

ECJ stem cell ruling poses serious threat to medical research

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A new ruling from the Court of Justice of the EU (ECJ) means that human embryonic stem cell-related inventions are deemed to be no longer patentable in EU Member States.

In making its ruling the ECJ has taken a broad interpretation of the term 'human embryo' (EU Directive 98/44/EC – 6 July 1998) to include any cell that is able to commence the process of development of a human being. Accordingly, EU Member States will now be required to refuse patent protection for inventions that benefit in any way from the destruction of a human embryo on the grounds that said destruction is 'contrary to public order or morality'.

The decision, issued on October 18 2011, follows a case originally filed by Greenpeace against Professor Oliver Brüstle, a neuropathologist and expert in stem cell research from the University of Bonn, Germany, who was awarded a patent in 1999 relating to neural precursor cells used to treat neurological diseases such as Parkinson's.

Stem cell research has enormous potential to dramatically change the way we treat human diseases. Some stem cell therapies already exist, notably bone marrow transplants to treat leukaemia, and scientists believe the technology can ultimately deliver treatments for a wide range of currently incurable illnesses from chronic heart disease and diabetes to Parkinson's and muscular dystrophy.

In recent years we have seen considerable investment in developing embryonic stem cell-based therapies in Europe. But the ECJ decision has left the scientific community in dismay while threatening to drive a crucial area of research overseas as researchers and companies seek to protect their investments.

With any new technological development, inventors invest many years researching to bring their inventions to market. In the case of stem cell research, because much work is needed to move from the laboratory to clinical application, that investment is even greater. And, even once researchers make that all important breakthrough, being a medical application, they still have to overcome the hurdles of testing, patient trials and ultimately licensing for use in humans – all of which require enormous resources of time and money.

Researchers need to have the security that, at the end of all this, their efforts are going to be rewarded and that they will recoup the costs of developing and commercialising the new medical treatment. Patents play an essential role in protecting inventions from unlimited use by competitors, who could potentially reap the rewards without spending a penny on research and development. Inadequate patent protection will therefore dramatically reduce the incentive that scientists and researchers have to invest in a crucial area of medical research.

It is important to note that the ruling is limited to embryonic stem cells that necessarily cause the destruction of a human embryo. As it stands, patent protection is not excluded for non-embryonic stem cells, such as induced pluripotent stem cells (iPS cells) and other adult stem cells, though more research is needed to demonstrate their clinical utility.

Nonetheless, I fear that the ECJ's ruling could drive research away from Europe, to parts of the world where there is a more permissive approach to what can and cannot be patented. This will not only mean we lose the economic benefits of this vital work from our shores, but could create a 'brain drain' as the most talented scientific minds in the field take their work elsewhere. At a time when Europe's economies are stumbling, and we are told that innovation, entrepreneurship and the 'knowledge economy' is vital to our future, the decision to limit protection for medical R&D gives a distinct advantage to our global competitors.

Yes, there are emotional, ethical and moral concerns associated with patenting and commercialising materials derived from human embryos. But in reaching this decision, EU institutions have gone against the advice of patent experts across Europe who have recommended a more fluid position. The research community is likely to feel its impact for many years to come.

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