Leibniz Association

7. 12. 2011

Press Release by the Alliance of Scientific Organisations in Germany

Do Interpretations of the ECJ Judgment on Embryos Affect Stem Cell Research?

The Alliance of Scientific Organisations in Germany is concerned about possible negative consequences for research resulting from the decision by the European Court of Justice (ECJ) on the interpretation of the term "embryo". The Alliance argues that the ECJ judgment is not in line with current thinking within the German society and is concerned that research with human embryonic stem cells could be collectively discredited. In the following statement, which is largely based on a paper published by the Senate Commission on Genetic Research of the Deutsche Forschungsgemeinschaft (German Research Foundation), the Alliance demands that the judgment should only be applied to patentability.

In its Brüstle vs. Greenpeace (C-34/10) judgment of 18 October 2011, the European Court of Justice (ECJ) adopted a far-reaching interpretation of the term "embryo" and thereby triggered serious consequences for the debate on stem cells.

Irrespective of the fact that the decision was initially aimed exclusively at addressing questions related to patent law, the statements by the Court have since been interpreted by various parties in ways which extend far beyond questions of patentability. The Alliance of Scientific Organisations in Germany is well aware of the diverse ethical, legal, social and political challenges associated with the protection of the human embryo. The scientific organisations that form the Alliance have therefore always advocated the responsible treatment of embryos. They also support the high standard of protection that has been developed in Germany through a broad public and parliamentary debate, and which is embodied in the Embryo Protection Act and the Stem Cell Act.

There is concern that the judgment goes beyond its immediate jurisdiction and could cast a negative light on research involving human embryonic stem cells (hESC) and morally discredit researchers in the field. Although the judgment does not directly affect research with induced pluripotent stem cells (iPS), which is ethically without controversy, it may have indirect and unintended implications for further research in this area, since hESCs represent an important benchmark for possible therapies based on iPS cells.

In Germany, very high standards on research with hESC were already in place long before the Stem Cell Act came into force in 2002, and this field is still a topic of controversial debate today. With its judgment, the ECJ has attempted to create an unequivocal position, which is not consistent with the current position within German society or that of neighbouring European countries. Even the EU Directive on the legal protection of biotechnological inventions (98/44/EC) itself was preceded by ten years of controversial discussion prior to its approval, since there was no universally accepted definition of the term "embryo" in Europe. This is still true today, as shown by the most recent case law from the European Court of Human Rights (ECHR) on the protection of the unborn child and the Austrian Reproductive Medicine Act. However, this time the ECJ does not provide room for interpretation, which is different from previous cases in which EU members were given broader ranges for interpretations of European laws concerning protection of public order and morality. Furthermore, in this judgment the ECJ veers away from central principles of intellectual property law that

are set out in international trade law. This is particularly true with regard to the fact that it is no longer the commercial exploitation aspects of the invention that are the focus of patentability examinations, but the factual background conditions giving rise to an invention. Of course, the conditions under which an invention is made must comply with the prevailing civil (and criminal) legal framework, but these have no direct bearing on the question of (non-) patentability. This applies even more in that a patent neither includes permission for the patent holder to conduct research activities, nor does it represent an official permit for production or marketing. On the contrary, a patent merely protects the intellectual achievement of the inventor. Therefore, according to legal doctrine, patent law is not the proper place to establish a European-wide "ordre public", of whatever nature.

Therefore, any attempts to attribute validity to the judgment of the ECJ beyond the already complex issues of patentability, in particular those related to research funding, should be discouraged. Any such attempt is neither normatively nor methodologically sustainable, and exceeds the limits of any justifiable interpretation.

The Alliance of Scientific Organisations in Germany

The Alliance of Scientific Organisations in Germany is the joint body of the leading German scientific research organisations. Members of the Alliance include the Alexander von Humboldt Foundation, the German Academic Exchange Service (DAAD), the German National Academy of Sciences Leopoldina, the German Research Foundation (DFG), the Fraunhofer-Gesellschaft, the Helmholtz Association, the German Rectors' Conference (HRK), the Leibniz Association, the Max Planck Society and the German Council of Science and Humanities.