

# Kluwer Patent Blog

## IPO decision ‘stems’ from Brüstle

Brian Cordery (Bristows) · Wednesday, October 3rd, 2012

The UK IPO has applied the decision of the CJEU in *Brüstle* on stem cells in a recent case that is likely to lead to more judicial comment on the patentability of stem cell inventions. *In International Stem Cell Corporation\**, the applicant appealed the Examiner’s rejection of two patents, relating to methods of producing human stem cells and corneal tissues derived from such stem cells, where those stem cells are produced using parthenogenesis (i.e. the development of an embryo without fertilisation) to activate a human oocyte.

The Hearing Officer (who hears internal appeals at the UK IPO) therefore had to apply the CJEU’s decision in *Brüstle*, where the CJEU had sought to define “human embryo” for the purpose of Article 6(2)(c) of Directive 98/44/EC (the Biotechnology Directive), which excludes from patentability the uses of human embryos for industrial or commercial purposes. The CJEU had held that in addition to any ovum after fertilisation, non-fertilised human ova whose division and further development have been stimulated by parthenogenesis fell within the concept of a human embryo, as these ova were capable of commencing the process of development of a human being. According to the CJEU, inventions relating to such cells therefore fell within the meaning of Article 6(2)(c) and were not patentable. Additionally, the CJEU had held that if the invention required the prior destruction of a human embryo then it would also not be patentable.

This obviously presented the applicant with a problem in the present case. The applicant therefore sought to argue that the CJEU had erred in fact in stating that non-fertilised ova subject to parthenogenic stimulation were just as capable of commencing the process of development into a human being as an embryo created by fertilisation of an ovum, which had led the CJEU to rule (allegedly incorrectly) that they were human embryos. Whilst it was accepted by the IPO that the UK Courts as well as the IPO were entitled to disregard a finding of fact made by the CJEU which was not itself based on a finding of fact made by the referring court if it considered that the CJEU was clearly incorrect, the UK IPO held that the CJEU had not made a finding of fact that was subject to challenge.

On appeal, the applicant emphasised that the cells in question were not capable of developing into human beings and adduced evidence to support this, a factual finding that was accepted by the Hearing Officer. However, the Hearing Officer ruled that the CJEU had focussed its assessment of the definition of a ‘human embryo’ on the start of the developmental process and paid less attention to whether or not the process could be completed. Indeed the latter approach had been suggested in the opinion of the Advocate General but not adopted by the CJEU. The question in this case was not therefore whether the cells in question could develop into human beings but

simply whether or not the entity in question consisted of a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis, the Hearing Office holding himself to be bound by the CJEU's finding that this constituted a human embryo for the purposes of the Biotechnology Directive.

Having made this finding, the Hearing Officer also had to decide whether the stem cells and corneal tissues derived from the parthenogenetic oocytes were themselves patentable. The applicant argued that it was possible to derive the claimed stem cells and tissue without destroying the material held to be a human embryo, referring to an academic paper published after the priority date but which referred to earlier work in the field. However, the Hearing Officer held that the teaching of the patent applications by themselves appeared solely to disclose methods which would inevitably result in the destruction of the 'human embryo' and thus the claims to the stem cells and corneal tissues were excluded from patentability. It will be interesting to see whether the Court, to which any appeal of the decision lies, will also apply the same 'sufficiency' of disclosure test when considering this exclusion to patentability.

\*BL O/316/12

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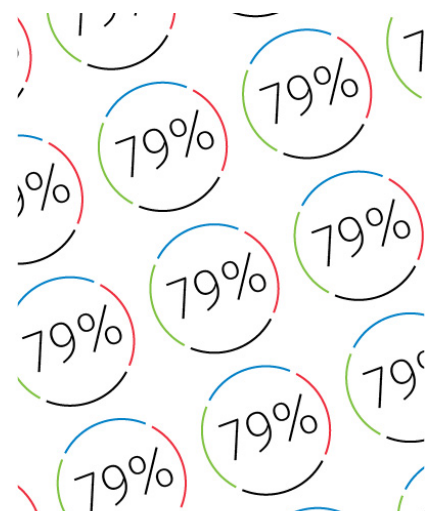
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