Embryonic stem cell derivations are not patentable in the EU

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The Court of Justice of the European Union (CJEU)\(^1\) ruled in *Brüstle v Greenpeace*,\(^2\) that processes involving derivation of stem cells from a human embryo at the blastocyst stage, entailing the destruction of that embryo, cannot be patented.

*Brüstle* concerns a patent for isolated and purified neural precursor cells derived from human blastocysts. Central to the case was the interpretation of Article 6(2)(c) of Directive 98/44/EC (the Biotech Directive),\(^3\) which excludes patentability of inventions involving “the use of human embryos for industrial or commercial purposes.”

The CJEU decision followed Advocate General Yves Bot’s March 2011 opinion that neither totipotent nor pluripotent stem cells from an embryo that has been modified or destroyed are patentable. In reaching its decision, the CJEU held that the definition of an “embryo” should be read broadly, to include any fertilized ovum whether created by transfer of a nucleus from another mature cell or stimulated to cell division by parthenogenesis. Further, the CJEU decided that processes involving a human embryo are only patentable if therapeutic or diagnostic purposes are applied to and are useful to the human embryo.

**The CJEU decision**

The CJEU determined that the intent and purpose of the Biotech Directive was to remove any possibility of patentability where human dignity could thereby be harmed. Thus, the concept of “human embryo” must be understood broadly. Accordingly, the CJEU ruled:

- Any human ovum after fertilization, any non-fertilized human ovum into which the cell nucleus from a mature human cell had been transplanted and any non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis constitute a “human embryo.”
- The referring court should ascertain whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a “human embryo” within the Directive’s meaning. However, it was clear from the CJEU’s ruling that such a cell line would not be patentable.
- The use of a human embryo for therapeutic or diagnostic purposes which were applied to the human embryo and were useful to it are *prima facie* patentable.
- If an invention does not itself “use” human embryos, but relates to a product necessitating prior destruction of a human embryo or a process requiring a base material obtained from such destruction, then that invention would not be patentable.

Some research has shown that human embryonic stem cells offer advantages in cellular therapies over other cell lines. By holding that inventions relating to processes for deriving cells from human embryos, or cell lines derived from those processes, are not patentable, the CJEU has reduced the scope within the EU of proprietary protection.
for inventions relating to embryonic stem cells. Its decision that the definition of embryo should encompass cells derived from parthenogenesis as well as any fertilized ova may also affect those with rights in cell lines and processes covering cell lines derived from fetal tissue.

The decision does not mean such processes or cell lines are not valuable or protectable. Research and innovation will go on and will likely be protected as trade secrets. This could mean that discoveries may be held closely, rather than shared in the scientific community.

There is concern in the industry that in the absence of patent protection, European companies and universities may find it harder to obtain funding for research, and investment may shift to markets that afford patent protection. Because Europe retains a significant knowledge base, it is likely research funding will go on; indeed, because of the Brüstle decision, activities enabling stem cell technologies, adult stem cells and iPS cell technologies may grow. In the race toward cellular therapies, companies with pioneering processes using human embryonic stem cell lines will have to decide whether to apply for patent protection in such countries, with no prohibition on others reproducing their work in Europe, or decide not to file for patent protection anywhere, keeping their knowledge confidential and thereby keeping a competitive edge.

The CJEU decision has firmly placed protection of commercial rights in embryonic cell lines, the processes to derive such stem cells and the application of those lines in cellular therapy into the realm of contractual rights. It remains to be seen whether the Brüstle decision will affect stem cell research toward therapeutic applications in the EU.

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1. Formerly the European Court of Justice (ECJ).
2. Case C-34/10 Oliver Brüstle v Greenpeace e.V.