Europe Discards Embryonic Stem Cell Patents

December 15, 2011

Adult stem cells, and processes for their manipulation, are generally patentable in Europe. Patentability of embryonic stem cell technology has been uncertain and controversial. The European Patent Office prohibits patent claims to stem cells prepared by a method or technique that involves the destruction of human embryos. A recent decision by the European Court of Justice (ECJ) has expanded the prohibition by ruling that processes or methods that result in any detriment to a “human embryo” are not patentable. This decision is controversial and expected to have a significant impact on the availability of patent protection in Europe for inventions related to human embryonic stem cells.

An environmental group started a court action in Germany to invalidate a patent originally filed by Oliver Brüstle in 1997, directed to isolated human neural precursor cells, methods for their production from embryonic stem cells, and their use for the treatment of neurological diseases such as Parkinson’s. The embryonic stem cells used in the Brüstle patent to produce the neural precursor cells were pluripotent stem cells removed from a fertilized ovum at the blastocyst stage, about 5 days after fertilization. Pluripotent stem cells are able to develop into a variety of tissues types but are not able to develop into a human being. In contrast, totipotent stem cells are able to develop into all the different cells in an organism and form a human being.

The European Directive on the Legal Protection of Biotechnological Inventions provides that inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality. The Directive specifically refers to “uses of human embryos for industrial or commercial purposes” as an example of unpatentable inventions. The ECJ was asked to consider what is meant by the term “human embryos” within the context of the Directive and in particular whether it includes all stages of development beginning with the fertilization of an ovum or if further requirements, such as reaching a certain stage of development, must be satisfied.

The ECJ broadly defined the term “human embryo” to apply “from the fertilization stage to the initial totipotent cells and the entire ensuing process of the development and formation of the human body.” A human blastocyst is therefore considered a “human embryo” as are unfertilized ova into which a cell nucleus is transplanted that results in a totipotent cell (i.e., cells prepared using somatic cell nuclear transfer or so-called “therapeutic cloning”).

The ECJ held that pluripotent embryonic stem cells can be patented as long as they are not capable of forming a human body. However the ECJ also held that any invention that “necessitates the prior destruction of human embryos or their use as base material are excluded from patentability, even if the description of that process does not contain any reference to the use of human embryos.” In the case of the Brüstle patent, the removal of pluripotent stem cells from the blastocyst results in the destruction of the remaining “human embryo” and is therefore invalid. Since many types of embryonic stem cell manipulations would destroy the embryo, this prohibition will likely pose considerable difficulties for patent holders and applicants in the area of embryonic stem cells.

In contrast to the situation in Europe, there are fewer restrictions on the patenting of cells or methods related to embryonic stem cells in the United States (e.g., see Brüstle’s US Patent No. 7,968,337 which claims a method for generating neural precursor cells from human embryonic stem cells). The Canadian Patent Office has taken the position that fertilised eggs and totipotent stem cells are “higher life forms” and therefore excluded from patentability. No patent has yet been granted from Brüstle’s corresponding Canadian Patent Application No. 2,315,538. However, methods, processes, or uses that relate to fertilized eggs or totipotent cells are not excluded from patentability in Canada nor are pluripotent stem cells, regardless of their origins (e.g., see Canadian Patent No. 2,190,528 which claims primate embryonic stem cells in culture and methods of isolating primate stem cells from the inner cell mass of a blastocyst).
Laurence MacPhie, Ph.D. (Human Gen.), J.D., is an associate lawyer in Bereskin & Parr LLP’s Biotechnology & Pharmaceutical practice group. He can be reached in Toronto at 416.957.1684 or lmacphie@bereskinparr.com.

Noel Courage, B.Sc. (Biochem.), LL.B. is a partner in Bereskin & Parr LLP's Biotechnology & Pharmaceutical practice group. He can be reached in Toronto at 416.957.1655 or ncourage@bereskinparr.com.

Information on this website is for information only. It is not, and should not be taken as, legal advice. You should not rely on, or take or not take any action, based upon this information. Professional legal advice should be promptly obtained. Bereskin & Parr LLP professionals will be pleased to advise you.