

Intellectual Property and Patent in Stem Cell Research Era

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Stem cell therapy has obtained much attention, not only for its exceptional promise for curing many chronic disorders and degenerative conditions but also for its great economic potential. Apart from expenses in research laboratories and ongoing clinical trials, intellectual properties, patent of stem cell differentiation protocols, and stem cell-derived medical products for cell and tissue therapy are of very high cost. Intellectual properties and patents are inevitably important issues for stem cell researchers. Stem cell researchers in most countries have a chance to develop affordable stem cell therapy, scientific progression, and innovations for their patients. However, for this to be done, appropriate solutions for international patent barrier must be created so that the owner of the original stem cell protocols and techniques can be acknowledge, build his reputation and reap reasonable financial benefits. International patent barriers will be a crucial step to move the whole stem cell research community forward.

Keywords: Intellectual property, Patent, Stem cell, International

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Stem cell therapy has obtained much attention not only for its exceptional promise to cure many chronic disorders and degenerative conditions but also for its great economic potential. Apart from all the expenses in stem cell research laboratories and ongoing clinical trials, intellectual properties, patent related to thousands of stem cell differentiation protocols, and stem cell-derived medical products are very expensive to develop and protect^(1,2).

Significance of intellectual properties and patent for stem cell research

Similar as information technology, intellectual properties, and patent will inevitably be an important issue for stem cell research. Before launching a new stem cell clinical trial, many crucial steps are required. These will be some of the milestones of stem cell product development. During each step, there are various stem cell stimulations and differentiation protocols involved. In addition, culture medias and

feeder layer cells also play a key role on successes in stem cell culture and expansion methods. Stem cell transplantation protocols to obtain appropriate stem cell homing and to prevent immunological reaction have a significant influence on successes in stem cell therapy. All of these protocols and techniques are patentable and are of potentially great financial value^(1,2).

In addition to economical benefits, a numbers of intellectual properties and patented protocols will be one of the key indicators for stem cell research strength and potential. They will reflect successes and be important resources for further growth and development of each stem cell group. Moreover, they will build the reputations of each stem cell center from academic achievement standard⁽¹⁻³⁾.

During the human genome era, there was a concern that human gene patents may inadvertently harm the research environment, lead to an inappropriate commoditization of life, and adversely effect public access to useful health care procedures^(4,5). The same possibility may occur in stem cell research. It has been noted that the number of patents applications in stem cell research has increased by 300% over the past few years⁽⁴⁾.

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Cell lines and genetically modified single cell organisms have long been considered patentable in many countries. To date, 2000 patents applications have been filed worldwide wherein inventions involving human and nonhuman stem cells are claimed. Of these, 500 applications refer to embryonic stem cells⁽⁴⁾. Currently several stem cell patents have already been issued. The first and most well known is held by the Wisconsin Alumni Research Fund (WARF) that first reported the isolation and differentiation of embryonic stem cells⁽¹⁾. Apart from an economic viewpoint, social and legal controversies have also played an important role on stem cell patency⁽⁶⁻⁸⁾. The controversies focus mainly on ethical issues associated with stem cell research^(9,10).

Problems and solutions for stem cell intellectual property and patent issues

Most of the techniques and protocols involved in stem cell research have been registered and patented as intellectual properties. As a result, to follow the established and previously patented protocols, a certain amount of fees has to be paid to patentees. These will inevitably be obstacles for a newly formed stem cell center that has no patented protocols and registered techniques and usually has limited grants and resources. At the end, there will be fewer stem cell research centers due to patent problems. Therefore, the stem cell research centers will eventually be owned by developed countries over developing countries with restricted resources. However, many patients in developing countries could surely gain benefits from the promising stem cell therapy⁽¹⁻³⁾.

Patents at the research stage of stem cell technology are two-edged swords. They promote innovation by rewarding the researcher who invents something patentable, but they may limit further improvements and divert efforts by other researchers if the patented innovations are not available on reasonable and affordable terms⁽¹¹⁾.

To overcome these stem cell patent problems, there are solutions proposed:

1. There should be "free of charge" pool of patents for common basic steps in stem cell derivation and differentiation protocol to help newly formed research centers begin their first few steps in stem cell research area.

2. The patency should not impose very restrictive terms for academic and/or not-for-profit institutions.

3. There should be a reasonable range of

charges or fees for stem cell lines distributed from the stem cell bank or supplier to recipients.

4. There should be special patent charges for academic and/or not-for-profit investigators.

5. There should be initial support for a newly formed research center and company. For example, NIH has established Small Business Innovative Research (SBIR) program to support small biotechnology companies to negotiate patency issue with patents' owners on a case-by-case basis.

