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hES cell patents in Europe – what's the point?

In "hES cell patents in Europe – the inescapable Brustle trap?", we discussed the controversy regarding hES cell patents in Europe following the ECJ's controversial "Brustle" decision. As a reminder, the ECJ's decision has been interpreted to mean that use of hES cells from established cell lines obtained by "destructive methods" is not patentable.

In spite of this, you may be able to get claims granted by the European Patent Office (EPO) which on their face encompass hES cells. But is there any point in getting claims like this granted, or is there freedom to operate?

Before we start, we need to distinguish between:

- use of hES cells obtained from cell lines whose creation involved destroying a human embryo to obtain the originator hES cells ("destructive methods"); and
- use of hES cells from cell lines whose creation did not involve destroying a human embryo ("non-destructive methods").

"Destructive methods" used to be the only way to generate hES cell lines, but in 2008, Chung's group published a method for obtaining hES cells non-destructively [Cell Stem Cell, Volume 2, Issue 2, 113-117, 7 February 2008]. Although there is some controversy over the exact date at which "non-destructive methods" became available, whether a patent was filed pre-Chung or post-Chung is currently decisive in determining patentability at the EPO. It may also be decisive in determining enforceability.

For post-Chung patents, it's likely it will be possible to enforce claims against parties using hES cells obtained by "non-destructive methods". The worry is if a Court finds that because a human embryo was "used" to make the hES cell line, the use of hES cells from the cell line is unethical even if the embryo wasn't destroyed in the process. It's less clear whether it would be possible to enforce pre-Chung patents against uses of hES cells obtained non-destructively, but it may be possible to do so. However, industry does not tend to use hES cells obtained in this way.

Most hES cells used in industry have been obtained by methods that would be deemed "destructive" even though the initial destruction of a human embryo to produce the originator cells may have occurred many years ago and the hES cells are now available without any further destruction of embryos. The big question is whether it would be possible to enforce patents against use of this type of hES cell? In EU countries, where the ECJ's decision is binding, it is thought that patents will not be enforceable against uses of hES cells obtained by "destructive methods". This means there would be a huge gap in patent protection. Our experience at the EPO suggests that Examiners require amendment of the examples in the patent to make it clear that it does not cover hES cells obtained by destructive methods. This may make it difficult to

argue that these patents cover hES cells obtained in this way. Enforcement of hES cell patents has not yet been tested, but if Courts take this view, there will be freedom to operate with these hES cells in EU member states, irrespective of when the patent was filed. As the ECJ's decision is not binding on non-EU member states such as Switzerland, broad claims encompassing hES cells obtained by any method could be of some value there.

The only hope that remains for patent holders is that there has been some confusion as to what the ECJ's Brustle decision excludes and what it does not. If this is the case, it may be possible to enforce at least some patents against uses of hES cells obtained by "destructive methods".

The argument in favour of protection is that the ECJ's Brustle decision does not exclude from patentability the use of all hES cells obtained by "destructive methods". It only excludes "inventions" which "require" the use of hES cells obtained by "destructive methods" because they could not be practised with any other cells at the filing date of the patent. Provided the invention could be practised with a cell other than an hES cell obtained by a "destructive method" at the filing date there is arguably no excluded subject-matter and such patents should be enforceable against parties using hES cells obtained by "destructive methods". This would be the case for both post-Chung and pre-Chung patents, but the argument is stronger for post-Chung patents. It would be interesting, although likely very challenging, to see whether it would be possible to convince a Court of this alternative interpretation. It may even require a further referral to the ECJ. However, if it turns out to be possible, then there is a point to hES cell patents (at least post-Chung ones) after all.

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