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Review Article

Review of Challenges in the Commercialization of Stem Cell Research Technologies

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Abstract

Stem cell technology, due to its high potential, is experiencing rapid growth in practical therapeutic applications. How patents affect the stem cell research industry continues to remains in chaos. The patent system's main aim is to promote creativity by giving the patent proprietor a provisional monopoly over the patented invention. Patent security is a key factor that influences the creation and commercial success of innovations in the regenerative medicine and life sciences. Biomedicine innovation in stem cell research demands balance between the various stakeholder interests. This paper explores etiological factors contributing to the current problems of patentability of human stem cell-based innovations in the stem cell research market.

Keywords: *Stem Cell Research; Stem Cell Technology; Patent System; Biomedicine Innovations*

Introduction

Stem cell is an immensely potential research area. The dynamic relationship between patenting and innovation in stem cell technology is being increasingly discussed both nationally and internationally. The commercialization of stem cell technology and new product production is a dynamic process away from basic science. The Intellectual property laws promote the scientific and economic benefits from invention and offer a fair and morally justifiable reward to researchers and organizations. Limited data is available on the amount of investments spent on stem cell research. There is a growing expectation that the private sector will play an rising role in stem cell research due to uncertainty in government funding and restrictions on patenting stem cells by patent organizations. The financing of stem cell research by the private sector raises questions about relying on corporate sponsorship and whether financial considerations would influence policy rather than science or medical needs [1].

Patent as a barrier for biomedicine innovations

Quantified criteria indicate that patenting and proprietary steps can only be used if there is appropriate overall social gain. Current norms and policies reflect established regulatory mechanisms that are increasingly using intellectual property as the key impetus for scientific advancement. As such, innovation schemes other than patents remain comparatively unmapped.

Alternative invention strategies include those operating under existing patent legislation (e.g. patent pools or secured commons approaches) or those that complement it (e.g. prizes or open access). Incentives for sharing data, resources, and a rational assessment of how the cost of sharing is to be distributed remain insufficient. For example, from the patentability point of view in Europe, EPC Article

53(a) of the EPC recognizes "inventions whose commercial use might be contrary to" public order "or" morality. Implementing Regulation 28(c) explicitly for stem cells considers "use of human embryos for industrial or commercial purposes" to be unpatentable. Some features of today's proprietary environment risk are slowing R&D innovation and skewing biomedicine markets, such as those for rare diseases and those present in developing economies. Although these issues are omnipresent in biomedicine, current Intellectual property relationships within the stem cell research area may be problematic in terms of both research performance and benefit-sharing due to innovation.

Innovation barriers and the use of stem cells in clinical therapeutics

Stem cell research is a fast-growing field. Present research and production of stem cells face significant challenges in terms of patent restrictions and heavy lobbying by life science organizations. Increased research could yield breakthroughs in all therapeutic areas, such as disease scenarios, trans-humanism, cloning and public health. Patents often impede innovation in biomedical fields, as patents also enable corporations to invest in large legal teams rather than researchers and resources to protect existing investments over new ones and monopolize claims based on the potential to restrict advances in public science to prevent further advancement. The main obstacle for stem cell patents in European markets is related to embryonic stem cells and the moral exclusions granted by the European Patent Convention (EPC) Directive 98/44/EC, especially on the industrial or commercial uses of human embryos. Scientists have increasingly recognized the need to establish international human embryonic stem cell registries (hESCs) and international stem cell banks that help researchers obtain stem cells from repositories. Such programs will offer a mechanism by which data and resources can be exchanged more easily; currently, they do not have IP policies or the terms of licensing agreements. Some of the above registries must aim to include the sharing of information about intellectual property/data and materials as part of the registry.

