

A Comparative Study on Human Embryonic Stem Cell Patent Law in the
United States, the European Patent Organization, and China

BY

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Brief Table of Contents

CHAPTER 1: INTRODUCTION	1
CHAPTER 2: SCIENTIFIC REVIEW	9
A. STEM CELLS.....	9
B. EMBRYONIC STEM CELLS [ESCs].....	19
CHAPTER 3: ETHICAL, RELIGIOUS AND PHILOSOPHICAL VIEWPOINTS ON HUMAN EMBRYONIC STEM CELL [HESC] RESEARCH	28
A. ETHICAL DEBATES OVER HESC RESEARCH	28
B. THE START-LINE OF PERSONHOOD AND ETHICS OF HESC RESEARCH FROM THE PERSPECTIVES OF RELIGION AND PHILOSOPHY	32
C. LAWS AND POLICIES ON THE STATUS OF HUMAN EMBRYOS.....	41
CHAPTER 4: PATENT LAWS REGARDING HESCS IN THE UNITED STATES	51
A. FEDERAL POLICY ON HESC RESEARCH	51
B. FEDERAL PATENT LAW REGARDING HESCS	57
C. STATES LAWS REGARDING HESC RESEARCH	82
D. ACADEMIC DISCUSSION CONCERNING HESC INVENTIONS	85
CHAPTER 5: LAWS REGARDING HESCS IN THE EUROPEAN PATENT CONVENTION	92
A. EUROPEAN PATENT SYSTEMS	95
B. EUROPEAN UNION PATENT LAWS	111
C. LAWS OF EUROPEAN COUNTRIES ON PATENTABILITY OF HESCS.....	124
D. ACADEMIC DISCUSSION ON HESCS' PATENTABILITY	128
CHAPTER 6: LAWS GOVERNING HESCS IN CHINA.....	132
A. INTRODUCTION TO CHINESE LEGAL SYSTEM	132
B. LAWS ON HUMAN EMBRYONIC STEM CELL RESEARCH, PATENT AND EMBRYONIC STEM CELL INVENTIONS	154
C. PATENT APPLICATIONS AND CASES CONCERNING HESCS	176
D. ACADEMIA IN HESC PATENT ISSUES IN CHINA	179
CHAPTER 7: COMPARISON AND SUGGESTIONS	182

A. DIFFERENCES OF LAWS AND JUDICIAL PRACTICES AMONG THE UNITED STATES, EUROPE AND CHINA INCLUDING REASONS FOR DIFFERENCES.....	182
B. RATIONALES FOR DIFFERENT LAWS TO HESC INVENTION APPLICATIONS	200
C. THE IMPORTANCE OF HESC LAWS	215
D. MODEL LAW—SUGGESTIONS REGARDING PATENT REGULATIONS ON HESCs	218
CHAPTER 8: CONCLUSION	241
GLOSSARY	247
BIBLIOGRAPHY	251

Table of Contents

CHAPTER 1: INTRODUCTION	1
CHAPTER 2: SCIENTIFIC REVIEW	9
A. STEM CELLS.....	9
1. <i>Definition and Characteristics of Stem Cells</i>	9
2. <i>Scientific and Therapeutic Values of Stem Cells</i>	14
3. <i>Global Investments on Stem Cell Research</i>	17
B. EMBRYONIC STEM CELLS [ESCs].....	19
1. <i>Definition and Formation of Embryonic Stem Cell</i>	19
2. <i>Scientific and Therapeutic Values of Embryonic Stem Cells</i>	24
3. <i>Scientific Uncertainty in hESC Research</i>	26
CHAPTER 3: ETHICAL, RELIGIOUS AND PHILOSOPHICAL VIEWPOINTS ON HUMAN EMBRYONIC STEM CELL [HESC] RESEARCH	28
A. ETHICAL DEBATES OVER HESC RESEARCH	28
B. THE START-LINE OF PERSONHOOD AND ETHICS OF HESC RESEARCH FROM THE PERSPECTIVES OF RELIGION AND PHILOSOPHY	32
1. <i>Religious Viewpoints on Human Embryo's Status and hESC Research</i>	32
2. <i>Philosophical Perspectives on Human Embryo's Status and hESC Research</i> 39	
C. LAWS AND POLICIES ON THE STATUS OF HUMAN EMBRYOS.....	41
1. <i>National Laws regarding the Status of Embryos</i>	41
2. <i>Laws and Policies towards hESC Research</i>	46
CHAPTER 4: PATENT LAWS REGARDING HESCS IN THE UNITED STATES	51
A. FEDERAL POLICY ON HESC RESEARCH	51
B. FEDERAL PATENT LAW REGARDING HESCS	57
1. <i>History of U.S. Patent System</i>	57
2. <i>Current U.S. Patent Law</i>	59
a. U.S. Patent System	59
b. The Current Patent Law.....	62
i. Subject matter.....	62
ii. Utility.....	65
iii. Novelty	66

iv. Nonobviousness	68
v. Morality Consideration	69
3. <i>hESC Related Patents Issued by the USPTO</i>	70
4. <i>Biotechnological Patent Case Law</i>	77
a. WARF Patents	78
b. Gene patents	81
C. STATES LAWS REGARDING HESC RESEARCH	82
1. <i>hESC Research in Constitutions</i>	82
2. <i>hESC Research in Statutes</i>	83
D. ACADEMIC DISCUSSION CONCERNING HESC INVENTIONS	85
1. <i>The Status of Human Embryos</i>	85
2. <i>Morality Consideration in Patent Law</i>	87
3. <i>Research Tool Doctrine</i>	88

CHAPTER 5: LAWS REGARDING HESCS IN THE EUROPEAN PATENT

CONVENTION 92

A. EUROPEAN PATENT SYSTEMS	95
1. <i>European Patent Convention</i>	95
a. Patentable Subject Matters in the EPC	98
b. Requirements of Patenting	100
2. <i>Decisions on hESC Patent Applications of the European Patent Office</i> <i>under the EPC</i>	104
3. <i>European Patent Court System (EPC-based)</i>	110
B. EUROPEAN UNION PATENT LAWS	111
1. <i>Conventions on hESC Research</i>	114
2. <i>Announcement of the European Parliament concerning hESC Research</i> <i>115</i>	
3. <i>The Biotechnology Directive (Directive 98/44/EC)</i>	115
4. <i>European Group on Ethics [EGE] Reports on hESC Research</i>	120
5. <i>Judicial Decisions</i>	123
C. LAWS OF EUROPEAN COUNTRIES ON PATENTABILITY OF HESCS	124
1. <i>United Kingdom</i>	124
2. <i>Germany</i>	126
3. <i>Other Countries</i>	126
D. ACADEMIC DISCUSSION ON HESCS' PATENTABILITY	128

CHAPTER 6: LAWS GOVERNING HESCS IN CHINA.....	132
A. INTRODUCTION TO CHINESE LEGAL SYSTEM	132
1. <i>Legislatures and Legal Effectiveness of Statutes</i>	135
a. Chinese Legislature Introduction	135
b. Issues of the Chinese Legislative System	137
c. Legal Force of Statutes.....	141
2. <i>Administrative Agencies and Legal Effectiveness of Regulations</i>	141
a. Administrative Agencies.....	142
i. Central Administrative Agencies.....	142
ii. Regional Level: Local Governments.....	147
b. Legal Effectiveness of Regulations.....	150
3. <i>Chinese Judicial System and Legal Force of Judicial Decisions</i>	150
a. Court System Hierarchy.....	151
b. Force of Judicial Interpretation and Judicial Decisions.....	154
B. LAWS ON HUMAN EMBRYONIC STEM CELL RESEARCH, PATENT AND EMBRYONIC STEM CELL INVENTIONS	154
1. <i>Legal Documents on Human Embryonic Stem Cell Research</i>	154
a. International Conventions.....	154
b. Chinese Law on Human Embryonic Stem Cell Research.....	155
i. Eleventh Five-year Plan.....	155
ii. Ethical Guiding Principles for the Research of Human Embryonic Stem Cell (2004)	156
2. <i>Chinese Patent Laws regarding hESC Inventions</i>	157
a. Current Patent Law (2008).....	157
b. The Detailed Rules for the Implementation of the Patent Law (2010).....	165
c. Examination Guidelines (2006).....	167
i. Part 1 of the Examination Guidelines.....	167
ii. Part 2 of the Examination Guidelines.....	168
iii. Parts 3, 4 and 5 of the Examination Guidelines.....	176
C. PATENT APPLICATIONS AND CASES CONCERNING HESCS	176
1. <i>hESC Patent Application Statistics</i>	177
a. Granted Patents.....	177
b. Patent Applications regarding hESCs	178
2. <i>Court Decisions on hESC Patents</i>	179
D. ACADEMIA IN HESC PATENT ISSUES IN CHINA	179
CHAPTER 7: COMPARISON AND SUGGESTIONS	182

A.	DIFFERENCES OF LAWS AND JUDICIAL PRACTICES AMONG THE UNITED STATES, EUROPE AND CHINA INCLUDING REASONS FOR DIFFERENCES.....	182
1.	<i>Differences of Laws and Judicial Practice regarding hESCs.....</i>	183
a.	Patent Laws	183
i.	Patentable Subject Matter	183
ii.	Morality Considerations in Patent Laws.....	187
iii.	Utility/ Industrial Applicability.....	191
iv.	Exemptions to Patent Infringement	194
b.	Judicial decisions and patent practice	196
B.	RATIONALES FOR DIFFERENT LAWS TO HESC INVENTION APPLICATIONS	200
1.	<i>Different Legal Systems.....</i>	200
2.	<i>Differences of Cultures and Value Orientation.....</i>	204
3.	<i>Research Progress in hESC Research.....</i>	212
C.	THE IMPORTANCE OF HESC LAWS	215
D.	MODEL LAW—SUGGESTIONS REGARDING PATENT REGULATIONS ON HESCS.....	218
1.	<i>Choice of Law.....</i>	219
2.	<i>Requirements of Patentability</i>	221
a.	Patentable Subject Matters.....	221
b.	Morality Issues in Patent Law	222
c.	Novelty.....	224
d.	Utility/Industrial Applicability.....	225
e.	Non-obviousness.....	227
f.	The model law	229
3.	<i>Other Clauses in Patent Law</i>	232
a.	Infringement Exemption	232
b.	Compulsory Licensing.....	233
4.	<i>The Morality Issue of hESC Research</i>	234
a.	Embryos from fertility clinics.....	235
b.	SCNT-produced embryos.....	236
c.	Induced Pluripotent Stem Cells	237
	CHAPTER 8: CONCLUSION	241
	GLOSSARY	247
	BIBLIOGRAPHY	251

List of Figures

Figure 2.1: Symmetric stem cell division.....	10
Figure 2.2: Asymmetric stem cell division	11
Figure 2.3: Development cycle of the human embryo.	12
Figure 4.1: U.S. human cell patents.....	56
Figure 4.2: U.S. hESC related patent and application categories	71
Figure 4.3: U.S. hESC related patents ownership categories.....	76
Figure 5.1: Member states of the EU and the EPC.....	93
Figure 5.2: EPO patent application status for hESC related inventions	104
Figure 5.3: EPO claim categories of patents and applications related to hESCs	105
Figure 6.1: Chinese patent application status for hESC related invention....	177
Figure 6.2: Claims of Chinese of patents and applications related to hESCs	177
Figure 7.1: Nationalities of hESC patents issued in the U.S., EPO and China	213
Figure 7.2: Comparison of ownership categories of hESC related patents and applications between the U.S., EPO and China.....	214

List of Tables

Table 2.1: Government grants on hESC research in the United States 18

Table 3.1: Startline of Personhood in Religions and Attitudes to hESC
Research..... 34

Synopsis

With the recent developments in biotechnology, associated patent law issues have been a growing concern since the 1980s. Among all the subcategories within the general field of biotechnology, human embryonic stem cell research, as one of the most controversial, is receiving different patent system treatment in different countries. China explicitly opposes the patentability of hESCs in its patent regulations on the basis that patenting hESCs is contrary to morality and the public interest. Similarly, the EPO, relying on ambiguous language in the European Patent Convention [EPC], excludes hESCs from patentability by broadly interpreting the morality clause of the EPC. In contrast, the United States has become the main progenitor of hESC patents. By analyzing the reasons to grant or deny patents on hESCs, and considering patent law doctrines and justifications, this dissertation reaches two conclusions. First, patent law should not include a morality clause and should only take into consideration technical concerns. Moral issues should be left to other mechanisms such as administrative law. This is an approach deeply rooted in the American patent system, but not in China or the EPO. Second, by reviewing the requirements of patentability such as novelty, non-obviousness and utility, it can be concluded that hESCs themselves are not patentable because they lack a specific concrete utility and, since they already exist in nature, they lack novelty as well. However, hESC production processes and derivative products are patentable.

Chapter 1: Introduction

In 2006, two crucial plans regarding human embryonic stem cell [hESC] research were issued in China. The first of these was the Outline of National Medium and Long Term Science and Technology Development Plan (2006-2020) issued by the State Council of the People's Republic of China. It adopted innovation as the new national strategy and established the goal of advancing China into an innovation-oriented country by 2020.¹ In order to reach this target, the outline called for China to increase its investment on research and development, encourage indigenous innovation, and adjust its patent laws to implement the new goal of becoming an "an innovation oriented country,"² which means a country that promotes social and economic development by enhancing science and technology and by increasing its globally influential scientific and technological achievements.³

The second plan called the National Eleventh Five-Year Science and Technology Development Plan (11th), was authoritative between the years of 2006 and 2010 and was promulgated by the Ministry of Science and Technology [MOST]. It called for the establishment of a bank of human embryonic stem cells as well as embryonic stem cells derived from non-human primates, the development of a differentiation model for embryonic stem cells, and progress on tissue engineering and animal cloning technology.⁴ The 11th Five-Year-plan was the initial implementation of the

¹ State Council, *Outline of National Medium and Long Term Science and Technology Development Plan (2006-2020)*, available at http://www.gov.cn/jrzq/2006-02/09/content_183787.htm (last visited Oct. 23, 3010) (translated by author).

² *Id.*

³ The 17th CPC National Congress of the Communist Party of China, *Interpretation of Congress Terms*, Oct. 11, 2007, available at <http://english.peopledaily.com.cn/90002/92169/92211/6281108.html> (last visited Jan. 1, 2011).

⁴ Ministry of Science and Technology of P.R.C., *National "Eleventh Five-Year" Science and Technology Development Plan (2006-2010)*, available at

broader outline's target, because science and technology development is an essential element in establishing China as an "innovation-oriented country." In addition, the plan demonstrated China's specific commitment to nourishing biotechnological research, including hESC.

In 2010, the MOST issued the Application Guideline for the National Basic Research Program and National Science Research Program for the Year 2010⁵ to implement the Outline of National Medium and Long Term Science and Technology Development Plan (2006-2020). The Application Guideline lists certain important fields for national support, including research into the basic properties and differentiation of human embryonic stem cells.

However, the corresponding patent protection laws have not been able to maintain the same developmental pace. Chinese patent law was recently amended in 2008 in an effort to embrace the Outline of National Medium and Long Term Science and Technology Development Plan (2006-2020). While the amendment addresses the scope of the novelty requirement, it fails to address either procedure or patent right enforcement. The revised patent law does not specifically discuss the protection of biotechnology innovation. Meanwhile, the Chinese Examination Guidelines, which regulate the patentability of biotechnological innovations, state that hESCs and their production are not patentable according to Article 5 in patent law⁶. This conflicts with the policies established in the two above-mentioned national plans. Encouraging innovation in science and technology is only one aspect of building an innovation-oriented country. Proper legal protection, especially patent protection, is another instrument to promote scientific research.

http://www.most.gov.cn/kjgh/kjfzgh/200610/t20061031_55485_6.htm(last visited Oct. 23, 3010) (translated by author).

⁵ Application Guideline of the National Basic Research Program and National Science Research Program of the Year 2010, *available at* http://www.most.gov.cn/wsbl/201001/t20100120_75591.htm (last visited Mar. 22, 2011) (translated by author)

⁶ Inventions that contrary to laws, social morality or public interest are not patentable. This article will be explained in details in Chapter 6.

There are many articles that discuss the hESC research policy in China, but very few articles focus on the patent issues directly related to hESC innovation. In order to fill this gap, I analyzed other countries' laws, and found that China is not the only country that has laws and regulations inconsistent with its future goals and outlooks. Both hESC research laws and patent laws are major issues in many countries. This dissertation focuses on the jurisdictions of the United States, the European Patent Organization, and China.

The close relationship between biotechnology and mankind brings about ethical, religious and public health issues that must be defined and addressed. Countries like China, America and many European countries are facing problems with adopting an attitude towards such issues and applying the appropriate laws to regulate the field and the results.

This dissertation focuses on patent law issues because patent law is designed to be a stimulus to scientific and technological progress.⁷ The mechanism of patent law is to reward inventors with monopoly rights in order to encourage scientific innovation. While simple in concept, it is the burden of patent law to adjust the degree of these monopolies in order to maintain a market with fair competition. The patent laws and practices in China have been gradually approaching those of developed countries due to international treaties, such as the World Trade Organization's [WTO] Agreement on Trade-Related Intellectual Property Rights [TRIPS Agreement]. However, the goal of Chinese legislation and policy concerning biotechnology is to enhance competition in both the scientific research and

⁷ See *i.e.*, Zhuan li fa [Patent Law](as Amended 2008) (promulgated by the Standing Comm. Nat'l People's Cong., Dec. 27, 2008, effective Apr. 1, 1985) (2000) art. 1 LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C)[hereinafter 2008 Patent Law].art. 28, "promoting scientific and technological progress as well as the economic and social development,"and U.S. Constitution, art. I, § 8, cl.8, "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries".

end-product industries. With respect to essential tools of discovery and research in biotechnology, one primary concern regarding the patent system is the side effect of stifling developmental innovations due to royalty requirements and negotiation time.⁸ Therefore, while patent protection is an important tool for encouraging inventors, patent rights are not absolute. In order to enhance the progress of biotechnology, the scope of patentable subject matter should be restrained and research tool and experimental use exception should be sustained.⁹

Granting patent protection to biotechnology inventions is not only intended to benefit public health, medical science and the drug industry, but also to enable states to maintain their competitiveness in the global market and remain independent from their partners in trading. Opponents of this viewpoint argue that patent protection stifles further development and innovation by awarding a monopoly, thereby limiting competition. In addition, they believe that it causes ethical issues due to the close relation between mankind and biotechnology science. Patenting human material to them symbolizes the commercializing of human beings, therefore degrading human dignity. This is the basis for the debate on whether patent law should be used for contentious biotechnological products such as hESC innovations.

Considering the importance of hESCs to medicinal manufacture, therapy and diagnostic research, many countries are cautious regarding the patentability of hESCs because regardless of which direction is taken, it will impact the fields of industry and science dramatically. China is maintaining a conservative viewpoint with respect to hESC patentability. Current Chinese

⁸ Vincent J. Filliben, *Patent Law and Regenerative Medicine: A Consideration of the Current Law and Public Policy Concerns Regarding Upstream Patents*, 9 WAKE FOREST INTELL. PROP. L.J. 238, 252 (2008)[hereinafter Filliben]

⁹ Gregory C. Ellis, *Emerging Biotechnologies Demand Defeat of Proposed Legislation That Attempts to Ban Gene Patents*, 15 Rich. J.L. & Tech. 1, 26 (2008)[hereinafter Gregory C. Ellis]; Yi-Chen Su & Albert Wai-Kit Chan, *Too Costly to Defend: Who is Benefited from the U.S. Supreme Court's Recent Holdings Concerning Biotechnology Patent Disputes?*, 18 Alb. L.J. Sci. & Tech. 53, 60 (2008) [hereinafter Su]

patent legislation on biotechnology covers almost the entire field of biotechnological research and expresses China's stance on some ethically controversial issues. On the topic of patenting hESCs, China holds that hESCs and their production are not patentable under morality clauses in the present patent law. While this is similar to the European policy, the U.S. protects patent rights on hESCs as well as their production. The policy of not protecting patent rights on hESCs does not foster as strong a debate in China as is seen in other regions such as Europe. This is primarily because most of the hESC research in China is conducted and supervised by national research institutes or public universities and is therefore carried out with a high degree of rigor and professionalism. This is beneficial in three ways. First, the research is conducted either by government agencies or under the supervision of the government, which may diminish the possibility of misuse or illegal conduct. Second, it dispels worries about future research being impeded by high royalties and lengthy negotiations. Because the government can supervise licensing and assignment activities in the interest of the country as a whole, there is no need to be concerned about research monopolies hampering further downstream development. Third, research results can be utilized and applied under the government's control for the public interest. In the case of emergencies, such as those involving public safety, decisions can be made more quickly and measures can be implemented more thoroughly.

Countries utilize the patent mechanism to stimulate science. Along with the benefits that patenting hESC inventions can bring, such as encouraging research, there are a number of concerns. It is possible to misuse or monopolize research results, which may stifle competition and lead to technological stagnation. This particular dilemma is the leading concern regarding patent rules on biotechnical products such as hESCs.

The diversity of national patent laws governing biotechnological products does not, on the surface, seem globally critical since such laws have only territorial legal force. Nonetheless, non-uniformity of patent laws may impact the international trade business in the global market and stifle the circulation of product innovations. Facing increasingly fierce industrial and scientific competition and an increasingly globalized market, it is crucial to consider the role of scientific innovation in patent law in order to avoid making bad decisions that will adversely affect industry and science. As for the U.S., hESCs are presently patentable subject matter. If these inventions are, in the future, deemed unpatentable and opened to the public, the licensees who spent tremendous time and money negotiating license agreements will be unfavorably impacted which will bring about instability in the industry. In contrast, with respect to those countries that do not presently patent hESC innovations, if their bans on patenting hESCs are removed in the future, countries patenting hESCs all along, like the US, will take advantage of the priority right in other countries based on international treaties such as the Paris Convention for the Protection of Industrial Property, the Patent Corporation Treaty [PCT] and bilateral agreements.¹⁰ Because hESC patent applicants filed applications in the US, they can claim priority right when they file applications in other contracting countries, which give them up to a one-year advantage as compared to European and Chinese applicants. Both Europe and China will lose not only the market for hESCs, but also the market for downstream products that are derived from hESCs. As a result, patentability of hESCs is a crucial subject to all countries' scientific research and industrial sectors.

¹⁰ Priority right is a right a person who filed a patent application in one of contracting state is entitled to a right of priority in certain period of time (usually it is one year for patents) to file the same or a subsequent application in other contracting countries. The date of priority will count as the filing date of the second application. The right will not be negated by another filing from a third person or the publication or exploitation of the invention. *See* Patent Cooperation Treaty with Regulations, June 19, 1970, 28 U.S.T. 7645, art. 8(1) and Rule 4.10(a) [hereinafter PCT].

Along with the rapid development of biotechnology, patent laws have been challenged substantially. Patent-eligibility issues on biotechnology are always contentious and sensitive. Which subjects are patentable, and which are not? Should patent law extend to new categories like hESCs? If so, how should patent law be applied to them? Should patent law be altered for new types of subject matter? How should patent laws be utilized to maintain the balance between scientific and industrial benefits and social morality concerns generated by new technology? Investors and researchers urgently require answers to these and other questions. Therefore, these difficult issues should be solved as rapidly as possible in order to guarantee and encourage further scientific and economic progress. The goal of this dissertation is to answer these questions.

By reviewing the background science of hESCs and relevant ethical issues, and by exploring and comparing different patent rules, patent practices and historical debates regarding hESC inventions in the European Patent Organization, the United States and China, this dissertation comes to the conclusion that hESCs themselves should not be considered patentable. While hESCs fail to meet the novelty and utility requirements of patent law, production methods and derivative products are found to be patentable. It is suggested that current patent rules be adjusted to consider only technical issues in the patent law. It is also suggested that the definitions and scopes of the novelty and utility requirements be altered in order to eliminate the conflicting rules regarding hESCs across the relevant countries. This study finds that the patent system is indispensable to biotechnological innovation and research goals, such as the development of methods for culturing, differentiating, and utilizing hESCs, and the development of downstream products from hESCs.

This dissertation is divided into six chapters. Chapter 2 provides a general scientific background regarding stem cells with an emphasis on embryonic

stem cells. Chapter 3 reviews religious, ethical and legal debates on hESC research along with varying national attitudes and corresponding policies on hESC research. Chapters 4, 5 and 6 introduce patent systems, patent rules on hESC related innovations and patent examination and litigation on hESCs and related innovations in the United States, the European Patent Office and China, respectively. Chapter VI summarizes the differences in patent rules and practice among the three legal regimes studied, explores the justifications behind these differences, and proposes a partial model patent law composed of a collection of modified patent requirement clauses with an emphasis on hESCs and related inventions.

Chapter 2: Scientific Review

A. Stem cells

1. Definition and Characteristics of Stem Cells

Stem cells are found in all organisms and are theoretically capable of self-renewing indefinitely and differentiating into a wide variety of specialized cells.¹¹ Self-renewal is the ability to produce a pool of identical cells¹², which is also called symmetric cell division¹³ (Figure 2.1). In addition, stem cells may differentiate into more specialized cells, such as red blood cells or muscle cells, in a process called asymmetric cell division¹⁴ (Figure 2.2 is an example of asymmetric cell division in the nervous system). When stem cells divide, they may self-renew or differentiate into specialized cells with particular functions.¹⁵ For instance, muscle cells have the function of contraction, while red blood cells deliver oxygen to body tissues.

¹¹ ANN A. KIESSLING & SCOTT C. ANDERSON, HUMAN EMBRYONIC STEM CELLS, 3 (Jones and Bartlett 2d ed. 2007)[hereinafter KIESSLING]; The National Institutes of Health Resource for Stem Cell Research, *Stem Cells Basis*, available at <http://stemcells.nih.gov/info/basics/basics1.asp> (Last visited Feb. 1, 2010) [hereinafter Stem Cell Basis]

¹² Stem Cell Basis, *supra* note 11; Peter J. Bryant & Philip H. Schwartz, *Stem cells*, in FUNDAMENTALS OF THE STEM CELL DEBATE 10 (KRISTEN RENWICK MONROE et al. eds., University of California 2008)[hereinafter Bryant]

¹³ *Id.*

¹⁴ *Id.*

¹⁵ Stem Cell Basis, *supra* note 11.

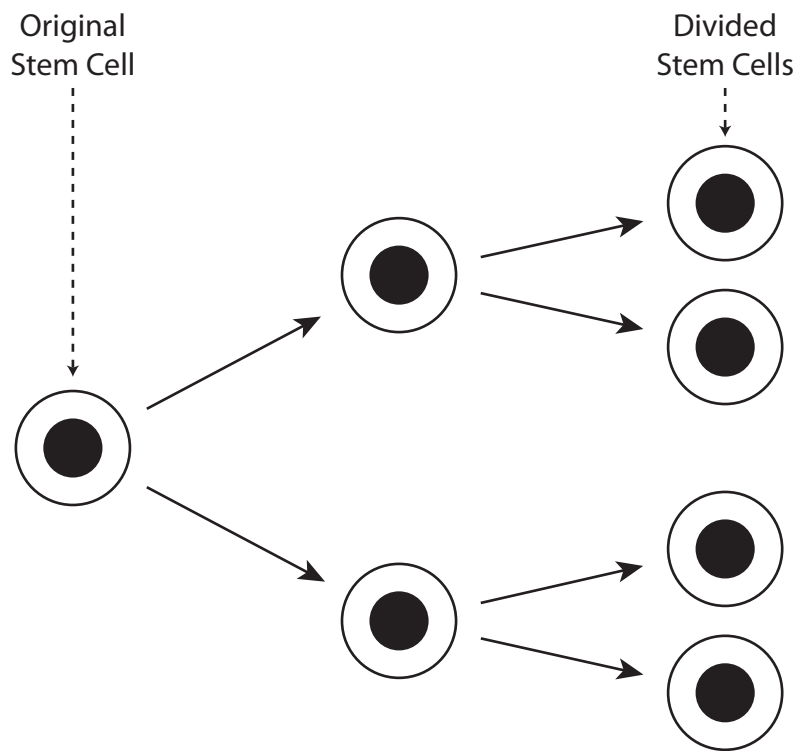


Figure 2.1: Symmetric stem cell division

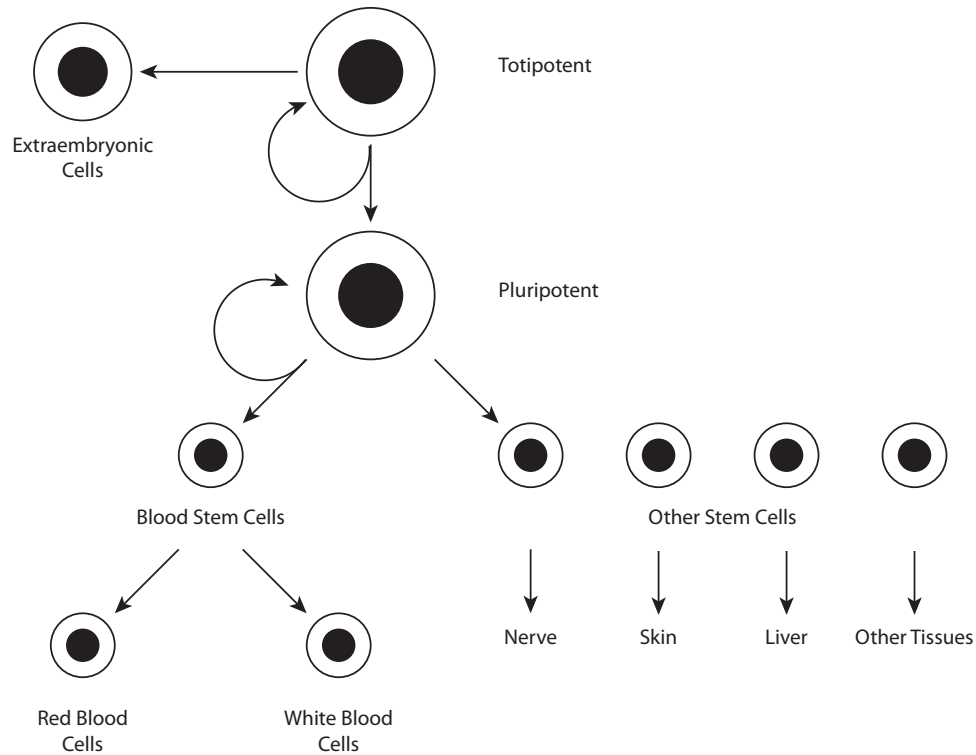


Figure 2.2: Asymmetric stem cell division

Stem cells can be divided into five categories based on their potency, a measure of their differentiation potential into specific cell types.¹⁶ In order to explain the various types of stem cells, it is necessary to discuss the early development of the embryo.

Stem cells can be divided into four categories based on their ability to differentiate: totipotent, pluripotent, multipotent and oligopotent. In order to understand the difference among these stem cells, it is necessary to know the development cycle of the human embryo.

¹⁶ Amy J. Wagers & Irving L. Weissman, *Plasticity of Adult Stem Cells*, 116 CELL 639, 639 (2004) [hereinafter Wagers]

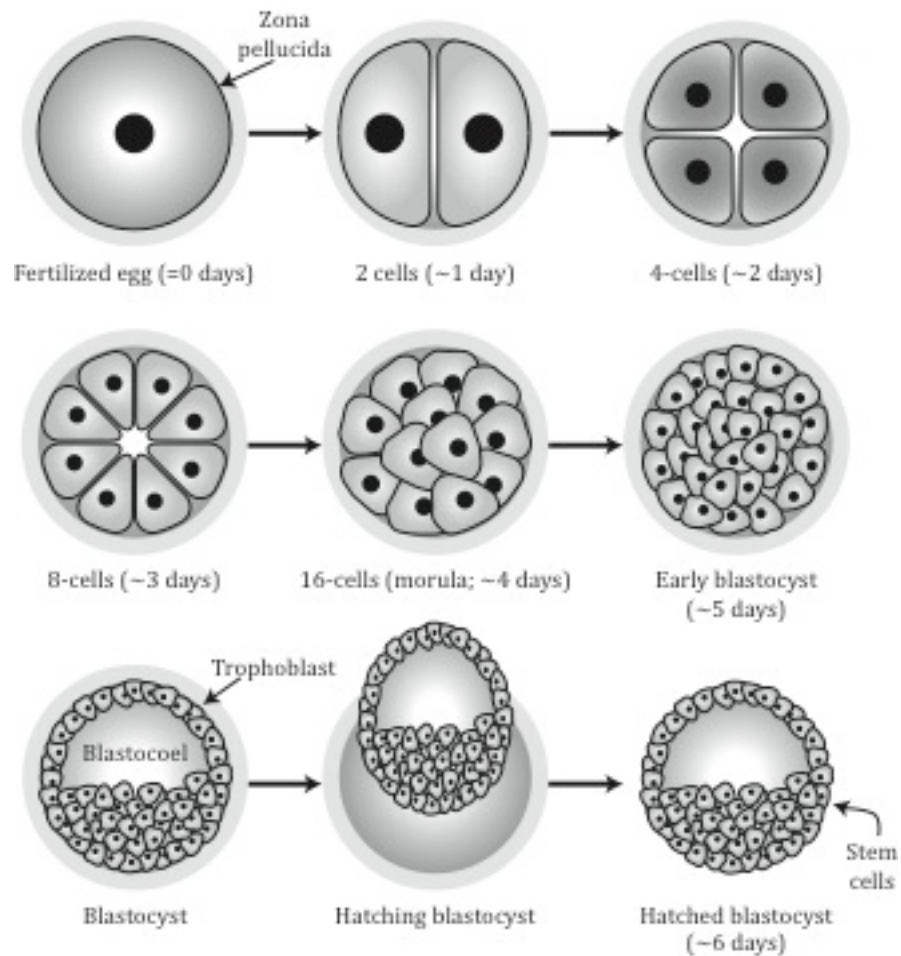


Figure 2.3: Development cycle of the human embryo.¹⁷

As shown in Figure 2.3, human embryos begin with the fusion of an egg and sperm, which forms a zygote,¹⁸ after which cell division begins. When the embryo is 5-6 days old, it can be referred to as an early blastocyst.¹⁹ The

¹⁷ Bryant, *supra* note 12, at 14.

¹⁸ KIESSLING, *supra* note 11, at 64.

¹⁹ Bryant, *supra* note 12, at 14. Blastocyst is a structure of early embryogenesis, which is formed after five to seven days' development, and consists 100 to 150 cells. It possesses an inner cell mass, which will develop into an embryo, and an outer layer called trophoblast, which will form the placenta, James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 Sci. 1145, 1147 (1998)[hereinafter James A. Thomson].

blastocyst segregates into trophoblast cells and an inner cell mass [ICM],²⁰ also known as the embryoblast. The trophoblast cells develop into the placenta while the ICM forms the three germ layers of embryo.²¹

Totipotent stem cells give rise to all embryonic cells and extraembryonic cell types.²² Zygotes are the prototype of totipotent cells.²³ Stem cells with the ability to form all of the cell types of the body are classified as pluripotent stem cells.²⁴ Stem cells that have the ability to form multiple related cell types are called multipotent stem cells.²⁵ An example of a multipotent stem cell is the hematopoietic stem cell, which can develop into different kinds of blood cells, but never into muscle cells or other cell types.²⁶ Oligopotent stem cells can differentiate into two cell types.²⁷ Unipotent stem cells can differentiate into one cell type,²⁸ such as vascular stem cells. Stem cells that can only form one differentiated cell type are termed unipotent stem cells²⁹, and include such cells as skin cells and the germline stem cells.³⁰

Stem cells can also be divided into three categories based on their source: embryonic stem cells, fetal stem cells and adult stem cells.

Embryonic stem cells [ESCs] are a main source of pluripotent stem cells³¹ because they theoretically have the capability to renew and differentiate into

²⁰ Inner Cell Mass is “the group of cells within the blastocoel of the blastocyst,” KIESSLING, *supra* note 11, at 258.

²¹ Bryant, *supra* note 12, at 11-15.

²² R. M. Ranganath, *Harnessing the Developmental Potential of Nucellar Cells: Barriers and Opportunities*, 22 TRENDS IN BIOTECHNOLOGY 504, 507 (2004)[hereinafter Ranganath]

²³ *Id.*

²⁴ Hans R. Schöler, *the Potential of Stem Cells: An Inventory*, in HUMANBIOTECHNOLOGY AS SOCIAL CHALLENGE 28 (NIKOLAUS KNOEPFFLE et al. eds, Ashgate Publishing 2008)[hereinafter Schöler].

²⁵ *Id.*, at 28.

²⁶ Wagers, *supra* note 16, at 640.

²⁷ Schöler, *supra* note 24, at 27-28.

²⁸ Wagers, *supra* note 16, at 639

²⁹ Schöler, *supra* note 24, at 27-28.

³⁰ Ranganath, *supra* note 22, at 507.

³¹ HERBERT GOTTSWEIS et al., THE GLOBAL POLITICS OF HUMAN EMBRYONIC STEM CELL SCIENCE 10 (Palgrave Macmillan 2008)[hereinafter GOTTSWEIS]

all possible cell types and tissues of the three germ layers in the appropriate environment.³² More information about embryonic stem cells will be given in the following section.

Fetal stem cells can be extracted from fetuses five to nine weeks after conception. These stem cells are responsible for the initial development of all tissues.³³ Both fetal and embryonic stem cell research triggers a similar ethical debate.

Adult stem cells, also called somatic stem cells, are undifferentiated cells found in certain organs and tissues that can renew themselves and differentiate into certain specialized cell types.³⁴ Although they are named “adult,” they can be found in fetuses, children and adults.³⁵ These stem cells retain the restricted capability of dividing and giving rise to specific cells.³⁶ The ability to differentiate into specific cells, or even “transdifferentiate” into other cell types under some special conditions, grants adult stem cells an important role in cell-based therapy.³⁷ Generally speaking, this category is either multipotent or unipotent.³⁸ Adult stem cells include hematopoietic stem cells, mesenchymal stromal cells and neural stem cells.³⁹

2. Scientific and Therapeutic Values of Stem Cells

³² Fatima Cavaleri & Hans Scholer, *Molecular Bases of Pluripotency*, in *STEM CELL ANTHOLOGY* 119-120 (BRUCE MC. CARLSON ed., Academic 2009). In practise, hESCs have not been shown to meet the definition of embryonic stem cells because people never use them to create new human beings.

³³ Ronald B. Miller, *Ethical Issues in Stem Cell Research, Therapy, and Public Policy*, in *FUNDAMENTALS OF THE STEM CELL DEBATE* 150 (KRISTEN RENWICK MONROE et al. eds., University of California 2008)[hereinafter Ronald Miller].

³⁴ Stem Cell Basis, *supra* note 11.

³⁵ *Id.*

³⁶ Wagers, *supra* note 16, at 640.

³⁷ George Q. Daley, *Prospects for Stem Cell-Based Therapy*, 132 *CELL* 544, 544-548 (2008)

³⁸ Bonnie Barrilleaux, *Review: Ex Vivo Engineering of Living Tissues with Adult Stem Cells*, 12 *TISSUE ENGINEERING*, 3007, 3008 (2006).

³⁹ Bryant, *supra* note 12, at 19-26; Stem Cell Basis, *supra* not 11.

Stem cells have tremendous scientific and therapeutic value thanks to their ability to proliferate indefinitely and differentiate.⁴⁰ An example of this value is their ability to repair and regenerate damaged tissues and organs from a variety of diseases.⁴¹ Great efforts have been made to utilize the characteristics of stem cells in therapy and treatment to meet the needs of aging populations and people suffering from disease.⁴² One example of this is bone marrow transplantation. Bone marrow cells have been widely used in both leukemia and aplastic anemia treatment as routine medical care. Bone marrow cells contain blood and immune system stem cells, which may broaden their therapeutic uses for other diseases.⁴³ Stem cells also have potential therapeutic value in Parkinson's disease, spinal cord injury, retinal degeneration, diabetes, brain tumors, and cardiovascular and metabolic diseases.⁴⁴

However, immune rejection of transplanted tissues can arise during stem cell therapy, as the immune system of the recipient may identify the transplanted cells as foreign.⁴⁵ In the case of bone marrow transplantation, the graft, which is the actual bone marrow that is being given to the patient, can also reject or react against the host, because bone marrow is the substance containing the immune system that produces the rejection response. This is known as graft-versus-host disease (GVHD).⁴⁶ To solve this problem, there are several theoretical solutions, including genetically manipulating embryonic stem cells or creating banks of histocompatible

⁴⁰ Philip H. Schewarz & Peter J. Bryant, *Therapeutic Uses of Stem Cells*, in FUNDAMENTALS OF THE STEM CELL DEBATE 37 (KRISTEN RENWICK MONROE et al. eds., University of California 2008)[hereinafter Schewarz].

⁴¹ JOSEPH PANNO, STEM CELL RESEARCH: MEDICAL APPLICATIONS AND ETHICAL CONTROVERSY 36-50 (Infobase 2005).

⁴² Schewarz, *supra* note 40, at 37.

⁴³ Thomas E. Donnell, *Bone Marrow Transplantation*, in KIESSLING *supra* note 11, at 55.

⁴⁴ Schewarz, *supra* note 40, at 37-46.

⁴⁵ *Id.*, at 46-47.

⁴⁶ *Id.*, at 38.

embryonic stem cells,⁴⁷ which may face challenges during the U.S. Food and Drug Administration [FDA] approval procedure. Another possible solution is to generate embryonic stem cells genetically identical to the patient by somatic cell nuclear transfer [SCNT], a process by which the nucleus of a donor egg is replaced with the nucleus from a somatic cell taken from the patient.⁴⁸ But considering the public's discomfort with cloning and the vague line between reproductive cloning and therapeutic cloning, this method is ethically controversial.

In addition to repair and regeneration, stem cells offer an alternative method of pharmaceutical testing. During an investigational new drug application [IND application] in a nation—take the U.S. as an example—applicants are required to submit safety reports⁴⁹ to demonstrate the safety and effectiveness of new drugs.⁵⁰ Historically applicants have relied upon animals testing. However, due to the significant differences between human and other animals, a drug's effectiveness and toxicity results from animals cannot be directly applied to human beings with confidence.⁵¹ For improved effectiveness and toxicity studies, applicants could test new drugs on actual human tissues or organs derived from stem cells. The application of stem cells in pharmaceutical testing could theoretically assure drug safety and efficiency.⁵² The acceptance of in vitro testing is confirmed in the U.S. Food and Drug Administration's [FDA] new rule, entitled Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence

⁴⁷ James A. Thomson, *supra* note 19, at 1147.

⁴⁸ Schewarz, *supra* note 40, at 47; J.A. Byrne, *Producing Primate Embryonic Stem Cells by Somatic Cell Nuclear Transfer*, 450 NATURE 497-502 (2007)[hereinafter Byrne]

⁴⁹ 21 C.F.R. 312.32(b)

⁵⁰ 21 U.S.C. 355(d)

⁵¹ James A. Thomson, *Human Embryonic Stem Cells*, in THE HUMAN EMBRYONIC STEM CELL DEBATE: SCIENCE, ETHICS, AND PUBLIC POLICY 20 (SUZANNE HOLLAND et al, eds., MIT 2001).

⁵² Janne Jensen et al., *Human Embryonic Stem Cell Technologies and Drug Discovery*, 219 (3) J. CELLULAR PHYSIOLOGY 513, 514 (2009) [hereinafter Jensen]

Studies in Humans, which adds in vitro study results as another source of information in safety reports.⁵³

Currently, generally speaking, stem cell research enhances public health and welfare by creating new treatments for human disease in the central nervous system.⁵⁴ In addition, it benefits the drug industry by improving therapeutic efficacy.⁵⁵

3. Global Investments on Stem Cell Research

Due to the special nature of stem cell research and its products, it takes approximately 10 to 15 years for companies engaged in stem cell research to start making profits and providing returns to investors.⁵⁶ It is therefore hard to interest business investors and the primary funding sources available are limited to donations and private funding.

Unlike the private sector, governments are willing to play the role of investor for two prime reasons. First, as previously discussed, stem cell research promotes national health and improves public welfare by delivering health benefits to the population. Second, since the era of a biotechnology economy has arrived, people understand how large and competitive the business will be in the global market. No country wants to fall behind in this biotechnology race.

Table 2.1 illustrates U.S. federal governmental funding on stem cells and embryonic stem cell research in the past several years.⁵⁷

⁵³ 75 FR 59935, 59943.

⁵⁴ KIESSLING, *supra* note 11, at 212-213.

⁵⁵ Jensen, *supra* note 52, at 519.

⁵⁶ GOTTWEIS, *supra* note 31, at 19.

⁵⁷ National Institute of Health, *Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)*, <http://report.nih.gov/rcdc/categories/> (Last visited Oct, 13, 2009)

Research Region (USD in millions)	FY 2006 Actual	FY 2007 Actual ⁵⁸	FY 2008 Actual	FY 2009 Actual ⁵⁹	FY 2010 Actual ⁶⁰	FY 2011 Estimate
Stem cell Research All	\$643	\$968	\$938	\$1231	\$1182	\$1100
Stem Cell Research Human	\$38	\$74	\$88	\$143	\$137	\$126
Stem Cell Research Nonhuman	\$110	\$120	\$150	\$177	\$161	\$155
Stem Cell Research Nonembryonic Human	\$206	\$226	\$297	\$397	\$388	\$358
Stem Cell Research Nonembryonic Nonhuman	\$289	\$400	\$497	\$638	\$616	\$580

Table 2.1: Government grants on hESC research in the United States

Beyond federal appropriations, states input millions of dollars toward stem cell research as well. New Jersey invested 10 million USD in January 2004 on stem cell research for the next 10 years, and it increased the appropriation to 270 million USD for research facilities in 2007.⁶¹ New York

⁵⁸ In the original text, there are two ways of FY 2007 calculation, one is NIH historic al method and the other one is revised method. Here only the number calculated by revised method is recorded.

⁵⁹ It includes funds from American Recovery & Reinvestment Act (ARRA) and appropriation from regular NIH projects.

⁶⁰ 2010 estimate also includes funds from both American Recovery & Reinvestment Act (ARRA) and regular NIH projects. But the ARRA section only reflects follow-on commitments related to grants in 2009.

⁶¹ Vestal Christine, *Embryonic Stem Cell Research Divides States*, Stateline Org, June 22, 2007, available at <http://www.geneticsandsociety.org/article.php?id=3496> (Last visited Oct, 7, 2009)[hereinafter Vestal].

created the Empire State Stem Cell Trust Fund in the 2007-2008 state budget report, providing up to 600 million USD over 11 years for stem cell research.⁶² Connecticut provided 100 million USD in state funding for embryonic stem cell research over 10 years. Illinois granted 10 million USD to stem cell projects over 10 years in 2005 and added an extra 5 million USD in 2006. Maryland handed out 9 million USD to 24 institutions for a three-year project.⁶³

In other countries, Canada is estimated to invest 40 million CAD per year on stem cell research on average, and Germany allocated 61.9 million EUR for stem cell research between 2000 and 2007.⁶⁴ Switzerland allocated 2.2 million CHF to adult stem cell research.⁶⁵ China increased stem cell research appropriation dramatically. It is expected to spend between 500 million and 2 billion RMB on stem cell research.⁶⁶

B. Embryonic stem cells [ESCs]

As is the case with all stem cells, embryonic stem cells have critical therapeutic and medical value. However, due to their production techniques, they bring about fierce controversy on human ethical grounds.

1. Definition and Formation of Embryonic Stem Cell

⁶² New York State, Department of Health, State Health Commissioner Announces \$2 Million in Stem Cell Research Planning Grants, Sept. 19, 2008, available at http://www.nyhealth.gov/press/releases/2008/2008-09-19_stem_cell_research_grants.htm (Last visited Oct. 13, 2009).

⁶³ Vestal, *supra* note 61.

⁶⁴ Department of Health, Global Position on Stem Cell Research (A-G), available at http://www.dh.gov.uk/ab/UKSCI/DH_096187#_4 (Last visited Oct. 13, 2009) [hereinafter Global Position A-G]

⁶⁵ Department of Health, *Global Position on Stem Cell Research (H-ZG)*, available at http://www.dh.gov.uk/ab/UKSCI/DH_096199 (Last visited Oct. 13, 2009).

⁶⁶ Global Position A-G, *supra* note 64.

Embryonic stem cells are cells that have the capability of self-replication and development into all cells and tissues of the three primary germ layers (the ectoderm, mesoderm, and endoderm).⁶⁷ There are currently two techniques used to obtain embryonic stem cells. The main technique, originally conceived by Dr. James Thomson in 1998,⁶⁸ is to derive embryonic stem cells from the inner cell mass [ICM] of blastocysts.⁶⁹ Recently, scientists have demonstrated that cells of 8-cell embryos (usually three days after fertilization) can be removed and cultivated in culture dishes to become hESCs,⁷⁰ but the embryos may die after having the blastomeres⁷¹ removed, which gives rise to ethical controversies.

Although ESCs have amazing pluripotent characteristics, many unresolved technical problems hinder their effective and routine use in cell-based therapies. For instance, no standardization in techniques for culture, maintenance and derivation of hESCs has been achieved. Recently, some researchers demonstrated that methods of culturing hESCs affect their potentiality of differentiation and integrity of genomic imprinting.⁷² Maintaining the hESCs in an undifferentiated state is another technique

⁶⁷ Definition in National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32170, 32173 (Jul.7, 2009) [hereinafter NIH Guideline 74]. The definition was edited in a later version, National Institutes of Health Guidelines on Human Embryonic Stem Cell Research, 75 Fed. Reg. 8085, 8085-8086 (Feb. 23, 2010)[hereinafter NIH Guideline 75] as “pluripotent cells that are derived from early stage human embryo, up to and including the blastocyst stage, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of three primary germ layers.” But the revision does not change the core of the definition.

⁶⁸ See James A. Thomson, *supra* note 19, at 1147.

⁶⁹ Stephen Sullivan, et al. *Derivation of Human Embryonic Stem Cell lines*, in HUMAN EMBRYONIC STEM CELLS 35 (STEPHEN SULLIVAN et al. eds., John Wiley and Sons 2007)

⁷⁰ KELLY A. HOGAN, STEM CELLS AND CLONING 4 (Pearson/Benjamin Cummings 2008)[hereinafter HOGAN]

⁷¹ Blastomere is a type of cell from the cleavage of egg after fertilization at the early stage of embryonic development. See KIESSLING, *supra* note at 11, 82.

⁷² Royer Laurie A et al., *Genetic and Epigenetic Analysis of Human Embryonic Stem Cells*, in HUMAN EMBRYONIC STEM CELLS 107 (STEPHEN SULLIVAN et al. eds., John Wiley and Sons 2007).

always being improved upon.⁷³ There are numerous in-lab techniques being used to cultivate hESCs in an appropriate environment with conditions that favor the desired differentiation.⁷⁴

Since the derivation of embryonic stem cells from embryos results in the destruction of embryos, in practice, the main sources from which to derive ESCs are excess embryos produced by assisted reproductive techniques. Most commonly, these are *in vitro* fertilization [IVF]⁷⁵ embryos left in fertility clinics. In the US, only a small number of embryos produced by IVF are transferred into a woman's uterus; therefore, many embryos are kept in freezers. Supporters of embryonic research claim that when these embryos are discarded by parents and are not going to become human beings, they are better used in hESCs research rather than simply being destroyed.

It is theorized that undifferentiated ESCs fertilized by sperm and egg may be more immunologically compatible with any recipient than other mature stem cells.⁷⁶ However, since the cells carry the specific DNA of the embryo from which they were derived, they have different DNA than the recipients. Due to antigenic differences, immunological rejection will happen after transplantation.⁷⁷ One possible solution to this problem, enabling ESCs to mirror the genetic compatibility of adult stem cells, is somatic cell nuclear transfer.

⁷³ See Gordon Keller, *Embryonic Stem Cell Differentiation: Emergence of A New Era in Biology and Medicine*, 19 GENES DEV. 1129–1155 (2005).

⁷⁴ Draper Jonathan S., Cheryle A. Seguin and Peter W. Andrews, *Phenotypic Analysis of Human Embryonic Stem Cells*, in HUMAN EMBRYONIC STEM CELLS 98 (Sullivan Stephen et al., 2007).

⁷⁵ In vitro fertilization is a technique to fertilize an egg by a sperm in a laboratory environment. KIESSLING, *supra* note at 11, 42.

⁷⁶ See Micha Drukker et al., *Human embryonic stem cells and their differentiated derivatives are less susceptible to immune rejection than adult cells*, 24(2) STEM CELLS 221 (2006)

⁷⁷ KIESSLING, *supra* note at 11, 186.

Somatic cell nuclear transfer [SCNT] is one way to reduce the possibility of immunological rejection.⁷⁸ SCNT is a laboratory technique that creates a genetically identical copy of human materials by inserting genetic materials—the nucleus—taken from a somatic cell or embryonic cell into an enucleated egg cell.⁷⁹ SCNT generates an unlimited source of cells and tissues for use in therapy for various diseases, and facilitates new ways of modeling human genetic diseases.⁸⁰ SCNT is used in both reproductive and therapeutic cloning. Reproductive cloning is the application of SCNT to produce a live birth. It requires the placement of an embryo into a woman's uterus to grow until sufficiently developed to survive independently. Therapeutic cloning, in contrast, takes place entirely in vitro. In this process, hESCs are derived from a blastocyst, grown and further differentiated into particular cell types as required for therapeutic uses.

Reproductive cloning is prohibited by most international organizations including the United Nations, and in most states because of ethical concerns, while therapeutic cloning is allowed, or even encouraged in some countries, like Iraq, China and the United Kingdom. In therapeutic cloning, scientists make hESCs following SCNT, cultivate them, and differentiate them into particular needed cell types. These differentiated cells can be implanted into the DNA donor's body to repair or replace damaged cells, tissues and even organs. However, therapeutic cloning is still somewhat theoretical.⁸¹ Korean scientist Dr. Hwang Woo Suk, who claimed to derive hESC lines from SCNT human embryos, was found to have fabricated key data in his research.⁸² In

⁷⁸ See Byrne, *supra* note 48, at 497-502.

⁷⁹ The biggest problem in SCNT in primate is low birth. Compared to SCNT, the technique of embryonic cell nuclear transfer (ECNT) is much more successful.

⁸⁰ See Henrik Semb, Human Embryonic Stem Cells: Origin, Properties and Applications, 113 APMIS 743 (2005)

⁸¹ HOGAN, *supra* note 69, at 28.

