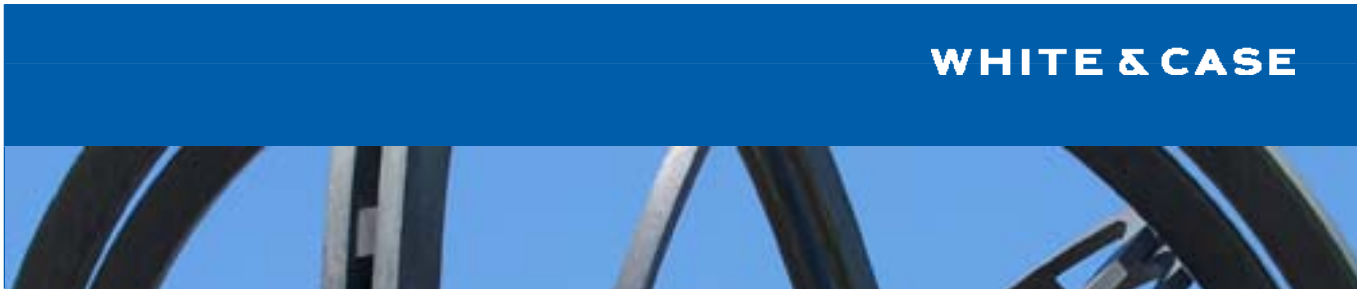

ECJ bans the patenting of hESCs: a new frontier in regulating R&D activities in Europe

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On 18 October 2011, the European Court of Justice (ECJ) rendered its decision regarding the patent-eligibility of human embryonic stem cells (hESCs), following the recommendation of the court's Advocate General that hESCs are not patent-eligible subject matter.[1] The Court was asked to give its opinion on the legality of the patentability of the use of stem cell techniques exclusively for research. It ruled against the patentability of this particular type of research on the basis that such use of embryos '*is not patentable*' and that '*the patenting of any processes, techniques and products in the European Union that involve stem cell research that involves destroying a human embryo on the basis of the fact that EU law protects human embryos from any use that could undermine their dignity*'.

The judgment states that any fertilised human egg is an embryo, that scientific research does fall within the scope of industrial or commercial purposes, and that the ban applies to any procedure that draws on stem cells created by destroying embryos. The decision from the European Court of Justice is a legal clarification for a court case brought by Greenpeace against a German scientist who patented a way to turn stem cells into healthy brain cells. However, despite the widespread protection of human embryos offered by this particular decision, the court does not enter into the wider debate regarding the limits of scientific research, but simply provides a legal interpretation of the Directive on the legal protection of biotechnological inventions. It should be noted though that the Directive does not mention embryonic stem cells, as the technology did not exist when the directive was discussed and adopted in 1998.

Background to the Decision C-34/10

The decision centered on the case of a University of Bonn researcher who in 1997 filed a patent on a technique to turn human embryonic stem cells into nerve cells (obtained 1999). According to the patent, the embryonic stem cells from which the neural precursor cells are created are pluripotent, which means that they have the potential to develop into all kinds of cell types, but not into a complete human being. In 2004, Greenpeace challenged Oliver Bruestle's patent, arguing that it allowed human embryos to be commercially exploited. Article 6(2)(c) of the Biotech Directive (98/44/EC) explicitly excludes - as being contrary to public order and morality - the patenting of the use of human embryos for industrial or commercial purposes and states that '*the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its*

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[1] http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&jurcdj=jurcdj&newform=newform&docj=docj&docop=docop&docnoj=docnoj&typeord=ALLTYP&numaff=&ddatefs=12&mdatefs=10&ydatefs=2011&ddatefe=19&mdatefe=10&ydatefe=2011&nomusuel=&domaine=&mots=&resmax=100&Submit=Rechercher

products, including the sequence or partial sequence of a human gene, cannot be patented.'

One of Brüstle's defenses against this argument was that it was not necessary to destroy human embryos in order to obtain pluripotent embryonic stem cells, as such cells can also be obtained by transplanting an unfertilised human ova with a cell nucleus from a mature cell, or by stimulating an unfertilised human ova into further development by means of parthogenesis.

