

The advocate general's opinion provides hope for the patentability of stem cell research

In light of the Brüstle decision of the Court of Justice of the European Union (CJEU), that we have reported previously, it is 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 is patentable in this arena.

A further case has been referred to the CJEU, Case C-364/13 International Stem Cell Corporation v Comptroller General of Patents. The case refers the question "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.

In July, the Advocate General delivered his opinion on the referred question 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 Advocates General are members of the CJEU and provide the court with an independent legal opinion on questions before the court. Their opinions are not binding on the court, but if followed, it would mean that parthenotes fulfilling these criteria are now patentable in Europe.

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Such a decision would be widely welcomed by those working in stem cell research. It would open up an avenue for alternative methods for obtaining stem cells that could be afforded patent protection. It would also lead to more investment in stem cell research, and help Europe retain its edge in this field.