



Press and Information

Court of Justice of the European Union

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Judgment in Case C-34/10
Oliver Brüstle v Greenpeace e.V.

A process which involves removal of a stem cell from a human embryo at the blastocyst stage, entailing the destruction of that embryo, cannot be patented

The use of human embryos for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it is patentable, but their use for purposes of scientific research is not patentable

Mr Oliver Brüstle is the holder of a patent, filed on 19 December 1997, which concerns isolated and purified neural precursor¹ cells produced from human embryonic stem cells used to treat neurological diseases. According to the information supplied by Mr Brüstle, there are already clinical applications, particularly for patients suffering from Parkinson's disease.

On application by Greenpeace e.V., the Bundespatentgericht (Federal Patent Court, Germany) ruled that Mr Brüstle's patent was invalid in so far as it covers processes for obtaining precursor cells from human embryonic stem cells.

The Bundesgerichtshof (Federal Court of Justice, Germany), hearing Mr Brüstle's appeal, decided to refer questions to the Court of Justice concerning the interpretation of, in particular, the concept of 'human embryo' which is not defined in Directive 98/44/EC on the legal protection of biotechnological inventions². The question is whether the exclusion from patentability of the human embryo covers all stages of life from fertilisation of the ovum or whether other conditions must be met, for example that a certain stage of development be reached.

On examination of the concept of 'human embryo', the Court points out firstly that it is not called upon to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive. Thus, the context and aim of the Directive show that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. It follows, in the view of the Court, that the concept of 'human embryo' must be understood in a wide sense. Accordingly, the Court considers that any human ovum must, as soon as fertilised, be regarded as a 'human embryo' if that fertilisation is such as to commence the process of development of a human being. A non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis must also be classified as a 'human embryo'. Although those organisms have not, strictly speaking, been the object of fertilisation, due to the effect of the technique used to obtain them they are capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so.

As regards stem cells obtained from a human embryo at the blastocyst stage³, – those which are concerned by the invention introduced by Mr Brüstle's patent – the Court finds that it is for the referring court to ascertain, in the light of scientific developments, whether they are capable of

¹ Precursor cells are immature corporeal cells which are still able to multiply. They are able to develop and change into particular mature corporeal cells. Neural precursor cells are defined as immature cells which can form mature cells in the nervous system, for example, neurones.

² 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).

³ A later stage of embryonic development considered at a certain point in time, almost five days after fertilisation.

commencing the process of development of a human being and, therefore, are included within the concept of 'human embryo'.

Next, the Court examines whether the concept of 'uses of human embryos for industrial or commercial purposes', not patentable, also covers the use of human embryos for purposes of scientific research. Thus, with regard to the latter use, the Court notes that the grant of a patent for an invention implies, in principle, its industrial or commercial application. Although the aim of scientific research must be distinguished from industrial or commercial purposes, the use of human embryos for the purposes of research which constitutes the subject-matter of a patent application cannot be separated from the patent itself and the rights attaching to it. In that regard, the use of human embryos for purposes of scientific research which is the subject-matter of a patent application cannot be distinguished from industrial and commercial use and, thus, avoid exclusion from patentability. Consequently, the Court concludes that scientific research entailing the use of human embryos cannot access the protection of patent law. Nevertheless, the Court points out that the patentability of uses of human embryos for industrial or commercial purposes is not prohibited under the Directive where it concerns the use for therapeutic or diagnostic purposes which are applied to the human embryo and which are useful to it – for example to correct a malformation and improve the chances of life.

Finally, the Court answers the question on the patentability of an invention involving the production of neural precursor cells. It points out, firstly, that this presupposes that stem cells are obtained from a human embryo at the blastocyst stage and, secondly, that the removal of a stem cell entails the destruction of that embryo. Not to exclude from patentability such an invention claimed would allow a patent applicant to avoid the non-patentability by skilful drafting of the claim. In conclusion, the Court holds that an invention is excluded from patentability where the implementation of the process requires either the prior destruction of human embryos or their prior use as base material, even if, in the patent application, the description of that process, as in the present case, does not refer to the use of human embryos.

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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The [full text](#) of the judgment is published on the CURIA website on the day of delivery.

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