

## European court of justice clamps down on human embryonic stem cell patents

A decision of the European court of justice has severely restricted the ability to obtain patents for stem cell-based inventions in Europe. The court has ruled that inventions that use or incorporate human embryonic stem cells cannot be patented – a position which contrasts with that taken in countries such as the USA. This decision applies to both stem cells obtained directly from human embryos, and also to inventions using human embryonic stem cell lines.

The court's decision does not prevent research using embryonic stem cells taking place. However, the decision may influence the availability in Europe of therapies based on such technologies, since many companies are unwilling to commercialise their products without the benefit of patent protection. The decision should not adversely impact inventions using stem cells from adult or artificial sources, and these remain promising candidates for future therapies. However these technologies are currently less developed than those based on embryonic cells.

### Background

Stem cells, which have the capacity to develop into a range of cell types, are viewed as promising therapeutic agents, able to replace or regenerate diseased or damaged tissues throughout the body. Embryos represent a rich source of high quality stem cells, which may be used directly, or in the form of embryo-derived cell lines.

European laws governing the patentability of biotechnology inventions prevent patenting of the use of human embryos for industrial or commercial purposes since such uses cause the destruction of the embryo. However, prior to last week's decision it had not been clear whether this ban also extended to the uses of embryos for scientific research, or to methods or products based on embryonic cell lines.

The European court of justice had been asked to consider a referral from the German national court (the Bundesgerichtshof) in the case of *Brüstle v Greenpeace e.V.* This case involved Greenpeace's attempt to seek annulment of a German patent that Professor Brüstle had obtained in connection with neural precursor cells that may be used in the treatment of neurological defects.

Prof. Brüstle had invented a method by which embryonic cells obtained from blastocysts could be turned into neural precursors, potentially providing an almost unlimited supply of such cells. He had patented the neural progenitor cells, and their therapeutic use, as well as their methods of production from embryonic cells.

Greenpeace had sought to have the patent annulled on the basis that it contravened the ban on patenting of inventions relating to the use of human embryos for industrial or commercial purposes.

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Before ruling on this annulment, the Bundersgerichtshof asked the European court of justice to decide:

1. What is meant by the term “human embryo” for purposes of European patent law (the German court will then determine whether this should be taken to encompass the blastocysts used in Prof. Brüstle’s invention);
2. Whether the expression “use of human embryos for industrial or commercial purposes” applies to uses for scientific research; and
3. Whether the bar to patentability applies only to inventions that explicitly refer to the use of a human embryo, or whether it also encompasses inventions that concern or make use of products that require earlier use (and so destruction) of an embryo.

The answers provided would determine how the European law in this matter is to be applied across all EU member states.

### The court’s judgement

The court indicated that the term “human embryo” must be “understood in a wide sense”. A human embryo should be taken as coming into being immediately post-fertilisation, and the term is to be given a broad interpretation, effectively covering any group of cells “capable of commencing the process of development of a human being”. In coming to this conclusion the court was clear that its interpretation encompasses not only a fertilised ovum, but also non-fertilised ova able to develop into a human (whether as a result of nuclear transfer or parthenogenesis).

It was left to the German national court to decide whether this definition encompassed the blastocysts used in Prof. Brüstle’s patent, though it would certainly seem likely that this will prove to be the case.

In answering the second question the court stressed that, while the purpose of the law in question was not to regulate scientific research using human embryos, the existence of a patent application connected with such research indicated that the research in question had an industrial or commercial aim. As a result, even patent applications in which human embryonic stem cells were used for scientific research should fall within the scope of this law.

Finally, in addressing the third question, the court considered that it was not essential that a claim of the patent application directly referred to the destruction or use of an embryo. If implementation of the invention would require prior destruction of an embryo then the invention cannot be patented, irrespective of the fact that this destruction is not recited as part of the claims.

The court was very clear that the position taken encompassed products or processes utilising embryonic stem cell lines where “destruction [of an embryo] may occur at a stage long before the implementation of the invention”. Furthermore, their decision was intended to ensure that the exclusion to patentability should not be rendered redundant by “allowing a patent applicant to avoid its application by skilful drafting of the claim” to avoid specifically referring to use of a human embryo.

The court’s decision sends a clear message that any technologies that involve the destruction of human embryos to provide stem cells will not be patentable in Europe, even if this destruction is not directly referred to in the claims. The only inventions using human embryos capable of patent protection are those that provide a benefit or therapy for the embryo itself.

The decision means that patent prosecution in Europe will have to move towards inventions using stem cells from sources other than embryos. Inventions utilising induced pluripotent stem cells, or stem cells from adult tissues or cord blood, will not be impacted by this case, and so will remain patentable. Technological developments may also give rise to inventions that will be allowable in future, if these enable human embryonic stem cells to be obtained without destruction of the embryo.

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