DOCTOR OF PHILOSOPHY

Regulation, patentability and morality of human embryonic stem cell in China: a comparative study of the US and Europe

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Award date:
2019

Awarding institution:
Bangor University

Bangor University

PRIFYSGOL
BANGOR
UNIVERSITY

REGULATION, PATENTABILITY AND MORALITY OF HUMAN EMBRYONIC STEM CELL IN CHINA

A COMPARATIVE STUDY OF THE US AND EUROPE

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Thesis submitted to Bangor University for the degree of Doctor of Philosophy

October 2014

REGUATION, PATENABILITY AND MORALITY OF HUMAN EMBRYONIC STEM CELL IN CHINA - A COMPARATIVE STUDY OF THE US AND EUROPE

ABSTRACT

This thesis is concerned with what is a better way to regulate Human Embryonic Stem Cell (HESC) research in China. It concludes that, neither moral control in the patent law nor federal funding control is a effective way to monitoring HESC research. The best way to control immoral HESC research in China is to regulate research at the international level. HESC holds the promise of treating many incurable diseases such as cancer, diabetes and Parkinson's Disease; however, the interplay between patent law and moral controversy has generated enormous variations in addition to the jurisdiction complexities. The diversity of HESC regulation has been considered problematic, since varied regulations in states might impede research collaboration and scientific advance. Researchers working across jurisdictions are required to meet different technical, ethical and legal standards. Some developing countries have sought to profit from the regulatory vacuum. Such a situation can be seen in China where unproven and unsafe stem cell therapies are currently offered to patients. While attempts have been made to examine the disparities in HESC regulations across countries, there is little work of significance addressing how to regulate HESC research in China.

This thesis attempts to find a better way to control HESC research in China. It is laid out from three perspectives. First, this thesis explores the legal challenges from the emerging areas raised by HESC technology. It illuminate the moral challenges associated with HESC research. It demonstrates that HESC research, like a double-edged sword, might bring tremendous benefits or, on the contrary, irreversible disaster. It can be distinguished that the success of HESC development depends largely on how the law participates in it. Second, the thesis examines two different approaches adopted by the Europe and US in HESC research. Apart from examining the incongruous

interpretations of moral definitions of human embryo in the EUROPE case law, this thesis also explores the inconsistent policies adopted by different administrations in the US. Through a detailed comparison, this thesis observes that both infusing moral exclusions into patent law and federal funding control are inefficient and ineffective ways to supervise immoral research. Third, the thesis explores the reconciling attempts of HESC regulation. Drawing lessons from reconciling attempts, the thesis finds out that minumin standard is practical and applicable since there are various interpretations of moral, human embryo and the commercial or industrial use addressing the adoptions of moral exclusions in national states.

The thesis argues that, the best way to control HESC research in China is to regulate research inself in a reconciled regulation at the international level. First, the patent prohibition of HESC related inventions based on morality issues doesn't seem to be an effective method to control immoral research. Morality is not a criterion that should be determinable by patent authorities. The various interpretations of moral exclusion in patent law result the legal uncertainty. Even if the results of HESC research would not be patented, HESC research could still be performed and funded. Immoral HESC research should be prohibited at the beginning of research instead of at the patent-application stage. Second, even if federal funding cannot be used in HESC research, private funding could still flow into this area. It is a waste of time, money and material resources since some halfway public funding research should be halt and private money reinvest in it. Third, from the economical perspective, regulate research is able to prohibit immoral research at the initial stage which saves time and money and is economically viable and legally feasible. In order to eliminate the phenomenom of "stem cell tourism" in China, it is best to regulate the research at the international level.

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ABBREVIATIONS

BPAI	The Board of Patent Appeals and Interferences
BCIL	The Biotech Consortium Inida Limited
BPAI	Board of Patent Appeals and Interferences
CDA	The Christian Democratic Party
CIRM	The California Institute for Regenerative Medicine
CNR	Cell Nuclear Replacement
CTCA	Cancer Treatment Centres of America
CPMP	The EUROPE Committee on Proprietary Medicinal Products
CTD	The Common Technical Document
CPHS	Commission for the Protection of Human Subjects of Biomedical and Behavioural Research
CJEU	The European Court of Justice
DCD	Discard-Created Distinction
DFG	The German Research Foundation
DHHS	The Department of Health and Human Services
EC	The European Commission
EPC	The European Patent Convention
EBA	The Enlarged Board of Appeal
EGE	The European Group on Ethics in Science and New Technologies
EMEA	The European Agency for the Evaluation of Medicinal Products
ESchG	The German Embryo Protection Act
FP7	The Seventh Framework Program
FTCR	Foundation for Taxpayer and Consumer Rights

GAEIB	The Group of Advisers to the European Commission on the Ethical Implications of Biotechnology
GPL	The German Patent Law
GFHCJ	The German Federal High Court of Justice
HESC	HESC
HFEA	The Human Fertilisation and Embryology Authority
HFE Act	The Human Fertilisation and Embryology Act
HGAC	Human Genetics Advisory Commission
IPS Cells	Induced Pluripotent stem cells
IVF	In vitro fertilisation
ISCI	The International Stem Cell Initiative
ISSCR	The International Society for Stem Cell Research
ICH	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IASCR	The Interstate Alliance on Stem Cell Research
NHS	National Health Service
NIH	National Institute for Health
NRLC	The National Rights to Life Committee
NBAC	The National Bioethics Advisory
OD	The Opposition Division
Proposition 71	California Stem Cell Research and Cures Bond Act
PUBPAT	The Public Patent Foundation
PGD	Preimplantation Genetic Diagnosis
Proposition 71	California Stem Cell Research and Cures Bond Act of 2004
SCNT	Somatic Cell Nuclear Transfer
SPS	The Sanitary and Phytosanitary Agreement

The Directive	The Directive 98/44/EC on the legal protection of Biotechnological Inventions
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TBT	The Technical Barriers to Trade Agreement
TBA	The Technical Appeal Board
CIRM	The California Institute for Regenerative Medicine
US	The United State
UK	The United Kingdom
UKSCB	The United Kingdom Stem Cell Bank
UNESCO	The United Nations Educational, Scientific and Cultural Organisation
USPTO	The United States Patent and Trademark Office
UKIPO	The United Kingdom Intellectual Property Office
Warnock Report	Report of the Committee of Inquiry into Human Fertilisation and Embryology
WTO	World Trade Organisation
WARF	Wisconsin Alumni Research Foundation

ACKNOWLEDGEMENT

Having worked on this thesis extensively for five years, I have finally typed the last line of the text. I still remember the day that HESC first came to my attention when I was a first year student studying Biotechnology at Beijing Science and Technology University. I was amazed and impressed by the great potential of HESC, and was intrigued by the legal and ethical challenges it faced. This, to some extent, explains why I chose law as my topic when pursuing my postgraduate studies at the Law School of Shandong University. Three years of postgraduate study has equipped me with the necessary multidisciplinary perspective, which in turn has inspired me to further my studies abroad. At Bangor University, I discussed these with my supervisor. I received my first encouragement to study this challenging topic. It was chosen as my PhD research topic. As I immersed myself into this subject, I realised that this topic would not only interest lawyers and academics but also businessman, doctors and patients.

During this time, I received immense encouragement, guidance and support. Without this help, the completion of this work would not be possible. First of all, I want to thank Dr. Wei Shi for his excellent advice and suggestions for improvement. He met me at his office, from which I received his keen comments which contributed to the production of my thesis. Also, his encouragement gave me a great deal of inspiration. I am very appreciative of

his generous support during my stay in Britain. Whenever I have been away in China, he has been fully supportive of my work, via Skype. Without his incisive comments, I would never have been able to publish my work. I also want to thank Howard Johnson, my LLM supervisor. He has given me guidance in learning about this controversial area. I offer thanks to all the staff at Bangor law school, including Professor Dermot Cahill, Zhen Jing, Mark Hyland, Sarah Nason, Anwen Evans, Mairwen Owen and Beth Hamiliton. Their help has been a great encouragement to my research.

I would like to thank Jarrad Wood, the Senior Articles editor of American University Intellectual Property Brief, for his insightful comments and careful editing. I also offer thanks to two anonymous referees for reviewing my article 'will diversity regulations disadvantage HESC research: a comparison between EUROPE and US '. Without the input of these individuals I would have been unable to bring the dream of publishing my work to fruition.

I would like to thank all my friends who supported me during the writing. Without their support and spurring on, the completion of this dissertation would not have been possible. Finally, I would like to thank my family, particularly my parents Zhengxing Jiang and Yueqin Jiang, my husband Zhengwei Zhang and my son Jixin Zhang. Whenever I encountered a problem, they were there with assistance. Without their encouragement, my research would have been stuck at some point.

I am indebted to the Bangor University (125 Anniversary Scholarship) and the Chinese Scholarship Council, who supported my studies in Bangor. I would also thank the following institutions for their assistance for my work: Bangor Law school (research seminars), the Society of Legal Scholars Conference (poster presentation), the Fourth International Graduate Legal Research Conference, UK-China Intellectual Property Symposium, Vitae (Leadership in action).

Some chapter sections have been accepted for publication by the following journals. Their inputs are appreciated and acknowledged. I offer my thanks to the following journals that reviewed my papers and made them available to a wider readership:

- 'Will diversity regulations disadvantage HESC research: a comparison between EUROPE and US' in Depaul Journal of Art, Technology and Intellectual Property Law;
- 'Between Scylla and Charybdis: Patentability And Morality Related To HESCs' in American University Intellectual Property Brief;
- 'Space for Flexibility: Lessons from the European Union Harmonization Model in HESC Regulation' in Intellectual Property Forum;
- 'Legal Response to Technology Change: the Example of HESC Regulation in China' in the reviewing process with the Journal of Bioethical inquiry.

CHAPTER ONE: INTRODUCTION

1.1 Reasons for Conducting This Research

1.1.1 Values of HESC (HESC) Research

Biotechnology raises many controversies, particularly in the area of HESC research.[1] As one of the most fascinating developments in the biomedical field over the past decade, HESC research holds great potential in tissue engineering, genetic engineering and other regenerating technology.[2] With the huge scientific, medical and commercial interest behind it, most countries have committed to securing a competitive position in the HESC research, transplantation and regeneration medicine industry.[3] As a consequence, tremendous amounts of money are spent on HESC research, especially in the United States.[4]

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[1] See Stephen R Crespi, 'the human embryo and patent law-a major challenge ahead?' (2006) 28 European Intellectual Property Review 569-575 (stating that beginning with the once controversial issue of micro-organism patenting, the debate soon extended into the sphere of higher life forms, including cell-lines, plants and animals.); see also Amanda Warren Jones, 'Finding a common morality codex for biotech-a question of substance' (2008) 6 International Review of Intellectual Property and Competition Law 638; see also Aurora Plomer and Paul Torremans, Embryonic stem cell patents: European patent law and ethics.

[2] See, for example, one immediate possible application of HESC would be strategies to quickly screen hundreds of thousands of chemicals for effective medicines. By measuring how pure populations of specifically differentiated cell respond to potential drugs, it would be possible to sort out those that may be both useful and problematic in human medicine, University of Wisconsin Stemcell & Regenerative Medicine Center, <http://www.news.wisc.edu/packages/stemcells/3327.html> accessed October 28 2013; also see, for example, the Japanese authorities tried to harvest stem cells from the bone marrow of workers at the Fukushima nuclear power plant and transplant them into their bodies for the purpose of repairing the damage caused by high dose radiation,
Meredith M 2011. Could stem cell transplants help the Japanese Nuclear Workers?' *The Time,* March 31. <http://healthland.time.com/2011/03/31/could-stem-cell-transplants-help-japanese-nuclear-workers/ > make it back accessed October 28 2013.

[3] See, for example, at the Cancer Treatment Centres of America (CTCA), HESCs have already been used in curing cancer diseases. the Cancer Treatment Centers of America available at <http://www.cancercenter.com/stem-cells.htm> accessed October 28 2013; also see for example, the researcher Igor Slukvin at the University of Wisconsin-Madison was the first to successfully reprogram blood cells obtained from a patient with leukaemia, which means the diseased cells are capable of turning back into pluripotent stem cells. This is important because it provides a new model for the study of cancer cells, <http://newsroom.stemcells.wisc.edu/18933> accessed October 28 2013.

[4] In fiscal 2010, National Institute of Health (government funding) spent approximately $200 million to

Beyond all doubt, embryonic stem cells have virtually limitless use and huge potential in the therapeutic medical field. Currently, one immediate possible application of HESC, as James Thomson observed, would be strategies to quickly screen hundreds of thousands of chemicals for effective medicines.[5] By measuring how pure populations of specifically differentiated cell respond to potential drugs, it would be possible to differentiate those that may be both useful and problematic in human medicine.[6] Even in the Japanese nuclear crisis of 2011, the Japanese authorities tried to harvest stem cells from the bone marrow of workers at the Fukushima nuclear power plant and transplant them into their own bodies for the purpose of repairing the damage caused by high dose radiation.[7]

However, although a bright future of HESC research in conquering incurable diseases has been offered, its development faces many legal and ethical challenges. The interplay between law and morality is natural but hardly new.[8] In the field of HESC, the creation, operation and interpretation of the patent law are linked to morality no matter you like it or not.[9] The complexity of HESC research creates most unusual and fraught situations for regulators across the globe.

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fund more than 200 human embryo research grants, <http://www.bloomberg.com/news/2011-04-29/stem-cell-research-funding-can-continue-during-legal-case-u-s-court-says.html> accessed April 4 2014.

[5] Terry Devitt, 'Wisconsin scientists culture elusive embryonic stem cells' 6 November 1998 (examining that a team of scientists from UW-Madison report the successful derivation and prolonged culture of HESCs-cells that are the parent cells of all tissues in the body; commenting that the achievement has profound implications for transplant medicine, drug discovery and basic developmental biology)) <http://www.news.wisc.edu/3327> accessed 14 July 2013.

[6] University of Wisconsin Stemcell & Regenerative Medicine Center <http://www.news.wisc.edu/packages/stemcells/3327.html> accessed 28 October 2013.

[7] Meredith Melnich, 'could stem cell transplants help the Japanese Nuclear Workers?' *The Time* (London, 31 March 2011) <http://healthland.time.com/2011/03/31/could-stem-cell-transplants-help-japanese-nuclear-workers/> accessed 28 October 2012.

[8] See Peter Drahos, 'Biotechnology patents, markets and morality'(1999) 21 European Intellectual Property Review 441 (pointing out some areas of law invite adjudicators to draw on morality in the process of legal decision-making. Somewhat surprisingly, given its characterization as a tool of economic regulation, patent law does just this. The express connection between patent law and morality is hardly new.)

[9] *ibid.*

1.1.2 Inconsistency HESC related regulations across Jurisdictions leads to stem cell tourism in China.

Cutting-edge stem cell research is not only restricted at the national level but also beyond national borders. The scientific community is becoming increasingly international because medical results can be widely disseminated hours after publication.[10] For instance, nearly 20% of total publications in science and engineering from 1998-2008 were internationally co-authored.[11] These data imply that the quality, productivity and effectiveness of international collaboration research is greater compared with that of national research products.[12] Researchers working across jurisdictions are required to meet different technical, ethical and legal standards. [13] However, standardisation is very important prerequisite, which provides the basis for comparing research results among the different institutions in the world.[14] As the Science Policy Briefing by the European Science Foundation, entitled Human Stem Cell Research: Scientific Uncertainties and Ethical Dilemmas, states, 'the lack of common criteria and universal standards for the preparation of stem cell research has greatly hampered further progress'.[15] To promote progress in the stem cell area, the International Stem Cell

[10] Peter Loser, Jaqueline Schirm, Anke Guhr, Anna M Wobus and Andreas Kurtz, 'HESC lines and their use in international research' (2010) 28 Stem Cells 240.

[11] Science and Engineering indicators 2010, published by the National Science Board, <http://www.nsf.gov/statistics/seind10/start.htm> accessed 1 July, 2012.

[12] Jingyuan luo, Jesse M Flynn, Rachel E Solnick, Elaine Howard Ecklund and Kirstin R W Matthews, 'international collaboration: how disparate policies between the United States and the United Kingdom impact research' (2011) 6 Plos One 17684.

[13] See Catherine Waldby and Brian Salter, 'Global Governance in HESC Science' (2008) 2 studies in Ethics, law and Technology 1-23. (stating that standardisation is very important in science because it creates the conditions for stable comparison and the interoperability of technical elements and it is a central process of all scientific practice and one of the major demarcators of scientific from non-scientific knowledge).

[14] In the 1994, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets a standard in biotechnology among members state of the World Trade Organisation (WTO), and it distinguished developing countries from developed countries to allow them a ten-year extension to execute the standard. See Drahos and Barithwaite, *information feudalism: who owns knowledge economy* (earthscan, London2002) 87.

[15] Human stem cell research and regenerative medicine, a European perspective on Scientific, Ethic and Legal issue. 2010 Science Policy briefing; see also Outi Hovatta, Miodrag Stojkovic, Maria Nogueira and Isabel Varela Nieto, 'European Scientific Ethical and legal Issues on Human Stem Cell Research and Regenerative Medicine' (2010) 28 Stem Cells 1005-1007.

Initiative (ISCI) was established to compare the differences and similarities between various countries.[16]

Since HESC regulation is different across jurisdictions, some HESC therapies that are prohibited in certain countries might be allowed in other nations. As a result, patients can freely choose where to receive medical treatments. Travel to another country for stem cell treatment, known as "stem cell therapy tourism", has flourished in recent years.[17] This new phenomenon has raised not only concerns over unverified medical treatment but also over international regulations for HESC research.[18] The divergence between different countries on HESC regulation has led to unequal access to treatment and the unbalanced distribution of benefits and duties.[19] Certainly, this phenomenon violates the principle that all people should have a fair right to share the results of scientific progress and access to therapy.[20] Moreover, the clinic or physician providing such a treatment does not guarantee safety, efficacy or results.[21]

In addition, there is growing concern as to how national systems of HESC regulations cope with increasing research collaboration. Some scholars have observed that 'an intensification of cross-continental biomedical and biological research collaboration has generated an urgent need to address questions around the ethical governance of biomedical research

[16] See, e.g. the second Initiative, ISCI2, that will focus on comparing the performance of different media for the culture of HESCs, and assessing the types of genetic change that accumulate in HESCs upon prolonged passage, <http://www.rcuk.ac.uk/OfficeintheuS/casestudies/Pages/StemCellForum.aspx> accessed online 28 October 2012.

