The obstacles to obtaining protection for human embryonic stem cells in Europe!

The patentability of human embryonic stem cells and associated products in Europe has followed a bumpy road over the last few years. The use of 'human embryos' is excluded from patentability in Europe.

What is considered to be a human embryo?

In the Brüstle decision, of the Court of Justice of the European Union (CJEU) in 2011, gave a broad interpretation of 'human embryos' that covered unfertilised eggs, known as parthenotes, because they were considered to be capable of commencing the process of developing a human being. This broad interpretation substantially reduced the products that were patentable in this arena.

At the end of 2014, the CJEU clarified its earlier guidance and lifted the ban on the patenting of embryonic stem cells made from parthenotes. The CJEU found that in order to be classified as a "human embryo", a non-fertilised human ovum must necessarily have the inherent capacity of developing into a human being. Thus, merely commencing the process of development is not sufficient for exclusion from patent protection. This means that parthenotes fulfilling these criteria i.e., embryonic stem cells that can commence the process of development but are not capable of developing into a human being, are now patentable in Europe.

Has a human embryo been destroyed?

A big question on whether or not human embryonic stem cells and associated products can be afforded patent protection is whether or not a human embryo has been destroyed in their development.

Prior to the Brüstle decision, it was possible to obtain protection for human embryonic stem cells derived from established cell lines. The reasoning behind the European Patent Office's (EPO's) approach was that the use of the established cells did not necessitate the further use a human embryo, despite the fact that a human embryo had, at some point, been destroyed to establish the cell line.

The Brüstle decision stated that subject matter was not patentable if, at some stage, it was necessary to destroy a human embryo to arrive at the invention. This meant that human embryonic stem cells and associated products that utilised established cell lines were no longer patentable because a human embryo had been

destroyed to establish the cell line. This provided an even greater limitation on the protection available in this arena.

The EPO are not bound by decisions of the CJEU, but have changed their practice in light of the Brüstle decision and will no longer grant patents for products obtained by methods that resulted in the destruction of a human embryo at some stage. However, new technology published in January 2008 (Chung et al.) enables human stem cells, and other products, to be developed from blastocysts that do not result in the destruction of the human embryo. For applications having a filing date after January 2008, protection can be afforded because the stem cells, and other products, can be obtained without destroying an embryo. However, this only applies if the stem cells or product can be derived from the specific methods in Chung et al. If evidence can be provided to show that earlier methods were available that did not destroy an embryo; then the EPO may afford protection to applications filed after this earlier date.

Can a disclaimer help?

A patent claim directed to human stem cells and/or other products may encompass products obtained from both destructive and non-destructive methodologies. In the past, the EPO has allowed applicants to disclaim products obtained from destructive methodologies by using the wording:

"with the proviso that [the invention] does not use human embryonic stem cells that have been obtained by destruction of a human embryo"

However, it has been determined in a decision by an EPO Opposition Division (on the Brüstle case) and a recent decision by an EPO Appeal Board that such a disclaimer cannot be used on cases having a filing date prior to January 2008. In each case, such a disclaimer was considered to add subject matter because no methods were disclosed in the application, or known in the art, that were only and exclusively non-destructive to a human embryo.

This is a problem for patents granted with such a disclaimer that have a filing date prior to January 2008, because removing the disclaimer to overcome an added subject matter objection will be considered to impermissibly broaden the scope of protection after grant. This will be fatal to the case if no other narrowing amendment can be made to cover patentable subject matter. If such patents are not opposed, the patent proprietor may see different results in the different jurisdictions. The German courts did not consider such a disclaimer in the Brüstle

patent to add subject matter, but it is expected that other jurisdictions may follow the EPO's approach.

It has also not been tested what is meant by "only and exclusively", so even for applications filed after January 2008, there is a question mark over the use of such disclaimers. The need for a disclaimer may be obviated if it is only necessary to show that non-destructive methodologies were known. In the absence of clear guidance, it would be safer to avoid introducing such disclaimers.

Conclusion

The likelihood of obtaining patent protection for human embryonic stem cells and associated products in Europe has improved greatly since the Brüstle decision.

Our practical tips are to include only non-destructive methodologies in the patent application, which may help avoid the need for a disclaimer, and ensure that your patent applications are drafted to make it clear that the organisms used do not have the inherent capacity of developing into a human being. Supporting experimental data should be included if available.