

## UK IPO stem cell decision that raise questions concerning the Brüstle decision

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Two UK applications were rejected by a UK examiner on the ground that they constituted the *'use of human embryos for industrial or commercial purposes'*, which is excluded from patentability. The applications met the other requirements for patentability.

A final decision on these applications was suspended until the referred questions on the Brüstle case were answered by the Court of Justice of the European Union (CJEU), because the decision would have a direct bearing on these applications.

Both applications are directed to methods for producing human stem cells/tissues that use parthenogenesis to activate the oocyte. The key issue is whether or not the activated oocytes produced by the claimed methods fall within the definition of a 'human embryo', and hence whether or not the claimed methods fall within the excluded category. The UK examiner's position was that the activated oocytes fell within the definition of a 'human embryo'. The CJEU's decision confirmed the examiner's position, and stated that although such activated oocytes had not, strictly speaking, been the object of fertilisation; due to the effect of the technique used to obtain them **they are capable of commencing the process of development of a human being**.

The applicant argued that the CJEU's decision was based on factually incorrect information because such activated oocytes are not capable of developing into a human being. On this basis, and in line with established case law, the applicant argued that the CJEU's decision should not be binding on the UK IPO.

The UK IPO agreed, based on evidence provided by the applicant that the activated oocytes could not develop into a human being due to inherent biological limitations. However, they noted the distinction that the CJEU's decision merely indicated that they were **capable of commencing** this developmental process, rather than **completing** this process. Therefore, they reached the decision that the CJEU's decision could not be ignored and refused the two applications.

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The case has been appealed to the UK High Court. It will be interesting to see if a UK national court believes that they can depart from the findings of the CJEU based upon the specific facts of the case in question.