Greenpeace argues that both methods lead to totipotent cells - capable of developing into a human being - and that these totipotent cells and all stages of development that follow are to be regarded as a human embryo. As these embryos will be destroyed when pluripotent embryonic stem cells are obtained, this would still fall under Article 6(2)(c), according to Greenpeace. Further points of debate were the questions whether the exclusion of the use of human embryos '*for industrial and commercial purposes*' also encompasses using embryos for scientific research, and whether the exclusion also applies when the use of the human embryo is not part of the technical teaching of the patent, but is a precondition for the application of said teaching.

The German Federal Court then decided Dr. Bruestle's patent was invalid on the basis of the German law that rules out the commercial use of human embryos. The researcher appealed the decision and Germany's Supreme Court (Bundesgerichtshof) referred the following questions to the ECJ:
1. What is meant by the term 'human embryos' in Article 6(2)(c) of the Biotech Directive ?
(a) Does it include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?
(b) Are the following organisms also included?
- unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted;
- unfertilised human ova whose division and further development have been stimulated by parthenogenesis?
(c) Are stem cells obtained from human embryos at the blastocyst stage also included?
2. What is meant by the expression 'uses of human embryos for industrial or commercial purposes'? Does it include any commercial use within the meaning of Article 6(1) of [the Biotech Directive], especially use for the purposes of scientific research?
3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive, even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching?
(a) because the patent concerns a product whose production necessitates the prior destruction of human embryos, or
(b) because the patent concerns a process for which such a product is needed as base material?

On 17 March 2011, the ECJ advocate-general, Judge Yves Bot, rendered an opinion that stem cell patents were 'contrary to ethics and public policy' because they required 'industrial use' of human embryos. This recommendation was not binding on the ECJ, but it was expected that the court would agree with the advocate-general since it is rare that such preliminary opinions are overruled. The possibility that the ECJ would adopt the Advocate General's position prompted several stem cell scientists in Europe to send a letter to the court, published in *Nature* on April 28th, expressing their "profound concern" and arguing that stem cells are cell lines, not embryos.

Summary of the ECJ's Judgment

The Court concluded that, given the context and objective of the directive, the EU lawmaker intended to exclude any possibility of patentability where human dignity could be affected. It said that the human body at the various

stages of its formation and development cannot constitute a patentable invention. It discussed the definition of 'human embryos' and their industrial and commercial use, stating that any fertilised human egg is an embryo, that scientific research does fall within the scope of industrial or commercial purposes, and that the ban on patentability applies to any procedure that draws on stem cells created by destroying embryos. The Court therefore confirmed that Member States do not have discretion with regard to the unpatentability of processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes. It emphasised that '*patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person*'.

The Court offered for the first time a definition of the concept of 'human embryo' recognising at the same time that this particular definition constitutes a very sensitive issue in many Member States, in light of their different traditions and value systems. The ECJ has stated that the exclusion from patentability set out in Article 6(2)(c) of the Directive *'does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it*.'

Comment

Although the Court was not called upon to discuss questions of a medical or ethical nature, but instead to restrict itself to a legal interpretation of the relevant provisions of the Directive, the judgment offered will have a series of multifaceted repercussions given the controversial nature of stem-cell technology, especially in Europe.

The ethical acceptability of research using embryonic stem cells, as well as of the patentability of the respective results and findings, has become the object of acrimonious debate and fierce discussion raising questions about the commercialisation of the human body and the patentability of human life. Such a decision should not be seen as a surprise given the European 'precedent' that exists on this matter (e.g., Decision in case G 2/06 of the Enlarged Board of Appeal of the European Patent Office ("EPO"), the relevant report of the **European Science Foundation** (**ESF**) and the relevant 2005 resolution of the European Parliament).

The ECJ Decision seems to broaden the protective scope of the Directive by rendering the entire human development process, starting from the stage of fertilisation, non-patentable by offering a wide definition of the term 'human embryo' -- considering it to be a human being with potential, and not just a 'potential human being'. The ruling may provide new impetus to research on alternative sources, such as stem cells taken from umbilical cord blood and iPS cells, obtaining pluripotent stem cells without destroying an entity that was capable of developing into a human being and reprogramming cells to turn them into stem cells.

The judgment does not refer to the patenting of the discoveries that result from the stem cell techniques but rather to the techniques themselves, thus leaving space for multiple interpretations. This is particularly so since the Court clarified that such research can be patented if it concerns use for therapeutic or diagnostic purposes '*which are applied to the human embryo itself and are useful to it.*'

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