⁸² The Associated Press, *Disgraced Korean Cloning Scientist Indicted*, New York Times, May. 12, 2006, available at http://www.nytimes.com/2006/05/12/world/asia/12korea.html?_r=1&oref=slogin (Last visited Oct. 7, 2009).

2008, scientists at one biotechnology company, Stemagen, claimed that they succeeded in creating a human blastocyst using SCNT, but they did not derive stem cells.⁸³

Since the above two methods of obtaining hESCs involve ethical issues,⁸⁴ scientists have been investigating other methods to obtain cells with the same pluripotent characteristics. Pluripotent stem cells can be obtained from parthenogenetically activated eggs, named human Parthenote stem cells [hPSCs], by artificially activating eggs with electrical pulses and several types of chemicals.⁸⁵ HPSCs have the same characteristics as other stem cells: the capability of endless self-renewal and cell division. Most importantly, they have been demonstrated to develop tissues from all germ layers but are not capable of developing into an offspring.⁸⁶ The hPSC technique avoids the ethical considerations regarding embryo destruction and human cloning, and also overcomes immunological problems. But since the technique only works in young women, it has limited applications and generates an ethical debate over gender and age applicability.

Another development is induced pluripotent stem cells. In 2007, Shinya Yamanaka of Kyoto University in Japan reported that he and his colleague successfully turned skin cells into embryonic stem [ES]-like cells, which were believed to be pluripotent and might have the capacity to grow into any tissue.⁸⁷ Later in the same year, both Japanese⁸⁸ and American scientists⁸⁹

⁸³ Andrew Pollack, *Cloning Said to Yield Human Embryos*, New York Times, Jan. 18, 2008, available at <http://www.nytimes.com/2008/01/18/us/18embryos.html> (Last visited Oct, 7, 2009).

⁸⁴ The ethical issue of SCNT focuses on the morality of reproductive cloning, and the technique of deriving ESCs from embryos brings about the ethical debate over human dignity and embryos' personhood.

⁸⁵ KIESSLING *supra* note 11, at 55.

⁸⁶ The invention has been filed as Patent application title: Patient-specific stem cell lines derived from human parthenogenetic blastocysts, U.S. Patent App. No. 12,082,028 (filed Apr. 7, 2008)

⁸⁷ Martin Fackler, *Risk Taking is in His Genes*, New York Times, Dec. 11, 2007, available at <http://www.nytimes.com/2007/12/11/science/11prof.html?pagewanted=all> (last visited Mar.2, 2011).

reported that they reprogrammed human skin cells into induced pluripotent stem cells [iPSCs],⁹⁰ which are similar to ESCs with the ability to differentiate into all cell types of the body. This is a huge step in stem cell research because if that characteristic is proven, people may not need hESCs, which are highly controversial, for disease treatment or drug testing any longer, as iPSCs may have the same function as ESCs without triggering ethical issues.⁹¹ However, whether iPS cells will replace ESCs is still an open question. Recently, two Chinese researchers created live mice from iPS cells, although one of the researchers, Qi Zhou, emphasized that “it is not intended to be a first step towards using iPS cells to create a human being.”⁹² This is one step to help discover the differences between ESCs and iPSCs. Even if scientists can prove that the iPSCs can replace ESCs, iPSCs may have a more restrictive application umbrella than ESCs. iPSCs require human manipulation, either genetically or chemically, which may affect their properties. Therefore, there is a chance that they may not be suitable for therapy, but only applicable for drug toxicity evaluation.

2. Scientific and Therapeutic Values of Embryonic Stem Cells

While there are a plethora of uses, the most well known value of ESCs is in the differentiation capability which can be used in regenerative medicine. For many diseases in which cells lose their functions, the best option is to regenerate well-functioning cells from ESCs and inject them into the patient’s

⁸⁸ Kazutoshi Takahashi et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 863-872 (2007).

⁸⁹ Junying Yu et al., *Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells*, 318 SCI.1917-1920 (2007)

⁹⁰ IPS cells are derived from transfection of stem-cell associated genes into non-pluripotent cells.

⁹¹ But in practice, ESCs are requested for the equivalent test between iPSCs and ESCs, whether the iPSCs can avoid ethical criticism is doubtful.

⁹² David Cyranoski, *Mice Made from Induced Stem Cells*, Nature News, July 23, 2009, available at <http://www.nature.com/news/2009/090723/full/460560a.html> (Last visited Oct. 14, 2009).

body. Sometimes, rather than repairing dysfunctional cells, whole organ replacement is required. In these cases, hESCs can be cultivated and differentiated under certain conditions until they become the organ or particular cells that are needed. For example, in the case of diabetes, insulin-producing pancreatic cells do not function well; therefore, scientists could inject ESCs-derived pancreatic cells into the body. In heart attack cases, physicians could repair the damaged heart by using heart cells differentiated from ESCs in a laboratory.

ESCs' therapeutic values have been recognized in the theoretical domain for an extended period of time. However, while the situation is changing, only one clinical trial is ongoing. Geron Corporation in the United States was the first to trial hESC research based therapy in patients with acute spinal cord injuries, which has been approved by the FDA in 2010.⁹³ The trials, using hESC therapy, mark the beginning of a new era of tissue and organ regeneration by ESC-derived cells.

In addition to therapeutic applications, ESCs can also be used for pharmaceutical testing in the field of disease research.⁹⁴ ESCs can be used for safety and effectiveness evaluations during an IND application. At the present time, researchers test new drugs on animals initially, and implement a second stage of trials on healthy volunteers and a small number of diseased people if the animal results are satisfactory. But due to the inherent differences between animal and human tissues, the drug under test may have dramatically different results when tested on humans. Due to the unpredictability of the results, a test program modeled on the above described protocol can place the human test subjects at undue risk. By modifying this protocol to utilize human tissues produced from stem cells,

⁹³ Andrew Pollack, *Stem Cell Trial Wins Approval of F.D.A.*, New York Times, July 30, 2010, available at http://www.nytimes.com/2010/07/31/health/research/31stem.html?_r=1 (last visited Mar. 21, 2011)

⁹⁴ GOTTWEIS, *supra* note 31, at 37.

the risk taken by the human subjects might be dramatically reduced. Researchers need a sample that is similar, or even exactly the same as human tissues or organs. For instance, to investigate a new drug for heart disease, researchers can test it on heart cells differentiated from hESCs before clinical trial, rather than testing it on volunteers directly after mice.

3. Scientific Uncertainty in hESC Research

Even though there have been advances in research, scientific uncertainty still exists regarding hESC therapeutic uses. A question regarding the genetic normality of hESCs has been raised and therefore the safety in using them in stem cell therapies is uncertain.⁹⁵ These types of questions and uncertainties might stifle their widespread use in therapy. In order to mitigate these safety concerns, some techniques may be applied such as using the preimplantation genetic diagnosis made during *in vitro* fertilization [IVF]⁹⁶ to vet embryos before using them to derive ESCs in practice.⁹⁷

After acknowledging the scientific background of hESCs, and their pharmaceutical and therapeutic value, it is nonetheless clear that the use of hESCs gives rise to a serious ethical debate. Because of its intimate relationship with human embryos and its unclear moral status, the legitimacy of hESC research is a values and culture based issue. Although hESCs are admitted to have incredible value in scientific research and therapy, hESC research triggers many debates among religions, philosophies and countries.

⁹⁵ Schewarz, *supra* note 40, at 51.

⁹⁶ Alan R. Thornhill & Karen Snow, *Molecular Diagnostics in Preimplantation Genetic Diagnosis*, J. MOLECULAR DIAGNOSTICS, Feb. 2002, at 11, 11.

⁹⁷ More other techniques can be found in Susannah Baruch et al., *Genetic Testing of Embryos: Practices and Perspectives of U.S. In Vitro Fertilization Clinics*, 89 FERTILITY & STERILITY 1053 (2008).

Chapter 3: Ethical, Religious and Philosophical Viewpoints on Human Embryonic Stem Cell [hESC] Research

No matter how amazingly hESCs may function, in practice, there are a number of unresolved issues in the field. This chapter explores a variety of ethical, religious, philosophical, and governmental views on hESC research. This chapter is designed to be a survey of general views due to the thesis of this dissertation; therefore, there are significant exceptions and nuances that are not introduced that one should research when trying to fully understand the complexity of this subject. However, these viewpoints do form part of the overall fabric of legal and political factors that have a bearing on the actual formulation and implementation of the rules about hESCs. So the following discussion is intended to sketch out the broader context in which those rules arise and function.

A. Ethical Debates Over hESC Research

Besides scientific uncertainties, hESC research gives rise to ethical debates within society. The main debate is focused on the moral status of embryos and whether utilizing embryos for hESC research is immoral. Opponents of hESC research have raised the idea that hESC research is murder because it is necessary to destroy human embryos, which, to some religions and cultures, are equivalent to human beings.⁹⁸ Advocates argue that the embryos used for

⁹⁸ Matthew C. Nisbet, *Public Opinion About Stem Cell Research and Human Cloning*, 68 PUB. OPINION Q. 131, 135 (2004)[hereinafter Nisbet].

research, which usually are early embryos, do not have the equivalent moral status of persons because life does not begin at the moment of conception.⁹⁹

Given this ethical controversy, discarded frozen embryos from IVF procedures are used to reduce the moral debate and therefore increase the general acceptance of hESC research. In a 2010 survey of public attitudes toward human embryo research in the United States, 72% respondents supported research utilizing excess embryos.¹⁰⁰ As mentioned above, couples undergoing fertility treatments usually produce more embryos than are needed. Once a couple has successfully reproduced, or the relationship ends, the other embryos become superfluous and will be disposed of according to the clients' wishes. Due to the high cost of the freezing process, people who cannot afford the charge can choose to either donate remaining embryos to infertile couples or have them destroyed. As a result, these embryos from clinics are considered perfect resources for ESC research because they will be destroyed and never have the chance to mature into human beings in any case. There is no additional harm to the embryos. In addition, they can be used for saving lives.¹⁰¹ According to George and Tollefson's nothing-is-lost principle, it is permissible to experiment on human embryos that are slated to be destroyed.¹⁰² However, there is an opposing voice, according to which the nothing-is-lost principle is considered intentional killing,¹⁰³ and human

⁹⁹ ROBERT P. GEORGE & CHRISTOPHER TOLLEFSEN, EMBRYO: A DEFENSE OF HUMAN LIFE 195 (Random House Digital 2008)[hereinafter ROBERT P. GEORGE]; G.R. Dunstan, *The Moral Status of the Human Embryo: A Tradition Recalled*, 10 J. MED. ETHICS 38, 38 (1984)[hereinafter Dunstan].

¹⁰⁰ Amanda Gardner, *Most Americans Back Embryonic Stem Cell Research: Poll*, US News, Oct. 7, 2010, available at <http://health.usnews.com/health-news/managing-your-healthcare/research/articles/2010/10/07/most-americans-back-embryonic-stem-cell-research-poll> (last visited Mar. 2, 2011)[hereinafter Gardner].

¹⁰¹ Gene Outcka, *The Ethics of Human Stem Cell Research*, 12 KENNEDY INST. ETHICS J. 175, 193 (2002)[hereinafter Outcka].

¹⁰² ROBERT P. GEORGE, *supra* note 99, at 192.

¹⁰³ *Id.*, at 193.

embryo research is thought to impose an unfair burden on “an innocent human being”¹⁰⁴ (the embryo) for the exclusive benefit of others.¹⁰⁵

Research on embryos obtained through other methods, such as somatic cell nuclear transfer, or research-purpose IVF, is more controversial because it involves another question: the moral status of human embryos. At what point is a human being entitled to dignity and the protection of the law? Since hESCs are derived from blastocysts, the status of blastocysts is the focus of the debate concerning hESC research.

Proponents of ESC research have various reasons from a scientific perspective to distinguish hESCs from living human beings. First, it is not known exactly when the complement of new genes takes over control of the embryo,¹⁰⁶ and in that sense, a zygote is not equal to a new born. ESCs have modified DNA methylation status, which is diametrically different from adult somatic cells. For example, in female ESCs, both X chromosomes are active. During embryonic development, one X chromosome is inactivated. Even after the new gene complement is finished, zygotes do not possess sufficient information to form a human being in that the formation of the embryo relies on factors other than genetic information; therefore, zygotes should not have the same moral status as human beings.¹⁰⁷ The case of identical twins is also used against the notion that life begins at fertilization because identical twins result from the separation of blastomeres.¹⁰⁸ Another argument opposed to the idea that human life begins at fertilization is that at any stage before the blastocyst (the five day pre-embryo), the nervous system and brain system are absent, the heart and blood vessels have not yet formed. Therefore, a

¹⁰⁴ *Id.*, at 201

¹⁰⁵ *Id.*, at 202.

¹⁰⁶ KIESSLING, *supra* note 11, at 65.

¹⁰⁷ Carlos Bedate & Robert Cefalo, *The Zygote: to be or not be a person*, 14 J. MED. & PHIL. 641, 644 (1989).

¹⁰⁸ Cells stemed from cell cleavage, during which the devided cells' size is reduced but the total volume is maintained. After the fusion these devided cells are called blastomeres. KIESSLING *supra* note 11 , at 81.

blastocyst does not have the same moral status as a person.¹⁰⁹ With regard to ESCs from SCNT, Some people claim that these cells have little potential to develop into human beings because they lack the attributes of normal embryos and harbor fundamental biologic deficiencies; therefore, using SCNT to produce embryonic stem cells is morally justified.¹¹⁰ An intention argument can also be made for weighting human beings over hESCs obtained by SCNT since SCNT is a manufacturing process that focuses on producing cells instead of infants, and therefore the embryos made by SCNT differ from early human embryos and are not human beings.¹¹¹

Opposing the above viewpoint, some people consider that since human life starts with fertilization, zygotes are also persons.¹¹² Human dignity and human rights are equally applicable at all of the various stages of human life.¹¹³ From the perspective of biology, an embryo is the beginning of a new entity because it is the start of distinction from the mother and the father; it is, by itself, a complete organism and is “fully programmed” to develop into a mature human being.¹¹⁴ The continuity argument states that the embryo has the potentiality of becoming a person.¹¹⁵ Therefore, all the various stages of human development should be considered human beings,¹¹⁶ to give “justice to the concept of potentiality and continuity.”¹¹⁷ The theory applies to

¹⁰⁹ Ronald Miller, *supra* note 33, at 153-154.

¹¹⁰ Rudolf Jaenisch, *Human Cloning—the Science and Ethics of Nuclear Transplantation*, 351 NEW ENG. J. MED. 2787, 2790-2791 (2004).

¹¹¹ Paul R. McHugh, *Zygote and “Clonote”—the Ethical Use of Embryonic Stem Cells*, 351 NEW ENG. J. MED. 209, 210 (2004).

¹¹² ROBERT P. GEORGE, *supra* note 99, at 50-51.

¹¹³ *Id.*, at 185.

¹¹⁴ *Id.*, at 50.

¹¹⁵ Ronald Miller, *supra* note 33, at 153-154; MICHAEL S. GAZZANIGA, *THE ETHICAL BRAIN: THE SCIENCE OF OUR MORAL DILEMMAS* 9 (HarperCollins 2006).

¹¹⁶ Joachim Wanke, *Ethical and Technological Challenges to Human Biotechnology: Observations from the Perspective of Catholic Theology*, in *HUMANBIOTECHNOLOGY AS SOCIAL CHALLENGE* 100 (NIKOLAUS KNOEPFFLE et al. eds, Ashgate Publishing 2008).

¹¹⁷ *Id.*, 102-103.

zygotes produced by both the IVF process and SCNT.¹¹⁸ According to this view, hESC extraction from embryos infringes on their human dignity.

B. The Start-line of Personhood and Ethics of hESC Research from the Perspectives of Religion and Philosophy

1. Religious Viewpoints on Human Embryo's Status and hESC Research

Similar to the ethical debates described previously, hESC research has prompted debates in the religious sector as well. One of the primary issues driving the debates is concerned with the moral status of human embryos: whether the embryos maintain human dignity at the same level as an advanced fetus or child. This topic is closely related to questions concerning abortion and human life. A technique to mitigate this question is to establish a timeline for the embryo that defines specific epochs and milestones of development.

Historically, human embryos did not always have the same status as persons in Christianity. The Septuagint version of the Bible¹¹⁹ compiled in the third century BCE, commonly used by “the early Christian fathers,”¹²⁰ stipulated that the fine for hurting a pregnant woman is dependent on the stage of the fetus. If the fetus is *me exeikonismenon*—not yet formed as a human portrayal, the punishment is in the form of a payable fine, but if the fetus is *exeikonismenon*, the punishment is elevated to execution with the justification being a life for life.¹²¹ In the 12th century, Pope Innocent III

¹¹⁸ ROBERT P. GEORGE, *supra* note 99, at 185.

¹¹⁹ It is also assigned as the LXX version and is recognized as the oldest Greek version of the Old Testament of the Bible.

¹²⁰ Dunstan, *supra* note 99, at 39.

¹²¹ *Id.*, at 39.

utilized the quickened status¹²² of the fetus to determine the eligibility of a priest to maintain his duties as a minister in the event he was involved in a forced miscarriage.¹²³ Pope Gregory XIV affirms this conception in 1591.¹²⁴ The method of rating the protection level on the stages of a human's development is maintained in some religions, but overturned by others including Catholicism. Table 3.1 demonstrates the start-line of personhood¹²⁵ along with the official and academic positions with respect to embryonic stem cell research in a collection of religions. The reasons for choosing these religions are that first, they represent a variety of religious viewpoints on the status of embryos and hESC research. They are also among the mainstream religions having large impacts on countries and ethnic groups. And they are the religions chosen for most studies on religious perspectives of hESC research found in books and the reports of the U.S. National Bioethics Advisory Commission on Ethical Issues in Human Stem Cell Research.

¹²² Quickening means the stage of pregnancy when the fetus can be felt to move.

¹²³ Dunstan, *supra* note, 99, at 40.

¹²⁴ SUSAN TYLER HITCHCOCK, ROE V. WADE: PROTECTING A WOMAN'S RIGHT TO CHOOSE 25 (Infobase 2006).

¹²⁵ Personhood is a generally accepted notion related to moral status. It involves the level of respect or value people attribute to a person. Conventional criteria for personhood include consciousness, self-consciousness and ability to reason. Ronald Miller, *supra* note 33, at 158. But in religions, personhood is used to describe the status with as the same degree of respect and value as persons.

Religion		Official Potential Personhood Startline	Official Stance on ESC Research	Academic Opinion	
Christianity	Catholicism	Conception	Opp	N/A	
	Protestantism	Methodism	Conception	Pro	N/A
		Presbyterian	None	Pro	N/A
		Episcopalian	None	Pro	N/A
		Lutheranism	Conception	None	Opp
	Eastern Orthodoxy	Conception	Opp	N/A	
Buddhism	Theravada	Conception	None	Unresolved	
	Mahayana	Conception	None	Pro	
Hinduism		Conception	None	Pro	
Islam	Shiite	Born	None	Pro	
	Sunni	120 days after conception			
Judaism	Reform Judaism	30 days after birth	Pro	N/A	
	Conservative Judaism				
	Orthodox Judaism				

Table 3.1: Startline of Personhood in Religions and Attitudes to hESC Research¹²⁶

Christianity has three mainstream variants, Catholicism, Protestantism and Eastern Orthodoxy. Most of them share similar ideas relating to personhood and policies on hESC research.

¹²⁶ This table is based on information from official websites or statements of the named religions. It does not represent every person, institute or sect within the various religions.

The Catechism of the Catholic Church states in paragraph 2270 that human life should be “respected and protected absolutely from the moment of conception” from which the embryo should be recognized as a person.¹²⁷ The Roman Catholic Church condemned hESC research that involves human destruction in an official statement.¹²⁸ The U.S. Conference of Catholic Bishops also opposes any research that deliberately destroys human life at any stage, including embryonic stem cell research that destroys human embryos.¹²⁹ But even Catholics admit that there is not a simple, single opinion in the Catholic community on topics such as hESC research¹³⁰ that are based on different interpretations of the moral status of human embryos and fetuses.¹³¹ Some Catholics allege that embryos should be protected at the same level as a person and not be created or destroyed for research purposes; research on human embryos should be banned, they say, because it spurs on embryo creation or abortion.¹³² However, others support hESC research because they believe that embryos in early states do not possess the same moral status as human beings because they lack the “settled inherent potential to become a human person.”¹³³

Like Catholicism, Protestantism has various opinions on embryonic stem cell research. Methodism asserts that the embryos have moral status, though

¹²⁷ Vatican, *Catechism of the Catholic Church*, available at http://www.vatican.va/archive/ENG0015/_P7Z.HTM (last visited Feb. 19, 2010).

¹²⁸ Rob Stein and Michelle Boorstein, *Vatican Ethics Guide Stirs Controversy*, Dec. 13, 2008, available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/12/12/AR2008121200774.html> (last visited Feb. 19, 2010).

¹²⁹ U.S. Conference of Catholic Bishops, *Catholic Support for Ethically Acceptable Stem Cell Research*, available at <http://www.usccb.org/prolife/issues/bioethic/stemcell/stemcath.shtml> (last visited Feb. 19, 2010).

¹³⁰ National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research* (Volume III religious aspects)[hereinafter NBAC Report], Testimony of Margaret A. Farley, D-3 (1999), available at <http://bioethics.georgetown.edu/nbac/pubs.html> (last visited Feb. 23, 2010)[hereinafter Farley].

¹³¹ *Id.*, D-4.

¹³² NBAC Report, *supra* note 130, Testimony of Kevin Wm. Wildes, I-3 [hereinafter Wildes].

¹³³ Farley, *supra* note 130, D-4.

not exactly the same moral status as more developed human life. Its attitude toward embryonic stem cell research depends on the source of the embryos. It supports embryonic stem cell research using spare embryos from IVF, but not any creation of embryos solely for research purposes.¹³⁴

The Presbyterian Church does not explicitly state when human life begins.¹³⁵ The 213th General Assembly of the Presbyterian Church (U.S.A.) in 2001 voted in favor of scientific research such as embryonic stem cell research because the goal of the research, which is saving lives, is so compelling and unachievable by other methods.¹³⁶ The policy was reaffirmed by the 216th Assembly in 2004.¹³⁷

The Episcopal Church also does not have an explicit statement on when human life begins.¹³⁸ Its governing body, the General Convention, declared its support for hESC research with embryos left over from IVF and other fertilization procedures as long as the embryos are no longer required for their original purposes or created for research purposes or sale, and the donors have given prior informed consent.¹³⁹

The Evangelical Lutheran Church in America considers that all human lives are granted by God and human life in any stage has intrinsic value and

¹³⁴ United Methodist Church Archives, *Ethics of Embryonic Stem Cell Research*, available at <http://archives.umc.org/interior.asp?ptid=4&mid=6560> (last visited Feb. 11,2010).

¹³⁵ General Assembly Mission Council, Abortion Issues, available at <http://gamc.pcusa.org/ministries/101/abortion-issues/> (last visited Feb. 11,2010).

¹³⁶ Overture 01-50: On Adopting A Resolution Enunciating Ethical Guidelines for Fetal Tissue and Stem Cell Research- from the Presbytery of Baltimore, BRENT WATERS & RONALD COLE-TURNER, GOD AND THE EMBRYO: RELIGIOUS VOICES ON STEM CELLS AND CLONING, Appendix F 185-189 (Georgetown University 2003).

¹³⁷ Presbyterian Church (U.S.A.), *Minutes of 216th General Assembly*, at 849, available at <http://oga.pcusa.org/ogaresources/journal2004.pdf> (last visited Feb. 11,2010).

¹³⁸ E-mail from Sarah Dana, Research Archivist, The Archives of the Episcopal Church (Feb. 11, 2011 3:23:49 PM CST) (on file with author).

¹³⁹ Archives of the Episcopal Church, *Support Human Embryonic Stem Cell Research*, 2003-A014, http://www.episcopalarchives.org/cgi-bin/acts/acts_resolution.pl?resolution=2003-A014 (last visited Feb. 19,2010).

dignity, but it also admits that in certain situations abortion is acceptable.¹⁴⁰ In 2005 the church created a task force to study the issue of biotechnology in the Church Wide Assembly and proposed that a social statement should be produced by 2011.¹⁴¹ Individually, some people consider hESC research on extra IVF embryos or from abortion to be justified considering its tremendous scientific and therapeutic value.¹⁴² But some believe that with the progress of scientific research and the rise of alternative techniques, the use of human embryos in research should be minimized.¹⁴³

Eastern Orthodoxy asserts that since human life begins at conception and all human lives should be entitled to the same level of protection, hESC research that involves destruction of embryos should be banned to avoid immoral and fundamental violations of human life.¹⁴⁴ Orthodox Christians also believe that embryonic stem cell research should be forbidden out of respect for human life except in the case of spontaneous miscarriage.¹⁴⁵

Adherents of Buddhism believe that the transmigration of consciousness occurs at conception; therefore, embryos have a right to life.¹⁴⁶ But there is

¹⁴⁰ Evangelical Lutheran Church in America, *Abortion*, available at <http://www.elca.org/What-We-Believe/Social-Issues/Social-Statements/Abortion.aspx> (last visited Feb. 1, 2011).

¹⁴¹ Evangelical Lutheran Church in America, *Genetics, Faith and Responsibility, a proposed social statement on genetics*, available at <http://www.elca.org/What-We-Believe/Social-Issues/Social-Statements-in-Process/Genetics.aspx> (last visited Mar. 1, 2011).

¹⁴² Mark J. Hanson, *the Ethics of Therapeutic Cloning*, Dec. 2000, available at <http://www.elca.org/What-We-Believe/Social-Issues/Journal-of-Lutheran-Ethics/Issues/December-2001/The-Ethics-of-Therapeutic-Cloning.aspx> (last visited Feb. 11, 2010).

¹⁴³ Paul T. Nelson, *Embryonic Stem Cells*, available at <http://www.elca.org/What-We-Believe/Social-Issues/Journal-of-Lutheran-Ethics/Issues/March-2007/Embryonic-Stem-Cells-2007.aspx> (last visited Feb. 11, 2010).

¹⁴⁴ Orthodox Research Institute, *Embryonic Stem Cell Research in the Perspective of Orthodox Christianity*, available at http://www.orthodoxresearchinstitute.org/articles/ethics/oca_embryonic_stem_cell.htm (last visited Feb. 21, 2010).

¹⁴⁵ NBAC Report, *supra* note 130, Testimony of Demetrios Demopoulos, B-3.

¹⁴⁶ Somparn Promta, *Buddhism and human genetic research*, 3. CHULALONGKORN J. BUDDHIST STUD., 233 246 (2004) ; James J. Hughes, *Buddhism and Medical Ethics: A Bibliographic Introduction*, available at <http://www.buddhistethics.org/2/dkhughes.html> (last visited Feb. 21, 2010) [hereinafter Somparn].

no official statement about hESC research. Some people disapprove of hESC research because it destroys potential life.¹⁴⁷ But Buddhist ethics are relative and situational. Based on personal ethics, human life is non-deprivable and embryonic stem cell research violates that theory, while social ethics support embryonic stem cell research because it benefits the whole society. In Theravada Buddhism, no official stance is taken and arguments are formulated both advocating and opposing hESC research.¹⁴⁸ In Mahayana Buddhism, the idea is to achieve self-emptying, and to return help for those in need. From this viewpoint embryonic stem cell research has a rational basis.¹⁴⁹

While there is no official ruling on hESC research, Hinduism asserts that life begins at conception.¹⁵⁰ In Hinduism, which is based on the principles of harmonization and balance of the world, even though abortion or killing potential lives are sins the, alternative of leaving diseased people suffering is also deemed as a sin, which actually outweighs the former one because living people are more important. Therefore, even though it considers conception as the beginning of human life, IVF and embryonic research are allowed because therapeutic benefits of hESC research outweigh the damage of sacrificing blastocysts.¹⁵¹

It is hard to find an authoritative body to represent a single Islamic stance on hESC research. A majority of the Sunni believes that there is a line of distinction at the end of the fourth month (120 days) of pregnancy,¹⁵² while a

¹⁴⁷ Ronald Miller, *supra* note 33, at 161.

¹⁴⁸ Somparn, *supra* note 146.

¹⁴⁹ Laurie Zoloth, *The Ethics of Human Stem Cell Research: Immortal Cells, Moral Selves*, in, ESSENTIALS OF STEM CELL BIOLOGY 497 (ROBERT PAUL LANZA ed., Academic 2006).

¹⁵⁰ Ronald B. Miller, *Twenty-Third Annual Health Law Symposium "Contemporary Issues in Children's Health": Ethical Issues in Stem Cell Research, Therapy, and Public Policy*, 26 WHITTIER L. REV. 845, 855 (2005).

¹⁵¹ Mahtab Jafari et al., *Religious Perspectives on Embryonic Stem Cell Research*, in FUNDAMENTALS OF THE STEM CELL DEBATE 90 (KRISTEN RENWICK MONROE et al. eds., University of California 2008).

¹⁵² NABC REPORT, Ttestimony of Abdulaziz Sachedina, G-4.

majorities of the Shia are cautious in drawing this line because they consider embryos as the pre-ensoulment stage.¹⁵³ However, research on stem cells, even though it interferes with the early stage of life, is justified as long as it is for improving human health.¹⁵⁴

“Jewish law does not recognize an embryo as having the full legal status of human beings until thirty-day-survival after being born.¹⁵⁵ Therefore, embryonic research is justified in the primary denominations of Judaism. The Reform Judaism denomination announced that it supports hESC research at its 2003 General Assembly,¹⁵⁶ Rabbinic Judaism,¹⁵⁷ Conservative Judaism¹⁵⁸ and Orthodox Judaism¹⁵⁹ have also announced the support for hESC research.

In general, religious groups have diverse viewpoints concerning hESC research. Some of them support hESC research but some do not. Their viewpoints on hESCs are usually consistent with their broader beliefs.

2. Philosophical Perspectives on Human Embryo’s Status and hESC Research

¹⁵³ *Id.*, G-5.

¹⁵⁴ *Id.*, G-6.

¹⁵⁵ Babbi Stephanie Dickstein, *Jewish Ritual Practice Following the Death of an Infant Who Lives Less than Thirty-one Day*, available at http://www.rabbinicalassembly.org/sites/default/files/public/halakhah/teshuvot/19912000/dickstein_infant.pdf (last visited Mar.22, 2011), “Talmud: ‘Rabban Simeon ben Gamliel said: Any human being who lives thirty days is not a *nephel* [abortus] because it is stated: ‘And those that are to be redeemed of them from a month old shalt thou redeem (Num. 18:16),’ since prior to thirty days it is not certain that he will survive.”

¹⁵⁶ Union for Reform Judaism, *Resolution on Stem Cell Research*, available at http://urj.org/Articles/index.cfm?id=7152&pge_prg_id=30698&pge_id=1625 (last visited Feb. 21, 2010).

¹⁵⁷ Rabbinical Council of America, *Statement on Stem Cell Research*, Oct. 22, 2004, available at <http://www.rabbis.org/news/article.cfm?id=100553> (last visited Mar. 2, 2011)

¹⁵⁸ United Synagogue of Conservative Judaism, *Stem Cell Research and Education (2003)*, available at http://www.uscj.org/Stem_Cell_Research_a6675.html (last visited Feb. 21, 2010).

¹⁵⁹ Orthodox Union, *Union of Orthodox Jewish Congregations Welcomes U.S. House Passage of Stem Cell Research Enhancement Act*, May 25, 2005, available at <http://www.ou.org/public/statements/2005/n11.htm> (last visited Feb. 21, 2010).

Unlike religions, which usually have governing bodies, philosophical theories are more varied and there is an absence of authority to unify different thoughts. Hence, almost all philosophical schools can be divided into favor-hESC research and against-hESC research factions. For instance, embryonic stem cell research can find both advocates and opponents within Kantianism. Some Kantian followers argue that the denial of the humanity of zygotes by declaring that humanity begins at birth is “scientifically obscurantist,” and one principle of Kantianism, defined in the phrase “it is impermissible for anybody at will to use force upon another” applies to both the born and unborn.¹⁶⁰ Another group of Kantian followers believes that the state of personhood is not established at the time of conception because a Kantian person is transcendental and intelligible rather than the empirical being.¹⁶¹ Based on this theory, some Kantian followers believe that embryonic stem cell research is beneficial to human health and life.¹⁶²

In contrast to the Kantian views, a number of alternative philosophical schools are more aligned with a supportive stance toward hESC research based on its value in a modern society.

As an example, most feminists do not consider embryos as having the moral or legal status of full-fledged persons.¹⁶³ From a feminist viewpoint, hESC research is justified, and even the creation of embryos for research purposes can be justified under certain conditions.¹⁶⁴

¹⁶⁰ ALAN DONAGAN, *THE THEORY OF MORALITY* 83 (University of Chicago 2d ed. 1977).

¹⁶¹ Bertha Alvarez Manninen, *Are Human Embryos Kantian Person?: Kantian Considerations in favor of Embryonic Stem Cell Research*, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2263072/?tool=pubmed> (last visited Mar. 21, 2010).

¹⁶² *Id.*

¹⁶³ Carolyn McLeod & Francoise Baylis, *Feminists on the Inalienability of Human Embryos*, *HYPATIA*, winter 2006, 1, 8.

¹⁶⁴ Guido de Wert and Christine Mummery, *Human Embryonic Stem Cells: Research, Ethics and Policy*, 18 *HUMAN REPRODUCTION* 672, 678 (2003).

In Confucianism, there is no specific discussion on the moral status of the human embryo. However, according to the successor of Confucius—Mencius—humans possess four moral capacities to be distinguished from animals: righteousness (yi), propriety (li), wisdom (zhi) and humanity (jen).¹⁶⁵ Based on this premise, embryos can hardly be considered persons. From a Confucian perspective, the family and society, instead of the individual, are the center of health care decision-making;¹⁶⁶ therefore, even though there is no explicit statement on embryonic stem cell research, it is justified under the Confucian principles.

Similarly, followers of Utilitarianism identify goodness not as the agent's own happiness, but as "the greatest amount of happiness altogether."¹⁶⁷ Some utilitarians insist that only autonomous creatures should be taken into account.¹⁶⁸ Using this view, embryos have no moral standing since they have no pain or pleasure feelings to intrinsically contribute to the whole.¹⁶⁹ It is because of this that Utilitarianism plays a critical role in favoring embryonic stem cell research.¹⁷⁰

C. Laws and Policies on the Status of Human Embryos

1. National Laws regarding the Status of Embryos

¹⁶⁵ D F-C Tsai, *Human Embryonic Stem Cell Research Debates: a Confucian Argument*, 31(11) J Med Ethics. 635, 637 (2005).

¹⁶⁶ Erika Yu & Ruiping Fan, *A Confucian View of Personhood and Bioethics*, 4 BIOETHICAL INQUIRY 171, 179 (2007)

¹⁶⁷ JOHN STUART MILL, *UTILITARIANISM: EASYREAD LARGE EDITION* 26 (ReadHowYouWant.com 2006) (1863).

¹⁶⁸ PETER SINGER, *PRACTICAL ETHICS* 104 (Cambridge University 2011).

¹⁶⁹ ROBERT P. GEORGE, *supra* note 99, at 94.

¹⁷⁰ *Id.*, at 94.

Regardless of religious assertions, at least until now, very few countries in the world stipulate that fertilized eggs are entitled to personhood or protect them under individual rights principles as human beings.

In the United States, the Supreme Court held in a well-known case, *Roe v. Wade*, (1973) that women have a fundamental right to abortion. This action was brought against a Texas criminal abortion law, which prohibited abortion at any stage of pregnancy except when necessary to save the mother's life. The Supreme Court admitted that when life begins is a question about which "those trained in the respective disciplines of medicine, philosophy, and theology are unable to arrive at any consensus," and decided that the judiciary is not the right place to answer it.¹⁷¹ However, it held that the word "person" as used in the Fourteenth Amendment does not include the unborn.¹⁷² In order to balance the state's interest in protecting potential human life and the liberty interest of women, a trimester based schedule was devised, rejecting any legislation limiting a woman's choice regarding the disposition of an embryo during the first trimester.¹⁷³ In conclusion, the Court held that the Texas criminal abortion statute failed to recognize the interests of the mother and violated the Due Process Clause of the Fourteenth Amendment.¹⁷⁴ It states,

"For the stage prior to approximately the end of the first trimester, the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician. . . . For the stage subsequent to approximately the end of the first trimester, the State, in promoting its interest in the health of the mother, may, if it chooses, regulate the abortion procedure in ways that are reasonably related to maternal health. . . . For the stage subsequent to viability the State, in promoting its interest in the potentiality of

¹⁷¹ *Roe v. Wade*, 410 U.S. 113, 160 (U.S. 1973).

¹⁷² *Id.*, at 158.

¹⁷³ *Id.*, at 163.

¹⁷⁴ *Id.*, at 159.

human life, may, if it chooses, regulate, and even proscribe, abortion except where necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.”¹⁷⁵

The Supreme Court rejected the idea that embryos have a right to life protected by the Fourteenth Amendment.

Planned Parenthood v. Casey, 505 U.S. 833 (1992) reaffirmed the judgment of *Roe v. Wade* and held that states’ interest in protecting life fell short of justifying the override of human liberty claims. In *Stenberg v. Carhart*, 530 U.S. 914 (2000), the Supreme Court reaffirmed women’s right to abortion, and held that “the state’s interest in regulating abortion previability of a fetus is considerably weaker than postviability of a fetus,” manifesting its intention to distinguish fetuses without the capacity of maintaining a separate existence from fetuses with that capacity. *Davis v. Davis*, 842 S.W.2d 588 (1992) held that fetuses were not human beings under the Tennessee Wrongful Death Statute, and were not entitled to the same protection as “persons.” *Jeter v. Mayo Clinic Ariz*, 211 Ariz. 386 (2005) held that pre-implantation fertilized human eggs were not “persons” under Ariz. Rev. Stat. § 12-611. After President Obama opened the gate to federal appropriation on hESC research, a group of people alleged that such policy violated human embryos’ constitutional rights. In the judgment of *Doe v. Obama*, 670 F. Supp. 2d 435 (2009), the Supreme Court dismissed the claim on the grounds that embryos had no constitutional rights since they were not considered persons under the law.

In China, the General Principles of the Civil Law of the Peoples Republic of China [GPCL] (1986), Article 9 stipulates that “a citizen shall have the capacity for civil rights from birth to death and shall enjoy civil rights and assume civil obligations in accordance with the law,” which means that China protects civil rights after birth. In practice, the courts embrace the

¹⁷⁵ *Id.*, at 164.

“independent breath” theory to determine the start of human life in laws,¹⁷⁶ which is when the fetus can breathe independently. Before that, the fetus has no civil legal capacity or legal responsibility. However, the fetus has certain rights of inheritance in civil law. In the Law of Succession of the Peoples Republic of China (1985),¹⁷⁷ Article 28 provides unborn children a reserved share at the time of the estate partitioning. In the event that the baby is stillborn, the share shall be managed according to statutory succession. In China, abortion is permitted, especially under the One Child Policy since the 1980s, according to which one couple shall have only one child except in exceptional conditions that are promulgated in regulations.¹⁷⁸ But any abortion performance is under the nation’s supervision. Any one who conducts an illegal abortion will receive an administrative penalty, fines and even criminal punishment.¹⁷⁹

In Europe, the countries maintain various laws concerning the status of embryos and the beginning epoch of human rights in the embryo or fetus timeline. As in China, according to Section 1 of German Civil Code, the legal capacity of a human being starts at the completion of birth. The Federal Constitutional Court in Germany has ruled that abortion within the first 12 weeks of pregnancy is allowed.¹⁸⁰ In the French Civil Code, Art. 725 states that a fetus’ right of inheritance is protected provided he/she is born alive subsequently.¹⁸¹ In contrast, some countries in Europe give unborn children more protection. Article 15 of the Spanish Constitution sets forth that everyone, rather than every person, has the right to life; Portugal protects

¹⁷⁶ JIANFU CHEN, CHINESE LAW: CONTEXT AND TRANSFORMATION 346 (Brill 2008)[hereinafter CHEN].

¹⁷⁷ Ji cheng fa [Law of Succession] 9[promulgated by the Nat’l People’s Cong., Apr. 10, 1985, effective Oct. 1, 1985] art. 26 LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C).

¹⁷⁸ Ren kou yu ji hua sheng yu fa [Law of the People’s Republic of China on Population and Family Planning] (promulgated by the Standing Comm. Nat’l People’s Cong., Dec. 29, 2001, effective Sept. 1, 2002) art. 18 LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C).

¹⁷⁹ *Id.*, Article 36.

¹⁸⁰ BERTRAND MATHIEU, THE RIGHT TO LIFE IN EUROPEAN CONSTITUTIONAL AND INTERNATIONAL CASE-LAW 23 (Council of Europe 2006)[hereinafter BERTRAND MATHIEU].

¹⁸¹ CHEN, *supra* note 176, at 346.

human life in the womb; Ireland also recognizes the right to life of unborn children.¹⁸² Among European countries, fetuses and embryos receive various amounts of legal protection. It is too absolute to say that a fetus or embryo has no legal rights, but it is also incorrect to claim that a fetus or embryo has the same legal rights as living people.

In European regional organizations, there is no official statement about the status of embryos considering the divergence of multiple cultures and traditions. Article 2 of the European Convention on Human Rights [ECRH] provides that everyone's right to life shall be protected. But whether "everyone" includes human embryos was questioned in the case of *Evans v. the United Kingdom* in 2007. The case focuses on whether the member states of the ECHR have the obligation to protect the right to life of embryos under Article 2. In a unanimous judgment, the Grand Chamber ruled that no European wide consensus has been established on the level of legal protection to grant a human embryo; therefore in this case, under English law, an embryo has no right to life as a person.¹⁸³ Instead of interpreting and defining the protecting scope of the ECHR, the court chose to evade the hardcore issue at bar and left the ambiguity to member states.

In the European Union, the status of human embryos is also blurry. The Charter of Fundamental Rights of the European Union also promises the right to life to "everyone" in its Article 2, but the definition and scope of "everyone" is not clear in this document either. None of the constitutional courts in Europe have defined the legal status of human embryos in practice.¹⁸⁴ The Convention on Human Rights and Biomedicine (1997) prohibits the creation of human embryos solely for research purposes, but allows research on embryos *in vitro* when adequate protection is given under Article 18. The Biotechnology Directive 98/44/EC of the European Parliament and of the

¹⁸² BERTRAND MATHIEU, *supra* note 180, at 24.

¹⁸³ See *Evans v. the United Kingdom*, App. No. 6339/05 (Eur Ct. H.R. Mar. 7, 2006)

¹⁸⁴ BERTRAND MATHIEU, *supra* note 180, at 23.

Council on the Legal Protection of Biotechnological Inventions [Biotechnology Directive] forbids patenting the human body at various stages and considers the use of embryos for industrial or commercial purpose to be a violation of morality in Article 6.¹⁸⁵ However, the definition and scope of the term human embryo as used in the Biotechnology Directives are ambiguous, and the scope of commercial or industrial purpose is undecided since all types of research can result in economic benefit somehow. Even after those provisions have been followed and copied by the European Patent Convention and applied by the European Patent Office in a hESC patent case, the definition of embryo is still left to be decided on a case by case basis.

In conclusion, while a majority of the international treaties and organizations choose to stay silent, most states do not grant a blastocyst or a fetus the same civil rights as a person.

2. Laws and Policies towards hESC Research

Another ethical debate beyond the beginning of human life is about policies and strategies of controlling human creation. There is a fear reflecting distrust of science and technology. Some people do not trust scientists or government oversight of science. Therefore, suspicions that scientists may misuse cloning techniques to create humankind arise. Actually, most countries that allow hESC research have explicitly banned human reproductive cloning or any ESC research on stem cells derived from embryos following cloning.

¹⁸⁵ European Parliament and the Council, *Directive 98/44/EC on the legal protection of biotechnological inventions* (July 6, 1998) Recital 8, 1998 O.J. (L 213) 18 [hereinafter Directive].

After President Obama opened the door for federal government funding support to hESC research on March 9, 2009,¹⁸⁶ the National Institutes of Health, an agency of the Department of Health and Human Services, promulgated the "National Institutes of Health Guidelines for Human Stem Cell Research"¹⁸⁷ [Guidelines for Human Stem Cell Research]. According to the Guidelines for Human Stem Cell Research, federal funding is only available to research with ESCs derived from human embryos which were created by IVF for reproductive purpose but were no longer needed, and were donated by the parents with written consent. The Guidelines for Human Stem Cell Research exclude the possibility of supporting hESC research in which SCNT techniques are involved.

China has few opposing voices in the ethical debate on hESC research. In the Chinese government, the Ministry of Science and Technology issued the Ethical Guiding Principles for the Research of hESC [Ethical Guiding Principles] in 2003, which took effect in 2004. The Ethical Guiding principles stipulates that only embryos satisfying one of the following conditions can be used in ESCs research: leftover blastocyst from IVF procedures, miscarried or aborted fetus, blastocyst created by SCNT, or donated germ cells. The Chinese government reiterated its support for therapeutic cloning, but opposition to reproductive cloning in international meetings.¹⁸⁸

Belgium has a similar policy. It issued the Law on Research on Embryos in vitro in 2003, stipulating that research on embryos is allowed under specific

¹⁸⁶ Exec. Order No. 13505, 74 Fed. Reg. 10,667 (Mar. 11, 2009)[hereinafter 74 Fed. Reg. 10,667].

¹⁸⁷ NIH Guideline 74, *supra* note 67.

¹⁸⁸ Permanent Mission of the People's Republic of China to the UN, *Statement of Chinese Delegate at the Sixth Committee of the 59th Session of the UN General Assembly on item 150: International Convention against the Reproductive Cloning of Human Beings*, Oct. 21, 2004, available at <http://www.china-un.org/eng/lhghyywj/smhwj/wangnian/2004/t560773.htm> (last visited Sept. 29, 2009).

conditions.¹⁸⁹ The creation of embryos solely for research purpose is conditionally allowed (Article 4, §1), but reproductive cloning of human beings is prohibited (Article 6).¹⁹⁰

In contrast, the United Kingdom, along with many other European countries, conditionally supports hESC research but limits the sources of embryos. It states that fundamental research on embryonic stem cells is necessary at present, even though the situation may be changing in the future.¹⁹¹ The source of embryonic stem cells for research is limited to extra embryos created for IVF treatment because embryos may not be created solely for research purposes.¹⁹² The government-financed stem cell bank provides embryonic stem cells for scientists both domestically and abroad.¹⁹³

Similarly, in Switzerland, embryonic stem cell research is supported by the federal government but restricted to the source of embryos permitted—surplus embryos left over from IVF and that will not be used for their original purpose.¹⁹⁴

Germany promulgated the Stem Cell Act (Stammzellgesetz) in 2002, which permits the import of hESCs from foreign countries for research purpose under certain conditions.¹⁹⁵

¹⁸⁹ Guido Pennings, *New Belgian Law on Research on Human Embryos: Trust in Progress Through Medical Science*, 20 J. ASSISTED REPRODUCTION & GENETICS 343, 344 (2003).

¹⁹⁰ *Id.*, at 344.

¹⁹¹ House of Lords of UK Parliament, *Stem Cell Research Report*, Feb. 27, 2002, Chapter 3.2, available at <http://www.parliament.the-stationery-office.co.uk/pa/ld200102/ldselect/ldstem/83/8301.htm> (last visited Oct. 2, 2009).

¹⁹² *Id.*, Chapter 5.2.

¹⁹³ See UK Stem Cell Bank homepage, available at <http://www.ukstemcellbank.org.uk/> (Last visited Oct. 2, 2009).

¹⁹⁴ Federal Office of Public Health, *Research involving Human Embryonic Stem Cell*, available at <http://www.bag.admin.ch/themen/medizin/03301/index.html?lang=en> (Last visited Oct. 3, 2009).

¹⁹⁵ Jan P. Beckmann, *On the German Debate on Human Embryonic Stem Cell Research*, 29 J. MED. & PHIL. 603, 605 (2004).

In addition, Finland, Denmark, France, Italy, Estonia, Hungary, Latvia, and Slovenia have all implemented legislation authorizing research on human embryos under certain conditions.¹⁹⁶

Among other European countries, Lithuania, Poland and the Slovak Republic prohibit human embryo research. No specific regulations regarding embryonic research exist in Luxembourg, Portugal, Cyprus, Malta and the Czech Republic.¹⁹⁷

Like most European countries, Canada has prohibited all types of human cloning, including therapeutic cloning under the Assisted Human Reproduction Act. It also governs all types of stem cell research and regulates acceptable practices in embryonic stem cell research including the permissible sources of human embryos.¹⁹⁸

Similarly, Japanese legislation permits stem cell research on surplus embryos and prohibits reproductive cloning; however, there is a sign of the Japanese government opening the door for therapeutic cloning and hESC research on additional embryos, by allowing the creation of new cloned embryos for research under specific conditions.¹⁹⁹

While nations such as the United States can easily change their policies, international organizations usually take a slower step forward because consensus is harder to achieve among their member countries with diverse cultural, historical and religious backgrounds. The United Nations has a long history of prohibiting reproductive cloning. In Article 11 of the Universal Declaration on the Human Genome and Human Rights, adopted in 1997, it

¹⁹⁶ EUROPA, *Report on Human Embryonic Stem Cell Research*, Apr. 7, 2003, available at http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/03/81&format=HTML&aged=0&language=EN&guiLanguage=en#file.tmp_Foot_8 (Last visited Mar. 22, 2010).

¹⁹⁷ *Id.*

¹⁹⁸ Assisted Human Reproduction Act, 2004 S.C., ch.2 (Can.).

¹⁹⁹ Angela Campbell, *Ethos and Economics: Examining the Rationale Underlying Stem Cell and Cloning Research Policies in the United States, Germany, and Japan*, 31 AM. J.L. & MED.47, 65 (2005).

states that any practice contrary to human dignity is prohibited, including reproductive cloning. The United Nations Declaration on Human Cloning at the 59th Assembly in 2005 reaffirms this principle and bans any form of human cloning if it is “incompatible with human dignity and the protection of human life.”²⁰⁰ But this guideline is too general to provide a definite answer to the status of human embryos and leaves the status of therapeutic cloning unclear. The European Union has a very clear viewpoint on reproductive cloning expressed in Article 3 of the Charter of Fundamental Rights of the European Union, which states that reproductive cloning of human beings is prohibited.²⁰¹ On the other hand, its opinion on therapeutic cloning is not clear. However, its standpoint on hESC research is less ambiguous. It created a registry system for hESC lines in 2007 to supervise and monitor embryonic stem cell research with strict ethical limits.²⁰²

Regardless of the various attitudes of regional institutes, philosophical schools, governments and international organizations towards the human body and embryonic stem cell research, the trend toward developing such research and the possibility of applying it to practice in the near future is undeniable.

²⁰⁰ United Nations Declaration on Human Cloning, G.A. Res. 59/280, U.N. Doc. A/RES/47/1 (Mar. 8, 2005)[hereinafter G.A. Reg. 59/280].

²⁰¹ European Parliament, the Council and the Commission, *Charter of Fundamental Rights of the European Union* (Dec. 7, 2000) (2000/C 364/01) 2000 O.J. (C 364) 1.

²⁰² EUROPA, *European Commission Creates Registry for Human Embryonic Stem Cell Lines*, Mar. 27, 2007, available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/437&format=HTML&aged=0&language=EN&guiLanguage=en> (last visited Jan. 14, 2009).

Chapter 4: Patent Laws regarding hESCs in the United States

A. Federal Policy on hESC Research

The U.S. federal government's policy on hESC research has gone through dramatic modifications. In 1996, Congress voted in favor of the Dickey-Wicker Amendment which prevents the use of federal funds for any research activity that involves "the creation of a human embryo or embryos for research purposes" or "research in which human embryo or embryos are discarded, destroyed, or knowingly subjected to a risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. 208(a)(2) or 42 U.S.C. 289g(b)."²⁰³ The term embryo in the clause includes any embryo that is "derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes."²⁰⁴ 45 C.F.R. 208(a)(2) and 42 U.S.C. 289g(b) are both rules regarding fetal research.²⁰⁵ However, the Dickey-Wicker Amendment expanded the scope of the restriction on research from fetuses to embryos.

In 1999, the Clinton Administration interpreted the Dickey-Wicker Amendment as inapplicable to derived hESC research since the cells used are already derived and not embryos.²⁰⁶ Harriet Rabb, the National Institutes of Health [NIH] general counsel, released a legal opinion stating that federal funds could not be used to derive stem cell lines which may cause the destruction of embryos, but federal funds could be applied to hESCs, which are not human embryos under the statutory definition and, therefore, are not

²⁰³ Dickey-wicker Amendment of 1996, Pub. L. No. 104-99, § 128,110 Stat. 26, 34 (1996)[hereinafter Dickey-wicker Amendment]

²⁰⁴ *Id.*

²⁰⁵ 42 U.S.C. 289g (2006). The 45 C.F.R. 208(a) revised as of October 1, 2000.

²⁰⁶ National Committee for a Human Life Amendment, *Stem Cell Policy*, available at <http://www.nchla.org/issues.asp?ID=6> (last visited Mar. 3, 2010).

restricted under the Dickey-Wicker Amendment.²⁰⁷ After that, the NIH promulgated guidelines regarding research using hESCs.²⁰⁸

But this policy did not last long. On August 9 of 2001, former President George W. Bush announced that federal funds would not be awarded for hESC research until the following criteria were met: the isolating process of hESCs, including the destruction of human embryos, must have been initiated before 9:00 pm. EDT on August 9, 2001; the stem cells must have been derived from embryos produced for reproductive purposes and not needed for further procreation; and the informed consent from the donor would be required without involving any financial inducement.²⁰⁹ The announcement banned research involving embryos produced after 9:00 pm. EDT on August 9, 2001 from receiving federal appropriation. In other words, after the announcement, researchers could not get federal support on their embryo-involving research unless their raw materials were preexisting embryos. Basically, it affected hESC research by limiting its resources to a great extent.

In 2007, Executive Order 13435 (hereinafter referred to as Order 13435) was signed by President George W. Bush, to promote scientific development while protecting human dignity. An executive order is an order issued by the President under his executive authority.²¹⁰ The Constitution does not explicitly authorize the executive order, but it is implied in the executive power granted in Article II, Section 1, Clause 1 of the Constitution,²¹¹ and the

²⁰⁷ Judith A. Johnson & Erin Williams, *CRS Report for Congress: Stem Cell Research*, (Aug. 13, 2004), available at <http://www.fas.org/spp/civil/crs/RL31015.pdf> (last visited Mar. 26, 2011) [hereinafter CRS Report].

