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Patentability of biotechnological inventions before the CJEU – A narrower construction of the "no-go zone" than in Brüstle or simply different facts?

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On 17 July 2014, Advocate General Pedro Cruz Villalón issued his opinion in Case C-364/13 *International Stem Cell Corporation v. Comptroller General of Patents*, whereby he proposed that the Court of Justice of the European Union ("CJEU") give the following response to a question referred by the High Court of Justice, Chancery Division (Patents Court), of England and Wales regarding the meaning of "human embryos" in article 6(2) (c) of Directive 98/44/EC: "Unfertilised human ova whose division and further development have been stimulated by parthenogenesis are not included in the term "human embryos" in 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 biotechnical inventions, as long as they are not capable of developing into a human being and have not been genetically manipulated to acquire such a capacity."

To use the Advocate General's words, such unfertilised human ova would not fall within the "no-go zone" that is common for all Member States as an expression of what has to be considered unpatentable in any case. To reach his conclusion, the Advocate General first reviewed the non-discrimination principle enshrined in article 27.1 of the TRIPS Agreement, although he did not really elaborate on its practical implications for resolving the case. He then moved his attention to article 52.1 of the European Patent Convention ("EPC"), although he did not extract any meaningful consequences either, perhaps being conscious that the CJEU lacks competence to interpret the provisions of the EPC. Finally, he looked to the European Union ("UE")'s legislative realm, that is, Directive 98/44/EC. After carefully reviewing the recitals and articles 5 and 6 of the Directive and noting that article 6(2) (c) of the Directive had been implemented in paragraph 3(d) of Schedule 2 to the Patents Act of 1977, which excludes from patentability "(d) uses of human embryos for industrial or commercial purposes", the Advocate General looked for guidance in *Brüstle* (Case C-34/10), considered the main precedent in this area to date.

When the *Brüstle* judgment was published, the rather restrictive conclusion reached by the CJEU was criticised among biotechnology R&D circles for discouraging research in this area. These concerns appeared to be embraced by the referring Court in the case discussed in this blog. As the Advocate General noted in paragraph 20 of his Opinion, the referring Court advanced its opinion that "if the parthenogenetically-activated oocytes at issue are incapable of developing into a human being, they should not be regarded as human embryos." The Advocate General also noted that "a different reading would, in the opinion of the referring Court, not strike the appropriate balance

between encouraging biotechnological research by way of patent law and respect for the dignity and integrity of the person, which the Directive was intended to achieve."

From then on, the Advocate General struggled to interpret the meaning of the sentence "capable of commencing the process of development of a human being" included in *Brüstle*. In particular, in paragraph 71 he highlighted that the CJEU, based on the specific information available to the Court in that case, "established a functional equivalence between fertilised ova, non-fertilised ova subjected to somatic-cell nuclear transfer and parthenotes." For the reader's benefit, it should be clarified that parthenotes are cells derived through "parthenogesis", which is a method whereby unfertilised ova are artificially induced into cell division by chemical and electrical techniques. Due to the absence of fertilisation, they lack paternal DNA and, therefore, cannot develop into human beings. In the last sentence of paragraph 71, the Advocate General added that "had the Court been aware of the fundamental difference between parthenotes and non-fertilised ova subjected to somatic-cell nuclear transfer and nevertheless wanted to establish a functional equivalence between the two, it would certainly have discussed this difference." And in paragraph 72, he concluded that "It is reasonable to assume that the observations submitted at the time in *Brüstle* caused the Court to have the impression that all three organisms possess the inherent capacity to develop into a human being." This paved the way for the conclusion reached by the Advocate General, based on "the facts stated unequivocally by the referring Court and the parties to the current proceedings", from which "it now appears that a parthenote does not, per se, have the required inherent capacity of developing into a human being and hence does not constitute a "human embryo" (paragraph 74). This led him to conclude that "Accordingly and with the one caveat that I shall come to subsequently, the question referred by the High Court has to be answered in the negative", meaning that the unfertilised human ova whose division and further development have been stimulated by parthenogenesis as described by the referring Court are not included in the term "human embryos" in article 6(2)(c) of the Directive. The caveat mentioned by the Advocate General is that if the parthenote were to be manipulated genetically so that it can develop into a human being, then it could no longer be patented (paragraphs 76-77).

This case has reopened the debate around finding the right balance between encouraging biotechnological research and the principles of bioethics. If the Opinion of the Advocate General is followed by the CJEU, the teaching from the case will be that the conclusions of the CJUE in these types of cases will be driven, to a very large extent, by the information sent by the referring Court. So the parties should concentrate their efforts on getting the facts well established before the referring Court, as they will predetermine the answers from the CJEU. If, as in this case, the referring Court already gives the answer to the CJEU, the latter will probably be relieved.

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