Stem Cell Research and Intellectual Property Rights

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Intellectual property rights in the life sciences

Intellectual property rights (IPRs) - generally - represent a way for those who have come up with a new idea or invention to prevent others to use it. They thus provide an economic incentive to the inventor (and potentially to investors in the associated research and development) by giving them a (limited) monopoly on its exploitation. Intellectual property rights take various forms, including copyright, trademarks, registered industrial designs, plant breeders’ rights and material transfer agreements. Together with patents (see below), these are thought to stimulate research and development (R&D) by ensuring that investors can recoup their costs during the period of monopoly. In addition, it is argued that the incentive for innovation can - in the long term - enable patients and consumers to access newer technologies that are able to serve their needs.

Patents are perhaps the best-known, most-widely-used and most controversial form of intellectual property in the life sciences. Patents on new inventions (not discoveries or abstract ideas) must first be ‘filed’ (applied for). After this, they are ‘examined’ and are then either approved or refused by a national patent office. After approval, the holder of the patent is able to prevent any others from exploiting (for economic purposes) their invention, or to demand license fees in order for them to do so for a set period of time (usually twenty years). There are various requirements that patents commonly need in order to be approved:

- Novelty/ no ‘prior art’ – this must be the first time that the ‘invention’ has been described
- Inventive step – the description must provide a non-obvious inventive addition to the previously-recorded inventions in the same area
- Industrial application – the invention must have a utility i.e. be able to be exploited in a certain economic context, or another useful way
- Clear and complete disclosure – this enables others to repeat the invention (assuming they have the legal right to do so)

In the European Union, patents also have a morality requirement (patented inventions cannot threaten legal and social foundations or ‘ordre public’) that is similar to clauses in some Asian (e.g. Indian and Chinese) patent laws. This has implications for EU-US commerce and collaboration, and creates problems when applied in regions that have different socio-political, legal and cultural structures and norms.

Patent systems have primarily developed at national levels. These display differences in the ways in which patents are examined and enforced (e.g. in European and Japanese law, researchers are allowed to employ patented inventions for non-commercial use without obtaining licenses, but this is not the case in the USA or Canada). Despite these differences, the international community has tried to enable commercial activity around patents and IPRs for many decades. In 1994, member countries of the World Trade Organisation...
(WTO) signed the ‘Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS agreement) – probably the most important international agreement in this area.

**Areas of tension and policy debate**

Like intellectual property rights (and especially patents) across the life sciences, IPRs around stem cell technologies are currently an area of significant uncertainty/debate/dispute. Questions arise in a number of areas:

- Does patenting incentivise innovation (as claimed by patent offices) or hold back innovation (as suggested by scholars such as Heller and Eisenberg 1995)?
- Are cell lines inventions or discoveries? If inventions, who are the inventors (researchers or the subject from whom they were taken)?
- Are patent laws and administrative systems able to keep up with the rapid advance of innovation in the biosciences, including in stem cell technologies?
- Do patents associated with stem cells violate morality or ‘order public’? Do they require a new set of intellectual property law/principles to overcome this issue?

The last of these questions was put to the test recently in Europe, when the European Court of Justice was asked by the German Federal High Court to clarify questions relating to a patent held by Professor Oliver Brüstle, a neuropathologist who had invented a way to produce (from embryonic stem cells) specialised cells for use in neurological treatments. The patent (which had already been granted by the German Patent Office) had been challenged by Greenpeace on the basis that it involved the use of human embryos and thus went against European Patent Directive 98/44/EC.

According to Article 6 of the directive,

“1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”

In their response (which was advisory rather than a binding decision), the European Court of Justice ruled that processes requiring the destruction of “human embryos” were not patentable, and provided a broad definition of
“human embryo” by suggesting that it referred to cells (either resulting from a fertilised ovum, or those produced artificially) that were capable of commencing the process of development into a human being. This decision has been seen as many to create a barrier to the enforcement of many patents already granted to stem cell-related inventions. In the case in point, the German Federal High Court in November 2011 exercised its discretion, arguing that the in vitro pluripotent embryonic stem cells used in Brüstle’s invention were not capable of developing into a human being. As a result they upheld – at least in part – the patent, on the basis that it included a disclaimer excluding the destruction of human embryos. However, the European Patent Office (EPO) in June 2013 revoked the corresponding patent at the European level.

Also recently, the UK High Court in April 2013 asked the European Court of Justice whether parthenotes (embryos created through parthenogenesis) should be seen as “human embryos” under the European Patent Directive. The UK Intellectual Property Office had previously refused two patent applications from the International Stem Cell Corporation (ISSC) on the basis that they were capable of commencing the process of development as specified in the Brüstle case (above). The response of the European Court of Justice is awaited.

Obviously, each of the questions above can be subject to differing interpretations and views by legal systems in national and regional contexts across the world. In addition to this, patent systems are dynamic and legal decisions are subject to amendment or modification as new information becomes available or technologies change.

References


Further Reading


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