Is there light at the end of the tunnel?

It is clear from an emerging practice of the European Patent Office (EPO) that they were not widely impressed by the controversial Brüstle decision issued by the Court of Justice of the European Union (CJEU).

The EPO has adapted its practice to be consistent with the Brüstle decision. However, it has also taken a position that will allow companies working in the area of stem cell research to obtain patent protection for their products and methodologies, by indicating that it will allow inventions that utilise human embryonic stem cell lines that have been established using a method that does not destroy the human embryo.

This emerging practice of the EPO could have a great impact on the future of stem cell research in Europe.

EPO previous practice

In Europe, inventions that necessitate the use of human embryos have been excluded from patentability for some time.

Prior to the issuance of the Brüstle decision the EPO's practice was that:

- a product, which 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;
- a product, which could be obtained from an established human embryonic stem cell line is patentable, provided the product fulfils the other requirements of patentability, because obtaining the product did not directly involve the destruction of a human embryo.

Brüstle decision

The main purpose of the Brüstle decision was to clarify the meaning of the term 'human embryo'. However, the CJEU also stated that the exclusion of human embryonic stem cells, and other products, was relevant to the destruction of a human embryoat any point in history.

EPO current practice

The EPO has stated, when adapting its practice in line with the Brüstle decision, that the exclusion to patentability can no longer be avoided by exclusively obtaining the stem cell/product indirectly from an established human embryonic stem cell line that required the destruction of a human embryo. At some point in history a human embryo has been destroyed to establish the cell line and any products derived, either directly or indirectly, are now excluded from patentability.

Accordingly, the EPO has changed its practice to:

- a product, which could be exclusivelyobtained by a method which necessarily involved the destruction of human embryos from which the said product is derived is excluded from patentability; the point in time at which such destruction takes place is irrelevant

There have been great concerns that this change in practice will severely limit the scope of protection available in the area of stem cell research and for other products obtained from human embryos.

EPO emerging practice

It appears that all may not be lost!

A new technology, Single Blastomere Biopsy (SBB), published for the first time in 2008 enables stem cells, and other products, to be obtained from a blastocyst that does not result in the destruction of the human embryo.

Based on the existence of this technology, at least one examining division of the EPO has stated that inventions directed to products obtained from cell lines established using this technology are not excluded from patentability.

The reasoning behind this new stance is that the human embryonic stem cell lines have be established using anon-destructive methodology; and the existence of such established cell lines means that the claimed invention does not constitute a new use of a human embryo.

In contrast, any method directed at manufacturing such cell lines would be excluded from patentability because, despite that fact that the methods are non-

destructive, the methods are anew use of a human embryo. Hence, it is only once a cell line has been established that stem cells, products and associated methods that are derived from such established cell lines are not excluded from patentability, provided they meet the other requirements of patentability.