²⁰⁸ National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976(Aug. 25, 2000) (corrected at 65 Fed. Reg. 69,951 Nov. 21, 2000). This Guidelines has been withdrawn, see 66 FR 57,107.

²⁰⁹ Press Release, *President George W. Bush, Remarks by the President on Stem Cell Research*, Aug. 9, 2001, available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html> (last visited Apr. 10, 2010).

²¹⁰ Kenneth R. Mayer, *Executive Orders and Presidential Power*, 61 J. POL. 445, 445 (1999) [hereinafter Mayer].

²¹¹ “The executive Power shall be vested in a President of the United States of America. “

duty to execute laws under Article II, Section 3, Clause 4.²¹² Because the power to issue executive orders is based on the President's constitutional power, executive orders have full legal force.²¹³ Order 13435 iterates the policy that hESC research is encouraged as long as it does not destroy human embryos or fetuses or create human embryos for research purposes.²¹⁴ Obviously, the resources available for hESC research were still strictly limited.

In addition, Order 13435 defined the human embryo as an organism "derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells,"²¹⁵ and renames "human embryonic stem cell" as "human pluripotent stem cell."²¹⁶ It supported hESC research on alternative embryonic sources, but prohibited embryos to be created for any purpose,²¹⁷ because the destruction of life, including embryos and fetuses, for research or commercial purposes, violates the principle of "no life should be used as a mere means for achieving the medical benefit of another."²¹⁸ The main idea of the Executive Order was consistent with President Bush's statement: no embryo production for whatever purpose. But, it did not illustrate what alternative embryo resources would be permitted.

On March 9, 2009, President Obama issued Executive Order 13505 (hereinafter referred to as "Order 13505"), removing the governmental financial constraints on scientific research involving hESCs, considering the potential importance of hESCs in the scientific field.²¹⁹ Order 13505 stated

²¹² The text is "he shall take Care that the Laws be faithfully executed."

²¹³ Mayer, *supra* note 210, at 448.

²¹⁴ Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 22, 2007), Section 1(a)[hereinafter 72 Fed. Reg. 34,591].

²¹⁵ *Id.*, Section 3.

²¹⁶ *Id.*, Section 1(b)(iv).

²¹⁷ *Id.*, Section 1(a).

²¹⁸ *Id.*, Section 2(c) and (d).

²¹⁹ 74 Fed. Reg. 10,667, *supra* note 186.

that all hESC research should be supported to the extent allowed by law,²²⁰ and ordered the NIH to issue new guidance consistent with this new policy.²²¹ Most importantly, Order 13505 revoked the presidential statement of August 9, 2001, which limited federal funding on hESC research; instead, it allows for funding research using hESCs derived from superfluous IVF embryos created for reproductive purposes but no longer needed for their original purpose.²²² Since then, federal government funding has been available for hESC research.²²³ It is good news for hESC researchers in the US, despite the restrictions on research that continue to exist.

Under the direction of Order 13505, the NIH started issuing new guidance to implement this new presidential policy. The NIH, as a part of the U.S. Department of Health and Human Services, is the primary federal agency responsible for supervising medical research, with its primary aim being to improve human health.²²⁴ As a federal agency, it implements the President's policy and plays a critical role in conducting hESC research. The NIH maintains the hESC registry, which lists all hESC lines eligible for use in NIH-funded research.

Shortly after the Executive Order 13505, the NIH promulgated the National Institutes of Health Guidelines for Human Stem Cell Research to implement Order 13505.²²⁵ According to the Guidelines for Human Stem Cell Research, federal funding is only available for research on hESCs derived from human embryos, which were created by IVF for reproductive purposes but no longer needed, and discarded by the parents with written consent. The Guidelines for Human Stem Cell Research excludes the possibility of

²²⁰ *Id.*

²²¹ *Id.*, Section 3.

²²² *Id.*, Section 5; 74 Fed. Reg. 32173.

²²³ *Id.*

²²⁴ See National Institutes of Health, *available at* <http://www.nih.gov/about/NIHoverview.html> (last visited Mar. 2, 2011).

²²⁵ NIH Guideline 74, *supra* note 67.

government supported hESC research using SCNT because this process involves complex ethical issues and does not have a consensus yet. It also defines hESC as “cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers,” and articulates that despite the fact that hESCs are derived from embryos, they are not human embryos themselves.²²⁶

These attempts to spur hESC research ran into many obstacles later. However, this is not the end of the story. Because the Dickey-Wicker Amendment is still in force, some challengers represented by James L. Sherley, a stem cell scientist, sought a preliminary injunction against the Department of Health and Human Services [HHS] to prevent the Guidelines for Human Stem Cell Research from taking effect on the basis that the Guidelines violated the Dickey-Wicker Amendment. On August 23, 2010, a district court granted a preliminary injunction. The court reasoned that during hESC research, ESCs have to be derived from embryos, which unavoidably results in the destruction of human embryos; thus, hESC research results in the destruction of human embryos and should not be granted federal funding according to the Dickey-Wicker Amendment.²²⁷ Considering the injury that the public interest and the plaintiff may receive from the enforcement of the Guideline, a preliminary injunction is granted.²²⁸

The changes in the legal status of hESC research funding have had a dramatic effect on patent application and issuance. Figure 4.1 charts the number and fluctuation of human cell (435/366) patents filed in U.S. since 1992. Since the survey only includes issued patents, the data cuts off after 2004 partially because patents filed after 2004 are mostly still under

²²⁶ NIH Guideline 74, *supra* note 67, at 32173.

²²⁷ *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 70-71 (D.D.C. 2010).

²²⁸ *Id.*, 72-73.

examination. There are 2714 published human cell patent applications currently under patent examination.²²⁹

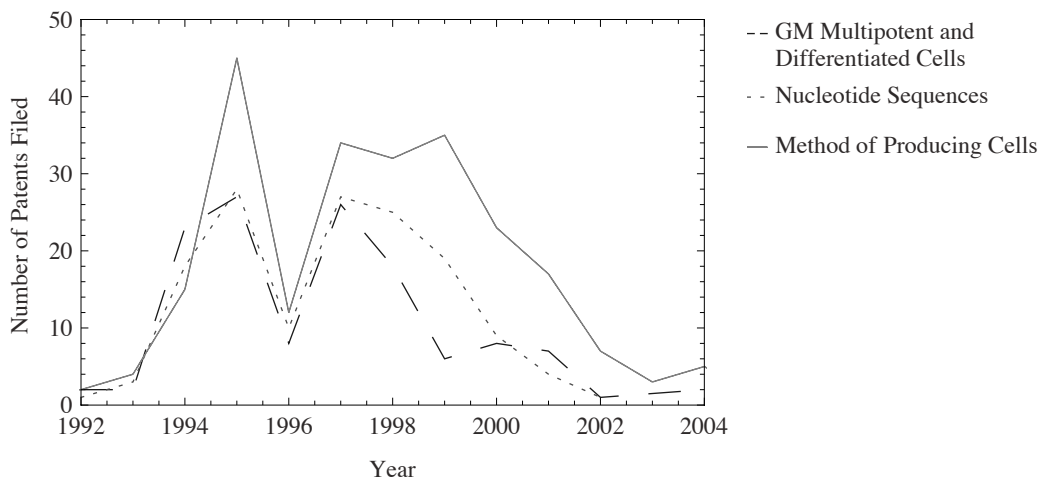


Figure 4.1: U.S. human cell patents

The fluctuations shown in the above graphic are consistent with the policy changes on human cells, especially hESC research in the US. From the plots, one can see that since 1996, there was a drop of both issuance and application of human cell patents. The reason behind this could be that in 1995, the U.S. Congress voted in favor of the Dickey-Wicker Amendment, which banned the NIH from funding any research in which embryos were destroyed, discarded or otherwise harmed.²³⁰ The enactment of the law not only impacted the enthusiasm of scientists to engage in human cell research and apply for patents, but also decreased the number of patents granted by the patent office. This law is still binding.

²²⁹ United States Patent and Trademark Office, *Patent Application Full Text and Image Database*, available at <http://appft1.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetacgi%2FPTO%2Fsearch-adv.html&r=0&p=1&f=S&l=50&Query=ccl%2F435%2F366&d=PG01> (last visited Mar. 23, 2011)

²³⁰ Dickey-wicker Amendment, *supra* note 203, § 128.

At the same time, SCNT was under rapid development; therefore, after a sharp drop in 1996, human cell patent applications rocketed after 1996. The technique was under development worldwide. The birth of the first cloned mammal “Dolly” in 1996 is one example.

In 1999, the Clinton Administration interpreted the Dickey-Wicker Amendment as banning federal funds for stem cell derivation from embryos, but allowing funding for research on cells that had already been derived,²³¹ which further encouraged stem cell research. However, in 2001, the policy limiting federal funding for research on hESC research announced by former President George W. Bush may be the reason for the reduction in the number of issued patents and applications on human cells since 2001.

Since the survey only includes patents issued before 2004, the trend of human cell patents after 2004 is not examined in this dissertation. It is believed that President Obama’s policy lifting the federal funding restriction on hESC research in 2009 and the court’s preliminary injunction granted in 2010 will heavily influence patent applications and issuances in the U.S.

B. Federal Patent Law regarding hESCs

1. History of U.S. Patent System

Historically, the American states received their patent customs primarily from the original thirteen American Colonies.²³² But patent customs were predicated on the activities of local legislatures, and no state enacted a

²³¹ National Committee for a Human Life Amendment, *Stem Cell Policy*, available at <http://www.nchla.org/issues.asp?ID=6> (last visited Mar. 3, 2010).

²³² Edward C. Walterscheid, *The Early Evolution of United State Patent Law: Antecedents (5 Part 1)*, 78 J. Pat. & Trad. Off. Soc’y 615, 630-631 (1996).

general patent statute with exclusive rights or a patent period.²³³ After the Revolution, the United States was formed, which finally triggered a uniform patent system.²³⁴ On September 5, 1787, the power of Congress to promote the progress of science and useful arts was proposed and later passed unanimously. This is embodied in Article 1, Section 8, Clause 8 of the Constitution, which became the foundation of American federal patent law.²³⁵ On April 5, 1790, the first patent statute was passed.²³⁶

The first patent statute did not create a patent office. Instead, all patent application files had to be submitted to the Secretary of State and examined by the Secretary of State, the Secretary of War and the Attorney General, based on the invention's utility.²³⁷ At that point, there were no specific rules about procedure or patent requirements, which made patent examination difficult.²³⁸ Once the patent was issued the patent lifetime was 14 years.²³⁹ However, In order to address the deficiency created by the lack of procedural and substantive rules in the Patent Act of 1790, the Patent Act of 1793 was created, which set up a registration system at the State Department, under which patents would become effective as soon as they were registered.²⁴⁰ Abandoning patent examination and leaving opposition to the courts resulted in abundant useless patents.²⁴¹

²³³ Edward C. Walterscheid, *To Promote the Progress of Science and Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution*, 2 J. INTELL. PROP. L. 1, 15-16 (1994).

²³⁴ Glynn S. Lunney, *E-Commerce and Equivalence: Defining the Proper Scope of Internet Patents Symposium: E-obviousness*, 7 MICH. TELECOMM. TECH. L. REV. 363, 363 (2000).

²³⁵ *Id.*

²³⁶ KENNETH W. DOBYNS, *THE PATENT OFFICE PONY: A HISTORY OF THE UNITED STATES PATENT OFFICE 22* (Sergeant Kirkland's Museum & Historical Soc'y 1994)[hereinafter DOBYNS].

²³⁷ Patent Act of 1790, Ch. 7, 1 Stat. 109. Chap. VII, Sec. 1.

²³⁸ DOBYNS, *supra* note 236, at 24.

²³⁹ *Id.*

²⁴⁰ *Id.*, at 35.

²⁴¹ Max Stul Oppenheimer, *The Rime and Palce for "Technology-shifting" Rights*, 14 Marq. Intell. Prop. L. Rev. 269, 283 (.2010).

To solve this problem, the Act of 1836 was passed.²⁴² The Act of 1836 distinguished the patent office from the Department of State as an independent bureau with specific responsibilities, created the position of commissioner of patents, and introduced the patent examination procedure and appellate structure.²⁴³ In 1870, Congress re-codified the Act of 1836, but emphasized the importance of the patent claim.²⁴⁴ The 1952 Act introduced some new statutory rules and addressed related court decisions. For instance, Section 103 overturned the “flash of creative genius”²⁴⁵ standard as a patent requirement. Instead, it set the standard of nonobviousness at an ordinary level, which is “a person having ordinary skill in the art.”²⁴⁶ The Act of 1952 was codified as Chapter 35 of the U.S. Code. Since then, several amendments have been added to the Act of 1952, but the requirements of novelty, nonobviousness and patentable subject matter remain unchanged.

2. Current U.S. Patent Law

a. U.S. Patent System

Although Secretary of State James Madison appointed Dr. William Thornton as the first administrator for patent matters in 1802,²⁴⁷ a separate patent office was first established by the Act of 1836.²⁴⁸ It is now called the United States Patent and Trademark Office [USPTO], a federal agency under

²⁴² *Id.*

²⁴³ Simone A. Rose & Debra R. Jessup, *Whose Rules Rule? Resolving Ethical Conflicts During the Simultaneous Representation of Clients in Patent Prosecution*, 44 IDEA 283, 290 FN 28 (2004).

²⁴⁴ Patent Act of 1870, ch. 230, § 26, 116 Stat. 198, 201 (1871).

²⁴⁵ *Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (U.S. 1941).

²⁴⁶ 35 U.S.C. §103 (a)(2006).

²⁴⁷ James P. Hughes, *Patent Law Through Patent Administration: The First Patent Superintendent's Creation of Reissue Practice and Law*, 18 FED. CIR. B.J. 451, 454 (2008).

²⁴⁸ *Id.*, at 458.

the Department of Commerce.²⁴⁹ The USPTO is responsible for examining and issuing patents and disseminating information to the public with the mission of promoting innovation and competitiveness in the market.²⁵⁰ To carry out its responsibility, the USPTO is entitled to issue regulations under its authority.²⁵¹ Therefore, all regulations the USPTO issues under its authority are legally binding. To implement the Patent Act [Chapter 35 of the U.S. Code, hereinafter 35 U.S.C.] and Chapter 37 of the Code of Federal Regulations [hereinafter 37 C.F.R.], the USPTO set forth the Manual of Patent Examining Procedure [MPEP].

The USPTO consists of the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the USPTO, a Commissioner for Patents, a Commissioner for Trademarks, and other officers and employees.²⁵² Under the Commissioner for Patents, there is a Deputy Commissioner for Patents, a Deputy Commissioner for Patent Examination Policy and a Deputy Commissioner for Patent Resources and Planning.²⁵³ In addition, the USPTO also has a Patent Public Advisory Committee and a Trademark Public Advisory Committee, as watchdogs over policies, performance, and budget.²⁵⁴

To apply for a patent, an applicant files an application with the USPTO. The application is published and made available to the public within 18 months after the filing date.²⁵⁵ After the USPTO examines the application, it will either grant the patent claims or reject them, considering the novelty,

²⁴⁹ 35 U.S.C. §1 (a).

²⁵⁰ See 35 U.S.C. §2 (a).

²⁵¹ See 35 U.S.C. §2 (b) (2).

²⁵² See 35 U.S.C. §3.

²⁵³ United States Patent and Trademark Office, *Office of the Commissioner for Patents*, available at <http://www.uspto.gov/about/offices/patents/index.jsp> (last visited Mar. 14, 2011).

²⁵⁴ See 35 U.S.C §5.

²⁵⁵ See 35 U.S.C. § 122(b).

non-obviousness and usefulness requirements, the disclosure requirements and other requirements of the law. If the application is finally rejected, the applicant can appeal to the Board of Patent Appeals and Interferences.²⁵⁶ Meanwhile, during the entire patent examination process, any person may file reexamination requests of any claim of a patent on the grounds of prior art.²⁵⁷

As mentioned above, the applicant may appeal the decision of the primary examiner to the Board of Patent Appeals and Interferences. Patentees and the third parties can also appeal the final decision of patent examiners.²⁵⁸ The Board of Patent Appeals and Interferences [BPAI] is the appeal body within the USPTO, which comprises the Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative judges.²⁵⁹ The BPAI reviews the appeals from the patent applicant against the examiner's decisions and determines patentability of inventions and priority in interferences.²⁶⁰

If the BPAI decision is adverse to the patent applicant, the applicant can appeal the decision to the U.S. Court of Appeals for the Federal Circuit [CAFC],²⁶¹ or file a civil action against the Director in the U.S. District Court for the District of Columbia.²⁶² In addition, a patent owner involved in any reexamination proceedings, or a third party involved in an inter partes reexamination proceedings who is dissatisfied with the decision of the BPAI, has the right to appeal to the CAFC.²⁶³ The Federal District Court has

²⁵⁶ 35 U.S.C. § 134.

²⁵⁷ 35 U.S.C. § 302 "*ex partes* reexamination" and 35 U.S.C. § 311 "*inter partes* reexamination".

²⁵⁸ 35 U.S.C. § 134.

²⁵⁹ 35 U.S.C. § 6 (a). According to 35 U.S.C. 135, when there are two or more pending patent applications claiming the same invention, the BPAI shall determine the priority of the inventions. It is unique to the U.S. because the U.S. adopts first-to-invent principle.

²⁶⁰ 35 U.S.C. § 6 (b).

²⁶¹ 35 U.S.C. § 141.

²⁶² 35 U.S.C. § 154.

²⁶³ 35 U.S.C. § 141.

jurisdiction over “any civil action arising under any Act of Congress relating to patents.”²⁶⁴

In 1982, The Federal Court Improvements Act created the CAFC as a unified forum for patent appeals, aiming at achieving uniformity on patent issues.²⁶⁵ The CAFC has jurisdiction on patent appeals from United States District Courts and from the BPAI.²⁶⁶

b. The Current Patent Law

Article 1, Section 8, Clause 8 of the Constitution is the basis for federal patent law in the U.S. It states that Congress has the power to “promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”²⁶⁷

Title 35 of the U.S. Code is the current Patent Act. It addresses all patent issues, including eligible subject matter, patent requirements, patent rights, enforcement, remedies and so forth. To be patented, an invention must concern appropriate subject matter and possess the characteristics of novelty, utility and nonobviousness. Only when those requirements are met, can a patent be granted.

i. Subject matter

²⁶⁴ 35 U.S.C. § 145.

²⁶⁵ Rochelle Cooper Dreyfuss, *Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U.L. REV. 1, 74 (1989) (“now more uniform, easier to apply”).

²⁶⁶ 28 U.S.C. §§ 1295(a)(4)(2006).

²⁶⁷ U.S. CONST. art. I, § 8, cl.8.

35 U.S.C. §101 sets forth the subject matter that is patentable, and includes process, machine, manufacture, and composition of matter inventions, along with “any new and useful improvement thereof.”²⁶⁸ *Sidney A. Diamond, Commissioner of Patents and Trademarks, v. Ananda M. Chakrabarty et al.* in 1980, which held that “anything under the sun that is made by man” is patentable subject matter under patent law,²⁶⁹ is a milestone in patenting biotechnology. The issue in *Diamond v. Chakrabarty* was whether a patent claiming a human-made, genetically engineered bacterium, which was capable of breaking down crude oil, was valid. The court upheld the patent’s validity and opened the gate to patenting vital inventions.

After *Diamond v. Chakrabarty*, the scope of patentable subject matter expanded to include living things. Furthermore, as the first patent claim on animals, U.S. Patent No. 4,736,866 (1988) [hereinafter *Harvard Mouse*] started the era of animal patents.²⁷⁰ Later, stem cell patents extended to other species like humans. The first human cell patent was granted in 1992.²⁷¹ It seems that with the development of case law, patentable subject matter has expanded, from the inanimate to the living, from animal materials to human materials.

However, this broad understanding of the patentable subject matter requirement was challenged in a recent judgment made by a U.S. District Court. The issue at hand was whether the patents on two genes relating to breast and ovarian cancer were valid. The court held that patentable subject

²⁶⁸ 35 U.S.C. §101.

²⁶⁹ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (U.S. 1980)

²⁷⁰ See *i.e.*, Mark Jagels, *Dr. Moreau Has Left the Island: Dealing with Human-Animal Patents in the 21st Century*, 23 T. JEFFERSON L. REV. 115, 133 (2000)[hereinafter Jagels]; Thomas Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J., 443, 444 (1999).

²⁷¹ *In vitro* propagation of embryonic stem cells, U.S. Patent 5166065 (filed on May 31, 1990)(issued Nov. 24, 1992)

products of hESC research and procedures are confirmed to constitute patentable subject matter as well, as long as they do not claim “human compositions.” They may, however, involve the use of hESCs and other human materials.²⁷⁹

ii. Utility

An invention must meet the utility requirement under 35 U.S.C. §101. The utility requirement can also be inferred from U.S. Const. Art.1, §8, cl. 8. To be granted, any patent application must be useful. To clarify the utility requirement, the USPTO issued the Utility Examination Guidelines in 2001,²⁸⁰ to demonstrate three criteria for utility, which are specific, substantial and credible utility.²⁸¹ In *In re Fisher*, the court held that to meet the requirement of substantial and specific utility under §101, an expressed sequence tags [ESTs] invention application should have prompt and particular benefits to the public; in the case at bar, the utility did not suffice. The court stated that the patent office did apply the correct legal standard in applying the substantial utility requirement. According to the court, the claimed ESTs are only “objects of use-testing.”²⁸² They do not ensure any anticipatable results at the end; instead, they are all merely hypothetical possibilities.²⁸³

Unlike other countries, the U.S. patent law does not contain public order or morality clauses.²⁸⁴ However, courts once took morality into account for

²⁷⁹ *Id.*, 378.

²⁸⁰ Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001)[hereinafter 66 Fed. Reg. 1092].

²⁸¹ Julian David Forman, *Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647, 680 (2002).

²⁸² *In re Fisher*, 421 F.3d. 1365, 1373 (Fed. Cir. 2005)

²⁸³ *Id.*, at 1373.

²⁸⁴ David B. Resnik, *Embryonic Stem Cell Patents and Human Dignity*, 15 HEALTH CARE ANAL. 211, 213 (2007)[hereinafter Resnik].

utility determination in case law.²⁸⁵ The USPTO also stated that moral utility could be a bar to patenting inventions involving human beings under certain circumstances.²⁸⁶ That situation has been changed; the moral component of the utility requirement was largely rejected in later case law.²⁸⁷ At present, patent law is widely considered an inappropriate tool with which to make moral judgments about science;²⁸⁸ therefore, morality is no longer an accepted consideration in applying the utility requirement.²⁸⁹ Accordingly, even though moral arguments on hESCs research have continued for over a decade,²⁹⁰ the chance of moral issues related to hESCs being addressed through the utility requirement is low.

iii. Novelty

The novelty requirement is set forth under 35 U.S.C. §102, in order to protect the information already in the public domain from being privatized. Since most biotechnological inventions already exist in nature,²⁹¹ judging

²⁸⁵ *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C. Mass. 1817), the court held that “(a)ll that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful,’ therefore, is incorporated into the act in contradistinction to mischievous or immoral”; *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903).

²⁸⁶ United States Patent and Trademark Office, *Facts on Patenting Life Forms Having a Relationship to humans*, Media Advisory No. 98-6, Apr.1, 1998, available at <http://www.uspto.gov/news/pr/1998/98-06.jsp> (Last visited Mar, 22, 2010) [hereinafter USPTO Facts].

²⁸⁷ See *i.e.*, *Whistler Corp. v. Autotronics, Inc.*, 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Tex. 1988); *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366-68 (Fed. Cir. 1999), the court held that “the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years.”

²⁸⁸ Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U.L. REV. 1623, 1651 (2001)[hereinafter Gitter].

²⁸⁹ Samantha A. Jameson, *A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in the United States and the European Union*, 35 AM. INTELL. PROP. L. ASS’N Q.J. 193, 203 (2007)[hereinafter Jameson].

²⁹⁰ Resnik, *supra* note 285, at 214.

²⁹¹ Phil N. Makrogiannis, *Review of the 1999 Patent Law Decisions of the United States Court of Appeals for the Federal Circuit*, 49 AM. U.L. REV. 1381, 1391 (2000)

their novelty becomes an essential issue. In *Diamond v. Chakrabarty*, the court held that the novelty requirement was met by a nonnaturally occurring composition of matter because it was “a product of human ingenuity ‘having a distinctive name, character [and] use.’”²⁹²

However, no further information is given regarding the scope and definition of a patentable composition of matter. The ambiguity is critical to biotechnological inventions since they already exist in nature and have a close relationship with products of nature. In the case of gene sequence inventions, genes are considered novel if they are purified or isolated from their original natural context.²⁹³ This policy has been challenged by a district court’s judgment in *Ass’n for Molecular Pathology v. United States PTO* case in 2010 and an *amicus curiae* (friend-of-the-court) brief filed by the Department of Justice.²⁹⁴

With regard to stem cell inventions, modified cells and cells isolated from their natural environment are still held patentable by some people while unmodified human cells in their biological context are not.²⁹⁵ Cloned embryos or embryonic stem cells are also considered novel because they are produced by SCNT; moreover, they are isolated from their original context.²⁹⁶

It is possible that the argument claiming that the isolation technique alone does not satisfy the novelty requirement will prevail. This would categorize non-modified hESCs as products of nature, making them unpatentable. However, very few people draw attention to this argument since the main

²⁹² *Diamond v. Chakrabarty*, 447 U.S. 303, 309-310 (U.S. 1980).

²⁹³ Matthew Erramouspe, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. REV. 961, 988-990 (1993).

²⁹⁴ United States Department of Justice, *Brief for the United States as Amicus Curiae in Support of Neither Party, Ass’n for Molecular Pathology v. United States PTO*, 702 F. Supp. 2d 181 (2010) (No 2010-1406)[hereinafter Brief].

²⁹⁵ Mikyung Kim, *Overview of the Regulation and Patentability of Human Cloning and Embryonic Stem Cell Research in the United States and Anti-Cloning Legislation in the South Korea*, 21 Santa Clara Computer & High Tech. L.J. 645, 710 (2005)[hereinafter Mikyung Kim].

²⁹⁶ *Id.*, at 709.

novelty issue of hESC patents is whether they are technically novel from the prior art in the USPTO. The litigation process and subsequent result of the human gene case may influence hESC patents and redirect the main issue. At present, artificial interventions, such as isolating hESCs from an in vivo environment or purifying them from their original biological context, are sufficient to satisfy the requirement of novelty. The success of the Wisconsin Alumni Research Foundation's hESC patents proves this standard.²⁹⁷

iv. Nonobviousness

Nonobviousness requires that the subject matter be different enough from the prior art that the subject matter as a whole would not have been "obvious at the time the invention was made to a person having ordinary skill in the art."²⁹⁸

The essential question is whether success is "reasonably predictable on the basis of the prior art": if a person having ordinary skill in the art has a reasonable expectation of success in achieving the invention, the invention fails to meet the non-obviousness requirement.²⁹⁹ In the case of *Graham v. John Deere Co. of Kansas City* (1966), the court held that both primary and secondary factors should be considered in the non-obviousness test.³⁰⁰ The primary factors include the content of the prior art, the differences between the invention at issue and the prior art and the ordinary skill level in the art. Secondary indications besides technical factors are critical to the test, too. For

²⁹⁷ Filliben, *supra* note 8, at 250.

²⁹⁸ 35 U.S.C. § 103(a).

²⁹⁹ Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 734 (1990).

³⁰⁰ *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1 (U.S. 1966).

instance, long-term demand in the market and commercial success of an invention are both suggestive of nonobviousness.³⁰¹

There is one important question in the obviousness determination concerning hESC inventions: whether the primate (human) stem cell technique is obvious to a person having ordinary skill in the art. This question was brought up in the Wisconsin Alumni Research Foundation [WARF] patent reexamination proceedings, where it was argued that the patents lacked novelty and nonobviousness because the technique for isolating and culturing murine, porcine, and ovine stem cells had been disclosed in the prior art. The USPTO decided that considering the biological differences between species, and the failure to apply the technique used on murine stem cells to isolate ovine cells, the technical differences between murine, porcine, and ovine stem cells and primate (human) stem cells are non-obvious.³⁰²

v. Morality Consideration

The U.S. Patent Act lacks any morality requirement, though historically, the federal courts took the issue of morality into account.³⁰³ However, courts today are reluctant to apply moral doctrine to judge patent applications.³⁰⁴ No biotechnological patent case has been found to be rejected on moral grounds.

³⁰¹ *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1324 (2004).

³⁰² He Ming, Xu Zhao, *WARF pei tai gan xi bao zhuan li fu shen an fen xi* [Analysis on WARF Patents Reexamination], CAJ (find at <http://china.eastview.com>) (last visited Nov. 1, 2009) (P.R.C.) [hereinafter Analysis on WARF].

³⁰³ See *i.e.*, *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C. Mass. 1817); *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903).

³⁰⁴ Jagels, *supra* note 271, at 138.

However, the USPTO has adopted a different policy. The USPTO tried to introduce morality considerations into the utility requirement. In 1998, the USPTO issued a media advisory stating that inventions directed at human/non human chimeras are not patentable because they fail to meet the “public policy and morality aspects of the utility requirement.”³⁰⁵ This statement does not only explicitly affirm the morality aspect to the utility criterion, but also demonstrates the USPTO’s opinion on patentability of inventions directed toward humans. But the USPTO fully realized that it could not deny a patent based on morality beyond Congress’ statutes and relevant court decisions.³⁰⁶ This limitation on its power has been confirmed by the courts. The Federal Circuit ruled that the USPTO has no authority to issue substantive rules because 35 U.S.C.S. § 2(b)(2) does not vest the USPTO with such power.³⁰⁷ Any attempt by the USPTO to impact patent applicants’ substantive rights is subject to judicial review according to 5 U.S.C. § 706.³⁰⁸ Meanwhile, Congress has not taken a definitive stand on the morality issue in patent law.³⁰⁹

3. hESC Related Patents Issued by the USPTO

The USPTO has issued patents claiming primate cells and human cells. So far, there have been 516 issued patents on human cells with 41 of these patents being related to hESCs. In addition, there are 80 published applications for inventions related to hESC which are currently pending in the patent examination process.³¹⁰ The USPTO has issued hESC patents since the 1990s. Figure 4.2 shows the subject matter of 133 claims closely related

³⁰⁵ USPTO Facts, *supra* note 288.

³⁰⁶ 66 Fed. Reg. 1092, *supra* note 281, 1095.

³⁰⁷ *Tafas v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009).

³⁰⁸ *Id.*

³⁰⁹ Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM AND MARY L. REV. 469, 516 (2003).

³¹⁰ Based on a 2010 survey the author conducted of U.S. patents on human cells and patent applications on hESCs. All the information is found online. Unpublished applications are not included in the data.

to hESCs and includes issued patents and applications currently under patent examination. The top two categories of claims are method of utilizing non-modified pluripotent embryonic stem cells [ESCs] (44 claims) and method of applying non-modified pluripotent ESCs (32 claims).

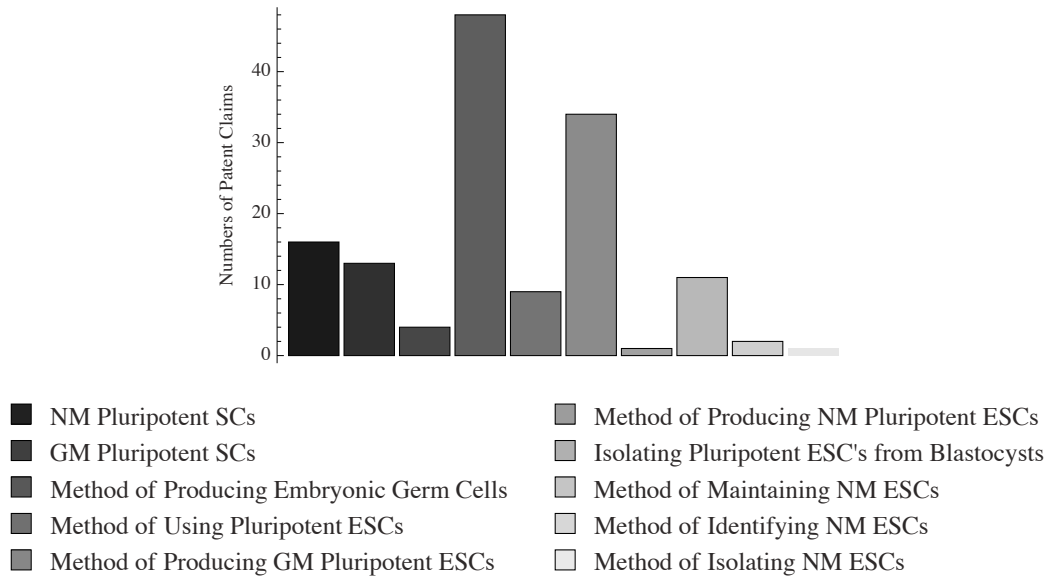


Figure 4.2: U.S. hESC related patent and application categories

Here is a list of U.S. patents claiming hESCs or involving the use of hESCs. The list is not exhaustive, but it gives general information about the subject matter claimed in hESC related patents. The list includes claims on hESCs, methods of culturing, maintaining, propagating, isolating and differentiating hESCs, and cellular compositions comprising hESCs.

- U.S. Patent No. 5,843,780 (Application No. 08/591,246)
Primate embryonic stem cells (issued on 12-01-1998)

This patent claims primate embryonic stem cells and cell lines and methods of isolating primate embryonic stem cell lines.

- U.S. Patent No. 6,200,806 (application No. 09/106,309)
Primate embryonic stem cells (issued 3-13-2001)

This patent is a division of US Patent 5,843,780. Its claims include a purified preparation of pluripotent hESCs and a method of isolating human pluripotent ESC lines. In fact, the claims define the term “pluripotent” as the ability to “develop into any cell derived from the three main germ cell layers or an embryo itself.”³¹¹ The stem cells claimed were not only pluripotent, but also totipotent. ‘806 maintains the same claims as ‘780, but focuses on human stem cells while ‘780 embraces all primate embryonic stem cells.

- U.S. Patent No. 7,029,913 (Application No. 09/982,637)
Primate embryonic stem cells (issued on 4-18-2006)

This patent is a continuing patent of Patent ‘806 and a divisional patent of Patent ‘780. It claims methods of replicating in vitro hESCs.

These three patents, called WARF patents as a whole, are claimed by James Thomson and his research team. The patents were later assigned to the WARF, an organization that manages intellectual property assets of the University of Wisconsin.³¹² WARF’s function is to file patent applications for discoveries made by UW-Madison and negotiate with companies that are interested in commercializing the patents in order to facilitate the use of UW-Madison research results.³¹³ With regard to WARF patents, WARF granted exclusive licenses to Geron Corporation to commercialize those products on certain cell types.³¹⁴ In 1999, WARF established a non-profit research institute called WiCell to manage WARF patents.³¹⁵ Besides this activity,

³¹¹ US ‘806, *supra* note 278.

³¹² See WiCell Research Institute, Inc.: About Us, *available at* <http://www.wicell.org/aboutus>

³¹³ See WARF, *available at* <http://www.warf.org/about/index.jsp> (last visited July 21, 2010).

³¹⁴ Amy Ligler, *Egregious Error or Admirable Advance: The Memorandum of Understanding That Enables Federally Funded Basic Human Embryonic Stem Cell Research*, *available at* <http://www.law.duke.edu/journals/dltr/articles/2001dltr0037.html> (last visited Mar. 3, 2010) [hereinafter Amy Ligler].

³¹⁵ Peter Yun-hyoung Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on Biotechnology Research Tool*, 19 HARV. J. LAW & TEC. 79, 90 (2005)[hereinafter Lee].

WARF is also a funding resource for UW-Madison research. It contributes over \$45 million for UW-Madison research every year.³¹⁶

Since those patents cover not only methods for obtaining pluripotent stem cells from human embryos but also the hESCs *per se*, they are broad enough to encompass all hESC research and all downstream products.³¹⁷ The enforcement of these patents has triggered problems for the public and other institutes which wish to gain access to hESCs for further research.³¹⁸ To solve this problem, WiCell and the Public Health Service of the U.S. Department of Health and Human Services [HHS] signed an agreement in 2001, the Memorandum of Understanding [MOU].³¹⁹

Under the MOU, WARF cells are available to scientists at the NIH for teaching or basic non-commercial research programs. In exchange, WiCell will charge transmittal fees for expenses related to the cells' supply. In addition, WiCell agrees to allow federal non-profit institutes access to the stem cells upon the negotiation of similar agreements.³²⁰ Because the MOU only entitles a third party to non-commercial use of the WARF materials, any person who attempts to commercialize new materials or discoveries made using WARF materials must first enter into another written agreement with WARF for a commercial license to utilize the WARF materials and patents.³²¹

Even so, because of the transmittal fees required for research use and the commercial license and fees required for commercializing end products,

³¹⁶ See WARF, available at <http://www.warf.org/about/index.jsp> (last visited July 21, 2010).

³¹⁷ Lori Knowles, *Stem Cell Patents*, available at <http://www.stemcellnetwork.ca/uploads/File/whitepapers/Stem-Cell-Patents.pdf> (last visited Mar. 3, 2010) [hereinafter Lori Knowles].

³¹⁸ Lee, *supra* note 316, at 90.

³¹⁹ U.S. Department of Health and Human Services, *Memorandum of Understanding Between WiCell Research Institute, Inc. and Public Health Service, at 5, Sept. 5, 2001*, available at http://stemcells.nih.gov/staticresources/research/registry/mtas/wicell_mou.pdf (last visited Mar. 31, 2010) [hereinafter MOU].

³²⁰ Amy Ligler, *supra* note 315.

³²¹ See MOU, *supra* note 320.

many organizations may choose to conduct research programs and further activities outside the U.S. in order to avoid infringing the WARF patents.

- U.S. Patent No. 5,166,065 (Application No. 07/477,960) In vitro propagation of embryonic stem cells (issued on 11-24-1992)

This patent claims a method of isolating ESCs from mammalian embryos in vitro, comprising deriving and maintaining embryos in certain culture mediums with certain amounts of recombinant leukemia inhibitory factor, and a method of maintaining mammalian ESCs in vitro while retaining their pluripotency.

- U.S. Patent No. 5,914,268 (Application No. 08/343,686) Embryonic cell populations and methods to isolate such populations (issued on 6-22-1999)

This patent claims pluripotent cells that are derived by cultured embryonic stem cells.

- U.S. Patent No. 6,090,622 (Application No. 08/829,372) Human embryonic pluripotent germ cells (issued on 6-18-2000)

This patent claims human pluripotential embryonic germ cells with specific culture characteristics.

- U.S. Patent No. 6,245,566 (Application No. 09/052,772) Human embryonic germ cell line and methods of use (issued on 6-12-2001)

The claims of this patent include one method for producing human pluripotent embryonic germ cells in described culture mediums, and a method for maintaining human pluripotent embryonic germ cells in an undifferentiated state.

- U.S. Patent No. 6,280,718 (Application No. 09/435,578) Hematopoietic differentiation of pluripotent human embryonic stem cells (issued on 8-9-2001)

The claims in this patent include a method of obtaining human hematopoietic cells by manipulating hESCs and a method of transplanting the cells into a human host.

- U.S. Patent No. 6,642,048 (Application No. 09/900,752) Conditioned media for propagating human pluripotent stem cells (issued on 11-4-2003)

This patent claims a method of proliferating human pluripotent stem cells derived from blastocysts in particular culture environments, and a method of preparing a medium for proliferating primate pluripotent stem cells.

- U.S. Patent No. 6,800,480 (Application No. 09/530,346) Methods and materials for the growth of primate-derived primordial stem cells in feeder-free culture (issued on 10-5-2004)

This patent claims cellular compositions comprising undifferentiated primate primordial stem cells and undifferentiated hESCs. The patent covers both totipotent and pluripotent stem cells, including human stem cells.³²²

- U.S. Patent No. 7,297,539 (Application No. 10/873,922) Medium for Growing Human Embryonic Stem Cells (Issued on 10-31-2007)

The main claim of this patent is a method for proliferating hESCs, comprising culturing hESCs in the presence of an extracellular matrix in a medium that comprises a fibroblast growth factor at a concentration of at least 40 ng/mL, wherein the culture is essentially free of feeder cells.

From the examples listed above, it seems that patents on human stem cells in the U.S. do not merely cover human primate embryonic stem cells, despite the statement of the USPTO that human beings at any stage are not

³²² Gregory R. Hagen & Sébastien A. Gittens, *Patenting Part-Human Chimeras, Transgenics and Stem Cells for Transplantation in the United States, Canada, and Europe*, 14 RICH. J.L. & TECH. 11 57 (2008).

patentable. Thus, it would appear that the USPTO does not regard hESCs as human beings.

Another interesting piece of information conveyed by the survey is the investment sources for hESC research. This can be inferred from patent ownership because usually inventors will assign their patents to investors. But there are exceptions. For instance, a research institute as an investor may assign its patent to a manufacturing company for industrial use. That situation is not considered in this dissertation.

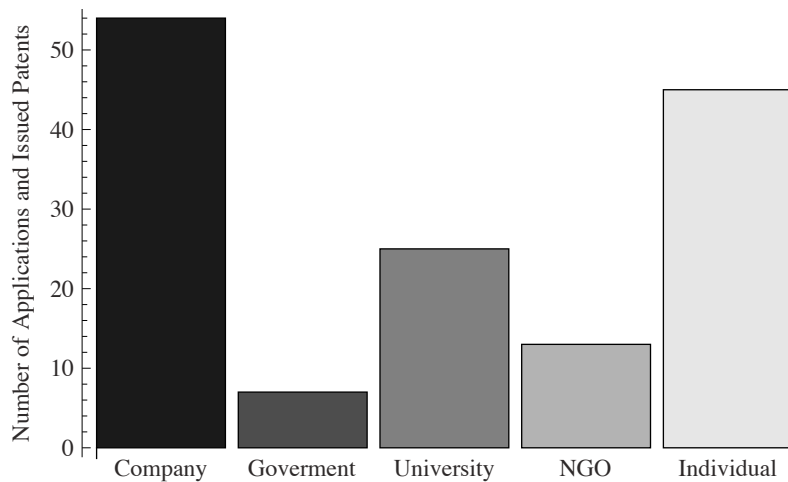


Figure 4.3: U.S. hESC related patents ownership categories

Figure 4.3 demonstrates the present number of patents owned by companies, the U.S. government, universities, 501(c)(1) institutes (tax exempt organizations, here labeled Non-Government Organizations [NGO]),³²³ and individuals. The categories of company and individual are the top two groups that own the most hESC relevant patents. Considering that hESC research involves ethical controversy and requires a long time line and significant expense, private investors are reluctant to provide financing to

³²³ 26 U.S.C. 501(c)(1) (2006)

hESC research.³²⁴ However, the long-term ban on federal investment on hESC research leaves states and private investors with the opportunity to engage in the field. The usual arrangement is that research institutes or companies hire individuals to implement their research activities. In the case of employee inventors, unless a contract regarding the ownership of inventions during the employment³²⁵ states otherwise, the inventor has the patent right, while the employer has the “shop right,” which means they can have free use of the patent.³²⁶ However, in most situations, to prevent employees from taking advantage of companies’ resources and to avoid losing valuable intellectual property, employers require the employees to sign an agreement concerning intellectual property rights on the work results before they begin work,³²⁷ such as an employee invention assignment agreement. It is possible that some inventors do not sign any assignment contract, or not all assignments to research institutes by employees have been completed, which may explain the large number of individually owned patents. Figure 4.3 also reveals that the government owns the fewest hESC related patents. One possible reason is the long term prohibition on hESC research using federal funds.

4. Biotechnological Patent Case Law

In the U.S, case law makes a distinction between artificially modified biological products and natural products in the early biotechnological patent cases.

³²⁴ Ella De Trizio & Christopher S. Bernnan, *The Business of Human Embryonic Stem Cell Research and an International Analysis of Relevant Laws*, J. BIOLAW & BUSI, 5, 16 (2004)

³²⁵ During the employment usually means the employees were working within the scope of their employment, using the employers’ equipment, or at the employers’ expense.

³²⁶ *Banner Metals, Inc. v. Lockwood*, 178 Cal. App. 2d 643, 654-655 (Cal. App. 2d Dist. 1960).

³²⁷ Vai Io Lo, *Employee Inventions and Works for Hire in Japan: A comparative Study against the U.S., Chinese and German Systems*, 16 TEMP. INT’L & COMP. L.J. 279, 291 (2002).

In 1964, in *Merck & Co. v. Olin Mathieson Chem. Corp.* which concerned the validity of a Vitamin B(12) patent, the Fourth Circuit held that products involving purification or isolation of natural materials were patentable.³²⁸ In 1977, the U.S. Court of Customs and Patent Appeals held that purified forms of natural products were patentable under §101 of the Patent Act, on the grounds that the pure culture of the claimed microorganism does not exist in nature; instead, it is man-made and only obtained under certain laboratory conditions.³²⁹ This distinction is confirmed in *Chakrabarty* in 1980, in which the Supreme Court held that a live, man-made microorganism was patentable.³³⁰

After this decision, human cells, cell lines and even hESCs were gradually considered to be patentable as long as human intervention was involved.³³¹ The following section introduces the main hESC patents in the U.S. Some of these patents are hESCs themselves, while others are methods, processes or derivatives from hESCs.

a. WARF Patents

The WARF patents, usually referring to U.S. Patent No. 5,843,780, U.S. Patent No. 6,200,806, and U.S. Patent No.7,029,913, focus on pluripotent primate embryonic stem cells, including hESCs. Before these patents expire, WARF has the right to enjoy all royalties earned by successful medical products or procedures based on its hESCs research.³³² After the WARF patents were issued, the Public Patent Foundation [PUBPAT] and the

³²⁸ *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 163 (4th Cir. 1958).

³²⁹ *In re Bergy*, 563 F.2d 1031, 1035 (C.C.P.A. 1977).

³³⁰ *Diamond v. Chakrabarty*, 447 U.S. 303, 309-310 (U.S. 1980).

³³¹ See *i.e.*, Mikyung Kim, *supra* note 296, at 696; Jameson, *supra* note 290, at 234-237.

³³² Lori Knowles, *supra* note 318.

California-based Foundation for Taxpayer and Consumer Rights [FTCR] challenged the validity of the WARF patents for lacking novelty and nonobviousness, and filed a request to reexamine these patents in 2006. At first, the challenge was upheld by the patent office, and some claims were held invalid.³³³ Nevertheless, after WARF submitted its defense and amended some claims to limit the patent claim scope by inserting “pluripotent” and “derived from a pre-implantation embryo” to define human embryonic stem cells in both patent ’780 and ’806 claims,³³⁴ these two patents were upheld by the USPTO on the grounds that they then satisfied the patent requirements of novelty, nonobviousness and utility.³³⁵ Later, claims 1-3 of patent ’913 were upheld by the USPTO as well.³³⁶ On the question of nonobviousness, the USPTO asserted that there were distinct biological differences among species like murine, porcine and human, so there was no reasonable expectation of success in deriving hESCs based on the prior art.³³⁷ However, the challengers were not satisfied with the result and they appealed to the Board of Patent Appeals and Interferences [BPAI].

In May of 2010, the Board of Patent Appeals and Interference reached its decision and rejected claims 1-3 of patent ’913. Claim 1 was directed towards

³³³ *Ex Parte Reexamination Communication Transmittal Form*, Control No. 90/008102, Mar. 30, 2007, available at <http://www.pubpat.org/assets/files/warfstemcell/780rejected.pdf> (last visited May. 1,2010); *Ex Parte Reexamination Communication Transmittal Form*, Control No. 90/008139, Mar. 30, 2007, available at <http://www.pubpat.org/assets/files/warfstemcell/806rejected.pdf> (law visited May.1, 2010)

³³⁴ The amendment files were both sent to the USPTO on Oct. 4, 2007. The documents are available on the USPTO website.

³³⁵ *Ex Parte Reexamination Communication Transmittal Form*, Control No. 90/008102, Mar. 5, 2008, available at http://www.warf.org/uploads/media/PTO_780_office_action.PDF (last visited May. 1,2010); *Ex Parte Reexamination Communication Transmittal Form*, Control No. 90/008139, Mar. 5, 2008, available at http://www.warf.org/uploads/media/PTO_806_Office_Action.pdf (last visited May. 1,2010).

³³⁶ Wisconsin Alumni Research Foundation, *Patent Office Upholds Remaining WARF Stem Cell Patents*, Mar. 11, 2008, available at http://www.warf.org/news/news.jsp?news_id=226 (last visited Mar. 29,2010).

³³⁷ *Ex Parte Reexamination Communication Transmittal Form*, Control No. 95/000154, Feb.25, 2008, at 20, available at http://www.warf.org/uploads/media/PTO_913_office_action.PDF (last visited Mar. 2, 2011)

pluripotent hESCs “derived from a pre-implantation embryo.” U.S. Patent No. 5,166,065 [Williams] issued in 1992 described and enabled methods of isolating mouse ESCs, which could have potentially been used to isolate hESCs. Even though the Williams method was not used to create the cells claimed in the WARF patent, this alone does not establish that the Williams method could not have succeeded in hESC isolation. Since the WARF ‘913 patent claims hESCs themselves rather than a process for producing them, the claim was rejected for obviousness.³³⁸ However, WARF claimed that *Strategies for the Isolation and Characterization of Bovine Embryonic Stem Cells*, by Robert Cherny in 1994 [Cherny’s publication], negated “Williams,”³³⁹ because it disclosed a failed attempt to use the ESC isolation technique for the murine model (mouse model) on domestic animals.³⁴⁰

This argument did not receive support from the BPAI, because Cherny’s publication only involved murine models but not humans or primates.³⁴¹ As the patent applicant with the burden of proving the novelty and non-obviousness when the USPTO thinks otherwise, WARF failed to prove that the Williams method did not apply to human embryos; therefore, Williams anticipated hESC derivation, anticipating claim 1.³⁴² The BPAI’s application of the standard of non-obviousness in this case implies that to achieve patent validity, inventors need to attempt very broad possibilities in the hESC field, rather than taking predictable steps that another individual with ordinary skills in the art would be able to anticipate.³⁴³ Disagreeing with the examiner, the BPAI believed the evidence demonstrated that the techniques for deriving mouse embryonic stem cells have been varyingly applied to other

³³⁸ Board of Patent Appeals and Interferences, *Foundation for Taxpayer and Consumer Rights v. WARF* (B.P.A.I. No. 2010-001854, 4/28/10), at 12 available at <http://www.consumerwatchdog.org/resources/WARFDecision042910.pdf> (last visited Aug. 26, 2010).

³³⁹ *Id.*, at 13.

³⁴⁰ *Id.*, at 9.

³⁴¹ *Id.*, at 14.

³⁴² *Id.*, at 14.

³⁴³ *Id.*, at 33.

species.³⁴⁴ The invention at bar is obvious to try in view of the predictable options explicitly taught in the prior art,³⁴⁵ inasmuch as the testimony from scientists in the art demonstrates that hESCs have been successfully derived from embryos by following the existent methods for mouse, rat, pig and sheep ESCs.³⁴⁶

WARF may request a rehearing before the board addressing the new grounds of rejection. Alternatively, it could reopen the prosecution before the examiner by either submitting new evidence to the original examiner or changing the patent's claims accordingly.³⁴⁷ WARF can also appeal the decision to the U.S. Court of Appeals for the Federal Circuit.³⁴⁸

b. Gene patents

Recently, a Federal District Court handed down a judgment ruling that gene inventions, without artificial intervention, are the same in bio-context; they are products of nature, therefore, they are not patentable. The court believed that the patent claims at bar were “improperly granted” because they were “directed to a law of nature.”³⁴⁹ In the opinion of the court, even the technique used to isolate them from the natural context does not change the quality of those genes and does not change the fact that they are discoveries.³⁵⁰ This case remains on appeal at this time. In October of 2010, the Department of Justice filed an *amicus curiae* brief to the court declaring that isolated human genes without alteration or manipulation are a product of nature and therefore not patentable, because they possess identical

³⁴⁴ *Id.*, at 36.

³⁴⁵ *Id.*, at 37.

³⁴⁶ *Id.*, at 37-38.

³⁴⁷ *Id.*, at 40.

³⁴⁸ 35 U.S.C. § 141.

³⁴⁹ *Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181, at 238.

³⁵⁰ *Id.*, at 223

structure as genes in the human body, but manipulated genes, DNA and methods of genetic modification are patentable.³⁵¹ At present, it is unclear how the position of the Department of Justice will affect the patent office and courts.

C. States Laws regarding hESC Research

The Constitution grants the patent authority to the federal government under Article 1, Section 8, Clause 8. Hence, this clause deprives state governments of patent authority. However, states have an alternative path in controlling hESC inventions. This alternative pathway is to regulate hESC research per se.

1. hESC Research in Constitutions

There are three states which refer to hESC research in their constitutions. The state of Michigan has adopted a prohibitory policy on human cloning.³⁵² However, human embryo and embryonic stem cell research permitted under federal law can be conducted in Michigan if it meets the additional requirements in Art. I, §27 of the Michigan Constitution. An example of this would be where the human embryos used in research for stem cell derivation would be no more than fourteen days old after cell division begins, the embryos were not created for research, therapeutic, or business purposes, and the research is conducted in accordance with state laws.³⁵³

³⁵¹ Brief, *supra* note 295.

³⁵² MICH. COMP. LAWS ANN. Const. art. I, § 27(1) (West Supp. 2011).

³⁵³ MICH. COMP. LAWS ANN. Const. art. I, § 27(2).

The Constitution of the State of Missouri has a similar statement to the Michigan Constitution. The right to conduct hESC research is confirmed the Constitution. Meanwhile, it stipulates requirements for lawful hESC research conduct, such as the fourteen day old embryo restriction, researcher eligibility requirements, research conduct norms, oversight processes, etc. In order to enforce these requirements, it sets forth punishments—either imprisonment or fine or both—for any violation of the said requirements.³⁵⁴

The Constitution of the State of California also guarantees the right to conduct stem cell research including research on pluripotent stem cells, either obtained by somatic cell nuclear transfer or from surplus in vitro embryos from fertility clinics.³⁵⁵

The above constitutions are the only three state constitutions that legitimize hESC research. Even though the Constitution of the State of California does not explicitly refer to human embryonic cells, it implies coverage of the embryonic stem cells because an embryonic stem cell is one type of pluripotent stem cell. Therefore, the clause applies to hESCs and relevant research.

