Human embryonic stem cells (hESCs): a balancing act of science and ethics

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Stem cells[2]

I recently attended a symposium in Copenhagen on the nature and impact of an EU law passed in October 2011 that prohibits the patentability of human embryonic stem cells, hESCs.

The day saw stem cell researchers from all over Denmark gathered to express their point of view, and their enthusiasm for the field was obvious.

hESCs have been a very hot research topic for more than a decade due to their promising potential impact on human development, drug discovery and transplantation medicine.

In 2007, cells similar to hESCs, but with a different origin, were generated for the first time. By the forced expression of key transcription factors, researchers found that they could reprogram human fibroblasts into human induced pluripotent stem cells (hiPSCs).

HiPSCs seemed to have the same characteristics as hESCs, however, rather than being derived from the inner cell mass of an embryo, they were generated from skin biopsies from humans.

The discovery excited the entire stem cell field, as hiPSCs offered a great alternative to the hESCs that were subject to criticism due to the ethical issues underlying the destruction of human embryos that is necessary in order to isolate hESCs.

However, in the last couple of years, it has been demonstrated by several research groups that hiPSCs differ from hESCs in expression profiles and epigenetic state. This has caused many researchers to come to the conclusion that in studies involving hiPSCs, hESCs should be included as control cell lines.

The EU law and the story behind the ruling

Although this seems to be the consensus among many researchers, an EU law passed in October 2011 now stands to potentially complicate things for the EU researchers.

The law from the EU Court of Justice prohibits the patentability of hESCs, and that decision has caused disappointment among many stem cell scientists, as they believe it will discourage investment in the therapeutic applications of hESC research.

The reasoning behind the EU law can be traced back to an EU ruling in a case led more than a decade ago. In 1999, Greenpeace challenged a German patent that covers methods for turning mammalian ES cells into neural precursor cells, because they believed it encouraged commercialization of human embryos. The year before, in 1998, an EU directive had banned “the use of human embryos for industrial or commercial purposes”.

However, since the German patent from 1999 did not involve human embryos, but mammalian hESCs, the
EU Court was asked about their definition of “human embryos.” The response was that the term “human embryo” in the European Patent Directive covers any “human ovum after fertilization” as well as the product of a nuclear transfer experiment.

In addition, the court ruled that if "the subject matter of the patent application requires the prior destruction of human embryos or their use as base material," the application is not patentable. Accordingly, the prohibition covers any present and future therapeutic product containing the hESCs.

**Potential consequences of the EU ruling**

One of the intriguing dilemmas caused by the ruling is that it will now be impossible to patent research that is lawfully practiced in a number of EU states, and as mentioned above, this could potentially have great consequences for stem cell research in the EU.

The restrictions on the patentability of the hESCs could potentially discourage investment which will eventually slow down the development of new treatments for diseases such as Alzheimer’s and Parkinson’s.

Another consequence of the ruling could be that researchers let patents dictate their research, and as a consequence decide to work with only hiPSCs even though these cells are not 100 percent equivalent to hESCs.

This could influence future results on which new therapies would be based. Not to say that this is bound to happen, but until we know more about hiPSCs, therapies should be based on results from both cell types.

With the new law, the EU court of law has effectively overruled the diversity of related laws and ethical perspectives that exist in the individual member states by dictating that the value attributed to human embryos takes priority over patients waiting for cures to be developed.

**Abbreviations:**
- hESCs: human embryonic stem cells. Pluripotent cells derived from the inner cell mass of the blastocyst. hESCs have two unique properties: the ability to self-renew indefinitely and the ability to give rise to all cell types of the human body.

- hiPSCs: human induced pluripotent stem cells. They are able to differentiate into all cell types, and they can proliferate indefinitely. hiPSCs are generated via reprogramming of somatic cells by forced expression of key transcription factors.

**Further reading:**

*The Guardian* [EU ban on stem cell patents is a threat both to science and the rule of law](http://www.guardian.co.uk/science/blog/2011/dec/12/eu-ban-stem-cell-patents)

*ScienceInsider* [European Court Disallows Patents Involving Human Embryonic Stem Cells](http://www.sciencenordic.com/content/human-embryonic-stem-cells-hescs-balancing-act-science-and-ethics)

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