Court of Justice of the European Union
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Press and Information

Judgment in Case C-364/13
International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks

An organism which is incapable of developing into a human being does not constitute a human embryo within the meaning of the Biotech Directive

Accordingly, uses of such an organism for industrial or commercial purposes may, as a rule, be patented

The Directive on the legal protection of biotechnological inventions[1] provides that uses of human embryos for industrial or commercial purposes are considered unpatentable.

In its judgment in *Brüstle* of 18 October 2011,[2] the Court held that the concept of a 'human embryo' includes unfertilised human ova whose division and further development have been stimulated by parthenogenesis,[3] since such ova are, just like embryos created by fertilisation of an ovum, capable of commencing the process of development of a human being.

The case before the High Court of Justice (England and Wales) involves a dispute between International Stem Cell Corporation (ISCO) and the United Kingdom Intellectual Property Office regarding the patentability of processes covering the use of parthenogenetically-activated human ova. The High Court asks the Court whether the concept of 'human embryo', as interpreted in the judgment in *Brüstle*, is limited to organisms capable of commencing the process of development **which leads to a human being**. In that regard, the High Court of Justice explains that, according to current scientific knowledge, organisms such as those which are the subject of the applications for patent registration are not capable of developing into a human being.

In today's judgment, the Court holds that, in order to be classified as a 'human embryo', **a non-fertilised human ovum must necessarily have the inherent capacity of developing into a human being.** Consequently, **the mere fact that a parthenogenetically-activated human ovum commences a process of development is not sufficient for it to be regarded as a 'human embryo'**.

By contrast, where such an ovum does have the inherent capacity of developing into a human being, it should be treated in the same way as a fertilised human ovum, at all stages of its development. In that regard, it is for the High Court of Justice to determine whether or not, in the light of knowledge which is sufficiently tried and tested by international medical science, the organisms which are the subject of ISCO's applications for registration have the inherent capacity of developing into a human being.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

[1] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13).
[2] Judgment in *Oliver Brüstle* v *Greenpeace eV* (Case C-34/10), see also Press Release No 112/11.
[3] Parthenogenesis consists in the activation of an oocyte, in the absence of sperm, by a variety of chemical and electrical techniques and the organism thus created is called a 'parthenote'.

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