2. hESC Research in Statutes

Beyond their constitutions, more states regulate hESC research in their statutes. While supporting hESC research, they set forth certain restriction related to the ethical controversy.

In the Health and Safety Code of California (Annotated California Codes), §125118 sets forth guidelines for hESC research, as well as the governing

³⁵⁴ MO. ANN. STAT. Const. art. III, § 38(d) (West Supp. 2011).

³⁵⁵ CAL. CONST. CODE art. XXXV, § 5 (West Supp. 2010).

agency.³⁵⁶ § 125119 establishes a stem cell research oversight committee in accordance with the Guidelines for Human Embryonic Stem Cell Research issued by the National Research Council and the Institute of Medicine of the National Academies. All of the research projects involving the derivation or use of hESCs are subject to the oversight of this committee.³⁵⁷

California is not the only state that has established a stem cell oversight committee. Connecticut General Statutes Annotated, § 19a-32d also sets forth an embryonic stem cell research oversight committee and further defines “embryonic stem cells” and “eligible institution” for regulating hESC related research.³⁵⁸

In Illinois, embryonic stem cell research is allowed and eligible for government funding only when it complies with the research policy of the State of Illinois.³⁵⁹

Massachusetts is another state that has opened the door to hESC research. It justifies hESC research based on its scientific and therapeutic value: any research or clinical application involving the use or derivation of hESCs is permitted as long as it is consistent with the state’s administrative requirements.³⁶⁰ For instance, all institutions must submit an application and receive a certificate from the government authority in order to conduct hESC research.³⁶¹

New Jersey law provides that research involving hESCs and clones is permitted in the state.³⁶² But all these research activities are under the

³⁵⁶ CAL. HEALTH & SAFETY CODE ANN. §§125118 (West 2006).

³⁵⁷ CAL. HEALTH & SAFETY CODE ANN. §§125119 (West Supp. 2011).

³⁵⁸ CONN. GEN. STAT. § 19a-32d, §19a-32g (West Supp. 2010).

³⁵⁹ 410 ILL. COMP. STAT. ANN. 110/5 (West 2011).

³⁶⁰ MASS. GEN. LAWS ANN. Ch. 111L §1, §3 (West Supp. 2010).

³⁶¹ MASS. GEN. LAWS ANN. Ch. 111L §10(f).

³⁶² N.J. STAT. ANN. § 26:2Z-1 (West 2007).

supervision of a review board and conducted with consideration of ethical and medical issues.³⁶³

Compared to these hESC research advocate states, Nebraska has adopted a tough attitude towards hESC research. It stipulates that any research or activity involving the use of hESCs is ineligible for state appropriation.³⁶⁴ The state of Virginia also prohibits state funding for research involving the use of stem cells derived from human embryos.³⁶⁵

D. Academic Discussion concerning hESC Inventions

This section is designed to give the reader a general feel for debates over hESC's patentability in American academia. It is not designed to be an exhaustive review. There are other arguments that are not introduced in this dissertation. From my study, while Congress has not addressed the inclusion of moral requirements in patent law and courts have tried to exclude moral elements from patent issues, American academia emphasizes the moral and ethical debates.

1. The Status of Human Embryos

Inventions involving human embryos are more controversial than those involving mere human cells. The debate over embryo-related inventions can be divided into two questions based on the source of the human embryos: whether human stem cells derived from embryos created by SCNT are

³⁶³ N.J. STAT. ANN. § 26:2Z-2 a.

³⁶⁴ NEB. REV. STAT. ANN. § 71-7606(3) (West 2009).

³⁶⁵ See *i.e.*, VA. CODE ANN. §23-286.1.C (West 2010), VA. CODE ANN. § 2.2-2233.2. I (West Supp. 2010).

patentable, and whether human stem cells derived from surplus embryos from fertility clinics are patentable.

Some people deny the human status of embryos based on technical and social perspectives. According to one source, embryos created with the SCNT technique, by replacing the nucleus of an egg with the nuclear material of a somatic cell, technically, are not embryos in a traditional sense because they are not created by the fusion of an egg and sperm.³⁶⁶ In addition, the conception of human beings comprises more than just a physical human organism; more must be done “beyond the competence of science” to constitute the human species.³⁶⁷

However, the opposite argument can also be made. Both cloned embryos and surplus IVF embryos can be defined as human beings since they have the potential to be born as infants after being implanted into a uterus.³⁶⁸ According to the U.S. Constitution, 13th Amendment, “[n]either slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction.” Any conduct utilizing human embryos is commercializing human beings, which therefore, can be construed to constitute a violation of the Constitution.³⁶⁹ Some people brought this argument before the courts, but the allegation was denied because “[t]he Supreme Court has already determined that the word ‘person [as used] in the

³⁶⁶ Mikyung Kim, *supra* note 296, at 700.

³⁶⁷ Juames J. McCartney, *Embryonic Stem Cell Research and Respect for Human Life: Philosophical and Legal Reflections*, 65 ALB. L. REV. 597, 614 (2002).

³⁶⁸ 149 Cong. Rec. H1397, H1401-02 (daily ed. Feb. 27, 2003), cited by Mikyung Kim, *supra* note 296, at 700.

³⁶⁹ Jonathan Grossman, *Human Embryos, Patents, and the Thirteenth Amendment*, 55 U. KAN. L. REV. 731, 733 (2007).

Fourteenth Amendment does not include the unborn” in *Doe v. Obama* (2009)³⁷⁰ and *Doe v. Sebelius* (2009).³⁷¹

2. Morality Consideration in Patent Law

As mentioned in the previous chapter, the status of embryos and other human tissues created by cloning is blurred. It not only involves science and technology, but also intersects with religion. Therefore, some scholars jump over the contentious status dispute, and target a more essential question: should the morality element be considered in the patent granting processes? Some assert that over the last decades of U.S. patent litigation, courts have repeatedly refused to make moral judgments in patent cases involving advancing technologies and limited the patent office’s power to its technical expertise.³⁷² As an expert in technology, the patent office should only focus on the classic patentability requirements and technology.³⁷³

As mentioned above, morality has now been removed from the hand of the patent office by case law. Therefore it is left to Congress.³⁷⁴ The argument can also be made by apogee. If a morality-based bar is applied to hESC innovations, it will undermine the function of the patent system by eliminating the exclusive right granted to the inventors and depriving the public of the right to use the new knowledge, which, eventually, will be an impediment to social innovation.³⁷⁵ Even if a patent on an immoral invention

³⁷⁰ *Doe v. Obama*, 670 F. Supp. 2d 435, 439 (2009), *aff’d*, *Doe v. Obama*, 2011 U.S. App. LEXIS 1373 (4th Cir. Md. Jan. 21, 2011).

³⁷¹ *Doe v. Sebelius*, 676 F. Supp. 2d 423, 429 (D. Md. 2009) (Embryos have no legally protected interests and thus do not have standing to pursue constitutional rights.)

³⁷² John Miller, *Comment: A Call to Legal Arms: Bringing Embryonic Stem cell Therapies to Market*, 13 ALB. L.J. SCI. & TECH. 555, 582 (2003)[hereinafter John Miller]; Joshua Whitehill, *Patenting Human Embryonic Stem Cells: What is so Immoral?* 34 BROOK.J.INT’L L. 1045, 1075 (2009)[hereinafter Whitehill].

³⁷³ *Id.*, at 1050.

³⁷⁴ *Id.*, at 1075.

³⁷⁵ *Id.*, at 1077.

is granted, patent law only grants a patentee the right to exclude others from using or producing the patent, rather than the right to practice it; therefore, those states concerned about the morality and ethics of the hESC innovations can choose to prevent the application or dissemination of issued patents by enacting legislation.³⁷⁶

Some people view the issue from the standpoint of maintaining the consistency and coherency of the patent system. Morality is a subjective issue and varies with social and cultural mores.³⁷⁷ Applying the morality criterion to the U.S. patent system is adding uncertainty and unpredictability into the patent granting process, and the revocation of patents will not only discourage the patentees, but also damage the interest of the public.³⁷⁸

As morality is a public interest consideration, once the morality criterion is applied to the patent system, the patent office needs to factor in all other public interest considerations, such as human health benefits.³⁷⁹ Compared to the huge benefit of hESC research, as evidenced by the research efforts around the world, morality should not stand in the way of further study.³⁸⁰

3. Research Tool Doctrine

Under the utility requirement in 35 U.S.C. §101, patents must have specific and substantial utility.³⁸¹ In *In re Fisher*, it was ruled that expressed sequence

³⁷⁶ Jenny Shum, *Moral Disharmony: Human Embryonic Stem Cell Patent Laws, WARF and Public Policy*, 33 B.C. INT'L & COMP. L. REV. 153, 170 (2010)[hereinafter Shum].

³⁷⁷ *Id.*, at 170.

³⁷⁸ *Id.*, at 172-173.

³⁷⁹ Whitehill, *supra* note 373, at 1077.

³⁸⁰ *Id.*, at 1077.

³⁸¹ See *i.e.*, *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005); also see *Brenner v. Manson*, 383 U.S. 519, 534-535 (1966), the court announced that only when "specific benefit exists in currently available form" can patents be granted. The requirement is further sustained in *Fujikawa v. Wattanain*, 93 F.3d 1559, 1563 (Fed. Cir. 1996). In 2001, the USPTO issued Utility

tag [EST] inventions should not be protected under the patent system if they act as “no more than research intermediates”³⁸² or do not provide “an immediate, well-defined, real world benefit to the public.”³⁸³ In that sense, a research tool should not be patented since it has no substantial or specific utility. Some people consider that hESCs are research tools; therefore, they are not patent-protectable.³⁸⁴ Research tools usually have foundational and broad applicability; they are essential input that cannot be duplicated.³⁸⁵ For instance, hESCs have irreplaceable importance in understanding cytology and human body development.³⁸⁶ Privatizing research tools restricts researchers’ use of these materials,³⁸⁷ which will impede further innovation and application. In addition, it may require an insurmountable investment for downstream developers to simply attain the research tools from their inventors.³⁸⁸ Therefore, research tools should be available to the public and are excluded from patenting on the basis of patent exceptions in the common law.³⁸⁹ hESCs have no direct benefits to consumers. As a necessary tool for research and development, their main value merely lies in achieving end products, i.e. differentiated cells for repairing injured organs or cells.³⁹⁰ The broad claim scope of the WARF patents hampers researchers because researchers must negotiate with the patentees for the ability to use hESCs,

Guidelines for utility determination under §110. See 66 Fed. Reg. 1092, *supra* note 281. Although the Guidelines has no binding on courts, it gives instruction to patent office on examining patent applications.

³⁸² *In re Fisher*, 421 F.3d. 1373.

³⁸³ *Id.*, at 1376.

³⁸⁴ Peter Yunhyong Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on Biotechnology Research Tools*, 19 HARV. J. LAW&TEC. 79, 92 (2005).

³⁸⁵ Amy Rachel Davis, *Patented Embryonic Stem Cells: The Quintessential “Essential Facility”?*, 94 GEO. L. J. 205, 232-239 (2005) [hereinafter Rachel Davis].

³⁸⁶ *Id.*, 207.

³⁸⁷ Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 Nw. U.L. REV. 77, 111 (1999).

³⁸⁸ Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI., 698, 700 (1998); Arti K. Rai, *Genome Patents: A Case Study in Patenting Research Tool*, 77 ACAD. MED. 1368, 1369 (2002).

³⁸⁹ Lee, *supra* note 316, at 82.

³⁹⁰ Rachel Davis, *supra* note 386, 212.

even though the hESCs they are using may be obtained by another method beyond the scope of patent claims.³⁹¹ Some people assert that the financial and time input for negotiation impedes the research process more than government restriction on federal appropriation to hESC research.³⁹² Therefore, they argue, such a monopoly over essential research tools is contrary to the antitrust laws and should be removed.³⁹³

In contrast, some commentators assert that patenting research tools may provide more research and development investments by attracting funding from downstream industry.³⁹⁴ Other arguments are made on the empirical ground that very few cases of breakdown or delay of projects caused by access difficulty to the basic techniques or negotiation over patent licenses have occurred, while it is admitted that patents on research tools impose a cost and limit access.³⁹⁵

In order to offset the side effects of patenting essential resources like hESCs and achieve the balance sought in patent law, some strategies are proposed. One proposal is to grant a shorter patent term for such patents.³⁹⁶ Another is to enact a compulsory licensing scheme to ensure researchers have access to the essential research tools for further experimentation.³⁹⁷

³⁹¹ Christopher D. Hazuka, *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157, 158 (2002).

³⁹² Jennifer Washburn, *The Legal Lock on Stem Cells*, Apr. 12, 2006, available at http://newamerica.net/publications/articles/2006/the_legal_lock_on_stem_cells (last visited Dec. 3, 2007) [hereinafter Legal Lock].

³⁹³ Filliben, *supra* note 8, at 254-255.

³⁹⁴ Frederic M. Scherer, *The Economics of Human Gene Patents*, 77 ACAD. MED. 1348, 1350 (2002).

³⁹⁵ John P. Walsh et al., *Research Tool Patenting and Licensing on Biomedical Innovation* (2003), at 20, available at <http://sippi.aaas.org/utt/WalshetalAAAS.pdf> (last visited Dec. 3, 2007); Legal Lock, *supra* note 393.

³⁹⁶ Laurie L. Hill, *The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs*, 11 TEX. INTELL. PROP. L.J. 221, 251 (2003).

³⁹⁷ Gitter, *supra* note 289, 1679.

This also stimulates smaller companies to enter the market and seek further innovations.³⁹⁸

So far, debates continue over whether hESCs should be protected in the patent system. However, compared to the U.S. which has already granted patents claiming hESC as such, the EPO and China are maintaining more conservative positions.

³⁹⁸ Filliben, *supra* note 8, at 254.

Chapter 5: Laws regarding hESCs in the European Patent Convention

Europe has several hierarchies within its patent system. At the lowest level, every nation in Europe has its own national patent system. Another facet is the European Patent Organization, set up by the European Patent Convention, which establishes a European patent system, within which a unified application process is set forth that simplifies patent application to multiple countries in Europe. Nonetheless, member states maintain their own national patent systems and have jurisdiction over patent right enforcement. Currently, the European Union [EU] does not have patent jurisdiction. However, in the past several years, the EU began the process of creating a common EU patent system. Membership in the EPO and the EU are independent from each other; hence their member states overlap. The details of the membership of both organizations are shown in the following plot. All of the European Union's member states are members of the European Patent Convention's members as well. Figure 5.1 provides an overview of the memberships for the European Union and European Patent Convention.

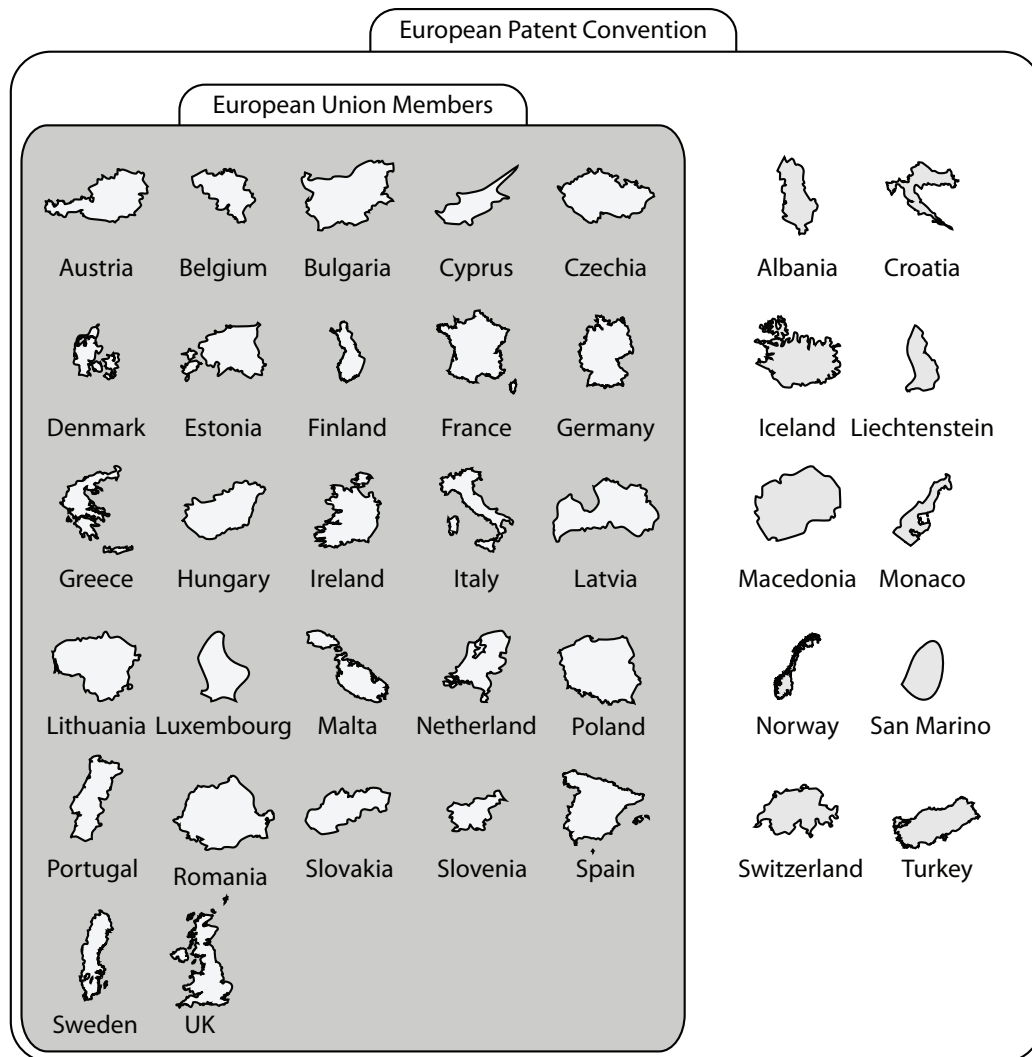


Figure 5.1: Member states of the EU and the EPC

Historically, patent applicants in European countries submitted applications to their national patent agencies for examination under national patent laws. However, since procedural and substantive laws vary in different countries, this mechanism was time-consuming and costly. It also could cause a situation in which some claims were granted in certain countries, while not in others. With the progress of European business and

trade cooperation,³⁹⁹ the following problem arose: how can patent holders' rights be enforced and infringement prevented when patents with different scopes—or even no legal protection—are circulating freely in states?

To eliminate this problem, the European Patent Convention was enacted in 1973. Its 178 articles established various institutions, procedural rules and substantive laws, created a centralized, unitary patent application process and instituted the European Patent Organization as its agency. The EPO granted patents on behalf of its member states, dramatically reducing the cost and time associated with the patent application process, especially considering that applicants desiring protection in multiple states no longer needed to deal with patent offices on an individual basis or spend money on language translation. This also eliminates the situation wherein varying scopes of patent protection are granted in different states. However, after patents are granted under the EPC, they enter into national protection in every designated state that has its own jurisdiction over patent enforcement and infringement disputes, which results in uncertainty of litigation outcome and extra cost. This is the main deficiency of the EPC patent system.

Meanwhile, the European Union has been seeking to unify the patent system of its member states in order to reduce the processing and translation costs, stimulate patent activity and enhance its economic competitiveness in the world. At present the EU is considering establishing a European Community patent system as well as a patent court⁴⁰⁰ to unify the patent litigation system (Unified Patent Litigation System [UPLS]). However, it is still under debate.

In addition, other agreements have been proposed to establish an integrated patent system in order to reduce the cost of application and

³⁹⁹ EC started tariff customs and has carried out the free circulation of goods since 1968.

⁴⁰⁰ European Commission, *Communication from the Commission to the European Parliament and the Council, Enhancing the Patent System in Europe*, COM (2007) 165 final (Apr. 3, 2007).

patent litigation; the European Patent Litigation Agreement [EPLA] and the London Agreement of 2000.⁴⁰¹ The EPLA's idea was initiated in the Paris Intergovernmental Conference in 1999, during which the member states of the EPC set about drafting an agreement on integrated litigation for European patents. The first draft was proposed in 2003. The EPLA was under negotiation until the EU document titled Enhancing the Patent System in Europe [COM (2007) 165] was released comprising the EPLA's idea.⁴⁰² The London Agreement of 2000, formally named Agreement on the Application of Article 65 of the Convention on the Grant of European Patents proposed by EPC member states, aimed at reducing application costs by eliminating states' authority to require translation of application files to state's languages, which paved the way for a community patent system.⁴⁰³ However, since the London Agreement is an optional agreement, only 15 member states ratified or acceded to it by May. 1, 2009.⁴⁰⁴

A. European Patent Systems

This section introduces the establishment of the European patent system and procedural rules for filing a patent application under the system. Furthermore, it presents patent requirements regarding hESC patents under the EPC.

1. European Patent Convention

⁴⁰¹ *Id.* More details of EPLA are given in the following part.

⁴⁰² European Patent Office, *European Patent Litigation Agreement*, available at <http://www.epo.org/patents/law/legislative-initiatives/epl.html> (last visited Jan. 15, 2010) [hereinafter EPLA].

⁴⁰³ Marco Tom Connor, *European Patents: What's New in 2008 for the Applicants?*, 90 J. PAT. & TRADEMARK OFF. SOC'Y 587, 606 (2008).

⁴⁰⁴ European Patent Office, *Lithuania Accedes to the London Agreement*, available at <http://www.epo.org/service-support/updates/2009/20090527.html> (last visited Aug. 2, 2010).

Before, 1973, every patent applicant had to submit application files in the individual countries in which the applicant desired to obtain patent protection, each with distinct procedures and different languages. In 1973, the Convention on the Grant of European Patents, also known as the European Patent Convention, took effect to provide a unitary system for patent protection. It was initially ratified by 32 member states. According to the EPC, the European Patent Organization was created in 1977 as an intergovernmental organization on the basis of the EPC, which has two bodies, the European Patent Office as its executive organ and the Administrative Council, a supervisor of the EPO. In 2000, the EPC was amended to keep pace with the TRIPS Agreement and other international treaties, which came into force in 2007. One main target of the amendment of 2000 was to simplify the language requirements and reduce translation costs. It also included amendments to prior art, priority right and claim amendment rules. At present, the EPC is effective in 36 member states and 3 extension states.

Under the EPC, member states defer to the EPO examination process, and recognize patents granted by the EPO. To gain a patent from the EPO, a patent applicant must file an application in one of three official languages, English, French or German.⁴⁰⁵ The patent office then performs a formalities examination,⁴⁰⁶ completes a search report and publishes it.⁴⁰⁷ After the report is published, the invention will be published and go through substantive examination by the examination division according to the request of the patent applicant.⁴⁰⁸ The examination office will determine whether to grant

⁴⁰⁵ European Patent Office, *European Patent Convention (2000)*, Article 14, Nov.29, 2000, available at <http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ma1.html> (last visited Dec. 2, 2009) [hereinafter *European Patent Convention*].

⁴⁰⁶ *Id.*, Article 90 (3).

⁴⁰⁷ *Id.*, Article 92.

⁴⁰⁸ *Id.*, Article 94.

the patent by considering if the invention meets the requirements of novelty, inventiveness and industrial application (Article 54, 55, 56 and 57), and if the files satisfy the written description, claims, drawings and abstract requirements (Article 83, 84 and 85). However, the EPC is only concerned with patent granting, not enforcement (Article 64(3)). As long as a European patent is granted by the EPO, it enters into the patent systems of designated countries on date it is filed with the European Patent Office, transferring it into a national patent with enforceability and revocability governed under national patent law (Article 64). Infringement or other disputes concerning a European patent will be processed under national law, which may result in disparate rulings and results. In other words, it is not a real community-wide patent.⁴⁰⁹

If the patent fails to meet all the substantive requirements or procedural clauses of the EPC, the EPO will reject the application (Article 97). But that is not definitive. Decisions of the Receiving Section, Examining Division, Opposition Divisions and the Legal Division can be appealed by any party adversely affected by it to the Board of Reexamination (Article 106 and 107).

Within nine months after a patent is granted, any third party is entitled to begin an opposition procedure (Article 99 and 100). During this process, the Opposition Division carries out the examination of the opposition and reaches a decision to maintain or revoke the patent (Article 102). As long as the patent is revoked in opposition proceedings, the patent right is deemed to not have existed in the first place.

The European patent system and national patent systems are independent to a certain extent. In particular situations, a European patent may be revoked under the national law of member state (Article 138). On the other

⁴⁰⁹ Kara M. Bonitatibus, *The Community Patent System Proposal and Patent Infringement Proceedings: An Eye Towards Greater Harmonization in European Intellectual Property Law*, 22 PACE L. REV. 201, 202 (2001).

hand, applicants can also bypass the European patent system and seek patent protection under the national patent system. Additionally, only states have authority over patent enforcement and maintains jurisdiction over patent disputes.

The EPC has twelve elements, which are general provisions,⁴¹⁰ substantive patent law, application procedure, procedure to grant patents,⁴¹¹ opposition procedure, appeals procedure, common provisions on procedure,⁴¹² impact on national law,⁴¹³ special agreements,⁴¹⁴ international application pursuant to the patent cooperation treaty,⁴¹⁵ transitional provisions⁴¹⁶ and final provisions.⁴¹⁷ For the purposes of this dissertation, only substantive patent law will be discussed.

a. Patentable Subject Matters in the EPC

Substantive Patent Law defines patentable subject matter and requirements of patents, legal status and rights of applicants, and effects of

⁴¹⁰ The General and Institutional Provisions is an introduction to all institutes under EPO and its general principles.

⁴¹¹ The Procedure includes procedure of formal examination, substantive examination, acceptance of application, refusal or grant.

⁴¹² This part regulates procedures on decision making, examination, hearing, evidence taking, notification, publication and other procedural issues during patent application.

⁴¹³ This part stimulates the conditions and procedure of national patent application in the contracting states.

⁴¹⁴ This part only applies to the contracting states which have consensus on a unitary character of European patent throughout their territories by any special agreement. For instance, they could set up special departments within the European Patent Office, a select committee of the Administrative Council to supervise the activities of the special department, and other exclusive or procedural issues.

⁴¹⁵ This part stipulates the roles and functions of the European Patent Office in international application under the Patent Cooperation Treaty.

⁴¹⁶ The Transitional Provisions are provisions during a transitional period.

⁴¹⁷ The final provisions part is relevant to about the legal force of implementing regulations and protocols, procedure of ratification, accession and reservation of the Convention, and other procedures about the application of the Convention.

European patent and property rights on patent applications. Unlike the U.S. patent law, the EPC has clauses on both affirmative and negative categories of patentable subject matter.

Article 52 of the EPC defines the scope of patentable invention by excluding discoveries, theories and mathematical methods, aesthetic creations, schemes, rules and methods of mental act performance, games, business methods, computer programs and information presentation.

Moreover, Article 53 illustrates a list of non-patentable inventions, which include those contrary to *ordre public* or morality, plant or animal varieties, essential biological processes for plants or animal production, and therapeutic and diagnostic methods for treatment of the human or animal body. But the EPC attempts to narrow these exclusions from patentable subject matter by including some restrictions on their application. For instance, the scope of *ordre public* or morality is not determined by law or regulations in individual states, but is determined by widely accepted and tradition-rooted beliefs and conduct. Microbiological processes or products do not fall into the scope of plant or animal biological process or products excluded from patentable subject matters. Any substances or compositions used in treatment, diagnosis or surgery on human or animal bodies are patentable.

The EPC does not explicitly refer to patentability of the human body or human tissues. This may be due to two reasons. First, at the time the EPC was first drafted and adopted, modern cellular research on the human body and tissues was too young a practice to draw the member states' attention. Second, the EPC is a guideline of principles which is essential to the European patent system, i.e., it consists of general ideas that provide direction to member states. It does not address every detail in the patent system considering the role supplementary documents, such as regulations,

protocols and so forth. Patent rules on human body and tissues are addressed in the Implementing Regulations to the Convention on the Grant of European Patents.

b. Requirements of Patenting

Articles 54, 55, 56 and 57 of the EPC manifest substantive requirements essential for the process of patent development and approval: novelty, inventiveness and industrial application.

Article 54 defines novelty as not “part of the state of the art,” which is interpreted in the next clause of the same article as “everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.” The EPC adopts the first to file principle in novelty requirement.⁴¹⁸ Even though some substance is already in the state of the art, its new use may still be beyond the prior art.⁴¹⁹

Article 55 supplements the novelty clause by regulating the non-prejudicial disclosures, which means that an invention that has been misused or displayed in officially recognized international exhibitions can still be considered novel as long as it is filed with the patent office within 6 months after its disclosure.

Article 56 defines the requirement of inventiveness, which requires it not to be obvious to a person skilled in the art and it must involve an inventive step.

⁴¹⁸ European Patent Convention, *supra* note 406, Article 54 (3).

⁴¹⁹ *Id.*, Article 54 (4) and (5).

The requirement of industrial application is quite restrictive under Article 57; it requires manufacture or use in industry, including agriculture, and anything not producible on a large-scale does not satisfy this requirement and cannot be patented.

An opposition can be filed on the grounds of non-patentability under Article 52 through 57,⁴²⁰ and a European patent may be revoked therein.⁴²¹

Besides these substantive requirements, patent applicants need to fulfill procedural requirements as well. The Article 78 illustrates the application documents, which includes a request form, description, claims, and abstracts.

To better implement the EPC and interpret it consistently in practice, the Administrative Council of the European Patent Organization adopted the Implementing Regulations to the Convention on the Grant of European Patents [the Implementing Regulation] in 2006, which interprets and explains the articles under the Convention with more detailed and specific instructions. According to Article 164 of the EPC, the Implementing Regulations and all protocols are integral parts of the EPC; therefore, the Implementing Regulations are legally binding, too. Corresponding to the structure of the EPC, the Implementing Regulations consist of 112 rules concerning the form and format of the application, administrative matters, the examination procedure, opposition procedure and appeal procedure. Since the Implementing Regulations are analogous to a manual of examination procedure, they do not mention any substantive issues.

⁴²⁰ *Id.*, Article 100. The other two grounds are the patent does not meet the requirement of enablement by disclosing the invention in a sufficiently clear and complete manner that any person skilled in the art may carry out the experiment and reach the same result without any unexpected problems, and the content of the patent extends beyond the content of application as filed.

⁴²¹ *Id.*, Article 138.

The Implementing Regulations explicitly incorporate some articles of Directive 98/44/EC, and considers themselves and the Biotechnology Directive “supplementary means of interpretation” of the EPC.⁴²²

Rule 26(1) of the EPC⁴²³ defines the term “biotechnological inventions” as “inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.” Generally, biotechnological inventions are patentable if they meet the requirements of patenting under Articles 52, 54, 55, 56 and 57 of the EPC, although the standards of novelty and inventiveness are slightly different.⁴²⁴ Meanwhile, Article 53 also applies to biotechnological inventions, but with more specific instructions, which are laid out in other clauses.

Rule 27 of the EPC (2000), also known as Rule 23(c) of the EPC (1973), encompasses the general rule of patentable biological inventions. It confirms the patentability of a biological material if it is “isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature.”

Rule 28 of the EPC (2000), also the same as Rule 23(d) of the EPC (1973), illustrates four types of biotechnological inventions which are not patentable under Article 53(a) due to the morality and *ordre public* requirements.

- a) processes for cloning human beings;
- b) processes for modifying the germ line genetic identity of human beings;

⁴²² European Patent Office, *Implementing Regulations to the Convention on the Grant of European Patents*, Rule 26 (1), available at <http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ma2.html> (Last visited Dec. 2, 2009) [hereinafter *Implementing Regulations*].

⁴²³ All the articles in the Implementing Rule is referred as Rule of the EPC.

⁴²⁴ More details can be found in Rule 27, 28, 29 of *Implementing Regulations*, *supra* note 424.

- 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.

According to Rule 26(1) of the EPC (2000), in order to interpret Article 53a and determine whether inventions are contrary to *ordre public* or morality under Article 53a, examiners shall resort to Rule 28 for more details in the case of biotechnological products or processes. Rule 28(c) stipulates that any use of human embryos for “industrial or commercial purposes” is considered to be contrary to the *ordre public*. This clause basically blocks any product or process regarding hESCs from patenting because it must concern the use of human embryos, including embryos from abortion, miscarriage, IVF or SCNT. Another technical question is how to define “industrial or commercial purpose.” There is no further regulatory explanation of the term, but the Enlarged Board of Appeal [EBA] interprets Rule 28(c) in the case of Primate stem cells (G0002/06) as including every situation in which embryos are involved except those in which the invention is for the benefit of the embryos themselves. More details on the case are presented below.

Rule 29 of the EPC (2000), also known as Rule 23 (e) of the EPC (1973), addresses the patentability of the human body and its components. It states that the human body at any stage is not patentable. It also distinguishes the discovery of human body elements from their isolation. The former is not patentable, but the later is as long as the subject is isolated from the natural context, even when “the structure of that element is identical to that of a natural element.”

2. Decisions on hESC Patent Applications of the European Patent Office under the EPC

Figure 5.2 is a graph illustrating the status of patent applications filed in EPO that are related to hESCs. Among those applications, eighteen are under patent examination process and nine are deemed as withdraw or rejected, only four are intended to grant.⁴²⁵

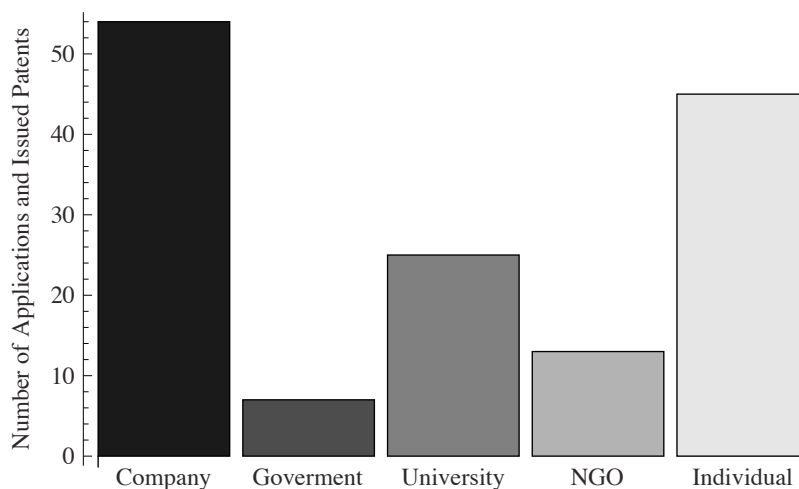


Figure 5.2: EPO patent application status for hESC related inventions

⁴²⁵ Intended to grant is one phase of patent examination before the patent is granted by the EPO. According to the Rule 71 of the European Patent Convention, *supra* note 406, “before the Examining Division decides to grant the European patent, it shall inform the applicant of the text in which it intends to grant it, and shall invite him to pay the fees for grant and printing and to file a translation of the claims in the two official languages of the European Patent Office other than the language of the proceedings within a period of four months. If the applicant pays the fees and files the translation within this period, he shall be deemed to have approved the text intended for grant.”

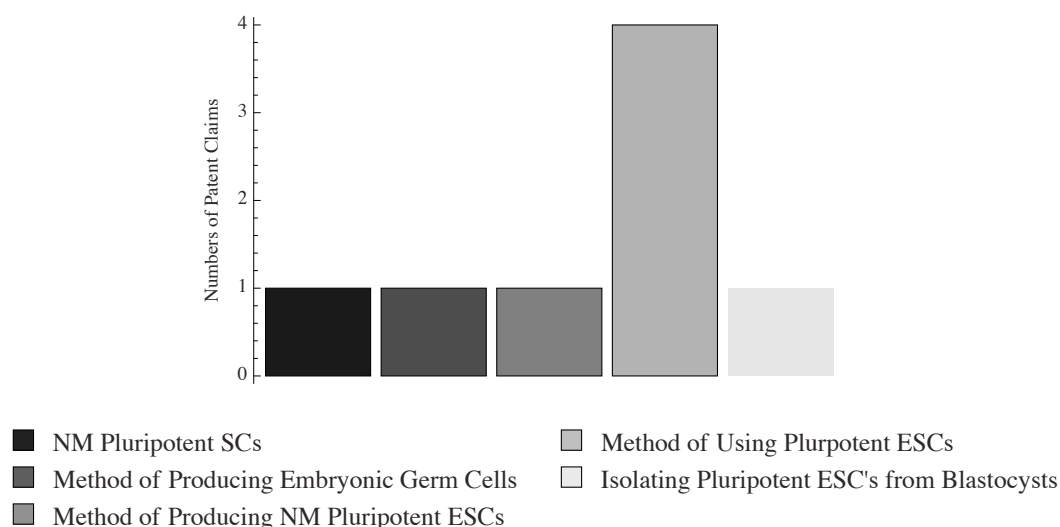


Figure 5.3: EPO claim categories of patents and applications related to hESCs

Figure 5.3 demonstrates claims categories of hESC related EPO patent applications, including those intended to be granted. The main category is method of applying pluripotent ESCs for further purpose. There are four claims. One of them is intended to be granted.

The milestone cases concerning hESC inventions in the EPO are the “Isolation, selection and propagation of animal transgenic stem cells” filed by Edinburgh University and the “Primate Embryonic Stem Cells” filed by the Wisconsin Alumni Research Foundation, both of which are essential to patentability of hESCs across Europe.

The “Isolation, selection and propagation of animal transgenic stem cells,” filed by Edinburgh University (EP0695351, Application No. 94913174) was granted in 1999 after it was amended to exclude “human cloning” from its claims. The claim first covered animal ESCs. After it was granted, it received oppositions from Italy, Germany, Netherland and the European Parliament. The Opposition Division Claimed that the granted patent violates the Article 53(a) and Rule 28 of the EPC. By the end, patent proprietor voluntarily added “non-human” in front of the word “animals” in Claim 48 in the English text,

because the English word “animal” does include human beings.⁴²⁶ The amendment does not change the scope of the patent because even without the wording of the qualifier, the patent does not include human cloning because the technique is not disclosed in the specification. At the end, the patent claim is limited to non-human animal ESCs and human adult stem cells; the claim no longer involves hESCs. The prosecution history demonstrates the fact that the EPO is cautious about patenting inventions involving hESCs.

Facing the issue of whether Article 53(a) of the EPC excluded the invention at bar, the Board interpreted the article narrowly, because Article 53(a) is an exception to the general entitlement to a patent found in Article 52(1) of the EPC, “given the EPC’s underlying objective of establishing a comprehensive patent protection between the contracting states.”⁴²⁷ To interpret Article 53(a) in a restrictive manner is supported and justified by previous decisions of the Opposition Division and the Board of Appeal. The exception to patentability only applies when the intended exploitation or publication of the inventions necessarily infringes on *ordre public* or morality, rather than in all cases where any conceivable exploitation or uses would be immoral. This is because many inventions can be used in anti-social or order-breaking ways, and even in ways that give rise to criminal offenses. There is no reason to deny products or processes from patent protection just because they may be abused in a certain way. In addition, Article 53(a) only refers to invention *per se* but not the scope of claims.

At the end, the Board emphasized that morality standards cannot be determined by the patent office, but should be determined by socioethic,

⁴²⁶ Brian Salter, *Patents and Morality: Governing Human Embryonic Stem Cell Science in Europe*, available at www.ncbi.nlm.nih.gov/pubmed/17511566 (last visited Mar. 22, 2011).

⁴²⁷ European Patent Office, *Euthanasia Compositions/Michigan State Univ. of 11.5.2005*, T 0866/01 (2005), point 5.2, available at <http://legal.european-patent-office.org/dg3/biblio/t010866eu1.htm> (last visited Jan,5,2010).

economic or religious principles in European culture. Based on this the Board favored the appellant and sustained the patent.⁴²⁸ This explanation narrows the application of Article 53(a) to intended exploitation and/or publication of products or processes. Only inventions with intended uses contrary to society's morality or constituting an *ordre public* breach under Article 53(a) would be denied patent protection.

The “primate embryonic stem cells” patent filed by the Wisconsin Alumni Research Foundation [WARF] claimed cell cultures including primate embryonic stem cells (EP0770125, application number 196903521.1). In 2004, the Examining Division refused to grant a patent based on the provisions of the EPC and the EU Biotechnology Directive. Considering the fact that the disclosed method of obtaining stem cells involved embryo destruction, the invention was considered to be the use of human embryos for industrial or commercial purposes and fell out of the scope of patentable subject matters, since the regulations banned inventions which are “contrary to ‘*ordre public*’ or morality” under Article 53(a) of the EPC (2000).⁴²⁹ The applicant appealed to the Technical Board of Appeal, which referred the question to the Enlarged Board of Appeal [EBA] for legal points.⁴³⁰ The EBA reached its decision in 2008.

The EBA interpreted Rule 28(c) of the Implementing Regulations to the Convention on the Grant of European Patents—Rule 28(c) of the EPC (2000)—in the context of its legislative history and supplementary documents. Since the Regulation was aligned with the Biotechnology Directive (in this case, the specific article is Article 6(2) of the Directive), the EBA decided to look at the meaning of the article by taking into account its context, object, purpose and preparatory documents.

⁴²⁸ *Id.*, point 6.12.

⁴²⁹ Wisconsin Alumni Research Foundation, Case T 1374/04, [2007] E.P.O. O.J 313, 315.

⁴³⁰ *Id.*, at 313.

According to the EBA, the first draft of the Biotechnology Directive did not mention any prohibition regarding the use of human embryos. Later, the Economic and Social Committee of the European Parliament proposed in its opinion to specifically exclude human embryos from patentability, which implies the committee's opposition to patents misusing human embryos. After hearing the opinion of the Committee, the Commission amended the proposal by adding "methods in which human embryos are used" under the clause of unpatentable subject matters.⁴³¹ The language was amended later in the Common Position EC No 19/98 adopted by the Council as "uses of human embryos for industrial or commercial purpose," which is also the final version of the Directive, as well as the wording in the Implementing Regulation. The EBA considered the language and its amendment history as a clear intention to prohibit commercialization of human embryos. The EBA claimed that since the present invention was not for therapeutic or diagnostic purpose, it was not patentable unless it was for the benefit of the embryo, which was not true in this case either considering the embryos were destroyed. To answer the appellant's question regarding the starting point for defining the term "embryo," the EBA leaned towards leaving the question to the fact of particular patent applications since both the EU and EPC seemed to make an effort to avoid any restrictive meaning of the word.⁴³²

Finally, the EBA concluded that Rule 28(c) of the EPC (2000) forbids the patenting of claims directed to products which are prepared exclusively by a method in which human embryos are misused, even if the method is not part of the claims. In other words, to determine whether an invention is forbidden, examiners should investigate the entire technical description of the application as to how the invention is to be performed, instead of the explicit wording of the claims. Since Rule 28(c) blocks patenting of such

⁴³¹ Wisconsin Alumni Research Foundation, Case G 0002/06, Eur. Patent Off., 23-26, at 25 (Nov. 25, 2008) [hereinafter CASE G 0002/06].

⁴³² *Id.*, at 23.

inventions, there is no need to discuss whether the morality requirement under Article 53 applies in this case. However, the EBA emphasizes that the decision only concerns inventions which are obtained by any methods involving destruction of human embryos, but not applicable to general inventions relating to human stem cells or human stem cell cultures. The EBA sustained the rejection. Finally, the application was withdrawn because the applicants failed to reply.

In summary, the EPO's refusal to grant patents for primate embryonic stem cells, especially hESCs, is based on moral grounds.⁴³³ However, the definition of the term embryos is not clear. It is still in doubt as to whether the word "embryo" in this matter means embryos produced in a natural way, or those obtained by artificial techniques such as IVF and SCNT as well. If one product is derived from embryos achieved by SCNT, which cannot lead to a birth, and therefore can hardly be classified as a traditional embryo, or if it is extracted from a disposed or donated embryo with its owners' consent, will the invention be covered by the exclusion? This question is left to member states.

This interpretation of the EBA differs from the decision in WARF's case, in which the EBA blocks the products from patenting on the grounds that their preparation inevitably causes the destruction of human embryos even if the method is not part of the claims, according to Rule 28(c) under Article 53(a) of the EPC (2000). The distinction is the subject matter. The "Euthanasia Compositions" case does not involve human beings while the WARF case directly relates to human embryos. Generally speaking, to determine whether inventions are contrary to "*ordre public*" or morality under Article 53(a), the Board leans towards interpretation of the exception clause narrowly, applying it only to the publication or exploitation of the products. Once the products relate to the human body or human embryos, Rule 28

⁴³³ *Id.*

applies automatically. Any product, whose preparation method or process requires the use of human embryos falls into the unpatentable category of Rule 28(c) if it brings no benefit to the embryos *per se* nor has therapeutic or diagnostic purpose.

3. European Patent Court System (EPC-based)

The high uncertainty of the EPC system is due to the possible different litigation outcomes achieved by national courts. While patents granted by the EPO are valid across all of the states, the courts' decisions are only binding within the borders of the state. Once entered into the national judicial system, the litigation cost, procedural laws, damage assessments, and quality of adjunctions may have strong variations across states. Patentees are not only facing the uncertainty of litigation results, but also the high litigation cost.

The European Patent Litigation Agreement started with the Paris Intergovernmental Conference in 1999. In this conference, the contracting state of the EPC set up a Working Party on Litigation, which was in charge of drafting the Agreement on integrated litigation for European patents. The latest draft was submitted to the Working Party on Litigation in 2005.

The draft Agreement includes substantive patent law, such as the definition of infringing acts and indirect infringement, burden of proof, procedural provisions, procedural remedies (appeal or petition to review of court decisions), as well as the remaining jurisdiction of national courts, and new organs of the European patent judicial system—European Patent Judiciary [EPJ], comprising the Court of First Instance, the Court of Appeal, a

Registry, and the Administrative Committee. After that, no further progress has been made by the Working Party on Litigation.⁴³⁴

In 2007, the European Commission proposed a document named Enhancing the Patent System in Europe [COM (2007) 165] to the European Parliament and Council, suggesting the combination of the EPLA and a community jurisdiction as an integrated judicial system. Since then, the project of creating an integrated judicial system has been shifted to the European Union. The progress made by EU will be introduced in the following section.

B. European Union Patent Laws

Although the European patent system is a major step forward, it is neither effective nor efficient enough compared to a single patent system due to its lack of enforcement mechanism. It only simplifies the application and grant procedure, but leaves enforcement and dispute litigation to member states. As patents are subject to diverse national laws and procedures, patentees bear the burden of litigation in a number of countries on one patent and the risk of variable or even contradictory results in different countries. Different rules of evidence, cost of litigation, speed of proceedings and even interpretation and application of substantial laws may give rise to “forum shopping”. The lack of legal certainty also has an impact on business decision-making. The European patent system is costly, cumbersome, risky and has limited practical value.

The idea of European community patent can be traced back to 1960s.⁴³⁵ A second attempt to create a community patent system led to the Luxembourg

⁴³⁴ EPLA, *supra* note 403.

Convention on the Community Patent in 1975, which never enters into force.⁴³⁶ In 2000, The Commission proposed the Community Patent Regulation to unify the complete patent process, including enforcement and dispute resolution.⁴³⁷ But this proposal failed. In 2009, the Council unanimously adopted a document regarding enhancement of the patent system by establishing a unified European Community patent system and the European and Community Patent's Court with a group of individuals with legal and technical expertise in patents.⁴³⁸ After the effectiveness of the Lisbon Treaty in 2009, which amends the Treaty on European Union and the Treaty establishing the European Community in order to promote the efficiency of the EU, the European Union replaced the European Community. Correspondingly, the European Community patent is renamed the European Union patent, and the European and Community Patent's Court is called the European and European Union Patent's Court [EEUPC].⁴³⁹

The endeavors of establishing a common EU patent system and European patent court are in different states of progress. In 2010, the European Parliament gave its consent to a common EU patent system by using the enhanced co-operation procedure.⁴⁴⁰ This procedure can only be used under the European Council's authorization or with the European Parliament's consent after a proposal from the European Council. Under the procedure, no

⁴³⁵ European Commission, *Commission Proposal for a Council Regulation on the Community Patent*, at 4, COM (2000) 412 final (Aug. 1, 2000) [hereinafter COM (2000) 412].

⁴³⁶ *Id.*, at 5.

⁴³⁷ *Id.*, at 9-16.

⁴³⁸ EUROPA, *EU Achieves Political Breakthrough on An Enhanced Patent System*, Apr. 12, 2009, available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1880&type=HTML&aged=0&language=EN&guiLanguage=fr> (last visited Jan. 14, 2010).

⁴³⁹ European Patent Office, *The EU Patent*, available at <http://www.epo.org/patents/law/legislative-initiatives/community-patent.html> (last visited Jan. 10, 2011).

⁴⁴⁰ European Parliament, *EU Patent: Parliament gives go-ahead for enhanced cooperation*, available at <http://www.europarl.europa.eu/en/pressroom/content/20110215IPR13680/html/EU-patent-Parliament-gives-go-ahead-for-enhanced-cooperation> (last visited Mar. 21, 2011).

unanimous agreement is required to adopt new rules when unanimity is unreachable.⁴⁴¹ After consent is obtained in the European Parliament, the Commission will submit two proposals concerning the establishment of a single patent system and the language requirements for the patent applications.⁴⁴²

However, the establishment of a European patent court encountered some obstacles. The European Court of Justice conveyed its opinion on the compatibility of the European and EU Patent Court Agreement with the provisions of EU treaties on Mar. 8, 2011, stating that the envisaged agreement fell outside the institutional and judicial framework of the EU, and divested the power of member states' courts over patent issues.⁴⁴³ The progress of establishing a common EU patent system is still ongoing.

Although a common EU patent system has not yet been established, there are some documents concerning patent rights in the EU. To date, a hierarchy of documents with different levels of legal effectiveness has been issued by the European Parliament, the European Community and the European Council. Regulations are documents self-executing in all EU institutes and all member states and can be applied directly. Therefore, regulations have supreme legal effectiveness over other EU documents and national laws of member states. Directives are more like guidelines or model texts than binding documents. They leave the member states the freedom to adopt any forms or methods to achieve the result as long as the principles and main content are consistent with the directives. The directives themselves cannot

⁴⁴¹ *Id.*

⁴⁴² *Id.*

⁴⁴³ Opinion 1/09 of European Court of Justice, *available at*

<http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&alljur=alljur&jurcdj=jurcdj&jurtpi=jurtpi&jurtfp=jurtfp&numaff=1/09&nomusuel=&docnodecision=docnodecision&allcommjo=allcommjo&affint=affint&affclose=affclose&alldocrec=alldocrec&docor=docor&docav=docav&docsom=docsom&docinf=docinf&alldocnorec=alldocnorec&docnoor=docnoor&docppoag=docppoag&radtypeord=on&newform=newform&docj=docj&docop=docop&docnoj=docnoj&typeord=ALL&domaine=&mots=&resmax=100&Submit=Rechercher> (last visited Mar. 23, 2011).

be applied as binding laws; they need to be transposed into national laws to take effect. Another type of EU document is the decision. Decisions are legal instruments issued by European institutions to solve or respond to any disputes or debates in the EU with the legal ramification affecting only the member states to which they are addressed.⁴⁴⁴ In addition, the European Court of Justice [ECJ] have the jurisdiction to give preliminary rulings on interpreting treaties and agencies' acts⁴⁴⁵, which become part of EU laws to promote the integration of European laws.⁴⁴⁶ The ECJ with the authority to apply and interpret laws ensures the laws are applied and interpreted consistently across member states.⁴⁴⁷ The following paragraphs contain EU documents concerning patent issues on hESC research.

1. Conventions on hESC Research

The Convention on Human Rights and Biomedicine took effect in 1999, setting forth EU general policy on embryonic research. In Article 18 of this convention, it entitles the authority of states to regulate embryo research, on two premises: "to ensure adequate protection of the embryo" and to prohibit "the creation of human embryos for research purpose." The Convention is only binding in states that have ratified it. So far, it has received ratification by twenty-seven countries. All of them are member states of the European Union.

⁴⁴⁴ Treaty on the Functioning of European Union, May 9, 2008, 2008 O.J. (C 115), Article 258 and 259 [hereinafter Treaty on the Functioning of European Union].

⁴⁴⁵ *Id.*, Article 267.

⁴⁴⁶ Clifford J. Carrubba, *Legal Integration and Use of the Preliminary Ruling Process in the European Union*, 59 INT'L ORG. 399, 399-418 (2005).

⁴⁴⁷ EUROPA, *The court of Justice*, available at http://europa.eu/institutions/inst/justice/index_en.htm (last visited Mar. 2, 2011)

2. Announcement of the European Parliament concerning hESC Research

The European Parliament explicitly demonstrates its attitude towards hESC research in the Patents on Biotechnological Inventions and European Parliament Resolution on Patents for Biotechnological Inventions, promulgated in 2006. In this announcement, it underlines support of stem cell research but rejects any research on human embryos which may destroy embryos.⁴⁴⁸ Reflecting that principle, it further states that the patenting of procedures involving hESCs and derived from hESCs violates Article 6(2)(c) of the Directive, because the creation of hESCs inevitably leads to destruction of embryos, which violates the principle of the EU and the Directive.⁴⁴⁹ It does not specifically mention the patenting of hESCs per se, but it can be easily inferred from the text that Parliament would consider that patenting of human embryonic stem cells is a violation of the Biotechnology Directive for the same reason. This document is an announcement of the Parliament's general policies, intend to reduce the uncertainty surrounding hESC patenting issues. Generally speaking, however, announcements of the Parliament have no binding effectiveness. They are guidelines or policy statements which direct the Council and the Commission's activities.

3. The Biotechnology Directive (*Directive 98/44/EC*)

Considering the importance of stimulating investment in research and industry, the important role of biotechnological inventions in industrial development, the necessity to protect these research results, and the fierce

⁴⁴⁸ European Parliament, *Patents on Biotechnological Inventions, European Parliament Resolution on Patents for Biotechnological Inventions* (Oct. 26, 2005) (P6_TA(2005)0407) Rule 3, 2006 O.J. (C272E) 440, 441 [hereinafter P6_TA(2005)0407].

⁴⁴⁹ *Id.*, Rule 14.

competition for biotechnological patents over the world, the European Community initiated the legislative process to provide patent protection for biotechnological inventions in 1988.

