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Press and Information

Advocate General's Opinion in Case C-364/13
International Stem Cell Corporation v Comptroller General of Patents

According to Advocate General Cruz Villalón, an ovum whose development has been stimulated without fertilisation and which is not capable of becoming a human being cannot be considered a human embryo

However, if this ovum is genetically manipulated in such a way that it can develop into a human being, it must be regarded as a human embryo and as such excluded from patentability

The Biotechnology Directive[1] sets out the rules regarding the patentability of biotechnological inventions. According to the Directive, the human body in any stage of its development cannot constitute a patentable invention. However, an element isolated from the human body or otherwise produced by means of a technical process may be subject to patent protection. Nevertheless, inventions whose commercial exploitation is contrary to *ordre public* or morality are excluded from patentability. In this context, uses of human embryos for industrial or commercial purposes are not patentable.

International Stem Cell Corporation (ISC), a biotechnology company, applied to the UK Intellectual Property Office for two national patents for a technology that produces pluripotent stem cells[2] from parthenogenetically-activated[3] oocytes. The Office rejected both applications on the grounds that the inventions in question entail uses and even the destruction of human embryos and are therefore not patentable under the *Brüstle*[4] judgment of the Court of Justice. In this judgment the Court stated that any non-fertilised human ovum whose development has been stimulated by parthenogenesis and which is capable of commencing the process of development of a human being constitutes a "human embryo".

ISC appealed the decision of the Office to the UK courts. It claims that as the activated oocyte, in the absence of paternal DNA, is not capable of becoming a human being, the restrictions on patentability resulting from the *Brüstle* judgment do not apply to its technology.

The High Court of Justice, hearing the case, has asked the Court of Justice whether unfertilised human ova whose development has been stimulated by parthenogenesis and which are not capable of becoming human beings should be considered as human embryos.

In his Opinion today, Advocate General Pedro Cruz Villalón considers that, when assessing if an unfertilised ovum should be regarded as a human embryo, the decisive criterion to be taken into consideration is whether **it has the inherent capacity of developing into a human being.** By contrast, the mere fact that an unfertilised ovum is capable of engaging in a process of cell division and differentiation similar to that of a fertilised ovum does not suffice in itself to consider it as a human embryo. The observations submitted by the parties as well as the explanations given by the

[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] Pluripotent cells can develop into all cells that make up the body, but not into extra-embryonic tissue such as the placenta and hence cannot develop into a human being. These cells can be used to treat numerous heretofore incurable diseases.
[3] Parthenogenesis refers to the initiation of embryogenesis without fertilisation by activation of an oocyte in the absence of sperm. Such activation can be induced with a variety of chemical and electrical techniques. The activated oocyte contains a single or double set of maternally derived chromosomes but does not contain any paternal DNA.
[4] Case C-34/10 *Oliver Brüstle* v *Greenpeace* (see also Press Release No 112/11).

High Court of Justice suggesting that the parthenotes, organisms resulting from parthenogenesis, do not as such have the inherent capacity of developing into a human being, the Advocate General proposes to the Court **to exclude them from the definition of human embryos**.

However, in the light of successful genetic manipulations conducted on mice, Mr Cruz Villalón cannot exclude the possibility that, in the future, human parthenotes can be altered genetically in such a way that they can develop to term and thus into a human being. For this reason, the Advocate General makes it clear that **parthenotes can only be excluded from the concept of "embryos" to the extent that they have not been genetically manipulated to become capable of developing into a human being.**

Finally, the Advocate General emphasises that, in his view, even if human parthenotes are to be excluded from the concept of human embryos, the **Directive does not prevent a Member State from excluding parthenotes from patentability on the grounds of ethical and moral considerations.** He is of the view that, by excluding human embryos from patentability, the Directive only expresses a minimum, EU-wide prohibition, whilst allowing the Member States to extend the prohibition of patentability to other organisms on the basis of ethical and moral considerations.

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.
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 EU 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.

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