[17] B D Colen, 'Stem cell tourism growing trend' (2012) Harvard gazette, November 30 <http://news.harvard.edu/gazette/story/2012/11/the-rise-of-stem-cell-tourism/> accessed January 2 2014. (Thousands, if not tens of thousands, of desperate people are clocking to clinics that charge tens of thousands of dollars for every unproven treatment. The stem cell tourism phenomenon hurts the legitimacy of the entire field of stem cell science and medicine).

[18] Sorapop Kiatpongsan and Douglas Sipp, 'Monitoring and regulating offshore stem cell clinics' (2009) 323 Science 1564.

[19] See Human stem cell research and regenerative medicine, a European perspective on Scientific, Ethic and Legal issue.2010. Science Policy briefing, <http://www.esf.org/publications/science-policy-briefings.html> accessed 28 October 2012.

[20] The human rights to equal access for all persons to productive resources, including land, credit and technology.

collaboration'.[22] Some scholars have commented that 'inconsistent regimes within legal jurisdictions have the potential to put researchers in unusually precarious positions with respect to their research methodology and output'.[23] The diversity of HESC regulation has been considered problematic, since the regulatory variation in states might impede research collaboration and scientific advancement. Although HESC research and patients benefit deeply from international collaboration, such collaboration is inevitably constrained by the tremendous divergence in national HESC legislation. Two primary issues in national variability can be traced to patent applications related to HESC; one issue is 'in the quality of the searches on prior art carried out by different patent offices', and the other issue is 'in the scope and/or application of the substantive patenting criteria of novelty, non-obviousness, and utility'.[24] Reconciling different regulations on the scope of patentability and substantive patenting criteria in this emerging area is urgent.[25]

However, the interplay between patent law and moral controversy has generated enormous variations in addition to the jurisdiction complexities. Some scholar suggested that 'once and for all, put an end to arguments that patenting has little or nothing to do with morality.'[26] However, some scholars hold that the absence of a tight patent system would 'produce social injustice by initially confining access to the benefits of research to those who are wealthy enough to pay the prices set by for-profit biotech corporations'.[27] This phenomenon is a "patchwork of patchwork" and is complex but

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[21] *Supra* note 16.

[22] Ayo Wahlberg, Christoph Rehmann Sutter, Margaret Sleeboom Faulkner, Guangxiu Lu, Ole Doring, Yali Cong, Alicja Laska Formejster, Jing He, Haidan Chen, Herbert Gottweis, Nikolas Rose, 'from global bioethics to ethical governance of biomedical research collborations' (2013) 98 Social Science & Medicine 293-300.

[23] Murdoch C J, 'intraoperability problems: inconsistent stem cell IP and Research regimes within nations' (2011) 3 Stanford Journal of Law Science & Policy 49-55.

[24] Aurora Plomer, 'stem cell patents in a global economy: the legal challenges' (2010) 3 Stanford Journal of Law, Science and Policy 5.

[25] *ibid*.

[26] *ibid*.

[27] Aurora Plomer, 'beyond the HFE Act 1990: the regulation of stem cell research in the UK' (2002) 10 Medical Law Review 132-164.

increasingly important in the new era of HESC research.[28] Regarding efficiency in the current HESC research environment, intellectual property regulations determine the flow of knowledge and materials in the "patchwork of patchwork".[29] Different intellectual property approaches adopted by various countries have created 'potential barriers to transnational collaboration and differential incentive structures with significant consequences for what kinds of research gets done'.[30] Therefore, clarifying the patentability and morality of HESC related invention at the international level is necessary.[31] Thus, an international reconciliation regulation should be produced to support the prosperity of a globally oriented HESC industry and to reduce the "stem cell tourism". Legal diversity is inevitable, but legal reconciliation is essential for the improvement of HESC regulation in China.

1.1.3 TRIPS Agreement cannot assure symmetrical coherence between moral provision within patent law and moral provision outside patent law

TRIPS Agreement: symmetrical incoherence between moral provision within patent law and moral provision outside patent law. Article 27 of TRIPS regulates 'members may exclude inventions from patentability, the prevention within their territory of the commercial exploitation of such inventions is necessary to protect ordre public or morality'.[32] The aim of TRIPS is to make sure 'that measures and procedures to enforce intellectual property rights do not themselves become barrier to legitimate trade'.[33] Although the objective in the preamble becomes the part to interpreting

[28] Timothy Caulfield, Amy Zarzeczny, Jennifer McCormick, Tania Bubela, Christine Critchley, Edna Einsiedel, Jacques Galipear, Shawn Harmon, Michael Huynh, Insoo Hyun, Judy IIIes, Rosario Isasi, Yann Joly, Graeme Laurie, Geoff Lomax, Holly Longstaff, Michael McDonald, Charles Murdoch, Ubaka Ogbofu, Jason Owen Smith, Shaun Pattinson, Shainur Premji,Barbara von Tigerstrom and David E Winickoff, 'the stem cell research environment: a patchwork of patchwork' (2009) 5 Stem cell Rev and Rep 82.

[29] *ibid*.

[30] Catherine Waldby, 'Embryos, Cell Lines, Oobytes: ESC Science and the Human Tissue Market' (2006) 10 Globe Biopolitics Research Group Working Paper.

[31] Rainer Moufang, 'Patenting of Human Genes, Cells and Parts of the Body? The Ethical Dimensions of Patent Law' (1994) 25 International Review of Intellectual Property and Competition Law 487-515.

[32] Agreement on Trade-Related Aspects of Intellectual Property Rights.

TRIPS Article 27[34], TRIPS does not provide the definition of the operative terms in Article 27.[35] Therefore, considerable freedom is left for member states on interpreting the Article 27 of TRIPS.

It is criticized that article 27 is an "escape hatch" of TRIPS for members to find an excuse to refuse to grant patents.[36] The limitation of "escape hatch" might differ according to the history, judicial environment, economic and social interests of member states. It is identified that 'the prohibitions on discrimination as to national origin and on the use of economic interests as a basis for derogation from fundamental principles provide the guidance necessary to limit TRIPS Article 27 (2)'.[37] In fact, the TRIPS do not leave a wide-open door to patenting life. But the morality exclusion imposed by TRIPS may either intentionally or unintentionally inhibit the patent process.[38]

In addition, members of TRIPS Agreement should assure symmetrical correspondence of ethical norms in or outside patent law. However, practically, moral standards differ within patent law and outside patent law, such as china. China joined the TRIPS Agreement in 2001. Article 27 (2) is accepted by China as the customary international law. As we all know, abortion is allowed in China. Foetus is not treated as human being. Moral standard outside patent law is very low. However, moral standard in patent law is high which prevents patenting HESC related inventions for the reason that it involves with human embryo. Therefore, TRIPS Agreement cannot

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[33] *ibid.*

[34] Nuno Pires De Carvalho, *The TRIPs Regime of Patent Rights*, (Kluwer Law International, The Hague, 2nd ed., 2005)33

[35] Rajarshi Sen and Adarsh Ramanujan, 'Pruning the Evergreen Tree or Tripping Up over TRIPS?-Section 3(d) of the Indian Patents' (2010) 41 International Review of Intellectual Property and Competition Law 170-186.

[36] Timothy G Ackermann, 'Dis'ordre'ly Loopholes: TRIPS Patent Protection, GATT and the ECJ' (1997) 32 TEXAS International Law Journal 489.

[37] *ibid.*

[38] Kenneth C Cheney, 'Patentability of Stem Cell Research under TRIPS: can Morality-Based Exclusions be Better Defined by Emerging Customary International Law' (2007) 29 Loyola Angeles International and Comparative Law Journal 503.

avoid the phenomenon of a symmetrical incoherence between moral provision within patent law and moral provision outside patent law.[39]

1.1.4 Inadequate regulation of HESC research in China

In terms of HESC transfer, China has been an ardent participator in pushing stem cell research from laboratories into the clinics, in particular regarding stem cell therapy. However, facing the increase of stem cell tourism, we should reconsider whether stem cell therapy could be used for patient treatment before clinical testing has been conducted. Although government institutions are concerned about the quality and safety of stem cell therapy provided by the clinics and they refute the commercialisation of HESC, the clinics, companies or hospitals facilitate stem cell therapy due to the ambiguity of regulation, lacking the transparent legal framework and proper supervision, hospitals, research institutes and companies are able to collaborate with each other on any level and thus facilitate stem cell therapy.

Given the ambiguity of regulation and the implementation predicament, the legal system of HESC research in China is far from perfect. Lacking the HESC regulation, the Ministry of Science and Technology jointly with the Ministry of Health released the Ethical Guideline for HESC research (Ethical Guideline) in December 2003. However, it is critized that 'ministry regulations are not backed up by any legal authority and the procedures for monitoring and ensuring compliance are often opaque'.[40] From one hand, there is an extreme tension between the HESC regulation and real practice. From the other hand, the success of HESC development depends largely on how law participates in, and interacts with the technological change. Current legal framework in China is too weak and too few to effectively monitor HESC research.

This research seeks to bridge the gap in the legal literature through a

[39] Enrico Bonadio, 'Biotech Patents and Morality after Brustle' (2012) 34 European Intellectual Property Review 433-443.
[40] Jane Qiu, 'China Clamps Down on Controversial Therapies' (2009) 373 World Report 1834-1835.

comparative analysis of the HESC regulation in the US, EUROPE and China in order to suggest ways to improve the effectiveness and efficiency of regulating HESC research in China.

1.2 Research Aims

This thesis addresses the failure of regulation in China: current legal framework is not effective to regulate HESC research. Since conflicts with national HESC regulations inevitably lead to stem cell tourim phonemon and impede technological advancement, international initiatives are necessary to regulate HESC in China. However, drawing clear and strong boundaries on what is or is not allowed and what is patentable or not patentable for reseach itself is a daunting challenge for both developed and developing countries. It tends to be problematic and needs to be properly and effectively addressed.

One of the most problematic issues in regulating HESC research in China is the relationship between patentability and morality of HESC related invention. The invention that obtains patent protection in one area might not be patented for the morality reason in other areas. This regulatory inconsistency leads to the phenomenon that scientists, research funding and patients flow to the area that has a liberal policy like China, which inevitably lead to the unequal access to health care. Taking this into consideration, the main argument of this thesis is distinguished. It is the firm belief of the author that, moral control in the patent law is not an effective way to monitor the best way is to regulate research itself with a wider international vision, with China joining in that new international regime, moral exclusion should not be within the patent law.

In China, the patent prohibition of HESC related inventions based on morality issues does not seem to be an effective method of controlling immoral research. The Patent Law of the People's Republic of China contains a moral exclusion clause whereby Chinese scientists and doctors will be unsure on

what can and cannot be done due to a lack of concerns about medical risks or morals. The fact that Chinese regulators have adopted the moral exclusion in patent law merely reflects the perception that the moral exclusion represents an international custom. There exist, however, few interpretations of moral exclusion in patent law. The considerable gap left by moral provision makes it confusing and controversial. In practice, many unproven and unsafe stem cell therapies, such as stem cell therapy for Cardiac Repair, stem cell therapy for Graft-Versus-Host Disease, stem cell therapy for Limb Ischemla, stem cell therapy for Liver Disease and stem cell therapy for Neural Repair, have been reported as being conducted in various Chinese hospitals.[41] Moreover, in response to pressure from stem cell markets, some scientists from areas with restrictive policies such as EUROPE will hasten areas of research that have permissive policies or alternatively, some might engage in activities conducted in more permissive regions such as China. It is therefore not surprising that HESC research involving therapeutic cloning and other sensitive procedures will be more difficult to effectively monitor, resulting in biomedical adventurism[42]that could create serious difficulties for the entire legal and social infrastructure in the world.

The argument of the failure of infusing moral control within the patent law is also supported by the EUROPE. On the one hand, the patent prohibition of HESC related inventions based on morality issues is unreasonable since the immoral research has been already carried out. This immoral research should not be funded nor carried out from the very start instead of merely not being patented. In the EUROPE, moral considerations are deeply rooted—and this is even true in the UK, which has liberal policies towards HESC research.[43] In

[41] Lianming Liao and Robert Chunhua Zhao, 'an overview of stem cell based clinical trials in China' (2008) 17 Stem Cells and Development 613-618.

[42] Doring Ole, *Chinese researchers promote biomedical regulations: what are the motives of the Biopolitical Daw in China and where are they heading?* 14 Kennedy Inst. Ethics J. 39, 42 (2004) (commenting that the positivistic principle "if an action is not illegal, by definition, it is legal" does not apply in China. Taking advantage of the fact that policymaking lags behind scientific and economic development, in terms of the entire legal and social infrastructure, amounts to biomedical adventurism.)

[43] The Warnock Report by Human Fertilization and Embryology Authorities, 1984, available at http://www.hfea.gov.uk/2068.html (discussing two extreme views, one is from religious persons of

the EUROPE harmonisation of HESC regulation, the thesis finds that the EUROPE has erected a moral barrier to patenting HESC-related inventions. The moral barrier in patent law seems to be ineffective and inefficient. First, although a great effort has been made in the European Patent Convention and EUROPE Biotechnology Directive, there remains an inconsistency related to the interpretation of morality standards for patentability, including the moral definition, human embryo definition and industrial or commercial use definition.[44] In addition, the ECJ and EPO's dual system of assessing morality standards has resulted in legal uncertainty. Also, member states interpret differently in adapting the moral exclusion of European Patent Convention. This legal inconsistency has added procedural complexity and thus hampered technological advancement. Second, many HESC related research projects are funded by the EUROPE; however, the results of these pieces of research cannot be granted patent.[45] It is apparently inconceivable and unreasonable, as immoral research should not be funded in the first place instead of just not being patented. On the premise that the research could be funded by the EUROPE, this research should be morally examined first and conducted later. Moreover, it is a waste of time and money that the results of funded research turn out to be unprotected by patent. It is therefore of both theoretical and practical significance to reconsider how far patent law can accommodate

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Catholic Church who believe human embryo has human status, and another is from utilitarians who insist human embryo has no moral status.); also see Aurora Plomer, *Beyond the HFE Act 1990:the regulation of stem cell research in the UK*, 10 Med. L. Rev. 132, 132-144 (2002) (stating that The UK currently stands alone in Europe in permitting the creation of human embryos specifically for research purposes, including the use of cloning techniques.)

[44] See Graeme Laurie, 'Patenting stem cells of human origin' (2004) 26 European Intellectual Property Review 59 (stating that despite the fact that disquiet and discussions of an ethic nature held up the adoption of the biotechnology Directive for so long, it is far from clear that we are any further forward in developing uniform, logical, principled and defensible ethical Guideline within European patent law); see also Amanda Warren Jones, 'A Mouse in Sheep's Clothing: The Challenge to the Patent Moraility Criterion Posed by "Dolly"' (1998) 20 European Intellectual Property Review 450; See also Amanda Odell West, 'The absence of informed consent to commercial exploitation for inventions developed from human biological material: A bar to patentability?'(2009) 3 Intellectual Property Quarterly 390.

[45] Since 2007, the EUROPE had funded 27 collaborative health research projects involving the use of HESCs with an EUROPE contribution of about €157 millioin. HESC research projects represent approximately one third of health projects on all forms of stem cells. In addition, the European Research Council had funded 10 projects for an EUROPE financial contribution of about €19 million and there have been 24 Marie Skłodowska-Curie actions involving HESC research worth €23 million <Europa.Europe/rapid/press-release_MEMO-14-385_en.doc> accessed June 25 2013.

morality issues.

Then the thesis discusses, in the circumstances that morality is not a barrier of patenting, whether federal funding control is better way to monitor HESC research. After exploring the US HESC related regulations, the author believes that it is technically manageable and pragmatically meaningful to supervise the HESC research without moral exclusion in patent law. A case in point is the US. Interestingly, there is no moral exclusion in US patent regulation.[46] The US government takes a rather practical approach of patenting to secure a competitive place in the HESC market.[47] HESC related inventions are not prohibited from patenting for moral reasons. Federal funding is only used for morally acceptable HESC research, which provides an important tool for monitoring HESC research.[48]This hands-off approach is market oriented.[49] Although opponents have strongly criticised this approach for its lack of ethical and social considerations[50], alternatively or additionally, funding control is a better way to monitor HESC research. From an economical perspective, deciding to prohibit immoral research at the initial stage saves both time and money. However, in the event that federal funding is not allowed, private funding could still invest on the immoral HESC research which might worsen moral concerns related to HESC research. It is a big waste for the laboratories to distinguish federal funding research from non-federal funding research because they need to buy extra equipment. Therefore, federal funding control is not an effective way to control HESC

[46] Title 35 of the United States Code.

[47] Gabriel S Gross, 'Federally funding HESC research: an administrative analysis' (2000) Wisconsin Law Review 855-884.

[48] *ibid*.

[49] Report of the US national Bioethics Advisory Committee, Ethical Issues on Human Stem Cell Research, September 13 1999.

[50] For example Scientific research can be conducted with little public oversight. In addition, when federal funding is limited, private funding is still allowed, which might worsen moral concerns related to HESC research. It is a big waste for the laboratories to distinguish federal funding research from non-federal funding research because they need to buy extra equipment. See Michael J Malinowsk and Littlefield Nick, *transformation of a research platform into commercial products: the impact of US federal policy on Biotechnology*, in Caulfield and Jones Williams, ed, *the Commercialisation of Genetic research: ethical, legal and policy Issues* 80, 80(Kluwer International 1999).

research.

The above comparison of the US and EUROPE with China demonstrates that both patent control and federal funding control are inefficient and ineffective way to monitoring HESC research. The main reason for "stem cell tourism" in China is partly due to the inadequate regulation of HESC in China and partly because of the failure of international mechanisms for transparency, accountability and ethical oversight on HESC research. Only international regulation will work for China. International reconciliation is crtical to the success of releasing patients from untested HESC-based therapies. It is the author's belief that the best solution of supervising HESC research is to regulate the research itself at the international level.

1.3 The Research Questions

This research is based on the recognition that a certain degree of reconciliation of HESC regulation is valuable for national regulation. This recognition is acknowledged by international organisations. For instance, the International Society for Stem Cell Research Committee stated that '[g]lobal harmonisation efforts will ultimately need to accommodate nuances of cultural dissimilarities and risk appetites to strike an acceptable balance between progress and safeguards'.[51]

The thesis addresses one main research question:

What is a better way to regulate HESC research in China?

In order to answer this question, the thesis first looks into the moral maze of HESC, including the moral status of HESC, moral source of HESC and moral use of HESC. Then the thsis examine the legal framework of HESC in China, including the effect of moral provision results in the Chinese patent system,

[51] The International Society for Stem Cell Research Committee Forum, Stem cell therapies in Clinical

shows that it fail to regulate the situation properly. The uncertain interpretive scope left by China's moral provision makes the patentability confusing and controversial. The uncertain interpretation results in HESC research, treatment and commercialisation in the absence of supervision.

