

## The CJEU liberalises the patentability of embryonic stem cell research

---

The Court of Justice of the European Union (CJEU), the highest Court in Europe, has clarified its earlier guidance and lifted the ban on the patenting of embryonic stem cells made from unfertilised eggs, known as parthenotes.

Thus, there is light at the end of the tunnel for companies engaging in embryonic stem cell research. This ruling serves to limit the earlier Brüstle decision of the CJEU, which we have reported previously ([see here](#)).

Prior to this ruling, it was increasingly difficult to obtain patent protection for embryonic stem cells and associated research in Europe. The use of "human embryos" is excluded from patentability in Europe. The Brüstle decision gave a broad interpretation of "human embryos" that covered parthenotes, because they were considered to be capable of commencing the process of developing a human being. This broad interpretation substantially reduced the subject matter that was patentable in this arena.

### **Questions referred**

This ruling resulted from the referral of Case C-364/13 International Stem Cell Corporation v Comptroller General of Patents to the CJEU.

The question referred was "Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term "human embryos"...?" (emphasis added).

The UKIPO rejected two of the International Stem Cell Corporation's patent applications that relate to parthenogenetically activated oocytes that contain the maternal derived genetic material but lack paternal chromosomes. The lack of paternal chromosomes means that these parthenotes are incapable of developing into a viable human being. The applications were rejected because the UKIPO applied the findings of the Brüstle decision that stated that parthenotes were considered to be "human embryos" because they are capable of commencing the process of developing a human being. The rejections were appealed to the UK high court, and the question was referred to the CJEU because it is not clear from the Brüstle decision whether a parthenote was considered to be a "human embryo" simply because it can commence the process of developing into a human being, or if the process also needs to be capable of producing a viable human being.

The CJEU liberalises the patentability of embryonic stem cell research

---

Often, before the CJEU hands down their ruling, a member of the Advocates General is asked to provide the court with an independent legal opinion on questions before the court. In July 2014, the Advocate General (AG) delivered his opinion on the referred question, which we have reported previously, ([see here](#)) indicating that parthenotes should not be considered to fall within the term "human embryos" as long as they are not capable of developing into a human being and have not been manipulated to acquire such a capacity.

### **The decision**

The CJEU followed the AG's opinion and found that in order to be classified as a "human embryo", a non-fertilised human ovum must necessarily have the inherent capacity of developing into a human being. Thus, merely commences the process of development is not sufficient for exclusion.

This means that parthenotes fulfilling these criteria i.e., embryonic stem cells that can commence the process of development but are not capable of developing into a human being, are now patentable in Europe.

### **Practical tips**

The CJEU has left it to the national Courts to determine whether the organisms disclosed in a patent application from which the embryonic stem cells are derived have the inherent capacity of developing into a human being.

Therefore, we recommend that going forward European patent applications involving embryonic stem cells are drafted to make it clear that the organisms used do not have the inherent capacity of developing into a human being. Supporting experimental data should be included if available.

For existing patent applications, supporting evidence may need to be filed to prove that the organisms used do not have the inherent capacity of developing into a human being.

Please contact your usual Forresters attorney if you would like more advice in this respect.

The CJEU liberalises the patentability of embryonic stem cell research

---

## **Conclusion**

This decision is widely welcomed by those working in embryonic stem cell research. It opens up an avenue for alternative methods for obtaining embryonic stem cells that could be afforded patent protection and should lead to more investment in embryonic stem cell research - helping Europe retain its edge in this field.