

The ethical, legal and political minefield of stem cell research

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Mines. Credit: The District

Human stem cell research holds promise for combating some of the most recalcitrant of diseases and for regenerating damaged bodies. It is also an ethical, legal and political minefield.

Human stem cell research is a thriving field of science worldwide – holding promise for treating diseases such as diabetes, multiple sclerosis and Parkinson's disease, as well as for furthering our understanding of how we develop from the very earliest stages of life.

But using human embryonic stem (ES) cells to improve the health of



other humans has also been the subject of comment, criticism and even court cases. Time magazine dubbed the "complexity and drama" surrounding these cells as the "Great Debate".

Most notably, the field witnessed the 2001 restriction on funding for ES cell research in the USA by President Bush and the lifting of the ban in 2009 by President Obama. Then in 2011, the Court of Justice of the European Union (CJEU) banned the patenting of inventions derived from human eggs or their equivalent on the basis that they were human embryos, the commercial exploitation of which "would be contrary to... morality."

While religious bodies and green lobbyists use patent law to elevate the status of the embryo, scientists argue that doing so threatens research that might benefit the health of millions.

International law permits states to refuse patents where necessary to protect morality in their territory. "Yet, how does a patent examiner or a court assess whether an invention is immoral to the point that, unlike other inventions, it can't be patented? That is a particularly difficult question," said Dr Kathy Liddell from the Faculty of Law. "It is a conundrum that runs headlong into the complex intersection of law and morality, intellectual property and philosophy."

It is precisely this intersection that a new research centre in the Faculty will investigate. The new centre – funded by the Hatton Trust and the WYNG Foundation – will focus on medical law, ethics and policy relating to controversial issues such as patenting inventions involving DNA and body parts, the regulation of medical research and technologies, assisted reproduction and surrogacy, and the governance of 'big data' in the medical field, as well as the regulatory and legislative issues that stem cell research is likely to meet en route from the lab to the clinic.



"These areas need to be considered not as a post hoc rationalisation of events that have already happened, but alongside and ahead of technological advances," said Liddell, who is centrally involved in the new centre, as well as being Deputy Director of the Faculty's Centre for Intellectual Property and Law. "To complement the extraordinary science that is happening, we need to consider the ramifications of biomedical advances in a thorough and timely way."

Liddell's own research interests relate to the pathway that leads from the research bench to clinically effective treatments. She sees the law's role as facilitating and supporting this pathway in morally responsible ways.

ES cells are useful because they are at the earliest point of human development and possess the full 'regenerative toolkit'. In other words, they can develop into any type of cell in the human body. Although <u>stem</u> <u>cells</u> found in the adult human also retain the self-renewing ability to develop into specific tissues, they cannot develop into all the tissue types needed for regenerative medicine; the genetic information needed for some developmental pathways has already been shut down.

"The CJEU was very reluctant to engage with the ethical and public policy debates surrounding human embryos. So it ended up answering the patent law questions with very little reasoning," added Liddell.

"For me, this was the biggest problem with the judgment. The Court has to have the courage, skills, wisdom and accountability to face up to the degree of judicial activism and policy shaping that is inevitable in these controversial areas. Likewise, citizens, researchers and NGOs have to accept that judges have to make difficult 'calls' in the face of moral and scientific uncertainty. They simply can't please everyone in a morally pluralist society."

Julian Hitchcock, a specialist in life science intellectual property at



London law firm Lawford Davies Denoon, who advises government and the Wellcome Trust on stem cell law, agrees: "The problem I see is that the CJEU's decision sends the message that scientists engaged in <u>stem</u> <u>cell research</u> are immoral. Moreover, the CJEU's decision is being used to attempt wider assaults on research, such as in a Citizens' Initiative called 'One of Us' which suggested that the principle of human dignity applies from the point of conception. Had this initiative succeeded, not only would it have undermined research funding, but it would also have impeded the fulfilment of urgent Millennium Development Goals."

Meanwhile, the great stem cell debate continues, with a recent challenge in the High Court by the International Stem Cell Corporation over a decision by the Patent Office that unfertilised human eggs that have been stimulated to divide (turning them into so-called parthenotes) be included in the term 'human embryos'. The implication is that parthenote inventions would also fall within the CJEU's zone of unpatentable inventions. The High Court referred the issue to the CJEU and, in July this year, the Court was advised to reject part of the decision by the Advocate General.

"It's a very complex area of the law – both highly technical and highly controversial. By supporting people to develop expertise in the life sciences and the law, we can better respond to these important discussions," said Liddell.

Hitchcock added: "Formulating laws and policies that are responsive to the needs of research, and which carry the support of the public, requires a deep understanding of the ways that biology and law intersect, as well as imaginative thinking, powerful advocacy and the courage to fight an often embattled corner."

"The quintessential justification for patent protection has always been that it's important for protecting investment in research and



commercialisation," said Liddell.

"We have yet to see whether the lack of patent protection for inventions involving human embryos has had a chilling effect on the transition of ideas to clinical realities, or whether it has nudged research in new, but similarly effective, directions that avoid the moral dilemmas and legal uncertainties of using embryos. We may never know – it is very difficult to gather this sort of empirical data. But for society to benefit properly and fully from medical advances, we do know that we need to be ready to enter any and all debates that wrestle with their ethical and moral implications."

Provided by University of Cambridge

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