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The Court of Justice of the European Union (CJEU) Decision on the Patentability of Human Embryonic Stem Cells - Brüstle v Greenpeace (C-34/10)

Summary of the Decision

On 18 October 2011 the CJEU answered questions that had been referred to it by the German Federal Court of Justice (BGH) concerning the exclusion from patentability of human embryonic stem cells. Whilst the ECJU took a very broad view of the exclusion and of what a 'human embryo' is, it left it to the referring court to decide on the question of the circumstances in which a stem cell obtained from a human embryo is still considered to be a 'human embryo'. The court also decided that scientific research using embryos fell within the 'industrial and commercial purposes' covered by the exclusion, and that the exclusion applied to any subject matter described in a patent document that required prior destruction of a human embryo, even if the patent document itself did not mention the process that caused destruction of the embryo.

The Biotech Directive

Inventions which are considered immoral are excluded from patentability in Europe. One of the purposes of the Biotech Directive[1] was to provide guidance on subject matter in the biotech area that was excluded from patentability for moral reasons. Article 6(2)(c) of the Biotech Directive deems 'uses of human embryos for industrial or commercial purposes' as unpatentable. Unfortunately the Directive provides little further guidance on the issue, and in particular does not specifically address the patentability of subject matter relating to embryo stem cell technology, given that this technology has mostly developed after the issuing of the Directive.

Background to the Present Decision

The present case arises from a nullity action brought by Greenpeace against a German patent that relates to neural precursor cells derived from human embryonic stem cells. Greenpeace argued that the subject matter of the patent was not patentable since it fell within the exclusion to patentability covered in Article 6(2)(c) of the Biotech Directive. The German Federal Court of Justice referred questions concerning the interpretation of this article to the CJEU. The questions that were referred and the answers that were given are shown in the attached annex.

Subject Matter that Falls Within the Exclusion

The CJEU looked at subject matter falling within the exclusion in two ways:

- the subject matter of the patent could directly relate to a human embryo. Thus the neural stem cells described in the German patent could be judged to be a 'human embryo'.

[1] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

- the subject matter of the patent could require prior destruction of a human embryo. In the present circumstances the neural stem cells are obtained from embryo stem cells, and obtaining embryo stem cells from a blastocyst stage embryo would have led to its destruction.

Continuing Uncertainty Over What the Term 'Human Embryo' Covers

In its answers the CJEU has given a broad interpretation to the term 'human embryo', considering fertilised human ova or unfertilised ova that are capable of development to be human embryos. However, an answer was not given to the crucial question of whether stem cells obtained from a human embryo at the blastocyst stage constitute a human embryo. Instead the CJEU said that the referring court would have to ascertain this 'in the light of scientific developments'.

The CJEU could have taken the opportunity to provide guidance as to the characteristics a cell must possess to be considered a human embryo, essentially providing a test that could be used to give a definitive answer in any given situation. Preamble (38)[2]of the Biotech Directive refers to processes for producing totipotent cells as being unpatentable, and so the CJEU could have devised a test based on whether the cell is totipotent. However the CJEU may not have wanted to give a blanket ruling excluding all pluripotent cells from being considered human embryos. In addition future developments might provide the means to make any human cell totipotent thus rendering meaningless any definition of 'human embryo' being based on the cell being totipotent.

Scientific Research

In its decision the CJEU made it clear that scientific research is regarded as being included within the 'industrial and commercial uses' mentioned in the exclusion. As a practical matter it is difficult to see how the claims of a patent application could be worded so that they were only directed to use of the subject matter in scientific research.

Prior Destruction of the Embryo

The CJEU held that the exclusion from patentability covers patents and application where the technical teaching requires destruction of a human embryo 'whatever the stage at which that takes place'. Thus subject matter that only relates to steps subsequent to destruction of a human embryo would still be covered by the exclusion. This of course prevents applicants from circumventing the exclusion by not mentioning in the patent application the step of obtaining cells from an embryo.

[2] (38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide referring courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability

However the CJEU failed to comment on the specific situation of where an embryo stem cell can be obtained from a cell line in a library at the filing date of the application. Although making the embryo cell lines that are now present in libraries did require destruction of embryos, once the cell lines are available in a library no further destruction of embryos is required.

The Position of the European Patent Office (EPO)

The Enlarged Board of Appeal of the EPO has already decided on the patentability of embryo stem cells in Decision G2/06 (Use of embryos/WARF). Rule 28(c) of the EPC is based on Article 6(2)(c) of the Biotech Directive and also excludes 'uses of human embryos for industrial and commercial purpose' from patentability. Decision G2/06 centred on the question of whether preparation of the relevant cells required destruction of an embryo at the filing date. Given that at the filing date embryo stem cells could only be obtained from an embryo, destroying the embryo in the process, the subject matter of the application was held to be unpatentable.

However from the present practice of EPO Examiners, it seems that applications in this area which are filed after embryo stem cells became available from libraries are deemed as no longer requiring destruction of an embryo. Thus the EPO is presently allowing applications relating to embryo stem cells as long as the filing date is late enough[3].

The Implications of the CJEU's Decision

The CJEU's decision ultimately fails to provide clear guidance on:

- the circumstances in which an embryo stem cell is still considered to be a 'human embryo', and

- whether the availability of embryo stem cell lines in libraries at the filing date means that subject matter relating to embryo stem cells is not considered as requiring destruction of an embryo.

Whilst this creates uncertainty it allows national patent offices and courts lee-way to decide on these issues. As a practical matter this will lead to a case-by-case analysis of patentability, and that is probably the best outcome for an area where both the technology and the moral acceptability of therapies using cells derived from embryos are changing rapidly.

[3] Epi Information September 2011, page 91 mentions that the Examiner on European Application No. 05740642.3 decided that 9 May 2003 was the point at which embryonic stem cells became publically available from libraries.

Annex

The German Federal Court of Justice asked the CJEU the following questions:

1. What is meant by the term "human embryos" in Article 6(2)(c) of [the 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 exploitation within the meaning of Article 6(1) of [the 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:

   – because the patent concerns a product whose production necessitates the prior destruction of human embryos,

   – or because the patent concerns a process for which such a product is needed as base material?

The CJEU answered these questions as follows:

1. Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that:

   – any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo';

– it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within the meaning of Article 6(2)(c) of Directive 98/44.

2. The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of Directive 98/44 also covers the use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it being patentable.

3. Article 6(2)(c) of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.