

# European Patent Office Refuses to Protect Invention that Involves Destruction of Human Embryos

By Amy Tindell

*In its rejection of a patent application* directed to the very first isolation of human embryonic stem cells, the European Patent Office (EPO) held that moral considerations preclude protection for an invention that necessarily involves the destruction of human embryos. Decision of EPO Enlarged Board of Appeal (November 25, 2008).

The application, filed by Wisconsin Alumni Research Foundation (WARF), defined a method by which primate (including human) embryonic stem cells can be maintained outside the body for long periods without losing their potential to differentiate into any type of cell in the body. When the application was filed in 1995, the only method of obtaining the stem cells required the destruction of an embryo.

The EPO based its holding on the European Patent Convention and the EU Biotechnology Directive. Rule 28(c) of the former prohibits the patenting of inventions that use human embryos for industrial or commercial purposes. Directive 98/44/EC in turn refuses protection to inventions whose exploitation would be contrary to public order or morality, listing uses of human embryos for industrial or commercial purposes in particular.

Even though the WARF application claimed only the stem cell *cultures*, not the embryos themselves, the EPO pointed out that the making of stem cells involves, of necessity, the destruction of human embryos. The EPO insisted on looking beyond the language of WARF's patent claims to "the technical teaching of the application as a whole as to how the invention is to be performed." The EPO concluded that "to restrict the application of [Rule 28(c)] to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such a claim."

The consequences of this decision are mixed. On the positive side, it could liberate academic research in Europe from the restraints previously imposed by the WARF patent application. Likewise, the European stem cell industry can avoid the shadow that a single dominant patent controlling human embryonic stem cells might have cast.

On the negative side, it will be more complicated to gain patent protection for, and therefore to market, cell therapy products based on stem cells. For example, it will not be possible to seek a single European patent for such products, as the EPO policy may now contrast with that of, say, the United Kingdom Intellectual Property Office, which allows patents that concern embryonic stem cells. The influence that the EPO decision may exert in the U.S. is hard to predict, as there is no U.S. counterpart to these EU biotechnology laws.

Further, academic and industrial research could suffer from the uncertainties created by the EPO decision regarding which inventions are protectable and which are not. Such uncertainties include whether patents will issue for products based on embryonic stem cell lines that did not themselves involve destruction of an embryo, but may or may not trace their origin to a destroyed embryo. In contrast to researchers who derived products according to the 1995 WARF application, inventors of modern stem cell products are able to obtain cells through stem cell banks, or isolate stem cells without actually destroying the embryo from which they came. Similarly, it is unclear whether the use of cell lines based on *fetal* stem cells would also be considered contrary to public order or morality.

The strong potential for stem cells to treat serious diseases should induce the EPO to encourage researchers, academic and industrial alike, to develop treatments through the use of stem cells. New methods of producing

stem cells, including therapeutic cloning, or transforming regular cells into multipurpose cells, further distance this research from the destruction of embryos and from the EU laws. The prospect of improving and saving lives may outweigh the cost of limited destruction of embryonic cells in an early phase of research, supporting the case for patentability of stem cell inventions.

What does the near future hold for stem cells at the EPO? The biotechnology company Geron issued a hopeful statement that the EPO decision should not

affect applications for later-developed technologies. The EPO's decision itself emphasized that its holding was immaterial to the patentability of stem cell products generally, and was limited to products that can be obtained only by destruction of human embryos. The outcome of several Geron applications directed to other inventions involving stem cells currently awaiting European examination likely will clarify the patentability fate of stem cell technologies. ✧