

**German Federal Court of Justice refers questions regarding the interpretation of the „Biotech Directive“ (Patenting embryonic stem cells) to the European Court of Justice.**

The German patent No. DE 197 56 864 C1 (patent proprietor: Professor Oliver Brüstle) comprises claims on neural precursor cells derived from embryonic stem cells (ES), and a method for the production of the neural precursor cells. According to the patent description, ES cells comprise human ES cells. They are obtainable by removing embryonic stem cells from the blastocyst, which is a stage of development of the human embryo. According to the prevailing opinion, ES cells cannot develop into a complete individual but are able to form certain types of tissue only under selected conditions. The claims do not comprise the feature of using embryos for the production of ES cells.

The patent was granted on April 29, 1999. Greenpeace filed a nullity action of this German patent with the Federal Patent Court, as far as the claims comprise neural precursor cells derived from human ES cells.

The nullity action is based exclusively on the reasons of offence against ordre public or morality. Section 2, paragraph 2 No. 3 of PatG (German Patent Act) in the version of February 28, 2005, regulates that no patents shall be granted for the use of human embryos for industrial or commercial purposes. The regulation of Section 2, paragraph 2 No. 3 of PatG (German Patent Act) is identical with Article 6, paragraph 2 of the European Directive 98/44 on the legal protection of biotechnological inventions, which has been implemented into national law.

On December 5, 2006, the Federal Patent Court decided to maintain the patent in an amended version excluding neural precursor cells derived from ES cells produced on their part from human embryos. The patent proprietor filed an appeal against this decision with the German Federal Court of Justice (BGH). Oral proceedings were held on November 12, 2009. As a result of these oral proceedings, the BGH stayed the proceedings and will submit questions on the interpretation of the Biotech Directive to the European Court of Justice. From the press release dated November 12, 2009 of the Federal Court of Justice the following questions may be attained:

1. Is a stem cell obtained from the blastocyst to be considered as an embryo, even though it does no longer have the capacity as such to develop into a human individual?
2. Is the blastocyst to be considered as an embryo within the meaning of the law?
3. If the answer to Question 2 is in the affirmative, is the use of embryos within the meaning of the law already the case, if obtaining the stem cells to be used according to the invention necessarily implies “use” of blastocysts?
4. Is any commercial (i.e non-private) use within the meaning of the Patent Act a “use for industrial or commercial purposes”? In particular, is any use for research purposes or for therapeutic purposes a “commercial” use within the meaning of the Article 6 of the Directive?

Questions 1 and 2 refer to the interpretation of the term „embryo“; in particular, to whether a cell (stem cell) removed from a development stage of the fertilized egg cell (blastocyst) or the blastocyst as such are to be considered to be an embryo. The EU Directive does not comprise any definition of the term „embryo“. Therefore, the European Court of Justice will have to determine how to construe this term. According to Section 8 ESchG (German Embryo Protection Act), the definition of an embryo is the fertilized egg starting from the point in time of the fusion of the nuclei, and any totipotent cell removed from there. Thus, an ES cell that is not able to develop into a complete individual is not an embryo, according to German Law,

Question 3, which is dependent on the reply to question 2, refers to the interpretation as to whether the explanation in the patent specification that ES cells are produced by using blastocysts already leads to an exclusion from patentability. Therefore, the question is directed at whether only the claim is to be considered or the patent as well.

Question 4 refers to the determination of the purpose “for industrial or commercial purposes” and to whether this purpose can also be fulfilled by therapeutic use. Recital No. 42 of the Directive explains that the use of embryos for therapeutic or diagnostic purposes for the

benefit of the embryo used is not excluded from patentability. Therefore, the Federal Supreme Court asks whether, according to the Directive, not only the use of embryos for therapeutic or diagnostic purposes for the benefit of the embryo is to be considered as being patentable but also for other benefits such as the benefit of a patient.

Only after a preliminary decision of the European Court of Justice, which may be expected in approximately 1 to 2 years, the Federal Supreme Court will decide about the German appeal proceedings, which have been stayed until then.

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