The European Commission introduced the first draft of the Biotechnology Directive in 1988 relevant to the patenting of biotechnological inventions, but this and was rejected by Parliament due to opposition from the Greens, an animal welfare activist and environmentalist group. The major reason given by opponents was that “it failed to deal adequately (or at all) with ethical concerns about patenting biotechnological inventions”⁴⁵⁰ and “it should identify certain specific topics that, for ethical reasons, should not be patentable.”⁴⁵¹ After revisions, a new draft of the Biotechnology Directive was approved by the European Parliament in May of 1998 and came into force two months later.

This Directive undoubtedly has succeeded in establishing unitary guidelines within the EU. Even though it is a directive that only functions once transferred into a member state’s national laws, it has been applied quite well in the EU. There are two reasons for this success. First, the Administrative Council of the European Patent Organization has already introduced the provisions of the Biotechnology Directive implementing the European patent laws. Rule 26(1) of EPC states:

The relevant provisions of the convention shall be applied and interpreted in accordance with the provisions of this chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.

⁴⁵⁰ Duncan Curley and Andrew Ahrples, *Patenting Biotechnology in Europe: The Ethical Debate Moves on*, 24 EUR. INTELL. PROP. REV. 565, 565 (2002) [hereinafter Curley].

⁴⁵¹ R. Stephen Crespi, *The Human Embryo and Patent Law: A Major Challenge Ahead?*, 28 EUR. INTELL. PROP. REV. 569, 571 (2006)[hereinafter Crespi].

This rule binds on the Opposition Divisions, the Appeal Board, and all of the EPC contracting states, most of which are also the member states of the EU. This rule assures legislative consistency between the EU and EPO, consequently carrying forward the implementation of the Biotechnology Directive throughout most European countries.

Secondly, the mechanism of the EU entitles either the European Commission or an aggrieved person the right to ask the European Court of Justice to impose a penalty on a member state that fails to transpose the Biotechnology Directive into national law.⁴⁵² Besides that, the Court of Justice held that a state that fails to transpose directives is liable for all damages to individuals or companies who had been adversely affected by the lack of implementation or faulty implementation.⁴⁵³ Later, the European Court of Justice developed a doctrine of direct effect holding that in those cases of non-implementation or wrong implementation, directives have direct legal force.⁴⁵⁴ Legal proceedings for failure to transpose the Biotechnology Directive to national law were initiated in 2003 before the Court of Justice against the countries which had not transposed the Directive.⁴⁵⁵ Infraction procedures were opened in December 2004 against two new member states, Lithuania and Latvia, which had not completed the transposition of the Directive.⁴⁵⁶

⁴⁵² Treaty on the Functioning of European Union, *supra* note 446, Article 258, 259, 260.

⁴⁵³ European Court of Justice, Joined Cases C-6 & 9/90, *Francovich v. Italy*, [1991] E.C.R. I-5357, available at <http://www.eurofound.europa.eu/areas/industrialrelations/dictionary/definitions/francovichprinciple.htm> (last visited Dec. 15, 2010).

⁴⁵⁴ Case 9/70, *Grad v. Finanzamt Traunstein*, [1970] E.C.R. 825, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61970J0009:EN:HTML> (last visited Mar. 3, 2011).

⁴⁵⁵ European Commission, *Report from the Commission to the European Parliament and the Council, Development and Implication of Patent Law in the Field of Biotechnology and Genetic Engineering*, COM (2002) 545 final (Oct. 7, 2002).

⁴⁵⁶ European Commission, *Report from the Commission to the European Parliament and the Council, Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, COM (2005) 312 (Jul. 14, 2005) [hereinafter COM (2005) 312]

These two factors ensure the Biotechnology Directive will function with real effectiveness and enforceability rather than being just a trumpery recommendation.

Generally speaking, the Biotechnology Directive is a compromise between the European Commission and Parliament. On one hand, it gives sanction endorsement to certain types of inventions relating to the human body, such as isolated or purified DNA sequences; on the other hand, taking parliament's concern over ethical issues into account, it prohibits patents on the human body and parts of the human body considering the public order and morality.

The Biotechnology Directive sets forth the basic requirements of patenting: novelty, inventiveness and industrial application as general patent rules. However, since the Biotechnology Directive is concerned with biotechnological inventions, it focuses on the patenting issues raised by inventions related to plants and animals, human bodies and organs, genes, DNA sequences and other applicable processes.

The Biotechnology Directive excludes certain categories from patenting in Articles 4, 5 and 6. Article 4 excludes plant and animal varieties, as well as essential biological processes for the production of animals or plants. Article 5 sets forth the patenting requirements for inventions relating to the human body, and states as follows:

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Inferring from the text, the clauses set forth a special standard of patenting for the human body. An element derived from the human body by techniques of identification, purification and multiplication is patentable even if it is identical to an element existing in nature, as long as it is novel,⁴⁵⁷ inventive and industrially applicable.

In addition, Article 6 stipulates the *ordre public* and morality clause, excluding the patentability of certain subject matters which does not fall into previous categories, when “their commercial exploitation would be contrary to *ordre public* or morality,” specifically:

- (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.

To clarify the exclusion, Recital 42 reiterates that the exclusion of patenting human embryos for industrial or commercial purposes should not affect inventions for therapeutic or diagnostic purposes. These are the basics rules governing patentability of biological materials relating to the human body and human embryo. But ambiguity in the language still exists. For

⁴⁵⁷ The author of this paper believes the special condition affects the meaning of novelty to some extent. Natural elements derived from the human body do not meet the standard of novelty, but moreso fall into the category of discovery. However, adding the techniques requirement of isolating or duplicating in an artificial environment turns them into human-intervened inventions.

instance, the definition of human embryo and the scope of “industrial or commercial purposes” have not been clarified.

The statutes of the Biotechnology Directive do not unambiguously refer to hESCs. Thus, application to hESCs is left to adjudication or judicial interpretation.

In the Commission report to the Council and Parliament titled *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*,⁴⁵⁸ the Commission stated that the patentability of totipotent stem cells was clear under Article 5(1) of the Directive, which precluded the patenting of the human body at its various stages, because totipotent stem cells had the ability to develop into human beings.⁴⁵⁹ However, according to the document, the situation of pluripotent embryonic stem cells was more complex since they lack the capacity to develop into human beings. Despite this lack of capacity, the matter still raises ethical questions, such as the status of human embryos, and the Commission thinks it is premature to unify the law in this area.⁴⁶⁰

The Board of Appeal of the EPO has interpreted Rule 53d(c), which is Article 6(2)(c) of the Directive, to exclude products or processes that are prepared exclusively by methods in which human embryos are used, unless intended for the benefit of the embryos themselves. That interpretation basically blocks all inventions using or relevant to embryonic stem cells. However, a conclusive interpretation has not yet been settled upon.

4. European Group on Ethics [EGE] Reports on hESC Research

⁴⁵⁸ COM (2005) 312, *supra* note 458.

⁴⁵⁹ *Id.*, Point 2.2.

⁴⁶⁰ *Id.*

The European Group on Ethics in Science and New Technologies to the European Commission [EGE] is an independent group in the EU, comprised of experts appointed by the Commission. The main tasks of the EGE are to review ethical issues arising from science and new technologies and submit its advice on those issues to the Commission for legislation or policy making. As an advising agency, the EGE only provides expert opinions to the Commission, which has no legal force and is not binding on any agency or state. However, the EGE is a persuasive source upon which the Commission relies and it has strong effects on Commission issued documents.

The EGE has worked on the ethical issues of biotechnological inventions, including those resulting from hESC research. In 1996, the EGE issued report entitled *Ethical Aspects of Patenting Inventions involving Elements of Human Origin*, giving some comments and opinions on the first proposal of the Directive.

Another report, *Ethical Aspects of Human Stem Cell Research and Use*, was issued on November 14, 2000. In this report, the EGE admitted that the embryonic stem cell research raised certain ethical issues and different sources could mean different ethical acceptability. Derivation of stem cells from embryonic blastocysts raises the issue of the moral status of embryos. Considering the decentralized structure of the EU, member states have the authority over human embryonic research with the obligation of protecting human dignity. For instance, making regulations on embryonic research and provisions against “arbitrary experimentation and instrumentalisation of human embryos.”⁴⁶¹ Even though the embryonic stem cell research has great potential from a therapeutic perspective, this must be balanced against the

⁴⁶¹ European Group on Ethics in Science and New Technologies, *Opinion of the European Group on Ethics in Science and New Technologies to the European Commission on the “Ethical Aspects of Human Stem Cell Research and Use”*, at 16, Nov. 14, 2000, available at http://ec.europa.eu/european_group_ethics/docs/avis15_en.pdf (last visited Oct. 2, 2009)[hereinafter EGE 2000].

possibility of misuse of embryos by the “proportionality principle and a precautionary approach.”⁴⁶² However, the EGE did not provide a line of reasoning to explain to how to balance the benefits of embryonic stem cell research against any risk to human dignity that might be impaired by the research.

The report entitled Ethical Aspects of Patenting Inventions Involving Human Stem Cells, released in 2002 was requested by the Commission to “evaluate all ethical aspects of biotechnology.” The EGE noted that use of human embryos in hESC research causes debate because it involves entities in the very beginning stage of human life. Although inventions involving the commercialization and industrialization of human embryos may be patented under Article 6 of the Directive, it is not clear which embryos are subject to this clause, nor is the patentability of cells derived from embryos directly addressed. To fill in the gap, several elements must be considered: content of patents, sources of stem cells, methods used to derive stem cells, protection of the donors, socio-economic consequences, and implication to the patent system.

The EGE held that unmodified stem cells are not patentable for several reasons. First, they do not fulfill the legal requirements, especially the industrial application requirement. Second, since they have a close relation to the human body, fetus or embryo from which they are derived, their patenting may be considered a commercialization of the human body. Third, unmodified stem cells lines are hardly patentable either because they have a large range of potential uses that are not described in patent application files. However, stem cell lines modified by *in vitro* treatment or genetic modification with specific industrial application are patentable. As to processes involving human stem cells, the EGE deemed that there is no ethical obstacle of patenting them; hence, they are patentable as long as they

⁴⁶² *Id.*, at 15.

fulfill the three requirements of patenting.⁴⁶³ The EGE explains its reasoning as follows:

(P)atenting of inventions allowing the transformation of unmodified stem cells from human embryonic origin into genetically modified stem cell lines or specific differentiated stem cell lines for specific therapeutic or other uses, is ethically acceptable, as long as the inventions fulfill the criteria of patentability...⁴⁶⁴

Based on this logic, unmodified embryonic stem cells are not patentable because they lack industrial application and contradict the public order, while modified embryonic stem cells with specific industrial application may be patented depending on the source of the stem cells. Are modified embryonic stem cells derived from human embryos produced by IVF or SCNT patentable? The report has no answer, but, from the reasoning the EGE gave, the answer appears to be positive.

5. Judicial Decisions

As mentioned above, there is no single, unified patent litigation system in either the EU or the EPO. The European courts have no jurisdiction over patent disputes. After the contracting states of the EPC began to work on drafting the European Patent Litigation Agreement [EPLA] in 1999, and proposed to establish a new jurisdiction for a European patent system—the European Patent Judiciary [EPJ]—the European Commission adopted a document titled “Enhancing the Patent System in Europe” in 2007. In it, the Commission suggested combining the EPLA and a community-wide jurisdiction to create an integrated judicial system and unify patent validity

⁴⁶³ European Group on Ethics in Science and New Technologies, *Opinion of the European Group on Ethics in Science and New Technologies to the European Commission on the “Ethical Aspects of Patenting Inventions Involving Human Stem Cells”*, May 7, 2002, available at ec.europa.eu/european_group_ethics/docs/avis16_en.pdf (last visited Oct. 2, 2009).

⁴⁶⁴ *Id.*

determinations and patent enforcement over most European countries.⁴⁶⁵ However, since this system requires member states to give up a degree of national sovereignty, it is still in under negotiation.

C. Laws of European Countries on Patentability of hESCs

Since the EPC does not explicate the patent-eligibility of hESCs, it leaves room for countries to come to their own interpretation in patent practice. Member states of the EPC have come to diverse decisions on the patenting of hESCs. Some countries allow both hESCs and process patents; some only legitimize the production processes, while some do not have explicit rules yet. The sections below introduce some European countries that have clear rules or judicial decisions on patenting hESC inventions.

1. United Kingdom

Schedule A2 of the Patent Act (1977) precludes certain subject matters from being patented. Paragraph 3 of Schedule A2, similar to the Directive, excludes from patentability the human body at its various stages, processes of cloning human beings, processes for modifying human germ lines, use of human embryos for industrial or commercial purposes and processes for modifying the genetic identity of animals without bringing benefit to man or animals. There are no specific rules regarding embryonic stem cells. However, this gap is filled by the Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office (2009)[UK Examination Guidelines].

⁴⁶⁵ *Communication from the Commission to the European Parliament and the Council, Enhancing the Patent System in Europe*, at 10, COM (2007) 165, final (Mar. 4, 2007)

The UK Examination Guidelines, issued by the Intellectual Property Office, is a resource for patent examiners to use in deciding patenting issues relating to biotechnological inventions on the basis of legislations and decisions of the courts and the EPO Boards of Appeal.⁴⁶⁶

In the UK Examination Guidelines, Article 107 to Article 113 concern hESCs. The Examination Guidelines exclude the patentability of any processes for obtaining stem cells directly from human embryos and stem cells derived from human embryos are not patentable either under Paragraph 3(d) of Schedule A2, which bans the patenting of uses of human embryos for industrial or commercial purposes. As previously stated, human totipotent cells have the potential to develop into human beings, and therefore, are not patentable under Paragraph 3(a) of Schedule A2. This also includes the processes of culturing or propagating them.⁴⁶⁷ In contrast, human embryonic pluripotent stem cells that cannot develop into human beings are patentable especially considering their scientific and medical values.⁴⁶⁸ On the grounds that the EPO Enlarged Board of Appeal's judgment in the WARF case—that the unpatentability holding only concerns embryonic stem cells obtained by destruction of human embryos—the UK Intellectual Property Office has stated that cells, the derivation of which does not result in human embryonic destruction, such as existing embryonic stem cell lines, induced pluripotent cells and altered nuclear transfer cells, are patentable.⁴⁶⁹

In the newest Practice Notice of Inventions involving Human Embryonic Stem Cells, published in February of 2009, the UK Intellectual Property Office iterates the aforesaid policy that cells satisfying the requirements of

⁴⁶⁶ United Kingdom Intellectual Property Office, *Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office*. (April, 2009) Para 7, available at <http://www.ipo.gov.uk/biotech.pdf> (last visited Mar, 9, 2010)[hereinafter UK Guidelines]

⁴⁶⁷ *Id.*, Para 108.

⁴⁶⁸ *Id.*, Para 109.

⁴⁶⁹ *Id.*, Para 110-112.

patentability should be patented as long as those cells are obtained by means other than the destruction of human embryos.⁴⁷⁰

2. Germany

Neither the German Patent Office nor German courts have issued any official statement regarding the patentability of hESC-related application. However, in practice, the German Patent Office has granted patent DE 10136702 B4, related to a process involving the use of pluripotent hESC's.⁴⁷¹ Another patent DE 197 56 864, claiming methods of obtaining progenitor cells from hESCs and the progenitor cells *per se*, is under appeal in Germany after the German Federal Patent Court invalidated part of the patent as falling into the moral exclusion transposed from the Directive. However, the ruling of the GFPC partly rests on the uncertainty as to the source of hESCs used in the application.⁴⁷² It appears that granting the patent is possible if the relevant hESCs or hESC lines have been imported legally under German laws.⁴⁷³ Nevertheless, at this point, it is unclear if that will turn into a generally applicable rule governing hESCs patents in Germany.⁴⁷⁴

3. Other Countries

⁴⁷⁰United Kingdom Intellectual Property Office, *Inventions Involving Human Embryonic Stem Cells*, available at <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm> (last visited Mar. 10, 2009).

⁴⁷¹ Aurora Plomer, *Stem Cell Patents: European Patent Law and Ethics Report*, at 30 available at <http://www.nottingham.ac.uk/~llzwww/StemCellProject/project.report.pdf> (last visited Mar, 9, 2010) [hereinafter Plomer Report].

⁴⁷² Aurora Plomer, *Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions*, in *EMBRYONIC STEM CELL PATENTS, EUROPEAN LAW AND ETHICS* 194 (EDITED BY AURORA PLOMER & PAUL TORREMANNS eds., Oxford University 2009).

⁴⁷³ German Ethics Council, *The Patenting of Biotechnological Inventions Involving the Use of Biological Material of Human Origin*, at 31, available at http://www.ethikrat.org/_english/publications/Opinion_patenting-of-biotechnological-inventions.pdf (last visited Mar, 9, 2010).

⁴⁷⁴ Plomer Report, *supra* note 473, at 30.

The Swedish patent office has granted a patent on a method of differentiation of pluripotent hESC's into hematopoietic cells.⁴⁷⁵ The office explained that the method disclosed in the patent application could be performed by using deposited lines without causing any direct damage to human embryos, so it fell outside the scope of the exclusion in Article 6(2)(c) of the Directive.⁴⁷⁶

Similarly, the Norway Intellectual Property Office has granted a patent claiming pluripotent stem cells from non-embryonic origins. But, how that result affects inventions of hESCs per se or involving the use of embryos is unpredictable.⁴⁷⁷

Unlike these countries more or less opening the door to hESCs-related patents, The Austrian Patent Act broadens the typical “use of human embryos for industrial or commercial purposes” to “uses human embryos” as a patent exclusion and applies the Austrian Reproductive Medicine Act to determine whether the inventions are contrary to morality or *ordre public*.⁴⁷⁸ Under the Reproductive Medicine Act, which prohibits any use of “developmental potential cells” for other purposes except assisted reproduction,⁴⁷⁹ there is little possibility of patenting hESCs since their derivation contravenes the laws.

As new EU members, Estonia and Slovakia both adopted the content of the Directive, precluding the patentability of processes for human cloning or modifying the germ line genetic identity of human beings, and any product or

⁴⁷⁵ Method of differentiation of pluripotent human embryonic stem cells into hematopoietic cells, Patent No. SE 526490. *See id.*, at 30.

⁴⁷⁶ *Id.*, at 31.

⁴⁷⁷ Asa Hellstadius, *A Comparative Analysis of the National Implementation of the Directive's Morality Clause*, in *EMBRYONIC STEM CELL PATENTS*, EUR. L. OPEAN LAW AND ETHICS 133 (AURORA PLOMER & PAUL TORREMANS eds., Oxford University 2009)[hereinafter Hellstadius].

⁴⁷⁸ *Id.*, 122.

⁴⁷⁹ *Id.*, 122.

process involving the utilization of human embryos for commercial purposes.⁴⁸⁰ However, the application of these clauses in practice is still unknown

In conclusion, the EPO applies Article 6(2)(c) to exclude any invention derived from embryos, but maintains silence in relation to hESCs attained by other means, and leaves the definition of embryo open to determination in individual cases. While most of the EU members are waiting for a further decision or statement from the EPO, the UK Intellectual Property Office is the first to explicitly state that except for totipotent ESCs, any other ESCs that do not bring about destruction of human embryos are patentable. The reason to exclude the patentability of totipotent ESCs is that they have the potential to develop into human beings and patenting or commercializing them will jeopardize human dignity. hESCs which have no potential to develop into a human being of their own at the blastocyst stage, are pluripotent stem cells,⁴⁸¹ and patentable under the condition that the hESCs are not derived from an embryo damaged in the process of derivation.

D. Academic Discussion on hESCs' Patentability

Article 5 and Article 6 of the Directive, along with Article 53(a) and Rule 23d of the EPC are the primary rules concerning human embryos and hESCs. Since the definitions are not given in the EPC, different interpretations of words can drive different conclusions, and therefore, different scopes of patentable and non-patentable subject matter can be inferred. In European

⁴⁸⁰ Josef Kure, *Human Embryonic Stem Cell Research in Central and Eastern Europe: A Comparative Analysis of Regulatory and Policy Approaches*, in *EMBRYONIC STEM CELL PATENTS, EUROPEAN LAW AND ETHICS 77* (AURORA PLOMER & PAUL TORREMANS eds., Oxford University 2009).

⁴⁸¹ EUR. GROUP ON ETHICS IN SCI. & NEW TECH. TO THE EUR. COMM'N, *STUDY ON THE PATENTING OF INVENTION RELATED TO HUMAN STEM CELL RESEARCH 9* (Office for Official Publications of the European Communities 2002).

countries, scholars are expressing varying viewpoints on hESC. This section provides a general review in academic discussion in European countries. The study is not exhaustive. Some significant scholar viewpoints may not be included in this section.

First, the definition of “embryo” is not clear. The scope of the definition depends on whether the word is interpreted narrowly or broadly. Under the narrow interpretation, “embryo” merely includes naturally conceived embryos. If the narrow definition is adopted, hESCs derived from embryos produced by an artificial method, such as IVF, are not inhibited by the Directive and are patentable⁴⁸² because they lack the capacity or intent to develop into adults. Furthermore, even embryos produced by therapeutic cloning may be patentable as well since the purpose of therapeutic cloning is treatment rather than human cloning.⁴⁸³ On the other hand, if the broad definition were adopted, all embryos would be covered under Article 6, and are therefore not patentable, no matter where they are from and what their potentiality is.

Second, the definition of “industrial or commercial purpose” in Article 6(c) is also ambiguous. The EPO interprets the phrase very broadly, including any use of embryos that is not for the benefit of the embryos themselves. Some scholars agree with the EPO that Article 6(c) should be interpreted broadly not only to exclude all claims to the industrial and commercial use of human embryos, but also “all claims to associated product[s] which necessitate the direct and unavoidable use of a human embryo,” such as embryonic stem cells.⁴⁸⁴ Some people argue that patents on hESCs can be considered patents on a human body or human body part, an offense against human dignity, or

⁴⁸² Graeme Laurie, *Patenting Stem Cells of Human Origin*, 26(2) EUR. INTELL. PROP. REV. 59, 62 (2004)[hereinafter Graeme Laurie].

⁴⁸³ Curley, *supra* note 452, at 567.

⁴⁸⁴ Ralf Perrey & Knostanze Lenhard, *Recent Developments in The Patentability of Inventions Relating to Medicine, Pharmaceuticals, and Biotechnology according to European Patent Practice*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 479, 489 (2004).

commercial or industrial uses of embryos, all of which fall into non-patentable categories in the Directive. Therefore, according to this view, totipotent ESCs are not patentable, but pluripotent or multipotent stem cells which cannot develop into an adult human being are patentable, albeit with deliberate supervision by patent agencies to ensure those patents will not adversely affect embryos or totipotent stem cells.⁴⁸⁵

There are some scholars do not agree with that interpretation. Some state that the therapeutic use of stem cells is thoroughly different from commercial or industrial use.⁴⁸⁶ For instance, they hold that utilizing stem cells for therapy or treatment should not be considered commercialization of human embryos, especially when the embryos used are produced by SCNT, and thus, such embryonic stem cells should not be excluded from patent protection.⁴⁸⁷ Some argue that the ultimate goal of any research is to commercialize the research results and apply them in industry. As long as the hESC research is legal, there is no reason to reject legal protection of research results.⁴⁸⁸ Others allege that the exception clause should be interpreted in a narrow way on the grounds of jurisprudence principles,⁴⁸⁹ which are established by the case law of European Court of Justice.⁴⁹⁰ Some scholars conclude from the legislative history of the Directive that the amendment changing “methods in which human embryos are used” in the draft to “for commercial and industrial purpose” in the final text manifests the purpose of the Parliament and the Council to narrow the exceptions to patent protection to only direct commercial and industrial use of embryos.⁴⁹¹

⁴⁸⁵ Resnik, *supra* note 285, at 212.

⁴⁸⁶ Graeme Laurie, *supra* note 484, at 62.

⁴⁸⁷ Curley, *supra* note 452, at 567.

⁴⁸⁸ Graeme Laurie, *supra* note 484, at 65.

⁴⁸⁹ Philippe Bouvet, *Patentability of Inventions involving Human Stem Cells in Europe*, J. COMM. BIOTECHNOLOGY SEP. 2002, 40, 43.

⁴⁹⁰ Dr Denis Schertenleib, *The Patentability And Protection Of Living Organisms In The European Union*, 26(5) EUR. INTELL. PROP. REV. 203, 213 (2004).

⁴⁹¹ Crespi, *supra* note 453, at 574.

Third, the line between Article 5(1) and Article 5(2) is blurred. Webber claims that Article 5(1) of the Directive applies to various stages of the human body, including zygotes and totipotent stem cells that have the capacity of developing into human beings; pluripotent and multipotent stem cells are not governed by Article 5(1), but are also precluded from patent under Article 6(2)(c).⁴⁹² In contrast, Hagen and Gittens argue that it is not clear whether 5(1) precludes the patentability of human stem cells that are not a natural stage in the development of a human body, for instance, embryonic stem cells extracted from an embryo which would not have developed into a mature human body on its own. Furthermore, if Article 5(1) prohibits the patenting of isolated totipotent cells, all human cells must be excluded from patenting because they could develop into a mature human by SCNT or through the reprogramming of adult cells.⁴⁹³ Aurora Plomer takes the middle ground, concluding that Article 5(1) governs totipotent hESC's while 5(2) applies to pluripotent stem cells; in other words, the former is nonpatentable while the latter is patentable.⁴⁹⁴

In conclusion, both opponents and advocates of hESC patents can find legal basis from Article 5 and 6 due to their indefinite language.

⁴⁹² Phillip M. Webber, *Patentability of Human Embryonic Cells under the EPO*, available at http://pharmalicensing.com/public/articles/view/1119630334_42bc33fe14906 (last visited Mar. 3, 2010).

⁴⁹³ Gregory R. Hagen & Sébastien A. Gittens, *Patenting Part-Human Chimeras, Transgenics and Stem Cells for Transplantation in the United States, Canada, and Europe*, 14 RICH. J.L. & TECH. 11, 79 (2008).

⁴⁹⁴ Plomer Report, *supra* note 473, at 67-70.

Chapter 6: Laws governing hESCs in China

A. Introduction to Chinese Legal System

China, one of the oldest countries in the world, has experienced dramatic changes of laws and legal systems during its long history. During the Chinese feudal dynasties, which can be traced back to the Xia Dynasty in 2000BC, the Chinese legal system consisted of Li (礼)⁴⁹⁵ and Xing (刑).⁴⁹⁶ The country was “ruled by Li and run by Xing.”⁴⁹⁷ In the Han dynasty, two main Chinese philosophic schools of thought—Confucianism⁴⁹⁸ and Legalism⁴⁹⁹—accomplished this combination.⁵⁰⁰ Han governors infused Confucianism with the written laws, administrative system and government structure of Legalism by using Confucian classics to create and interpret written codes and published documents.⁵⁰¹ In the Tang dynasty, this characteristic was more systemized.⁵⁰² This legal system lasted for more than 1000 years until legal reform occurred during the Qing Dynasty in AD 1901. That reform was triggered by both requirements of internal reformers and pressure from

⁴⁹⁵ Li is the general name for a series of long-existing spiritual principles and norms in ancient Chinese society in order to maintain the patriarchal hierarchy. It was evolved from social norms established in the Xia dynasty, the first of China. The name “Li” was given in the West Zhou. Mo Zhang, *The Socialist Legal System with Chinese Characteristics: China’s Discourse for the Rule of Law and A Bitter Experience*, 24 TEMP. INT’L & COMP. L.J. 1, 9 (2010) [hereinafter Mo Zhang].

⁴⁹⁶ Xing means all kinds of punishment which will be imposed on people who break the Li and the procedures for implementing the punishment. *See Id.*, at 9.

⁴⁹⁷ *Id.*

⁴⁹⁸ Confucianism is an ethical and philosophical system, which includes the rules of behavior, ceremony and morality. Confucianism emphasizes that there is no need for written law. All rules should be established by good moral example (in most cases, it is the emperor) and punishment should be replaced by a sense of shame.

⁴⁹⁹ Legalism supports a “rule by law”. It emphasizes using laws as the primary tool to prevent social chaos and protect the state, the emperor and his military, and focuses on strengthening the power of written law and promoting the idea of “equal punishment”. Mo Zhang, *Supra* note 497, at 19.

⁵⁰⁰ *Id.*, at 9-10.

⁵⁰¹ Yu Fang & Stephenie Wang, *The Triumph of Confucianism: How a Subjugated Legal System Is Failing A Generation of Chinese Women and Girls*, 15 CARDOZO J.L. & GENDER 691, 698 (2009).

⁵⁰² Mo Zhang, *Supra* note 497, at 24.

some Western countries. As a result, China began to import some laws from other countries, especially Germany and Japan. During this short period, China promulgated many new laws, for instance, a Constitutional law, Civil Code, Criminal Code, Company law and Bankruptcy law. However, these laws did not last long due to the Xinhai Revolution in 1911.

In 1912, Sun Zhongshan initiated a provisional Constitution of the Republic of China, which was replaced by several constitutions generated by other parties or warlords. By 1949, the Communists had unified the whole country, except HongKong, Macau and Taiwan, signifying the beginning of a new era with a legal system strongly influenced by the Soviet model.

However, that legal system was gradually destroyed during the “Anti-Rightist Campaign” (1950s to early 1960s) and “the Great Cultural Revolution” (1966-1976). Therefore, after the “Great Cultural Revolution,” President Deng Xiaoping, emphasizing the importance of the legal system, signed a new Constitution (1978 Constitution) as well as some statutes such as the Criminal Law, the Criminal Procedure Law, the Organic Law of the People's Courts of the People's Republic of China and so forth.

From this beginning, China embarked on the arduous process of rebuilding the judicial branch and commensurate laws. Since 1978, China has promulgated the laws listed below among other legislations:

- the Constitutional Law (1982) and its four amendments in 1988, 1993, 1998 and 2004;
- the Organic Law of the National People's Congress of the People's Republic of China (1982) (effective);
- the Electoral Law for National People's Congress and People's Congresses at Local Levels and the Organic Law of the Local People's

Congresses and Local People's Governments (1982) (last modified in 2004);

- the Law of the People's Republic of China on Regional National Autonomy (1984) (last modified in 2001);
- the General Principles of Civil Law (1986) (last modified in 2009);
- the Civil Procedure Law (1991) (last modified in 2007);
- the Law on the Protection of Rights and Interests of Women (1992) (last modified in 2005);
- the Company Law (1993) (last modified in 2005);
- the Criminal Procedure (1996);
- the Law on Administrative Penalty (1996) (last modified in 2009);
- the Criminal Law (1997) (last modified in 2009);
- the Law of Contract (1999);
- the Administrative Reconsideration Law (1999) (last modified in 2009);
- the Law on Legislation (2000);
- the Real Right Law (2007).

Chinese government can be divided into three branches—the Legislative, the Executive and the Judiciary. Unlike the “check-and-balance” system in western countries, the Legislature, which in China is the National People's Congress [NPC], has the highest power. The State Council is the highest executive agency, assisted by many departments and local agencies. The People's Courts are the judicial agents, and the People's Procuratorates are the agencies for legal supervision as well as prosecution and investigation.⁵⁰³

⁵⁰³ The People's Procuratorate's powers and functions are introduced in details in the Jian cha yuan zu zhi fa [Organic Law of the People's Procuratorates] (promulgated by the Standing Comm. Nat'l People's Cong., Sept. 2, 1983, effective Sept. 2, 1983) LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C).

All administrative agencies, courts and procuratorates are supervised by the NPC. The functions of these entities will be introduced in detail in the following sections.

1. Legislatures and Legal Effectiveness of Statutes

- a. Chinese Legislature Introduction

As mentioned previously, the NPC is the highest organ of state power. But since the NPC meets only once a year with some exceptions,⁵⁰⁴ there must be some entities to carry out the NPC's functions regarding decision making or initiating statutes when it is not in session. That organ is the Standing Committee of the National People's Congress⁵⁰⁵ [the Standing Committee], which possesses less power than the NPC.

The NPC exercises the exclusive power to enact and amend the Constitution and criminal laws,⁵⁰⁶ and maintain nonexclusive legislative power to enact statutes. It has approval and removal rights over the heads of governmental institutions and maintains control of the state budget. It is also responsible for the establishment of administrative systems and regionalization.⁵⁰⁷

⁵⁰⁴ Meetings will be held also when the Standing Committee thinks it is necessary or more than one-fifth of the deputies propose, according to Xian Fa [Constitution] art. 57 (1982) (P.R.C.) [hereinafter PRC Constitution].

⁵⁰⁵ *Id.*, art. 57.

⁵⁰⁶ *Id.*, art. 62.

⁵⁰⁷ *Id.*, art. 62. It exclusively exercises the power to elect and remove the President and the Vice-president of China, as well as the President of the Supreme People's Court and the Procurator-General of the Supreme People's Procuratorate. It also is granted the power to approve upon the nomination by the President and remove the Premier, Vice-Premiers, State Councilors, officers in charge of ministries or commissions and the Secretary-General of the State Council. In other words, the NPC has the ultimate power over election and removal of

The NPC Standing Committee [Standing Committee] is the permanent body of the NPC. It has the authority to stipulate and modify all statutes except for the Constitutional Law, to interpret all laws, and to supervise the work of the administrative agencies and the judiciary as well as other significant activities which are essential to state interests or governmental functioning.⁵⁰⁸

The NPC members are elected by lower level regional congresses, whose members are, in turn, elected by still lower level legislative bodies. Direct elections are held at the lowest tier of the People's Congress system, i.e., at a town or municipal level. Every citizen registered in a town or city over the age of 18 with political rights, has the right to vote for the deputies of that area.⁵⁰⁹ After this electoral process, the deputies of provinces, autonomous regions, municipalities, special administrative regions and the armed forces in turn are entitled to vote for the deputies to the NPC. Every minority ethnic group is entitled to appropriate representation.⁵¹⁰ The term of representation is five years.⁵¹¹ 2,987 deputies were elected to the current 11th NPC.⁵¹² The members of the NPC Standing Committee are elected by the NPC every five years. Currently, it has 176 members.⁵¹³

leaders of administrative agencies and judicial organs, promulgation of statutes and Constitution.

⁵⁰⁸ More details can be found in PRC Constitution, *supra* note 506, art. 67.

⁵⁰⁹ Quan guo ren min dai biao da hui he ge ji ren min dai biao da hui xuan ju fa [Law on Deputies to the National People's Congress and to the Local People's Congresses at Various Levels] (promulgated by the Nat'l People's Cong., Apr. 3, 1992, effective Apr. 3, 1992) art. 26 LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C).

⁵¹⁰ PRC Constitution, *supra* note 506, art. 59.

⁵¹¹ *Id.*, art. 60.

⁵¹² National People's Congress of the People's Republic of China, *Organization-National People's Congress*, available at http://www.npc.gov.cn/englishnpc/Organization/node_2846.htm (last visited Mar. 2, 2011).

⁵¹³ National People's Congress of the People's Republic of China, *Organization-Standing Committee*, available at http://www.npc.gov.cn/englishnpc/Organization/node_2847.htm (last visited Mar. 2, 2011).

The NPC and its Standing Committee have the highest, but not the exclusive, legislative authority. There are many local People's Congresses established at various levels in provinces, municipalities, counties and towns, under the guidance of the central government, with comparatively independent power.⁵¹⁴ Their authority includes enacting local regulations,⁵¹⁵ electing and removing governors, court presidents and chief procurators, and supervising the governments, courts and procuratorates at the corresponding level.⁵¹⁶ Since local congresses are elected from bottom to top rather than designated by the upper level congresses, theoretically, congresses at various levels should be independent from each other. However, the authority of congresses at lower levels is subject to the upper level congresses to some extent. For instance, the regulations they make must not contravene statutes or regulations promulgated by the NPC or the Standing Committee, and must be reported to the Standing Committee.⁵¹⁷ Local congressional members are elected either by direct election or by the People's Congress at the next lower level, or constituencies if there is no lower level of congress.⁵¹⁸ In this paper, only laws that are national in scope will be discussed.

b. Issues of the Chinese Legislative System

There are two main issues that have been questioned regarding China's governmental system. One criticism is the relationship of the Communist Party of China [CPC] to the legislative, executive and judicial bureaucracies. The CPC has an impact on legislation and administration. In China, for many

⁵¹⁴ PRC Constitution, *supra* note 506, art. 95 & 96.

⁵¹⁵ *Id.*, art. 100.

⁵¹⁶ *Id.*, art. 101.

⁵¹⁷ *Id.*, art. 100.

⁵¹⁸ *Id.*, art. 97.

years, Mr. Jiang Zemin, the former President of China, has stated that all groups, including congresses, governments, courts and procuratorates must be supervised by the CPC,⁵¹⁹ which connotes the supremacy of the CPC. In addition, the CPC has a substantial affect on the election of delegates to the NPC.⁵²⁰ As the highest entity of state power, the NPC have to follow the CPC's lead and was therefore undeniably under the control of the CPC.⁵²¹ Whether the CPC is subject to laws is questionable. The influence of the CPC on the judiciary is never described in the Constitution. Instead, the Constitution stipulates that the judicial power of the people's courts is independent from "interference by any administrative organ, public organization or individual."⁵²² Nonetheless, the fact is that the judiciary in China is always subject to the leadership of the CPC.⁵²³ A lack of check and balance may cause corruption and abuse of power.⁵²⁴

The second criticism, mainly from western countries, is China's rule-by-law instead of rule-of-law.⁵²⁵ Rule-by-law refers to "an instrument conception of law in which law is merely a tool to be used as state sees fit" while rule-of-law indicates that "law applies equally to rulers and

⁵¹⁹ JIANG ZEMIN ANALECTS, Vol. 1, 112 (2006)

⁵²⁰ Mo Zhang, *Supra* note 497, at 59

⁵²¹ *Id.*

⁵²² PRC Constitution, *supra* note 506, art. 126.

⁵²³ The Three Supremacies Doctrine, means supremacy of the business of the CCP, the interest of the people and constitutional law, was first announced by President Hu Jintao's speech at a meeting with the representatives of the National Conference on Politics and Law and judges and prosecutors in 2007. He pronounced that the cause of the CPC, the interest of people, and the legal force of the Constitution and laws should be considered the three supremacies in judicial exercise. *See Hu Jintao Emphasized to Establish Legal Practice Based on the Development of the Socilise Cause with Chinese Characteristics*, CCTV, Dec. 25, 2007, Available at http://news.xinhuanet.com/newscenter/2007-12/25/content_7312439.htm (last visited Feb. 10, 2010)(translated by author). The doctrine was emphasized in Speech at the National Teleconference of People's Courts given by President of the People's Court in 2008, Zhang Shouzeng & Li Jiahun, Let the Three Supremacies Doctrine Rooted in the Court System, Chinacourt, Aug. 18, 2008, available at <http://www.chinacourt.org/html/article/200808/15/317092.shtml> (last visited Jan. 3, 2011)(translated by author).

⁵²⁴ *Id.*

⁵²⁵ RANDALL PEERENBOOM, CHINA'S LONG MARCH TOWARD RULE OF LAW, 8 (Cambridge University 2002)[hereinafter RANDALL PEERENBOOM].

commoners alike.”⁵²⁶ Some commentators insist that China fails to meet the rule-of-law standard because the CPC still intermittently exercises extra-legal power and the CPC has large influence over the legislature and the judiciary.⁵²⁷ Others, realizing the progress that the Chinese legal system has made, classify China as in transition to rule-of-law.⁵²⁸ But, China believes that rule-of-law is determined by “national condition and social system.” China adopts a different definition for rule-of-law. According to the Chinese government, rule of law means governing a country according to law, along with the main goal of establishing a consistent, stable and authoritative system of laws, and having “laws to go by, laws that must be observed and strictly enforced, and lawbreakers prosecuted.”⁵²⁹ Based on that definition, China describes itself as a country under the rule-of-law.⁵³⁰ Meanwhile, while admitting the leadership role of the CPC, China considers that a characteristic adherent to China’s national condition.⁵³¹

The legislature, including the NPC and local people’s congresses, are only bound by the Constitution, the Electoral Law, the Organic Law of the National People’s Congress and the Organic Law of the Local People’s Congresses and Local People’s Governments, all of which are promulgated by the NPC. The Constitution is at the top of the hierarchy of legal power.⁵³² However, Article 62 of the Constitution authorizes the Standing Committee of the NPC and the NPC to propose amendments to the Constitution, and grants the NPC the power to adopt those amendments. This provision creates a paradox because

⁵²⁶ *Id.*, at 8-9.

⁵²⁷ Eric W. Orts, *The Rule of Law in China*, available at <http://law.vanderbilt.edu/publications/journal-of-transnational-law/archives/volume-34-number-1/download.aspx?id=2015> (last visited Mar. 22, 2011).

⁵²⁸ RANDALL PEERENBOOM, *supra* note 527, at 8-9.

⁵²⁹ Office of the State Council of China, *White Paper Published on China’s Rule of Law*, Chinadaily, Feb.28 2008, available at http://www.chinadaily.com.cn/china/2008-02/28/content_6494029.htm (last visited Jan.10, 2011).

⁵³⁰ *Id.*

⁵³¹ *Id.*

⁵³² Jihong Mo, *The Constitutional Law of the People’s Republic of China and Its Development*, 23 COLUM. J. ASIAN L. 137, 148 (2009) [hereinafter Mo Jihong].

it allows the legislative body the ability to amend the Constitution which is the source of the legislative body's authority.⁵³³ This contravenes one of the foundations of the modern constitution, which is that the power to establish a constitution belongs to the people while the legislative power belongs to the legislature.⁵³⁴

According to the Constitution, the congresses and the Standing Committee represent the interests of the public and the public oversees them by an election mechanism. However, whether it functions as well in practice as stated in the Constitution is questionable. Theoretically, the NPC represents the voice of the people, but it fails in practice due to the fact that the members of the NPC are indirectly elected.

The relationship between the NPC and administrative agencies often triggers questions about whether this mechanism works effectively to curb corruption and abuse of power.⁵³⁵ This system might not combat corruption or power abuse effectively because members of the NPC might not have a chance to access governmental information due to the relative non-transparency in administrative agencies, and the NPC's lack of ability to investigate.

Additionally, even during the legal reform process, unlike Europe or the United States, the Chinese legal system is not only a protector of individual rights, but also "a mechanism by which political power is exercised and protected."⁵³⁶ However, the same situation has ensued in western countries, as well. As an example, the United States, since the 911 attack, has

⁵³³ *Id.*, at 148.

⁵³⁴ *Id.*, at 148.

⁵³⁵ Chen Sheng, *Establishment of a Country under the Rule of Law*, available at http://www.jsrd.gov.cn/jsrd/qk/rmyql/2007/200704/3/200901/t20090108_38057.html (last visited Mar. 16, 2009).

⁵³⁶ Pitman B. Potter, *The Chinese Legal System: Continuing Commitment to the Primacy of State Power*, 159 PRC. Q., 674, 673-683 (1999).

proclaimed the so-called “war on terrorism,”⁵³⁷ which has put human rights at risk and created certain human-rights-violations through the use of some questionable detention and interrogation methods in the name of national security. Laws protect an individual’s rights, but also maintain the national security.

The Judicial system of China also has deficiencies. It is hard to maintain the neutrality of courts and procuratorates because of the influence of the CPC and the procuratorates’ conflicting functions. When the procuratorates play the role of prosecutor and watchdog simultaneously, it is hard for them to maintain neutrality and exercise their supervisory authority perfectly.

c. Legal Force of Statutes

According to the Constitution, which has supreme legal effectiveness, any statutes, regulations or governmental decisions that contravene this document are invalid and will be annulled by the Standing Committee, rather than the courts.⁵³⁸

Statutes promulgated by the NPC or the Standing Committee apply to either the whole country, or certain regions of the country with the exception of autonomous areas and special administrative regions.⁵³⁹ No administrative decisions, regulations, or local statutes can conflict with national statutes.

2. Administrative Agencies and Legal Effectiveness of Regulations

⁵³⁷ Paul Hoffman, *Human Rights and Terrorism*, 26 HUMAN RIGHTS Q. 932, 936 (2004).

⁵³⁸ PRC Constitution, *supra* note 506, art. 67.

⁵³⁹ For instance, Hong Kong and Macau have legislative power over economy, education, tax, science, finance and civil affairs. They also have their own legislation laws, administrative agencies and judicial system.

a. Administrative Agencies

Similar to the legislature, the executive body can also be further subdivided into national and local levels and is a vast and complex system governed by the Organic Law of the State Council, the Organic Law of the Local People's Congresses and Local People's Governments, the Law on Administrative Penalty, the Law on Public Security Administration Punishment, the Law on State Compensation, the Administrative Reconsideration Law, and the Administrative Procedure Law in general.

i. Central Administrative Agencies

The Prime Minister leads the highest executive body, the State Council.⁵⁴⁰ Its functions include adopting administrative measures and regulations to implement or supplement the Constitution and statutes, or to exercise administrative functions,⁵⁴¹ submitting proposals to the NPC and its Standing Committee, leading local executive agents by producing national economic and social development plans and state budgets and directing and providing general guidance for its subordinate agencies.⁵⁴²

The State Council is composed of the Premier, Vice-Premiers, State Councilors, the officers in charge of ministries and commissions, the Auditor-General and the Secretary-General, who are all designated by the NPC and its

⁵⁴⁰ PRC Constitution, *supra* note 506, art. 85.

⁵⁴¹ *Id.*, art. 98 and Li fa fa [Law on Legislation] (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 15, 2000, effective July 1, 2000) art. 56 LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C.) [hereinafter Legislation Law].

⁵⁴² PRC Constitution, *supra* note 506, art. 89.

Standing Committee.⁵⁴³ A single term for each office is five years, and incumbents cannot be reappointed after two successive terms. The Premier assumes overall responsibility for the State Council as director, and is assisted by Vice-Premiers and State Councilors.⁵⁴⁴

The State Council is a giant agency with many commissions that have responsibilities for respective fields. These commissions have authority to issue directives and rules within their areas of competence.⁵⁴⁵ All administrative agencies at the central level are divided by function into seventeen ministries and commissions, one special organization,⁵⁴⁶ eighteen organizations directly under the State Council, four administrative offices, fourteen institutions and ten bureaus.⁵⁴⁷

The seventeen ministries and commissions perform the basic executive functions under the direction of the State Council. They are established to handle different responsibilities, including foreign affairs, national defense, education, science and technology, industry and information technology, public security, civil affairs, justice, finance, etc. While performing their administrative functions, they also issue orders, directives and regulations to carry out the statutes and policies which the legislature and the State Council make within their respective jurisdictions.⁵⁴⁸ These documents will be not be enforced by the State Council if they conflict with the Constitution, statutes or the administrative rules and regulations, decisions and orders issued by the State Council.⁵⁴⁹

⁵⁴³ *Id.*, art. 80.

⁵⁴⁴ Guo wu yuan zu zhi fa [Organic Law of the State Council] (promulgated by the Standing Comm. Nat'l People's Cong., Dec. 10, 1982, effective Dec. 10, 1982) art. 3 LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C).

⁵⁴⁵ PRC Constitution, *supra* note 506, art. 90.

⁵⁴⁶ State-owned Assets Supervision and Administration Commission of the State Council.

⁵⁴⁷ More details could be found at http://english.gov.cn/2008-03/16/content_921792.htm (last visited Mar, 19.2009).

⁵⁴⁸ PRC Constitution, *supra* note 506, art. 90.

⁵⁴⁹ *Id.*, art. 89§13.

The only special organization directly under the State Council is called the State-owned Asset Supervision and Administration Commission. This group generally supervises state-owned enterprises and state-owned assets in other entities, as well as guiding and facilitating the reform of state-owned enterprises.⁵⁵⁰

The eighteen organizations directly under the State Council⁵⁵¹ take charge of certain specialized affairs such as customs, taxation, intellectual property, tourism and transportation. The State Intellectual Property Office is one of those organizations.

The fourteen institutions include three types of organizations with oversight functions. The Banking Regulatory Commission, organizations of special importance such as the Academy of Social Sciences, and organizations that require technical or scientific specialty, such as the Earthquake Administration are charged with these oversight duties. In fact, these institutions do not perform any administrative functions, nor have their acts governed by administrative law. Therefore, strictly speaking, they are not administrative agencies. However, because of their importance to society and economy in administration, they are organized in forms analogous to administrative agencies and under the direction of the State Council as well.

The administrative offices assist the State Council with routine paper work. They have no other specialized function.⁵⁵²

⁵⁵⁰ See State-owned Asset Supervision and Administration Commission of the State of Council, *Main Responsibility*, available at <http://www.sasac.gov.cn/n1180/n3123702/n3123717/n3162319/index.html> (last visited Mar. 18, 2009).

⁵⁵¹ Chinese Government's Official Website Portal, *Organizations directly under the State Council*, available at <http://english.gov.cn/links.htm#3> (last visited Mar. 18, 2009).

⁵⁵² Chinese Government's Official Website Portal, *Administrative Offices under the State Council*, available at http://english.gov.cn/2005-08/07/content_20958.htm (last visited Mar. 18, 2009).

Among these dozens of agencies, biotechnological research and the patentability of research results are governed by certain agencies. First, the State Council is responsible for carrying out patent law in general and stating policies and regulations on scientific research. The subordinate agencies involved include the Ministry of Health [MOH], the Ministry of Science and Technology [MOST], the State Intellectual Property Office [SIPO] and the State Administration for Industry and Commerce [SAIC].

The MOH is involved because it administers activities essential to human health, such as collecting blood and bone marrow, abortion and other activities involving the human body.

The MOST promotes, launches and supervises scientific research not only involving biotechnology but also other subjects as well. The SIPO manages the protection of intellectual property rights by carrying out the statutes including Patent Law, Copyright Law and Trade Mark Law, and drawing up regulations or guidelines for the interpretation of statutes, if necessary. SIPO also bears the duty of examining patent application, granting patents and resolving patent infringement issues. The SAIC is responsible for overseeing commercial activities and maintaining market order. Every business entity must register at the local Industry and Commerce Bureau to obtain a business license before launching its business activity. Any conduct beyond its license or detrimental to product quality will be subjected to administrative investigation and penalty or even a criminal sentence. Therefore, as long as commercialization of biotechnology materializes, companies or factories must register in the Industry and Commerce bureaus, and products and manufacturers are subject to SAIC and local branches' supervision. Any violation of statutes by business organizations will result in administrative or even criminal punishment.

Besides these managerial agencies, scientific and technical organizations are also vital for biotechnology development. The more advanced research is done, the more globally competitive the achievements will be, and therefore, the greater the potential for the results of such research to be patentable. Only if the research is conducted can the patent system play its role. The mission of conducting research rests on the shoulders of these research organizations involved. For instance, the Academy of Social Sciences not only pioneers research on philosophy and social sciences, including jurisprudential studies, but also offers a platform for exchanging and publishing academic achievements, from which one might not only discover the latest research results, but, also the fiercest debates. The Academy of Sciences conducts research in basic and technological sciences and undertakes surveys on natural resources and the environment, which direct Chinese scientific and technical research. In addition, the Academy of Engineering works to initiate and conduct scientific studies, to provide consultancy services for decision-making on key national issues in engineering and technological sciences and to promote the development and undertaking of these sciences. Although the Academy of Sciences and the Academy of Engineering are the only two organizations specializing in biotechnological research, they are also the only two academic organizations directly under the State Council's direction. It is easy to see how significantly their work influences the policy of the State Council.

One other agency is worthy of special mention. This is the Legislative Affairs Office, one of the administrative offices. The Legislative Affairs Office is not a policy-maker; nevertheless, it is essential to all the regulations promulgated by the State Council and subordinate agencies of the State Council because it proposes, drafts and also interprets regulations and rules. Although it is not a specialized agency that is charged with biotechnology and patent issues, it still plays a significant role.

There are various levels of local governments, which are the executive agencies of the congresses at the corresponding levels.⁵⁵³ They exercise executive authority by producing orders, promulgating regulations, and conducting other administrative activities.⁵⁵⁴ Unlike congresses, the governments at the upper level direct the work of all subordinate departments as well as lower level governments, with the power to alter or annul their inappropriate decisions or conflicting regulations.⁵⁵⁵

ii. Regional Level: Local Governments

The organization and function of local governments is analogous to that of the central government. The local government is composed of one general office, and several bureaus, commissions, and specialized offices. The general office, similar to the administrative office in the State Council, conducts everyday paper work and deal with logistical concerns.

There is one difference between the State Council and local government. The State Council is only subordinated to the NPC, but the local governments are under a dual supervision system. They are subject to both levels of people's congress as well as the upper level of government. Local governments are the executive bodies of local congresses, so they are subject to the supervision of local congresses.⁵⁵⁶ Meanwhile, because there are corresponding agencies in the upper and lower administrative levels, the upper agencies are entitled to supervise the activities of the lower agencies. One example is that the upper agencies can review the adjudications made by

⁵⁵³ PRC Constitution, *supra* note 506, art. 105.

⁵⁵⁴ *Id.*, art. 107.

⁵⁵⁵ *Id.*, art. 108.

⁵⁵⁶ *Id.*, art. 110.

the lower agencies based on a request for administrative reconsideration made by citizens, legal entities or any other organization.⁵⁵⁷

There are some exceptions to the dual-supervision system. The eighteen organizations mentioned above are exclusively supervised under the State Council. Because some affairs are so essential and vital to the national economy, for example, customs, foreign exchange, taxation, and intellectual property rights, they need to be unified across the state and taken under direct control of the central government to avoid any intervention from local congresses.

The patent agency is different. The patent administration system is not vertical like the other seventeen organizations mentioned above. The local Intellectual Property Offices are subordinate to the corresponding local congress as part of local agencies, but they have very limited authority and no authority over patent examination or review. The state Intellectual Property Office is the only agency that accepts and examines patent applications,⁵⁵⁸ defines the scope of patent rights and the patentable subject matters and determine patent infringement by interpreting statutes or drawing up and implementing regulations and rules.⁵⁵⁹ Thus, it exclusively controls the pathway to patent. Local patent agencies, under authorization of the State Intellectual Property Office, are entitled to provide patent consultations, deal with patent infringement disputes and other administrative services concerning patents, but are incapable of granting a patent.⁵⁶⁰ The reason for this pattern is that due to the nation-wide

⁵⁵⁷ Xing zheng fu yi fa [Administrative Reconsideration Law] (promulgated by Nat'l People's Cong., Apr. 29, 1999, effective Oct. 1, 1999) art. 6 LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C).

⁵⁵⁸ 2008 Patent Law, *supra* note 7, art. 28.

⁵⁵⁹ More details about State Intellectual Property Office could be found at SIPO's website, *available at* http://www.sipo.gov.cn/sipo_English/ (last visited Oct. 21, 2010)

⁵⁶⁰ More details *see* Regulations on Management of Patent Agencies of State Intellectual Property Office's website, *available at*

effectiveness of patents, it is necessary to unify the standards and requirements for patents in order to prevent unfairness and injustice.

