

Act implementing the Directive on the legal protection of biotechnological inventions in Germany (BioPatG)

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I. Introduction

On June 06, 1998, after almost 10 years of consultation, Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (the Biotechnology Directive) was passed by a large majority. This Directive obliges the Member States to protect biotechnological inventions by way of patents. The Directive was to be implemented into national law by July 30, 2000, but only 18 of the 25 EU Member States met this deadline. The defaulters were France, the Benelux countries, Austria, Italy, and also Germany. On October 28, 2004, Germany was convicted by the European Court of failure to implement the Directive. By delaying implementation any longer, Germany would have risked high fines. The German parliament finally passed the Bill implementing the Biotechnology Directive (BioPatG), introduced by the Federal government, on December 03, 2004.

This belated passing of the Act implementing the EU Directive was preceded by many years of intensive public debate in Germany, the key point under discussion being the absolute product protection of genes. Absolute product protection means that the patent on a new product applies without restriction, independent of how the product is used. In the Bill presented by the German government, it was proposed to restrict the absolute protection stipulated by the EU Directive in the case of natural human gene sequences. While critics were fundamentally opposed to product protection for natural gene sequences, and to the granting of product patents on genes generally, the representatives of major research companies and institutions expressed unanimous support for

unrestricted absolute product protection at a hearing of experts convened by the German parliament.

In the Act that has now been passed (the BioPatG), the coalition partners have agreed on a compromise, providing only restricted product protection to gene sequences of human origin. Under the BioPatG, only the specific function of a gene, or its application, can be patented. Product protection then applies to human genes only to the extent of the use specifically described in the patent; other uses are not covered. For animal and plant genes, on the other hand, comprehensive (absolute) product protection remains. In implementing the Biotechnology Directive, the German government therefore goes beyond the requirements of the EU Directive in this respect.

II. Content of EU Directive 98/44/EC (the Biotechnology Directive)

The goal of the Biotechnology Directive is a consistent application of patent provisions and exclusions across the whole of the EU. A major purpose of the associated EU-wide legal protection of intellectual property in biotechnological inventions is to promote investment into this technology of the future.

The most important elements of the Biotechnology Directive are set out below:

1. The distinction between inventions and discoveries is precised. Only biological material isolated from its natural environment or produced by means of a technical process may constitute an object of an invention, not the human body itself. The simple sequencing of a gene or its

code is generally not patentable (see Art. 5 of the Directive).

2. Plant and animal varieties are excluded from patent protection, as are essentially biological processes for the production of plants or animals (Art. 4(1) of the Directive). Under Art. 4(2) of the Directive, however, inventions comprising multiple varieties may be patented, i.e. where the technical feasibility of the invention is not confined to a particular plant or animal variety (e.g. in the case of a resistance to herbicides in several crop varieties produced by a genetic modification).

3. The ethical limitations of patentability have been specified (until now, there was only the general *ordre public* clause). Under Art. 6 of the Directive, the following matters are not patentable:

- processes for cloning human beings;
- processes for modifying the germ line genetic identity of human beings;
- use 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.

4. The so-called "farmer's privilege" set out in Art. 11 of the Directive restricts patent protection in favour of farmers. This allows the farmer to retain the product of his harvest that has properties protected by a patent, and use it for propagation on his own farm.

III. The implementation of the Biotechnology Directive into German law

The Act implementing the Biotechnology Directive (BioPatG) passed by the German parliament on December 03, 2004 also

brought changes to the German Patent Act, the Utility Models Act and the Plant Varieties Protection Act.

The change to the **Utility Models Act** (GbmG) is that biotechnological inventions can no longer be protected by a utility model, as a utility model (as opposed to a patent) does not undergo any substantive examination proceedings. Only biotechnological inventions are excluded; the general product protection covering non-biotechnological products remains in place.