Since different regions adopt various approaches when dealing with this extremely complex issue, the thesis explores strategies used in the EUROPE and the US. First, this thesis explores the incongruous interpretations of moral standards and industrial or commercial use in the EUROPE case law. The inconsistent interpretation of moral provisions has led to controversy and confusion in the patentability of HESC, which would definitely become a barrier to technology progress.[52] Therefore, infusing moral control in the patent law does not work for monitoring HESC. Second, the thesis seeks to examine the developing policies of HESC research in the US. This thesis demonstrates that the moral exclusion occurs in public policy rather than the patent system. However, the federal funding control on HESC research is not an alternative way to monitor immoral research since private.

1.4 Research Context in Which this Thesis Is Located

The research examines the emerging areas raised by HESC research, focusing particularly on the moral and legal issues of the HESC research.

1.4.1 The failure of HESC regulation in China: a call for international regulations

China has a striking development and opaque governance framework regarding HESC research. The Chinese government is very liberal and flexible

Trials: *workshop on Best Practices and the need for harmonization* (Cell Stem Cell 7, 451 2010).

[52] See, for example, EUROPE has diversity national jurisdiction from constitutional and legislative to administrative. HESC regulation differs in degree from restrictive to intermediate to liberal. This systemic legal inconsistency impede scientific advance, see PLOMER AUROAR & PAUL TORREMANS, EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS 16-124 (1st ed., Oxford University Press 2009).

towards regulating HESC research. Moral objections do not seem to be obstacles in China.[53] In addition, the government has invested a huge amount of money in HESC research and has launched some specific projects to fund relevant research.[54] HESC research in China highlights to some extent a national importance and has fewer moral barriers compared to other countries.[55] Furthermore, some evidence shows that the laboratories conduct 'international quality science with facilities in most cases better funded, equipped and staffed than UK laboratories'.[56]

Despite of the rapid development of HESC technology in China, it could be deemed as a regulation vacuum of HESC in China. Although the Minstry of Health launched an ethical guideline on HESC research, this guidline includes none legal or criminal liability for violations.[57] This unrestrictive HESC policies lead to the phenomenon called "stem cell tourism".[58] Many unproved and unsafe stem cell therapies are used in patients. For example,

[53] Margaret Sleeboom Faulkner and Prasanna Kumar Patra, 'The Bioethical Vacuum: National Policies on HESC Research in India and China' (2008) 5 Journal of international business law 221-229. (stating that both China and India have problems with the implementation of bioethical regulation for stem cell research and therapy. As stem cell science moves from the laboratory to the clinic and the experimental treatment of patients, in both China and India it does so in a governance vacuum).

[54] *ibid.* (Stating that Beijing has been spending millions of dollars annually to offset and advance its biomedical research. Between 1996 and 2000, the central government invested over 1.5 billion Yuan in biotechnology, as part of its main programme to Kick-start the sector. In February, the government announced an additional $350 million funding for genomics and biotechnology through it priority 863 R&D programmes over the period 2000-2005).

[55] Salter Brian, Cooper Melinda and Dickins Amanda, 'China and the Global Stem Cell Bioeconomy: an Emerging Political Strategy?' (2006) 1 Regenerative Med 671-683

[56] Salter Brian, 'Governing Stem Cell Science in China and India: Emerging Economies and the Global Politics of Innovation' (2008) 27 New Genetics and Society 145-149.

Ministry of Health, People's Republic of China, Ethical Guiding Principles on Human Embryonic Stem Cell Research, Dec. 24, 2003, <http://www.chinaphs.org/bioethics/regulations_&_laws.htm#-TOC113106142> accessed 28 October 2013 .

[57] Bruce H Dobkin, 'Cellular Transplants in China: Observational Study from the Largest Human Experiment in Chronic Spinal Cord Injury' (2006) 20 Neurorehabilitation and Neural Repair 5.

[58] *ibid.*

fetal brain tissue is allowed to transplant into the lesions of patients to curing spinal cord injury at hospitals in Beijing, China.[59]

Whereras there is a regulation vacuum in HESC regulation and globalisation of research and therapy, international regulation is needed for intense scruntiny of stem cell tourism. It is observed that 'lack of international mechanisms for accountability, transparency, and ethical oversight as the main reasons for scientific regularoty system failures'.[60]

1.4.2 The Role of Regulation in HESC Research – a Halt to the Opening of the 'Pandora's Box'?

The role of regulation in HESC research is critical. HESC research is a double-edged sword which can bring tremendous benefits or, on the contrary, irreversible disaster. The effect of utilising HESCs can be explained by an analogy to 'Pandora's Box': when you open it, you can never know what is inside, and once opened, it can never be closed. Therefore, despite the tendency in many areas for law to develop after a real problem arises, the wait-and-see strategy in regulating HESC research seems to be a highly risky approach. The disastrous results of obscurity in law might be the cloning of human beings, tissue factories, 'designer babies' or even human-animal creatures. Just as John Harris stated, '[m]any people think looking too far into the future is irresponsible or frivolous … future and possible dangers have an unerring habit of becoming real and present ones. And when they do, they may be more difficult to control'.[61]

One major reason embodying the importance of regulation in HESC research

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[59] *ibid.*

[60] Lesley N Derenzo, 'Stem Cell Tourism: the Challenge and Promise of International Regulation of Embryonic Stem Cell-Based Therapies' (2011) 43 Case Western Reserve Journal of International Law 877.

[61] Ryan Morgan, 'Embryonic Stem cells and Consent: Incoherence and Inconsistency in the UK Regulatory Model' (2007) 15 Medical Law Review 279-282

is that, in terms of businessmen, researchers and investors, consistency and transparency in HESC research is significantly crucial. This safe environment could only be provided by regulation rather than policy, custom or ethics code. Regulating HESC research helps to meet the highest standards not only in the laboratory but also in their clinical application. As some US scholars have commented, 'in any case, regulation in the US must keep in mind the rapid pace of technology development'.[62]

At the same time, however, regulations about financial resources of HESC research seem to be essential to building this innovative biotechnology. Similar to most other biotechnologies, HESC research is marked as being time consuming and costly. The ethical and safe procedure of donating oocytes would be very expensive.[63] Therefore, researchers need stable and adequate funds to manage the project.

1.4.3 Reasons for Choosing the US and EUROPE

This research will specifically examine two regions: the US and the EUROPE. The US is chosen as an object to demonstrate that regulating funding policies would not be workable for monitoing immoral HESC research. The US is chosen as an object because it has one of the world's leading regulatory frameworks in the world. During the Bush administration, no federal funds were allocated to HESC research, except in two states – New Jersey and California.[64] On March 9, 2009, President Barack Obama signed an executive order claiming that 'we will bring the change that so many scientists and researchers; doctors and innovators; patients and loved ones have hoped for, and fought for, these past eight years: we will lift the ban on federal funding

[62] Quellette Alicia, Caplan Arthur, Carroll Kelly, Fossett W James, Bjarnadottir Dyrieif, Shickle Darren, 'Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States' (2005) 31 American Journal of Law & Medicine, 419-446

[63] Mertesl Heidi and Pennings Guido, 'Oocyte donation for stem cell research' (2007) 22 Human Reproduction, 629-634

[64] S1909/A2840 is a bill that was passed by the New Jersey legislature in December 2003, and signed into law by Governor James McGreevey on January 4, 2004, that permits human cloning for the purpose of developing and harvesting human stem cells; On November 2, 2004, voters in California approved

for promising embryonic stem cell research. We will vigorously support scientists who pursue this research. And we will aim for America to lead the world in the discoveries it one day may yield'.[65] Recently, the Stem Cell Research Advancement Act of 2011, which permits federal funds to be used on embryo research, came under consideration in the US Congress. If approved, this new legislation would codify the US National Institutes of Health's (NIH) Guideline for human embryonic stem cell research and 'place into statute a framework to ensure such critical research can be conducted unimpeded by political interference'.[66]

The reason for choosing the EUROPE as an object is to demonstrate infusing moral exclusion with the patent law would not be workable for monitoing immoral HESC research niether. It has unique framework combined with its 28 member states. As European Research Commissioner Philippe Busquin noted, '[i]n Europe, we have a legitimate diversity of rules and ethical frameworks in the field of HESC research'.[67] In October 2006, the Seventh Framework Program (FP7) commenced, which contains a major improvement in the budget compared to the FP6; however, human reproductive cloning, germ line gene therapy, creation of human embryos for research and for stem cell procurement are still precluded in the FP7 funding.[68] The European Group on Ethics organisation claims responsibility for 'the lubrication of the ethical interaction through its elaboration of fresh ethical distinctions and perspectives as well as the facilitation of decision making through the judicious use of its claim to impartiality'.[69] The UK, within the EUROPE, is

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Proposition 71, which allows the state to borrow $3 billion for research on stem cells.

[65] Jesse Lee, 'a debt of gratitude to so many tireless advocates' the White House Blog <http://www.whitehouse.gov/blog/09/03/09/A-debt-of-gratitude-to-so-many-tireless-advocates/> accessed 28 October 2012.

[66] Satkunarajah Nisha, 'US stem cell legislation to be introduced' (2011) BioNews 615 <http://www.bionews.org.uk/page_98986.asp> accessed online 28 October 2012.

[67] See European Commission publishes background paper on stem cell research, the Public Health Genetics Unit <http://genome.wellcome.ac.uk/doc_WTD020783S.html> accessed online 28 October 2012.

[68] See The Seventh Framework Programme (2007-2013) <http://www.investni.gov.uk/e-flyer_233.pdf> accessed 28 October 2012.

[69] Salter Brain, 'Bioethics, politics and the moral economy of HESC science: the case of the European

the first nation to allow HESC research, the first nation to issue the Human Fertilisation and Embryology Bill (HFE ACT), the first nation to establish a stem cells bank and the first nation to allow human-animal embryos to be created and used for research.[70] As Professor Sheng pointed out, the UK is 'currently a world leader not only in embryological research and cloning but also in policy making in this field. UK policy has positively influenced the policy making in other countries, including China, Japan, USA *et al*'.[71] Nevertheless, the UK regulatory model has received a great deal of criticism for its incoherence and inconsistency.[72] Apparently, the strategies adapted within the EUROPE hold a precious and intrinsic value in an international context.

1.4.4 The Potential solution: regulating moral or immoral research itself through reconciling HESC regulation at the international level

The challenges of reconciling HESC regulation are daunting and the objective of reconciliation process is dispiriting. The attempts at reconciling HESC regulation should be proceeded with discretion. In particular, the lessons from the reconciliation model in relevant area might inform the potential risk of reconciling HESC regulation, such as the dangers of Global Patent Policy Harmonisation. As indicated by Sngeeta Shashikant, the potential risk of patent policy harmonisation is "exporting a Dysfunctional System".[73] The reason is due to the diversity of the world. 'Balance is needed between developed and less-developed countries, discovery and exploitation in science, private and public interests, free release and monopoly'.[74] Nobel laureate Sulston of the Human Genetics Commission further concluded that

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Union's Sixth Framework Programme' (2007) 32 New Genetics and Society 1-28

[70] 'Human-animal' embryo green light, *the BBC* (London, 5 September 2007) <http://news.bbc.co.uk/1/hi/health/6978384.stm> accessed 28 October 2-12.

[71] See Government proposals for the regulation of hybrid and chimera embryos, fifth report of session 2006-2007,<http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/169we83.htm> accessed 28 October 2012.

[72] *Supra* note 11.

[73] Sangeeta Shashikant, *The Substantive Patent Law Treaty: The Dangers of Global Patent Policy Harmonization* (Third World Network, Penang 2009) 1.

'regrettably, harmonisation is a way for those who have already arrived at a prosperous situation to pull up the ladder and stop other joining them'.[75] Therefore, the policy reconciliation might be utilised as instrument to decrease developing countries competency. It seems to be unbearable and unequal particularly to the undeveloped countries.

One main reason for a reconciled framework is uncertainty between different jurisdictions and disagreement within different countries. In terms of global society, reconciled regulations might have an effect on public interest because patients will be able to seek their prioritised treatment. The national states enforcement of reconciled framework could guarantee the equal access to healthcare and medicine. However, bringing HESC regulation into line with one another is so complex and a comprehensive proposal for the uniformity of moral standards seems to be unrealistic in the foreseeable future.

While the risks of reconciliation exist, there are also some important benefits. The reconciliation of HESC regulation could eliminate the phenomenom of "stem cell tourism". The reconciliation of HESC regulation could promote public health and enhance research quality in China. Furthermore, reconciled framework could provide minimal standards for monitoring immoral research in China, and therein the minimal standards could include that funds allocation ethically conforms to the reconciled regulations. The minimal standards could also include the ethical criterion for importing and exporting HESC as well as the enforcement regulations such as arbitration and procedure rules.

In addition, reconciled regulation would increase the patent office's efficiency. In aid of the unified standard provided by the reconciled regulation, the patent applicants might be confidence of managing prior art research and patent examinations.[76] Under the reconciled framework, most countries

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[74] *ibid.*

[75] *ibid.*

[76] Sadaf Shariat, 'response to global ethical concerns regarding patentability of HESC researches' (2011)

equally have the opportunity to start and develop relevant stem cell therapy.[77] On the one hand, in the aids of reconciled HESC regulation at the international level, the phenomenon of stem cell tourism might be decreased. Patients will not rush into the nations that could provide the most risky treatment under the most lenient and unethical regulations. On the other hand, reconciled HESC regulation at the international level will promote the ethical stem cell research since only high standard research could be allowed to carry out in the worldwide.[78]

Reconciled HESC regulation is also in favour of public interest. Because everyone has an interest in research, everyone should have equal right to access it and everyone should have equal right to benefit from it. In the reconciled framework, the theorists believe that quality research and discover tends to be stimulated and international collaboration is likely to be promoted under the uniform standard.[79] However, not only the HESC research might progress but also the application of HESC research would develop.

1.5 Research Methodology

This thesis focuses on international HESC regulation on the basis of international and transnational methods. Three main methodologies - comparative, historical and doctrinal - are utilised. These methods are used to analyse the conventional and alternative approach to the reconciliation of HESC regulation.

1.5.1 Comparative Method

A distinctive methodology of this dissertation is the comparative analysis of

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International conference on management proceeding 1675-1684 <http://www.internationalconference.com.my/proceeding/icm2011_proceeding/115_324_ICM2011_PG1675_1684_STEM_CELL.pdf> accessed 24 July 2014.

[77] *ibid*.

[78] Allison C Ayer, 'stem cell research: the laws of nations and a proposal for international Guideline' (2001) 17 Connecticut Journal of International Law 414.

[79] *ibid*.

regulations in three different regions, considering the practical situation, culture, economic factors and policy which all play important roles in the law making process. The comparison of legislations from different regions should be a proper methodology to study this universal controversy. Measuring and comparing the effectiveness of the regulations in the US, the EUROPE and China helps to obtain a better understanding of the various legal rules that benefit the reform legislation—the systematic construction and reconciliation of the regulations. As Ferdinand Stone stated: '[w]e must study the history, the politics, the economics, the cultural background in literature and the arts, the religions, beliefs and practices, the philosophies, if we are to reach sound conclusions as to what is and what is not common'.[80]

The comparative research about the regulations in these three regions is conducted on both macro and micro levels. On the macro level, the study first distinguishes between the different areas—whether belonging to civil law families or case law families—because of the wide divergence between these two categories. Then, the research investigates the relevant documents and analyses the underlying legal philosophy. Finally, after the macro analysis, the research attempts to identify the problem and make recommendations. On the micro level, the research first tries to explain the precise meaning of some terms and explore the intrinsic value of the legal principles. Then, according to the various interpretations in different areas, the study hopes to draw conclusions about the proper way to explain moral exclusion in patent law towards embryonic stem cell research in diverse customs and social norms. Through both the macro- and micro-level examinations, the research will seek to develop a regulatory model for this intricate issue.

1.5.2 Historical Method

Historical method explains 'the historical context of some legal text or

[80] Zaid Muhmoud Aqaileh, 'legal cultures dialogue benefits and obstacles of comparative law studies' (2013) 54 Journal of Sharia and Law 23-68.

institution' and 'shows how that context has disappeared or otherwise changed rendering the text or institution obsolete or unsuitable'.[81] It is particularly true in the field of intellectual property law, as 'the historical analysis (i) has influenced intellectual property law, (ii) is capable of prescribing its future development, and/or (iii) is linked to intellectual property law in any other manner'.[82] Historical perspective is vital because the patentability and morality of HESC related inventions are developed in accordance with the era. By examining historical method, using historical concepts and finding historical legal sources, the thesis seeks to develop the historical understanding of HESC regulation problems.

The historical method may be found in examining US and EUROPE HESC regulations. In terms of the US mode of moral-based HESC regulation, historical and political interventions of federal funding control under moral concerns are examined, including the Dicky-Wicker Amendment in the Clinton administration, the Bush compromise in the Bush administration and the Executive Order in the Obama administration. In the context of the EUROPE mode of moral-based HESC regulation, historical cases rulings of morality assessment are examined, including the *Howard Florey/Relaxin* case, the *Harvard/Onco-mouse* case, the *Plant Genetic System v Greenpeace* case, the *University of Edinburgh* case, the *WARF/Stem cells* (G2/06) case and the *Oliver Brüstle v Greenpeace* case.

1.5.3 Doctrinal Method

Doctrinal method with the analysis of legal principles maps the structure of this thesis. 'Valid research is built on sound foundations, so before embarking on any theoretical critique of the law or empirical study about the law in operation, it is incumbent on the researcher to verify the authority and status

[81] Allison J W F, 'history to understand, and history to reform, English public law' (2013) 72 Cambridge Law Journal 526-557.

[82] Jeremy Phillips and Ilanah Simon, 'Going down in history: does history have anything to offer today's intellectual property lawyer?' (2005) 3 Intellectual Property Quarterly 225-235.

of the legal doctrine being examined'.[83] It is critical to the thesis because it conveys an overview of the law by arranging legal principles, legal concepts, legal rules and legal ruling. Doctrinal analysis is commented on as 'scholarship of law application' and a scholarship to prepare decision'.[84]

The sources of law involved in this thesis mainly stem from three regions: the US, the EUROPE and China. Primary resources include but are not limited to the legislation, case law, Directives, Guideline, while secondary resources cover journal articles, books, reports and websites. These two sources both contribute to the judicial reasoning and legislative enactment.

