

Amendments to the German Patent and Utility Model Law

I. German Patent Law

In order to implement the EU directive on the legal protection of biotechnological inventions ("biopatent directive", 98/44/EG of July 6, 1998), the German patent and utility model law was amended in January 2005. The new law came into effect as of February 28, 2005. (Please note that the following translation is no official translation but has been prepared in our office) In particular, the German Patent Law was amended as follows:

1. A new subsection 2 is introduced into § 1 German Patent Law (PatG) which states that patents ... are also granted for inventions which concern a product consisting of or containing biological material, or a process by means of which biological material is produced, processed or used.

Thus, the German Patent Law now explicitly acknowledges the patentability of inventions relating to biological material; this issue has recently been the subject matter of extensive political and ethic debate in Europe and Germany.

2. Of special importance is newly introduced § 1a which reads as follows:

§ 1a

- (1) *The human body, at the various stages of its formation and development, including the 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 applicability of a sequence or a partial sequence of a gene must be concretely disclosed in the application by indicating the function fulfilled by the sequence or partial sequence.*
- (4) *If the subject matter of the invention is 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, the susceptibility of industrial applicability of which is concretely described according to Subsection 3, is to be included into the claim.*

Thus, subsection (4) of newly introduced § 1a stipulates:

- a) *If a gene sequence or partial sequence is identical to the sequence or partial sequence of a human gene, it cannot be patented as such, even if it is novel, based on an inventive step, etc.*
- b) *The protection of such sequences will be restricted to the use of such sequences for a special purpose which must be indicated in the claims. According to the reasons given for the new law, a patent covering any further use of a*

gene should then be not dependent on a previous patent covering the same gene but for a different use.

3. New § 2 reads as follows:

(1) *Patents will not be granted for inventions if 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) *Patents will especially not be granted for*

- 1. processes for cloning human beings;*
- 2. processes for modifying the germ line's genetic identity of human beings;*
- 3. uses 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.*

According to the reasons given for this new law, this paragraph is to be interpreted very narrowly. This means, that § 2 excludes only those inventions from patentability which contravene basic principles of the legal system, some (but not all) of which are mentioned in § 2 (2).

Moreover, the following § 2a is added:

§ 2a

(1) *No patents will be granted for plant and animal varieties or for essentially biological processes for the production of plants or animals.*

(2) *Inventions shall be patentable,*

1. which concern plants or animals as subject matter if the technical feasibility of the invention is not confined to a particular plant or animal variety;

2. which concern as subject matter a microbiological or other technical process or a product obtained by means of such a process, unless a plant or animal variety is concerned.

§ 1a subsection 3 applies mutatis mutandis.

(3) *For the purpose of this law:*

1. "biological material" means any material containing genetic information and capable of reproducing itself or being reproducible in a biological system;

2. "microbiological process" means any process involving or performed upon or resulting in microbiological material;

3. "an essentially biological process" means a process for the production of plants or animals, which process consists entirely of natural phenomena such as crossing or selection;

4. "plant variety" means a variety in accordance with the definition of Regulation (EC) No. 2100/94 of the Council of July 27, 1994 ...

4. § 9 subsection 1, first sentence will be amended as follows:

The patent has the effect that only the holder is entitled to use the patented invention without prejudice to the provisions of existent law.

Subsequent to § 9, the following § 9a has been added:

- (1) *If the patent refers to biological material possessing specific characteristics as a result of an invention, the effects of § 9 shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.*
- (2) *If the patent refers to a process that enables a biological material to be produced possessing specific characteristics as a result of an invention, the effects of § 9 shall extend to the biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.*
- (3) *If the patent refers to a product consisting of or containing genetic information as a result of an invention, the effects of § 9 shall extend to any material in which the product is incorporated and in*

which the genetic information is contained and performs its function. § 1a subsection 1 remains unamended.

It is of special importance that the protection conferred by a patent does also extend to biological material which has been obtained by propagation or multiplication from patented biological material.

5. Finally, §§ 9b, 9c, 11, 16a, 24, 34a, 39 and 85 have been added and amended, respectively.

6. There are a number of questions, however, which need to be answered in the future by German jurisdiction:

- How does this new law affect granted German patents?
- How does it affect pending German applications?
- Does this new law contravene the TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) agreement?
- Are artificial variants of human DNA sequences patentable?
- To what extent must a new (partial) gene sequence differ from a human gene in order not to fall under the restriction of §1a (4) PatG ?
- Does the scope of protection of a process claim still cover the product directly obtained if the product is a (partial) human gene ?

II. German Utility Model Law

The German Utility Model Law was amended so that biotechnological inventions cannot be protected by utility models any more.

As an aside, the grace period of Utility Models now starts six months prior to their priority date.

III. European Patent Law

1. Contrary to the new German Law the European Patent Convention (EPC) does not require that a special purpose must be indicated in claims covering a gene sequence. Thus, under the EPC a (partial) gene sequence is protected for any purpose (absolute product protection).

2. Further, it should be stressed that the German part of a European patent cannot be revoked based only on the fact that a claim for the (partial) gene sequence does not mention any use of the (partial) gene sequence. This is because the German courts responsible for revocations may not apply German Law (§ 22 Patent Act) but substantive European Law (see Art. 52 to 57 EPC) which does not require a restriction of a claim for a DNA sequence to a specific purpose.

IV. Summary

There are three major consequences concerning protection of DNA sequences:

1. Inventions concerning DNA sequences should not be filed as national German applications but as European applications designating Germany.

2. All applications (National "priority" applications, PCT applications, European applications) should indicate as many potential uses as possible in their description.

3. Biotechnological inventions cannot be protected by German Utility Models.