With respect to the changes to the **Plant Varieties Protection Act** (SortSchG), the granting of compulsory licences for inventors whose work builds on the patented inventions of others, stipulated in Art. 12 of the Directive, is implemented into the new § 12a SortSchG. This allows the owner of a patent on a biotechnological invention to apply for a compulsory license, where he cannot exploit his invention without infringing a plant variety right granted earlier. However, the owner of the plant variety right will be entitled to a cross-licence on reasonable terms. The patent owner must also demonstrate that his invention constitutes significant technical progress of considerable economic interest compared with the protected plant variety.

IV. Changes to the German Patent Act (PatG)

As a result of the implementation of the Biotechnology Directive by the BioPatG, a number of paragraphs within the German Patent Act have been amended or inserted. In particular, the following paragraphs are affected:

1. In § 1 PatG, the following paragraph 2 has been inserted:

"(2) Patents will also be granted on inventions within the meaning of subsection (1) where they concern a product consisting of or containing biological material, or where they concern

a process by which biological material is produced or modified, or in which it is used. Biological material isolated from its natural environment or produced by means of a technical process may also constitute an object of an invention, even if it was already present in nature."

2. Following § 1 PatG, the following § 1a has been inserted:

"(1) The human body, at the various stages of its formation and development, including germ cells, 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 under description of the function performed by the sequence or partial sequence.

(4) If the object of the invention concerns a sequence or partial sequence of a gene, the structure of which is identical to the structure of a natural sequence or partial sequence of a human gene, its use, for which the industrial application is specifically described under subsection (3) must be included in the patent claim."

3. § 2 PatG is worded as follows:

"(1) Patents shall not be granted in respect of inventions the industrial exploitation of which would be contrary to *ordre public* or morality; the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

(2) Patents shall not be granted in respect of:

1. Processes for cloning human beings;
2. Processes for modifying the germ line genetic identity of human beings;
3. Use of human embryos for industrial or commercial purposes;
4. 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.

In the application of subsections 1 to 3, the relevant provisions of the Embryo Protection Act will take precedence."

4. Following § 2 PatG, the following § 2a has been inserted:

"(1) Patents shall not be granted in respect of plant and animal varieties or essentially biological processes for the production of plants and animals.

(2) Patents may be granted in respect of inventions

1. which concern plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety;
2. which concern a microbiological or other technical process or a product obtained by means of such a process, where this is not a plant or animal variety."

5. Following § 9 PatG, §§ 9a to 9c have also been inserted, referring to product protection of biological material and biological material as a direct product of a process (§ 9a PatG as amended, and Art. 8 and 9 of the Directive, respectively), to the exhaustion of propagation material (§

9b PatG as amended, and Art. 10 of the Directive, respectively) and to the “farmer’s privilege” for plants and farm animals (§ 9c PatG as amended, and Art. 11 of the Directive, respectively).

6. In § 11 PatG, a subsection 2a following subsection 2 has been inserted, adding to the list of limitations of the effects of a patent the use of biological material for the purposes of breeding, discovering and developing a new plant variety and exempting same from infringing acts.

7. § 24(2) PatG is worded as follows:

“(2) If the applicant for a license is unable to exploit an invention for which he holds protection under a patent of later date without infringing a patent of earlier date, he shall be entitled to request the grant of a compulsory license with respect to the owner of the patent of earlier date if

- b. the requirements of subsection 1(1) are met, and
- c. his own invention comprises, in comparison with that under the patent of earlier date, an important technical advance of considerable commercial significance.

The patentee may require the applicant for a license to grant him a cross license under reasonable conditions for the exploitation of the patented invention of later date.”

In the new version, subsection (2) then refers only to subsection 1(1); the public interest as a condition for the granting of a compulsory licence, as stipulated in subsection 1(2) is no longer a prerequisite for granting a compulsory licence.

8. Following § 34 PatG, a new § 34a has been inserted, regarding the obligation to specify the geographical origin of biological material in the application.

The amendments to the existing Act resulting from the implementation of the Biotechnology Directive are mainly intended to make the patent provisions clearer and more specific, wherein the wording has been largely copied directly from the Biotechnology Directive into the German Patent Act. Under the amended PatG, patents on human embryos, processes to clone human beings and the use of human embryos for industrial purposes are prohibited (§ 2 PatG as amended). Nor can “the human body at the various stages of its formation and development” be patented (§ 1a(1) PatG as amended). This provision expressly includes “germ cells”. On the other hand, “isolated elements” of the human body can be patented (§ 1a(2) PatG as amended).