1.6 Scope and Limitations of the Thesis

This thesis addresses problems in finding a better soluation to regulating HESC in China. This research focuses on the patentability and morality of HESC research and compare the approach which adopted by the US and EUROPE. This thesis argues that the reconciliation of HESC at the international level should be attempted for monitoring "stem cell tourism" in China, but other issues are beyond the scope of this research.

The research does not cover all aspects of reconciling HESC regulations at an international level. The author has found that it is extremely difficult, if not impossible, for an individual to complete this research. Reconciliation of HESC regulation in this thesis focuses solely on the patentability and morality of HESC and the degree of reconciliation. Although reconciliation of HESC broadly covers competition policy, medical regulation, clinical Guideline, scientific standards and research ethics, these areas of reconciliation are not the focus of this thesis. Therefore they fall outside the scope of the thesis.

[83] Hutchinson Terry C, 'Doctrinal research: researching the jury' in Watkins D & Burton M (eds.) *Research Methods in Law* (Abingdon, Routledge 2013) 7-33.

[84] Anne Peters, 'realizing utopia as a scholarly endeavor' (2013) 24 European Journal of International Law 533-552.

Therefore, the thesis focuses on two main dimensions: one is the patentability and morality of HESC related invention; the other is the extent to which reconciliation should be achieved.

One key limitation is the absence of empirical studies. Reasons of complexity prevented the author from conducting interviews with a number of scientists, lawyers, doctors and patients. The lack of empirical studies fails to reveal the practical voices supporting the patentability of moral based HESC related invention. Examining the interplay between patent law and morality will be limited to the scholars' work.

The other limitation is information disclosure based on the decisions by the Patent Office in China. Similar limitations are associated with the judicial judgments rendered by the People's Courts in Beijing and the reexamination decisions by the Patent Review Committee in China. There are few reports or studies concerning the patentability of HESC related to invention in China. Further to the above, the decisions by the People's Courts and by the Patent Review Committee solely provide answers and outcomes without necessary judicial interpretations. Also, efforts to obtain sources from certain governmental authorities in China met with failure.

1.7 Thesis Outlines

This dissertation consists of seven chapters. The first chapter states the rationale of the research the reasons for choosing this topic. This chapter also introduces the background of the research, including the research question, the research aims, the scope of research and the methodology.

Chapter two briefly introduces the technical terms, and the history of HESC research development. Then, it discusses some specific issues, such as moral regulations in embryo donation, human dignity and the rights of human embryos, creation of embryos for research, impeding effects of stem cell patents and the public's right to know. The moral dilemma mainly consists of

three parts. The first is the moral status of the human embryo. Some scholars argue that human embryos are individual human beings, but some insist that human embryos are not human beings. Some academics fall in between these two standpoints. They have created the "personhood" theory: that human embryos are human beings but not human persons. The second part is about the moral source of the human embryo. One dominant view is that creating human embryos for research is the instrumentalisation of human life.[85] However, spare human embryos from IVF can be used for research. Does the "discard-created distinction" theory not respect human life? In this part, the author also discusses whether it is morally permissible to compensate donors. The third part concerns whether the use of therapeutic cloning will lead to reproductive cloning use. This part consists of two questions: whether therapeutic cloning use will turn into commercial use and whether the distinction between therapeutic cloning use and reproductive cloning use will be impossible to police.

Taking this into consideration of "stem cell tourism", Chapter Three examines the regulatory system of HESC research in China. It finds that, even if the patent law contains strict moral provisions, scientists could adopt a hazy approach to moral research and immoral research. Because most HESC research is sponsored by the government, it is indispensable to introduce the government bodies involved in this area and the major projects conducted by them. As a civil law country, the most important source of law is Statute Law. In China, the Patent Law 2008 is the fundamental source of the patentability of HESC research, in particular Article 5 which precludes granting a patent to 'any invention-creation that is contrary to the laws of the state or social morality or that is detrimental to public interest'.[86] The specific meaning of some key words in China such as "moral", "embryo", "commercial or industrial use", "public interest" and so on are detailed. Chinese authority is

[85] Radhika Rao, 'Coercion, commercialization, and commodification: the ethics of compensation for egg donors in stem cell research' (2006) 21 Berkeley Technology law Journal 1055.
[86] Patent Law of People's Republic of China 2008

in a dilemma on prohibiting HESC research because abortion is not against the law in China. Therefore, the relevant legislation and policy on abortion is also laid out in this chapter. HESC research in China is not morally criticised, as characterised by the EUROPE. The responsible authority in this field is the ethics committees that are established at both national and regional levels. In addition, the ethical Guideline for HESC research in China was released in 2004.[87] All relevant important policy initiatives and state administration orders are explored in this chapter.

Chapter Four is mainly about the regulations in the US, which separate the morality and patentability of HESC related inventions. Chapter Six also examines and evaluates the federal funding policies in different administrations, including the National Institutes of Health Revitalisation Act which allows federal funding of research related to embryos at an early stage, the Dickey-Wicker Amendment which regulates no federal funding for HESC research involving the destruction of embryos, the NIH Guideline 2000, the Bush Compromise which accepted the narrow explanation of Dickey-Wicker Amendment but exercised its executive power instead of its legal power to allocate funding, the Report from President Council on Bioethics which clarified that the enforcement law was Dickey-Wicker Amendment and the Executive order by President Obama which reversed the Bush policy.

Chapter Five will appropriately explore the relevant regulations and cases in the EUROPE. The moral criterion of the European Patent Convention as well as some important opinions of the European Group on Ethics in Science and New Technologies (EGE) will be discussed in this chapter. The essence of this chapter will mostly entail a sort of analysis of the Biotechnology Directive which precludes the patentability of uses of human embryos for industrial or commercial purposes. In addition, through case studies, this chapter will discuss how to assess morality, whether HESCs should be included in the

[87] The Ethical Guideline for HESC research of People's Republic of China, 2003 <http://www.cncbd.org.cn/News/Detail/3376> accessed November 23 2013.

concept of "human embryo" and the scope of "industrial or commercial use". The different regulatory approaches adopted by member states, including liberal policy, restrictive policy and intermediate policy will also be examined in this chapter.

Chapter Six focuses on the reasons for and the degree and scope of reconciliation efforts for moral-based HESC regulations at an international level. The reasons why regulations on HESC research need to be reconciled at an international level are implied by economic, scientific and legal fundamentals. With regard to the degree of reconciliation needed at an international level, the research refers to lessons learnt from drug agreement reconciliation and the reconciliation of the environmental and human safety aspects of international trade regulations. In terms of the scope of reconciliation of HESC regulation, the research is based on the Guideline set by the international society. In a geographical context, this chapter examines the regulations of HESC research in the EUROPE. Since moral concerns are deeply rooted in the EUROPE, moral exclusion is the patent barrier for HESC research. In order to promote trade and research within the community, the EUROPE launched the Biotechnology Directive to harmonise relevant regulations. However, uncertainty still exists when the regulations are implemented in member states. For instance, although the EUROPE reached a consensus on the human embryo concept, it did not have the uniform legal status of human embryo as well as moral definition. Furthermore, the EUROPE adapted the strategy that infuses moral control into patent law. The patent application might be rejected due to the violation of morality. Despite the fact that the EUROPE mode tries to harmonise HESC regulations in the community, it leaves room for member state in adaption, which is benefit of releasing the tension of moral conflicts between member states.

In the final chapter, from the comparative analysis of the regulatory frameworks in the US and the EUROPE with China, the research attempts to discern the advantages and disadvantages of strategies concerning the

patentability and morality of HESC research in the separate areas. Ultimately, the research hopes to draw together the explored frameworks and develop a better solution for regulating HESC in China. The research also provides a platform that helps others to better understand the regulations in these three areas, especially China.

CHAPTER TWO: THE MORAL MAZE IN HESC RESEARCH REGULATION

2.1 Introduction

Although this research is about how to tackle with the HESC regulation in China, it will inevitably encounter moral issues when examining problems related to HESC. In most circumstances, morality may not coincide with the law. But, moral obstacles are significant issues to inventions related to HESC research. The main arguments against HESC research centre on questions to do with the violation of morality. This chapter aims to clarify the moral maze in HESC regulation, that is, the debate over the moral status of the human embryo, the moral source of the human embryo and the relationship between therapeutic cloning use and reproductive cloning use.

Generally in HESC research, the moral maze stems from the ethical dilemma of using human embryos. From a systematic way of thinking, some analysis has suggested that the HESC shares the same moral status as the human embryo.[1] For example, Robert George and Patrick Lee affirmed that 'the human embryo is the same individual as the human organism at subsequent stages of development'.[2] However, some scholars, such as Thomas Douglas and Julian Savulescu, have suggested that 'moral intuitions seem to be incompatible with the view that embryos are persons'.[3] Another moral maze in the regulation of HESC research is the moral source of human embryos. Is discarding embryos from IVF morally different from creating and using embryos for research? Is the creation of embryos for research morally permitted? Is it morally acceptable to pay for the donations? Those questions do not yet have absolute answers. Nevertheless, this moral uncertainty leads

[1] Agata Sagan and Peter Singer, 'the moral status of stem cells' (2007) 38 Metaphilosophy 264.
[2]Robert P George and Patrick Lee, 'Embryonic human persons' (2009) 10 European Molecular Biology Organization Reports 301.
[3] Thomas Douglas and Julian Savulescu,'Destroying unwanted embryos in research' (2009) 10 EMBO Reports 307.

to legal uncertainty. In addition, the distinction between therapeutic cloning and reproductive cloning should never be over or underestimated. Reproductive cloning is morally forbidden in most countries. [4] Will therapeutic cloning be allowed for commercial use? Will therapeutic cloning cross a moral line and develop into reproductive cloning? These moral controversies will be discussed in this chapter.

2.2 Research Background

Human Embryo

The human embryo, is a multi-cellular organism that will extensively grow and differentiate into higher forms.[5] In human biology, it is the baby in the early development stage.[6] The term is applied to the unborn child until the seventh week following conception.[7] The development of the embryo is called embryogenesis.[8]

The human embryo comes from the union of an ovum with a sperm.[9] It is the result of fertilisation and becomes a zygote, which will undergo divisions called cleavages.[10] During the differentiation process, the embryo divides into three types of tissue: the ectoderm developing into the skin and nervous system; the mesoderm developing into connective tissues, the circulatory system, muscles and bones; the endoderm developing into the digestive system, lungs and urinary system.[11]

HESC

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[4] The United Nations report, Is human reproductive cloning inevitable: future options for UN governance, 2007.
[5] See biology online <http://www.biology-online.org/dictionary/Embryo> accessed September 21 2014.
[6] *ibid.*
[7] Encyclopaedia Britannica <http://www.britannica.com/EBchecked/topic/185610/embryo> accessed September 21 2014.
[8] See <http://en.wikipedia.org/wiki/Human_embryogenesis> accessed June 30 2013.
[9] *ibid.*
[10] *ibid.*
[11] *ibid.*

The HESC, according to the science technology dictionary, is derived from the inner cell mass, which has the ability to differentiate to all cell types of human.[12] However, the embryonic stem cell itself is undifferentiated and could originate either from embryo tissue or adult tissue.[13]

The embryonic stem cell is one kind of stem cells which have a greater differentiation capacity than other stem cell type adult stem cell and embryonic germ line stem cell. Also, based on the data from experiments, the embryonic stem cell has the advantage of being easily isolated, steadily growing and flexibly transferred compared to adult stem cells. But in terms of being homogeneous in differentiated cells, the embryonic stem cell seems to be inferior to the adult stem cell which could generate uniformly wanted cells. Another issue which should not be ignored is that the embryonic stem cell has the potential to cause an immune rejection because of the random embryo.[14]

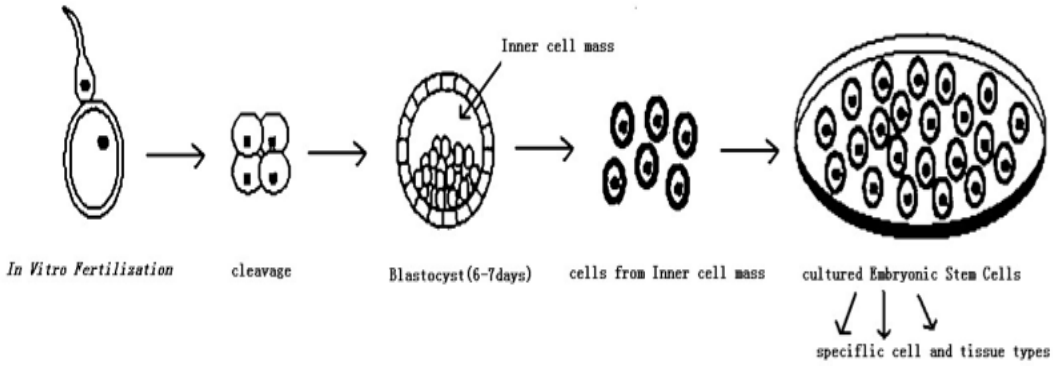

Figure 1: The derivation of HESC[15]

As Figure 1 shows, HESC is isolated from embryos left by In Vitro Fertilisation. The early embryo is divided by cleavage. About six to seven days after fertilisation, the cleavage becomes the formation of the blastocyst. Inside the blastocyst, there is an inner cell mass lying in a hollow sphere,

[12] <http://stemcells.nih.gov/info/scireport/pages/chapter3.aspx> accessed June 30 2013.
[13] *ibid*.
[14] See stem cell research report, stem cell research committee publications, 2001, <http://www.publications.parliament.uk/pa/ld/ldstem.htm> accessed June 7 2013.
[15] Figure 1 is from Gabriel S Gross, 'federally funding HESC research: an administrative analysis' (2000) Wisconsin Law Review 858.

which acts as 'precursors to all adult tissues, can proliferate and replace themselves in the intact embryo only for a limited time before they become committed to specific lineages'.[16] Cells from the inner cell mass could be cultured and extracted as embryonic stem cell, and finally decide the structure of the foetus.

Therapeutic Cloning

In the UN report, therapeutic cloning is 'medical and scientific applications of cloning technology, which do not result in the production of genetically identical fetus'.[17] Compared to this, there is another type of cloning called reproductive cloning which can 'produce one or more individuals genetically identical to another individual'.[18] Embryonic stem cell has a very close relationship with therapeutic cloning. In fact, therapeutic cloning which refers to the development of embryo is the root of the development of embryonic stem cell research.

As for the cloning, the cell nuclear replacement (CNR) is another important term. The CNR which was used in Dolly the sheep's case, in brief, is 'a form of cloning whereby a nucleus of a cell taken from an adult, embryo or foetus is transferred into an unfertilized egg which has had its nucleus removed'.[19] Using CNR to produce embryonic stem cell is crucial to solving the problem of organ transplant and immune rejection.

Somatic Cell Nuclear Transfer (SCNT)

The SCNT which is in some cases called therapeutic cloning is 'a laboratory technique for creating a clonal embryo, using an ovum with a donor nucleus (see process below). It can be used in embryonic stem cell research, or,

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[16] The national bioethics advisory commission, ethical issue in human stem cell research 9 (1999) <https://bioethicsarchive.georgetown.edu/nbac/pubs.html> accessed December 3 2013.

[17] See is human reproductive cloning inevitable: Future options for UN governance, the United Nation, October 2007 <http://www.ias.unu.edu/sub_page.aspx?catID=111&ddlID=588> accessed 08 June 2012.

[18] *Ibid.*

[19] Regina v Secretary of state for health, house of lords <http://www.publications.parliament.uk/pa/ld200203/ldjudgmt/jd030313/quinta-2.htm> accessed 08 June 2012.

potentially, in regenerative medicine'.[20] The SCNT holds the promise of generating the stem cell lines specifically for the patients.[21] So far, the SCNT approach has been tested on animals but not on human beings, therefore no human ES cell lines have been derived.[22]

Induced Pluripotent Stem Cells (IPS)

IPS, according to its name, is a kind of pluripotent stem cell and its origin is from a non-pluripotent cell.[23] The concept of a pluripotent stem cell is distinguished from the stem cell's differentiation degree and self-renewal capability. Based on this, the stem cell could be grouped into five categories. If the stem cell has 'the ability to construct a complete, viable organism such as a fertilised egg cell and differentiate into every cell type of an organism', it is called totipotent stem cell.[24] The descendants of totipotent cells are pluripotent stem cells, which are also able to generate various cells.[25] However, multipotent cells can only 'differentiate into a number of cells and only those of a closely related family of cells'.[26] The next Oligopotent stem cells are limited to a few cells and the final unipotent cell can merely split into one cell type.[27]

IPS was first applied in an experiment on mice in 2007. At that time, the researcher used this technology to generate liver cells from adult skin cells.[28] The valuable aspect of this new method is 'the ability to perform disease modelling.'[29]

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[20] <http://en.wikipedia.org/wiki/Somatic_cell_nuclear_transfer> accessed 30 June 2012.
[21] McNeish John, 'Embryonic stem cells in drug discovery' (2004) 3 Nature. Review Drug Discovery 70-80
[22] Hug K, 'Therapeutic perspectives of HESC research versus the moral status of a human embryo-does one have to be compromised for the other?' (2006) 42 Medicina Kaunas 107-114.
[23] *ibid*.
[24] Scholer H R, 'The potential of Stem Cells: an inventory' (2004) 47 natural science review 565-577
[25] *ibid*.
[26] *ibid*.
[27] *ibid*.
[28] Induced Pluripotent Stem Cell Technology Used to Generate Hepatocytes From Skin Cells, 20 October 2009 <http://www,genengnews.com/gen-news-highlights/induced-pluripotent-stem-cell-technology-used-to-generate-hepatocytes-from-skin-cells/65932826> accessed 30 June 2012.
[29] Stem cells: a new path to pluripotent, 451 Nature 858, 13 February 2008

HESC Research

The opening event of this new field is the first successful derivation embryonic stem cell by a group of scientists in University of Wisconsin in 1998.[30] Shortly after that, John Gearhart found another way to generate similar cells from foetal gonadal tissue.[31] Both two ways could provide enough pluripotent stem cells for the ongoing studies about therapeutic applications of embryonic stem cells. However, these pieces of research inevitably lead to the ethical debate in numerous countries, cultures and religions. With regard to this, six policy options have been distinguished according to the policies adapted in different region:

Option 1: No human embryo research is permitted and no explicit permission is given to perform research on existing HESCs;

Option 2: Research is permitted only on existing HESC lines, not on human embryos;

Option 3: Research is permitted only on remaining embryos no longer needed for reproduction;

Option 4: Research is permitted both on remaining embryos and on embryos created specifically for research purposes through in vitro fertilization (IVF);

Option 5: Research is permitted both on remaining embryos and on embryos created specifically for research purposes through somatic cell nuclear transfer into human eggs or zygotes;

Option 6: Research is permitted both on remaining embryos and on embryos created specifically for research purposes through the transfer of human somatic cell nuclei into nonhuman animal eggs, for example,

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<http://www.nature.com/nature/journal/v451/n7180/full/451858a.html> accessed 30 June 2012.

