society and thus the European economy more strongly than any other technical area. The protection of biotechnological inventions must therefore be a matter of fundamental importance.

Innovation in the area of gene technology is expensive and risky and only profitable with appropriate legal protection. However, differences exist in the legislation and practice of Member States of the European Union in the field of the protection of biotechnological inventions. This can lead to trade barriers and thus obstruct the functioning of the internal market.

The European Parliament and the Council therefore adopted Directive 98/44/EC on 6 July 1998. This Directive, which has not been uncontroversial, does not have a direct legal impact in any Member State. As of April 2006 all Member States have implemented the Directive.(see state of play)

As the Directive followed the case law based on the EPO Boards of Appeal decisions regarding the Munich Convention on the Grant of European Patents (EPC) (dated 5 September 1973), the Directive provisions were added to the Implementing Regulations to the Convention (EPC), introducing chapter VI on "Biotechnological inventions". Moreover, the Directive 98/44/EC on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation of EPC provisions related to European patent applications and patents to biotechnological inventions (Rule 23b(1) of Implementing Regulations).

According to current law a biotechnological invention can be protected by means of national and European patents in Europe. For plant varieties special protection comes into consideration in accordance with the laws protecting plant varieties applying in the various Member States as well as by Regulation No. 2100/94 (EC), the EC protection of new plant varieties ("Community plant variety right") we will not consider these particulars further here. Rather the European Patent Convention (EPC) and the practice of the European Patent Office form the basis of this presentation.

1. The European Patent and biotechnological inventions

Inventions in the field of biotechnology must meet patentability requirements in the same way as inventions in other technical areas. So the invention must be new, involve an inventive step, and be industrially applicable (Article 52 EPC). In deciding whether a biotechnological invention is patentable, one must also consider the exception stated in Article 53(b) of the EPC. This reads:

"European Patents shall not be granted in respect of:

b) Plant or animal varieties, or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes and to the products thereof."

The question whether a patent can or cannot be granted for the invention therefore depends primarily on whether this patenting exclusion is relevant.

1.1. Exceptions to patentability

The terms "*plant varieties*", "*animal varieties*", "*biological processes for the production of plants or animals*", and "*microbiological processes*" mentioned in Article 53 b are not defined in more detail in the EPC. In the last years the Boards of Appeal of the European Patent Office (EPO) have issued a number of fundamental decisions for the interpretation of these terms, decisions which naturally have an influence on whether biotechnological inventions are patentable at all.

1.1.1 Plant varieties

TThe Act of the International Union for the Protection of New Varieties of Plants (UPOV) Convention, provides a definition of Plant Variety in Article 1 (vi), which in the nearly unanimous opinion of the UPOV States participating in the preliminary work should also be relevant to Patent Law.

This procedure specifies as a plant variety:

"*a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:*

- *defined by the expression of the characteristics that results from a given genotype or combination of genotypes,*
- *distinguished from any other plant grouping by the expression of at least one of the said characteristics, and*
- *considered as a unit with regard to its suitability for being propagated unchanged.*"

An identical provision is found in Article 5(2) of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (Regulation 2100/94/EC) and in the Rule 23b(4) of the Implementing Regulations to the EPC.

Furthermore, according to a decision of the EPO, whether the plant variety resulted from conventional breeding processes or from a genetic process is irrelevant. A genetic modification of the genome of a plant can thus result in a new plant variety. Until recently it was however not been totally made clear, how genetic inventions, which are not specifically directed toward the entire genome of the plant, but concern only a certain DNA sequence of the genome, are to be treated. Such an invention could also cover new plant varieties, because due to fundamental biomolecular technologies such inventions regularly go far beyond the narrow taxonomical limit of an individual plant variety, and can be applicable to whole plant categories, if not to an indefinite multiplicity of plant varieties. In its ruling (G 1/98 of 20 December 1999) the EPO enlarged board of appeal makes clear that the exclusion of plant varieties should be interpreted in a narrow sense. It refers to the intention of Art 53b EPC that aims at excluding a double protection by traditional plant breeders' rights and patent law. According to this decision a genetically altered plant could be patented if the claim is not restricted to a certain plant variety but to larger plant groupings. This decision is in agreement with Directive 98/44/EC where it is stated that: Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties…

Anyway plant cells are not covered by the patenting exclusion.

Specific protection for plant varieties is created in all other respects by the protection of new plant varieties, which exists alongside patent law. The protection of new plant varieties depends on the procedures currently valid in Member States and on the procedures of Regulation No. 2100/94 (EC), which are generally based on the UPOV conventions. Protection of new plant varieties will not be dealt with further here.

1.1.2 Animal varieties

Just like plant varieties animal varieties (in the sense of "breeds of animal") are also covered by the patenting exclusion. It must be noted however that no other commercial protected right systems are available for animals, unlike plants where the system of protection of new plant varieties is applicable.

