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epi Position Paper on Patentability of Human Embryonic Stem Cells (hESCs) following CJEU Decision C-34/10 (Oliver Brüstle vs. Greenpeace)

Background

This paper sets out the comments of the epi on the policy that the EPO should follow concerning the patentability of human embryonic stem cells (hESCs). It takes account of the paper CA/PL 6/11 (put forward in November to the Committee on Patent Law, CPL) and the SACEPO Working Party Rules paper SACEPO/WPR 3/12, which is due to be considered at the meeting on Friday 3 February 2012.

Legal Basis

The European Patent Organisation decided to incorporate some (but not all) of the provisions of the EU Biotechnology Directive 98/44/EC dated 6 July 1998 into the EPC. In particular, these were Articles 5 and 6 and Recital 42. They were introduced, inter alia, into new Rule 28(c) EPC.

Article 6 says that inventions shall be considered unpatentable “where the commercial exploitation would be contrary to ordre public or morality”, which is further clarified (in paragraph 2c) which states that “uses of human embryos for industrial and commercial purposes” shall be considered unpatentable.

Impact on EPO practice

The EPO’s policy following this CJEU ruling can only be decided by the Board of Appeal (BoA). Thus the EPO needs a decision from the Technical Board of Appeal (or the Enlarged Board of Appeal) before it can change its existing practice. The Board of Appeal is the

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highest decision making organ within the EPO on substantive patent law, and thus legally speaking only the Board can decide the impact of this CJEU decision.

Thus only the Board of Appeal can therefore first decide whether (or not, as the case may be) the EPO is bound by this CJEU ruling (and if it is, in what way), or secondly how this decision should be interpreted by the EPO. Thus there should be no rush to immediately follow C-34/10 and change the EPO's practice (assuming that this would be the correct approach).

The question therefore arises as to what the EPO's policy should be in the meantime, before and until a decision by the Board of Appeal is given. This needs to be carefully considered, because the EPO must not refuse European patent applications on grounds that might be criticised or overturned by the Board of Appeal. At the current point in time, therefore, the EPO can therefore only guess as to what the Board will eventually decide regarding C-34/10.

The EPO does, though, need to consider how to deal with this Brüstle decision, even though as yet it has no guidance from the Boards of Appeal. A cautious approach therefore needs to be taken, otherwise the EPO could end up refusing patent applications on grounds which might later be considered by a Board of Appeal to be unfounded. Examining Divisions should not raise objections under Rule 28 that could later be ruled wrong by a BoA.

The EPO is, in effect, entering a new era here. This is the first time that a CJEU decision arguably affects the EPO's policy on what subject matter is patentable (or not). It is therefore an unusual situation legally. Furthermore, the issue of patentability of hESCs is controversial, especially as it includes moral and ethical aspects, and needs to be treated cautiously.

Legal Issues concerning C-34/10

The EPO, and in particular the Boards of Appeal, will first need to decide whether or not the CJEU decision is binding on the EPO. It is indeed true that the EPC now contains certain provisions of the EU Biotechnology Directive. However, it must be remembered that the EPO is not an EU organisation, as the EPC contains several non-EU states. Legal opinions, including those from EU lawyers, confirm this view, namely that the EPO is, in the strictest sense, not legally bound by the CJEU. Note also that in G2/06 the EPO decided that it did not have power to refer a question concerning interpretation of the Biotech Directive to the CJEU.

If a BoA decides that it is in fact bound by CJEU decisions, then arguably this will apply to all CJEU decisions, and not just C-34/10.

The EPO's view that it should not grant patents that will clearly be invalid in EU states is sensible (even though this may be contrary to the EPC). However, that raises the question of what precisely is in fact patentable in various EU member states in view of C-34/10. This has yet to be determined. Indeed, the German court will now have to decide, as a result of C-34/10, how that impacts on the patentability of the invention by Oliver Brüstle, and it has not yet made a decision. The epi thinks it would be sensible for the EPO not to "jump the gun", and implement a policy on patentability of hESCs without at least first seeing the decision from the German courts and waiting for a decision from a BoA.

It has to be remembered that, legally, national courts of the EU member states are only constrained to follow CJEU decisions if the issue under consideration by that court is "acte clair". In other words, if the facts of a case are sufficiently different from a CJEU decision, then the national court may reach a different conclusion. Indeed, in that case a further referral to the CJEU may even be necessary. For example, the Brustle patent has a relatively early priority date, of 19 December 1997. Courts may take a different view regarding later EP patent applications relating to hESCs, especially if (at the priority date) the invention could be practiced using a publicly available human ES cell line, without destruction of an embryo.