[30] Walters Leroy, 'HESC research: an intercultural perspective' (2004) 14 Kennedy Institute of Ethics Journal 3-38.

rabbit eggs.[32]

Because of the high risk of embryonic stem cell research, such as short supply and high cost of human oocyte, the researchers want to use animal eggs to replace human eggs.[33] The first hybrid embryo that contains both contain human and rabbit DNA was created in China in 2003.[34] In addition, in the UK, human-animal embryos were allowed and are permitted by the Human Fertilisation and Embryology Authority.[35] The British health minister said that 'the overarching aim is to pursue the common good through a system broadly acceptable to society'.[36] Many scientists applauded the permission and commented that '[i]t is a positive outcome not just for our work but for the progress of British science in general and we hope that this will lead to new technologies to benefit everyone'.[37]

In May 2008, a vote of 336 to 176 in the House of Commons allowed the study of hybrid human-animal embryos.[38] Although scientists might not hope to create actual human-animal embryos, 200 medical charities support the legislation to permit it.[39]In a report by the Academy of Medical Science, research on animals containing human material is beneficial to 'determine the role of a specific piece of human DNA, our genetic material, by seeing what effect it has in a living animal' and 'to test and develop methods of diagnosis,

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31 *ibid*.

32 *ibid*.

33 H Mertes and G Pennings, 'Oocyte donation for stem cell research' (2006) 1 Human Reporduction 1-6.

34 Rick Weiss, 'cloning yields human-rabit hybrid embryo' (2003) the Washington Post, 13 August < http://www.washingtonpost.com/ac2/wp-dyn/A55911-2003Aug13?language=printer 14aug03> accessed 21 June 2013.

35 *ibid*.

36 Gudrun Schultz, 'UK Government Proposals Approve Human/Animal Embryo Hybrids', Life Site News, 12 December 2006 <http://www.lifenews.com/idn/2006/dec/06121205.html> accessed 30 June 2012

37 Human animal embryo green light, 5 September 2007 <http://news.bbc.co.uk/1/hi/health/6978384.stm> accessed 30 June 2012

38 see MPs vote against ban on bybrid embryos, 19 May 2008, <http://www.independent.co.uk/news/uk/politics/mps-vote-against-ban-on-hybrid-embryos-830969.html> accessed 30 June 2013

39 Bioethics: human animal hybrid embryos, <http://www.bbc.co.uk/ethics/animals/using/hybridembryos_1.shtml> accessed 30 June 2013.

drugs and other treatments for human disease'.[40]

The bright future of HESC research is mainly reflected in three aspects. First, the precious information about early embryo development will bring benefits to curing diseases in foetuses. Second, with the large investment in biotech companies, we will anticipate some exciting new pharmaceutical products. For example, some people envisage an omnipotent drug can 'active bone marrow cells and encourage them to migrate to parts of the body where repairs are needed'.[41] Finally, we will have the ability to generate a variety of tissues for implanting and repairing. The risk of immune system rejection will be at a minimum because embryonic stem cells generate cells that are homogeneous with those of the patient.[42] This indicates that, perhaps in the near future, people may stop aging and might never die because we would always replace their old organs with new ones.[43]

At the Cancer Treatment Centres of America (CTCA), HESCs have already been used in curing cancer diseases.[44] For example, the researcher Igor Slukvin at the University of Wisconsin-Madison was the first to successfully reprogram blood cells obtained from a patient with lEuropekaemia, which means the diseased cells are capable of turning back into pluripotent stem cells. 'This is important because it provides a new model for the study of cancer cells'.[45]

In addition, HESCs demonstrate the ability to generate human organs that

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[40] See animal contains human material, report of the Academy of Medical Science, 22 July 2011 <http://www.acmedsci.ac.uk/p118pressid83.html> accessed 30 June 2012

[41] Jahanara Parveen, 'stem cells, the future therapy', Bio Spectrum, 10 March 2009 <http://www.biospectrumindia.com/biospecindia/news/157607/stem-cells-future-therapy> accessed 30 June 2012

[42] David M Gilbert, 'The future of HESC research: addressing ethical conflict with responsible scientific research' (2004) 61 Medical Science Monit 99-103.

[43] Kathy Hudson, 'New international society for stem cell research guideline skirt issue of egg donor compensation', Genetics & Public Policy center, 1 February 2007 <Http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=70> accessed 30 June 2012

[44] See the Cancer Treatment Centers of America <http://www.cancercenter.com/stem-cells.htm> accessed 28 October 2012.

[45] Terry Devitt, 'new induced stem cells may unmask cancer at earlier stage, 4 Feb 2011 <http://newsroom.stemcells.wisc.edu/18933> accessed 28 October 2012.

could be broadly used in tissue transplantation. As a result, the dilemma of the lack of donors and patients suffering endless waiting might be relieved because the organs could be provided through HESCs.[46] In a recent advance, scientists have already created synthetic blood through HESCs. This unlimited blood supply for infection-free transfusions could 'help to save the lives of anyone from victims of traffic accidents to soldiers on a battlefield by revolutionising the vital blood transfusion services, which have to rely on a network of human donors to provide a constant supply of fresh blood'.[47]

Another piece of exciting news from HESCs is that, according to the experiments in rats by researchers at Stanford University, nEuroperal cells originating from embryonic stem cells have the ability to repair the brains of rats damaged by stroke.[48] The observations made by the study of Su-Chun Zhang showed that oligodendroglial progenitors derived from HESCs helped cure myelin disorders, traumatic brain and spinal cord injuries.[49]

All in all, just as President Barack Obama remarked insigning of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum, 'at this moment, the full promise of stem cell research remains unknown, and it should not be overstated. However, scientists believe these tiny cells may have the potential to help us understand, and possibly cure, some of our most devastating diseases and conditions. It may be possible to regenerate a severed spinal cord and lift someone from a wheelchair; to spur insulin production and spare a child from a lifetime of needles; to treat Parkinson's, cancer, heart disease and others that affect millions of Americans and the

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[46] Lerou H Paul and Daley G Qeorge, 'Therapeutic potential of embryonic stem cells' (2005) 19 Blood Reivew 321-331

[47] Steve Connor, 'British scientists to create synthetic blood' *The Independent* (London 23 March 2009) <http://www.independent.co.uk/news/science/british-scientists-to-create-synthetic-blood-1651715.html> accessed 28 October 2012.

[48] Amy Adams, 'Neural stem cells helped repair stroke damage in rats' brains' (2003) Stanford Medical Center report <http://med.stanford.edu/mcr/2008/stroke-stem-0220.html> accessed online 28 October 2012.

[49] Zhang Su Chun, Li Xue Jun, Johnson M Austin and Pankratz T Matthew, 'HESC for brain repair?' (2008) Philos Transaction of the Royal Society B 363, 87-99

people who love them'.[50]

2.3 Overview of Moral Issues on HESC Research

Before discussing HESC research in legal dimension, it is essential to have an overview of the major hotly debated moral issues. Many ethics questions, such as the moral status of embryo, tissue transplant, egg donation, human dignity and patents on life, have emerged in this area. Moral acceptability has a decisive influence as to whether and to which extent conducting HESC research is allowed. There are serious debates about the ethics of HESC research in the world.

In the US, the National Institutes of Health (NIH) is the nation's medical research agency—making important discoveries that improve health and save lives, as well as administering the implementation of the federal health policies.[51] In the NIH guideline 2001 during George W. Bush Administration, the federal funds were only available when three criteria were met: (1) with the donors' informed consent and without financial inducements involved; (2) the line 'must have been derived from an embryo that was created for reproductive purposes and was no longer needed'; (3) 'the derivation process, which begins with the destruction of the embryo, was initiated prior to 9:00 P.M.EDT on August 9, 2001'.[52]

On March 9, 2009, the NIH published new "National Institutes of Health Guideline for Human Stem Cell Research".[53] Compared with the vague description that "informed consent must have been obtained", the Guideline indicate the compulsory parts of informed consent. There are three points to

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[50] See Remarks of President Barack Obama-as Prepared for Delivery Signing of Stem Cell Executive Order and Scientific Intergrity Presidential Memorandum, Washington DC, 9 March 009, <http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/> accessed 28 October 2012.

[51] The National Institutes of Health, <http://www.nih.gov/about/> accessed 28 October 2013.

[52] See HESC Policy Under Former President Bush, the National Institutes of Health <http://stemcells.nih.gov/policy/2001policy.htm> accessed 28 October 2013.

[53] See <http://stemcells.nih.gov/policy/Pages/2009Guideline.aspx> accessed 28 October 2013.

be considered during the consent process: '(1) informed of other available options pertaining to the use of the embryos; (2) offered any inducements for the donation of the embryos; (3) informed about what would happen to the embryos after the donation for research'.[54] And the Guideline increase the amount of Federal funding of HESC research. Federal funding could be used in HESC lines created for research purpose, derived pluripotent cells and somatic cell nuclear transfer (SCNT).[55] However, the most straightforward influence of the Guideline is the consistency in ethical and legal standards among institutions, funders and regulators.[56]

In the EUROPE, the Council and the EC proposed a set of ethical Guideline that were on the docket to be adapted before the end of 2003.[57] The Guideline states that:

> '(1) The EUROPE will not fund HESC research where it is forbidden by a Member State; (2) HESCs can only be derived from supernumerary embryos that are donated for research by parents and that were created before 27 June 2002, the date of the adoption of the Framework Programme. These embryos are destined to be destroyed at some point in time; (3) Potential research project partners applying for EUROPE funding must seek ethical advice at national or local level in Member States where the research will take place, even in countries where obtaining such ethical advice is not mandatory; (4)

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[54] See National Institutes of Health Guideline on human stem cell research, the National Institutes of Health <http://stemcells.nih.gov/policy/2009Guideline.htm> accessed 28 October 2013.

[55] *ibid*.

[56] Michelle N Meyer and Fossett A James, 'The More Things Change: The New NIH Guideline on Human Stem Cell Research' (2009) 19 Kennedy Institute of Ethics Journal 289-307 (pointing out that with respect to the goal of ameliorating the patchwork of standards governing US stem cell research, although the Guideline centralize crucial aspects of federal policy, and may exert influence even over non-NIH-supported researchers and other research funders and regulators, they almost certainly will not substantially reduce the multiple standards for conducting HESC research that exist in the United State, much less in the world).

[57] Commission staff working paper in support of the Communication from the Commission to the European Parliament, the Council and the Economic and Social Committee on Second Progress Report and Future Orientation of Life science and Biotechnology-life sciences and biotechnology- a strategy for Europe <http://ec.Europa.Europe/research/index.cfm?pg=whatsnew&StartMonth=January&EndMonth=December&CurrentYear=2003> accessed November 21 2013.

> Research will be funded only when it is demonstrated that it meets particularly important research objectives; (5) Research will be funded only when there is no adequate alternative available. In particular, it must demonstrated that one cannot use existing embryonic or adult stem cell lines; (6) Supernumerary embryos will be used only if informed consent has been given by the donor(s); (7) Embryo donor(s) will not be permitted to make any financial gain; (8) Data and privacy protection of donors must be guaranteed; (9) Traceability of stem cells will be required;(10) Research consortia will be required to engage in making available new HESCs to other researchers.'[58]

Meanwhile, the Ministry of Science and Technology coordinated by the Ministry of Health in China launched the ethical Guideline on December 24, 2003. This effective principles state that:

> 'HESCs used for research purpose can only be derived from the following means with voluntary agreement: (1) Spared gamete or embryos after in vitro fertilization (IVF); (2) Foetal cells from accidental spontaneous or voluntarily selected abortions; (3) Embryos obtained by somatic cell nuclear transfer technology or parthenogenetic split embryos; (4) Germ cells voluntarily donated.'[59]

Also the Guideline provides that all research activities relevant to HESC research should meet the following requirements:

> '(1) Embryos obtained from IVF, human somatic cell nuclear transfer, parthenogenesis or genetic modification techniques, its in vitro culture period shall not exceed 14 days starting from the day when fertilization or nuclear transfer is performed. (2) It shall be prohibited

[58] See European Commission proposes strict ethical Guideline on EUROPE funding of HESC research, Brussels, 9 July 2003 <http://Europa.Europe/rapid/pressReleasesAction.do?reference=IP/03/969&format=HTML&aged=0&language=EN&guiLanguage=en> accessed 28 October 2012.

[59] The article 5 of Ethical Guiding Principle on HESC , People's Republic of China, <http://www.Chinalawedu.com/falvfagui/fg22598/23975.shtml> accessed October 23 2013.

to implant embryos created by means described above into the genital organ of human beings or any other species. (3) It shall be prohibited to hybridize human germ cells with germ cells of any other species.'[60]

In general, the Guideline aims to comply with the rule of respect. It requires informed consent and non-commercialisation of HESC research.[61]

2.3.1 Human dignity and the Rights of Human Embryo

The argument against HESC research refers to the violation of human dignity.[62] Human dignity is a philosophically, religiously and morally complicated concept. However, when it is used in the bioethical debate, it should have a clear meaning.

According to Professor Aurora Plomer, human dignity is 'inherently indeterminate and ambivalent as between thick and thin conceptions of the bearer of dignity and rights'.[63] The "thick" conception lays on the United Nation's Universal Declaration that sates that '[a]ll human being are born free and equal in dignity and rights'.[64] It shows that all economic, cultural and social rights of the human dignity belong to the existing human precluding the embryo or foetus. However, the 'thin' conception rests on the United Nations Educational, Scientific and Cultural Organization (UNESCO) Declaration on Bioethics. Article 1 of the Declaration states that the concept of human dignity should cover all human life which includes human embryos.[65]

Despite the existence of some definitions on the international instruments, interpretations of the definition from scholars have been divergent. In the

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[60] The article 6 of Ethical Guiding Principle on HESC , People's Republic of China, see *ibid*.
[61] Wang Y G, 'Chinese Ethical View on Embryonic Stem Cell Research' in Song S Y, Koo Y M and Macer D R J (ed), *Asian bioethics in the 21st century,* (Eubois Ethics Institute, Bangkok2003)
[62] Plomer Aura and Torremans Paul, *Embryonic Stem Cell Patents-European law and Ethics*, (Oxford:Ocford University express 2009)
[63] *ibid*.
[64] The Article 1 of The United Nation's Universal Declaration of Human rights
[65] UNESCO, 'Universal Declaration on Bioethics and Human rights', <http://portal.unesco.org>

Beyleveld and Brownsword's opinion, the core of human right is 'the property of being an agent'.[66] From this premise, human embryo is not an agent. They have deduced that 'to destroy an embryo or foetus cannot be said to violate its dignity unequivocally'.[67] Another philosopher Immanuel Kant put the emphasis on the character rationality, which indicates that human dignity exists only when the human body exists.[68] In the Christian view, human life begins the moment of conception.[69] Unsurprisingly, human embryo owns human dignity.[70]

2.3.2 Create Embryos for Research

Creating embryos for research is relatively easy, but it has received much criticism even without the intention of implantation.[71] Some scholar states that creating embryos for research purposes is equal to slaughter, especially for those who believe that an embryo has the moral status as a person.[72] Some scholar argues that, as the embryo is a potential human, a special organisation should be established to monitor and control it.[73] Other people are anxious about the increasing and uncontrolled number of embryos that might be produced and implanted into women's wombs.[74]

In fact, the debate of creating embryos for research is partly related to the

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[66] Beyleveld Deryck and Brownsword Roger, *Human dignity in Bioethics and Biolaw* (Oxford: Oxford University Press 2001) 110-121.
[67] *ibid*.
[68] Kant Immanuel, *Groundwork of the Metaphysic of Morals* (New York, Hackett Publishing Company 1981) 78
[69] Charles I Lugosi, 'Conforming to the Rule of Law: When Person and Human Being Finally Mean the Same Thing in Fourteenth Amendment Jurisprudence' (2007) 22 Issues in Law & Medicine 287-289.
[70] Cole Turner Ronald, 'Cloning humans from the perspective of the Christian churches' (1999) 5 Science Engineering Ethics 33-46 (pointing out that human embryo research through the fourteenth day of development is in a concern for social justice); see also Walters Leroy, 'HESC research: an intercultural perspective' (2004) 14 Kennedy Institute of Ethics Journal 3-38 (asserting that the living human embryo is from the moment of the union of the gametes-a human subject with a well defined identity, which from that points begins its own coordinated, continuous and gradual development, such that at no later stage can it be considered as a simple mass of cells).
[71] Matthew Rimmer, *Intellectual Property and Biotechnology* (Edward Elgar Pbulishing, Cheltenham 2008) 248-280.
[72] Annas George, 'the politics of human embryo research-avoiding ethical gridlock' (1996) 334 New England Journal of Medicine 1329.
[73] Knowles P Lori, 'the use of human embryos in stem cell research', (2009) 6 stem cell network 151-161
[74] Mcleod carolyn and Baylis Francoise, 'Feminists on the inalienability of human embryos' (2006) 21 Hypatia 1-14

source of the embryo. Most research currently uses the stem cell lines or spare embryos left by the IVF procedures. Inevitably, these two methods also raised moral questions. Some people were concerned that the popularity of stem cell therapy could possibly destroy the sanctity of the embryo.[75] Even some philosophers think it is, in substance, a passive killing, which is worse than active murder.[76]

As a result of the above ethical objection, scientists have made efforts to find alternative ways. One alternative is using the human adult cell and the CNR technology. The researchers at Newcastle University have already discovered a way to transform adult skin cells into artificial human sperm. [77] Furthermore, some people suggest letting the embryo split, then part of it could preserve the genetic code and the other part could be used for research.[78] Another possible solution is 'genetically modified the oocytes derived from embryonic stem cell in some way guaranteeing that they would never have the potential to develop into a viable human being'.[79]However, none of these methods is perfect, and each of them has its own deficiencies.

2.3.3 Moral Issues in Embryo Donation

The moral standard affecting the donation of embryos is easily ignored when the research is deemed to be significant. In the notorious Hwang Woo case, he lied about the source of ES cell and forced his former junior staff members to donate ova. This behaviour seriously violated the ethical conduct of egg donation.

