

EIP

Human Embryonic Stem Cells Precluded From Patentability

In its judgement of 18 October 2011, the Court of Justice of the European Union (CJEU) has confirmed that human embryonic stem cells (hESCs) do not constitute patentable subject matter, given the ban under European law on patents for technologies entailing the uses of human embryos for industrial or commercial purposes.

The patent which gave rise to this ruling relates to neural precursor cells and methods for their production from hESCs. Proceedings were brought before the German courts, but as the case concerned an interpretation of European law, the case was referred to the CJEU. Both the laws of the EU and the EPO prohibit patents for technologies the commercial exploitation of which would be contrary to ordre public or morality, and this is specifically stated to include uses of human embryos for industrial or commercial purposes. The CJEU was first required to assess how the term “human embryo” should be interpreted in relation to this prohibition.

The CJEU sought to answer this solely by reference to the law, rather than in relation to medical, ethical or religious considerations. They noted that Recitals 16 and 38 of the relevant Directive^[1] emphasised that patent law must be applied to safeguard the dignity of the person, and that all processes the use of which offend against human dignity are excluded from patentability. Given this, they felt that patentability should be precluded where there is any possibility that respect for human dignity is affected. Consequently, the CJEU held that the term “human embryo” must be interpreted widely, such that as soon as a human ovum is fertilised it should be considered an embryo. The term was also held to encompass a non-fertilised human ovum into which a mature nucleus has been transplanted, or which has had its development stimulated by parthenogenesis.

The court did not rule on whether hESCs obtained from a blastocyst would be covered, leaving it to national courts to decide on a case by case basis whether such cells had the potential to develop into a human being. Following the court's logic, it seems totipotent cells will be considered embryos, but pluripotent cells will not.

The CJEU was also required to address whether the exclusion extended to patents which do not themselves entail the use of human embryos, but instead claim products which are obtained via the destruction of human embryos, or are obtained from base materials which are in turn obtained via the production of human embryos. The CJEU, diverging from the practice of the EPO, felt that such products must be excluded from patentability as otherwise the prohibition would be rendered redundant by skilful patent drafting. In the words of the CJEU, "The fact that destruction may occur at a stage long before implementation of the invention...is irrelevant".

The CJEU's judgment states that this conclusion is consistent with the EPO's interpretation. However, the EPO when assessing this issue [2] in fact reached a different conclusion, namely that the prohibition only related to the commercialisation of embryos themselves, rather than uses of cells derived from embryos. The EPO actually reached its conclusion on the basis of the changes made during the development of the law creating the prohibition, a factor seemingly not considered by the CJEU. Nevertheless, the CJEU's ruling is almost certain to restrict the EPO's approach, significantly limiting the availability for patents for HESCs.

This result is not surprising, given it is in line with Advocate General's opinion of earlier this year. Greenpeace have welcomed the court decision, commenting that "By blocking the patenting and commercialisation of human embryos, the European Court of Justice has today strengthened the protection of human life against commercial interests within the EU". Industry comments have ranged from describing it as being of uncertain effect to a huge setback for hESC research in Europe. However, technologies related to induced pluripotent stemcells or to pluripotent hESC cells which have not required the destruction of an embryo will still be patentable in Europe.

[1] Directive 98/44/EC on the Legal Protection of Biotechnological Inventions.

[2] G2/06