Animal breeding today involves the genetic manipulation of animals to an increasing extent.

The first clause of Article 53(b) of the EPC expressly forbids the patenting of animal varieties, or rather in the two other languages of the convention " Tierarten" and "races animales".

Higher taxonomic units, like Orders, Families, or Genera, do not fall into the category "animal varieties" and are therefore not covered by the exclusion.

Therefore Directive 98/44/EC specifies that an invention whose object is an animal can be the subject of a patent, if the technical feasibility of the invention is not confined to a particular animal variety (Article 4(2) of the directive).

Furthermore animal cells as such, which thanks to modern technology can be cultivated more or less like bacteria and yeasts, are not covered by the patenting exclusion.

Like plant cells they are rather considered by the present practice of the EPO to be "microbiological products" in a broader sense.

1.1.3 Essentially biological processes

Finally, essentially biological processes fall under the patenting exclusion of the EPC. An identical provision is also found in Directive 98/44/EC. The term "biological process" is to be understood as limited strictly speaking to technical procedures, in which the course of events is influenced by means other than those which occur in nature, for example chemical or physical means.

In accordance with the EPC the patenting exclusion specifically does not apply to microbiological processes and the products made by such means. This refers to procedures for extracting, transforming, and using micro-organisms, but also the fields of cell and molecular biology, which in accordance with the practice of the EPO are assigned to the category of microbiological processes. Furthermore patent protection is available for inventions, which relate to genes or proteins.

Whether a procedure is " essentially biological ", depends above all on, to what extent the procedure is technically influenced by human action. If this intervention plays a significant role, it is not possible to see it as a substantially biological process. On the other hand conventional breeding procedures, which are wholly within the natural limits of crossing and selection, should be treated as substantially biological processes.

Thus for example a procedure for cross-breeding or a selective breeding procedure, in which only the animals which show certain features were selected for breeding or crossing, would therefore be seen as "essentially biological " and would thus be covered by the

patenting exclusion. On the other hand procedures for the treatment of plants or animals for the improvement of their characteristics, or their profitability, or for the promotion of their growth, irrespective of whether a mechanical, physical, or chemical procedure is involved, such as for instance a procedure for pruning plants, would not be substantially biological. The patenting exclusion does not apply even though the invention includes biological processes, if it is essentially of a technical nature.

Thus a patent can be granted for a process for breeding plants which is not essentially biological. Similarly biological processes, which are not directed to the cultivation of plants, are patentable, that is to say procedures for the manufacture of products utilizing higher plants, but not the plants themselves.

1.2. Discoveries

Only an invention can be the subject of a patent. Discoveries, which do not extend human ability, but only human knowledge, are not patentable. It is often held that all biological inventions, which deal with human, vegetable, or animal genes, involve materials which already occur in nature and can therefore under no circumstances be invented, but only discovered.

Thus the mere sequencing of a genome belongs to the area of discovery and for that reason alone cannot take advantage of patent protection. It is different if a DNA sequence is released from its natural surroundings by means of a technical procedure and is made available for the first time to a commercial application. Here there is a step taken from knowing to being able. Such a gene is new in the patent sense, if it was not previously accessible to the public as such, and thus technically was not available. The same applies to micro-organisms and natural materials, which are extracted from their complex natural surroundings by technical procedures. It is however essential, when patenting the material which has been isolated, that its special function or useful characteristics can be defined.

Directive 98/44/EC also takes this line. Among other things it says: "... the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step, and industrial application; whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application.

Whereas a DNA sequence without the indication of a function does not contain any technical information and is therefore not a patentable invention.

The question as to how explicitly the functions must be described especially for sequences that code only for parts of genes (like ESTs) is not yet clarified. In December 1999 the US Patent and Trademark Office issued "Revised Utility Examination Guidelines" that seem to raise utility standards for the protection of DNA sequences. Further clarification is also needed for the breadth of claim when patenting DNA sequences with regard to codon variations and variation of cDNA or amino-acid substitutions.

1.3. Offences against "ordre public" or the rules of propriety

European patents are not granted for inventions which violate "ordre public" or the rules of propriety.

Article 53(a) of the EPC states:

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;

The discussion of patent law aspects of this exception to patentability took place particularly with regard to gene technology.

According to the practice of the European Patent Office only very exceptional cases, which the public regards as particularly abhorrent, fall under the exception. When discussing the question of whether the requirements of the exception are satisfied, particularly the possible harmful impact and dangers of the invention, must be evaluated and weighed against the benefits of the invention. A case, which dealt with patenting a mouse for experimental purposes, was referred back by the technical board of appeal of the EPO, with the reasoning that the suffering of the animals associated with the use of the invention, and the possible danger to the environment, must be weighed against the benefit of the invention for mankind.