International trends and collaboration for intellectual properties and patent in stem cell research era

The emerging issues of intellectual properties and patents for stem cell research concern research products resulting from international collaboration. There should be an agreement among researchers established before an initiation of a research study to prevent possible problems on valuable patentable products. However, there is currently a great variation among countries on policy and regulations for stem cell research⁽¹²⁾. The UK, Saudi Arabia, Israel, Singapore, and China have been relatively open to the full range of embryonic stem cell research. Other countries, such as Germany, have been quite restrictive. In the USA, the private sector has been largely unregulated whereas publicly funded research is limited to existing embryonic stem cell lines. As a result, this may make patent issues more complicated than other research areas.

In addition, there are different approaches for each country on stem cell patent issues. For example, the Canadian Biotechnology Advisory Committee (CBAC) issued a report that strongly endorses the concept that "no patents should be granted on human bodies at any stage of development". However, CBAC is very careful to suggest that despite the force of the non-patentability recommendation, it is not meant to apply to stem cells. Specifically, it is stated in the CBAC report that the above concept will apply only to entire human bodies from the zygote to an adult body; DNA sequences, gametes, stem and other cells, or organs will remain patentable⁽⁴⁾. In Europe, the patent system has a 'public policy' provision that allows a consideration of broader social and ethical concerns. However, it remains unclear how the ethical issues will impact patents involving embryos and cloning technologies⁽¹³⁻¹⁵⁾. In the USA and Canada, for instance, the patent system is not designed to handle ethical or social issues. The appropriateness of a patent is purely evaluated on the principles of the existing technical patent criteria⁽⁴⁾.

Conclusion

Intellectual properties and patents are inevitably important issues for stem cell research. With appropriate solutions for patent barrier, most countries will have a chance to develop affordable stem cell therapy for their patients, while keeping acknowledge, reputation, and reasonable benefits to patent holders of stem cell protocols and techniques involved. These will be a crucial step to move forward together for better health and better quality of life with stem cell knowledge and technology worldwide.

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ทรัพย์สินทางปัญญาและสิทธิบัตรในยุคการวิจัยเซลล์ต้นกำเนิด

สรภาพ เกียรติพงษ์สาร

เซลล์ต้นกำเนิดบำบัดได้รับความสนใจอย่างมาก ทั้งนี้เนื่องจากมีศักยภาพสูงที่จะสามารถรักษาโรคเรื้อรัง และโรคที่เกิดจากความชราภาพหลายชนิดให้หายขาดได้ และมีมูลค่าสูงทางเศรษฐกิจ ซึ่งหมายถึงประมาณจำนวนมากที่ใช้ในห้วงปฏิบัติการและเพื่อการวิจัยทดลองทางคลินิก รวมทั้งทรัพย์สินทางปัญญาและสิทธิบัตรที่เกี่ยวข้องกับขั้นตอนต่าง ๆ ตลอดจนจนเวชผลิตภัณฑ์ที่พัฒนาขึ้นจากเซลล์ต้นกำเนิดเพื่อใช้เป็นเซลล์บำบัดและเนื้อเยื่อบำบัด ประเด็นปัญหาและข้อจำกัดเรื่องทรัพย์สินทางปัญญาและสิทธิบัตรเป็นเรื่องสำคัญที่หลีกเลี่ยงได้ยากสำหรับนักวิจัยเซลล์ต้นกำเนิด แต่คาดว่าด้วยกลไกการบริหารจัดการที่ดีจะช่วยให้ นักวิจัยเซลล์ต้นกำเนิดจำนวนมากทั่วโลก สามารถพัฒนาการรักษาโรคด้วยเซลล์บำบัดวิธีใหม่ขึ้นได้ด้วยค่าใช้จ่ายที่เหมาะสม เกิดความก้าวหน้าทางวิทยาศาสตร์ และเกิดนวัตกรรมใหม่ในการรักษาโรค ในขณะที่ยังคงให้เกียรติยกย่อง เคารพ และให้ผลตอบแทนอย่างเหมาะสม ต่อผู้ค้นพบเทคนิควิธีการต่าง ๆ ขึ้น การบริหารจัดการด้านทรัพย์สินทางปัญญา และสิทธิบัตรที่ดีและมีประสิทธิภาพนี้ จะเป็นบันไดขั้นสำคัญสู่การพัฒนาและความก้าวหน้าของวงการวิจัยเซลล์ต้นกำเนิดทั่วโลก