V. Corresponding provisions in the European Patent Convention

The wording of §§ 1, 1a, 2 and 2a of the amended PatG now essentially matches Rules 23d to 23e and Article 53 of the European Patent Convention (EPC). Only in § 1a(1) PatG does the amended German Patent Act diverge from Rule 23e(1) EPC, in that German law explicitly states that germ cells are not patentable; also, § 1a(3) PatG has the passage “with details of the function performed by the sequence or partial sequence” inserted, contrary to Rule 23e(3) EPC.

The European Parliament has placed great emphasis on the indication of the function of gene sequences. According to Recital 23 to the Directive, a mere DNA sequence without indication of a function does not contain any technical teaching. The indication of the function in accordance with § 1a(3) PatG as amended must be included in the patent application itself. This constitutes a departure from the principles underlying case-law from the German Supreme Court (BGH), which allows indications of the commercial application of product inventions to be submitted later. In the light of Recital 23 to the Directive, however, this difference appears logical. It

follows that the description cannot be expanded later to provide details about industrial application of gene sequences, particularly indications of function, without expanding the scope of the original application (see also Schulte, *Commentary to the PatG*, § 1a, para 30).

VI. Restriction of absolute product protection for human gene sequences

In one point, the German government's BioPatG actually went further than required by the EU Directive on the patenting of gene sequences. Under § 1a(4) PatG as amended, only a precisely defined function of a human gene sequence and its application will now be patentable in Germany. This use must be disclosed in the patent claim. Under the EU Directive, on the other hand, it would be sufficient to indicate just one of possibly hundreds of functions of a gene – and then only in the description – to obtain a patent on the gene sequence including all known and (as yet) unknown functions (absolute product protection).

While the requirement to indicate a function in the application, stipulated by § 1a(3) PatG as amended, refers to gene sequences in general (i.e. to gene sequences of all species, regulator sequences etc. included), the requirement to indicate the function in the patent claim only applies to human gene sequences or parts thereof, but not to the gene sequences of plants and animals.

VII. Implications of restricting absolute product protection

Under earlier German law, it was possible to obtain absolute product protection, i.e. product protection covering all uses, also for human genes. For patent protection, the decisive point was that the natural material – e.g. a gene with a given sequence – did not exist before in an isolated form and was provided as such for the first time by the invention. In this sense, the existing German law matched the practice of the European Patent Office,

which grants product patents on genes without their specific use having to be indicated in the claim.

The German Patent Act amended by the BioPatG, on the other hand, places severe restrictions on absolute product protection for human gene sequences. In Germany, for a human gene, only a precisely defined function of the gene and its application will be patentable from now on, and no longer the gene sequence as such. The change to the German Patent Act, and the new practice that may be expected in relation to patents in Germany, is thus no longer in line with EPO practice under the European Patent Convention (EPC). It is therefore questionable how a European patent, effective in Germany, that includes a claim for human gene sequences without any indication of function, will be assessed by German courts in the future.

A) Invalidation procedure

The first question is whether a European patent on gene sequences might be regarded as invalid in Germany because of the lack of any indication of use, as it would not meet the requirements of § 1a(4) PatG as amended. Such an outcome appears rather unlikely for the following reasons.

Art. 138 of the EPC contains a definitive list of the grounds for revocation. It states that a European patent may only be revoked under the law of a Contracting State on the following grounds:

- if the subject-matter of the European patent is not patentable within the terms of Articles 52 to 57 EPC;
- if the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC);
- if the subject-matter of the European patent extends beyond the content

- of the application as filed (Article 123(2) EPC);
- if the protection conferred by the European patent has been extended (Article 123(3) EPC);
- if the proprietor of the European patent is not entitled under Article 60(1) EPC.

Under the EPC – in contrast to § 1a(4) PatG as amended – the indication of use for a human gene sequence in a claim is therefore not a condition for granting an EP patent. Consequently, a European patent effective in Germany could not be declared void in Germany based on the lack of any indication of use.

