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Patentability of biotechnology inventions: "O time thou must untangle this, not I. It is too hard a knot for me to untie"

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Although Brian Cordery will try to have you believe that the title of this blog is borrowed from William Shakespeare's *Twelfth Night*, it may well have been taken from the Report from the Commission to the Council and the European Parliament dated 14 July 2005 on Development and implications of patent law in the field of biotechnology and genetic engineering, where the Commission wrote that:

"There is no immediate answer to the question of the patentability of embryonic pluripotent stem cells and indeed at this stage it would appear premature to come to a definitive conclusion. The Commission will continue to monitor developments in this area."

No additional progress appears to have been made to date, which has left the Court of Justice of the European Union ("CJEU") and national courts in the dark.

To sum-up, the organ of the European Union ("EU") supposed to inspire the EU's legislative proposals that courts must then apply and interpret, simply left it to the passage of time to untangle the thorny debate around where the right balance lies between promoting innovation in the biotechnological sector in Europe whilst respecting the principles of bioethics. Although Directive 98/44/EC was meant to harmonise the legal regime of patents protecting biotechnological inventions, there does not seem to be agreement as to which public order and morality principles constitute common ground across Europe. This has resulted in paradoxical situations, such as the EU Legislature, for example, producing Directives (e.g. *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*) and Regulations (e.g. *Regulation EC 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation EC 726/2004*) governing the requirements for medicaments obtained using embryos for purposes such as research, development and gene therapies, without having really agreed on whether certain inventions resulting from such research should be patentable.

The complexity and lack of consensus on the ethical debate, coupled with the complexity of the technical debate, caused Advocate General Bot to lead the CJEU onto the rocks in the Judgment of 18 October 2011 (Case C-34/10 *Oliver Brüstle v. Greenpeace*), one of the masterpieces of the CJEU's collection of patent monsters. The monster was so hairy and ugly that in his Opinion of 17 July 2014 (Case C-364/13 *International Stem Cell Corporation c. Comptroller General of Patents*) Advocate General Pedro Cruz Villalón has tried to justify the Brüstle "accident" on the grounds that in that case

the CJEU was not provided with the correct scientific information:

"71. In my view, in Brüstle the Court has established a functional equivalence between fertilised ova, non-fertilised ova subjected to somatic-cell nuclear transfer and parthenotes. Even though parthenotes, as it is now apparent, are the only organisms among these three that cannot develop into human beings, the Court treats parthenotes and non-fertilised ova subjected to somatic-cell nuclear transfer within the same paragraph without mentioning any distinction between them and stating instead that both organisms 'are, as is apparent from the written observations presented to the Court, capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so'. 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.

72. It is hence 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. The Commission supported this point of view in its submission in the present case, giving examples of statements in submissions made in Brüstle that could have created this impression. The assumption is also confirmed by the opinion of Advocate General Bot, which argues that parthenotes are embryos 'in so far as, according to the written observations submitted to the Court, totipotent cells' could be obtained from them, i.e. cells that can develop into a human being."

So he has suggested that the CJEU change direction, leave Brüstle behind and provided the following answer:

"74. Given the facts stated unequivocally by the referring court and the parties to the current proceeding it now appears 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'

75. 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 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."

So, confronted with exactly the same technology, only three years after the accident, alleging a better understanding of the tenets of biotechnological inventions, the Advocate General is now trying to drag the CJEU off the rocks.

Another example of the formidable difficulties faced by Judges on both sides of the Atlantic in understanding the technology behind this type of inventions may be found in the separate opinion signed by Judge Antonin Scalia in the Judgment of 13 June 2013 of the U.S. Supreme Court (*Association for Molecular Pathology v. Myriad Genetics).* As readers will be aware, this judgment is the American biotechnology monster, which is even uglier and hairier than its European counterpart, as in a single blow it put hundreds of billions of US dollars invested into research and development at risk, making good the thinking that it is a risky business to let a generalist court decide complex patent cases. In particular, Judge Scalia wrote the following:

"I join the judgment of the Court, and all of its opinion except Part I-A and some portions of the rest of the opinion going into fine details of molecular biology. I am unable to affirm those details on my own knowledge or even my own belief. It suffices for me to affirm, having studied the opinions below and the expert briefs presented here, that the portion of DNA isolated from its natural state sought to be

patented is identical to that portion of the DNA in its natural state; and that complementary DNA (cDNA) is a synthetic creation not normally present in nature"

No doubt, he should be praised for having been so honest as to disclose that this was too hard a knot for him to untie. Reading the commentaries that this judgment has received from leading American experts, it would appear that the rest of the bench did not really do a better job at untying the knot. One may of course wonder how a Judge can sign a judgment without having untied the knot showing the technical background of the case in the first place.

While Judges on both sides of the Atlantic continue to work hard to try to ensure justice is done when confronted with these complex cases, notwithstanding their difficulties in untying the technological knot, will Brussels continue to let time go by in the hope that time may prove Shakespeare to be right?

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