Note that current EPO policy is that if the priority (or filing) date is later than May 2003, when stem cell lines were publicly available, then Rule 28(c) does not apply, and the invention is not considered to be immoral under Article 53(a) EPC.

A Board of Appeal will also need to decide whether or not C-34/10 is contrary to TRIPS, in which Article 27(1) states that "patents shall be available for any inventions, whether products or processes in all fields of technology".

Interpretation of C-34/10 and question 3

The relevant legal provision is that inventions are unpatentable if they relate to "uses of human embryos for industrial and commercial purposes". It was on this provision that the three questions were referred to CJEU. The answer to the third question is perhaps the most important, where it is stated that an invention is not patentable where:

"the technical teaching which is subject matter of a patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and if the description of technical teaching claimed does not refer to the use of human embryos".

This quote is only one English translation of the answer to 3rd question, which was originally given in German. The CJEU initially issued a first English translation, which was later

amended. There is therefore some doubt over the exact meaning of the answer to question 3 in the German language, let alone exactly what it means in English.

The answer to question 3 would, at first sight appear to go beyond decision G2/06. This is because the EPO's current practice is to allow cases filed after May 2003 and where reliance can be made on a publicly available stem cell line. The practice of the EPO concerning deposited stem cells lines flows from the G2/06 decision, and any policy by the EPO, prior to a decision of the Boards of Appeal, that goes beyond G2/06 is arguably ultra vires. Decision C-34/10 arguably goes beyond G 2/06, and indeed the EPO's current policy (with the May 2003 threshold) and so a further BoA decision is needed to see if this indeed so. Note that G 2/06 only dealt with the situation where the performance of the invention "necessarily" involved the destruction of a human embryo. This is not the case for many later, downstream, inventions.

The law says that what is unpatentable is the commercial exploitation of inventions, not the making of the invention itself.

This is confirmed by paragraph 49 of C-34/10, which states that an invention is regarded as "unpatentable.....where the implementation of the invention requires destruction of human embryos". In other words, if the performance of the invention requires destroying human embryos, then it is unpatentable. That does not, however, mean that an invention is unpatentable if at some stage, far upstream and distant from making the invention, a human embryo was destroyed. In any event it may not be possible for the EPO (or indeed the applicant) to be absolutely sure that an embryo was in fact destroyed many years before the invention claimed, possibly by a third party and in a different country. Thus the EPO faces a real practical problem in that it will not be able to clearly check for embryo destruction, and so apply the law, when the invention claimed is so far removed and distant from any such destruction.

The answer to question 3 refers to the prior destruction of human embryos, or their use as base material, even if the technical teaching claimed does not refer to the use of human embryos. However, it is established and incontrovertible EPO law that the invention is defined by the claims, and supported by the description. So, as a practical matter, one cannot ignore the description, nor the scope of matter that is being claimed. Otherwise, every EP patent application, even ones that only in passing mention hESCs, become unpatentable.

The technical teaching of the patent application must therefore be considered, and cannot, as a practical mater, just be ignored. If, for example, a technical teaching refers to human ES cells, as well as other cell types, this must not be used to taint the entire application given that there may be non-ES cell aspects to the invention.

Thus, the epi considers that, when sensibly interpreted, the C-34/10 cannot render unpatentable an invention which clearly does not require the destruction of a human embryo. So, a method of producing pluripotent stem cells (iPS), for example by expressing an adult cell genes that are merely identified by screening human ES cells, should be patentable. In addition, new culture media or a culture vessels should be patentable, as the invention will be applicable to ES as well as non-ES cells. In a similar vein, methods of culturing or preserving cells should not be excluded, even if the claims cover culturing hECSs (as well as other cell types).

None of these inventions require the destruction of human embryos for its exploitation or performance, and therefore they must all be patentable.

Commercial Implications

Stem cell research is an extremely important and growing area of science. It is capable of huge potential, and shows enormous promise. It may be able to treat patients for diseases which otherwise do not currently have a cure, such as neurodegenerative disorders such as ALS and Parkinson's disease. It should be remembered that the EU actually funds research in this area. The EPO's mandate is to grant patents, and to encourage innovation in EPC states. It should not therefore deny patent protection for inventions arising from scientific research in this area, at least not until a Board of Appeal has decided on the impact of C-34/10.

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