B) Infringement procedure / scope of protection of EP Patents designating Germany

A further area of uncertainty concerns the scope of protection of a claim in a European patent effective in Germany, where the claim relates to a human gene sequence with no indication of use. According to European patent practice, a patent may be granted on a human gene sequence even without any indication of its use in the claim. However, as a result of the changed legal position in Germany it is questionable how the scope of protection of such a claim might be assessed in Germany in the future.

The scope of protection of a European patent is defined in Article 69 EPC. Under Article 69(1) EPC, the scope of protection is determined by the terms of the claims. The description and drawings should, however, be used to interpret the claims. Article 69 EPC is supplemented by the Protocol on the Interpretation of Article 69 EPC, dated October 05, 1973. This states that

“Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined

by the strict, literal meaning of the wording used in the claims (...). Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.”

Hence, the Interpretation Protocol only specifies the relative weighting of the claims against the description/drawings in determining the scope of protection conferred by the European patent. Notwithstanding the Protocol, Article 69 EPU still offers ample room for interpretation by national courts. So it is not surprising that national case-law in the individual Member States varies greatly (see e.g. the various decisions of European courts in the “Epilady” Cases or “Rapamycin” Cases). Another example of the still widespread differences in national practice in interpreting European patents is the recent decision of the House of Lords in Great Britain in the matter of Amgen-Kirin / TKT, in which a product-by-process claim has been interpreted differently by British courts than is the case under German legal practice.

It is therefore at least theoretically possible that the scope of protection of a European patent on human gene sequences may be more narrowly interpreted in Germany in the future on the basis of the amended Patent Act. For example, if the description in a European patent only indicates one of many possible functions and/or uses, a use not mentioned in the patent could be seen in Germany as falling outside the scope of protection, based on the more narrow interpretation of the scope of protection due to the requirement for a restriction of a gene sequence to a specific use.

In this connection, it should, however, be pointed out that the provision for restricting product protection for natural human gene sequences in Germany is only set out in § 1a PatG as amended. This paragraph is concerned exclusively with the prerequisites for the patentability of biotechnological inventions. §§ 9 and 9a PatG as amended, which refer to the effect of the patent (i.e. the scope of protection), have not been amended accordingly. It can therefore be assumed that the German law was not intended to limit the interpretation of a patent claim of a European Patent during infringement proceedings in Germany to a specific use. It follows that the German part of a European patent should be interpreted as before. The scope of protection should not then change even after the implementation of the Biotechnology Directive into German law. A use X of the patented gene would then also be regarded as an infringement in Germany, even if the use in question was not disclosed as such in the European patent, but only a use Y.

C) Scope of protection of German Patents

The legal restriction contained in § 1a(3) PatG as amended, under which the description of a specific industrial application of a claimed gene, giving details of the function performed by a gene sequence in the patent application itself, is a condition for granting a patent, raises the question as to whether this implies a restriction of absolute product protection for gene sequences in general – regardless of their origins. This question is hotly discussed in the literature. In view of the chosen wording of subsection 4 in § 1a PatG as amended, which expressly refers to *human* genes only, there seems to be no detectable tendency towards a general restriction of product protection for gene sequences as subject matter of biotechnological inventions. If it were really the intention of the legislator to no longer provide absolute product protection for gene sequences in general, then it would not have been necessary to request the

indication of a use in a patent claim for human gene sequences only. Therefore, it is reasonable to assume that the scope of protection for human gene sequences only shall be limited by the new law.

VIII. Conclusions

The Act implementing the Biotechnology Directive (BioPatG) consigns absolute product protection for human gene sequences in Germany to the past. As for the possible implications of the changes to the German Patent Act for the effect of European patents in Germany, it appears unlikely on the face of it that a European patent could be declared void in Germany based on a lack of any indication of use in a claim directed to a human gene sequence. There are also good reasons to suppose that the determination of the scope of protection conferred by the German part of a European patent will continue to be governed by the existing case-law on absolute product protection.