Stem cell patents are immoral, rules ECJ

In a recent legal decision from the Court of Justice of the European Union (CJEU), the Court has decided that inventions which make use of human embryos are not patentable on morality grounds. The decision has been welcomed by Greenpeace and some church groups. However, it has been greeted with dismay by the European stem cell industry since this fledgling industry relies on patents for such inventions to attract the large amounts of investment which are needed to take stem cell-based therapies from the laboratory to the market.

The decision is based on European patent law which states that patents are not allowed for inventions "the commercial exploitation of which would be contrary to ordre public or morality". Historically, this morality hurdle has been considered to be very high and to apply only to items such as letter bombs which have no moral use. However, in 1998, the European Commission passed a directive on the patenting of biotechnological inventions (known as the "Biotech Directive", EC/98/44). This directive confirmed the patentability of isolated genes and purified proteins (even if they were previously known in the human body) and it included for the first time a list of inventions which were considered to be immoral. This list included “uses of human embryos for industrial or commercial purposes”.

At the time that the Biotech Directive was passed, stem cell technology was in its infancy and hence the directive did not directly address the patentability – or morality – of human stem cell based inventions. Such cells have high potential value because they can be grown in the laboratory essentially indefinitely and the cells can be used to provide a wide range of specialised cells such as heart cells or neurons, for treatment of disorders such as heart disease or Alzheimer's disease, respectively. However, the morality of such inventions was questionable due to the fact that human embryonic stem cells are obtained from human embryos by a process which results in the death of the embryo. It is also worth noting that the Biotech Directive did not state that research on human embryos was immoral. It was the potential marketing and commercialisation of human embryos via the patent system which was considered to be contrary to human dignity and hence immoral.

The first time that the "uses of human embryos" rule was tested was in 2008 when the European Patent Office (EPO) was asked to decide on the patentability of an invention made by the Wisconsin Alumni Research Foundation (WARF). In that case, WARF's European patent application had claims which covered human embryonic stem cells. This case caused a significant problem for the EPO because their legal and technical experts were not qualified or experienced in judging the morality of inventions. After all, what is an immoral invention? What should the test for morality be? And though whose eyes should morality be judged? The way that the EPO avoided having to address any of these difficult issues was to refer to the Biotech Directive and its "uses of human embryos" rule. Essentially, the EPO decided that the WARF invention related to a use of a human embryos (which had been deemed to be immoral by the drafters of the Biotech Directive) and hence the WARF invention was unpatentable on morality grounds. It is important to note, however, that the EPO decided that the WARF invention was immoral because, at the filing date of the patent application, there was no other way to put the invention into practice, that is, human embryos had to be destroyed in order to make the human embryonic stem cells which were claimed in the WARF patent application. Since that time, however, the EPO has confirmed that inventions which use human embryonic stem cells are patentable, as long as the inventions can be put into practice at the filing date of the patent application without destroying human embryos (for example, if the inventions are based on human embryonic stem cells which are grown in the laboratory).
This has therefore been the established practice of the EPO for the past few years.

The recent decision of the CJEU has, however, said that the EPO’s approach to the morality of such inventions is not correct.

The CJEU decision arose after the grant of a German patent by Oliver Brüstle which had claims to neuronal stem cells. The morality of this patent was challenged in the German courts by Greenpeace under the Biotech Directive and the "uses of human embryos" rule in particular. The CJEU was asked by the German court to provide guidance on how this latter rule should be applied to human stem cell-based inventions.

In a preliminary opinion on this matter which was given in March this year, the Advocate General, a legal advisor to the CJEU, took the view that all inventions based on human embryonic stem cells were immoral - and hence not patentable - because human embryonic stem cells had to be obtained – at some point in their history - from human embryos by a process which lead to the death of those embryos. The publication of this opinion lead to profound concern being expressed by a considerable number of stem cell-based companies and institutions, with dire warnings being given about the effect that such a ruling would have upon stem cell research in Europe.

Despite intense lobbying, the fears of the stem cell companies were realised when the CJEU agreed with the opinion given by the Advocate General, stating that "The fact that destruction [of the human embryo] may occur at a stage long before the implementation of the invention ... is irrelevant." Hence the CJEU has essentially said that if the invention makes use of a human embryo - at any point in its past - then the invention will be unpatentable in Europe on morality grounds. Given that there are no such rules under US patent law, there is concern that many European stem cell companies will now flee to the US.

The decision of the CJEU is binding on all of the courts of the member states of the EU, but it is not in fact binding on the EPO (because the EPO is not an EU institution). The EPO is already, however, taking steps to change its examination practice to bring it into line with the decision because it would be absurd if the EPO were to grant European patents which were then not valid in the member states of the EU.

As to the correctness of the decision, is it right for the CJEU to use a directive - which was supposed to promote biotech innovation within Europe - to deny society the potential benefits of embryonic stem cell inventions or to decimate European stem cell industry? Or is the decision a timely reminder that, whatever the benefits this new technology might hold, we must not lose track of our moral compass.

Philip Webber, Partner
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