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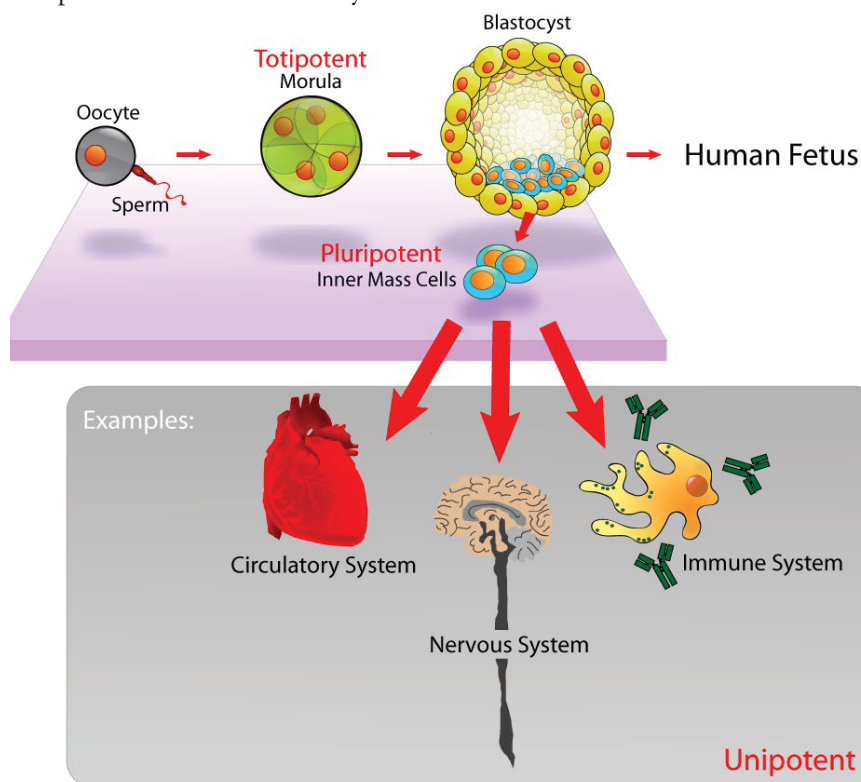
by Amer Raja

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Recently, the European Court of Justice was asked to determine the patentability of stem-cell products derived from human embryos. While the question submitted to the Advocate General was not as straightforward, both the Advocate General and the Court seemed to have little trouble in taking a position in this case. At the heart of this query was “whether the human embryonic stem cells which serve as base material for the patented processes constitute ‘embryos’ within the meaning of Article 6(2)(c) of the Directive.” The Court’s decision in this case, therefore, also necessarily addressed the patentability of “embryonic base material” and subsequent lines of products arising from base material.

The dispute arose from Mr. Oliver Brüstle’s patent on “isolated and purified neural precursor cells produced from human embryonic stem cells used to treat neurological diseases.” Mr. Brüstle works at the University of Bonn in Germany as a Professor of Reconstructive Neurobiology. Greenpeace, along with a number of religious organizations, contested the patent and sued for “ethical reasons,” to invalidate Mr. Brüstle’s ownership rights in the patent. The patent was declared “invalid insofar as it covers precursor cells obtained from human embryonic stem cells,” by the Federal Patent Court (Bundespatentgericht), and the case was subsequently referred to the European Court of Justice.

The issues that the European Court of Justice was asked to determine largely arose from the European Union’s approach to patentability and embryonic research. The relevant legislation and treaty language can be found in the German national law, TRIPS article 27, CGEP articles 52(1) and 53, and Directive 98/44 with respect to article 6(2)(c). Of these sources of law, the Court particularly focused on the directive since the case turned on the definition of “embryo” and the “dignity and integrity” of a person. The Court’s decision was largely centered on the concepts of order public and morality that are included in the laws and treaties. However, since there is some question as to whether a stem cell or purified precursor cell could be considered to be an embryo,



the Court first attempted to define and interpret the concept of human embryo with respect to article 6(2)(c).

To give some context to the Court’s ruling, I will briefly outline a few relevant points in stem cell research. While there are a few different types of stem cells, embryonic stem cells are probably the most potent and controversial since production starts with the fertilization of a human ovum (“egg”). Within a few days after fertilization, a blastocyst is formed, which

is comprised of a number of cells and regarded by a number of scientists to be an early stage embryo. In the interim period between fertilization and blastocyst formation, the ovum (now a “zygote”) undergoes a number of changes.

These changes include the formation of totipotent cells (unspecialized cells which can form anything in a human body) and eventually pluripotent cells (which can form a number of things but within one of three categories). Totipotent cells precede pluripotent cells chronologically and denote different stages of development. Therefore, the issue the Court had to wrestle with determining the moment at which an embryo could be regarded to exist, since it would be protected by national law.

In the end, the Court determined that while the pluripotent cells and blastocyst are more specialized in the development of a human being, that totipotent cells were also necessarily included in the definition of an embryo. The Court stated that “[A]ny 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.” This definition is also meant to include traditionally and non-traditionally matured ova, such as in parthenogenesis (maturation of an ovum without fertilization). However, the Court seems to have left open the question of whether a stem cell obtained at the blastocyst stage is an embryo, which may lead to further debate in the field. In addition to its determination that an embryo exists once an ovum is fertilized, the Court determined that scientific research and industrial use of embryos cannot lead to patents and further excluded any materials obtained from the destruction or use of embryos as base material.

While the implications of this decision are not entirely clear at this point, Mr. Brüstle and a number of other scientists have articulated that this decision comes as a huge blow to the scientific community. The scientists feel that this decision will serve as a huge setback in the development of stem cell products and may result in a greater advantage for their Asian counterparts. Greenpeace, the Catholic Church, and a number of religious organizations, however, feel that this decision comes as “a victory for human dignity.”

However, Mr. Julian Hitchcock, a lawyer with Field Fisher Waterhouse LLP also voiced his opinion that this decision may not actually be too detrimental to stem cell research; it could very well provide scientists and researchers with more freedom to not “worry about infringing someone else’s patent.” Furthermore, he points out that “While the ruling restricts patentability of such inventions, it doesn’t in any way restrict the use

of embryonic stem cells.”

As a result the Court’s decision may not really do much at all in the way of discouraging stem cell research – it may very well promote it. While in the United States we have the Bayh-Dole act to promote non-commercial research which can later become commercialized; embryonic stem cell products could very well start as non-commercial ventures in Europe and later lead to greater developments that may be nevertheless be patentable as well. The incentive in obtaining a patent and conducting a research may merely be delayed as opposed to entirely eliminated.

Furthermore, some practitioners have even posited the idea that researchers could depend on trade secrets and regulatory procedures to sidestep the hurdle. Lastly, the Court through its ruling has not foreclosed all embryonic stem cell research as such. Scientists may still be able to patent embryonic stem cell products by establishing that a stem cell obtained at the blastocyst should not be considered an embryo and therefore could potentially be patentable subject matter. In sum, the Court’s decision may provide very little guidance at all, and certainly leaves open the question of how to implement this new restriction on patentability; it will certainly be interesting to see how scientists, organizations, and Courts deal with this matter in the coming months and years.