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[75] Campbell A V, ethical issues in therapeutic cloning,round table ethical aspects of human stem cells research and uses, Brussels,2000 <http://Europa.Europe.int/comm./European_group_ethics/doc/dp15rev.pdf> accessed 20 October 2011.

[76] Rickard Maurice, *key ethical issues in embryonic stem cell research* (National government publication, 2003) 31.

[77] Fiona Macrae, 'ethical storm flares as British scientists create artificial sperm from human stem cells' *The Mailonline* (london, 8 July2009) <http://www.dailymail.co.uk/health/article-1198132/Ethical-storm-flares-british-scientists-create-artificial-sperm-human-stem-cell> accessed 28 October 2012.

[78] Knoepffler Nikolaus, 'stem cell research: an ethical evaluation of policy options' (2004) 14 Kennedy institute ethics 55-74

One controversy in donation procedure centres on informed consent. According to the consent rule, gamete donors must be completely informed, including being informed of the purpose of research, the risks and benefits of participation, the right of withdraw, in formation about what will happen to the donated embryos and collected stem cells, information on how the privacy is protected and so on.[80] Then, the researchers should obtain the donor's agreement before they continue their work. Moreover, if the donation is conducted in clinics, the consent forms should contain two copies, 'one is for the gamete collection or donation for purposes of IVF treatment, and the other for donation of embryos to HESC research'.[81]The current report shows that many ova are acquired without the women's consent.[82] In the United States, one in four embryonic stem cell lines were generated from illegally obtained ova.

The other controversy is whether it is reasonable to compensate the donor.[83] In the field of biomedical research, some common arguments are against the idea of providing payment. One viewpoint is that compensation 'undermines the voluntariness of the donation decision and can be coercive'.[84] But some people believe that like other types of transaction, if the donators give informed consent for the donation, it is voluntary and he/she has the right to get compensation.[85] Another opinion is that compensation is equal to treating the human as a commodity that destroy the sanctity of human dignity.[86] Moreover, some people opposed the compensation because it increases the

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[79] Kristina hug, 'Sources of human embryos for stem cell research: ethical problems and their possible soltuons' (2005) 41 Medicina Kaunas 12-43.
[80] ISSCR sample for embryo donation, <http://www.isscr.org/Guideline/cfembryos.doc> accessed 28 October 2012.
[81] Nelson Erin, Ubaka Ogbogu and Timothy Caulfield, 'An investigation of embryo donation, informed consent, and research oversight in Canadian HESC research' (2007) 29 health policy 997-1002.
[82] Han Aera, 'the ethical and regulatory problems in the stem cell scandal' (2007) 4 Journal of International Business and Law 45-68.
[83] Sheryl de Lacey, 'Embryo research: is disclosing commercial intent enough?' (2006) 21 Human Reproduction 1662-1667.
[84] Korobkin R, 'buying and selling human tissues for stem cell research' (2006) 49 Arizona Law Review 45-67.
[85] *ibid*.
[86] Harrison H Charlotte, 'Neither moore nor the market: alternative models for compensating contributors of human tissue' (2002) 28 American Journal of Law & Medicine 77-105

cost of the research. Related to it is the argument that compensation hampers medical research.[87]

However, in practice, many researchers tend to ethically provide compensation to the donors. As has been pointed put by Professor Bonnie Steinbock, 'any time that we asked people to do things that impose significant burdens and some degree of risk, fairness may require that they be adequately compensated'.[88] The Guideline by International Society for Stem Cell Research (ISSCR) states that 'in locals reimbursement for research participation is allowed'.[89]

2.4 The Moral Status of Human Embryo

The moral status of the human embryo has been extensively discussed. The distinct views of the moral value of human embryo seem to be irreconcilable, and either scientific progress or political victory will bring resolution.[90]

2.4.1 Human Embryos are Individual Human Beings

The core issue of the view that human embryos are individual human beings is that any harvesting or commercial using of human embryos, like utilising human organs or foetus, is morally and legally forbidden.[91] Therefore, neither government funds nor private sponsors should be granted license to conduct HESC research.[92]

The Debate on Bailey's Argument: Because HESC are Similar to Somatic Cells, no Human Dignity Should be Granted to Human Embryos

To Bailey's point, 'the DNA content within a skin cell, a stem cell and a

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[87] Gitter M Donna, 'Ownership of human tissue: a proposal for federal recognition of human research participants property rights in their biological material' (2004) 61 Washington & lee law Review 257-345
[88] Steinbock Bonnie, 'payment for egg donation and surrogacy' (2004) 71 Mt Sinai Journal Medicine 255-256
[89] The International Society for Stem Cell Research Guideline.
[90] R. Stephen Crespi, 'the human embryo and patent law-a major challenge ahead?' (2006) 28 European Intellectual Property Review 569.
[91] Janet L Dolgin and lois l Shepherd, *Bioethics and the law* (2nd ed, Aspen Publishers 2009) 112.
[92] *ibid*.

fertilised egg are exactly the same'.[93] Moreover, all of these cells have the potential to develop into human beings.[94] Therefore, there should be no relevant moral difference between human embryo stem cells and somatic cells. Because it is absurd to provide moral protection to somatic cells, human embryos do not deserve to be equated to human beings.Some bioethics scholars are against this view, such as Robert P George and Patrick Lee. They believed that Bailey made a false analogy between somatic cells and human embryos because human embryos are already 'distinct, self-developing and complete human organisms', while somatic cells are not.[95]

Some scientists favoured Bailey's opinion through analysing what type of potentiality actually matters. During the full range of biological development of a human being, enucleated ovum or ovular cytoplasm[96] merely plays an environmental role. They infused different eggs with different cytoplasm. They found the changing cytoplasm had no significant influence on the identity of being, just like a human embryo being in a different woman's womb.[97] Thus, the potential of development of human beings from somatic cells is not intrinsically different from the potential derivation of human beings from HESC.[98]

Robert P George and Patrick Lee Argument: Even in Embryonic Stage, Human Embryos are Worthy of Morality Concern

However, some bioethicists such as Robert P George and Patrick Lee have provided evidence to show that human embryos are human beings and

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[93] Ronald Baliey, 'Are Stem Cells Babies? Only if every other human cell is, too' reason.com, July 11, 2001) <http://reason.com/archives/2001/07/11/are-stem-cells-babies> accessed 6 April, 2012.

[94] Through somatic cell nuclear transfer (SCNT), somatic cell could be developed to human being. First, an adult cell rather than a sperm or egg cell is distracted. Its DNA is retained and the other is discard whereas the nucleus of an egg cell is removed. Then the DNA of somatic cell is insert into the enucleated egg cell. By electrical stimulation, the reprogrammed cell could be possibly divided and developed into human being.

[95] *Supra* note 2。

[96] The cytoplasm is 'all of the contents outside of the nucleus and enclosed within the cell membrane of a cell. This includes the cytosol and in Euckaryotic cells, organelles such as mitochondria and nibosomes. Also located within the cytoplasm is the cytoskeleton, a network of fibers that helop the cell maintain its shape and give it support', <http://biology.about.com/od/biologydictionary/g/cytoplasm.htm> accessed 29 April, 2012.

[97] Agata Sagan and Peter Singer, 'the moral status of stem cells' (2007) 38 Metaphilosophy 264.

therefore deserve human dignity.[99] First, during various developmental stages, human embryos have the same genetic and epigenetic composition of human organisms[100]. Second, from the embryological dimension, human embryos are the 'whole although obviously immature, human being'.[101] In particular, Robert P George and Patrick Lee emphasised that human embryos are not similar to human tissues or human cells that are only part of the human body.[102] The human embryo is one stage of a mature human being.[103] With the continuity of embryonic development, human embryos deserve the same respect as human infants.[104] Third, when the DNA molecules are infused with ovular cytoplasm, Robert P George and Patrick Lee believed that 'it is obvious that the cytoplasm is more than just a suitable environment' and that the transformation is 'a coming to be of a new organism'.[105] Fourth, in terms of their fundamental natural characteristics, there is no significant difference between the human embryo and the human being.[106]Robert P George and Patrick Lee concluded that 'to destroy a human embryo is precisely to destroy a new, distinct and complete human organism, an embryonic human being'.[107]

The author stands on Robert P George and Patrick's side. One reason is that the author thinks Bailey's argument has a flaw. Although somatic cells and HES cells both have the ability to develop into a human being, these two cells still have other different features. Thus, these two cells should not share the

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98 *ibid.*

99 *Supra* note 2.

100 In biology, epigentics means 'the study of heritable changes in gene expression or cellular phenotype caused by mechanisms other than changes in the underlying DNA sequence, it refers to functionally relevant modifications to the genome that do not involve a change in the nucleotide sequence', <http://en.wikipedia.org/wiki/Epigenetics> accessed 5 April 2013.

101 *Supra* note 2.

102 *ibid.*

103 *ibid.*

104 *ibid.*

105 They thought the transformation was obviously to a new organism for two reasons. First, the stem cell was not 'a whole organism before this fusion; it functioned together with the other parts of a larger organism for the survival and flourishing of that organism, not of itself'; Second, 'something that qualifies as merely environmental does not enter into an organism and modify its internal parts resulting in an entity with a new developmental trajectory'. In this case, however, 'the ovular cytoplasm does just that in regard to the nucleus placed within it'. Supra note 2

106 *ibid.*

107 *ibid.*

same moral standards. It is fallacious to make an analogy between HES cells and somatic cells. HES cells and human embryos, the author thinks, seem to be similar with regard to this moral dilemma. The other reason is that, according to the theory of evolution[108] and biological classification[109], human embryos and human beings are categorised as the same species. Hence, human embryos to some extent are human beings.

Catholic View: Life Begins from Fertilisation, therefore Human Embryos are Human Being

The notion that human embryos are human beings is deeply rooted in Catholic ethics. The Catholic Church believes that human dignity begins at the moment of fertilisation. In support of this argument, they looked to biological evidence. When the sperm and egg fuse at fertilisation, a one-cell zygote is formed.[110] The potential of future embryos, foetus or young adults are all inside the zygote. Some human embryologists insist the zygote is the beginning of life.[111] Kischer, a specialist in human embryology, noted in his book that 'after that initial contact of sperm and egg, there is no subsequent moment or stage which is held in arbitration or abeyance by the mother, or the embryo or foetus. Nor is a second contribution'.[112]

Another contribution to this argument is some historical evidence of progress made towards the concept of human life. From Thomas Aquinas

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[108] The theory of Evolution was first formulated by Charles Darwin as the base of biology. Evolution is 'any change across successive generations in the heritable characteristics of biological populations. Evolutionary processes give rise to diversity at every level of biological organisation, including species, individual organisms and molecules such as DNA and protein. <http://en.wikipedia.org/wiki/Evolution> accessed 29 April 2012.

[109] Biological classification, also called scientific classification in biology, means 'a method to group and categorize organisms into groups such as genus or species', <http://en.wikipedia.org/wiki/Biological_classification> accessed 29 April 2012.

[110] A zygote means 'the initial cell formed when two gamete cells are joined by means of sexual reproduction. In multicellular organisms, it is the earliest developmental stage of the embryo. In single-celled organisms, the zygote divides to produce offspring, usually through meiosis',<http://en.wikipedia.org/wiki/Zygote> accessed 1 May 2012.

[111] For example, Sadler T.W. said 'the development of a human being begins with fertilisation'; Moore, Keith L said 'this fertilised ovum, known as a zygote, is a large diploid cell that is the beginning, or primordium, of a human being'; Carlson, Bruce M said 'human pregnancy begins with the fusion of an egg and a sperm', see C. Ward Kischer, 'the beginning of life and the establishment of the continuum' (1996) Linacre quarterly 76.

[112] *ibid*.

differentiating the human being as the intellective soul to the entire human substance[113] to Locke defining personhood as 'sensible or conscious of pleasure and pain, capable of happiness or misery, and so is concerned for itself, as far as that consciousness extends'[114], the modern concept of the human being is a connotation and denotation of modern culture.[115] A similar situation could be found in the change in moral status of foetuses. In the mid-1970s, when the pro-life movement began in the US, the foetus was treated like the appendix of woman's body.[116] With the social culture change, it is a general consensus that infant has its own life and is worth the respect of a human being.[117] Thus, the consensus that human embryos are human beings could be reached in the near future.

In the author's opinion, the Catholic argument is too subjective and lacks scientific evidence. It seems that much of the evidence from biologists and embryologists were referred to in support of this argument. However, all of this evidence is simply subjective judgments instead of experiment clues or scientific data. In addition, the moral change regarding foetuses cannot be generalised to human embryos despite them being similar to some extent.

2.4.2 Human Embryos are Human Beings, But They are Not Human Persons.

"Personhood" Theory: Human Embryos are Human Beings Instead of Human Persons, Therefore Human Embryos Have no Human Dignity

In the historical tradition, human persons and human beings are initially established as the same entity from the moment of conception.[118] The

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113 Thomas Aquinas, *Summa Theological* (Echo Library, 2007) 100-572.
114 John Locker, *an essay concerning human understanding* (1st ed, Oxford University Press 1975) 60-78.
115 Kevin D.O'Rourke, 'is the human embryo a person?' 3 (2006) Newsletter of the Neiswanger institute for bioethics and public policy <http://www.domcentral.org/study/kor/Embryo%20as%20Person.pdf> accessed 3 May 2012,
116 Keith Cassidy, 'The historical roots of the pro-life movement: assessing the pro-choice account' (1995) 5 Life and learning 350.
117 *Supra* note 26.
118 Charles L.Lugosi, 'conforming to the rule of law: when person and human being finally mean the same thing in fourteenth amendment Jurisprudence' (2006) 22 issues in law & medicine 119.

protection of the Doctrine (The Congregation of the Doctrine of the Faith)[119] clearly holds that 'the dignity of a person must be recognised in every human being from conception to natural death'.[120] Then, in its special doctrinal instruction towards HESC moral controversies, Dignitas personae, delivered a stronger phrase indicating that 'the human embryo has, therefore, from the very beginning, the dignity proper to a person'.[121] However, in questioning the concept of the human being and the human person, some differences were found by various philosophers. For instance, Thomas Aquinas believed that despite human person being a specific name for human being, human person maintains the body and soul, while human being stresses matter and form.[122] Another philosopher, Jacques Maritain, also explained that the main distinguishing feature of the human person and the individual is between the personality and the individual. The personality is spiritual, while the individual is material.[123]

Why make a distinction between human persons and human beings? Some people argue that human persons are entitled to receive human dignity. Because human embryos are merely human beings instead of human persons, they should not be granted moral respect.[124] This is also called the "personhood" theory.[125] This theory provided the legitimate basis for

[119] The Congregation for the Doctrine of the Faith consist of 'Catholic Church's document dealing with doctrinal and theological issues related to church teaching. It also contains information on political trials that were carried out when the papacy had temporal power over the papal states', <http://en.wikipedia.org/wiki/Archive_of_the_Congregation_for_the_Doctrine_of_the_Faith> accessed May 6th, 2012.

[120] *ibid*.

[121] See the Article 5 of Dignitas Personae. Dignitas Personae is 'the title of a 2008 instruction by the Congregation for the Doctrine of the Faith giving doctrinal directives on certain embryonic ethical controversies that had emerged since 1987, after Donum Viate was released', <http://en.wikipedia.org/wiki/Dignitas_Personae> accessed May 9 2012.

[122] *Supra* note 28.

[123] Jacques Maritain, *The person and the Common good* (Indiana USA, University of Notre Dame Press 1966) 31

[124] For example, some British and US bioethics scholars, such as Michael Tooley and H. Tristram Engelhardt, see also Kevin D.O'Rourke, 'The embryo as person' (2005) life and learning 281-296.

[125] This theory has several artificial boundaries between human being and human person, including the following: (1) moment of conception (assignment of genetic identity), (2) beginning of the primitive streak (after which time twinning is no longer possible), (3) implantation of the embryo in the womb, (4) formation of the nervous system and sentience (the ability to feel pain), (5) formation of the cerebral cortex of the brain (the ability to reason is a concern, as well as the logic of paralleling brain life with brain death), (6) quickening (when the mother can feel the baby move), (7) when the foetus looks like what people expect a human being to look like (morphological similarity), (8) foetal viability (when a

allowing research on embryos up to 14 days.[126] Because spiritual things such as consciousness and feeling develop after 14 days, human embryos before 14 days cannot be treated as human persons.[127]

Whether Absolute Protection from the Moment of Fertilisation at the International Level Goes Too Far?

Although there is no definite answer from the scientific perspective about when human life begins[128], many scientists believe that the actual moment life begins is the formation of the primitive streak 14 days after fertilisation.[129] In this stage, the fertilised egg is to some extent related to the formation of the cortex, in other words, the formation of feeling and thinking.[130] The 14 days boundary has been widely accepted. Both the Human Embryo Research Panel in the US and the Human Fertilisation and Embryology Authority in the UK recommended that only embryos after 14 days be used in HESC research. However, from the Catholic view, this "personhood" theory was a threat to the *Universal Declaration of Human Rights*, whose intention is for 'the sake of freedom, justice and peace in the world'.[131]The *Universal Declaration of Human Rights* asserts that men and women only promote the creation of human beings originating from the philosophy of the spiritual soul created by the

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pre-mature baby can survive outside the womb with medical assistance and the help of others, (9) Birth (the moment of fully emerging from the mother's body-as distinguished from partial birth), (10) acquisition of self-consciousness, (11) acquisition of ability to reason, (12) demonstration of intelligence (a minimum I.Q.), (13) self-determination (assertion of will), (14) socialization (the formation of conscious relationships to other peo-ple); see Charles L. Lugosi, 'conforming to the rule of law: when person and human being finally mean the same thing in fourteenth amendment Jurisprudence' (2006) 22 issues in law & medicine 119; also see Etsuko Akiba, 'the dignity of the human embryo from the moment of fertilisation' (2006) personality bioethics 81-109.

126 In the UK, research could be licensed on embryos up to 14 days.

127 The consciousness comes from the neuron that is developed in the stage of primitive streak, which occurs after 14 days.

128 There are two main views: one is the formation of primitive streak, which happens 14 days after fertilisation;, and the other is that the chromosomes of the mother and father merge, which happens at the two-cell stage 30 hours after fertilisation.

129 Such as O'Rahily, Karen Dawson and Moore. See Dianne N Irving, 'When do human beings begin? Scientific myths and scientific facts' (1999) 19 International Journal of Sociology and Social Policy 22.

130 *ibid*.