However, this system does not work efficiently because central control of patent application means that all applicants must submit their application forms directly to SIPO, which is extremely inconvenient for applicants considering the vast territory of China. To solve this practical problem, SIPO sets up patent application receiving offices at Intellectual Property offices at provincial levels, to perform certain duties of SIPO, such as receiving application documents and fees. So far, 26 receiving offices have opened across the country since 1985, which have accepted more than 2/3 of the patent applications.⁵⁶¹ However, SIPO is still the only agency to examine claims and issue patents.

Nevertheless, the receiving offices cannot replace the role of SIPO in patent application. First, the receiving offices have restricted jurisdiction. They are only available for national residents of China, not for foreigners or legal entities from Taiwan, Hong Kong and Macau. Therefore, all foreign enterprises or other foreign organizations, whether having habitual residences or business offices in China or not, must submit applications directly to the state Intellectual Property Office in Beijing, in person or through the Internet. The only difference between foreigners with residence or offices in China and those who are not is that the latter must appoint a patent agency designated by the state to process applications,⁵⁶² while the former can apply in person. Second, the receiving offices do not accept

http://www.sipo.gov.cn/sipo2008/zcfg/flfg/zl/bmgfxwj/200804/t20080415_375839.html (last visited Oct. 21, 2010)(translated by author)

⁵⁶¹ National People's Congress, *SIPO: 26 Receiving Offices over the Country*, available at http://www.npc.gov.cn/npc/xinwen/fztd/yfzx/2008-12/15/content_1462016.htm (last visited Mar. 2, 2011)(translated by author)

⁵⁶² 2008 Patent Law, *supra* note 7, art. 19.

priority applications, or Patent Cooperation Treaty [PCT] applications.⁵⁶³ These applications can only be accepted by SIPO. Third, the receiving offices are not widespread. Compared to 34 municipalities and provinces, there are 8 provinces that have not established receiving agencies. How do people in these 8 regions process patent applications? They must either submit materials online, or turn to receiving agencies in other regions. However, most of the regions without receiving agencies are comparatively poverty-stricken, where the Internet is not widespread, and a patent application is time-consuming for applicants.

b. Legal Effectiveness of Regulations

As mentioned above, administrative regulations or rules must not contravene any statute promulgated by the NPC or the Standing Committee. Administrative rules created by departments or commissions must not contravene regulations of the State Council. All regulations or rules made at the national level direct the local regulations.

The State Council has the right to alter or annul inappropriate orders, directives, regulations and rules issued by ministers, commissions or state administrative agencies at various levels.⁵⁶⁴ In other words, statutes or regulations enacted by the upper level administrative agencies have stronger effectiveness.

3. Chinese Judicial System and Legal Force of Judicial Decisions

⁵⁶³ State Intellectual Property Office of PRC, *The Scope of Application Accepted by the Receiving Offices*, available at http://www.sipo.gov.cn/sipo2008/zldbc/zldbcgk/200804/t20080402_367776.html (last visited March 13, 2009)(translated by author).

⁵⁶⁴ PRC Constitution, *supra* note 506, art. 89 §13 &14.

a. Court System Hierarchy

According to the Constitution, the courts are judicial agents.⁵⁶⁵ There are four layers of courts: the Supreme People's Court, High People's Courts at the provincial level, Intermediate People's Courts at the municipal level⁵⁶⁶ and Basic People's Courts at the town or county level. Courts exercise judicial power independently and are not subject to interference by any administrative agents or public organization.⁵⁶⁷ However, courts are not independent from people's congresses. As stated in the Constitution, the Supreme Court is responsible to the National People's Congress and its Standing Committee; local people's courts at different levels are responsible to the corresponding organs of state power,⁵⁶⁸ which means local people's congresses. Theoretically speaking, courts are not supervised or reviewed by the people's congress. However, because congresses are the most powerful organs, in practice, their policies or attitudes may influence the decisions of courts in an indirect way.

All judicial decisions can be appealed to the next level in the judicial system, except that the decisions rendered by the Supreme Court are final and unappealable.⁵⁶⁹ The upper courts also have the authority of instruction of retrial.⁵⁷⁰

⁵⁶⁵ *Id.*, art. 123.

⁵⁶⁶ Special courts including military courts, maritime courts and railway transportation courts, are established because of their specific jurisdiction. All military, maritime and railway issues are hardly confined to certain regions, therefore, states sets up special courts to avoid conflict of jurisdiction. They are considered as the same level as Intermediate People's Court.

⁵⁶⁷ PRC Constitution, *supra* note 506, art. 126.

⁵⁶⁸ *Id.*, art. 128.

⁵⁶⁹ Fa yuan zu zhi fa [Organic Law of the People's Court](as Amended in 2006) (promulgated by the Standing Comm. Nat'l People's Cong., Oct. 31, 2006, effective July 1,

Each court level has its own jurisdictions. For instance, death penalty judgment must be reviewed by the Supreme Court before they take effect;⁵⁷¹ the Basic People's Courts have no jurisdiction over custom or patent right disputes.⁵⁷²

The constitution provides that the People's Procuratorates are state organs of legal supervision and prosecution.⁵⁷³ The procurator offices are implemented in several different layers of the administration hierarchy.⁵⁷⁴ The highest level of the procurator offices is the Supreme People's Procuratorate which is tasked with supervising and directing the work of the lower level offices.⁵⁷⁵ Each office has a procuratorial committee which is expected to institute the system of democratic centralism and discuss important cases. The role of these committees can loosely be compared with that of a legal consultant group.

Procuratorates functions include exercising procuratorial authority; reviewing cases investigated by the public security organs and deciding whether to prosecute; investigating cases involving graft, infringement of citizens' democratic rights or dereliction of duty and deciding whether to initiate prosecution; supervising criminal trials in the courts; reviewing verdicts, sentences and the execution of sentences in criminal cases to

1979) art. 12, LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C)[hereinafter Organic Law of Court]

⁵⁷⁰ *Id.*, art. 14.

⁵⁷¹ Xing shi su song fa [Criminal Procedure Law] (promulgated by the Nat'l People's Cong., Apr. 4, 1989, effective Oct. 1, 1990) art. 199 LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C); and Zui gao fa yuan guan yu fu he si xing an jian ruo gan wen ti de gui ding [Provisions of the Supreme People's Court on Several Issues Concerning the Review of Death Penalty Cases] (promulgated by the Supreme People's Court, Feb. 27, 2007, effective Feb. 28, 2007) LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C).

⁵⁷² Xing zheng su song fa [Administrative Procedure Law] (promulgated by the Nat'l People's Cong., Apr. 4, 1989, effective Oct. 1, 1990) art. 14 LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C)[hereinafter Administrative Procedure Law].

⁵⁷³ PRC Constitution, *supra* note 506, art. 129.

⁵⁷⁴ *Id.*, art. 130.

⁵⁷⁵ *Id.*, art. 132.

determine whether they conform to the law; and exercising supervision over civil trials of civil suits and administrative litigation in the courts.

However, this system has some deficiencies. One concerns the functions of the procuratorate department. It is highly doubtful if the procuratorate can maintain a neutral position while functioning as a prosecutor and a supervisor at the same time. However, there is no sign of change on the system in the short term. Another concern is the internal influence on the judicial decision-making process. Other judges and even higher courts may review the judgment before they are issued⁵⁷⁶ in order to minimize conflicts between judicial decisions and the possible reversal later. In that sense, the people's courts closely resemble a hierarchy rather than being operated as independent agencies.⁵⁷⁷ A third concern is the external impact on the judiciary system. The impact of the media and public voice as well as the pressure from higher-level courts and the CPC on the judiciary is also criticized.⁵⁷⁸ It not only distracts courts from applying laws as the sole base of their judgment, but also sends the public the message that courts "are easily manicured."⁵⁷⁹ The CPC also has influence on judicial independence since most of the senior judges are members of the CPC.⁵⁸⁰ These external impacts need to be removed to ensure the independence of the judiciary. A fourth criticism concerns the immense gap of legal professional levels between developed areas such as Shanghai and Beijing, and underdeveloped regions such as small the cities in Western China.⁵⁸¹ This situation has been improved by stipulating some minimum qualifications for judges including

⁵⁷⁶ David T. Wang, *Improving Arbitration Award Enforcement by Establishing A Federal Court System*, 48 SANTA CLARA L. REV. 649, 652 (2008)[hereinafter T. Wang].

⁵⁷⁷ *Id.*, at 652.

⁵⁷⁸ Benjamin L. Liebman, *Assessing China's Legal Reforms*, 23 COLUM. J. ASIAN L. 17, 24 (2009) [hereinafter Liebman].

⁵⁷⁹ *Id.*, at 24-25.

⁵⁸⁰ Jerome A. Cohen, *Reforming China's Civil Procedure: Judging the Courts*, 45 AM. J. COMP. L. 793, 797 (1997)

⁵⁸¹ Liebman, *supra* note 580, at 27.

receiving professional training, falling within an age range, and passing the legal qualification exam.⁵⁸²

b. Force of Judicial Interpretation and Judicial Decisions

The NPC and the Standing Committee have authority over the interpretation of laws. However, sometimes courts will still find some vague or ambiguous language in laws when they are applied in practice. In that situation, the trial court will submit the specific issue concerning the law application to the upper court until it reaches the Supreme Court, which is the only court with judicial interpretation power. Judicial interpretation issued by the Supreme People's Court is binding.⁵⁸³

B. Laws on Human Embryonic Stem Cell Research, Patent and Embryonic Stem Cell Inventions

1. Legal Documents on Human Embryonic Stem Cell Research

a. International Conventions

In 2005, the UN General Assembly, in its 59th general assembly, passed the United Nations Declaration on Human Cloning. China voted against the Declaration. Since this is a political announcement, it has no legal force. China

⁵⁸² T. Wang, *supra* note 578, at 662-663.

⁵⁸³ Zui gao ren min fa yuan guan yu si fa jie shi gong zuo de gui ding [Provision of the Supreme People's Court on the Judicial Interpretation Work] (promulgated by the Supreme People's Court, Mar. 23, 2007, effective Apr. 1, 2007) art. 5 LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C.) [Judicial Interpretation Work].

insisted on supporting therapeutic cloning while opposing reproductive cloning. After this vote, China stated:

Different countries varied in their understanding of the text's inherent moral, ethical and religious aspects, and it was regrettable that the Declaration failed to give effect to the concerns of those countries. The prohibitions contained in the text could be misunderstood as covering all forms of cloning. Having voted against the Declaration, the Chinese Government would continue to adhere to its position against reproductive human cloning, while maintaining strict controls over therapeutic cloning.⁵⁸⁴

b. Chinese Law on Human Embryonic Stem Cell Research

The Chinese government's support for hESC research reflects on domestic laws and policy. There is no law explicitly manifesting China's advocacy of hESC research. However, the attitude is represented in many government documents.

i. Eleventh Five-year Plan

In the Eleventh Five-year Plan, promulgated in 2006 by MOST, it is disclosed that one goal is to establish a human embryonic stem cell bank, as well as a bank for non-human primate stem cells. It also recommends establishing a model of embryonic stem cells differentiation and promoting research on both tissue engineering and animal cloning. However, as it is promulgated by an administrative agency, this plan has lower legal

⁵⁸⁴ G.A. Reg. 59/280, *supra* note 200.

effectiveness than other legal documents. Especially considering that it is a national plan rather than a regulation, it is more advisory than enforceable. There is no punishment for violation, either.

ii. Ethical Guiding Principles for the Research of Human Embryonic Stem Cell (2004)

In the Ethical Guiding Principles for the Research of Human Embryonic Stem Cells, disseminated by MOST and MOH in 2004, is a guideline for hESC research under internationally recognized ethical criteria and Chinese specific conditions, in order to promote healthy development of hESC research. According to the Principles, the hESC mentioned include stem cells originated from human embryos, stem cells originated from germ cells and those obtained by SCNT.

It regulates only four methods of obtaining hESCs: from a surplus gamete or blastocyst created from in vitro fertilization, from a miscarried or aborted fetus, from a blastocyst produced by SCNT, or from donated germ cells.⁵⁸⁵

During hESC research, some rules apply. For instance, a blastocyst used in the research shall not be kept for more than 14 days, nor shall a blastocyst be implanted into any human being or other animal.⁵⁸⁶ No purchase of germ cells, zygotes, embryos or fetal tissues is allowed.⁵⁸⁷ All personnel involved must be notified of all potential risks.⁵⁸⁸

⁵⁸⁵ Ministry of Science and Technology of the P.R.C., *Ethical Guiding Principles for the Research of Human Embryonic Stem Cell* (2004) Art.8, available at http://www.most.gov.cn/fggw/zfwj/zfwj2003/200512/t20051214_54948.htm (last visited Feb.23, 2011) (translated by author) [hereinafter Ethical Guiding Principles].

⁵⁸⁶ *Id.*

⁵⁸⁷ *Id.*

⁵⁸⁸ *Id.*

However, the Principles do not introduce any punishment clause. Therefore, what penalty will be imposed for activities violating the Principles is unknown at this time.

2. Chinese Patent Laws regarding hESC Inventions

a. Current Patent Law (2008)

The first Patent Law entitled Provisional Regulation on the Protection of the Invention Right and the Patent Right was issued in 1950, but the state owned these inventions.⁵⁸⁹ During the Cultural Revolution from 1966 to 1975, patent rules hardly functioned.⁵⁹⁰ A new modern Chinese patent law was adopted by the Standing Committee of National People's Congress on March 12, 1984, and became effective on April 1, 1985. The patent law was amended in 1992, in order to carry out the Memorandum of Understanding signed by the United States and China in 1992,⁵⁹¹ which commits China to provide improved protection in the patent, copyright and trade secret areas.⁵⁹² A second amendment was made in 2000, to implement the obligations committed to in WTO accession.⁵⁹³

Different from the first two amendments, which were forced by relations with countries and international organizations, the latest revision of the Patent Law, which was adopted in 2008 and became effective on October 1,

⁵⁸⁹ Louis S. Sorell, *A Comparative Analysis of Selected Aspects of Patent Law in China and the United States*, 11 PAC. RIM L. & POL'Y J. 319, 321 (2002).

⁵⁹⁰ *Id.*

⁵⁹¹ Joy Y. Xiang, *How Wide Should the Gate of "technology" Be? Patentability of Business Methods in China*, 11 PAC. RIM L. & POL'Y J. 795, 802 (2002)[hereinafter Xiang].

⁵⁹² Trade Compliance Center, People's Republic Of China Intellectual Property Rights Memorandum Of Understanding—1992, *available at* http://tcc.export.gov/Trade_Agreements/All_Trade_Agreements/exp_005362.asp (last visited Mar. 22, 2011)

⁵⁹³ Xiang, *supra* note 593, at 802.

2009, occurred due to the internal needs of China. This amendment aimed at raising the bar of novelty requirement⁵⁹⁴ and improving the protection of human genetic resources. It was intended to advance the development of scientific research and lead to a transition of China's economy from technology import model to technology innovation model.⁵⁹⁵ Among the total 76 articles, the following articles are worthy of attention.

Article 2 classifies and defines three categories protected under Patent Law: invention, utility model and design. Invention is a "new technical solution relating to a product, a process or an improvement thereof"; utility model is a "new technical solution relating to a product's shape, structure, or combination, which is fit for practical use"; and design means a "new design of the product's shape, pattern, or combination, as well as color, pattern and combination, which is aesthetic and fit for industrial application."

Article 5 contains the general principle of exclusions from patentability of inventions that are contrary to national laws, social morality or anything that is detrimental to the public interest; any inventions relying mainly on genetic resources, for which said genetic resources are illegally obtained, may not be patented.

Article 25 further states that six kinds of subject matters cannot be patented:

- (1) scientific discoveries;
- (2) rules and methods for mental activities;
- (3) methods for the diagnosis or for the treatment of diseases;

⁵⁹⁴ The standard transfers from relative novelty standard towards absolute novelty standard. The definition of "prior Art" is broadened to include public use or other disclosure, besides publication outside China, which was only referred to publication within China. This change enhances the threshold of patentability. Although it may bring challenges to domestic industry, which has in to fact international patent competition, it reduces the cost of repeating investment, and advancing the quality of the patent.

⁵⁹⁵ 2008 Patent Law, *supra* note 7, art. 1

- (4) animal and plant varieties;
- (5) substances obtained by means of nuclear transformation;
- (6) identifying design, color or combination for printed matter.

For processes used in producing products referred to in items (4) of the preceding paragraph, patent right may be granted in accordance with the provisions of this Law.

This law excludes some categories from being patented as general principles. It does not preclude human body specifically, which leaves this category unclear.

The revised patent law modifies the requirements of patenting. There are still three conditions—novelty, inventiveness and practical applicability, but with different definitions. Novelty means the invention has not been disclosed in the prior art, nor a priority claimed before the filing date. Inventiveness means that compared to the technology existing in the prior art, the new invention has prominent substantive features and represents notable progress. Practical applicability means the invention can be made or used in manufacture with effective results. The revised Article 22 adds the definition of prior art, which means any publicly known technology in the country or abroad before the filing date. This clause enhances the requirement of novelty and inventiveness and broadens the scope of prior art.⁵⁹⁶

However, Article 24 introduces an exemption clause to novelty requirement, which gives a six-month grace period to a patent which loses its novelty before the filing date, when it was first exhibited at an international exhibition recognized by the Chinese government, first made public at an academic or technological meeting or disclosed by another person without consent.

⁵⁹⁶ Before the revision, the prior art only referred to technology disclosed in publications in the country or abroad, or publicly used or made known to the public in the country.

Patent applications must be filed with a request form, a written description, an abstract and claims,⁵⁹⁷ and a claim of right of priority if there is one.⁵⁹⁸

All applications must progress through a preliminary (format) examination and substantial (content) examination. After preliminary examination, the application will be published.⁵⁹⁹ During the substantive examination, the patent office will inspect the application's novelty, inventiveness and practical applicability, then reject the application or grant the patent right.⁶⁰⁰

Once a patent is granted, the duration of patent right, which is 20 years, tracks back to the filing date.⁶⁰¹ Any individual or entity which does not agree with the result may appeal to the Board of Patent Appeals and Interferences [BPAI] and request that the patent to be annulled.⁶⁰² Any party (either the applicant or the appellant) who is dissatisfied with the BPAI decision may bring a lawsuit to the courts within three months of receipt of the notification.⁶⁰³ Any decision declaring a patent invalid relates back to the time of its issue.⁶⁰⁴ However, the invalidation of a patent has no retroactive effect on any patent infringement judgment or performed contract, though the patentee must compensate third parties for damages suffered.⁶⁰⁵

⁵⁹⁷ 2008 Patent Law, *supra* note 7, art. 26.

⁵⁹⁸ *Id.*, art. 29. It says that the international priority only exists when it is regulated in any agreement, international treaty or under the principle of reciprocity. Right of priority shall be claimed within twelve months from the date on which patent applicant filed in a foreign country. There is also a domestic priority, which provides that within twelve months from the date on which any application of invention or utility models was filed, the applicant has the priority right to apply for new invention or utility models application on the same subject matters and basis of previous application.

⁵⁹⁹ *Id.*, art. 34.

⁶⁰⁰ *Id.*, art. 38, 39.

⁶⁰¹ *Id.*, art. 42.

⁶⁰² *Id.*, art. 45.

⁶⁰³ *Id.*, art. 46.

⁶⁰⁴ *Id.*, art. 47(1).

⁶⁰⁵ *Id.*, art. 47(2).

In addition, the revised patent law added additional circumstances under which compulsory licenses may be ordered for patented drugs. There are three types of licenses: qualified compulsory license,⁶⁰⁶ domestic emergency compulsory license⁶⁰⁷ and cross compulsory license.⁶⁰⁸ The patent administrative department may also grant a compulsory license for manufacturing and exporting drugs patented in China to designated countries or regions, which include least-developed countries, or WTO member countries or regions with no or insufficient capacity to manufacture the patented drug, if the public health interest in those countries so requires.⁶⁰⁹

Any patent infringement disputes may be solved by negotiation or litigation.⁶¹⁰ Trial judgment is appealable.

There are five exceptions to patent infringement: exhaust of patent right, prior use exemption, temporary transport, scientific research and products for examination or approval.⁶¹¹

⁶⁰⁶ *Id.*, art. 48, Where any entity which is qualified to exploit the invention or utility model has made requests for authorization from the patentee of an invention or utility model to exploit its or his patent on reasonable terms and such efforts have not been successful within a reasonable period of time, the patent administrative department of the State Council may, upon the application of that entity, grant a compulsory license to exploit the patent for invention or utility model.

⁶⁰⁷ *Id.*, art. 49, Where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires, the patent administrative department of the State Council may grant a compulsory license to exploit the patent for invention or utility model.

⁶⁰⁸ *Id.*, art. Article 51, Where an invention or utility model for which the patent right was granted has major technical progress of prominent economic significance when compared with another invention or utility model for which the patent right has been granted earlier, and the exploitation of the later invention or utility model depends on the exploitation of the earlier one, the patent administrative department of the State Council may, upon the request of the later patentee, grant a compulsory license to exploit the earlier invention or utility model. Where, according to the preceding paragraph, a compulsory license is granted, the patent administrative department of the State Council may, upon the request of the earlier patentee, also grant a compulsory license to exploit the later invention or utility model.

⁶⁰⁹ *Id.*, art. 50.

⁶¹⁰ *Id.*, art. 60.

⁶¹¹ *Id.*, art. 69.

Patent exhaustion means that after a product that is patented or directly obtained from a patented processes sold by the patentee or with the permission of the patentee, anyone can resell or import the product to China without infringing the patent right. This means that as long as a patented product is sold, the patent right on that product exhausts.

Unlike the United States, China has adopted the first-to-file principle, which means that no matter who practices an invention first, whoever files the application first acquires the patent. It would seem unfair to those individuals who generated the idea first,⁶¹² but it enhances the administrative efficiency and certainty of the patent holder.⁶¹³ In order to mitigate the unfairness to the first creator, the patent law provides the users before the filing date a grace period.⁶¹⁴ In addition, people who made the same products, practiced the same methods, or even made necessary preparations before the filing date are still entitled to make such products or use such processes within their original scope of use.⁶¹⁵

The research and experimental use exception to patent infringement is important to stimulate scientific development while maintaining patent protections generally. Under this exception, any person who uses a patent solely for the purposes of scientific research and experimentation will not be liable for patent infringement.⁶¹⁶ A broad scope for this exception protects a

⁶¹² Michael A. Van Lente, *Building the New World of Nanotechnology*, 38 CASE W. RES. J. INT'L L. 173, 214 (2006).

⁶¹³ Brad Pedersen & Vadim Braginsky, *Recent Development: The Rush to a First-to-File Patent System in the United States: Is a Globally Standardized Patent Reward System Really Beneficial to Patent Quality and Administrative Efficiency?* 7 MINN. J.L. SCI. & TECH. 757, 564 (2006).

⁶¹⁴ Jeffrey A. Andrews, *Pfizer's Viagra Patent and the Promise of Patent Protection in China*, 28 LOY. L.A. INT'L & COMP. L. REV. 1, 18 (2006).

⁶¹⁵ *Id.*, art. 69 (2).

⁶¹⁶ See Katherine J. Strandburg, *What Does The Public Get?: Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81 (2004).

patentee's exclusive right to commercialize his patent while encouraging scientific and technologic innovation.⁶¹⁷

Any person convicted by effective judgment of patent infringement will have an administrative penalty imposed,⁶¹⁸ be required to pay compensation under the Patent Law, and incur other civil or criminal penalties in accordance with other statutes. Judicial decisions must be enforced. The Civil Procedure Law (2007) and Criminal Procedure Law (1996) have specific chapters on enforcement or compulsory enforcement, and impose penalties for failure to comply, which could be fines, detention or criminal liability.

One of the patent infringement cases relevant to biotechnology patents is that of *Eli Lilly and Com. v. Gan Li Med. Co., Ltd.*⁶¹⁹ This case involved a patent that claimed a process for producing pharmaceutical preparations containing insulin analogues. The process consisted of mixing Type (I) insulin analogues or medicinal salts having therapeutic properties with one or more kinds of medicinal excipient vehicles or carrier. The patent was issued by SIPO to Eli Lilly and Company ("ELI") on March 26, 2003, with the patent number of 961066350, and was effective at the time of the trial. In 2002, the Gan Li Medicine Co. Ltd (the "GAN LI") submitted a registration application for a new product called "Two Phase recombinant Insulin Lispro Injection 75/25 " to the State Food and Drug Administration [SFDA]. It was given approval for clinical study by the SFDA on January 23, 2003, but was not issued approval to register the new medicine during the study. In accordance with descriptions of the preparation in GAN LI's application data, the active components in the new medicine developed by GAN LI were Insulin Lispro

⁶¹⁷ Kevin Sandstrom, *How Much Do We Value Research and Development?: Broadening the Experimental Use Exemption to Patent Infringement in Light of Integra Lifesciences Ltd. v. Merck*, 30 WM. MITCHELL L. REV. 1059, 1106 (2004).

⁶¹⁸ The administrative penalty includes confiscating illegal income and fine.

⁶¹⁹ *Eli Lilly and Com. v. Gan Li Med. Co., Ltd*, available at <http://bjgy.chinacourt.org/public/paperview.php?id=26943> (Beijin Interim. People's Ct., Aug 20, 2007)(translated by author)

with medicinal excipient vehicles or carriers including distilled water, hydrochloride, zinc oxide, glycerol, m-cresol, phenol, disodium hydrogen phosphate and protamine sulfate. GAN LI promulgated introductory materials concerning the aforesaid new medicine on its website <http://www.ganli.com>.

ELI claimed that the active component of GAN LI's medicine was Insulin Lispro with certain carriers which were contained and revealed in the patent possessed by ELI; GAN LI had obtained the approval for clinical study for the aforesaid medication and propagandized the medicine through the internet, which should be deemed to constitute the behavior of imminent infringement and offering for sale, infringing ELI's patent. GAN LI denied any patent infringement.

The court held that ELI's patent was effective and under the protection of the Patent Law. However, GAN LI's disputed medicine was in the application process for registration, and had not yet coming onto the market. GAN LI's behaviors—initiating a clinical study and filing an application for production approval—were meant to meet the medicinal registration requirements of the SFDA, and were not for the purpose of making profits by direct sale, and, therefore, were not deemed to be patent infringement under Article 69 of Patent Law. Nor was propagandizing the new medicine recognized as the behavior of offering for sale. Thus, the court denied ELI's claim for patent infringement.

In summary, the Patent Law introduces general ideas and principles of the patent mechanism, including definitions of invention, patentable subject matters, and the requirements for patenting—novelty, inventiveness and utility. It is also the primary source of law addressing the patentability issue of biotechnological inventions, especially hESC research results. It does not explicitly outlaw the patenting of hESCs and the preparation processes

thereof. However, there are so many undefined words in the statute that other documents must be referred to in these situations.

b. The Detailed Rules for the Implementation of the Patent Law (2010)

The Detailed Rules for the Implementation of the Patent Law [Detailed Rules], promulgated by the State Council, is an implementing guideline for the Patent Law. It further explains vague and ambiguous language or fills in the loopholes in the statute. It also regulates more details of the procedure of patent examination and approval, for instance, the conditions of circumvention,⁶²⁰ documents required for reexamination of an application,⁶²¹ and documents required for requesting a compulsory license.⁶²²

Article 10 explains Article 5 of the Patent Law regarding the unpatentability of certain inventions that are contrary to national laws or social morality, or detrimental to the public interest. It states that Article 5 only applies to the inventions themselves, but not the use of them that violates the law. In other words, Article 5 only precludes the patentability of inventions with illegal purposes; for instance, a method or instrument to counterfeit bills. Inventions that have both legal and illegal applications, depending on what the original use is, may still be patentable according to Article 5. Some chemical substances could be used in medical treatment, but also in drug addiction. Their legitimacy depends on the situation in which they are used. Therefore, they do not fall into the category of Article 5 and

⁶²⁰ 2008 Patent Law, *supra* note 7, art. 37.

⁶²¹ *Id.*, art. 65

⁶²² *Id.*, art. 73

are patentable. Article 10 is further explained in Section 3 of the Examination Guidelines.

Article 44 illuminates the preliminary examination. To survive this stage, an application must disclose patentable subject matter, it must be submitted with required documents, and other procedural requirements must be met.

Conditions for dismissing patent applications during substantive examination are specified in Article 53, including lack of novelty, unclear claim scope, broadened amendment beyond the scope of the description and claims and so forth. Generally speaking, the Detailed Rules are a guidebook for patent offices to use in applying Patent Law during patent examinations.

By analyzing these rules, one cannot deny that hESCs' preparation processes fall into the scope of invention, which is defined as a "technical solution concerning product, process or improvement." It is also clear that the law violation clause by narrowing its application, so that it only applies to inventions with illegal purposes rather than merely illegal potential uses. It is a subjective standard. The reason may be that since Article 5 is an exemption clause of Patent Law, it should apply narrowly.

By this interpretation, hESC research does not violate any law, and the results of such research constitute patentable subject matter because the purpose of hESCs research is to save people by curing heretofore incurable diseases. No one would deny that the original intention of hESCs research is to develop valuable cures in good faith. Although some people object that it potentially kills human beings due to the personhood of a blastocyst, or that its application is immoral as it might be abused to clone human beings. People are worried more about the application of hESCs than the intention.

Besides Article 5, an invention needs to satisfy other requirements of the Patent Law to be patented.

c. Examination Guidelines (2006)

The Examination Guidelines is a guidebook stipulated by SIPO, for patent offices to carry out their functions more effectively by answering questions patent offices have encountered while applying Patent Law and Detailed Rules. Since the Examination Guidelines is promulgated by SIPO, a department under the State Council, the legal force of it is lower than the Patent Law and Detailed Rules. The authority clause for the Examination Guidelines is Article 121 of the Detailed Rules that the patent administrative agency created in accordance with Patent Law and Detailed Rules. The 2006 version is the latest version. But, a new version is expected to be delivered due to the implementation of the new Patent Law.

There are five parts in the Examination Guidelines. Part 1 covers preliminary examination, Part 2 covers substantive examination, Part 3 covers examination of international applications entering China, Part 4 covers reexamination procedure, and Part 5 covers processing and procedural matters of patent application.

i. Part 1 of the Examination Guidelines

The first part of the Examination Guidelines addresses the principles, procedures, and document requirements for patent application covering utility models and design, as well as classification. Different rules apply to different categories, for instance, inventions and utility models enjoy longer patent right periods than designs, and in their application documents, even substantive requirements are different. Sometimes the lines between the

three categories are vague, and therefore, the classification is essential to both applicants and patent examiners. The classification of designs is dealt with in Chapter 3 of the same part. Therefore, Chapter 4 is only about the classification of inventions and utility models. The classification scheme helps to establish properly categorized patent application files for patent researching, and distributes patents into corresponding examination departments for more efficient work.⁶²³

Generally speaking, the classification should be based on the invention's technical subject,⁶²⁴ which is determined by the claims, descriptions and drawings if they are present.⁶²⁵ The technical subjects could be products, apparatus, or the processes used or created.⁶²⁶ In determining the classification, the technical subject shall be determined as a whole⁶²⁷ by function or application or both.⁶²⁸

ii. Part 2 of the Examination Guidelines

Chapter 1 deals with unpatentable subject matter. Rule 2.1 in Chapter 1 clarifies the scope of invention defined in Article 2 of the Detailed Rules. It emphasizes that an invention must adopt a technical means to solve a technical problem and achieve a technical effect. Any solution without technical means cannot constitute the subject matter of a patent. It also states that smell, signal or energy is not patentable.

⁶²³ State Intellectual Property Office of P.R.C, *Examination Guidelines (2006)*, Part 1, Chapter 4, Rule 1, available at <http://www.sipo.gov.cn/sipo2008/zlsqzn/scz/> (last visited Apr. 17, 2010) [hereinafter 2006 Examination Guidelines].

⁶²⁴ *Id.*, Chapter 4, Rule 2.

⁶²⁵ *Id.*, Part 1, Chapter 4, Rule 3.2.

⁶²⁶ *Id.*, Part 1, Chapter 4, Rule 3.1.

⁶²⁷ *Id.*, Part 1, Chapter 4, Rule 4.1.

⁶²⁸ *Id.*, Part 1, Chapter 4, Rule 4.2.

Rule 3 reiterates the unpatentable subject matter under Article 5 of the Patent Law, as “contrary to national laws, social morality or that is detrimental to public interest,” and Rule 3.1 to Rule 3.4 further define the scope of the terms national laws, social morality and public interest. Because Article 5 is essential to this article, Rule 3.1 to 3.4 will be introduced in detail.

Rule 3.1 defines national laws, which means statutes promulgated by the NPC and the Standing Committee except administrative regulations. Any invention contrary to the laws is not granted a patent, such as gambling facilities, devices or instruments, drug-taking appliances, and apparatus for counterfeiting currencies, official documents, certificates, seals or others. But any invention with a legal purpose whose application may be contrary to laws is still patentable. Examples would be intoxicants, anesthetics, sedatives and analeptics.

Rule 3.2 refers to social morality as rules generally recognized and accepted by the public in China. It depends on the cultural background and changes with time and social progress. Certain anti-social morality inventions include an artificial sexual organ or its substitute not for medical use, a method of mating a human with an animal, a process for modifying the germ line genetic identity of human beings or a human modified, a cloned human being or a process for cloning human beings, and use of human embryos for industrial or commercial purposes. These inventions should be not granted patents under the Patent Law.

Rule 3.3 exemplifies the inventions detrimental to public interests, which cause harm to the public or society or disrupt the order of the State and society, such as an invention that may severely pollute the environment or waste energy or resources.

Any invention partially contravening Article 5 will be requested to amend or delete the contravening part; otherwise the whole invention must be denied patent protection.⁶²⁹

Rule 4.1 to 4.5 further interprets the five⁶³⁰ categories of unpatentable subject matter under Article 25 of the Patent law. It differentiates invention from discovery by inputting intervention by human beings. It also exemplifies mental activities as thinking movements, such as traffic rules, schedules, competition rules, business methods, calculation methods, methods of editing a dictionary, searching information or classifying books and computer programs.⁶³¹ Diagnostic methods or disease treatments are not patentable for ethical reasons. Besides, those methods or treatments that are utilized on humans or animals tend to be unsuited for industrial application.⁶³² But Rule 4.3.1.2 precludes the patenting of certain inventions that are not diagnostic methods, including methods of pathological anatomy practiced on dead humans or animals, and methods with the purpose of obtaining information from the testees or processing such information. Rule 4.3.2.1 exemplifies diseases treatments, and Rule 4.3.2.2 exemplifies inventions not constituting methods of treatment. Rule 4.3.2.3 also mentions that methods of surgery on living humans or animals are not patentable. But the patentability of surgery on a dead body depends on its purpose. Any therapeutic surgery is not patentable under Article 25(1)(3)⁶³³ of Patent

⁶²⁹ *Id.*, Part 2, Chapter 1, Rule 3.4.

⁶³⁰ In the old version of Patent Law (2002), there were only five categories of unpatentable subject matters. But it increases to six in the latest Patent Law amendment in 2008.

⁶³¹ More examples could be found in Rule 4.2 of 2006 Examination Guidelines, *supra* note 625.

⁶³² *Id.*, Rule 4.3. A method could not be patented if it is practiced on a living human or animal, and its purpose is to obtain diagnostic result or health condition.

⁶³³ 2008 Patent Law, *supra* note 7, art. 25 (1)(3). It stipulates that methods for the diagnosis or for the treatment of diseases shall not be granted patent right.

Law, while methods of surgery for non-treatment purpose still should not be granted patent rights due to lack of industrial applicability.⁶³⁴

Rule 4.4 defines “animal” in the Patent Law as a life form which cannot synthesize carbohydrate and protein by itself, but maintains life only by absorbing carbohydrate and protein, but not a human being. Even though the processes of producing animals and plant varieties may be patented under Article 25 (2),⁶³⁵ those processes refer to non-biological processes rather than essentially biological processes. One way to decide processes is to determine whether the human technical involvement in the process is dominant or decisive.

Chapter 2 concerns the requirements of description and claims. Unlike Part 1, which deals with format requirements, this chapter in Part 2 is about the content of those sections and whether they satisfy substantial requirements. For instance, a description must be clear, complete and enable a person skilled in the art. The definition of “person skilled in the art” is referred to Chapter 4, Rule 2.4 in the same part.⁶³⁶ The Examination Guidelines further explains the clarity, completeness and enablement requirements of the description. It also mentions that the abstract is a summary of the description; it provides helpful information but has no legal effect.⁶³⁷ Claims can be either product or process related. They are based on the description, which has the purpose of clearly and concisely define the

⁶³⁴ 2006 Examination Guidelines, *supra* note 625, Part 5, Rule 3.2.4.

⁶³⁵ 2008 Patent Law, *supra* note 7, art. 25(2). It states that for processes used in producing products referred to in items (4) of the preceding paragraph, patent right may be granted in accordance with the provisions of this Law.

⁶³⁶ 2006 Examination Guidelines, *supra* note 625, Part 2, Chapter 4, Rule 2.4. This clause defines person in the skilled art as a “fictional person who is presumed to be aware of all the common technical knowledge and have access to t all the technologies existing before the filing date or the priority date in the technical field to which the invention pertains, and have capacity to apply all the routine experimental measures before that date” but without creativity.

⁶³⁷ *Id.*, Part 2, Chapter 2, Rule 2.4.

claim scope.⁶³⁸ Claims shall not go beyond the scope of content disclosed in description. However, if a person skilled in the art can reasonably infer any equivalents or obvious variants, which have identical characteristics or uses, these equivalents or variants will also be protectable under claims.⁶³⁹ Thus, the Guideline adopts the doctrine of equivalents rather than the literal doctrine.

Chapters 3, 4 and 5 introduce definitions and examination standards of novelty, inventiveness and industrial applicability. Since the regulation of novelty was modified in the Patent Law in 2008, some changes to Chapter 3 are expected. Section 4 of Chapter 3 in Part 2 addresses the priority rights under the Patent Law for inventors who first filed for a foreign patent. To qualify for priority rights, the application filed in China must solve the same technical problem in the same way and with the same anticipated result as the application first filed in a foreign country.⁶⁴⁰ Section 5 is a grace period rule. It also clarifies the difference between grace period and priority. The priority right is considered to be the first filing date as the filing date; therefore, it blocks others from applying for the same subject matter during that period, while the grace period is only an exemption clause to novelty and does not change the filing date, nor does it stop others from applying for the same invention before the inventor does so.⁶⁴¹

Whether an invention is inventive, which includes both substantive features and notable progress, should be evaluated on the basis of a person skilled in the art. The method of evaluating substantive features is similar to the American mechanism: determining the prior art and features of the invention, and then determining whether the invention is obvious to a

⁶³⁸ *Id.*, Part 2, Chapter 2, Rule 3.2.

⁶³⁹ *Id.*, Part 2, Chapter 2, Rule 3.2.1.

⁶⁴⁰ *Id.*, Part 2, Chapter 3, Rule 4.1.2.

⁶⁴¹ However, the other applicant may not be granted patent right since the invention has been in the prior art. Therefore, the grace period of novelty only applies to the inventor himself.

person skilled in the art; in other words, whether there is a technical suggestion in the prior art that gives a person skilled in the art enough information to reach the same invention.⁶⁴² The assessment of notable progress is determined on social basis, that is, whether the invention would bring any social benefits.⁶⁴³ Other factors that suggest an invention's inventiveness should also be considered, for instance, solving a long-standing but unsolved problem, overcoming a technical prejudice, producing unpredicted technical results, or achieving commercial success due to technical features.⁶⁴⁴

Industrial applicability, unlike the utility requirement in U.S. patent law, requires that an invention be capable of being manufactured or used in industry with positive effects. It emphasizes reproducibility of the invention, and manifests that methods of surgery on human or animal bodies for non-treatment purposes are examples of unpatentable subject matters, because they are not industrially applicable.⁶⁴⁵

Chapter 10 of Part 2 introduces special rules for chemical products, including biotechnology. In Section 9 of Chapter 10 in Part 2, the Examination Guidelines lays out rules for examination of invention application in the field of biotechnology. In the beginning, the definition of "biological material" is given as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system, such as genes, plasmids, microorganisms, animals, plants etc.

Section 9 precludes certain biotechnological inventions under Article 5 of the Patent Law as unpatentable subject matters. Embryonic stem cells of human beings and a preparation method thereof are not patentable under

⁶⁴² *Id.*, Part 2, Chapter 4, Rule 3.2.1.1.

⁶⁴³ *Id.*, Part 2, Chapter 4, Rule 3.2.2.

⁶⁴⁴ *Id.*, Part 2, Chapter 4, Section 5.

⁶⁴⁵ *Id.*, Part 2, Chapter 4, Rule 3.2.4.

the public interest and social morality clause Article 5.⁶⁴⁶ Human bodies at the various stages of their formation and development, including germ cells, zygotes, embryos and even an entire human body are unpatentable under the same article.⁶⁴⁷ However, this rule does not reflect China's attitude toward embryonic stem cell research or embryo research.

Rule 9.1.2 deals with patentability of biotechnological materials in details. There are four categories.

Rule 9.1.2.1 addresses the patentability of microorganisms, including bacteria, actinomycetes, fungi, viruses, protozoa and algae, etc. Generally speaking, microorganisms are patentable because they fall outside the exclusion clause in Article 25.1(4) of the Patent Law because they are neither animals nor plants. This section also defines the differences between invention and discovery. A microorganism existing in nature without artificial involvement is a scientific discovery, which is not patentable. But if it is isolated from its natural environment and has a particular industrial use, it could be patented. Therefore, as for microorganisms, the involvement of isolation or purification techniques and industrial applicability are two requirements of patenting. But this section does not mention the requirement of novelty.

Rule 9.1.2.2 concerns the patentability of genes or DNA fragments, including those isolated from microorganisms, plants, animals or human bodies, or by other means. The method to determine whether a gene or DNA fragment is patentable subject matter or a scientific discovery is to examine whether it is unknown in the prior art and definitely characterized (novel), isolated or extracted from nature for the first time (inventive) and can be exploited industrially (industrial applicable). In other words, genes and genetic sequences are viewed as other chemical substances. According to

⁶⁴⁶ *Id.*, Part 2, Chapter 10, Rule 9.1.1.1.

⁶⁴⁷ *Id.*, Part 2, Chapter 10, Rule 9.1.1.2.

these words, one can imply that isolation of partial genetic sequences from known full-length sequences could be patentable if it is the first time to characterize the sequences or its functions. Full-length genetic sequence contains patented partial sequences and is still patentable if new characteristics and functions are found. However, this section does not explain how to identify infringement between two sequences that are overlapped.

Rule 9.1.2.3 contains rules governing the patentability of animals, plants and constituent parts thereof. The definition of “animal varieties” includes embryonic stem cells of animals, animals at the various stages of their formation and development, such as germ cells, a zoosperm and so on. These are not patentable under Article 25 (1)(4) of Patent Law. But somatic cells, tissues and organs (except for embryo) of animals do not fall into the scope of animal varieties; thus they are patentable.

Transgenic animals and plants are not patentable because they fall into the category of “variety” of Article 25 of Patent Law according to Rule 9.1.2.4. Because of the broad definition of “variety,” genetically modified organisms are excluded from patenting. This is not the trend in international legislation. Since some European countries and the United States have allowed the patenting of genetically modified organisms, China will lose its competition position in the international trade market, and will also lose benefits derived from a patent regime such as the impetus for promoting innovation and economic growth.

Rule 9.2.2 covers about genetic inventions relating to “genetic engineering,” which means the technology of manipulating genes through gene recombination and cell fusion. These inventions include genes, vectors, transformants, proteins, monoclonal antibodies and the processes of

producing these products. They can be patented as long as they meet the requirements of novelty, inventiveness and industrial applicability.

Document procedural examination is governed under Rule 9.3, while substantive examination is governed under Rule 9.4. Specific requirements of novelty, inventiveness and industrial applicability of those genetic products and the production processes thereof are regulated under Rule 9.4.

iii. Parts 3, 4 and 5 of the Examination Guidelines

Part 3 promulgates the procedures for international applications in the national phase, Part 4 discusses invalidation requests and reexamination procedures, and Part 5 concerns a special aspect of application processing and procedure. Since procedure is not the main topic of this article, these three parts will not be discussed here.

It is quite clear that the Examination Guidelines explicitly preclude the patentability of hESCs and preparation processes under the morality clause of Article 5 of the Patent Law. However, as introduced before, departmental regulations have limited legal force. Besides, this interpretation is inconsistent with the SIPO decision, which has already granted one patent on a hESC culture system and preparation process. The Examination Guidelines was enacted in 2006, while the patent was granted in 2008. Perhaps SIPO will change its viewpoint after two years of witnessing hESC development in other countries.

C. Patent Applications and Cases concerning hESCs

1. hESC Patent Application Statistics

There have been forty-five patent applications—including granted ones—involving hESCs in China. Figure 6.1 shows the current number and status of patent applications.

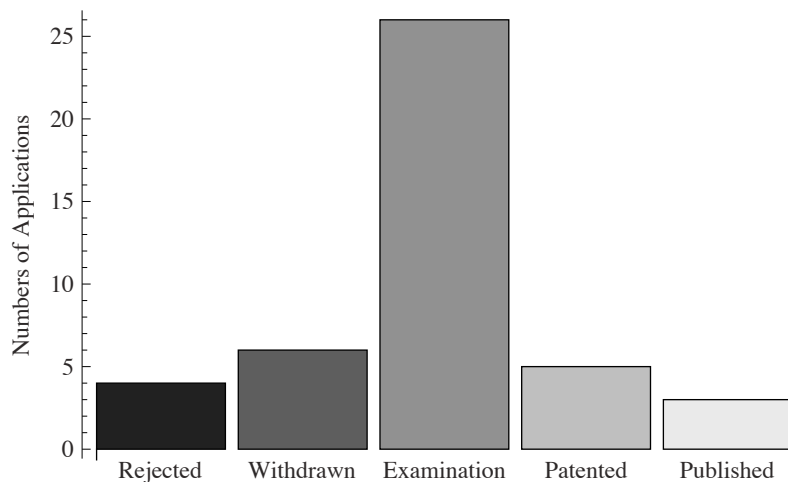


Figure 6.1: Chinese patent application status for hESC related invention

a. Granted Patents

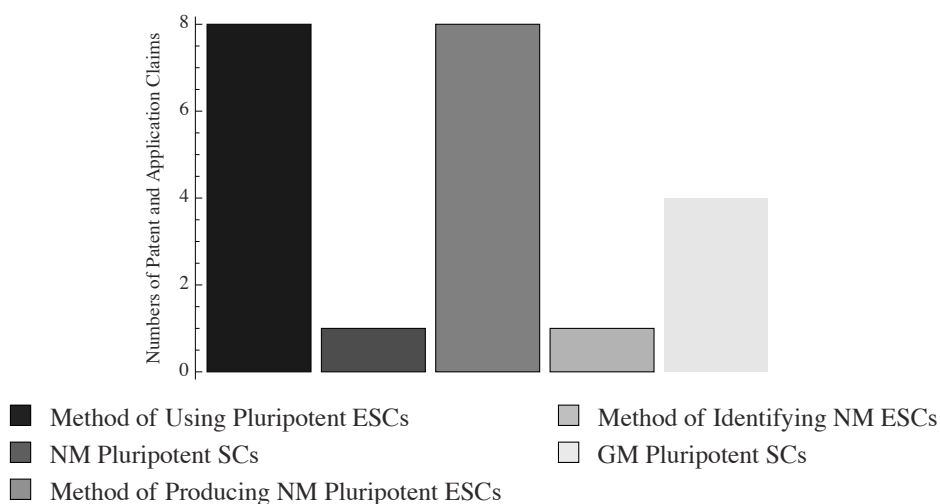


Figure 6.2: Claims of Chinese of patents and applications related to hESCs

Figure 6.2 demonstrates the status of all the hESC related patent applications in China. There are five issued patents related to hESCs in China. The claims are mainly for methods or culture media. As stated in the Examination Guidelines, no hESC is granted patentable according to the morality clause in Article 5 of Patent Law. But methods of producing non-modified pluripotent embryonic stem cells are patentable, which is contrary to the current state of the Examination Guidelines. Thus, patent examination practice is inconsistent with the Examination Guidelines. But since the Examination Guidelines as an agency manual has no binding legal force, the conflict will not cause invalidity of those patents. This contradiction needs to be corrected.

b. Patent Applications regarding hESCs

As demonstrated in Figure 6.1, there are twenty-five applications currently under examination. Four applications have been rejected, six are deemed to be withdrawn, and three applications have been recently published. One item worth mentioning here is that there are three applications claiming on non-modified pluripotent embryonic stem cells and none of them was filed by domestic institutes or companies. Among those applications, one was rejected (CN1350059), one was deemed to be withdrawn (CN1350059), and the other one is under examination (CN101233226). It will be interesting to know the final decision of the patent examiners. More than likely, CN101233226 will have the same experience as CN1350059, unless the applicant makes an amendment to the patent claims.

WARF also filed five patent applications in China and one was already granted. But they are all for processes, including methods of culturing or producing pluripotent hESCs and multipotent stem cells. Why WARF never

filed the equivalent applications of U.S. Patent No. 7,029,913, 6,200,806, and 5,843,780 is unclear. Possibly it is because at the time 5,843,780 was first filed in the U.S. and Europe in the early 1990s, China had no sophisticated legal system for protecting biotechnological inventions.

2. Court Decisions on hESC Patents

So far, there is no published judgment on hESC patenting or patent litigation in China. This may be because China's only patent on an invention involving hESCs was granted just one year ago. Perhaps after more patents are granted, the situation will change.

D. Academia in hESC Patent Issues in China

There are very few articles that discuss patenting of hESCs in China at present. The main reason may be that the Examination Guidelines has already precluded the patentability of embryonic stem cells and their production processes on the grounds that "they are contrary to morality and public interest."⁶⁴⁸ The human body at the various stages of its formation and development, including germ cells, zygotes, embryos, and entire human bodies are not patentable.⁶⁴⁹ Neither is the use of human embryos for industrial or commercial purposes.⁶⁵⁰

However, there is one article questioning this conclusion by analyzing the WARF patent reexamination. It predicts that WARF patents will be affirmed because they are non-obvious, novel and have utility; they meet all of the

⁶⁴⁸ *Id.*, Part 2, Chapter 10, Rule 9.1.1.1.

⁶⁴⁹ *Id.*, Part 2, Chapter 10, Rule 9.1.1.2.

⁶⁵⁰ *Id.*, Part 2, Chapter 1, Rule 3.2.

requirements of patenting and should not be precluded due to their relevance to human embryos. It is suggested that China consider broadening the scope of patentable subject matter since the U.S. and the European Union hold a comparatively tolerant attitude toward the patenting of hESCs.⁶⁵¹

There are some articles that discuss the ethical issues surrounding hESC research. The following overview is necessarily general in character and therefore subject to significant exceptions. With realizing the importance of protecting medical ethics, some scholars support hESC research for therapeutic purposes, however, these activities should be conducted in accordance with the law.⁶⁵² It is admitted that science is complex and unpredictable, and ethical rules should be updated with the development of scientific research.⁶⁵³ It is believed that thics could be used to guide the direction of scientific progress, and position the bottom line of scientific research; scientific research could be regulated by ethics, but not restricted. The more advanced the science is, the more mature ethical rules will be.⁶⁵⁴

It is also emphasized that reproductive cloning and therapeutic cloning need to be distinguished to implement scientific research: the former creates a person while the later only creates a blastocyst which will never have the chance to grow or have consciousness before it is destroyed. If we say that the former research is contrary to morality, the later one obviously triggers much less moral concerns.⁶⁵⁵

⁶⁵¹ Analysis on WARF, *supra* note 303, at 24-27.

⁶⁵² See *i.e.*, Lihui Wu, *Relativity of Medical Ethics Evaluation in Translormation Period*, CHINA HIGHER MED. EDUC., Oct. 2008, 021 [hereinafter Wu]; Lejun Pang et al., *Analysis of Policies on Human Embryonic Stem Cells in Foreign Countries*, CHINESE MED. ETHICS, June 2007, 42 [hereinafter Pang]; Ruiying Zhang, Linan Zhou, *Issues concerning the Application and Ethics of Embryonic Stem Cell*, 11 J CLINICAL REHABILITATIVE TISSUE ENGINEERING RES. 2919 (2007); Xishan Zhu & Chunhua Zhao, *Embyonic Stem Cell: The Contradiction between Science and Ethics*, CHINESE MED. ETHICS, Dec. 2006, 57 [hereinafter Xishan Zhu]; Miao Zhu, *Ethical Issues concerning Human Embryonic Stem Cells*, CHINESE MED. ETHICS, Apr. 2003, 6.

⁶⁵³ *Id.*, at 44.

⁶⁵⁴ *Id.*, at 44.

⁶⁵⁵ Wu, *supra* note 654, at 121; Xishan Zhu, *supra* note 654, at 58.

Chapter 7: Comparison and Suggestions

After introducing the respective laws and legal practice of the US, Europe and China in prior chapters, this chapter begin a comparison of the varying rules in their patent laws, and then explores the reasons behind the differences. As an effective method to promote innovation in biotechnology research and the pharmaceutical industry, patent law must be adjusted in order to embrace modern hESC related research. A model law will be proposed below to answer the unsettled questions about the patent-eligibility of hESCs.

A. Differences of Laws and Judicial Practices among the United States, Europe and China including Reasons for Differences

Since 1984, procedural regulations in national patent laws have been discussed at World Intellectual Property Organization [WIPO] meetings and some agreement on procedural—but not substantive—regulations have been achieved.⁶⁵⁶ After failed attempts to harmonize substantive patent law under WIPO, the WTO designated a minimum standard of patent protection. Every member state of the WTO including the US, the European Union and China must accept the WTO agreements encompassing the TRIPS Agreement, which contains a minimum threshold of intellectual property protection, including patent protection in international trade. Therefore, national patent laws are similar at a threshold level, but vary in some substantive legal aspects. In today's world, international organizations are still working on harmonizing substantive patent laws. For instance, negotiations on the Substantive Patent Law Treaty under WIPO are ongoing.⁶⁵⁷

⁶⁵⁶ GRAEME B. DINWOODIE et al., INTERNATIONAL AND COMPARATIVE PATENT LAW, 342 (LexisNexis 2002)[hereinafter DINWOODIE].

⁶⁵⁷ *Id.*, at 342.

