

## **Ingrid Schneider nimmt Stellung zum Urteil des Europäischen Gerichtshofs zur Nicht-Patentierbarkeit von menschlichen embryonalen Stammzellen (C-34/10)/**

### **Ingrid Schneider comments on the European Court of Justice's ruling on embryonic stem cells (C-34/10)/**

In a final judgement, the European Court of Justice (ECJ) ruled on 18 October 2011 that any invention based on human embryonic stem cells which involves the prior destruction of human embryos or their prior use as base material cannot be patented.

In 1997, German Scientist Oliver Brüstle was granted a German patent neural precursor cells derived from human embryonic stem cell lines ([DE 19756864 C1](#)), patent family can be obtained at: <http://www.patentlens.net>

This German patent was successfully contested by the environmental NGO Greenpeace at the German Federal Patent Court (Bundespatentgericht). Following an appeal by Brüstle to the German Federal Court (Bundesgerichtshof), the ECJ was asked for a ruling. The ECJ was asked to clarify three questions arising from the EU biotechnology patent directive (98/44/EC). These included the definition of the term "human embryo", whether a patent filed for scientific research constituted "use of human embryos for industrial or commercial purposes", and whether procedures that indirectly involved embryonic stem cells were patentable.

In its decision-making the ECJ followed the opinion of the Advocate General, Judge Yves Bot. The ECJ has taken a broad definition of the human embryo, starting from the fertilised ovum, and also including human oocytes that have had their nucleus replaced by an adult human cell (SCNT embryos) as well as unfertilised ova that have been prompted to divide, (parthenogenetic embryos).

The ECJ has also taken a broad interpretation of the term "use" of the human embryo, stating that scientific research for which a patent is granted implies its industrial and commercial application. In this, it followed the Enlarged Board of Appeal of the European Patent Office (G2/2006).

Concerning the patentability of the invention in question which is based on human embryonic stem cells (hESC), the Court has made explicitly clear in its press release that "this presupposes that stem cells are obtained from a human embryo at the blastocyst stage and, secondly, that the removal of a stem cell entails the destruction of that embryo. Not to exclude from patentability such an invention claimed would allow a patent applicant to avoid the non-patentability by skilful drafting of the claim. In conclusion, the Court holds that an invention is excluded from patentability where the implementation of the process requires either the prior destruction of human embryos or their prior use as base material, even if, in the patent application, the description of that process, as in the present case, does not refer to the use of human embryos."

Thus, even though the Court has held pluripotent stem cells as such as patentable, it does not allow to circumvent the exclusion from patentability for human embryonic stem cells by skilful drafting of the claims, and by referring to the derivation of stem cells from a human blastocyst in the description of the application only, or by not mentioning the sourcing from human embryos at all. The Court thus does not interrupt the necessary logical and empirical chain of action (available human embryonic stem cell lines necessitate the derivation from human embryos and the embryo to be destroyed in this process) by legal means.

In my view, this is a good judgment, for several reasons:

1) The ruling confirms and specifies the concretized Ordre Public Clause in Article 6(2)(c) of the EU's biopatent Directive, which was one of the preconditions for the European Parliament to pass Directive 98/44/EC. It reaffirms the democratic process of interpreting this Ordre Public Clause as a Public Policy Clause entailing a modern mode of democratic, socio-political regulation of technological trajectories, in accordance with social values and norms (genuine European Ordre Public). The broad interpretation of both the legal concept of the human embryo, and the term "use for industrial and commercial purposes" is in accordance with the spirit, intentions and will-formation of the European Parliament. In its formation of political will in the 1990s, the Parliament intended to include any possible use of human embryos (except for recital 42, in which stating that the use is for therapeutic or diagnostic purposes for the particular embryo's sake itself - however not for any third party).

The ruling prevents patent attorneys and applicants to evade the law through creative drafting of patent claims.

2) The ruling is good for research, as it assures researchers' freedom to operate, without having to navigate patent thickets, and neither having to fear "innocent" nor "wilful" infringement of patents owned by other researchers. As stem cell research is still in its infancy, and as long as basic questions of safety and efficacy remain unresolved, clinical applications of hESC research are far away. Most of this basic research is state-funded anyway, and results are published according to the norms and rules of science. As research is paid by taxpayers, there is no reason for taxpayers to pay again for patent licences and high prices due to patent monopolies or stacked royalties. (Just as an annotation: the patent in question is owned by Oliver Bruestle himself, not by his university). Moreover, human embryonic stem cell research by and large is still basic research, and it does not make a lot of sense to have patents in basic research, as broad, unrestricted, universal sharing of elementary knowledge and skills is essential for the advancement of science.

3) The argument that exclusions from patentability may be difficult for start-ups, as providers of capital may refrain from investment, may have a certain validity. But here it must also be noted that pharmaceutical companies and venture capital have not invested heavily in stem cell research previously and would probably also not invest if patentability were possible, because clinical application is insecure and far away. Moreover, competitive leads can also be gained by first-mover advantages and other means, patents are neither the first nor the best economic strategy for clinical innovation.

Furthermore, it should not be forgotten that it was the explicit will of the European Parliament to remove incentives for what it has deemed unethical research (based on the use and destruction of human embryos). So should the incentive argument for patents be valid, then giving less incentives for research on human embryonic stem cell research - and thus redirecting research to ethically less controversial research on adult stem cells or reprogrammed (iPS) cells - is exactly what the European legislator intended.

4) The decision of the ECJ is very much in line with previous decisions of the European Patent Office (Edinburgh Case, WARF Case). In clarifying the interpretation of statutory law as codified by the European legislator, it harmonizes European patent law. In addition, it fosters the joint co-evolution of the dual pillar patent system of the European Patent Organisation on the one hand and the European Union on the other hand.

It will now be up to the German Federal Court to apply the European Court of Justice's ruling in making its final ruling on Brüstle's patent. The judgement of the ECJ will likewise be applied in any other national court of the EU member states hearing similar cases. The ECJ's

ruling will also have to be accounted for in the examination guidelines of the European Patent Office as well as of the national patent offices of the European Union's member states.

Therefore, in my conclusion, this has been a good day for democracy within the European patent law.

Hamburg, 18.10.2011

The EJC's press release is available at:

<http://curia.europa.eu/jcms/upload/docs/application/pdf/2011-10/cp110112en.pdf>

The full ECJ judgement can be found here:

<http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=rechercher&numaff=C-34/10>

### **Contributions to German newspaper articles:**

#### **Die Welt, 19.10.2011**

[http://www.welt.de/print/die\\_welt/politik/article13668377/Kein-Patent-auf-Embryo-Stammzellen.html](http://www.welt.de/print/die_welt/politik/article13668377/Kein-Patent-auf-Embryo-Stammzellen.html)

#### **"stern online", 18.10.2011**

<http://www.stern.de/wissen/mensch/grundsatzurteil-aus-luxemburg-eu-gericht-verbietet-patent-auf-embryonale-stammzellen-1739945.html>.