131 The *Universal Declaration of Human rights* believed human dignity is the foundation of international law. It states that 'the inalienable right to life of every human individual from the first moment of conception is a constitutive element of civil society and its legislation. When the State does not place its power at the service of the rights of all and in particular of the more vulnerable, including unborn children, the very foundations of a State based on law are undermined'; also see *supra* note 170.

God.[132] Therefore, the dignity of human beings depends on the moment of fertilisation instead of other physical characteristics such as DNA. The research exploration of human embryos that accord with the "personhood" theory is opposed from the Catholic position. Some historic evidence also shows that providing absolute protection for the human embryo from the moment of fertilisation is a tradition in Western Christianity.[133]

The author believes that, despite of the strong support from the religious perspective, absolute protection of human embryos from the moment of fertilisation at the international level might go too far. One reason is that scientific evidence already demonstrated the formation of consciousness begins from the impossibility of twinning, which can only take place 14 days after fertilisation.[134] The moment of fertilisation is not the same as the moment of conception. Another reason is from evidence showed in the European case *Vo v France*.[135] The key legal question in this case is whether unborn foetuses deserve the human rights under Article 2 of the European Convention of Human Rights.[136] When answering this question, the Grand

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[132] The catholic use "procreate" to describe the creation of human beings because "procreate" means promote the creation of God. After human being possess the spiritual soul, the dignity of procreation begins, see *supra* note 170.

[133] St Gregory of Nyssa said 'for just as it would not be possible to style the unformed embryo a human being, but only a potential one-assuming that it is completed so as to come forth to human birth, while so long as it is in this unformed state it is something other than a human being-so our reason cannot recognise as a Christian one who has failed to receive, with regard to the entire mystery, the genuine form of our religion', St Gregory of Nyssa, *Adversus Macedonianos* (Walce H, Schaff P ed, Oxford and New York 1893) 320; Also St Augustine of Hippo said 'if what is brought forth is unformed but at this stage some sort of living, shapeless thing, then the law of homicide would not apply, for it could not be said that there was a living soul in that body, for it lacks all sense, if it be such as is not yet formed and therefore not yet endowed with its senses', <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/705.htm> accessed 12 September 2013.

[134] Karen Dawson found in embryo experimentation 'Conjoined twins arise from the twinning process occurring after the primitive streak has begun to form, that is, beyond 14 days after fertilisation', see Dianne Irving, 'when do human being begin? Scientific myths and scientific facts' (1999) 19 International Journal of Sociology and Social Policy 22-36.

[135] Case *Vo v France* (2005) EHRR 12.

[136] The Article 2 of the European Human rights Convention states that '1.Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law; 2.Deprivation of life shall not be regarded as inflicted in contravention of the Article when it results from the use of force which is no more than absolutely necessary: (a) in defence of any person from unlawful violence; (b) in order to effect a lawful arrest or to prevent the escape of a person lawfully detained (c) in action lawfully taken for the purpose of quelling a riot or insurrection'. Karen Dawson, 'Segmentation and moral status', in Peter Singer ed., *Embryo experimentation* (Cambridge university Press, 1990) 133.

Chamber of the European Court of Human Rights found the intention behind Article 2 is 'a clear desire to strike a balance' in this legal, moral and religious controversy.[137] They also noted that most member states do not have an absolute definition of the status of human embryos even under the circumstances where a consensus on the protection of human embryos is required.[138] Lacking a unified moral and legal status of the human embryos, the answer to the question of whether unborn foetuses share human dignity seems to be inadvisable.[139] Furthermore, absolute protection of human embryos at the international level might impede scientific progress and stop people from curing some deadly diseases. If absolute protection of human embryos at the international level is provided, people will lose one of the most promising treatments that have already showed unbelievable potential. Thus, in my understanding, the adequate protections of human embryos are much better than the absolute measures.

2.4.3 Human Embryos are Not Human Beings

The main point of the argument that human embryos are not human beings is that fertilisation should not be treated as the decisive moment moral rights could be granted. Thus, many philosophers, especially utilitarians, believe that human embryos cannot meet the standard of human beings.[140]

"Human Organisms View" vs "Interest View"

One argument proposed by Warren is that human embryos are only human organisms lacking person characteristics.[141] No human organism has moral status. The human embryo is no exception, even if they have potential to develop into human beings.[142] Obviously, human embryos do not have the

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137 Case Vo v France (2005) EHRR 12 at Para. 82.
138 The Protection of the human embryo in Vitro, reports by steering committee on bioethics, 2003 <http://www.coe.int/t/dg3/healthbioethic/activities/04_human_embryo_and_foetus_en/CDBI-CO-GT3(2003)13E.pdf> accessed 21 July 2013.
139 Aurora Plomer, 'A foetal right to life? The case of *Vo v France*' (2005) 5 Human rights law review 311.
140 *Supra* note 48.
141 Warren M A, *Moral status: Obligations to persons and other living things*, (New York, Oxford University Press 1997) 43-45.
142 *ibid*.

same DNA as human beings, and having the potential to become human beings does not necessarily entitle them the same respect as human beings.[143] Moreover, some psychological abilities such as communication using language are related to the moral status. Because human embryos fail to meet this requirement, they might be not deserved human dignity.[144]

Another argument is called the "interest" view, distinguished by Joel Feinberg.[145] From a sentience-based theory, it can also be demonstrated that human embryos are not human beings.[146] First, the interest view requires the right holders to manage their own rights. In terms of human embryos, they must have the ability to protect their own interests and take their interests seriously.[147] Then, by connecting interest to sentience, Feinberg concluded that non-sentient or non-conscious beings have no interest. Because many stages of human embryos, such as fertilisation and blastocyst period before development of a nervous system, human embryos have no experience of sentience.

Both these two arguments seem to be reasonable; however, they have some flaws. As Bonnie Steinbock stated in her book, if the ability to use language is relevant to moral status, the Warren's argument seems to exclude many examples that generally should be within the moral community.[148] As to the "interest view", Feinberg appears to confuse two senses of interest: one is to "take an interest in something", the other refers to "things that are in someone's interest".[149] Furthermore, as Marquis noted in his article, the "interest view" cannot explain the situation of killing a temporary comatose

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143 *ibid.*
144 *ibid.*
145 Feinberg J, *Philosophy and Environmental Crisis*, (Athens, University of Georgial Press 1974) 43-66.
146 *ibid.*
147 *ibid.*
148 For example 'elderly people with advanced dementia, individuals with severe developmental disabilities and even more normal newborns', see Bonnie Steinbock, *The Oxford handbook of bioethics*, (Oxford, Oxford university press 2007) 427.
149 *ibid.*.

human being.[150]

Thomas Douglas and Julian Savulescu Argument: Human Embryos Lack Consciousness, Self-consciousness, Sensitivity to Pleasure and Pain, and Rationality, Therefore They are not Human Beings

The view that human embryos are human beings has two instinctive implausible implications in terms of Thomas Douglas and Julian Savulescu.[151] First, through a hypothesis that helps to test human's moral intuitions, they developed so-called "embryo-rescue" cases: when the embryos and people are in danger of a fire at the same time, which one has top priority for rescue.[152] General fire fighters intuitively will save people. Hence, human embryos should be sacrificed in order to save many patients who can only rely on stem cell treatment.[153] Second, through an empirical study on spontaneous abortion, Douglas and Savulescu developed a rationale that could testify to human embryos being falsely treated as human beings. Initially, they found people's intuition ignored the importance of spontaneous abortion, even it result in average 220 million natural embryo deaths every year.[154] If human embryos are human beings, then more than 220 million are dead each year in the world, which is almost seven times the number of people dying from cancer.[155] However, in fact, spontaneous abortion received far less focuses than diseases like cancer. Obviously, the inferior status of spontaneous abortion is contrary to the danger it presents.[156] Therefore, the premise that human embryos are human beings is untruthful.[157]

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150 Marquis D, 'why abortion is immoral' (1989) 76 Journal of philosophy 183.

151 *Supra* note 3.

152 Thomas Douglas and Julian Savulescu imaged the "embryo-rescue" cases that 'suppose that thousands of embryos have been created as the by-products of assisted reproduction. These are no longer wanted; however, they have been frozen and stored in a large warehouse, perhaps because the government prohibits their destruction. Someone notices that a fire has started in the warehouse, which might destroy the embryos but which is also threatening the life of a single employee of the warehouse. As a fire fighter, you are faced with a choice: either you can save the thousands of unwanted embryos or you can save the life of the warehouse worker', supra note 3.

153 *ibid.*

154 Ord T, 'the scourge: moral implications of natural embryo loss' (2008) 8 American Journal bioethics 12.

155 *Supra* note 3.

156 *ibid.*

157 *ibid.*

This argument, in the understanding of the author, might have a major mistake—a flawed dualistic anthropology. The reasoning is questionable in that Thomas Douglas and Julian Savulescu seem to compare two different issues. In addition, because there is no guarantee about HESC research, the sacrifice of human embryos will not necessarily save people's life. The author also agrees with Thomas Baldwin's opinion, 'if current embryo research by using this argument, they would have to endorse the implication that there is nothing morally objectionable about a child survival lottery'.[158]

2.5 What is the Moral Source of Human Embryos: Use the Discard Human Embryos or Create Human Embryos for Research?

There are three major sources of HESC research: using already derived embryonic stem cell lines, using discarded human embryos and creating human embryos for research. There was a consensus that using already derived embryonic cell lines was an acceptable source of HESC research.[159] Compared with the first source, using discarded human embryos and creating human embryos for research received greater moral concern.

2.5.1 Use the Spare Human Embryos from IVF

It is interesting to note that embryos outside the body and embryos inside the body might have different moral status.[160] Because the spare embryos from IVF are simply left alone and discarded, they might be eligible for HESC research.[161]

Does the "Discard-Created Distinction" (DCD) Theory not Respect of Human Life?

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158 Child survival lottery means 'children who are not wanted by their parents are selected at random for medical research projects comparable to current embryo research', see Thomas Baldwin, 'Morality and human embryo research' (2009) 10 EMBO reports 299.

159 In the US, UK, German, Japan and so on, exist stem cell line is regulated as a permissible source of HESC research. The relevant regulations will examine in the following chapters.

160 Alta B Charo, 'ethical and policy considerations in embryonic stem cell research' in J Odorico, S Zhang and R Pedersen (eds), *HESC* (Bios Scientific publishers 2005) 391.

161 IVF is in vitro fertilisation that can help the couples to get the baby. In order to increase the chance of successful embryo, the clinic usually produce more embryos than it needs. Some inferior embryos or unsuccessful embryos are unwanted and destroyed.

Supporters of using spare embryos in HESC research developed the "discard-created distinction" (DCD) theory to indicate that a moral distinction exists between spare embryos and embryos created for HESC research. The spare embryos are morally acceptable, while created embryos are not.[162] This argument is based on some fundamental principles: "the principles of beneficence and nonmaleficence"[163], "the principle of proportionality"[164], "the principle of subsidiarity" [165] and "the principle of avoidance of waste".[166]However, facilitating HESC research within a moral landscape in practice is complex process. In an empirically conducted analysis, Mette N Svendsen and Lene Koch provided evidence that the moral landscape of using spare embryos from IVF has changed with 'organizational relations, research protocols, techno-scientific objects, clinical classifications and notions of professional responsibility'.[167]

However, some opponents claimed that using spare human embryos decreases respect for human life.[168] Human embryos still deserve to be treated morally even if they are an extra part of a family plan.[169] One reason is that there is a danger in using human embryos in routine treatment, in which we inevitably would tolerate the devaluation of human embryos.[170] This is also called "the slippery slope argument".[171] Another reason is related to the "proportionality" principle, providing that some research involved

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[162] Katrien Devolder, 'creating and sacrificing embryos for stem cells' (2005) 31 Journal Medicine Ethics 366-370.

[163] The principles of beneficence and non-maleficence mean that 'it is right to benefit people if we can and wrong to harm them', see Katrien Devolder, 'HESC research: why the discarded-created-distinction cannot be based on the potentiality argument' (2005) 19 Bioethics 172.

[164] The principle of proportionality means 'human embryos can only be used for research if this serves an important purpose, such as a major health interest'. See *Ibid.*

[165] The principle of subsidiarity means 'the derivation of ESCs from spare embryos is only ethically justified if there is no suitable and less controversial alternative means of achieving the purpose of the research'. See *Ibid*.

[166] The principle of the avoidance of waste means 'if these frozen spare embryos are going to be destroyed anyway, shouldn't they be used for a greater good, for research that has the potential to save and improve other lives?' See *Ibid*.

[167] Mette N Svendsen and Lene Koch, 'unpacking the spare embryo' facilitating stem cell research in a moral landscape' (2008) 38 Social Studies of Science 93.

[168] Kant Immanuel, *Groundwork of the Metaphysic of Morals* (New York, Hackett publishing company 1981) 24-89.

[169] *Supra* note 2.

[170] *ibid*.

[171] *ibid*.

with human embryos might not serve an important goal.[172] The last reason is relevant to the "subsidiary" principle, arguing that because some alternatives could play the same role as HESC, there is no reason to destroy human embryos in research.[173]

In the opinion of the author, using spare human embryos does not devalue their dignity and the DCD theory does not reduce respect of human life. First, considering that spare human embryos left from IVF are destroyed anyway, itis the author's belief that utilising spare human embryos in HESC research is better than wasting them. If it is morally prohibited to use the spare embryos, IVF technology should be morally forbidden too. However, in most countries, IVF is accepted as a treatment to help couples conceive children.[174] Because spare human embryos are inevitably produced for therapeutic use, why not use them to treat more incurable disease? Second, although alternatives to adult stem cells could replace HESC in some research, HESC cannot be substituted in some special areas of research.[175] In addition, the alternatives all have their limits compared to HESC.[176] Third, according to a national survey in the US, when facing decisions on embryo disposition, infertility patients in IVF prefer that their unwanted embryos be used in research.[177]

Whether It is Morally Permissible to Compensate for Donation?

In most types of research, compensation for donors is allowed with no moral objections.[178] However, in terms of payment for human embryos, two common moral concerns are raised to prohibit it.

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172 *ibid*.

173 Xeno transplantation, human embryonic germ cells and adult stem cells are three alternatives of HESC in research. See *Ibid.*

174 See <http://en.wikipedia.org/wiki/In_vitro_fertilisation> accessed October 14 2013.

175 For examples of adult neural stem cells, see Galli R, Borello U, Gritti A, Minasi M G, Bjornson C, Coletta M, Mora M, De Angelis, M. G., Fiocco R and Cossu G, 'skeletal myogenic potential of human and mouse neural stem cells' (2000) 3 Nature Neurosci 986.

176 Guido de Wert and Christine Mummery, 'HESCs: research, ethics and policy' (2003) 18 Human Reproductive 672.

177Anne Drapkin Lyerly and Ruth R Faden, 'willingness to donate frozen embryos for stem cell research' (2007) 317 Science 46.

178 Dickert Neal and Christine Grady, 'what's the price of a research subject? Approaches to payment for research participation' (1999) 341 The New England Journal of Medicine 198.

One objection is that payment for human embryos means treating them as a form of property. This argument is based on the view that human embryos are human beings.[179] Then, any type of buying or selling of human embryos is offensive. As noted by the US National Research Council and Institute of Medicine's Guideline for HESC research, 'the treatment of the developing human embryos as an entity deserving of respect may be undermined by the introduction of a commercial motive into the solicitation or donation of foetal or embryonic tissue for research purpose'.[180]

Another objection is that payment for human embryo will lead to the overexploitation of them. If researchers in clinics and laboratories could obtain eggs or human embryos simply through providing compensation, biotechnology companies and pharmaceutical companies would take advantage of this and overexploit the donation market to gain financially from HESC research. Furthermore, patients are potentially induced by financial payments to donate their eggs or embryos.[181] The Ethics Committee of the American Society for Reproductive Medicine indicated the relation between the payment and the risk: 'as payments to women providing oocytes increase in amount, the ethical concerns increase as well. The higher the payment, the greater the possibility that women will discount risks'.[182] From upstream to downstream, the human embryo market might boom in a short term.

From my understanding, these two objections are not justified. As the preceding sections discussed, whether human embryos are human beings remains a controversy. Therefore, the basis of the first objection is not solid.

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[179] Radhika Rao, 'coercion, commercialization, and commodification: the ethics of compensation for egg donors in stem cell research' (2006) 21 Berkeley Technology law Journal 1055.

[180] See National Research Council & Institute of Medicine, Guideline for HESC research (2010) <http://www.nationalacademies.org/morenews/20100526.html> accessed 5 June, 2012.

[181] Angela Ballantyne and Sheryl de lacey, 'wanted egg donors for research: a research ethics approach to donor recruitment and compensation' (2008) 1 International Journal of Feminist Approaches to Bioethics 145.

[182] See the Ethics Committee of the American Society for Reproductive Medicine, Financial composition of oocyte donors (2007) <http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Ethics_Committee_

With the second objection, the author believes appropriate payment for the risk and discomfort brought to the donors is to some extent beneficial in avoiding the formation of the human embryo market.

2.5.2 Create Human Embryos for Research

Compared to using spare human embryos from IVF, human embryos created especially for research are destined for destruction in the course of conducting research. Inevitably, this has received more moral objections than using spare embryos.

The Creation of Human Embryos for Research Means the Instrumentalisation of Human Life

The main objection of creating human embryos solely for research is the fear that human life would be instrumentalised. The fundamental principle of this argument is that human embryos should respect as persons. Creating "persons" for research is morally wrong. Unsurprisingly, the US National Bioethics Advisory Committee warned in its report that 'the act of creating an embryo for reproduction is respectful in a way that is commensurate with the moral status of embryos, while the act of creating an embryo for research is not'.[183] A similar view was delivered by the European Commission: 'the creation of embryos for the sole purpose of research raises serious concerns because it represents a further step in the instrumentalisation of human life'.[184] The 12 members of EGE unanimously believed that allowing creation human embryos for research would be unethical.[185]

Although many countries prohibit the creation of human embryos for research, it is still allowed in some countries. For example, in the UK, according to the data from HFEA, 118 embryos were created solely for

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Reports_and_Statements/financial_incentives.pdf> accessed 6 June, 2012.

[183] Ethical issues in human stem cell research, the report of US National Bioethics Advisory Commission, 1999, <http://stemcells.nih.gov/info/pages/ethics.aspx> accessed 20 July 2014.

[184] David Dickson, 'European panel rejects creations of human embryos for research' (2000) 408 Nature 277.