The following paragraphs illustrate three aspects of regulatory and case law differences between Chinese, American and European patent law.

1. Differences of Laws and Judicial Practice regarding hESCs

There is minimal similarity among these three regions/countries: all have three requirements for patents—novelty, nonobviousness/inventiveness and utility/industrial applicability; all require a description in the patent application; all open the door to biotechnological inventions as long as the inventions are isolated and purified from their natural environment and subject to human intervention. These three regions/countries vary dramatically in their history, culture and legal systems; therefore, differences in patent law are to be expected. Many distinctions are maintained in both legislation and legal practice. Each region/country's law has been introduced in previous chapters in detail. Below is a summary of the relevant differences.

- a. Patent Laws

- i. Patentable Subject Matter

Both Chinese and European patent laws have specific articles for patentable and non-patentable subject matter, while the American patent law does not. In U.S. patent law, any process, machine, manufacture, composition of matter and improvement can be patented.⁶⁵⁸ The U.S. Patent Act does not mention any unpatentable subject matter. However, case law restricts the scope of patentable subject matter with the rule that “phenomena of nature, mental processes, mathematical formula[e] and

⁶⁵⁸ 35 U.S.C. §1.

abstract intellectual concepts” are not patentable,⁶⁵⁹ because they are basic tools of science and technology and they should not be monopolized.⁶⁶⁰ However, methods of practical application or implementation with new devices of law of nature, abstract ideas and mathematical formulas are patentable.⁶⁶¹ Methods of treatment or diagnosis that are tied to a machine/apparatus or transform a particular article into a different state or thing are patentable.⁶⁶² Life forms modified, isolated or purified by human intervention are manufactures / composition of matter under the statute, and therefore are patentable.⁶⁶³ Any naturally occurring phenomenon that does not occur in an isolated form in nature is patentable, including DNA and human cells.⁶⁶⁴ The U.S. has the broadest scope of patent subject matters among the three regions/countries, partially because its courts are reluctant to narrow the scope of patentable subject matter. The court restricts its task in interpreting statutory language and leaves policy consideration to the legislature.⁶⁶⁵

In China and the European Patent Convention [EPC], explicit rules are present regarding unpatentable subject matter. Article 52(2) of the European Patent Convention specifies that discoveries, theories and mathematical methods, aesthetic creations, schemes, rules and methods of mental acts performance, business methods, computer programs and information presentation are not patentable. Article 53(b) and (c) also exempts plant or animal varieties or biological productions of plants or animals or methods for treatment of human or animal bodies from patentability. In total, the EPC has more patent exemptions than have developed in the U.S. case law. For

⁶⁵⁹ *Gottschalk v. Benson*, 409 U.S. 63, 67 (U.S. 1972).

⁶⁶⁰ *Id.*, at 67.

⁶⁶¹ *Diamond v. Diehr*, 450 U.S. 175, 187 (1981); *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010).

⁶⁶² *Bilski*, 130 S. Ct. at 3249; *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1342 (2009).

⁶⁶³ Filliben, *supra* note 8, at 244.

⁶⁶⁴ Filliben, *supra* note 8, at 245-246.

⁶⁶⁵ *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (U.S. 1980).

instance, business methods can be patented in the U.S.,⁶⁶⁶ while that not true in the EPC. Methods of treatment of the human body are patentable and have been patented in the US, but are considered unpatentable in the EPC. However, in order to compete with the U.S. in the patent market, the European Patent Organization, an organization set up by the EPC for patent issuance, developed its own case law, and granted its first business method patent in the *Pension Benefit System* case, reasoning that the inventions had some technical character such as “performing or supporting an economic activity.”⁶⁶⁷

Besides the listed categories in Article 52 of the EPC, additional examples of unpatentable subject matters—such as surgery, therapy and diagnostic methods for humans or animals—are illustrated in the Guidelines for Examination in the European Patent Office, which is the executive body of the European Patent Organization. Article 53(a) generally exempts inventions against *ordre public* or morality from being patented. This is a general rule for unpatentable subject matter separate from the listed categories under Article 52, thus leaving the European Patent Office the power to determine the patentability of subject matter outside that excluded in Article 52. Implementing Regulations to the Convention on the Grant of European Patents further enumerates unpatentable categories under the Article 53(a) *ordre public* and morality clause. Rule 28 classifies processes for cloning human beings, using human embryos for industrial or commercial purposes,

⁶⁶⁶ Business methods are patentable under Examination Guidelines for Computer Implemented Inventions in 2006, which is confirmed in *State Street Bank v. Signature Financial Group*, (47 USPQ 2d 1596 (CAFC 1998)), *AT&T Corporation v. Excel Communications, Inc.*, (50 USPQ 2d 1447 (Fed. Cir. 1999)), and *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

⁶⁶⁷ European Patent Office, *T 0913/95 () of 19.12.2000*, T 0913/95 (Dec. 19, 2000), available at <http://www.epo.org/law-practice/case-law-appeals/recent/t950913eu1.html> (last visited Sep. 12, 2010). In February of 2002, the European Commission proposed a Directive on the Patentability of Computer-implemented Inventions, but the European Parliament rejected the proposal. European Commission, *Patentability of Computer-implemented Inventions*, available at http://ec.europa.eu/internal_market/indprop/comp/index_en.htm (last visited Mar. 1, 2011).

and genetically modifying the human germ line as unpatentable subject matter contrary to morality. This is also incorporated into the Biotechnology Directive (98/44/EC) under Article 6(c). Rule 29 (1) excludes human bodies from being patented, which is encompassed in Article 5(1) of the Biotechnology Directive.

Chinese patent laws have similar regulations. Article 5 of Chinese Patent Law creates the general principle of exclusions from patentability of those inventions/creations that are contrary to national laws, social morality or that are detrimental to the public interest. This is similar to a clause in the EPC but with different wording. In the EPC, “*ordre public* and morality” is the only criterion; while in China, laws and public interest are also considerations. According to the morality clause, human embryo and embryonic stem cell related products trigger breaches of public order and social morality because they involve destruction of human embryos; therefore they are not patentable. However, Article 10 of the Detailed Rules for the Implementation of the Chinese Patent Law (2010) imposes a patentability requirement based on the legal use intention of the invention. If the invention was originally designed with an illegal purpose in mind, the invention is not patentable. It should be noted that in some cases the invention, while being designed with a legal purpose in mind, can be used in an illegal manner. In this case the invention is still patentable. According to this rule, human embryonic inventions should be patentable as long as they are used for therapeutic purpose rather than reproductive cloning. But this conclusion conflicts with the current regulations contained in the Patent Examination Guidelines of China, stating that human embryos and embryonic stem cells are not patentable.

Chinese patent law also has a clause regarding unpatentable subject matter: scientific discoveries, mental activities, diagnoses or treatments, animal and plant varieties and substances obtained by nuclear

transformation. Among these categories, both the EPO and China consider treatment and diagnosis to be unpatentable for public benefit, but this is not the case in the U.S. Nuclear transformed substances is a unique Chinese category of unpatentable subject matter, but not one that is seen in either the U.S. patent laws or the EPC. While the EPO and the U.S. started patenting business methods and computer programs, China chose another road. Business methods and computer programs *per se* or their recorded representations are rules and methods for mental activities and therefore are not patentable according to Article 25(2) of the Chinese Patent Law.⁶⁶⁸ Instead, these innovations are protected under Chinese copyright law in the Regulation for Computer Software Protection.⁶⁶⁹ By contrast, if computer programs have technical features and constitute technical results, they are patentable under the Examination Guidelines.⁶⁷⁰ While the U.S. and Europe have abandoned the technical feature requirement, China continues to maintain this requirement and therefore provides computer programs less patent protection.

The scope of patentable subject matter in the U.S. has the largest coverage closely followed by the EPC. Chinese patent laws protect a much smaller scope of patentable subject matter, especially in regards to the aspect of hESCs. The United States grants such patents while the EPO and China generally refuse to do so.

ii. Morality Considerations in Patent Laws

⁶⁶⁸ 2006 Examination Guidelines, *supra* note 625, Part II, Chapter 10, Rule 9.2(1).

⁶⁶⁹ Zhu zuo quan fa [Copyright Law] (as Amended in 2010) (promulgated by the Standing Comm. Nat'l People's Cong., Feb. 26, 2010, effective June. 1, 1991) art. 3(8) LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C), and Ji suan ji ruan jian bao hu tiao li [Regulations on the Protection of Computer Software] (promulgated the Sta. Council, Dec. 20, 2001, effective Jan. 1, 2002) LAWINFO CHINA (last visited Feb. 2, 2011) (P.R.C).

⁶⁷⁰ 2006 Examination Guidelines, *supra* note 625, Part II, Chapter 10, Rule 9.2(2).

The U.S. patent law does not have morality requirements, in either statute law or case law. There was a period of time when courts and the patent office considered a the morality element under the utility requirement, but this is not the case anymore, since the courts hold that the morality issue should be left to Congress instead of the patent office to weight.⁶⁷¹ Currently, Congress has not addressed this matter with legislation.⁶⁷² However, President William J. Clinton announced his opposition to patenting human clones, and President George W. Bush urged Congress to promulgate laws to ban patenting human beings. The USPTO also stated his policy about human being are not patentable subject matter.⁶⁷³ Nonetheless, there is no single morality requirement in the U.S. patent law.⁶⁷⁴ People still consider that patent law is an inappropriate tool for making moral judicial decisions concerning matters of science.⁶⁷⁵

By contrast, the legislatures of both China and the EPO are more morality-minded when it comes to patent law. Both have morality clauses in their laws, and even more detailed articles concerning morally excluded categories in light of ambiguous definitions of morality and *ordre public*.⁶⁷⁶ Because the definitions vary from country to country, the scope of the patent exclusion clause in the Chinese and the European laws is slightly different.

Article 53(a) of the EPC contains the general rule regarding morality and *ordre public*: any invention, the commercial exploitation of which violates morality and *ordre public* should not be patented. Rule 28 of the EPC consists of a list of unpatentable subject matter under the morality rule of Article

⁶⁷¹ Resnik, *supra* note 285, at 213.

⁶⁷² Andrew W. Torrance, *Physiological Steps Doctrine*, 23 BERKELEY TECH. L.J. 1471, 1472 (2008)

⁶⁷³ *Id.*

⁶⁷⁴ Jameson, *supra* note 290, at 203.

⁶⁷⁵ Gitter, *supra* note 289, 1651.

⁶⁷⁶ The text of EPC does not give the definition or scope of these two terms. But in Recital 36 of Directive, *supra* note 185, at 16, *ordre public* and morality refer to human, animal or plant life or health or to avoid serious prejudice to the environment.

53(a), and includes processes that using human embryos for industrial or commercial purposes. The application scope of the morality and *ordre public* clause was narrow at the beginning. The EPO claimed that only when the disclosure/publication of one invention application violates the morality and *ordre public*, could it be excluded from patent protection.⁶⁷⁷ In other words, to determine if an invention violates the morality and *ordre public* clause, the intended purpose and the direct result are the only considerations; other potential applications or processes which may contravene morality or *ordre public* do not trigger the morality and *ordre public* clause and do not affect an invention's patentability. This interpretation is similar to the scope of morality and *ordre public* clause in Chinese patent law. However, the scope of the morality and *ordre public* clause has been broadening in the EPO. Not only must the teachings and disclosures of the invention comply with the law, but also any process enabling the invention.⁶⁷⁸ In the WARF case, the patent application was rejected based on commercial exploitation of human embryos contrary to the morality clause in the EPC.⁶⁷⁹ Although the direct basis of the rejection is not Article 53(a), but Rule 28(c), Rule 28(c) is a subcategory of Article 53(a); the interpretation of Rule 28(c) indicates the interpretation of Article 53(a). There is a tendency to extend the application of morality and *ordre public* requirement to manufacturing processes that enable inventions as well as the inventions themselves.

The definitions of *ordre public* and morality are different. The EPO has distinguished *ordre public* and morality in Decision T 356/93. The EPO defines *ordre public* as societal peace and quiet, encompassing public security and physical integrity of individuals; morality refers to the belief that some

⁶⁷⁷ Franze-Josef Zimmer & George Seisenberger, *Stem Cell Patents: Does T 0866/01 ('Euthanasia Composition') of an Appeal Board of The EPO Provide the Answers for the Enlarged Board of Appeal Case G2/06 ('Primate Embryonic Stem cells')?*, BIOTECHNOLOGY L. REP. Mar. 2007, 1, 4.

⁶⁷⁸ Wisconsin Alumni Research Foundation, Case G 0002/06, at 23.

⁶⁷⁹ Audrey Chapman, *The Ethics of Patenting Human Embryonic Stem Cells*, 3 KENNEDY INST. ETHICS J. 261, 261 (2009).

behaviors are right whereas some are wrong. These behaviors should be culturally dependent, conventionally accepted, and deeply rooted norm in European civilization.⁶⁸⁰ According to Article 53(a) of the EPC, *ordre public* and morality are not determined by the criteria in national laws. The European Parliament also agrees that hESC inventions violate Article 6(2)(c) of the Biotechnology Directive 98/44 on the grounds that they involve the destruction of human embryos, and therefore, they are not patentable.⁶⁸¹ As a result, in the EPC, morality and *ordre public* standards not only apply to the end-purpose of a product, but also to the manufacturing processes by which it is obtained, even if such processes are not claimed in the patent application.

In Chinese patent law, there is a corresponding clause that bans the patentability of hESCs and preparation methods.⁶⁸² China admits that the definition of national laws, morality and public interest is very broad and may vary with time and social progress.⁶⁸³ It limits the definition of laws to those formulated by the NPC or its Standing Committee, but excludes administrative regulations or local legislation,⁶⁸⁴ and defines morality as “ethical or moral norm and rules generally recognized as justifiable and accepted by the public.”⁶⁸⁵ With respect to the public interest, it represents benefits and good order of the state and society, including the environment, the sentiment of the people or ethnic group, and the health and life of the people.⁶⁸⁶

The scope of the general exception rule in China is broader than the rule in the EPO, mainly because China is a unitary sovereign state with a similar

⁶⁸⁰ T 365/93, O.J. Eur. Pat. Off. 1, 16-17 (1995); DINWOODIE, *supra* note 658, at 73.

⁶⁸¹ See P6_TA(2005)0407, *supra* note 450.

⁶⁸² 2008 Patent Law, *supra* note 7, art. 5; 2006 Examination Guidelines, *supra* note 625, Part II, Chapter 10, Rule 9.1.1.

⁶⁸³ *Id.*, Part II, Chapter 1, Rule 3.

⁶⁸⁴ *Id.*, Part II, Chapter 1, Rule 3.1.

⁶⁸⁵ *Id.*, Part II, Chapter 1, Rule 3.2.

⁶⁸⁶ *Id.*, Part II, Chapter 1, Rule 3.3.

culture and moral norm. The EPO is a regional organization with more than 30 member states; therefore it is harder for the EPO to achieve consensus on such a culture-and-tradition-based matter. The most important point to be emphasized is that no matter how the Biotechnology Directive is interpreted, it is impossible politically to satisfy and resolve all issues of morality among the member states of the European Union. Attitudes toward embryonic research differ widely. Therefore, the EPO must adopt the minimum requirement for morality in order to be accepted by all member states.

In conclusion, in the EPO and China, hESC patent applications are usually rejected under morality clauses, though hESC derivation or production processes may be patentable and the application of the morality clause remains undetermined, especially on the grounds that the morality connotation is changing due to the technological and scientific development. American patent law leaves the discretionary power of patenting hESCs and preparation methods to the USPTO and courts. Nonetheless, PBAI and the courts are attempting to impose obstacles to hESC patents under other requirements, for instance, utility and non-obviousness.

iii. Utility/ Industrial Applicability

The U.S., Europe and China have different requirements for the element of utility. The U.S. utilizes utility, while China and Europe employ industrial applicability. The difference not only exists in terminology, but also in content.

U.S. laws do not have a morality proviso, but that does not mean morality has never been considered in patent examination. As a matter of fact, historically it was included as part of the utility requirement. In case law, the courts customarily held that inventions should not be detrimental to the

well-being or morals of society, but should be morally useful.⁶⁸⁷ But later, courts began to abandon the moral requirement to patent inventions.⁶⁸⁸ After the Supreme Court broadened the scope of patentable subject matter in the *Diamond v. Chakrabarty* case in 1980⁶⁸⁹ and started a new era for biotechnological inventions, the USPTO considered reemploying the morality requirement⁶⁹⁰ but did not ultimately introduce morality as a basis for rejection. Today, the conception that patent law is an inappropriate tool to make moral judgments regarding science has been widely accepted.⁶⁹¹ Instead, patent examination should be focused on technical matters.⁶⁹²

At present, utility in the U.S. patent law means that the patent applications should have substantial, specific and practical utility, and bring a particular benefit to society.⁶⁹³ As mentioned above, since the Supreme Court opened the patent door to “anything under the sun that is made by man” in the *Diamond v. Chakrabarty* case,⁶⁹⁴ patent-eligibility has expanded in scope to include living things. Meanwhile, the criteria of specific and substantial utility apply to this new category as well.⁶⁹⁵

By contrast, the EPC adopts the term “industrial application” rather than “utility” in patent laws. This term corresponds closely to the requirement of utility; however, it is different in substantial ways. The similarity of these two terms is that they both require practical and profitable applications for an

⁶⁸⁷ See *i.e.*, *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C. Mass. 1817); *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903).

⁶⁸⁸ *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366-68 (Fed. Cir. 1999).

⁶⁸⁹ *Diamond*, *supra* note *Diamond*, at 309.

⁶⁹⁰ USPTO Facts, *supra* note 288.

⁶⁹¹ Gitter, *supra* note 289, 1651; Jameson, *supra* note 290, at 203.

⁶⁹² Resnik, *supra* note 285, at 213.

⁶⁹³ See *i.e.*, *In re Fisher*, 421 F.3d. 1365, 1371 (Fed. Cir. 2005); *In re Brimonidine Patent Litig.*, 666 F. Supp. 2d 429, 450 (2009).

⁶⁹⁴ *Diamond*, *supra* note *Diamond*, at 309.

⁶⁹⁵ 66 Fed. Reg. 1092, *supra* note 281, the patent application must have specific, substantial and credible utility; *In re Fisher*, *In re Fisher*, 421 F.3d. 1371 (expressed sequence tags (ESTs) should have specific utility to be granted patents).

invention.⁶⁹⁶ Also the burden of proving utility is imposed on patent applicants.⁶⁹⁷

However, the differences are obvious as well. The EPC requires inventions to have an industrial use rather than merely a general use, which means that patentable inventions must be made or used in industry. Scientific achievement or research value does not necessarily equate to industrial application.⁶⁹⁸ There is more content in the industrial application clause than in the clause related to utility,⁶⁹⁹ and the industrial application clause excludes more subject matters than the utility requirement. For instance, to some scholars, business methods *as such* are not patentable bound to the industrial application and technical effect requirements.⁷⁰⁰

Chinese patent law has a similar “practical application” clause which requires an invention to be made or used industrially, solve a technical problem or achieve effective results.⁷⁰¹ This clause has stricter implications than the corresponding clause in the United States. It is significant to substances naturally existing. One way to differentiate patentable substances found in nature from non-patentable counterparts is that only substances which can be isolated or extracted from their natural environment and exploited industrially in order to produce technical effects can be patented.⁷⁰²

⁶⁹⁶ European Patent Office, *T 0870/04 (BDP1 Phosphatase/Max-Planck) of 11.5.2005*, T 0870/04 (2005), at 9, available at <http://www.epo.org/law-practice/case-law-appeals/recent/t040870eu1.html> (last visited Mar.1. 2011).

⁶⁹⁷ European Patent Convention, *supra* note 406, Article 57.

⁶⁹⁸ *BDP1 Phosphatase/Max-Planck*, T 0870/04 (2005), at 9

⁶⁹⁹ Craig E. Groeschel, *Tax Strategy Patents Considered Harmful*, 8 Hous. BUS. & TAX L.J. 271, 279 (2008).

⁷⁰⁰ Brian P. Biddinger, *Limiting the Business Method Patent: A Comparison and Proposed Alignment of European, Japanese and United States Patent Law*, 69 FORDHAM L. REV. 2523, 2542 (2001)[hereinafter Biddinger].

⁷⁰¹ 2008 Patent Law, *supra* note 7, art. 22.

⁷⁰² 2006 Examination Guidelines, *supra* note 625, Part II, Chapter 10, Rule 2.1.

iv. Exemptions to Patent Infringement

The three differences above are all related to patent examination. Another difference between these three countries relative to the enforcement of patents is patent right exemption. When inventions are widely used in the arts as a research tools, a research use exception can impact significantly on enforceability of issued patents.⁷⁰³ Especially under U.S. law, the exemption only applies to uses “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”⁷⁰⁴ A use is disqualified from the exemption if it is for commerce or for a legitimate business objective,⁷⁰⁵ which includes a university educating students, enhancing the status of the institution, competing for grants, and attracting students and faculty.⁷⁰⁶

In the European countries, using the experimental use exemption to block enforcement of hESC patents is not that common. This is partially due to Article 64(3) of the EPC which states that infringement issues will be left to national laws. The EPC does not extend its authority to patent enforcement; hence, it does not mention an experimental use exception. On the other hand, most European countries have similar clauses of experimental use exemption⁷⁰⁷ such as the German Patent Act, which excludes from infringement “acts done for experimental purposes relating to the subject matter of the patented invention.”⁷⁰⁸ The exemption covers testing of how a

⁷⁰³ Jameson, *supra* note 290, at 203.

⁷⁰⁴ *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

⁷⁰⁵ *Id.*

⁷⁰⁶ *Id.*

⁷⁰⁷ Wolrad Prinz zu Waldeck und Pyrmont, *Research Tool Patents After Integra v. Merck - Have They Reached a Safe Harbor?*, 14 MICH. TELECOMM. TECH. L. REV. 367, 394 (2008)[hereinafter Pyrmont]

⁷⁰⁸ Heinz Goddar, *The Experimental Use Exception: A European Perspective*, www.law.washington.edu/casrip/Symposium/Number7/1-Goddar.pdf (last visited Mar. 3, 2010).

patented invention works and whether it can be improved.⁷⁰⁹ The European exemption is broader than that in the U.S. because experiments even with ultimate commercial intention may trigger the exemption clause.⁷¹⁰

In China, exemption clauses exist as well. Article 69 of the Chinese Patent Law sets forth several situations as non-infringing. One clause states that using patents only for scientific research and experimentation does not constitute patent infringement. There is little explanation about the experiment exemption, either in laws or judicial rulings. With respect to the literal meaning of “only,” it suggests that the exemption may apply narrowly to scientific research and experiments.⁷¹¹ Since there is so far no case or dispute over the scope of the research and experiment exemption, it is unclear if the scope of the experiment exemption in Chinese law leans more towards the American scope, blocking all uses for legitimate business objective, such as in a university setting to educate students or research institutes for gaining grants, or toward the European scope, applying to any experimental use for any ultimate purpose. However, research or experimental conduct as the ultimate purpose is not normally carried out in China as most research is carried out for commercial purposes.⁷¹² Therefore, it is suggested that in order to keep pace with the needs of scientific research and public welfare, a broad approach to the experimental use exemption should be supported.⁷¹³

From the analysis above, it can be concluded that the U.S. is relatively stricter with experimental use exemption than European countries, which means patentees’ rights are more broadly protected. China has similar

⁷⁰⁹ Kevin Iles, *A Comparative Analysis of the Impact of Experimental Use Exemptions in Patent Law on Incentives to Innovate*, 4 NW. J. TECH. & INTELL. PROP. 61, 76-77 (2005) [hereinafter Iles].

⁷¹⁰ *Id.*

⁷¹¹ Deming Liu, *Now the Wolf Has Indeed Come! Perspective on the Patent Protection of Biotechnology Inventions in China*, 53 AM. J. COMP. L. 207, 251 (2005)[hereinafter Demin Liu].

⁷¹² *Id.*, at 251.

⁷¹³ *Id.*, at 252.

experimental use exemptions, but the government's attitude toward the scope of the exemption is unclear.

b. Judicial decisions and patent practice

The differences in patent law concerning hESC inventions are further evidenced by the experience of one WARF patent in the EPO and the USPTO.

Since the moral issue is not relevant during patent examinations in the U.S., the WARF patents, U.S. Pat. No. 5,843,780, U.S. Pat. No. 6,200,806 and U.S. Pat. No. 7,029,913 were granted by the USPTO,⁷¹⁴ albeit with some challenges. The Public Patent Foundation [PUBPAT] and the California-based Foundation for Taxpayer and Consumer Rights [FTCR] challenged the validity of these WARF patents for lack of novelty and non-obviousness, and filed a request to reexamine these three patents in 2006.⁷¹⁵ The main issue was whether the WARF patents were novel and non-obvious in the prior art to people with ordinary skills. In other words, the question was whether the patents fell into the literal interpretation of the prior art patents.

In the case of '780, the reexaminer stated that techniques for the isolation and maintenance of animal embryonic stem cells already existed in prior art, and formed a correlation to the derivation of hESCs.⁷¹⁶ Furthermore, the maintenance time difference between the methods claimed and the prior art was indistinguishable, and therefore that the application failed to meet the novelty requirements to justify patentability.⁷¹⁷ With respect to the patentability issue, however, the reexaminer considered positively the fact

⁷¹⁴ Strictly speaking, the equivalent patent was 08/376,327, but it was deemed to be abandoned during the application. The three patents are its continuity patents.

⁷¹⁵ More details see <http://www.pubpat.org/warfstemcell.htm>.

⁷¹⁶ *Ex Parte Reexamination Communication Transmittal Form*, Control No. 90/008102, Mar. 30, 2007, at 10-12, available at http://www.warf.org/uploads/media/PTO_780_office_action.PDF (last visited May. 1,2010).

⁷¹⁷ *Id.*

that the claimed hESCs involved human preparation and differed from naturally occurring stem cells.⁷¹⁸ Unlike the EPO, the U.S. reexaminer focused on the obviousness and novelty of the said claims rather than the patentability of the subject matter or public policy issues. The patent was first rejected for lacking novelty and obviousness,⁷¹⁹ and later upheld by the reexaminer.⁷²⁰ Similar situations occurred with Patent '806.⁷²¹

Unfortunately for Patent '913, after the reexaminer confirmed the validity,⁷²² the challengers appealed the holding on patent validity to the BPAI which overruled the patent validity.⁷²³ Again, the BPAI pinpointed the non-obviousness requirement and its application in the present case. The BPAI held that the patentees had the burden to prove the non-obviousness of patents, which the patentee failed to prove.⁷²⁴ Based on the evidence at hand, the prior art disclosed the derivation and preparation of hESCs in general and thus anticipated the patent at bar.⁷²⁵

The differences between the USPTO and the BPAI also lie in the interpretation of non-obviousness. The USPTO asserted that the prior art only provided a murine model, which is yet to prove applicable to human/primates, but no precise protocol with all the characteristics listed in

⁷¹⁸ Dillon Beardsley, *A Two-Front Assault on the Stem Cell Patents*, 6 J. MARSHALL REV. INTELL. PROP. L. 501, 513 (2007)[hereinafter Beardsley].

⁷¹⁹ *Ex Parte Reexamination Communication Transmittal Form*, Control No. 90/008102, at 17-19.

⁷²⁰ *Id.*

⁷²¹ *Ex Parte Reexamination Communication Transmittal Form*, Control No. 90/008139, available at Mar. 5, 2008, http://www.warf.org/uploads/media/PTO_806_Office_Action.pdf (last visited May. 1,2010).

⁷²² *Ex Parte Reexamination Communication Transmittal Form*, Control No. 95/000154, Feb.25, 2008, available at http://www.warf.org/uploads/media/PTO_913_office_action.PDF (last visited May,1,2010).

⁷²³ Board of Patent Appeals and Interferences, *Foundation for Taxpayer and Consumer Rights v. WARF* (B.P.A.I. No. 2010-001854, 4/28/10), at 12 available at <http://www.consumerwatchdog.org/resources/WARFDecision042910.pdf> (last visited Aug. 26, 2010).

⁷²⁴ *Id.*, at 14.

⁷²⁵ *Id.*, at 14.

the pending patent.⁷²⁶ The BPAI adopted a different standard, reasoning that a broad application of the prior art techniques to other species implies its success on human beings, therefore making it obvious to apply the technique to human cells. Under this standard, the invention at bar loses its non-obviousness.⁷²⁷ But, a different voice states that “obvious to try” is not sturdy ground for denying a patent’s non-obviousness, and an invention may still be considered non-obvious if the prior art only reveals a general methodology or technology in a new area of research.⁷²⁸ In the case of WARF patents, evidence shows that people with ordinary skills in the art did not have a reasonable expectation of success in generating hESCs from the techniques then available in the prior art.⁷²⁹ Moreover, there are secondary factors for non-obviousness determination, such as long-term need, failure of others, unexpected results, unexpected properties, licenses of the invention and so forth.⁷³⁰ All of these factors indicate the non-obviousness of the WARF patents.⁷³¹

In 1996, WARF also filed an equivalent application with the EPO, Primate Embryonic Stem Cells (EP0770125), claiming a cell culture comprising primate embryonic stem cells which are capable of proliferating in vitro for over one year. Compared to the USPTO, the EPO process was more difficult. The issue was referred to the Enlarged Board of Appeal [EBA].

In answering the question of the relationship between the morality clauses and hESCs under the EPC, the EBA stated that even though Rule 28(c) did not directly exclude the claimed invention because the claimed invention was related to making rather than using hESCs, the technical teaching of the

⁷²⁶ *Ex Parte Reexamination Communication Transmittal Form*, Control No. 95/000154.

⁷²⁷ *Foundation for Taxpayer and Consumer Rights v. WARF* (B.P.A.I. No. 2010-001854, 4/28/10), at 36-37.

⁷²⁸ *In re Patrick H. O’Farrell*, 853 F.2d 894, 902-903 (1988); *In re Dow Chemical Co.*, 837 F.2d 469, 473 (1988).

⁷²⁹ Beardsley, *supra* note 720, at 515.

⁷³⁰ *Amgen, Inc. v. Hoescht Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 113 (D. Mass. 2001).

⁷³¹ Beardsley, *supra* note 720, at 516.

invention and the related commercial exploitation of embryos were factors to be considered as well.⁷³² In order to use the said invention, it must first be created; making the product is usually one step necessary to commercialize or industrialize the invention. In this case, the teaching of the invention involves the use and destruction of human embryos. The EBA regarded the unavoidable destruction of human embryos in the process as a violation of Rule 28(c). The EBA further clarified that Rule 28(c) could not be circumvented by claiming the invention *per se* rather than associated embryo-destroying enabling process. In other words, Rule 28(c) applies to all activities required to make the inventions available to the public, not only the ultimate use of the inventions.⁷³³

However, the EBA leaves the definition of embryo blank; it is not known whether Rule 28(c) applies to inventions involving human embryos produced by other routes, which avoid the destruction to human embryos resulting from fertilization.⁷³⁴ Even if the EBA precludes the application of Rule 28(c) to the above situations in future litigation, which, according to the statement of the EBA case at bar, is very possible,⁷³⁵ Article 53(a) is still a potential bar to the hESC-related invention applications. As a general public policy, it may exclude any inventions whose commercial exploitation is contrary to *ordre public* or morality, including but not limited to those involving human embryo destruction. Article 53(a) requires inventions to pass a public security, individual integrity and conventionally accepted, deeply rooted norm tests.⁷³⁶

⁷³² Rainer Plaggenborg & Franz-Josef Zimmer, *The EPO's Decision G2/06 on the Patentability of Human Embryonic Stem Cells: Sounding the Bell for the Next Round?* 28 BIOTECH. L. REP. 332, 334 (2009)[hereinafter Plaggenborg].

⁷³³ Wisconsin Alumni Research Foundation, Case G 0002/06, at 30.

⁷³⁴ There are other routes of producing hESCs, ie, therapeutic cloning course. See Plaggenborg, *supra* note 734, at 335.

⁷³⁵ *Id.*, at 345-336.

⁷³⁶ European Patent Office, *T 0365/93 () of 27.7.1995*, T 0365/93, O.J. Eur. Pat. Off. 1, 16-17 (1995).

Remarkably, the mechanism of the EPO leaves its member states alternative. Even if the EPO excludes hESCs from patentability, member states still may grant patent protection on such innovations.

In 2006, WARF filed an additional application EP1640448 (primate embryonic stem cells), but later withdrew the application later.

There is no equivalent invention application filed in China. To date, WARF has filed five patent applications in China and one was already granted, but they are all pertain only to processes. Hence, it is difficult to compare the Chinese patent office's practice in like cases. There have been no hESCs *per se* patented in China thus far.

B. Rationales for Different Laws to hESC Invention Applications

There are a number of explanations behind the fact that the U.S., EPO and China adopt different opinions towards hESC inventions. The differences are not generated by judges' decisions or presidents' announcement, but caused by more deep-rooted elements, such as legal systems, cultures and values, and economic processes.

1. Different Legal Systems

The U.S, European Patent Office and China encompass different sources of law. The U.S. is a representative common law country, in which both codified law and case law are valid sources of law. The American legal system has a traditional principle called *stare decisis*, meaning courts not only have the right to apply the law, but also the authority to interpret and make binding

rulings.⁷³⁷ The decision of the courts is not merely considered a good guide, but is binding on later cases in courts that are at equal or lower level, if the fact and issue of the later cases are similar to the previous one. In that sense, courts make case law, to the extent that their judgments are cited as precedent in future cases.⁷³⁸ Due to this, courts and judges can easily direct the law in the relevant area. Consider *Diamond v. Chakrabarty* (1980) as an example. The U.S. Supreme Court held that no further restriction from the court should be imposed on the patent scope beyond Congressional legislation, unless Congress stated otherwise.⁷³⁹ Hence, the court interpreted the statutory language in favor of the patentee and granted a patent on live, man-made microorganisms, thus inspiring biotechnological innovations and ultimately promoting scientific research on biotechnology.

In contrast, China's legal system is similar to the civil law system in France, Germany and Japan, using codes of law to ensure uniformity of legislation.⁷⁴⁰ According to the Law on Legislation of the People's Republic of China (2000), the binding sources of law in China are the Constitution, statutes, administrative regulations, local regulations, autonomous regulations and special rules.⁷⁴¹ Besides that, judicial interpretation issued by the Supreme People's Court has legal effect and can be used as a source of law under some conditions.⁷⁴² No other source can be used as a legal basis of the courts, not even administrative rules. Administrative rules issued by administrative agencies can only be used as references rather than grounds when the court

⁷³⁷ Dana T. Blackmore, *Eradicating the Long Standing Existence of a No-Precedent Rule in International Trade Law - Looking Toward Stare Decisis in WTO Dispute Settlement*, 29 N.C.J. Int'l L. & Com. Reg. 487, 494 (2004).

⁷³⁸ ANTONIN SCALIA & AMY GUTMANN, *A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW* 3-13 (Princeton University 1998).

⁷³⁹ *Diamond*, *supra* note *Diamond*, at 318.

⁷⁴⁰ John S. Mo, *The Code of Contract Law of the People's Republic of China and the Vienna Sales Convention*, 15 AM. U. INT'L L. REV. 209, 211 (1999)

⁷⁴¹ Legislation Law, *supra* note 543, art. 2.

⁷⁴² The judicial interpretation power is in Judicial Interpretation Work, *supra* note Judicial Interpretation Work, art. 5. But the interpretation power is different from and subject to the interpretation power of the legislature, ie. the Standing Committee. The legislature can overrule the judicial interpretation.

thinks it is necessary and consistent with the laws.⁷⁴³ The Supreme People's Court is the only court that has judicial interpretation power to interpret ambiguous laws or legal loopholes found in litigation, before legislatures—the National People's Congress and its Standing Committee—have time to respond. Other than that, China's legal system does not recognize prior judgments as precedents. Decisions and judgments of courts have no legal force.⁷⁴⁴ Even though in practice certain decisions of the Supreme People's Court have already been repetitively cited as precedents by courts at lower levels, the practice is not yet recognized in any law or other legal documents.⁷⁴⁵ Therefore, theoretically speaking, judgments have no binding force as precedents. They only affect the parties to the cause of action at bar. Judgments are based on codified laws, but not prior cases.

The limited legal sources restrict the patentable subject matter to the categories listed in statutes, regulations or rules. Even after a patent is granted by the patent office, any individual still has the right to challenge the validity of the patent before the courts, and judges may revoke a patent under current codified laws; but judges have no discretionary power to broaden the scope of patentable subject matter. The only way to broaden the patentable subject matter scope is to create laws. However, it is always convoluted and time-consuming process to modify an existing law or enact a new one. A new law or modification must be approved by the legislature under specific procedures.⁷⁴⁶ It is a lengthy process for a new law or amendment to become a reality. The time from proposal to actual effect can be extensive. Hence, it is harder to expand the scope of patent-eligible subject matter in China than in the US.

⁷⁴³ Administrative Procedure Law, *supra* note 574, art. 53.

⁷⁴⁴ Charles D. Paglee, *Chinese Trademark Law Revised: New Regulations Protect Well-Known Trademarks*, 5 U. BALT. INTELL. PROP. L. J. 37, 60 (1996).

⁷⁴⁵ Hou Meng, *Zui gao ren min fa yuan pan jue de bi jiao you shi (Comparative Advantages of the Supreme People's Court Judgment)*, 6 J. OF PEKING U. 21, 23 (2008)(translated by author).

⁷⁴⁶ Legislation Law, *supra* note 543, art. 56.

In the case of patentable subject matter, the Chinese patent laws exclude any invention contrary to public interest, national laws or morality from being patented. Besides that, no law either excludes or authorizes the patenting of hESCs and their production process. The Examination Guidelines do exclude hESCs and their preparation on the grounds of Article 5 of the Patent Law. But, this is simply an administrative rule implemented in the patent office for patent examination; it has no legal force in the courts. Courts maintain discretion regarding the review of patent validity referring to the Examination Guidelines or not as they choose. Since there is no such litigation challenging the validity of the Examination Guidelines or the validity of granted patents on hESC making processes, it is too early to predict what the courts' response will be. The courts may optionally refer to the Examination Guidelines, or submit a request to the Supreme People's Court for judicial interpretation or proposal of legislation. But the judicial interpretation is still subject to the oversight of the Standing Committee, which has the ultimate law interpretation power.⁷⁴⁷

The legal system in the EPO is more complicated. The decisions or opinions of the EBA "*de facto*" bind the corresponding Board of Appeal and the examination office for specific issues in question. The decisions and opinions from the EBA are also available to the national level patent offices and courts as a courtesy.⁷⁴⁸ While the EBA's decisions are binding in specific cases at bar, the decisions are not universally binding. Because of this, if the EPO broadens its interpretation of patentable subject matter in one case, and grants a hESC patent, even though the law is very restrictive on the patenting of human cells at present, the decision would have very limited effect on other patent applications or patent cases. In order to widen the subject matter scope, the member states of the EPC must come together to modify

⁷⁴⁷ *Id.*, art. 42.

⁷⁴⁸ European Patent Office, *Referral on the Patentability of Programs for Computers*, available at <http://www.epo.org/topics/issues/computer-implemented-inventions/referral/cii.html> (last visited Sep, 2, 2010).

the EPC; the EPO has no authority over such changes. With regard to controversial topics such as hESCs patentability, it is always difficult to achieve a consensus among member states because of the ethical implications of such topics and the various standpoints of the countries, especially considering that the legal status of hESC research is unsettled in the EPO. It is a more formidable task to patent hESC's in the EPC than in China, because the later is a sovereignty country and the former is an assembly of countries. It will be many years before the EPO starts patenting controversial inventions like hESCs if it actually occurs at all.

The European Union has been endeavoring to establish a European patent court. In a recent opinion issued by the European Court of Justice, it stated that the European and EU Patent Court Agreement was not compatible with EU treaties.⁷⁴⁹ However, this is not the final decision. If the proposed European patent court is established, it will change the judicial system on patent issues in the European Union.

From the foregoing analysis, it can be seen that the legal system of a country impacts its patent scope heavily, especially on controversial subjects. In common law countries, policy and law can be decided or changed by judges through judicial decisions, which favors the broadening of subject matter scope to keep pace with technological developments. In contrast, in civil law countries, any change or extension of patentable subject matter must be done by legislature with specific procedures, which impedes the process of broadening the allowable patent subject matter.

2. Differences of Cultures and Value Orientation

The Declaration of Independence and the Constitution of the United States, as the foundations of the American system, limit government's power

⁷⁴⁹ Opinion 1/09, *supra* note Opinion 1/09.

to those areas authorized by the people.⁷⁵⁰ Because the United States is a comparatively new country, there is no lengthy history of feudalism to impede the social revolution.⁷⁵¹ Also, possibly because of its geographic independence, it did not suffer from the continuing influence of European colonists' native cultures on its own social values: democracy,⁷⁵² autonomy,⁷⁵³ liberty and equality.⁷⁵⁴ Individual rights play an essential role in American moral vocabulary.⁷⁵⁵ Government's authority is restricted.⁷⁵⁶

Property and liberty are not independent from each other.⁷⁵⁷ Congress confirmed a patent has the attributes of property,⁷⁵⁸ and some courts consider a patent right to be a property right too.⁷⁵⁹ As an individual right,⁷⁶⁰ patent rights entitle patentees to exclusive control over their works.⁷⁶¹ Meanwhile, the public has a right to access information in the public domain. One example is the public's right to use inventions disclosed in invalid or

⁷⁵⁰ William A. Galston, *Expressive Liberty and Constitutional Democracy: the Case of Freedom of Conscience*, 48 AM. J. JURIS. 149, 149(2003)[hereinafter Galston].

⁷⁵¹ Pedro J. Martinez-Fraga, *Examining the Codification of History and the Search for First Principles in Professor Alejandro Guzman Brito's History of the Codification of Civil Law in Iberoamerica*, 39 U. MIAMI INTER-AM. L. REV. 503, 519 (2008).

⁷⁵² Robert Justin Lipkin, *Which Constitution? Who Decides? : the Problem of Judicial Supremacy and the Interbranch Solution* 28 CARDOZO L. REV. 1055, 1106 (2006) FN 148.

⁷⁵³ Blake D. Morant, *Electoral Integrity: Media, Democracy, and the Value of Self-Restraint*, 55 ALA. L. REV. 1, 16 (2002).

⁷⁵⁴ Christopher A. Bracey, Symposium: Of John Brown: Lawyers, The Law, and Civil Disobedience: Adjudication, Antisubordination, and the Jazz Connection, 54 ALA. L. REV. 853 (2003)

⁷⁵⁵ Galston, *supra* note 752, at 149.

⁷⁵⁶ See *i.e.*, *id.*, at 149; Alexander Tsesis, *Principled Governance: The American Creed and Congressional Authority*, 41 CONN. L. REV. 679 (2009)

⁷⁵⁷ Wendy J. Gordon, *A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property*, 102 YALE L.J. 1533, 1559 (1993).

⁷⁵⁸ Amy L. Landers, *Working Together in a Digital World: An Introduction: Article: Liquid Patents*, 84 DENV. U.L. REV. 199, 211 (2006).

⁷⁵⁹ See *i.e.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002); also *Carl Schenck, A.G. v. Nortron Corp.*, 713 F.2d 782, 786 n.3 (Fed. Cir. 1983).

⁷⁶⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81 [hereinafter TRIPS Agreement]. In the Preamble, it states that "intellectual property rights are private rights". Although the ultimate goal of patent laws is not to reward individual but accomplish social goals, to the author, it does not change the concept that patent right is an individual right.

⁷⁶¹ Joshua I. Miller, *Unknown Futures and the Known Past: What Can Patent Learn from Copyright in the New Age?*, 21 ALB. L.J. SCI. & TECH. 1, 55, FN 334 (2011).

expired patents.⁷⁶² Another example is the excluded subject matter not eligible for patent protect, such as discoveries, theories and mathematical methods, aesthetic creations, and schemes. In order to promote innovation in science and technology properly, the patent law must balance the exclusive right granted to laborers with the public's right to use the common wealth of knowledge. There are two ways to solve the conflict between individual rights and public rights. One is to control the threshold of patenting; the other is to set the patent duration.⁷⁶³ The former includes the requirements of patenting, for instance, the scope of patentable subject matters, and the criteria of novelty, non-obviousness and utility. These determine the scope of the individual right against the common wealth available to the public. Compulsory licensing is a power of the government to force the patentee to license his patent to a third party for using or selling the product under certain conditions.⁷⁶⁴ Public interest is one justification for compulsory license, and includes public health, social welfare, environment, and national defense.⁷⁶⁵

In the U.S., since the individual right has higher priority, patent law weight more heavily on the side of protecting patentees' rights. One example is that the criteria for patenting in American patent law is comparatively lower than in China and the EPC, in order to give the individual as broad protection as possible. Another example of the emphasis on individual rights in the U.S. is the limited the use of the compulsory license. Compulsory licensing is rare in the U.S. patent system.⁷⁶⁶ This is also because compulsory licensing is

⁷⁶² David E. Shipley, *Congressional Authority over Intellectual Property. Policy after Eldred v. Ashcroft: Deference, Empty. Limitations, and Risks to the Public Domain*, 70 ALB. L. REV. 1255, 1257 (2007).

⁷⁶³ Robert Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1295 (1996)[hereinafter Merges]

⁷⁶⁴ Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 NW. J. INT'L L. & BUS. 666, 670 (1988)[hereinafter Fauver].

⁷⁶⁵ *Id.*, 670.

⁷⁶⁶ *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980), "Compulsory licensing is a rarity in our patent system, and we decline to manufacture such a requirement

considered less flexible than patent pools.⁷⁶⁷ In addition, it stifles the inventors' incentive to develop technology.⁷⁶⁸

In contrast, China has a different history. Historically, China was a "bureaucratically organized country" which emphasized the good of the country and the authority of the government.⁷⁶⁹ After the foundation of the People's Republic of China, a system called "democratic centralization of authority" was adopted, which shares some features with the traditional Chinese bureaucratic system.⁷⁷⁰ Over many years, state interest was a dominant factor in almost all social and economic activities. The government played an essential role in economy. State-owned corporations were the main investors and participants in the market.⁷⁷¹ The decision-making power was in the hands of the state.⁷⁷² In recent decades, China has gradually encouraged private economy to develop. Various aspects of a private economy have come into being and have become an important part of the overall economy.⁷⁷³ Thus, a market-oriented mechanism was introduced.⁷⁷⁴

However, the public interest still remains of great importance. The phrase, public interest, is used several times in the current Constitution. For instance, Article 51 of PRC Constitution prohibits citizens from infringing on the interests of the state, society and the collective while they are exercising their individual rights and interests; Article 53 requires citizens to observe public order and social ethics. The public interest has a very broad scope. It includes

... ." But in very few cases, compulsory license applies for public interest, such as for pollution control under the Clean Air Act, 42 U.S.C. § 7608 (1970).

⁷⁶⁷ Merges, *supra* note 765, at 1369-71.

⁷⁶⁸ Fauver, *supra* note 766, 676-77.

⁷⁶⁹ Mo Zhang, *Supra* note 497, at 41.

⁷⁷⁰ *Id.*, at 42.

⁷⁷¹ Yongxin Song, *Some Special Features of the Organs of Governance of Chinese Business Corporations*, 24 CAP. U.L. REV. 207, 214 (1995).

⁷⁷² Guanghua Yu, *The Emerging Framework of China's Business Organizations Law*, 10 TRANSNT'L L. 39, 39 (1997).

⁷⁷³ It is documented in 1999 Constitution Amendment, Art. 11.

⁷⁷⁴ This policy has been iterated in 1993 Constitution Amendment, 1999 Constitution Amendment and 2004 Constitution Amendment.

state interest, societal interest, collective interest, public order and national security.⁷⁷⁵ Public interest and public order occupy a very important position in Chinese society and the state is the guide to public interest.⁷⁷⁶ Individual rights are subject to the state interest test.⁷⁷⁷

It is also true in patent laws, inferring from the rules. Article 5 of the Patent Law stipulates an exclusion of patenting certain inventions for reasons of public interest and social ethics. This is an example of weighing public interest over individual patent rights. There is an entire chapter regarding compulsory license in Chinese patent law. Article 50 of Patent Law states that:

Where the invention or utility model for which the patent right was granted is of important technical advance of considerable economic significance compared with another invention or utility model for which a patent right has been granted earlier and the exploitation of the later invention or utility model depends on the exploitation of the earlier invention or utility model, the patent administrative organ under the State Council may, upon the request of the later patentee, grant a compulsory license to exploit the earlier invention or utility model.

Where, according to the preceding paragraph, a compulsory license is granted, the patent administrative organ under the State Council may, upon the request of the earlier patentee, also grant a compulsory license to exploit the later invention or utility model.

⁷⁷⁵ Hu Linguang, Wang Kai, *The Definition of Public Interest in the Constitution*, 1 P.R.C. L. SCI. 18, 21-23 (2005) [hereinafter Hu Linguang].

⁷⁷⁶ *Id.*, at 20.

⁷⁷⁷ Jamie P. Horsley, *China Adopts First Nationwide Open Government Information Regulations*, at 5, *available at* http://www.law.yale.edu/documents/pdf/Intellectual_Life/Ch_China_Adopts_1st_OGI_Regulations.pdf (last visited Mar. 21, 2011)

Compulsory licensing breaks the deadlocks on research progress when a patentee and other researchers cannot achieve an agreement to remove patent obstacles, provided that the patent is critical to further study or future innovations in some extreme cases.

The concern for public interest leads to caution in the scope of patent subject matter and patentability of hESCs. hESC research and inventions involve contentious ethical issues in Chinese law.⁷⁷⁸ Patenting the innovations not only confirms the legal status of conducting such research and making related products, but also legally monopolizes the research results through the patent system. hESCs and derivative productions have such tremendous importance to human beings for diagnosis, disease treatment and medicinal development that nobody should exclusively take advantage of the benefits by excluding the public from using them. Compared to the lives waiting to be rescued by applying new techniques and applications of hESCs, the individual patent right of the patentees is negligible. The research on hESCs is still encouraged in China.⁷⁷⁹ But the research result is not protected in patent law.

Like China, the EPC has similar public order and morality clauses. For instance, Article 53(a) of the EPC sets forth the general public interest rule, and Rule 28 and Rule 29 provide specific rules regarding public order and morality. The European patent office excludes hESCs in patent law due to their close relation to human embryos and fear that the commercial exploitation of hESCs results in commercialization of human beings.⁷⁸⁰ Since the EPO is merely a patent issuing institute, it has no authority over patent enforcement and there is no direct clause regarding compulsory licensing in

⁷⁷⁸ Details are discussed in Chapter III.

⁷⁷⁹ The conduct of research on hESCs is ruled in The Ethical Guideline of Human Embryonic Stem Cell Research, issued by the Ministry of Science and Technology and the Ministry of Health in 2003.

⁷⁸⁰ See Wisconsin Alumni Research Foundation, Case G 0002/06.

the EPC. However, it does define compulsory license as “including ex officio licenses and the right to use patented inventions in the public interest.”⁷⁸¹

In conclusion, the U.S. focuses on rewarding hESC inventors for their efforts by entitling the inventors to patent law protection as an incentive for scientific innovation. By contrast, the EPO and China focus more on the impact of patents on the public interest. For instance, avoiding the commercialization of humans including human embryos in order to protect human dignity, and ensuring that any resources vital to human life and health are available to the public without any obstacle. Both strategies have logical rationale, however, they simply have different points of emphasis. It is difficult to determine which one is better.

It is noteworthy that the U.S. may adopt another strategy to cope with the continually broadening patent monopoly. Since, in the U.S., the perception has already been created that morality should be the concern of Congress rather than the patent office,⁷⁸² both the courts and patent office avoid mentioning morality in cases. Instead, courts and the patent office have exhibited the trend of becoming stricter with other requirements of patenting. A Federal District Court issued a judgment declaring that gene inventions, without human modification, are still products of nature and that isolation is not sufficient to distinguish a human element from a product of nature; therefore, nonmodified human genes, even when they are isolated from their natural context, are not patentable.⁷⁸³ This case is still in progress and whether it will change the picture of human gene patents remains to be seen. Similarly, the BPAI invalidated the latest WARF patent, 7,029,913, in a recent decision in 2010, on the grounds of lacking non-obviousness. It reached this decision by applying a different criterion of non-obviousness—that being obvious to try in view of prior art is ample to meet the

⁷⁸¹ Implementing Regulations, *supra* note 424, Rule 33(2)

⁷⁸² John Miller, *supra* note 373, at 582; Whitehill, *supra* note 373, at 1075.

⁷⁸³ *Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181, at 185.

obviousness standard. The BPAI believed that the patent at issue does not satisfy the non-obviousness requirement because the technique it employs is obvious to try based on the techniques disclosed in the prior art.⁷⁸⁴ These two decisions apply different requirements, one is novelty and the other is non-obviousness, but the end results are similar: denying the validity of human body related patents.

The real intention behind the wording of these decisions remains unclear. Maybe it is the American strategy to restrain monopolies on human elements even in the absence of a morality clause. After the WARF patents were granted, Geron Corporation acquired exclusive license on three significant cell types: neural cells, cardiomyocytes (heart muscle tissue), and pancreatic islet (insulin-producing) cells made from embryonic stem cells. Thus, all individuals seeking to use these particular stem cells must contract with Geron.⁷⁸⁵ This creates a perfect monopoly on hESCs in the hands of WARF and Geron. Even though WARF signed a Memorandum of Understanding [MOU] with the Public Health Service of the U.S. and the HHS to supply WARF cells to scientists at the NIH for teaching or basic non-commercial research programs, and allows federal non-profit institutes access to the stem cells upon the negotiation of similar agreements,⁷⁸⁶ this only entitles such third parties to non-commercial use of the WARF cells and precludes commercialization of inventions developed using the WARF patents; anyone who attempts to use or experiment on WARF cells for commercial purposes

⁷⁸⁴ Board of Patent Appeals and Interferences, *Foundation for Taxpayer and Consumer Rights v. WARF* (B.P.A.I. No. 2010-001854, 4/28/10), at 37 available at <http://www.consumerwatchdog.org/resources/WARFDecision042910.pdf> (last visited Aug. 26, 2010).

⁷⁸⁵ Geron, *Stem Cell Lines*, available at <http://www.geron.com/technology/stemcell/stemcelllines.aspx> (last visited Sep, 12, 2010).

