Policy Paper PP13/13

Court of Justice case C-364/13 (International Stem Cell Corporation)

Introduction

The IP Federation represents the views of a significant number of major innovative UK companies in matters concerning intellectual property policy. A list of members is attached. Its members include a number of research-based biopharmaceutical companies that are committed to the discovery and development of therapies that extend and significantly improve lives, including cell therapy products.

The decision

Following a judgment in the High Court in the case International Stem Cell Corporation (ISCC) and Comptroller General of Patents [2013] EWHC 807 (Ch), the case has been referred to the ECJ. The case concerns an appeal in the UK High Court concerning two patent applications in the Legal Protection of Biotechnological Inventions. In particular, what was meant by the CJEU in Case 34/10 *Oliver Brüstle v Greenpeace eV* [2012] 1 CMLR 41 by the expression "capable of commencing the process of development of a human being"?

The IPO has asked for comments by **18 August 2013**.

The question referred to the court

The question referred to the Court of Justice of the European Union is:

> Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term "human embryos" in Article 6(2)(c) of Directive 98/44/EC on the legal protection of biotechnological inventions?

Background and context

Cell therapies may be defined as any treatment for a medical condition that employs at its core one or more types of viable human cells. This encompasses both use of the patient's own cells (autologous) and donor derived (allogeneic) cells including adult stem cells, adult somatic cells, embryonic stem cells, induced pluripotent stem cells and immune cells.

Cell therapy products are being developed for many different indications, such as diabetes, stroke, cancer, retinal disease or degenerative brain diseases. Continued investment in cell therapy research is critical for the development of new and effective ways of preventing serious, life-threatening illness.

The development of such unprecedented and complex products is lengthy and expensive. In order for such investment to be commercially viable, it is critical that the innovation underlying new cell therapy products can be subject to patent protection allowing a reasonable economic return.

This principle is clearly expressed in recitals (1) and (2) of Directive 98/44/EC on the legal protection of biotechnological inventions which reads as follows:

(1) Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development;
(2) Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

Brief legal arguments

The IP Federation would urge the UK to intervene in Court of Justice case C-364/13 (International Stem Cell Corporation) for the following reasons.

In the case International Stem Cell Corporation *v* Comptroller General of Patents, the UK High Court of Justice has posed questions to the Court of Justice of the EU (CJEU) asking whether unfertilised human ova whose division and further development have been stimulated by parthenogenesis (known as "parthenotes"), and which, in contrast to fertilised ova, contain only pluripotent cells and are **incapable of developing into human beings** are included in the term "human embryos" in Article 6(2)(c) of Directive 98/44/EC on the legal protection of biotechnological inventions?

Article 6(2)(c) of Directive 98/44/EC provides that the uses of human embryos for industrial or commercial purposes shall be considered unpatentable.

The term "human embryo" has been further interpreted in case C-34/10 of the CJEU (Oliver Brüstle v Greenpeace eV). In particular, in paragraphs (35) and (36), the court considered that a fertilised human ovum and certain categories of non-fertilised human ovum must be regarded as human embryos as they are "capable of commencing the process of development of a human being".

One aspect of the question asked by the High Court of Justice is therefore whether cells which do not have the capacity to develop into a human being, such as pluripotent cells, should be considered as included in the term "human embryos" in Article 6(2)(c) of Directive 98/44/EC.

We note that recital (38) of Directive 98/44/EC refers to processes to produce totipotent cells as an example of inventions that should be excluded from patentability as their commercial exploitation offends against *ordre public* or morality. Totipotent cells are capable of differentiating into any human tissue and have the capacity to develop into a complete human being, in contrast to pluripotent cells. Directive 98/44/EC does <u>not</u> suggest that pluripotent cells should be excluded from patentability. On the contrary, cell therapy products comprising pluripotent cells are examples of non-totipotent cells, frequently used in cell therapy programs, deserving

adequate legal protection mentioned in recitals (1) and (2) of Directive 98/44/EC.

Pluripotent cells used in therapeutic drug development programs include, for example:

- adult stem cells (ASCs), which can obtained from sources other than human embryo such as for example bone marrow, adipose tissue or placenta; and
- induced pluripotent stem cells (iPSCs) obtained by "reprogramming" of adult somatic cells.

Examples of UK preclinical or clinical programs involving ASCs or IPSCs can be found for example at http://ct.catapult.org.uk/.

We submit that the language "*capable of commencing the process of development of a human being*" as used by the CJEU in C-34/10 presupposes that the respective cells are inherently capable of developing into a human being. Such a construction appears to be reasonable not only from the language and context of the decision, which was concerned with totipotent cells, but also the legislative intent underlying the respective exclusion from patentability, i.e. the respect for human dignity.

Extending the meaning of "capable of commencing the process of development of a human being" to include cells which do not themselves have the capacity to develop into a human, such as pluripotent cells, would be detrimental to the innovative projects mentioned above as it could lead to the impossibility of validly protecting an invention related to pluripotent cells by a patent in the EU, thereby jeopardising the commercial viability of these projects, even though they do not relate to totipotent cells. Such interpretation would be contrary to recitals (1) and (2) of the Directive 98/44/EC and would be prejudicial to innovation in EU.

Request for intervention

We therefore urge the UK Government to intervene in this case and to argue that the question referred to the CJEU should be answered in the negative: i.e. cells capable of commencing the process of development of a human being but which do not have the capacity to develop into a human being, such as pluripotent cells, should NOT be considered as included in the term "human embryos". Such a position supports research in the cell therapy area in the UK and in EU and is consistent with the purpose of the Directive 98/44/EC to further research in biotechnology while fully safeguarding human dignity, morality and *ordre public*.

In closing we note that the Deputy Judge gave his own view on this issue in paragraphs 57 and 58 of the case. We agree with his view completely.

IP Federation
14 August 2013

IP Federation members 2013

The IP Federation represents the views of UK industry in both IPR policy and practice matters within the EU, the UK and internationally. Its membership comprises the innovative and influential companies listed below. Its Council also includes representatives of the CBI, and its meetings are attended by IP specialists from three leading law firms. It is listed on the joint Transparency Register of the European Parliament and the Commission with identity No. 83549331760-12.

AGCO Ltd
ARM Ltd
AstraZeneca plc
Babcock International Ltd
BAE Systems plc
BP p.l.c.
British Telecommunications plc
British-American Tobacco Co Ltd
BTG plc
Caterpillar U.K. Ltd
Delphi Corp.
Dyson Technology Ltd
Element Six Ltd
Eli Lilly & Co Ltd
ExxonMobil Chemical Europe Inc
Ford of Europe
Fujitsu Services Ltd
GE Healthcare
GKN plc
GlaxoSmithKline plc
Hewlett-Packard Ltd
IBM UK Ltd
Infineum UK Ltd
Johnson Matthey PLC
Merck Sharp & Dohme Ltd
Microsoft Limited
Nokia UK Ltd
Pfizer Ltd
Philips Electronics UK Ltd
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