

What is an Embryo? Europe Decides

In 2009 the German Federal Court of Justice had asked the Court of Justice of the European Union (CJEU) to decide whether embryonic stem cell research methods were patentable. Earlier this year we reported the Advocate General's opinion on the referred questions. The CJEU has now issued their decision.

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 first issue addressed is what the term **“human embryo”** means. The CJEU decided it should restrict itself to the legal interpretation of the relevant provisions, rather than address the questions from a medical or ethical perspective.

It concluded that the term “human embryo” covers any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis. **Accordingly, the term has a wide interpretation to cover any cell, including those artificially stimulated or manipulated, that is capable of developing into a human being.**

The decision clarifies that **“the use of human embryos for industrial or commercial purposes”** covers the use of human embryos for purposes of scientific research; the only patentable uses are those for therapeutic or diagnostic purposes, applied to the human embryo, which benefit it. **This importantly clarifies that use of a human embryo is patentable if there is a benefit to the embryo itself.**

The decision also confirms that an invention is not patentable if, **at some stage, it is necessary to destroy a human embryo** in order to arrive at the invention. The decision specifically indicates that the destruction can occur at a stage long before the implementation of the invention – for example, it is now irrelevant that stem cells used in an invention could be derived from a lineage of stem cells, because at some point a human embryo was destroyed to establish the cell line. It is also irrelevant if the patent claims and/or the description do not refer to the destruction of the human embryo.

Significantly, all current embryonic stem cell lines, and inventions developed from them, are unpatentable.

This decision is not in line with the current practice of the European Patent Office (EPO). The CJEU decision is binding on all European states and, although not binding on the EPO, it seems certain that the EPO will follow it.

The UK, the CJEU and the EPO are consistent that human totipotent cells are unpatentable. Until now the UK and EPO have taken different approaches to patentability of pluripotent cells. In light of this CJEU decision, the EPO and national patent offices of Europe will have to harden their stance on patenting pluripotent embryonic stem cells.

The CJEU passed the specific question, of the patentability of the neural precursor cells, back to the German Federal Court of Justice. It appears that the only possible decision will be that the neural precursor cells are not patentable, because, at some point, their preparation required the destruction of a human embryo.