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German Federal Supreme Court rules on the patentability of neural precursor cells

Thomas Musmann (Rospatt Osten Pross) · Monday, January 21st, 2013

by Miriam Büttner

On 27 November 2012 the German Federal Supreme Court (BGH) decided on the ethical problematical question, if neural precursor cells which origin from human stem cells are patentable or not (case no. X ZR 58/07).

Background of the decision:

Subject of this BGH decision is the validity of German patent no. 197 56 864, which Oliver Brüstle, a German scientist, applied for in 1997 and which was granted by the German Patent and Trademark Office (DPMA) in April 1999. This patent concerns the protection of neural precursor cells, a procedure to cultivate these cells and the usage of these cells in therapies for neural defects of humans and animals. According to the explanation in the patent specification these neural precursor cells are obtained from embryonic stem cells. The embryonic stem cells in turn could be inter alia obtained from an embryo in an early stage of development, which leads to the destruction of the embryo.

In October 2004 Greenpeace e. V. filed a nullity action before the German Federal Patent Court (BPatG) with the aim to destroy the patent as far as human embryonic stem cells are concerned. Greenpeace argued that the patent would not be in line with the public policy and common moral principles as it leads to a destruction of human embryos and therefore be invalid.

In accordance with this argumentation the BPatG ruled in December 2006 that the patent was mainly invalid (BPatG, Decision of 5 December 2006, case no.: 3 Ni 42/04). The patent owner, Oliver Brüstle, filed an appeal against this decision to the BGH, who suspended the case and requested for a preliminary ruling of the European Court of Justice (ECJ) (BGH, decision of 17 December 2009, case no.: Xa ZR 58/07) inter alia on the interpretation of the term “human embryo” and the term “use of human embryos for industrial or commercial purposes”.

In October 2011 the ECJ decided on the interpretation of Art. 6 of Directive 98/44/EC, which is consistent with para. 2 sec. 2 of the German Patent Act (PatG) (ECJ, decision of 18 October 2011, case-no.: C-34/10). The ECJ closer defined the term “human embryo” referring to a human (fertilized or un-fertilized) ova, but left it open to the national courts to ascertain whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a “human embryo” within

the meaning of Art. 6 of Directive 98/44 or not. Furthermore, the ECJ found that Art. 6 of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.

The decision of the BGH:

In accordance with the interpretation of the ECJ, the BGH found that the patent-in-suit would be invalid as far as the patent comprises neural precursor cells of human embryonic stem cells which have been obtained by destroying embryos. Otherwise the impression could have been created that the German government approves the exploitation of human embryonic stem cells from embryos, which is repeatedly described in the patent specification, and would be comprised from the patenting as well.

The BGH upheld the patent as far as other methods to obtain embryonic stem cells are concerned. In this regard the BGH found that it would be sufficient that other methods to obtain embryonic stem cells exist, which do not require the destruction of an embryo.

Furthermore, in the opinion of the BGH the use of human embryonic stem cells itself cannot be qualified as a use of an embryo in the meaning of Directive 98/44 as stem cells do not have the capability to start the process on the development of a human being.

Thus, also after this BGH decision patent protection in the field of stem cell research is possible as long as the needed embryonic stem cells are not obtained from the destruction of an embryo

[The written decision of the Federal Supreme Court is not yet available. The decision will be published on the website of the Federal Supreme Court (www.bundesgerichtshof.de).]

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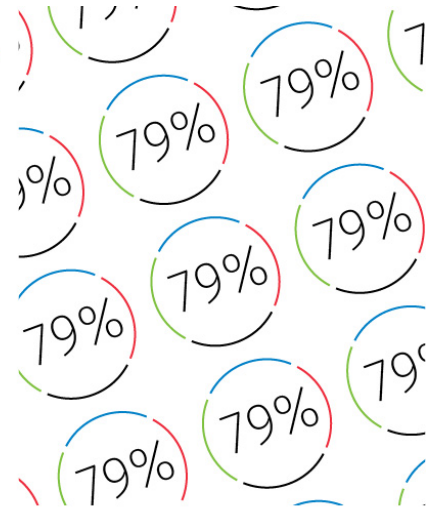
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