Stem cells

Stem cells are undifferentiated cells that can differentiate into many different adult cell types or can divide to produce more stem cells. Particularly of interest are 'pluripotent' stem cells which are able to differentiate into any adult cell type. Such cells are valuable tools in repairing damaged tissues or replacing damaged organs. Furthermore, stem cells derived from a patient's own tissues can avoid the problems of rejection that are found with donated tissues or organs.

However, the production of pluripotent human embryonic stem cells (hES cells) can involve the destruction of human embryos, raising moral questions. The European Patent Convention (EPC) contains a provision, Art. 53(a) EPC, which prohibits an invention from being patented if exploiting it commercially would be contrary to morality. In 1998 the European Union provided guidance in relation to the morality of patenting biotechnological inventions in EU Directive 98/44/EC (the "Biotech Directive"). The Biotech Directive directs that certain biological inventions are excluded from patentability. Inventions excluded from patentability on moral grounds include "*uses of human embryos for industrial or commercial purposes*". This exclusion was implemented within the EPC: EPO Rule 28.

Subsequently, the question of human stem cell patentability was referred to the Court of Justice of the European Union (CJEU) in Brüstle v Greenpeace (C-34/10), on Brüstle's patent EP 1040185B9 . In their ruling, the CJEU confirmed that a process which involves removal of a stem cell from a human embryo at the blastocyst stage, entailing the destruction of that embryo, cannot be patented. They gave a broad interpretation of 'embryo' to include a parthenote (a proto-organism produced from an unfertilized ovum, which is incapable of developing beyond the early embryonic stages due to the absence of paternal DNA).

The patent prospects would be more favourable if the destruction of the human embryo could be avoided. In May 2003, hES cell lines were first deposited and made available and in January 2008 Chung Y. et al., Cell Stem Cell 2008, 2(2), 113-117 published a process for obtaining human embryonic stem cells from human blastocytes without having to destroy the human embryo blastomere biopsy (SBB). This publication was taken into account in an EPO decision T1441/13 (on patent application EP02799217A-WO03/050249) where the EPO allowed stem cell claims on the basis that embryo destruction was no longer needed. Thus, human embryonic stem cell patent applications may now avoid objections under Article 53(a) and Rule 28(c) of the EPC, provided the stem cells can be obtained without destroying human embryos.

In a dispute involving the International Stem Cell Corporation the English Patent Court referred questions to the CJEU regarding the patentability of parthenotes. In December 2014 the CJEU handed down its decision (C-364/13), holding that in order to be classified as a human embryo, a non-fertilised human ovum would need the inherent capacity to ultimately develop into a human being which was not the case with parthenotes. .

Stem cell inventions which do not require the destruction of human embryos are not affected by the morality exclusion of the EPC. The exclusion does not apply to non-human embryonic stem cells; or to pluripotent stem cells which can be derived from adults; or in circumstances where the hES cells are derived from an umbilical cord. An example of a patent in this field is UK patent GB2427873B, which claims a differentiation method for making heart muscle preparations from pluripotent stem cells such as hES cells. The EPO will also grant patents that concern products such as culture apparatus or culture media that are suitable for use with hES cells. For example, European patent EP1809739B1 claims cell culture media for the proliferation and scale-up of hES cells.

Whilst the number of EP patent applications is now rapidly increasing, patent applications in this area still need to be very carefully written. They should disclose methods of obtaining stem cells which do not involve embryo destruction. Non-contentious uses and methods should be described in patent applications, as far as is possible. Additionally it must be remembered that claims to medical methods are not permitted in EP patents.

For historical patent applications, depending on the filing date, the EPO may also allow the introduction of 'disclaimers' in the claims so as to disclaim human embryos from the claimed subject matter. Disclaimers may of course pose problems from a sufficiency point of view if at the filing date the only way to work the invention would have been to destroy an embryo. The table below illustrates when the use of disclaimers is appropriate and should be permissible.

Filing Date	Technology	Sufficiency	Disclaimer
Before 2003	hES cells derived from destruction of embryos	Claim insufficient if disclaimer used (G1/03)	Not permitted (G1/03)
2003 - 2008	hES cell lines available	Claim sufficient	Should be permitted
After 2008	hES cells can be derived by non-destructive methods	Claim sufficient	Not required

We have explained the general principles of protecting inventions relating to stem cells in this AL Factsheet but it is only an introduction, and any live situation will need individual assessment. Please contact us if you need more detailed information.