

Patenting human embryonic stem cell related inventions in China

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Valorization Addendum

1. SOCIAL AND ECONOMIC RELEVANCE

Over almost the last two decades, the question of whether or not to grant and how to grant patents on hESC-related inventions has perplexed jurisdictions around the world, including China and the EU. Determining the patent eligibility of hESC-related inventions is important to the hESC industry and research. In a jurisdiction, how the legislation and policies respond to the issue of patenting, to some extent, will profoundly influence whether and how research and the industry develops there. Moreover, in terms of the patenting of hESC-related inventions, on the face of it, it seems to be an IP question. However, it requires a much deeper and more fundamental exploration, since this legal issue is intertwined with ethical, sociological, and economic issues. Given this, the thesis aims to seek fair designed patent rules and policies to ensure the hESC industry has sufficient incentives to continue to research and develop hESC-related inventions on the one hand, while recognizing the value of Chinese and outside moral culture on the other hand.

This thesis is the very first study to take on both the narrow IP issue—the patenting of hESC-related inventions, and the “broader” issues surrounding it, including ethical and sociological considerations, in China particularly. Indeed, it is believed that hESC research has opened the door to a wide variety of new therapies and other medical applications for mankind. Over recent years, results from hESC research have been increasingly applied in the fields of diagnostics and therapy for diseases. In this regard, promoting the advance of hESC research and industry through a series of fair designed patent rules and policies, based on the recommendations of the thesis, will of course be beneficial to finding cures for terrible diseases, and will indirectly facilitate the improvement of human healthcare. With regard to the wider ethical and sociological considerations that spring from the patenting of hESC-related inventions, these issues have been discussed in the thesis. One example concerns the legal and moral status

of the human embryo in China, and another one concerns the public perception of patents in China. The analysis in this thesis will help the industry around the world pay more attention to China's specific culture and public debates surrounding hESC research and by extension the patenting of hESC-related inventions. It will also help scientists in China rethink the moral issues behind hESC research. The thesis shows that China's current development level of hESC research and industry is still relatively low, especially compared with its technologically advanced counterparts, such as the EU, the US, and Japan. Based on a careful consideration of this fact, the designed legal rules and policies concerning patenting hESC-related inventions proposed in the thesis will of course promote the advance of China's domestic research and industry. In other words, the results of the study, will hopefully help China take full of advantage of the government's generous institutional patronage in the field of hESC research. Moreover, the outcomes of the thesis will in general promote the advance of hESC and industry, and further promote socio-economic development.

2. TARGET GROUPS

In general, the thesis will be a useful and valuable read for legal scholars, students of IP and medical law, and executives and investors, as well as practitioners seeking a deeper understanding of the rules and policies regarding this topic. Legal scholars, who have problems, especially concerning patents, underlying the international and national regulation of stem cell research, will find in this thesis a relatively useful case study of China. The unique situations in China discussed in this thesis can provide observers a ready resource for future research. Certainly, executives and investors who are going to conduct investment and research in the hESC industry and seek reliable patent protection in China will also find value in this text. In addition, the exploration of these issues will be of interest to lawyers, law practitioners curious about patenting hESC-related inventions, even biotechnological inventions, in China, and scientists and researchers around the world who intend to conduct research or collaborate with their peers in the field of hESC research in China. Furthermore, industrialists and scientists working in hESC research and industry will also be interested in the thesis, since even if they are working outside China, if they are planning to market their products in China or file a patent application there, they still need to pay attention to the rules and policies in China. The legislators and policy makers in China should be quite interested in this thesis, particularly in terms of the analysis of China's patent legislation and the SIPO's policies in the thesis. Moreover, the recommendations proposed in the thesis should be valuable to the legislators of China and policy makers of the SIPO. Of course, legislators and policy makers from some other jurisdictions may find this thesis interesting, and may consider the discussion of the thesis as a course of legislation and as a forum for

discussing issues regarding patenting morally controversial biotechnological inventions.

