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Press and Information

Opinion of the Advocate General in Case C-34/10
Brüstle v Greenpeace eV

According to Advocate General M. Yves Bot, totipotent cells carrying within them the capacity to evolve into a complete human being must be legally classified as human embryos and must therefore be excluded from patentability

Nor can a procedure using other embryonic stem cells, known as pluripotent cells, be patented where it first requires the destruction or modification of the embryo

Mr Oliver Brüstle holds a patent, filed in December 1997, which concerns isolated and purified neural[1] precursor[2] cells, produced from human embryonic stem cells used for the treatment of neural defects. According to information provided by Mr Brüstle, the first clinical applications have already been developed, in particular for patients suffering from Parkinson's disease.

On the application of Greenpeace eV, the Bundespatentgericht (Federal Patent Court, Germany) declared Mr Brüstle's patent invalid, in so far as it related to procedures allowing precursor cells to be obtained from human embryonic stem cells.

The Bundesgerichtshof (Federal Court of Justice, Germany), to which Mr Brüstle had appealed, decided to stay proceedings and refer questions to the Court of Justice on the interpretation, in particular, of the term "human embryo", which is left undefined by European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions.[3] The questions concern, essentially, whether the exclusion of the human embryo from patentability concerns all stages of life from the fertilisation of the ovum or whether other conditions must be satisfied, such as the attainment of a certain stage of development.

As a preliminary, the Advocate General, Mr Yves Bot, makes the point that the Court is being called upon for the first time to consider the concept of 'use of embryos for industrial or commercial purposes' contained in Directive 98/44. Having stated at the outset his awareness of the extreme sensitivity of that question and the importance of the philosophical, moral, human, economic and financial issues at stake, the Advocate General begins his legal analysis by stating that, since the directive pursues the objective of establishing effective and harmonised legal protection of biotechnological inventions, the embryo needs to be given an autonomous definition in EU law. That analysis is supported by the first interpretations by the Court in its case-law concerning that directive.

After pointing out the major divergences existing between the legislation of the Member States and the impossibility, in the current state of scientific knowledge, of using a criterion of that nature capable of being recognised by all the Member States, the Advocate General fixes upon the wording of the directive, which, in Article 5(1), protects 'the human body, at the various stages of its formation and development'.

[1] Neural cells are defined as immature cells which are capable of forming mature nervous system cells, such as neurons.
[2] i.e. immature body cells which are still able to multiply. These precursor cells have the capacity to develop and differentiate into specific mature body cells.
[3] 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 231, p. 13).

He then observes that totipotent cells, appearing after fusion of the gametes and existing in that form only for the first days of development, have the essential characteristic of carrying within each of them the capacity to develop into a complete human being. **Thus, those cells, since they represent the first stage of the human body which they will become must be legally classified as embryos, the patentability of which must be excluded.** This definition therefore covers unfertilised ova into which a cell nucleus from a mature cell has been transplanted and unfertilised ova whose division has been stimulated by parthenogenesis in so far as totipotent cells would be obtained in those ways.

Similarly, the **blastocyst stage of development**, reached around five days after fertilisation, **must also be classified as an embryo**, since, according to the Advocate General, the principle of human dignity, to which the directive refers[4], is a principle which must be applied not only to an existing human person, to a child who has been born, but also to the human body from the first stage in its development, i.e. from fertilisation.

By contrast, **pluripotent embryonic stem cells, taken in isolation, do not fall within the definition of an embryo, since, individually, they are no longer capable of developing into a complete human being**. They can 'only' differentiate themselves into various organs forming parts of the human body. It is those cells which are concerned by the invention concerned by Mr Brüstle's patent, their removal from the embryo taking place at the blastocyst stage.

However, it is not possible to ignore the origin of these embryonic stem cells. The fact that they come from some stage in the development of the human body is not in itself a problem, provided only that their removal does not result in the destruction of that human body at the stage of its development at which the removal is carried out. In the opinion of the Advocate General, it must therefore be agreed that **inventions relating to pluripotent stem cells can be patentable only if they are not obtained to the detriment of an embryo, be that it's destruction or its modification**.

To make an industrial application of an invention using embryonic stem cells would amount to using human embryos as a simple base material, which would be contrary to ethics and public policy.

In conclusion, the Advocate General considers that an invention cannot be patentable where the application of the technical process for which the patent is filed necessitates the prior destruction of human embryos or their use as base material, even if the description of that process does not contain any reference to the use of human embryos.

The Advocate General observes, however, that the patentability of uses of human embryos for industrial or commercial purposes is not prohibited under the directive where it concerns only inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it – for example to correct a malformation and improve its chances of survival.

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 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.

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[4] Article 5 and sixteenth recital of Directive 98/44.

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