Ethical issues in patenting of stem cell research in Europe

The human embryos standing at the point of the blastocyst: the level from which stem cells are normally separated has elevated moral censuses. Work on human blastocyst has created political and regulatory controversy since 1998 when hES cells were first successfully cultivated in laboratories [2], hindering hES cell research in the European Union (EU) [3]. Different views on human embryos moral status before implantation are still fiercely debated [4]. Comparative analysis of nine European countries showed a plurality of views on embryo science, ranging from the view that human embryos are of the same status as living human beings, as in Austria and Germany, to the view that human embryos are not yet adequately formed in their earliest stages to constitute individual human beings, as in Denmark and the U.K [5]. A human blastocyst shall have full moral status immediately after the egg is fertilized [6]. According to different rules, the harm of the human blastocyst may be considered morally questionable for different reasons, e.g., perhaps because no living human being should be used purely as a means of attaining the ends of someone, no matter how good those ends may be. This philosophy is understood by views of some scholars as the Kantian objection [7].

Patients and patient organizations, which could potentially benefit from the clinical translation of stem cells, are often not shared of disapproval of hES cell research, leading some to advocate their interest in the decision-making process over the use hES cells [8]. Although previously existing embryonic stem cell lines tend to be the least controversial source of hES cells, questions have been raised as to whether the use of such lines does not promote the destruction of human embryos to produce stem cell lines and thus whether the product can be rationalized whilst opposing the source [9]. Formation of human embryos are formed from hiPS cells, it may raise many ethical questions [10]. Some have debated that unlike gamete-fusion or cloned embryos iPS cells cannot be ascribed moral status, because iPS cells on their own are unable to generate a full-grown organism; they require the provision of a surrogate trophoblastic by tetraploid helper cells to do so [11]. The distinction between hiPS cells and human embryos is likely to be considered ethically important from the perspective of those who convict the destruction of early human embryos as moral status. Contrary to this, regenerated tissues and organs will normally be patentable because they are not necessarily exactly the same as real tissues and organs [12]. During the past

decades, debates have focused on how to regulate genetic research and use genetic technology alongside the exploration of human genetic information [13].

Challenges in stem cell research patenting

Current patenting/IPR models can limit or hinder public access to research benefits. Both the information generated by the scientific endeavor and the innovative products and thus hinders the use of stem cell technology for the public good. Some licensing and trade practices can limit access to the advantages of stem cell technology. Certain limitations include the use of very restricted or exclusive licensing terms, multiple licensing requirements for the use of a particular technology or testing tool that makes access more expensive and time-consuming. Due to the high transaction costs involved in operating in the arena of multiple intellectual property rights, the entry of new businesses is very difficult for companies to decide not to apply for licenses, reducing competition and allowing large companies to dominate markets. Navigation and enforcement of the patent scheme, arbitration, and litigation require exorbitant skills, and even the present proprietors of IP rights cannot benefit entirely from their own IP rights because of the costs involved in defending these rights.

Discussion

The European Patent Commission (EPC)'s official patenting status for the stem-cell line is still in flux. The field of human stem cells in induced pluripotent stem cells (ips) through the patent setting is still not established in a whole [14]. Different countries hold different views on the patentability of stem cell lines, which require a complicated collection of legal and ethical considerations. One can see convergence of consequences of various US and EU laws on eligibility for stem cell patents [15]. In addition to differences in the structure of patent law, policymakers around the world have adopted a wide variety of restrictions on stem cells, from permissive to prohibitive approach. Japan has taken permissive approach and imposed a moral exclusion in patent law, although it does not clarify whether harming human embryos would result in an innovation that would affect public order, morality or public health [16]. China is close to Europe but more pretentious in its perception of trade or industrial uses of human embryos [17]. Levine [18] found that scientists faced difficulties in breaking down hESC lines from their colleagues, and that these sharing constraints contributed to their choice.