⁷⁸⁶ See MOU, *supra* note 320.

or legitimate business purposes must negotiate with WARF for another commercial license.⁷⁸⁷

This inconvenience for other researchers and obstacle to further stem cell research raises the public's concern and may also cause the courts and patent office's concerns as well. I speculate that after noticing the voice of opposition to human genes and hESCs patents, the patent office and courts gradually realized the side effects of the monopoly on the public welfare and subsequent research programs. While Congress still has not taken any measures to preclude such patents, the courts and patent office are using the requirements of novelty and non-obviousness as a shield to clear the obstacles and monopoly for hESC and other scientific research. It will be interesting to perceive the policy orientation behind the decisions. The end result is that hESCs and other human element patents are restricted in the United States in practice even though they are perfectly patentable under current U.S. patent law.

3. Research Progress in hESC Research

Another reason for the different policies adopted is the different status of hESC research in the regions under study. The U.S. receives the most applications and patents on hESC related inventions.

Figure 7.1 shows the top ten countries that own the most hESC related patents issued respectively in the U.S., the EPO and China. It illustrates that the U.S. is the top country, owning the most patents in relation to hESCs. It is also the country that issues the most patents applied for by foreigners. It also shows that while the EPO grants patents regarding hESCs, none of them belongs to the EPO member states.

⁷⁸⁷ *Id.*, at 5.

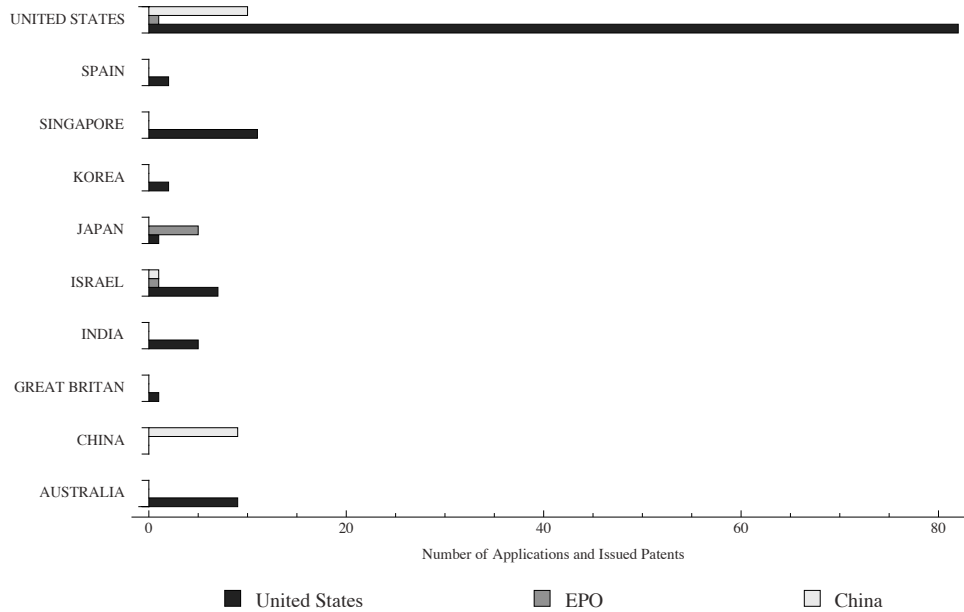


Figure 7.1: Nationalities of hESC patents issued in the U.S., EPO and China

The status and development of hESC research affects states' policies because the more hESC research achievements in a country, the more competitive the country is in the hESC related pharmacy, research and therapy fields of the global market and the more motivation it has to issue protective policies and laws in order to safeguard and utilize its research advantages. In contrast, if a country has only minimal hESC research programs or the research it has is comparatively lagging, it will tend to remove any monopoly protection on research result, so as to share in the research progress, and prevent other countries with higher research levels from taking take advantage of the patent system.

The U.S. has the most advanced hESC research in the world. Although the policy of the federal government on hESC research is shifting, state governments and private research institutes have never stopped their research and progress. Therefore, the U.S. protects these achievements to profit from domestic advances.

Comparatively, in China, very few other companies or institutes have the economic capability to afford such expensive and time-consuming research projects. Therefore, while China has few research projects, most of them are supported by the government and most are contained within universities or state-owned research institutes. Figure 7.2 demonstrates this information.

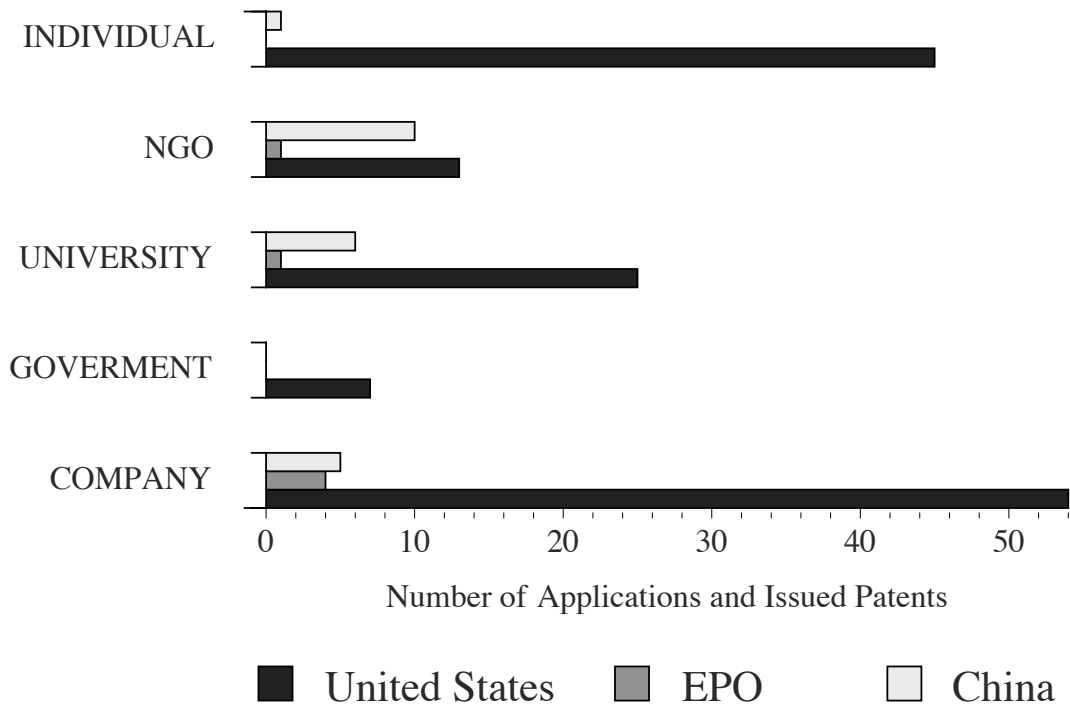


Figure 7.2: Comparison of ownership categories of hESC related patents and applications between the U.S., EPO and China

Since the research activities are primarily led and financially supported by the government and the innovation results are in the hands of the government, there is little domestic benefit to be achieved through the patent law, which aims “to protect patent rights for inventions-creations, to encourage inventions-creations, to foster the spreading and application of inventions-creations, and to promote the development of science and technology, for meeting the needs of the construction of socialist

modernization.”⁷⁸⁸ This is good for public interests, because the state can use its power to initiate research, further develop the research results, and apply the result to the people whenever they are needed. In addition, since a patent right is only a territorial right, the government can always turn invention applications from other countries down for national patent laws regardless of the patent regulations in other countries. It does not have to worry about the research results or resources being monopolized. Thus, within the territory of China, there is no scientific research demand or market needs for patenting hESCs.

Regarding the European Patent Office, the policy making is more independent from research progress motivations than is the case in individual countries with national patent systems. As a regional organization, the EPO has a neutral policy-making process and administrative office; as a result, the EPO’s patent rules are more independent from the objective of stimulating research development.

Due to the different levels of hESC research progresses and the different legal statuses of the relevant policy-making agencies, the U.S., China and Europe have differing policies on patenting hESC innovations.

C. The Importance of hESC Laws

Regulation of biotechnology inventions is necessary not only for the good of public health, medical development and pharmaceutical processes, but also to enable states to maintain their its competitiveness in the patent world and remain independent from their partners in trading. The patent laws and practices in China have been gradually catching up with those of developed countries and international laws, such as the TRIPS Agreement. The goal of

⁷⁸⁸ 2008 Patent Law, *supra* note 7, art. 1.

legislation and policy concerning biotechnology is to bring China into the competition in scientific study and the end-product industry.

Because of its cultures and transitions, China has a tendency to maintain a conservative view toward any ethical or controversial issues. Wherever negative impacts are possible, China may tend to be very careful and cautious. This general tendency applies to biotechnological inventions, too. Current Chinese patent legislation regarding biotechnology covers almost the entire field of biotechnological research and expresses China's stance on some ethically controversial issues, such as hESC research and its patentability. However, the current legal system is not perfect. It is the main goal of this dissertation to analyze the legal issues, especially in patent law, in relation to hESC research, in order to unify the laws on hESC innovation among countries.

The main goal of patent law is to grant monopolies to inventors in order to promote science and technology.⁷⁸⁹ The degree of monopoly is the main factor to be adjusted through patent law in order to stimulate scientific innovation while maintaining a market with free competition.⁷⁹⁰ But the line is difficult to draw. With respect to essential tools of discovery and research in biotechnology, the main concern is over the side effects of patenting—stifling further developmental innovations due to the high costs of licensing.⁷⁹¹ In the meantime, lack of adequate patent protection may also cause stagnation in scientific research. Without patent law, research results may remain undisclosed as trade secrets and therefore never be published

⁷⁸⁹ See *i.e.*, 2008 Patent Law, *supra* note 7, art. 1, “promoting scientific and technological progress as well as the economic and social development,” and U.S. Constitution, art. I, § 8, cl.8, “promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries”.

⁷⁹⁰ Michael A. Carrier, *Unraveling the Patent –antitrust Paradox*, 150 U. PA. L. REV. 761, 806, FN 201 (2002).

⁷⁹¹ Filliben, *supra* note 8, at 252.

and shared with the public.⁷⁹² Thus, it is accepted that while patent rights promote innovation, they should not restrain research on essential tools.⁷⁹³ However, there is no consensus on whether patent law should be used for hESC innovations and if so how.

Considering the importance of hESCs to medicinal manufacture, therapy and diagnostic research, each country should be concerned regarding the patent status of hESCs, because the fields of industry and science are impacted. To some, patent law may not seem critical because it has only territorial jurisdiction. Nonetheless, the world faces greater and fiercer industrial and scientific competition and an enlarging globalized market. Thus, it is crucial for countries to consider the place of hESCs in patent law in order to allow the patentees to have the advantage of an initial monopoly and to avoid making decisions that will negatively affect industry and scientific research. As for the U.S., hESCs are presently patented. If these patents were to be considered invalid and opened to the public in the future, the licensees who spent tremendous time and money negotiating license agreements would be negatively impacted, which would, in turn, stifle the enthusiasm of research pioneers and bring about instability of the industry as well as the market. On the other hand, with respect to states that ban the patenting of hESC innovations such as China, if the ban is ultimately removed, countries that had previously allowed the patenting of hESCs, such as the U.S, will have the advantage due to the international priority right of their inventions. Europe and China will lose not only the market for hESCs, but also the market for downstream products derived from hESCs. As a result, patentability of hESCs is an essential issue in every country's science, research, and business sectors.

⁷⁹² Gregory C. Ellis, *supra* note 9, at 26; Filliben, *supra* note 8, at 254.

⁷⁹³ Gregory C. Ellis, *supra* note 9, at 26.

One concern with reference to biotechnological research is the misuse or monopolization of research results. This does not cause as much concern in China as in the US. The main reason for this is that most of the biotechnological research in China, especially hESC research, is conducted and supervised by national research institutes or public universities due to the fact that such research is costly and requires highly professional researchers. This type of research could hardly be conducted by individuals or small enterprises.

Three major benefits are realized from this situation. First, the research findings are primarily under the control of the government, which diminishes the possibility of misuse or illegal conduct. Second, it dispels worries about future research being impeded by high royalties and lengthy negotiations because the government will supervise licensing and assign activities for the maximum benefit of the country as a whole; therefore, people do not need to worry about a research monopoly hampering further downstream development. Third, research results can be utilized and applied under macro-control for the public interest. In case of emergencies, such as those situations in which public safety is at risk, decisions can be made more quickly and measures can be implemented more thoroughly.

However, every country has its own system and circumstances, which cannot be changed in a short period of time. The model law below is created for general situations, not for special cases.

D. Model law—Suggestions regarding Patent Regulations on hESCs

Considering the close relationship between hESC innovations and culture, social values, and religion, the model law below is created for general situations overall and not specific nations. In the mean time, all countries

should combine the law with their own administrative, economic and legal systems in order to fully use these suggestions to their best advantage.

1. Choice of Law

There are different types of rights in a legal system. These rights include but are not limited to the right to freedom, physical property rights, and intellectual property rights. In order to protect and use the intangible values of intelligence and biotechnological techniques, intellectual property law is a good option.⁷⁹⁴ This category includes patent, trade secret, copyright and trademark areas.⁷⁹⁵ Compared to trade secret protection that enables the developer of an invention to maintain “an advantage over competitors who do not know or use it” as long as the information is a secret,⁷⁹⁶ patent protection has more advantages in protecting and promoting hESC research.

First, a patent right is an exclusive right in modern patent law.⁷⁹⁷ It is a right to the patent right holder to exclude others from making, constructing, using and selling his inventions without his consent though it does not grant the patent holder an affirmative right to make, use or sell it himself.⁷⁹⁸ This right protects the first inventor.⁷⁹⁹ In this era of high-speed information and technology flows, there is no substantial time lag between the first inventor

⁷⁹⁴ Graeme B. Dinwoodie, *Developing Defenses in Trademark Law*, 13 Lewis & Clark L. Rev. 99, 102 (2009).

⁷⁹⁵ *Id.*

⁷⁹⁶ Francis J. Duffin & Bryan S. Watson, *Best Practices in Protecting and Enforcing Trademarks, Copyrights*, 28 Franchise L.J. 132, 178 (2009) (citing Restatement of Torts, § 757 (1939)).

⁷⁹⁷ Historically, patent right was considered as a property right that entitles the owner exclusive right to use the property. Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 HARV. J. L. & TECH. 321, 347-359 (2009).

⁷⁹⁸ *See i.e.*, Patent Law, *supra* note Patent Law, art. 11.

⁷⁹⁹ The rules on priority are different. The U.S. applies the first-to-inventor rule, which means whoever invented first is awarded the patent, taking into account the time to conceive the idea and reduce to practice; while China and Europe employ the first-to-file rule, which means no matter who comes up with the idea or reduces to practice, whoever files the patent application first is granted the patent.

and the second one. Considering the difficulty of biotechnology research and the great expense of such research programs, adequate payback to the investors and/or inventors is essential to the field. Patent law can protect the exclusive interest of patentees in order to stimulate innovation. In addition, it provides the patentee the right to transfer and license his patent to a second individual or group.

Second, a patent right has a term period. An appropriate term of patent protection can guarantee a patentee the benefit of his exclusive right and yield profit from his investment. Meanwhile, it also ensures the public's access to the innovation by public disclosure, which is not required in trade secret protection, and guarantees that the invention will be added to the public wealth after the patent term expires, benefitting the whole of society. This is one of the main distinctions between patent rights and trade secrets. With trade secrets, people can enjoy the economic value of their innovations as long as they keep it a secret. But, they do not have an exclusive right to the innovation; they cannot prohibit others from achieving the same inventions thereafter.⁸⁰⁰

Third, given the experiences of countries around the world, patent law appears to be the best option for biotechnology innovation protection. The U.S. utilizes patent law to protect research findings on hESCs. The European Union also chose patent law to protect biotechnological innovations by issuing Directive 98/44/EC.⁸⁰¹ hESC research is merely a category of biotechnology research and is essentially not much different from other categories, such as gene sequence research. Therefore, patent law is a viable way to protect all biotechnological innovations, including hESCs and related processes.

⁸⁰⁰ The trade secret is governed under state laws. The National Conference of Commissioners issued the Uniform Trade Secrets Act (UTSA) for a comprehensive model of trade secret legislation.

⁸⁰¹ Directive, *supra* note 185, at 13-21.

2. Requirements of Patentability

a. Patentable Subject Matters

Patentable subject matter is usually not specified in one individual clause, but is combined within definitions and exceptions. U.S. patent law defines patent subject matter as any “process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,”⁸⁰² and also imposes the utility requirement. Chinese patent law defines patentable inventions as “any new technical solution relating to a product, a process or an improvement thereof.”⁸⁰³ The European Patent Convention describes patent as innovation “in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.”⁸⁰⁴ In addition, Chinese and European patent laws have specific non-patentability clauses while the exclusion of patentable subject matter in the U.S. is contained in the case law. They all have a definitive clause enumerating broad patentable categories, limited by a list of exclusions. This is mainly because the scope of eligible subject matter for patenting is fairly broad and it is easier to define the scope of subject matter by exception rather than illustration. Today, compositions of matter, living or not, and processes and improvements thereof are eligible for patenting. With the development of biotechnology, this scope is broadened to include more highly developed animals and related products, such as human tissues and materials.

The sources of the nonpatentability clauses are different between the countries studied, with European and Chinese exclusions adopted in statutory law and U.S. exclusions developed through case law. They have

⁸⁰² 35 U.S.C. §101.

⁸⁰³ Patent Law, *supra* note Patent Law, art. 2.

⁸⁰⁴ European Patent Convention, *supra* note 406, Article 53.

unpatentable categories in common, such as scientific discoveries, phenomena of nature, mental activities, and mathematical formulae. But they also have some categories that differ due to different laws. However, each country's list of unpatentable substances is consistent with the patent requirements in its own laws. Subject matter is not patentable because it is either not novel, or has no specific and substantial utility, or, in the case of the EPO's practice and Chinese patent laws, is contrary to social norms or public interest. The clauses enumerating specific exceptions to patentability are not a necessity since they are merely illustrative interpretations of the patent requirements stipulated by legislatures.

b. Morality Issues in Patent Law

Whether to include morality requirements within patent law is a contentious question. The TRIPS Agreement gives member states the freedom to incorporate morality and public order clause in patent law. Article 27.2 regulates "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment."⁸⁰⁵ By realizing the controversy of the morality requirement in patent law, the TRIPS Agreement leaves it to countries to decide. While China has adopted the morality and public order clause, the U.S. has chosen to not include the clause in patent law. There are two reasons for not employing morality clauses in patent law.

⁸⁰⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299, available at http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (last visited Mar. 22, 2011)

The U.S. refuses to consider morality in patent law because patent examination is about technique and science, not ethics.⁸⁰⁶ I am in favor of this opinion that patent law should focus solely on technical requirements and leave the moral and ethical issues to the legislature or relevant administrative agencies, not only because patent officers are technical experts, not ethicists or politicians, but also because states should allow them to concentrate on their expertise, not rely on them to make judgments regarding moral norms. This guarantees the efficiency and accuracy of patent examination, while leaving the morality considerations to more appropriate agencies, such as the National Institutes of Health [NIH] in the U.S., and the Ministry of Science and Technology [MOST] and Ministry of Health [MOH] in China. In the EU, the morality issues can be determined by the EU decision-making process and those EU executive agencies under their authority, such as the European Research Council.⁸⁰⁷

Second, the patent system is incapable of adequately governing research conduct. States should be fully aware that the patent law is a poor tool for governing inventions or research contrary to morality or public order. A patent can be considered a negative right. Once a patent is obtained, an inventor can reap the benefits of his creation and has the right to exclude others from using his invention without permission. But patent law is neither appropriate, nor designed, to supervise inventions on a basis of morality. If the patent law incorporates morality considerations and rejects some inventions based on morality, instead of eliminating these inventions, it actually put them back into the free market so that everyone can make use of

⁸⁰⁶ Resnik, *supra* note 285, at 213; *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366-68 (Fed. Cir. 1999), the court held that “the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years.”

⁸⁰⁷ The European Research Council is the first European funding body established to support investigator-driven frontier research. See European Research Council, *Mission*, available at <http://erc.europa.eu/index.cfm?fuseaction=page.display&topicID=12> (last visited Mar. 3, 2011).

them. This result contradicts the original intent of the morality clauses. Therefore, patent law is the wrong tool to govern morality.

Therefore, excluding the patentability of hESCs in a patent regime is ineffective in accomplishing the goals of those who advocate such exclusion. The suggestion is that countries should remove the morality clause from patent law. China should remove Article 5 of its Patent Law, and European Patent Convention should eliminate its Article 53(a) and corresponding Rule 28. Instead, they should set forth in public law or administrative law direct prohibitions on research activities deemed immoral or contrary to social norms, such as the use of hESCs for human cloning purposes.

c. Novelty

The novelty clause involves the requirement of being new, not used, known, or filed for in a patent application by a third party before the filing date of the patent application. One distinction between invention and discovery is if it previously existed.⁸⁰⁸ Materials existing in nature but not previously known to human beings due to a shortage of tools or knowledge are discoveries rather than inventions once they are revealed. However, that criterion is not strictly true any longer.⁸⁰⁹

According to the current European Patent Convention and Chinese patent law, the novelty requirement for biotechnological innovation is that it must be separated or isolated from its original natural environment, with its structure or physical characteristics revealed and a viable method to obtain it provided. However, novelty should require more than that. In order to meet the novelty requirement, the technique of separation or isolation should

⁸⁰⁸ Stephen McKenna, *Patentable Discovery?* 33 SAN DIEGO L. REV. 1241, 1247 (1996).

⁸⁰⁹ *Id.*, at 1247.

include conceiving an idea and reducing it to practice, and inventions should be created through the intervention of human beings to achieve some status that does not exist in the nature world. This criterion should apply to all kinds of human materials such as human genes, and human cells.

With respect to hESCs, as long as they are manipulated, isolated or refined by people, and demonstrate a new stage, new characteristics or new use compared to the prior art, they meet the requirement of novelty. hESCs isolated from embryos and cultured in specific media are novel because after being cultured in an artificial environment, the molecular structure, characteristics and even chromosomal structure may be changed and differ from the cells of the embryos from which they were derived.⁸¹⁰ hESCs obtained with SCNT that have unstable and irreversible gene representation⁸¹¹ and iPSCs are created with human manipulation. They are novel only if they comprise distinctive characteristics from naturally occurred human cells. Genetically altered hESCs are even more artificially modified. They have distinctive characteristics that differentiate them from natural hESCs and involve more human intervention; and therefore, they satisfy the novelty requirement.

d. Utility/Industrial Applicability

As mentioned in Chapter 3, many scholars oppose the patenting of hESCs based on their status as a research tools or essential scientific commodities. The general value in research and medicine is so unique and irreplaceable that it becomes a necessary aspect for further research and downstream

⁸¹⁰ Mats G. Hansson et al., *Isolated Stem Cells-Patentable as Culture Artifacts?* 23 STEM CELL 1507, 1508 (2007)

⁸¹¹ *Id.*, at 1508-1509.

industry.⁸¹² This problem can be solved by setting up the requirement of industrial applicability; merely scientific or research utility should not be sufficient for patenting.

The requirement of industrial applicability means that first, inventions being considered for patenting must have a practical, immediate, specific and profitable use.⁸¹³ The use must be concrete, practical, and substantial. Furthermore, patentable inventions must be capable of being made or used in industry, solve a technical problem, and achieve effective results.⁸¹⁴ Only a substance able to be isolated or extracted from its natural environment and exploited industrially in order to produce technical effects can be patented.⁸¹⁵ Mere scientific achievement or research value does not satisfy this requirement because it does not have immediate, specific and practical value. Methods for treatment by surgery or therapy and diagnostic methods cannot be industrially applied because they are based on patients' personal situations and everyone's reaction to a medicine or treatment may vary; therefore, they have no industrial value, but they do have clinical use. Nor do business methods meet the industrial application requirements.⁸¹⁶ Regarding biotechnological inventions, any product or process that utilizes random mutation under chemical or physical conditions that cannot be repeated in manufacture is not industrially applicable, and as a result, is not patentable.

The same criterion applies to methods of using or producing hESCs. hESC related processes are patentable if they have industrial application and can

⁸¹² Although the search for the substitute of hESCs has been making progress, such as the innovation on induced pluripotent stem cells. But whether iPSCs can take over hESCs is unclear.

⁸¹³ European Patent Office, *T 0870/04 (BDP1 Phosphatase/Max-Planck) of 11.5.2005*, T 0870/04 (2005) at 9, available at <http://www.epo.org/law-practice/case-law-appeals/recent/t040870eu1.html> (last visited Mar.1. 2011).

⁸¹⁴ European Patent Convention, *supra* note 406, Article 57 & Rule 29(3). It states that industrial application is required in gene sequence patent applications; European Patent Office, *BDP1 Phosphatase/Max-Planck*, T 0870/04 (2005) at 9.

⁸¹⁵ 2006 Examination Guidelines, *supra* note 625, Part II, Chapter 10, Rule 2.1.

⁸¹⁶ Biddinger, *supra* note 702, at 2542.

achieve concrete, substantial and practical results. Only when they meet these requirements, can they be patented.

Non-modified hESCs *per se* have no present direct and concrete technical results in the real world. Their utility relates to the process of their differentiation into multipotent stem cells, or their existence in a transformed state.⁸¹⁷ In terms of practical and specific use, therefore, they have no immediate benefit to the public. The main use of hESCs is to utilize their pluripotent properties. This is similar to the expression “biological properties,” which is nebulous and general.⁸¹⁸ In conclusion, non-modified hESCs do not meet the requirement of industrial applicability; hence, they are not patentable.

e. Non-obviousness

As modern developments in industry and technology emerge, the patent system is evolving beyond the primitive industry for which it was originally conceived.⁸¹⁹ Instead, it covers new industries, such as biotechnology, semiconductor, computer hardware and software, and electronic communication.⁸²⁰ Distinct standards should be applied to different subjects due to their different characteristics. The unique character of biotechnology, for instance, with its close relation to nature and the human body, requires specially tailored rules.

Non-obviousness means that an invention is so original that it is not obvious for a person who has ordinary skill in the art to assume from the

⁸¹⁷ See the discussion in Section B (2) in Chapter 2.

⁸¹⁸ *In re Fisher*, 421 F.3d. 1365, 1371 (Fed. Cir. 2005).

⁸¹⁹ Georgios I. Zekos, *Nanotechnology and Biotechnology Patents*, 14 INT'L J.L. & INFO. TECH. 315 (2006)

⁸²⁰ *Id.*

prior art. In the USPTO, there are two different interpretations of non-obviousness: “obvious to try” and “obvious to achieve.”⁸²¹ These two standard should be applied together.

First, patent offices should determine whether an invention is “obvious to try” based on the current technique, which includes several factual determinations, such as the scope of prior art, the difference between the invention at hand and the prior art, and the predictability of the result. If so, further inquiry should be made into whether the claimed result is obvious to achieve. To answer the second question, patent offices should consider other factors, such as the failure of others, the needs of the market and any commercial success achieved.⁸²²

This requirement was the main divergence between the BPAI and the patent office on WARF patent ‘913. On the issue raised in that case, the first considerations should be how different the embryonic stem cell-deriving techniques employed on other mammal species are from the derivation technique claimed in the present patent; whether the difference is large enough to be obvious “to try” to people practicing the art with ordinary skill and creativity; and whether the technique at bar solves problems known in the prior art. These are technical questions, and need to be determined by relying on expert testimony. Besides that, as a secondary consideration, patent offices should consider the time spent and numbers of attempts made to apply the techniques proven on other species to human beings.

⁸²¹ This difference is the main cause of the different decisions of the patent office and the BPAI. The BPAI adopts “obvious to try” standard, which increases the difficulty to satisfy the requirement.

⁸²² These are so called secondary considerations in some cases in US., *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1324 (2004) (citing *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988) (commercial success)); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1054 (Fed. Cir. 1988) (long-term need); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1574 (Fed. Cir. 1996) (copying).)

f. The model law

Based on the above analysis, example rules articulating patent requirements, taking into account the new developments in biotechnology follow:

Article 1. In order to encourage inventions, to foster the spread and application of inventions, and to promote the development of science and technology, this law is enacted to protect inventors' exclusive rights on creations that are new, inventive and industrially applicable, including process, products, or any improvement thereof for up to 20 years.

Article 2. No patent right shall be granted for any invention that is contrary to the laws; inventions shall not be deemed to be contrary merely because their publication or exploitation is prohibited by laws or regulations.

Article 3. Novelty

(1) An invention shall be considered to be new if it does not form part of the present state of the art.

(2) Inventions shall not be considered new if (a) the invention was in use by others in public, or patented or described in a printed publication by others in this country or abroad before the filing date of the patent application, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country by the applicants, more than one year prior to the filing date of the patent application in this country.

Article 4. Industrial Utility

An invention shall be considered to be susceptible to industrial application if

(1) it can be made or used in one or more industries, including agriculture, and

(2) it can be made or used with substantial, concrete and practical results.

Article 5. Inventiveness

(1) An invention should be considered inventive compared to the technology existing in the art to which it pertains if the differences between the invention and the prior art are so substantive that the invention would not be obvious with reasonable expectation of success to a person having ordinary skill in the art at the time the invention was made.

(2) Other elements should also be considered in determining non-obviousness of the invention, such as the needs in the market, commercial success, and long-term attempts but failure in the art.

There is no need to list all of the unpatentable categories in law because they all fail to meet at least one of the patenting requirements. According to the rules in the model law, discoveries should not be regarded as inventions because they fail the creation element in Article 1 and the novelty requirement in Article 3.

However, to be clear, states can incorporate this content in implementing rules, i.e., Implementing Regulations to the EPC, Detailed Rules for the Implementation of the Patent Law in China.

Rule 1. Presentations of information, scientific theories, mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body are not patentable since they do not possess industrial applicability. They either cannot be manufactured, or do not achieve substantial, concrete and practical results.

Rule 2. Human embryonic stem cells, human genes and other human cells without modification are not patentable even if they are isolated or purified from human body, or created with the somatic cell nuclear technique. However, methods of isolating, purifying or modifying human materials are patentable. Induced pluripotent stem cells are patentable if they meet the requirements of novelty, industrial utility and inventiveness.

Rule 3. Computer software is protected by copyright therefore should not be subscribed to patent law. Plant and animal varieties or essentially biological processes and should not be subordinate to patent law either because they should be subject to plant variety and animal varieties protection laws.

As for the U.S, the Utility Examination Guidelines already explicitly defines the three criteria of utility. The main task is for the courts and the USPTO to apply the criteria. Additionally, courts and the USPTO can adopt the reasoning in *Ass'n for Molecular Pathology v. United States PTO* (2010) that ruled that hESCs are not novel if they are not manipulated since they are products of nature.

3. Other Clauses in Patent Law

Patent requirements determine the patentability of inventions, while other clauses heavily affect the enforcement of hESC related patents.

a. Infringement Exemption

Considering the importance of hESC related innovation to public interest and science and technology, some exemption to infringement is necessary. The U.S., China and most European Countries⁸²³ have scientific research and experimental use exemptions. However, the interpretation of the exemption is different among the EPO, the U.S., and China. In the U.S. this exemption is interpreted very narrowly, merely for non-business purposes, which is defined very narrowly. Other uses, even for legitimate business purposes, are considered infringement. In the EPC, patent enforcement is left to member states as well as the interpretation of the infringement exemption. In some European countries, the exemption is given broad interpretation. The exemption for experimental use is based on the idea that no direct profit will be gained.⁸²⁴ This interpretation of the exemption clause is broader than in the U.S. because experiments, even with commercial intention, are also protected under such interpretation.⁸²⁵ In China, Article 63(4) articulates the exemption clause for scientific research and experiment. No further explanation concerning the exemption is given either in Article 63 or in other patent laws.⁸²⁶ Therefore, the scope of permissible experimental use in China is still uncertain.

⁸²³ Pymont, *supra* note 709, at 394.

⁸²⁴ Mayer, *supra* note 210, at 76-77.

⁸²⁵ *Id.*, at 76-77.

⁸²⁶ Demin Liu, *supra* note 713, at 251.

In order to protect public interest and spur scientific development to the maximum extent possible, the exemption clause needs to be broadened.

There is hardly a research program that has pure scientific inquiry as its ultimate goal. Most research activities have a business purposes to one degree or another,⁸²⁷ either to enable the creation of a downstream product, or to apply a technique or composition in practice to solve a practical problem. Therefore, it is suggested that in order to keep pace with the needs of scientific research and public welfare, the exemption should include any scientific research or experimental use without a direct business purpose.

b. Compulsory Licensing

As mentioned above, compulsory licensing is a tool the government exercises to force a patentee to license his patent to a third party to enable the use or sale of the invention under certain conditions, in order to ensure the full use of patents and attain the maximum benefit from patents for the public in certain special cases.

For instance, states can rule that in the case of a national emergency or other extraordinary circumstances, or where the public interest requires, a compulsory license should be granted to use or exploit relevant patents. In addition, whenever an invention of technical significance requires access to another patent granted earlier, and the exploitation of the later invention depends on the exploitation of the earlier invention, a compulsory license should be granted upon the request of the later patentee.

Patents on hESCs, relevant processes and certain downstream products should be subject to such restrictions as well. Given the irreplaceable

⁸²⁷ Demin Liu, *supra* note 713, at 251.

significance of hESCs and related processes and products in science, therapy and pharmacy, the enforcement of patents related to hESCs should be subordinated to the compulsory license clause; states should adopt compulsory licensing measures on hESC's relating patents if it is necessary to further the societal or public interest.

4. The Morality Issue of hESC Research

Europe and China both include morality requirements in patent laws, while the U.S. patent law does not. Whether to consider morality issues in patent law is essential to the patentability issue of hESC innovations, because patenting hESCs can easily be considered contrary to social morality and ethics since it involves commercializing the human body, monopolizing the commons and diverting essential facilities and research tools from the public. At the same time, hESC research is encouraged at the government level in China, most countries in Europe, and to some extent in the U.S., and inconsistencies exist between patent law and research policy. In order to resolve the conflict, it is crucial to explore the morality issue relevant to hESC research. The issue can be divided into two parts: morality of hESC research and morality of hESC patents, which in present debates, both depends on the sources of human embryos.

To discuss the morality issue, there is one fundamental prerequisite that needs to be clearly understood: the starting point of personhood. Does it begin at fertilization, birth, or some point in between? As introduced before, this is a complex question not only involving biology and science, but also ethics, religion and sociology, because scientific research cannot be completely isolated from other social elements. But the overall viewpoint is that personhood does not start at the zygote stage, but some time later. It is implausible to insist that zygotes have the same legal status and legal rights

as persons. Nonetheless, this idea may be changed with the development of science. The following analysis on the morality of hESC research is based on this premise.

a. Embryos from fertility clinics

Most people support hESC research on extra embryos left over from fertility clinics.⁸²⁸ The reason is that these embryos are no longer needed; therefore, they would serve a better purpose enabling research than being thawed and thus destroyed.⁸²⁹ This involves a contentious issue—the status of human embryos. As stated above, zygotes that have no consciousness or nerves should not be considered persons. Hence, relevant research utilizing them should be allowed.

There are other issues that may arise due to research on these embryos. Reproductive technology, which assists infertile couples to achieve their dream of pregnancy, also creates some unexpected difficulties. It has caused custody disputes during divorce proceedings. When a couple divorces, who has custody of unused frozen embryos and who has the final word on the disposition of these embryos? Since there is no law directly addressing this issue, courts have taken four paths to answer it: considering embryos as persons, as potential human life, somewhere between tissues and human beings, and mere property.⁸³⁰ Because there is no consensual way to determine the legal status of embryos, contracts between couples are

⁸²⁸ Nisbet, *supra* note 98, at 135.

⁸²⁹ Outcka, *supra* note 101, at 193; ROBERT P. GEORGE, *supra* note 99, at 192.

⁸³⁰ Katherine Poste Gunnison, *Poaching the Eggs: Courts and the Custody Battles over Frozen Embryos*, 8 J. L. FAM. STUD. 275, 270 (2006)[hereinafter Gunnison]. *See i.e., Davis v. Davis*, 842 S.W.2d 588, 597 (Tenn. 1992), the court stated that “preembryos are not, strictly speaking, either “persons” or “property,” but occupy an interim category that entitles them to special respect because of their potential for human life,” but the parents “have an interest in the nature of ownership”; *Roe v. Wade*, 410 U.S. 113, 158 (U.S. 1973), the court alleged that the Fourteenth Amendment did not include the unborn.

recommended.⁸³¹ Besides that, when research on embryos achieves success and starts making profits, do the parents of the embryos have a right to share in the profits? This is another potential issue. Until now, there is no published litigation regarding this issue. But a similar issue occurs in the case of ownership of research results and profits derived from biological material taken from patients.

The current practice is that cells and tissues removed from patients are bought and sold without the patient's consent. As long as body tissues are removed, the patients lose their property rights in them. The patients should not share any profits of research findings based on their body materials.⁸³² In a more current case, *William J. Catalona v. Washington University* (2006), the court states that the materials removed from the patients are "inter vivos gifts"; after the donation is performed, the patients lose their right to repossess or transfer the materials.⁸³³ Tissue from human bodies is slightly different from the embryos because unless discarded, frozen embryos belong to the parents. By discarding the embryos, the parents give up the ownership interest as well as the future profits that may be generated from the embryos. Instead, the clinics have the right to claim the embryos, launch research activities and reap the profits thereafter. However, research conduct is subject to relevant research guidelines or policy, which will be discussed below.

b. SCNT-produced embryos

⁸³¹ *Id.*, 290.

⁸³² Claire Devine, *Tissue Rights and Ownership: Is a Cell Line a Research Tool or a Person?*, available at <http://www.stlr.org/2010/03/tissue-rights-and-ownership-is-a-cell-line-a-research-tool-or-a-person/> (last visited Oct. 2, 2010).

⁸³³ *Wash. Univ. v. Catalona*, 490 F.3d 667, 676 (8th Cir. Mo. 2007).

With respect to the hESC research on non-traditionally produced embryos, such as SCNT-produced embryos, the main issue is whether the SCNT is permissible. In the United Nations Declaration on Human Cloning, human cloning is prohibited out of consideration for human dignity, women rights and human life.⁸³⁴ But there are several countries that voted against the Declaration because it arbitrarily bans on all forms of human cloning, including therapeutically cloning.⁸³⁵ These countries include China and most of the European Union members.⁸³⁶ The U.S. voted in favor of the Declaration. However, the document is a non-binding political statement, which means that countries still have the freedom to maintain their individual attitude towards therapeutic cloning. Regarding the different purposes⁸³⁷ and processes⁸³⁸ of reproductive cloning and therapeutic cloning, the former should be banned because it creates a live birth; while therapeutic cloning should be permitted since it only cultivates cells, which hardly infringes upon human dignity or human rights.

As a result, hESC research on SCNT-produced embryos should be allowed since the ultimate purpose of the cloning activity is to generate cells rather than human beings.

c. Induced Pluripotent Stem Cells

⁸³⁴ G.A. Reg. 59/280, *supra* note 200.

⁸³⁵ *Id.*

⁸³⁶ Those European countries are: Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Spain, Sweden, United Kingdom.

⁸³⁷ Reproductive cloning is applying SCNT to produce a live birth, during which embryos would be placed in the uterus to go from gestation to birth. Therapeutic cloning is for producing stem cells, during which ESCs would be derived from a blastocyst and grown in vitro and further differentiated into particular cells for therapeutic uses.

⁸³⁸ Therapeutic cloning is a process that scientists use to extract ESCs from embryos, cultivate them, and differentiate them into particular needed cell types. Those differentiated cells can be implanted into human body to repair or replace damaged cells, tissues and even organs. The whole process of therapeutic cloning does not create the whole human body.

Similarly, research on induced cells is allowed in most countries since the technique is to induce embryonic-like stem cells, which have similar characteristics to ESCs, from somatic cells. The farther away the research source is from human embryos, the lower the chance it will bring about ethical controversy. To date, iPSC research has achieved some progress. iPSCs may ultimately be a replacement for hESCs for research or therapy, which would cause fewer ethical concerns, but their clinical function and value compared to ESCs are unclear.

Due to the huge prospective value of hESCs for human beings in the fields of medicine, pharmacy and clinical treatment, which is demonstrated by the research achievements attained so far, the importance of hESC research is undeniable and the future of hESC research is inevitable. In order to fully utilize such a precious resource for human welfare to the full extent that is ethically allowed, the research would benefit if the limits were explicitly defined in laws. States should promulgate law on hESC research to clarify the status of human embryos and the legal status of hESC research. As for the U.S., implementation is more complicated. Both federal and state government have discretion regarding the conduct of hESC research. As a matter of fact, some states have been supporting hESC research programs. The policy of the federal government is more inconsistent than that of state governments. The federal government used to prohibit the funding of hESC research entirely because of its damage to human embryos and, for the same reason, it later funded only that hESC research conducted on cells derived from sources that do not cause human embryo destruction.⁸³⁹ After the election of President Obama, he attempted to lift this ban.⁸⁴⁰ But the new policy encountered some opposition. Although the case has been finally decided by the appeals court in favor of President Obama to sustain the federal advocacy of hESC research, the instability of federal policy is worrisome. It not only causes confusion and

⁸³⁹ 72 FR 34,591, *supra* note 214.

⁸⁴⁰ 74 FR 10,667, *supra* note 186.

decreases the enthusiasm of the researchers and scientists conducting hESC programs who are trying to obtain already received federal governmental support, it also impedes and slows research progress because policies are changing back and forth. For the sake of hESC research, the U.S. federal government should adopt a consistent and stable policy standpoint by consulting Congress and Judiciary in order to gain the support from legislative and judicial branches and achieve consistency in the long run.

There are three aspects that should be emphasized in hESC research in distinguishing legal hESC research activities from illegal activities. First, the research must have a legal aim. The state should consider the purpose of the programs. If the goal of research programs is to extract, culture or derive cells from human embryos, they should be allowed due to their legal purpose. As to the concern that the ultimate purpose is difficult to predict from the beginning of research work, it should be left to government agencies to oversee research conduct. Second, the state should supervise the embryo source of hESC research because the source of the embryos is the main key to the legality of the research program. Human embryos produced through reproductive cloning should be prohibited; hence research conducted on cloned embryos or human beings should be banned as well. Similarly, embryonic research on material from unknown sources should be suspect; unless the researchers can prove the legal origin of embryos used in the program, the research should be banned. If the embryos are obtained from fertility clinics, the researchers should present the consent of the parents or proof of embryo disposition. Third, states should issue codes of research conduct, for instance, the blastocysts used in research should be no more than 14 days old after their creation by *in vitro* fertilization or nuclear transfer; germ cells derived from embryos should not be combined with other species.

However, patenting of biological materials is a sensitive issue with ethical and social aspects. Countries should be wise in assuring that legislation seeks to balance the commercial needs of industry with ethics and health concerns based on their specific conditions. This is neither straightforward nor easy.

Chapter 8: Conclusion

Human embryonic stem cell research is an essential branch of biotechnology due to its critical therapeutic and medical values. While a substantial amount of research has already been accomplished, there are still many aspects of hESCs that are not completely understood which leaves some properties and potentials unclear. In addition, there is an open question regarding the ability to use other types of stem cells as replacements for the therapeutic and medicinal values attributed to hESC's. Because of the tight bond between hESCs and human embryos, hESC research receives opposition from both religious and ethical perspectives. Although this dissertation is focused on the legal aspects of hESC patent protection, certain religious and ethical issues are presented as background due to their large influence on the law-making process. There are a number of religions that have a firm viewpoint on hESCs, however, there are other religions that do not have a clear or official viewpoint on hESCs research. The religious arguments are, in general, against hESC research while the ethical arguments can take the form of both support and opposition.

Due to the complexity of hESC issues, countries are adopting a variety of policies toward hESC research. The United States has a history of federal appropriation policy changes swinging between supporting and opposing viewpoints on hESC research. In contrast, China has been very consistent with its policy of supporting hESC research. Considering the variation in legitimacy and progress on hESC research in member states of the European Union, the European Union has chosen to leave the topic out of their jurisdiction and maintain an agnostic viewpoint.

It is worth mentioning that even though the patent system is known as a stimulus to scientific research and progress, the patent protection on hESCs

in the U.S. and China is not always consistent with their hESC research policies.

Historically, the U.S. government hesitated and was reluctant to appropriate hESC research funding due to ethical concerns, though the situation has changed recently. However, the long held policy of the U.S. patent office confirming the patent-eligibility of hESCs results in making the U.S. the country that accepts and grants the most hESC related patent applications.

This situation is beginning to reverse. The federal government started to allow federal appropriations for hESC research after President Obama was elected. At the same time, the validity of some hESC patents has been challenged for lacking non-obviousness and novelty in recent cases. At present, the validity of one WARF human embryonic stem cell patent was denied for lacking non-obviousness. The final outcome is uncertain and will depend on whether the inventor decides to appeal the denial. In the meantime, the validity of human gene patents is facing challenges from another perspective. The varying techniques used for stem cell isolation and purification have been justifying the validity of human gene patents. This is now under question and is the main debate in the current human gene patent case. More specifically, an example of this would be whether the technique of isolation and purification is essential to distinguish isolated human genes from the native genes in the human body. A U.S. federal district court invalidated two isolated human gene patents because it found them to constitute a mere product of nature. Following this, the Department of Justice filed an *amicus curiae* brief and declared that human genes without alteration or manipulation are not patentable because they are a product of nature. Currently, the case is on appeal. If the district court's judgment is affirmed, it will influence future hESC patents.

Despite its positive attitude toward hESC research, China is fairly conservative with regard to its patent laws related to hESC innovations. China excludes the patentability of hESCs and production citing the morality clause, yet encourages hESCs research at a national level. The gap between patent law and laws governing hESC research is not compatible with the essential motive of the patent system—promoting science. This apparent conflict confuses hESC researchers and investors. The result is in direct conflict with the ideas behind patent law and counteracts the facilitating function normally associated with patent law. In China, the consequence of having conflicting hESC research laws and patent laws is reflected in a lack of legal protection for research achievements. This lack of protection directly stifles the normal impulse towards scientific development. China has been improving its patent protection during the past thirty years since China entered the WIPO in 1980. From 2008 to 2009, the number of patent applications in most countries grew slowly, with an average growth rate of 2.6%, while China reported a growth rate of 18.2%.⁸⁴¹ In 2009, China had 7946 patent applications through the PCT, which places it fifth in the world; representing a growth rate of 29.7%.⁸⁴² As of April of 2010, China had received 6,095,949 applications, and granted 3,369,718 patents.⁸⁴³ While the national average for overall patent issuance is close to 50%, hESC related inventions lack patent protection due to the adopted patent policy. Currently, the consequence of this shortfall to hESC inventions may not seem so critical because most of the hESC research is funded or supervised by the government. However, in the long term it hinders the scientific progress and

⁸⁴¹ State Intellectual Property Office of P.R.C, *WIPO: China's Patent Application is Thriving*, Sept. 17, 2010, available at http://www.sipo.gov.cn/sipo2008/yw/2010/201009/t20100917_537479.html (last visited Mar.2, 2011)(translated by author).

⁸⁴² World Intellectual Property Organization, *China's IP Journey*, Dec. 2010, available at http://www.wipo.int/wipo_magazine/en/2010/06/article_0010.html (last visited Mar. 2, 2011)

⁸⁴³ Xiao Xiao, *The Thirty Anniversary of China's Accession to WTO*, available at http://www.sipo.gov.cn/sipo2008/yw/2010/201006/t20100603_520932.html (last visited Mar.2, 2011)(translated by author).

reduces advantages present in the global market. Therefore, it is crucial to understand and maintain consistency between patent law and other public laws.

The situation in Europe countries is slightly different. Both the European Union and the European Patent Office are regional organizations that have less authority than sovereign states. In the EU, the patent system is still under construction and has not yet been established. With respect to the European patent office, it does have the power to grant European patents but it lacks jurisdiction over patent enforcement. In addition, the European Patent Convention establishes an autonomous patent examination system. Unfortunately, it leaves the national patent offices with the authority to revoke these patents within their national jurisdictions. The EPO ruled that the hESC invention at bar was not patentable because it violated the clause under the EPC that any commercial or industrial use of hESCs was considered a violation of the public order and morality. This leaves the definitions for patentability ambiguous. It is understandable that as a regional organization, the EPO has avoided wading into controversial debates over ethics, and there will not be a hard rule on hESC inventions in a short period of time considering the variety of cultures and traditional backgrounds in member states of the EPC. Since the EPO's decisions are not binding on the patent offices in member states, how the member states accept that ruling is of interest. With the deficiencies present in the patent system governed by the EPO, a new patent system is warranted. The European Union infrastructure is being designed to mitigate the majority of the problems present in the EPO system.

This dissertation studied and compared the main requirements of patenting in the United States, China, and the EPO. Patents need to meet the requirements of novelty, non-obviousness and utility to be issued in all countries, but the wording and specific requirements of patenting are slightly

different, which makes the scope of patentable subject matter vary. This dissertation further examined the hESC patent prosecution history, hESC patent litigation process, and scholarly opinions on the patentability of hESCs in each country or region studied in Chapters 4, 5, and 6 respectively. In Chapter 7, after studying patent principles and exploring the reasons for rejecting or confirming the patentability of hESC inventions in the U.S., China and the EPO, it is determined that hESCs, *per se*, are not patentable because they do not have specific, concrete utility, and they result from a law of nature. However, it is found that methods of producing hESCs are patentable, and therefore derivative products from hESCs are also patentable. Whether specific inventions fulfill novelty and non-obviousness requirements should be determined on a case-by-case basis.

A model patent law for hESC innovation, which sets forth the three requirements of patenting, is proposed by this author to countries including the U.S., China and the EPO. Novelty means that the invention should be new, which includes existing in a new format. The non-obviousness requirement comprises two levels of obviousness: obvious-to-try, and if so, obvious-to-succeed to a person with ordinary skill and ordinary creativity in the art. A utility clause indicates the invention should be able to be manufactured in industry and have a concrete and specific industrial application. Morality should not be incorporated into patent law because only technical issues should be regulated in patent law; moral issues such as the legality and administration of hESC research should be governed by other public laws.

Current legislation on hESC research varies between countries due to their different knowledge and cultural / traditional backgrounds. These variations dictate that the current lack of consensus between countries will not change in the foreseeable future. With the progression of scientific research and its utility in industrial development—especially the internationalization of the patent market and trade market—eventual convergence of patent rules

around the world is inevitable. However, considering the complexity and controversy of hESC research, it will be a long time before countries eventually achieve a consensus on the legality of hESC research, and the appropriate protocols to supervise the sources, and manage the production and manipulation of hESCs and derivatives.

Glossary

Biotechnology Directive: Biotechnology Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions

Blastocyst: a structure of early embryogenesis, which is formed after five to seven days' development, and consists 100 to 150 cells. It possesses an inner cell mass, which will develop into an embryo, and an outer layer called trophobalst, which will form the placenta

Blastomere: cells from the clavage of egg after fertilization at the early stage of embryonic development

BPAI: Board of Patent Appeals and Interferences

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CAFC: United States Court of Appeals for the Federal Circuit

CPC: Communist Party of PRC

Detailed Rules: Detail Rules for the Implementation of the Patent Law of PRC

EBA: Enlarged Board of Appeal

ECJ: European Court of Justice

ECRH: European Convention on Human Rights

EEUPC: European and European Union Patent's Court

EGE: European Group on Ethics in Science and New Technologies to the European Commission

EPC: European Patent Convention

EPJ: European Patent Judiciary

EPLA: European Patent Litigation Agreement

EPLA: European Patent Litigation Agreement

EPO: European Patent Office

ESC: embryonic stem cell

EST: expressed sequence tags

Ethical Guiding Principles: Chinese government, the Ministry of Science and Technology issued the Ethical Guiding Principles for the Research of hESC

Ethical Guiding Principles: Ethical Guiding Principles for the Research of hESC of PRC (2003)

EU: European Union

Examination Guideline: Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office of PRC (2009).

FDA: U.S. Food and Drug Administration

FTCR: California-based Foundation for Taxpayer and Consumer Rights

FTCR: the California-based Foundation for Taxpayer and Consumer Rights

GPCL: General Principles of the Civil Law of the PRC

Guidelines for Human Stem Cell Research: National Institutes of Health Guidelines for Human Stem Cell Research of the U.S. (2009)

hESC: human cells that have the capability of self-replication and development into all cells and tissues of the three primary germ layers (the ectoderm, mesoderm, and endoderm)

hPSC: human Parthenote stem cell. It is pluripotent stem cell obtained from parthenogenically activated eggs.

ICM: the group of cells within the blastocoel of the blastocyst.

Implementing Regulations: Implementing Regulations to the Convention on the Grant of European Patents

iPSC: induced pluripotent stem cell. It is a type of cells that are induced from somatic cells into pluripotent stem cells.

IVF: In vitro fertilization. It is a technique to fertilize an egg by a sperm in a laboratory environment

MOH: Ministry of Health

MOST: the Ministry of Science and Technology

MOU: Memorandum of Understanding

MPEP: the Manual of Patent Examining Procedure promulgated by the USPTO

NIH: National Institutes of Health of the U.S.

NPC: National People's Congress of PRC

PCT: Paris Convention for the Protection of Industrial Property or Patent Corporation Treaty

PHS: the Public Health Service of the U.S. Department of Health and Human Services

PUBPAT: Public Patent Foundation

SAIC: the State Administration for Industry and Commerce

SCNT: somatic cell nuclear transfer, a process by which the nucleus of a donor egg is replaced with the nucleus from a somatic cell taken from the patient

SFDA: State Food and Drug Administration of PRC

SIPO: the State Intellectual Property Office

Standing Committee: Standing Committee of the National People's Congress of PRC

TBA: Technical Board of Appeal

The Public Patent Foundation

TRIPS Agreement: World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights

trophoblast: the outside cells of a blastocyst that can develop into extra-embryonic materials.

UPLS: Unified Patent Litigation System

USPTO: United States Patent and Trademark Office

WARF Patents: U.S. Patent No. 7,029,913, Primate embryonic stem cells (filed Oct. 18, 2001, issued Aug. 18, 2006); U.S. Patent No. 6,200,806 (Primate embryonic stem cells, filed June 26, 1998, issued Mar. 13, 2001); U.S. Patent

No. 5,843,780 (Primate embryonic stem cells, filed Jan. 18, 1996, issued Dec. 1, 1998)

WARF: Wisconsin Alumni Research Foundation

Williams: U.S. Patent No. 5,166,065, In vitro propagation of embryonic stem cells (filed Mar. 31, 1990, issued Nov. 24, 1992)

WIPO: World Intellectual Property Organization

WTO: World Trade Organization

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