It must however be noted that a patent does not give a positive right to a particular use of the invention, but grants a right to exclude others from the use of the invention for a limited period. Ultimately the legislators have to decide whether and under which conditions particular technical knowledge may be used. Certainly a patent does not represent the right means for preventing misuse of an invention, the handling of dangerous materials, or putting the public at risk. Thus, only the conventional exploitation of the invention compliant with the law can fairly be drawn on to judge this point.

Moreover the rejection of a patent application does not necessarily mean that use of the invention is prevented. Rather a refusal of the grant of a patent places the invention into the public domain and makes it freely available to everyone.

Directive 98/44/EC also addresses this question. Article 6(1) states:

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.

This paragraph specifies a number of cases, in which it is to be assumed that such a breach is present and for that reason alone the invention cannot be patented. The following cases are mentioned:

- processes for cloning human beings;
- processes for modifying the germ line genetic identity of human beings;
- uses of human embryos for industrial or commercial purposes;
- 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.

1.4 Conclusions

Summarizing it must be noted that patent protection is available for DNA sequences, genes, gene segments, vectors, and micro-organisms. The legal decisions are however not yet fully clarified at the margins, so that uncertainties still exist at present.

In any case it is advisable to disclose a DNA sequence in sufficient detail in a patent specification, taking the special provisions of the European Patent Office (Official Journal EPO, No. 11/1998) into account because sequences must be submitted on a specific data medium with the application.

As for the protection of plants and animals, they can be the subject of patent protection as such, but not plant varieties or animal breeds. The not undisputed biotechnology directive was

adopted in this spirit. It must be mentioned in this context that the Netherlands and Italy have instituted proceedings against the directive in the European Court of Justice.

It must also be pointed out that in the case of the protection of new micro-organisms, which cannot be isolated and/or reproduced on the basis of the patent specification without reasonable expenditure, sample organisms must also be lodged with the submission of the application.

2. Appendix

2.1 Patent claims

By way of illustration here are some patent claims from various patent specifications:

EP 0695351 B1:This patent granted by the EPO in December 1999 in the field of biotechnology has caused turmoil in the beginning of 2000. Due to a translation error the patent seemed to include also humans in the term "method of preparing a transgenic animal...". The English wording of the claim should have included the qualification "non-human". After opposition against this patent was filed the patentee suggested to narrow the wording of the claim to non human application. The proceedings are not yet closed.

US 5817479: The first patent for an expressed sequence tag (EST) was granted in November 1998 by the US Patent and Trademark Office. The gene fragments described in the patent consisted of partial cDNAs coding for novel human kinases. The granting was heavily criticised by legal and biotechnology communities fearing that the broad patent rights will lead to a licensing cascade for adjacent sequences or even the full-length gene.

1. EP 771874 B1 : These are the claims of a patent granted by the EPO, concerning genetically altered mammals, which produce human albumen. Environmentalists have indicated that they will oppose the grant of this patent. The patent claims of the respective European patent application are published in EP 771874 A2
2. EP 169672 B1: The subject of the claims of this patent is the universally known Harvard cancer mouse. The patent claims of the respective European patent application are published in EP 169672 A1
3. EP 44723 A2 : These patent claims in this published patent application concern hybrid plants.
4. EP 93619 B2 : The claims of this patent cover the extraction of DNA isolate. The patent claims of the respective European patent application are published in EP 93619 A1

2.2 Links

The following links are recommended in connection with this article:

1. Further literature:
   - www.cipa.org.uk
2. UPOV Homepage
3. The UPOV convention
4. Some agencies for the protection of new plant varieties:
   - France
   - Germany
   - USA
   - Community Plans Variety Office (CPVO)
5. Dictionary

- www.biocrawler.com
- www.ams.usda.gov

6. Studies on biotechnology patent practices
   - Biotechnology and United States Patent Practice
   - Joint report comparing the positions of the European Patent Office, the Japanese Patent Office and the US Patent and Trademark Office on patentability of DNA fragments (June 1999)
   - Biotechnology Comparative Study on Biotechnology Patent Practices of the European Patent Office, the Japanese Patent Office and the US Patent and Trademark Office
7. Recent decisions of the EPO:

   T_0315/03 - 3.3.8 [2004.07.06]
   T_0579/01 - 3.3.4 [2004.06.30]
   T_0272/95 - 3.3.4 [2002.10.23]
   T_0870/04 - 3.3.8 [2005.05.11]
   G_0001/98 - EBA [1999.12.20]
   T_1054/96 - 3.3.4 [1997.10.13]
   T_0179/01 - 3.3.8 [2005.04.06]
   T_0606/03 - 3.3.08 [2005.01.12]
   G_0001/03 * - EBA [2004.04.08]