In addition, the situation in human embryonic stem cell research (hESC) is not exceptional, and general concerns about decreasing scientific integrity are more strongly focused in a hESC study. It may be partly due to the hESCs scientific, policy/regulatory and ethical background. In stem cell research, several technical problems are important to note, i.e. a small number of cell lines and the high degree of technical expertise needed to manipulate them, which makes a hESC research technologically inaccessible to many scientists and moreover, It is worth noting that Stem cell banks and registries face complex problems of informed consent and human donor identity which is an ongoing and growing challenge for both genomics and stem cell research [19].

Conclusion

Even after some limitations, hESC work continues to progress. Different country cultures have different attitudes towards using stem cells as beneficial, which will possibly affect whether patenting is permissible. Throughout international stem cell research, identifying the challenges raised by existing proprietary systems needs ongoing review of specified criteria and actual practices. For greater coordination and promotion of stem cell science research, we need to identify our priorities in major research policies at hESC.

Bibliography

1. Fallone. "Funding Stem Cell Research: The Convergence of Science". *Religion and Politics in the Formation of Public Health Policy* (2011): 12.

2. Robertson JA. "Embryo stem cell research: ten years of controversy". *The Journal of Law Medicine and Ethics* 38.2 (2010): 191-203.

3. Hoppe N and Denoon A. "An ethical framework for expanded access to cell-based therapies". *Regenerative Medicine* 6.3 (2011): 273-275.

4. Andersson AK. "Embryonic stem cells and property rights". *The Journal of Medicine and Philosophy* 36.3 (2011): 221-242.

5. Pardo R and Calvo F. "Attitudes toward embryo research, worldviews, and the moral status of the embryo frame". *Science Communication* 30.1 (2008): 8-47.

6. Brock DW. "Creating embryos for use in stem cell research". *The Journal of Law, Medicine and Ethics* 38.2 (2010): 229-237.

7. Hoppe N and Denoon A. "An ethical framework for expanded access to cell-based therapies". *Regenerative Medicine* 6.3 (2011): 273-275.

8. Euro Stem Cell Film "Conversations: science, ethics, stem cells". *Euro Stem Cell* (2006).

9. Neri D. "The Race Toward „Ethically Universally Acceptable‟ Human Pluripotent (Embryonic-Like) Stem Cells: Only a Problem of Sources?" *Bioethics* 25.5 (2011): 260-266.

10. Hug K and Hermerén G. "Do we Still Need Human Embryonic Stem Cells for Stem Cell-Based Therapies? Epistemic and Ethical Aspects". *Stem Cell Reviews and Reports* 7.4 (2011): 761-774.

11. Condic ML., *et al*. "Ontological and Ethical Implications of Direct Nuclear Programming: Response to Magill and Neaves". *Kennedy Institute of Ethics Journal* 19.1 (2009): 33-40.

12. Tran JL. "Patenting Bioprinting". Harv. J.L. and Tech. Digest (Symposium) (2015).

13. Wilkinson R. "The Governance of Genetic Information: Who Decides? (Publication Review)". *Medical Law Review* 18.2 (2010): 267-273.

14. Schwartz RM and Minssen T. "Life after Myriad: the uncertain future of patenting biomedical innovation and personalized medicine in an international context". *Intellectual Property Quarterly* 3 (2015): 189-241.

15. Davey S., *et al*. "Interfacing of science, medicine and law: The stem cell patent controversy in the United States and the European Union". *Frontiers in Cell and Developmental Biology* 3 (2015): 71.

16. Kariyawasam K., *et al*. "Legal implications and patentability of human stem cells: Australia and Japan compared". *Journal of Intellectual Property Law and Practice* 10.3 (2015): 198-209.

17. Farrand B. "Human embryonic stem cells and patent law in the EU and China: convergence in standards through divergence in institutions". *Intellectual Property Quarterly* 3 (2016): 260-277.

18. Levine AD. "Access to human embryonic stem cell lines". *Nature Biotechnology* 29.12 (2011): 1079-1081.

19. Mathews DJH., *et al*. "Access to stem cells and data: persons, property rights, and scientific progress". *Science* 331.6018 (2011): 725-727.

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