3. ACTIVITIES AND PRODUCTS

The results of this research will be published in the form of a book. As a result, it will be available to readers, as previously mentioned, including students, academics, judges, legislators, policy makers, scientists and researchers who are interested in or want to know something about this topic. Moreover, parts of this study have already been published in academic journals. For instance, parts of Chapter 5 in relation to the patentability of hESC-related inventions in China as well as the dynamic development of patenting these inventions in the SIPO are updated versions of the article “*The Patentability of Human Embryonic Stem Cell Technology in China*”, published by *Nature Biotechnology*, Volume 34, Number 1, January 2016. Parts of Chapters 3, 4, and 5 in relation to regulating and patenting hESC-related inventions and some endemic problems in China are updated versions of a Chinese article “*Intellectual Property Protection Concerning Stem Cell Research in China: Predicament and Solutions*”, published by *Bulletin of Life Science*, Volume 28, Number 8, August 2016. Parts of Chapters 4 and 5 in relation to the moral dilemma concerning patenting hESC-related inventions in Europe and China, and some recommendations in Chapter 5 are updated versions of a conference paper “*Europe and China in the Area of Patenting Human Embryonic Stem Cells: Finding the Way in the Moral Dilemma*”, submitted to and presented at “Intellectual Property Work-in-Progress Colloquium” held in the UW in 2015. In addition, during the period of this research, some findings and results have also been presented in many international academic conferences and workshops, held by organizations such as the Institute for Globalization and International Regulation (IGIR), the *Ius Commune* Research School, the European Intellectual Property Institutes Network (EIPIN), Applied Research Centre for Intellectual Assets and the Law in Asia (ARCIALA), etc.

4. INNOVATION

Recently, there have been an increasing number of studies on patent-related issues in the field of biotechnology in China. At the same time, there is considerable scholarship on patent-related issues concerning hESC research in Western countries, particularly in Europe and in the US. However, very little research can be found on patenting hESC-related inventions in China, which has made considerable progress in this research field over the past decade. Moreover, previous studies using a comparative law analysis did not take into consideration China’s specific social and moral culture or the domestic development stage of hESC research and industry, and instead only took the current

legislation and practice of other jurisdictions as a reference,¹ which may result in an inappropriate patent system for China's current research and industry environment.

This thesis tries to provide one of the first comprehensive, systematic, and comparative treatments of hESC technology and patent protection concerning Chinese law, which is increasingly important in the context of China's growing internal strategic needs and the growing impact of this country on the global stem cell market. It is an important narrative that suggests that developing countries with a relatively advanced technological capability, such as China, can tailor an optimal patent policy to promote the advancement of their domestic hESC research and industry. In other words, the practice of China in terms of patenting hESC-related inventions can provide an attractive alternative model for other developing countries that are struggling to catch up economically and technologically in the present international economic system. Moreover, the findings of the thesis will contribute to the setting of international and/or domestic patent rules and the tailoring of patent policies not just restricted to hESC-related inventions, but extending to biotechnological inventions, since the controversy over patenting hESC-related inventions is merely one of the most typical representatives of patenting biotechnological inventions in the past several decades.

The thesis attempts to draw all this complex IP issue and ethical content together in one place. The explicit focus on the patent issue concerning hESC-related inventions in China gives the research a unique flavour, since China is a newly emerging power as well as a jurisdiction where the public has not been influenced very much by religious ideas, especially Christian morality. Thus, research on the patenting of hESC-related inventions in China can offer a fresh look at how an emerging economic and legal power with its own socio-cultural, religious, economic, and historical considerations will utilize patent law to serve its own development of research and industry.

5. SCHEDULE AND IMPLEMENTATION

Whether and how to grant patents upon hESC-related inventions are still on-going, controversial issues, which have attracted and will continue to attract more attention of academics and practitioners. The problems addressed in the thesis are considerably complex. Not surprisingly, the long-term consequences of concrete policy recommendations proposed by the thesis are in most cases difficult to predict. But the foremost step for the policy options suggested by the thesis to be realized is to spread the outcomes of the thesis as much as possible. In this regard, the author plans on presenting the results

1 See generally, LI JIANG, *REGULATING HUMAN EMBRYONIC STEM CELL IN CHINA: A COMPARATIVE STUDY ON HUMAN EMBRYONIC STEM CELL'S PATENTABILITY AND MORALITY IN US AND EU* (Springer 2016).

of the study in more seminars, workshops, and conferences both within and outside China. Also, as mentioned above, some contents in the thesis have been published in academic journals during the PhD research, but some have not. Given this, it is planned that within one year (before 2019), some remaining parts of the thesis that have not been published will be singled out and be further polished, and then published in academic journals ultimately. Within two years (before 2020), the author will also try to publish this thesis in book form through an international publishing house. In that case, there will be both physical and e-book versions available. The author will try his best to make the outcomes of the thesis accessible to everyone who is interested in this topic. By doing so, the outcomes of the thesis can be better spread, and the content can be further polished, and the policy options proposed by the thesis can be further improved. It is hoped that the outcomes of this thesis will bear fruit by sparking deeper and wider discussions, and stimulate investigation and evaluation in future research, specifically concerning the topic of this thesis in China. Hopefully, the discussion in this thesis will have far-reaching consequences for our society at large.