On October 18, 2011, the European Court of Justice (ECJ) issued its decision on the patentability of human embryonic stem cells. In its decision, the ECJ ruled that any cell derived from a human embryo has the capacity to develop into a human being, including a fertilized ovum, a non-fertilized ovum to which a nucleus was inserted, a non-fertilized ovum that has been stimulated to divide and develop, and is unpatentable. Additionally, the ECJ also ruled that the use of such a cell for research does not render it patentable. Moreover, the ECJ also ruled in its decision that where an invention necessitated the destruction of a human embryo or its use as a base material, such invention would not be patentable. The decision may have a significant effect on stem cell research and on investment in this important field.

Stem cell research, particularly that focusing on totipotent stem cells, is a promising field of medical research as it holds potential for a cure of a variety of degenerative and other human diseases. The primary source for totipotent stem cells are excess fertilized eggs and embryos in very early stages of development, obtained through in vitro fertilization (IVF) that were donated for research after termination of a fertility treatment. However, as such a process involves the destruction of a living entity that may (at least theoretically) develop into a human being, such research is met with significant controversy. It is not surprising that patenting of the product of such research also meets with considerable resistance. It was now the turn of the ECJ to have its say on this issue.

The matter before the ECJ concerned a German patent owned by Prof. Dr. Oliver Brüstle, who at the time was the Director of the Institute of Reconstructive Neurobiology at the University of Bonn. The patent, granted in 1999 on an application filed at the end of 1997, concerns neural precursor cells that had been produced from human embryonic stem cells. These cells are contemplated for the treatment of neural defects. The first clinical application of such cells is

It directed the referring court (namely the German Federal Court of Justice) to rule, on the basis of scientific evidence, whether they may develop into a human being and therefore should be included within the scope of ‘human embryo’, within the meaning of Article 6(2)(c) of the Directive.

The second question before the ECJ was the scope of definition of “uses of human embryos for industrial or commercial purposes”; in particular, whether it encompasses use of human embryos for scientific purposes.

The ECJ noted that the purpose of the Directive is to address issues of patentability of biotechnological inventions and not to regulate the use of human embryos in the context of scientific research. However, seeing that patents, by their very nature, imply an industrial or commercial application, the patentability exclusion applies to “the use of human embryos for industrial or commercial purposes also covers the use of human embryos for purposes of scientific research”. The ECJ also noted that a similar conclusion was reached by the Enlarged Board of Appeals (EBA) of the European Patent Office (EPO) in its interpretation of Rule 28(c) of the Implementing Regulations to the European Patent Convention.
being pursued is the treatment of patients suffering from Parkinson’s disease.

The legal question before the ECJ was the interpretation of Article 6(2)(c) of the European directives on the legal protection of biotechnological inventions3 (the “Directive”), which excludes from patentability “uses of human embryos for industrial or commercial purposes”4. Corresponding provisions were entered into national laws in Germany and other European Union (EU) states.

Originally, Greenpeace applied to the Federal Patent Court in Germany to invalidate the patent. This court found the patent to be invalid in view of the Directive and the patentee appealed to the German Federal Court of Justice, who referred the case to the ECJ. In referring the case, the German Federal Court of Justice presented the ECJ with 3 questions relating to the patentability of stem cells in light of Article 6 of the Directive. Other than the original parties, observations were also submitted by the Governments of Ireland, Portugal, Sweden and the United Kingdom and by the European Commission.

The first phase of an ECJ proceeding involves the issuance of an opinion by the Advocate General (AG), which is then usually followed by the ECJ. The AG opinion in this case, issued by advocate general Mr. Yves Bot, was reported in our May 2011 newsletter entitled “Europe: Patentability of Stem Cells”. Indeed, as will be elaborated below, the ECJ decision largely follows that AG opinion.

The first question before the ECJ was the interpretation of the term “human embryo” in Article 6(2)(c) of the Directive, for the purpose of determining “the scope of the prohibition on patentability laid down in that provision”. Noting that the EU legislator had the intention of excluding patentability of inventions where human dignity could be compromised5, the ECJ concluded that “the concept of ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive must be understood in a wide sense”. This means that a fertilized ovum, as well as a non-fertilized ovum to which a nucleus was inserted or a non-fertilized ovum that has been stimulated to divide and develop, should all be regarded as an embryo, that includes an identical exclusionary language6. Thus, the ECJ concluded that the patentability exclusion of the use of human embryos covers also use for the purpose of scientific research.

The third question before the ECJ was the patentability of an invention that does not use human embryos but nonetheless was arrived at by the “destruction of human embryos”. It should be noted that the invention in the patent at issue involved the production of neural precursor cells that are derived from stem cells obtained from human embryos at the blastocyte stage, a process that causes destruction of the human embryo.

The ECJ concluded, on the basis of human dignity criteria, that where an invention was arrived at through the destruction of a human embryo, it is unpatentable even where the destruction occurred “long before the implementation of the invention”. The ECJ noted that the EBA of the EPO arrived at a similar conclusion in its aforementioned decision7. Thus, an invention that requires prior destruction of a human embryo or the use of a human embryo as a base material would be unpatentable, regardless of when such destruction took place or whether the patent specification does not make any reference to the use of human embryos.

This decision affects the ability to obtain valid patent protection on many stem cell-related inventions in Europe. As such, it places the EU apart from other countries, such as the US, where no limit exists to patent protection of stem cells, even such derived from a human embryo. However, seeing that the vast majority of clinical stem cell research is currently centered on adult stem cells, the effect of this decision may be relatively minor, after all.

It is to be noted that the ECJ has no formal jurisdiction over the EPO and thus this decision does not legally bind the EPO. However, it is hard to believe that the EPO will implement a policy that will lead to the grant of patents that will not withstand legal challenges in EU states; and moreover, it is to be remembered that the EBA already ruled along the same lines in its 2008 decision, noted above. Accordingly, it is likely that the legal principles laid down by the ECJ will also be applied by the EPO. Thus, obtaining stem cell-related patents in Europe will now be more difficult.
since all may develop into a human being.

The ECJ left open the question of whether a stem cell obtained from a human embryo at the blastocyte stage should be regarded as a “human embryo”.

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1 Totipotent stem cells are stem cells that have the potential to develop into any cell found in the human body.
2 At the time, President Bush partially banned Federal funding in the US for embryonic stem cell research, a ban that was lifted by President Obama in 2009.
4 Article 6 of the Directive reads (relevant parts):
   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:
      .......
      (c) uses of human embryos for industrial or commercial purposes;...
   5 The intention to safeguard human dignity is noted in two preamble (“whereas”) clauses in the Directive. The first one is clause 16 (“Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person”); and the second one is clause 38 (“whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability”).
7 In paragraph 22 of that decision.

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