The Court of Justice of the European Union (CJEU) has recently delivered its judgement in case C 34/10 which concerned the patentability of inventions involving human embryonic stem cells. The CJEU ruled on the interpretation of Article 6(2)(c) of European Directive 98/44/EC which excludes from patentability uses of human embryos for industrial or commercial purposes. This Directive has been implemented into both UK and EPO law and thus its interpretation and the decision of CJEU will effect practice both at the EPO and UKIPO.

The CJEU decision
The CJEU decided that the term "human embryo" should be interpreted broadly in the exclusion to include any entity that is "capable of commencing the process of development of a human being". Such entities include a fertilised human ovum at any developmental stage (assuming that the fertilisation will begin the process of development into a human being), a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted (assuming this is capable of beginning the process of development into a human being) and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis (assuming that this is capable of beginning the process of development into a human being).

Further, the CJEU ruled that the use of human embryos occurs if the implementation of the invention requires the destruction of a human embryo, even if the claims of the patent do not refer to the use or destruction of a human embryo. The CJEU indicated that the destruction includes destruction of a human embryo at any stage and thus encompasses destruction of a human embryo before the development of the invention.

UKIPO's implementation of the decision
The UKIPO have now issued a practice note on how they will implement the CJEU decision on the patentability of inventions involving human embryonic stem cells. It is indicated in the note that where an invention requires the use of cells that originate from a process which requires the destruction of a human embryo, the invention is not patentable at the UKIPO. This includes inventions requiring the use of a human embryonic stem cell line which was originally established by the destruction of a human embryo.

The UKIPO have indicated that human stem cells that are not derived from human embryos e.g. induced pluripotent cells and adult stem cells, are not excluded from patentability and patents for inventions concerning such cells will be granted provided that they meet the usual requirements for patentability.

Further, the UKIPO will continue to issue patents for inventions that are for therapeutic or diagnostic purposes that are applied to and useful to the human embryo, provided again that these meet the usual requirements for patentability.
EPO's implementation of the decision

The EPO have included a new passage in their Guidelines for Examination in light of the CJEU ruling. In this regard, the EPO indicate that “a claim directed to a product, which at the filing date of the application could be exclusively obtained by a method which necessarily involved the destruction of human embryos from which the said product is derived is excluded from patentability”. Again, the EPO indicate that the point in time when the destruction takes place is irrelevant.

The EPO further state that when examining subject matter relating to human embryonic stem cells, the entire teaching of the application should be considered and the relevant disclosure in the description should be examined in order to establish whether products such as stem cell cultures are obtained exclusively by the use and destruction of a human embryo. The disclosure is considered in view of the state of the art at the date of filing.

Similarly to the UKIPO, the EPO indicate that therapeutic or diagnostic inventions which are applied to the human embryo and which are useful to it are not excluded from patentability.

Summary

Thus, the EPO and UKIPO's positions on the patentability of inventions relating to human embryonic stem cells may be different. Particularly, the EPO's use of the term "exclusively" implies that inventions involving human embryonic stem cells, which can be obtained by a method which does not necessarily require the destruction of a human embryo at the filing date of the application, may not be excluded.

Further advice

If you would like any further advice please contact us at Dehns using the details below.