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What is an Embryo? Europe Ready to Decide

In 2009 we reported (Human Embryonic Stem Cell Research) that the German Federal Court of Justice had asked the European Court of Justice (ECJ) to decide whether embryonic stem cell research methods were patentable.

The case concerned a German patent to methods of cultivating human embryonic stem cells. The patent covered neural precursor cells, derived from human embryonic stem cells. Greenpeace had objected that this was an industrial or commercial use of human embryos, which is not allowed under German patent law, which corresponds to European and UK patent law.

The Advocates General are members of the ECJ. They provide the court with an independent legal opinion on questions before the court. Although their opinions are not binding on the court, the court often follows the opinion of an Advocate General.

The Advocate General has given an opinion on the questions before the ECJ, relating to the patentability of human embryos.

The first question is what the term “human embryo” means. The Advocate General is of the opinion that the term covers any totipotent cell from the moment of fertilization (or creation, in the case of synthetic totipotent cells).

The term “human embryo” includes the blastocyst, which is the ball of 70 to 100 cells formed first in the growth of the embryo.

The second question is whether pluripotent cells (cells which cannot develop into an entire organism) should be considered to be “embryonic stem cells”. The Advocate General is of the opinion that such cells are not considered to be a “human embryo”, and should be patentable.

However, he placed restriction on the patentability of such pluripotent embryonic stem cells. These cells are obtained from the blastocyst. In doing so the blastocyst is inevitably destroyed. The Advocate General stated that any invention which necessitates the destruction of a human embryo is also excluded from patentability. Therefore, pluripotent embryonic stem cells (as opposed to induced pluripotent stem cells), which are obtained by destroying the blastocyst, are not patentable, despite the cells themselves not being unpatentable “human embryonic stem cells”. The Advocate General did not place any historical limit on the blastocyst destruction. If the judges follow his opinion it is possible that all the current embryonic stem cell lines, and inventions developed from them, will be unpatentable.

The ECJ decision will be binding on all European states and, although not binding on the European Patent Office, it is highly likely that the European Patent Office will follow it. The Enlarged Board of Appeal of the European Patent Office has already addressed the issue, as we reported in 2008 (Human Embryonic Stem Cells – A Decision at Last)

If the ECJ followed this opinion, then the UK, the ECJ and the European Patent Office will have been consistent, in deciding that human totipotent cells are unpatentable. There are differences in the approach to patentability of pluripotent cells. If the ECJ follows the opinion of the Advocate General, the national patent offices of Europe will have to harden their stance on pluripotent embryonic stem cells.

We expect that the ECJ will issue the final decision later this year and we will, of course, report it as soon as it issues.