

Federal Court of Justice

Press Release

[Translation by Vossius & Partner]

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The Federal Court of Justice refers questions as to the interpretation of the Biotechnology Patent Directive to the European Court of Justice

Defendant Professor Dr. Brüstle is owner of a patent granted by the German Patent and Trademark Office, which relates to isolated and purified neuronal precursor cells, methods for their production from embryonic stem cells and their use for the therapy of neuronal defects.

According to the description in the patent specification, the transplantation of brain cells into the nervous system is a promising method for the treatment of numerous neurological diseases. Since mature neuronal cells have only low regenerative capacity, it is necessary to transplant immature precursor cells capable of development. These cells, however, are only present during the development of the brain. With human embryos, however, the use of embryonic brain tissue cannot be considered for ethical reasons. In this context, the patent describes a possibility to obtain cells which are suitable for transplantation ("precursor cells" in the meaning of the patent) from embryonic stem cells, claiming protection for the precursor cells and the method for their obtention.

The Plaintiff - Greenpeace e.V. - requested that the patent be revoked since it is contrary to public policy and morality to the extent in which the claims comprise precursor cells obtained from human embryonic stem cells. In the first instance, the Federal Patent Court essentially allowed the appeal and revoked the patent to the extent in which it relates to cells obtained from embryonic stem cells of human embryos. The Federal Patent Court held that the exploitation of the invention, within the scope mentioned, would be contrary to public policy or morality. This is clear from § 2 Subsection 2 of the German Patent Act, in the version entered into force on 28 February 2005, and also from Directive 98/44/EC of the European Parliament and Council on the legal protection of biotechnological inventions dated 6 July 1998 (hereinafter "Directive"), which has to be considered for the interpretation of the provision of the German Patent Act. The Patentee has appealed against the decision of the Federal Patent Court.

In a similar case, the European Patent Office, the competent authority as to granting European patents recently held that pursuant to pertinent provisions, a European patent must not be granted for products which, on the date of filing, could exclusively be prepared by means of a method which inevitably involves the destruction of human embryos from which the products are derived, even if this method is not part of the technical teaching protected by the patent in question (Decision G 2/06 of the Enlarged Board of Appeal of the European Patent Office dated 25 November 2008).

Civil Senate Xa of the Federal Court of Justice, which is responsible for patent nullity suits, intends to stay the appeal proceedings and to refer the questions regarding the interpretation of Community Law to the European Court of Justice (ECJ) for a preliminary ruling. In fact, the interpretation of § 2 PatG [German Patent Act], which prohibits the grant of patents the commercial exploitation of which would be contrary to public policy or morality, is crucial for the decision in this law suit. Specifically, § 2, Subsection 2, Sentence 1 (3), stipulates that “patents shall not be granted for uses of human embryos for industrial or commercial purposes”. The correct interpretation of this provision of the German Patent Act, however, depends on the interpretation of the provision of Article 6 of the Directive, which is implemented by and identically worded in German legislation by § 2 PatG.

According to the Federal Court of Justice, the wording of Article 6 is unclear and ambiguous in more than one respect. The first question is how the Directive defines the term “human embryos”. In particular, it will have to be determined whether a stem cell obtained from a blastocyst, i.e. a particular developmental stage of a fertilized ovum, is to be considered an embryo even though it is no longer capable of developing into a human being. Thus, in turn, it will also have to be determined whether a blastocyst is an embryo within the meaning of the law.

The answer to the last question will be decisive if the criterion “use of embryos” within the meaning of the Directive is already fulfilled by the fact that obtaining the stem cells to be used according to the invention (which are not to be considered embryos themselves) necessarily requires the destruction of blastocysts. Finally, if this is the case, another question is whether all exploitation (i.e. non-private) within the meaning of the German Patent Act is to be considered “use for industrial or commercial purposes”, in particular, whether an exploitation for research or therapeutic purposes is to be considered “commercial” use within the meaning of Article 6 of the Directive.

Decision Xa ZR 58/07 dated 12 November 2009

Federal Patent Court – Decision 3 Ni 42/04 dated 5 December 2006

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