

Patenting Human Embryonic Stem Cells in Europe

In 1996 the European Parliament voted into law the EU Biotechnology Directive. The primary purpose of the Directive was to harmonise across EU member states the law regarding what can and cannot be patented in the field of biotechnology. One of the provisions of this Directive was that inventions relating to “*the commercial use of human embryos*” would not be deemed patentable. What exactly this exclusion was supposed to cover was not clear from the wording, and it was left up to the tribunals of the European Patent Office to determine the scope of the exclusion.

The question was first considered by the Opposition Division of the European Patent Office (in the case of European Patent No: 065 351 - the “Edinburgh” Patent) who decided that human embryonic stem cells (hESC’s) per se, in both pluripotent and totipotent forms, and processes for their production, should be excluded from patentability as the technical realisation of these inventions involved the “commercial use of human embryos”. The Decision also noted that other types of stem cells, such as adult stem cells, and stem cells obtained from cord blood, would not be excluded from patentability.

The question was revisited more recently in November 2008 by the Enlarged Board of Appeal, the most senior tribunal of the European Patent Office. In the case of the so-called “WARF” patent, the Enlarged Board decided that inventions directed to processes for producing human embryonic stem cells, and hESC’s per se, shall not be patentable if the process for producing the cells *as described in the patent* necessarily involves the destruction of a human embryo.

Thus, many of the early patents directed to hESC’s, and processes for their production, will be revoked as the only way of performing the invention as described in these patents as filed necessarily involved destruction of a human embryo. This



finding is made irrespective of the fact that many of the processes could be enabled today without involving destruction of a human embryo, for example through use of deposited hESC lines or iPS.

This Decision clarifies that hESC's, and process for their production, may be patented at the European Patent Office provided that the technical realization of the invention as described in the patent does not necessarily involve the destruction of a human embryo.

If you require further information about this decision, or any other Life Sciences matter, please contact Barry Purdy at barry@purdylucey.com.