The Court of Justice of the European Union clarifies when Human Embryonic Stem Cells can be patented

I. Introduction

On 18 December 2014, in *International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trade Marks* (C-364/13), the Court of Justice of the European Union (CJEU) delivered an important decision regarding the scope of the exclusion from patentability on morality-related grounds under Article 6(2) of the Directive 98/44/EC ("*Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions*"; hereinafter the "Biotech Directive").

The Court made first an important distinction between embryonic stem cell technologies based on fertilised human ovum and those based on unfertilised human ovum stimulated by parthenogenesis. The CJEU held, in particular, that a human ovum: *(i)* who is unfertilized and *(ii)* whose division and further development has been stimulated by parthenogenesis, is not a human embryo under Article 6(2)(c) of the Biotech Directive, if it in itself has not the inherent capacity of developing into a human being, this matter to be ascertained by the national court in the light of current scientific knowledge. It follows that stem cells obtained from such human ova cannot be considered unpatentable.

II. Legal context and background

The Biotech Directive affirms the patentability of inventions related to life forms, subject to some important exceptions. Indeed, the need to reconcile the objective of promoting research and investment with the protection of the right to life and the fundamental principles of ethics has led the EU legislator to exclude from patentability certain categories of biotech inventions, whose exploitation would be contrary to *ordre pubic* and accepted principles of morality. That is why Article 6(2) has been inserted into the Biotech Directive: this provision contains a non-exhaustive list of biotech inventions that cannot be considered patentable on morality-related grounds, including uses of human embryos for commercial or industrial purposes (see Article 6(2)(c) of the Biotech Directive).

The need to strike a balance between different (and often conflicting) needs and interests is clearly reflected in several recitals of the Biotech Directive:

- Recital 1: "*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*";

- Recital 2: "*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*";

- Recital 16: "*patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle 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 products, including the sequence or partial sequence of a human gene, cannot be patented*;

- Recital 37: "*the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against ordre public or morality must also be stressed in this Directive*".

In *Oliver Brüstle v. Greenpeace* (C-34/10, decision of 18 October 2011), the CJEU had already given an interpretation of human embryo under Article 6(2)(c) of the Biotech Directive – and had considered unpatentable stem cells obtained by destroying human embryos. The Court held, in particular, that EU law excludes "*any possibility of patentability where respect for human dignity could thereby be affected*", hence the term «*"human embryo"* [...] *must be understood in a wide sense*» (par. n. 34); then «*any human ovum must, as soon as fertilised, be regarded as a 'human embryo' within the meaning and for the purposes of the application of Article 6(2)(c) of the Directive, since that fertilisation is such as to commence the process of development of a human being*» (par. n. 35); this concept also includes "*a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis*" (par. n. 36).

Three years later in *International Stem Cell Corporation* the CJEU has had the chance to shed light on an issue left unclarified by *Brüstle*. The case started when the US biotech company, International Stem Cell Corporation, filed two applications for UK patents with the British Intellectual Property Office (IPO). The applications related to the use of oocytes activated by parthenogenesis and human stem cell lines. Following the CJEU's findings in *Brüstle* (see, eg, paragraph 36), the IPO held that these inventions were not patentable because "*capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so*": their economic exploitation would therefore constitute an unpatentable economic use of human embryos under Article 6(2)(c) of the Biotech Directive. The refusal to grant a patent was challenged by the applicant before the High Court of England and Wales, which then referred the case to the CJEU basically asking whether the ruling in *Brüstle* applies in relation to parthenogenetically-activated unfertilised human ova "*which in contrast to fertilised ova* [...] *are incapable of developing into human beings*".

III. The decision

Preliminarily, the CJEU noted that the definition of "*human embryo*" is an autonomous concept of EU law. Should it not be the case, as the Court also noted in *Brüstle*, the functioning of the European common market would be jeopardised: indeed, in the presence of different legislative definitions of "*human embryo*" among Member States, enterprises, researchers and scientists would be tempted to file their patent applications in the country that embraces the more restrictive definition of "*human embryo*" (paragraphs 25-28).

Then the Court – and this is the main point of the ruling – clarified that in order to constitute a "*human embryo*" for the purposes of the Biotech Directive, the stimulated ovum must have the "*inherent capacity to develop into a human being*". This is in contrast to its previous decision in *Brüstle* where the CJEU held that such an ovum would only constitute a '*human embryo*' if it were "capable of [just] *commencing* the process of development of a human being" (emphasis added). After *International Stem Cell Corporation*, therefore, the mere fact that a parthenogenetically-activated human ovum commences a process of development is not sufficient for it to be considered as a "*human embryo*".

The Court thus accepted the interpretation given by Advocate General Cruz Villalón, who had pointed out that the decisive criterion to determine what is and what is not "*human embryo*" within the meaning of the Biotech Directive is "***the inherent capacity*** *of developing into a human being,*

i.e. whether it really constitutes the functional equivalent of a fertilised ovum" (see para. 73 of the Opinion and para. 28 of the decision, emphasis added); the Advocate General had added that «*a parthenote* ***does not, per se, have the required inherent capacity*** *of developing into a human being and hence as such does not constitute a 'human embryo'*» (para. 74 of the opinion, emphasis added).

It is national courts – the CJEU added - that have to determine whether a parthenote may or may not develop into a human being on the basis of the actual knowledge of medical science. Should the answer be negative, such parthenote cannot be considered unpatentable under Article 6(2)(c) of the Biotech Directive.

The CJEU has been careful to label its decision as a clarification to its previous ruling in *Brüstle*. Obviously, the Court did not admit that in *Brüstle* it had committed a technical error or that it had misunderstood the science.

IV. Conclusion

This decision has already been welcomed by the European biotech and pharmaceutical industry as it will make easier for companies in this field to obtain patents for inventions from human embryonic stem cell research. To their eyes, the ruling will open the door for other patent applications using similar methods. Indeed, these industries strongly rely on patents to recoup the investments made to carry out research and development: in other words, without the possibility of relying on the monopolistic rents secured by patents, their business would be seriously jeopardised.

It thus seems that the decision in *International Stem Cell Corporation*, narrowing the scope of the exclusion from patentability on morality-related grounds, has basically rebuild trust in an industry which had been hit hard by the ruling in *Brüstle*. Indeed, the finding in *Brüstle* that all stem cells that had been obtained by destroying human embryos should be considered unpatentable, regardless of whether there is a capability to develop into a human being, had been strongly criticised as it would be capable of triggering a brain drain of stem cells researchers and scientists towards more business-friendly countries such as US and Japan.

The industry is thus convinced that the ruling in *International Stem Cell Corporation* will provide more legal certainty and encourage investments in a field which is considered by many commentators and scientists as key for the development of new medical treatments and drugs.

Yet, this decision might not turn out to be entirely beneficial to the industry. It could indeed be argued that, notwithstanding this ruling, EU Member States could still exclude parthenote-based inventions from patentability on morality-related grounds under the first paragraph of Article 6 of the Biotech Directive, according to which "[i]*nventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality*". This is a general clause "borrowed" from both the European Patent Convention (Article 53(a)) and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (Article 27, para. 2): it basically grants Member States wide discretion when it comes to excluding the patentability of subject matter on ethical grounds, as it has already been noted by the CJEU in *Brüstle* (see para. 29 of the decision).

The saga in the patentability of human embryonic stem cells in the EU might therefore not be over.

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