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EU Opines on the patentability of human embryonic stem cells

Brian Cordery (Bristows) · Monday, March 28th, 2011

On 10 March, the Court of Justice of the European Union ("CJEU") issued its long-awaited opinion on the patentability of human embryonic stem cells in *Brüstle v Greenpeace C-34/10*.

Biotechnological inventions are subject to *Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions* (the "Directive"). Article 6(1) provides that inventions must be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality. Article 6(2)(c) specifies that the use of human embryos for industrial or commercial purposes is unpatentable.

In 1997, Mr Brüstle filed a German patent for a method of producing neural precursor cells from human embryonic stem cells. These precursor cells, when transplanted into the nervous system, allow the treatment of numerous neurological diseases, such as Parkinson's disease. Greenpeace applied to invalidate the patent on the grounds that the human embryonic stem cells used in the invention originated from fertilised human eggs. The German Federal Patent Court partially invalidated the patent and Mr Brüstle appealed the decision to the German Federal Supreme Court. Before giving judgment, the court referred a number of questions to the CJEU regarding the interpretation of the Directive, in particular, the meaning of the term "human embryos", and whether the prohibition under Article 6(2)(c) extended to patents, which technical teaching did not include the use of human embryos but necessitated the prior destruction of human embryos or their use as a base material.

Advocate General Bot explained that the aim of the Directive was to harmonise protection throughout the Member States and therefore the term "human embryo" had to have a community understanding. He held that the concept of human embryo encompassed every stage of development from fertilisation of the egg to the formation of the human body, and included products of cloning techniques, where the nucleus from a mature human cell is transplanted into an unfertilised egg. Although the concept did not include pluripotent embryonic stem cells, which themselves do not have the capacity to develop into a human being, an invention was excluded from patentability where the application of the technical process for which the patent was filed necessitated the prior destruction of human embryos or their use as base material. The exception to the non-patentability of uses of human embryos for industrial or commercial purposes concerned only inventions for therapeutic or diagnostic purposes which were applied to the human embryo and were useful to it.

This opinion raises questions over the validity of previously granted human stem cell patents and

the future of investment by the life sciences industry in this area. If this decision is upheld by the CJEU, the research in Europe may have to move towards the use of induced pluripotent stem cells, which are artificially derived from non-pluripotent cells – typically adult somatic cells – and which do not involve the controversial use of human embryos.

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This entry was posted on Monday, March 28th, 2011 at 4:03 pm and is filed under Biologics, European Union, Exceptions to patentability, Scope of protection
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