Europe: Patentability of Stem Cells

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The controversial issue of patentability of stem cells was recently brought before the European Court of Justice (ECJ). In an opinion issued by the Advocate General and presented to the Court, pluripotent embryonic stem cells are patentable as long as their origin did not involve the destruction or modification of a human embryo.

The European Union (EU) guidelines on the patentability of biotechnology inventions, including stem cells, were laid down in the EU biotechnology directives of 6 July 1998 (the biotechnology directives). The biotechnology directives state in Paragraph 1 of Article 6 that inventions will be unpatentable should their commercial exploitation be contrary to “ordre public or morality”.

Paragraph 2 of this Article defines such unpatentable processes and uses, and includes, among others, the “uses of human embryos for industrial or commercial purposes”.

In 2010 the German Federal Patent Court referred questions relating to patentability of stem cells to the ECJ. At the center of legal debate before the German Court was a patent owned by Prof. Dr. Oliver Brüstle, the Director of the Institute of Reconstructive Neurobiology at the University of Bonn, that was granted in 1999 on an application filed in 1997. The patent concerns neural precursor cells that had been produced from human embryonic stem cells, used for the treatment of neural defects. The first clinical application of such cells that is being pursued is the treatment of patients suffering from Parkinson's disease.

In 1999 Greenpeace instituted invalidation procedures at the Federal Patent Court in Germany that in 2006 found the patent to be invalid. The patentee, appealed to the Federal Court of Justice that decided to stay the proceedings and refer questions to the ECJ on the interpretation, in Thus, the Advocate General’s opinion was that pluripotent stem cells, derived out of human embryos and that their production resulted in the destruction of the embryo, would not be patentable.

A totipotent cell, appearing after fusion of the male and female gametes and also a totipotent cell obtained by artificial means, such as introducing a mature nucleus into an unfertilized ova or unfertilized ova whose division has been stimulated, which have the capacity to develop into a complete human, where classified by the AG to be embryos. So is also the blastocyst stage of development, reached around five days after fertilization. The principle of human dignity, referred to in the biotechnology directive, must be applied, so he concluded, to the human body from the first stage in its development, i.e. from fertilization.

By contrast, it was noted that pluripotent embryonic stem cells, taken in isolation, do not fall within the definition of an embryo, since, individually, they are no longer capable of developing into a complete human being, but rather only develop into various organs. These are the type of cells utilized in the invention claimed in the patent. However, the origin of these embryonic stem cells cannot be ignored. It is not the fact that they come from some stage in the development of the human body that is of importance; rather that their removal will not result in the destruction of the embryo. Thus, in the opinion of the Advocate
The referral requested the court’s clarification of the two terms that are the main essence of paragraph 2(c) of Article 6 of the biotechnology directive:

Whether the exclusion of “human embryo” from patentability concerns all stages of development from fertilization of the ovum or, or whether specific conditions must be satisfied for the cell to be considered unpatentable, such as the attainment of a certain stage of development; and

What acts and conditions are encompassed by the term “commercial purposes” of these cells.

In proceedings before the ECJ it is the role of the Advocate General to provide a complete independent opinion on the legal question at issue. However the ECJ is not bound by the opinion of the Advocate General although it usually plays a decisive role. The opinion of the Advocate General in this case was issued on March 10, 2011.

According to that opinion, where the invention results from prior destruction of human embryos or the use of such embryos as base material, the invention will be unpatentable. However, it was also noted that patentability should not be denied where the purpose of the invention is the treatment or diagnosis of a condition of a human embryo, such as, to ameliorate a certain defect in an embryo.

The Advocate General’s opinion was met with wide-spread concern and criticism among the scientific community and the life science industry. It was feared that such a ruling, which would make it considerably more difficult to obtain patents on inventions involving human embryonic stem cells lines, that are widely used in research (as the manner in which such cell lines were obtained in the first place may affect patentability of such inventions) Origin of such cells may negatively affect investments in this important field by the European life science industry.

It now remains to be seen whether the ECJ, which will likely decide on the issue in a few months, will follow the Advocate General’s opinion or not. Also, while the European Patent Office (EPO) is ex territorial and not bound by the decisions of the ECJ; it is to be expected that the EPO will take note of the eventual ECJ ruling.

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2 Article 6:

1. Inventions shall be considered unpatentable where 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. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) 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.

The judges at the ECJ are assisted by Advocates-General who are responsible for presenting legal opinions on issues that raise new points of law before the ECJ judges convene to deliberate on the case and deliver their judgment. The AGs opinions are advisory and do not bind the Court, but they are nonetheless very influential and are followed in the majority of cases.

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