[185] *ibid.*

research between 1991 and 2000.[186] Supporters claim that the created embryos will never end up being implanted in a human ovum.[187] They criticised the DCD theory defenders' lack of full consideration of the moral value of human embryos.[188] They affirmed that spare embryos and created embryos for research share the same moral value.[189]

The author favours the point made by the EGE. The creation of human embryos for research to some extent addresses the instrumentalisation of human life. In practice, surplus embryos from IVF already meet the demand for research use. Why do we not recycle those discarded embryos instead of producing more embryos to end up destroying? The author doe s think it is another killing.

The Creation of Human Embryos for Research is not Morally Commensurate With the Potential Status of the Embryos

Another strong objection to creating human embryos for research is on the basis that human embryos have the potential to be human persons. Although human embryos are not certain to be human persons, its potentiality already deserves full moral respect.[190] Heather Johnson Kukla, in his article, argued that:

> [C]reating embryos for research purpose does not show appropriate respect for embryos as a symbol of human life because it indicates that the procreative process and intention to create a child are not

[186] Developments in human genetics and embryology, the report of House of Commons Science and Technology Committee, 2002, <http://www.parliament.the-stationery-office.co.uk/pa/cm200102/cmselect/cmsctech/791/791.pdf> accessed 20 July 2013.

[187] Radhika Rao, 'coercion, commercialization, and commodification: the ethics of compensation for egg donors in stem cell research' (2006) 21 Berkeley Technology law Journal 1055.

[188] Katrien Devolder, 'HESC research: why the discarded-created-distinction cannot be based on the potentiality argument' (2005) 19 Bioethics 1467.

[189] *ibid.*

[190] Katrien Devolder, 'The ethics and regulation of HESC research: a critical analysis of the debate' (2005) University Gent, Doctor of Philosophy thesis.

important and that the value of the embryo is merely found in its status as a research subject, not its status as a symbol of human life.[191]

This potential argument appears to be reasonable for some people. Nevertheless, it does not provide an explanation for why the expression 'the embryo is a potential person' could serve as 'an argument to defend a certain moral position'.[192] The moral respect we normally give to human persons should not be taken for granted and given to the mere potential to be human persons.[193] Two factors contribute to the development of persons from human embryos: internal[194] and external[195]. In terms of the internal factor, there is no difference between embryos created for research and spare embryos from IVF. However, the external factor is that embryos created for research are different from spare embryos. At least, the intention of spare embryos is for them to become persons, while for created embryos, it is not.[196] From this aspect, created embryos could be viewed having no potential to be persons.

The author agrees with the opinion that moral differences exist between persons and the potential to be persons. Although human embryos could become persons, they are still two different things. Therefore, they should have different characteristics, including different moral values. The objection to creating human embryos for research is not morally commensurate with the potential status of the embryos. In my opinion, the instrumentalisation objection seems better.

2.6 Will Therapeutic Cloning Use Lead to Reproductive Cloning Use?

Because of the strong moral objections to implanting a cloned human embryo

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[191] Heather Johnson Kukla, 'Embryonic stem cell research: an ethical justification' (2002) 90 The Georgetown Law Journal 503.
[192] *ibid*.
[193] *ibid*.
[194] Internal factor means embryo itself, for example its genetic constitution, its developmental potential. See *ibid*.
[195] External factor is in the genesis of the embryo, for example the application of SCNT, implanted to the womb or discarded, see *Ibid*.

into human womb, ethicists make a distinction between therapeutic cloning use and reproductive cloning use.[197] The term "therapeutic cloning use" means 'the procedure of deriving an embryonic stem cell line from an embryo created by means of this technique, using nucleus from the patient's somatic cell'[198], while the term "reproductive cloning" is the 'use of cloning technology to produce one or more individuals genetically identical to another individual'.[199] It means the DNA sequence of the embryos is exactly the same as that in an already existing mature life form. Most moral arguments made against human cloning are focused on the moral and semantic legitimacy of this distinction.

2.6.1 Will Therapeutic Cloning Use Turn to Commercial Use?

In fact, an alliance between the moral view and the scientific view of therapeutic cloning has not been achieved.[200] In the area of medical treatment, scientists have already showed evidence of the huge potential of therapeutic cloning in curing diabetes[201], tissue engineering applications[202] and heterologous transplantation[203]. However, further moral consideration of therapeutic cloning might raise an argument concerning the exploitation of women.[204] Because a large number of eggs are required in therapeutic cloning, women are inevitably exposed to pressure to donate eggs. The notorious scandal of a Korean research team is an example.[205] The leader of

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196 *ibid*.

197 Cloning refers to making an exact copy. Cloning technology is already accomplished in some animals, for example, Dolly the sheep.

198 Therapeutic cloning is also called research cloning. *Supra* note 51

199 Is human reproductive cloning inevitable: future options for UN governance, the United Nations report, 2007 <http://unu.edu/publications/policy-briefs/is-human-reproductive-cloning-inevitable-future-options-for-un-governance.html> accessed 22 July 2014.

200 *ibid*.

201 Ben Yehudah A, Witchel S F, Hyun S H, Chaillet J R and Schatten G, 'Can diabetes be cured by therapeutic cloning?' (2004) 5 Pediatric Diabetes 79.

202 Hipp J and Atala A, 'Tissue engineering, stem cells, cloning and parthenogenesis: new paradigms for therapy' (2004) 1 Journal Experiment Clinic Assist Reproductive 3.

203 *Supra* note 89.

204 Peter A Whittaker, 'Therapeutic cloning: the ethical limits' (2005) 270 Toxicology and Applied Pharmacology 689.

205 Hwang H S, Ryu Y J, Park J H, Park E S, Lee E G, Koo J M, Chun H Y, Lee B C, Kang S K, Kim S J, Ahn C, Hwang J H, Park K Y, Cibelli J B and Moon S Y, 'evidence of a pluripotent HESC line derived

the team, Woo Suk Hwang, admitted that he forced junior researchers in his laboratory to donate eggs.[206] The reason for this is the contradiction between the massive demand for egg donation and the lack of willing egg donors due to the time consuming, uncomfortable and potentially risky procedure.[207]

There is a fear that the success of therapeutic cloning might turn human embryos into commercial goods, along with a danger of reducing respect for human dignity.[208] The issue of whether therapeutic cloning use is under the risk of commercial use has been widely debated in many countries' scientific and medical communities.[209] For example, in Sweden, the Swedish research Council found it urgent that the moral use of human embryos be protected by criminal law despite the strong international interest in HESC.[210] The Swedish government also required the commercialisation of embryos to be compatible with good research ethics.[211] Another fear related to the commercialisation of human embryos comes from the religious view on the moral status of the human embryo. As Kristina Hug indicated in her article, 'it does not require religious beliefs to recognise that we belong to a wider society that has embedded traditions about how we reproduce. Therefore, the way we treat the beginning of human life, particularly if we commercialise them, has wider implications'.[212]

In contrast to the speculation, the author personally think that therapeutic cloning use likely will not turn into commercial use. The author admits that the moral limits between therapeutic cloning use and commercial use might be overstepped without proper control, but it is unjustifiable to abandon

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from a cloned blastocyst' (2004) 303 Science 1669.

[206] Robert Steinbrook, 'egg donation and HESC research' (2006) 354 New England Journal Medicine 324.

[207] *ibid*.

[208] Kathinka Evers, 'European Perspectives on therapeutic cloning' (2002) 346 New England Journal Medicine 1579.

[209] See a discussion document of the bioethics work group of the church and society commission in a society, religion and technology project, <http://www.wcc-coe.org/wcc/what/jpc/biodocs.html> accessed 22 July 2014.

[210] Opinion on the preliminary draft revision of the laws on bioethics, No 67, 2001.

[211] *ibid*.

[212] *Supra* note 83.

therapeutic cloning merely because carries the risk of commercial use. In a risk-benefit analysis, 'any commercialisation of unborn humans must either be completely prohibited or be subject to strict international legislation ensuring the protection of human rights and the dignity of all humans, especially those in a weak social position'.[213] I believe, even if therapeuetic cloning becomes routine clinical practice, it is unrealistic for human embryos to become commercial products under strict regulations.

2.6.2 Will the Distinction Between Therapeutic Cloning Use and Reproductive Cloning Use be Impossible to Police?

The reproductive cloning of human embryos has been morally rejected in most places of the world.[214] The United Nations initially made efforts to create an international convention for prohibiting human reproductive cloning.[215] However, considering the irreconcilable differences towards research cloning, the United Nations adopted the declaration on the issue of prohibiting human reproductive cloning.[216] The Declaration required contracted states to

> [P]rohibit all forms of human cloning is as much as they are incompatible with human dignity and the protection of human life; adopt and implement without delay national legislation to bring into effect. Although there is no direct reference to research cloning the section can be construed as urging countries to ban all types of cloning.[217]

However, the Declaration, different from other international laws or international conventions, has no legal binding force to member states. The evidence shows that the Declaration emerged with customary law to

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213 *Supra* note 104.
214 *Supra* note 97.
215 *ibid.*
216 United Nations Declaration on Human Cloning (A/RES/59/280) 2005, <http://legal.un.org/cloning/index.html> accessed 22 July 2014.
217 Section D of the Declaration. See *Ibid.*

prohibit reproductive cloning.[218]

The problem is whether therapeutic cloning will inevitably extend to reproductive cloning. To answer this question, we first need to identify the connections between reproductive cloning and therapeutic cloning. The "leaked" embryos from therapeutic embryos increase the risk that reproductive cloning will occur.[219] Although human embryos might be produced for therapeutic cloning, the patient could change her mind during the cloning procedure. By the "reproductive liberty" argument, men and women should allow to use their frozen embryos created by IVF.[220] The desire to have a baby will motivate reproductive cloning. This is one reason that therapeutic cloning might lead to reproductive cloning.

Another reason is the argument from fertility experts and philosophers[221] that the medical value criterion is not strong enough to distinguish therapeutic cloning from reproductive cloning.[222]Logically, 'almost any product, procedure or technology can find a condition to demonstrate its therapeu

tic benefit'.[223] According to Grayling, childlessness is to some extent entitled to the label of a disease.[224] Practically, 'human cloning would be extremely wasteful of embryos and fetuses, that it would be an abuse of the women who supplied the eggs and miscarried the foetused'.[225] From

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[218] *ibid.*

[219] Alexander Morgan Capron, 'placing a moratorium on research cloning to ensure effective control over reproductive cloning' (2002) 53 Hasting law Journal 1057.

[220] *ibid.*

[221] Such as Antinori, Harris and Grayling, <http://www.hiddenancestors.com/Texas/marriage/Marriage_2003.txt> accessed 22 July 2013.

[222] Finn Bowring, 'therapeutic and reproductive cloning: a critique' (2004) 58 Social science & medicine 401.

[223] *ibid.*

[224] Grayling A C, 'we should not let baby eve tempt us away from progress' *the independent* (London, 29 December 2002) <http://www.independent.co.uk/voices/commentators/a-c-grayling-we-should-not-let-baby-eve-tempt-us-away-from-progress-137578.html> accessed 22 July 2013.

[225] According to a survey of the literature conducted by sloter in 2000, the portion of cloned animals reaching adulthood in manipulated eggs is nearly 0.3 per cent for cows and less than 1 per cent for sheep. See Solter D, 'mammalian cloning: advances and limitations' (2000) 1 Nature reviews genetics 199.

perspective of medical value, why do we choose such a painful and wasteful type of cloning if we have other alternatives?[226] Therefore, these arguments concluded that 'if scientists are allowed to create cloned embryos for therapeutic purposes, we can be sure that, in the long term, this will lead to a progressive improvement in the success rates for human cloning, and the perfecting of the techniques involved'.[227]

The author believes that regulatory agencies could solve this problem. If we can strictly curb the transplantation of gamete cells into women's wombs, the concern about reproductive cloning is unnecessary. What we urgently need is strict governance and perfect legislation in the area of therapeutic cloning and reproductive cloning.

2.7 Whether Adult Stem Cell Could be Fully Used as an Alternate to Embryonic Stem Cell?

Because embryonic stem cells face the moral problem, many scholars choose adult stem cells as an alternative to embryonic stem cell. One groundbreaking discovery was the successful transformation of adult cells into embryo-like stem cells by Japan and UK scientists.[228] The Nobel committee believed these discoveries 'have also provided new tools for scientist around the world and led to remarkable progress in many areas of medicine'.[229]This technique seems to revolutionise embryonic stem cell research because a sample of skin cells could be used to create stem cells. However, is adult stem cell research a realistic substitute for embryonic stem cell? The answers differ.

2.7.1 Adult Stem Cell Can be Fully Used As an Alternate to Embryonic Stem Cell

Many scholars are hopeful that adult stem cells could be fully substituted for

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[226] *ibid.*
[227] *Supra* note 120.
[228] James Gallagher, 'Gurdon and Yamanaka share Nobel prize for stem cell work' *The BBC* (London, 8 October 2012) <http://www.bbc.co.uk/news/health-19869673> accessed 28 October 2012.
[229] *ibid.*

embryonic stem cells in therapeutic use. First, as medical research shows, adult stem cells actually have more plasticity and are more effective than we originally thought.[230] Also some evidences indicates 'much excitement over the possibility that adult mammalian stem cells may be capable of differentiating across tissue lineage boundaries, and as such may represent novel, accessible, and very versatile effectors of therapeutic tissue regeneration'.[231]Second, adult stem cells compared to embryonic stem cells, have an advantage in identifying, isolating, growing and being transplanted back into the patient.[232] The recipient using adult stem cells would experience less immune rejection than if embryonic stem cells were used. Third, adult stem cell research goes far beyond embryonic stem cell research.[233] For decades, adult stem cells have been studied as a cure for heart disease and diabetes as well as being used for transplanting into bone marrow and the cell itself.[234]

2.7.2 Adult Stem Cell Cannot be Fully used as Alternate Embryonic Stem Cell

Some people favour the view that embryonic stem cells still could not be fully substituted by adult stem cells in research; instead,they claimed that 'embryonic stem cell research, has been conducted for decades, and scientists have learned a great deal – things like what factors induce the cells to grow and differentiate and migrate to different parts of the body – about these early master cells'.[235]According to the US National Health Institution, compared

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[230] Dr David Prentice, a professor of life sciences at Indiana State University, said 'those adult stem cells, this alternative, are actually much more effective at reaching these goals of therapeutic treatment'. See Elizabeth Cohen, 'adult stem cell or embryonic? Scientist differ' The CNN (Washington, 09 August 2001) <http://articles.cnn.com/2001-08-09/health/stem.cell.alternative_1_cell-research-professor-of-life-sciences-embryos?_s=PM:HEALTH> accessed 28 October 2012.

[231] Amy J Wagers and Irving L Weissman, 'Plasticity of adult stem cells' (2004) 116 Cell 639-648.

[232] Lauren Pecorino, 'stem cells for cell-based therapies' (2001) American Institute of Biological Sciences <http://www.actionbioscience.org/biotech/pecorino2.html> accessed 28 October 2012.

[233] Malcolm Ritter, 'adult stem cell research far ahead of embryonic' The USA Today (New York, 8 April 2012) <http://usatoday30.usatoday.com/news/health/2010-08-02-stem-cells_N.htm> accessed 28 October 2012.

[234] *ibid*.

[235] Elizabeth Cohen, 'adult stem cell or embryonic? Scientist differ' The CNN (Washington, 09 August 2001)

with embryonic stem cells, adult stem cells show limited potential.[236] Moreover, 'adult stem cells are difficult to obtain, since they are often present in only minute quantities. They are difficult to isolate and purify, and their numbers appear to decrease with age'.[237]In addition, adult stem cells may contain more DNA damage compared to embryonic stem cells. The life span of adult stem cell seems to be shorter too.

Adult stem cells could not fully substitute for embryonic stem cells. The potential of embryonic stem cells suggests that it would be extremely short-sighted to discard using them. In my opinion, the idea of completely shifting to only adult stem cells is premature.

2.8 Conclusion

This chapter is intended to be the first stage for answering the main research question based on the thesis statement. In chapter two, the author discusses the major disputes in HESC research, including the moral status of human embryos, the moral source of human embryos and the moral use of human embryos. This section is based on the hypsometrical argument: human embryos are human beings instead of human persons, therefore human embryos have no human dignity, it is one thing to say that human embryos after 14 days fertilisation might be treated as human being. This thesis is also concerned with the moral source of human embryos. The author argues that using spare human embryos do not devalue human dignity. However, creation of human for research use should not be allowed because spare embryos from IVF possibly satisfy the need of research. Meanwhile, the author defends the opinion that created human embryos for research may lead to the instrumentalisation of human life and the moral use of human embryos should be maintained. The author further argues that therapeutic

<http://articles.cnn.com/2001-08-09/health/stem.cell.alternative_1_cell-research-professor-of-life-sciences-embryos?_s=PM:HEALTH> accessed 28 October 2012.

[236] See NIH fact sheet on human pluripotent stem cell research Guideline, <http://stemcells.nih.gov/news/newsarchives/stemfactsheet.asp> accessed 28 October 2012.

[237] *ibid*.

cloning use is possible to police under the curb speculation despite of the confusing distinction between therapeutic cloning use and reproductive cloning use.

The major moral disputes surrounding HESC research focus on the moral status of human embryos, the moral source of human embryos and the moral use of human embryos. In terms of the moral status of human embryos, the author personally favours the "personhood" theory: human embryos who have consciousness and rationality 14 days after fertilisation could be treated as human beings. Either absolute protection of human embryos from the moment of fertilisation or the complete absence of protection for human embryos is the extreme perspective. As for the moral source of human embryos, the author disagrees with the creation of human embryos solely for research because spare embryos from IVF could fully meet the demands of HESC research. Human embryos created for research, in the long term, might turn into the instrumentalisation of human life. With respect to the moral use of human embryos, the author believes that therapeutic cloning use under the strict regulation control and governance speculation could prevent the tendency for commercial use. The distinction between therapeutic cloning use and reproductive cloning use is possible to police. The author hopes that answering these 'moral mazes' connected with HESC research in a convincing way will pave the way for justified regulation.

CHAPTER THREE: THE CHINA MODE ABOUT MORAL-BASED REGULATIONS OF HESC RESEARCH: INCONSISTENT MORAL STANDARDS BETWEEN PATENT LAW AND PRACTICAL APPLICATION

3.1 Introduction

In the previous chapter, the problematic issues that the source and derivation of HESC leads to the immoral research were addressed. It was also stressed that such problematic matters could be the reasons for the disparities on HESC regulation among nations. HESC research and advanced clinical stem cell therapy in China are still seriously unregulated. Moreover, where moral exclusion is concluded in the patent system, HESC researches are not properly supervised in China. Even if immoral research cannot be patented, immoral research can still be carried out. Given that the scientific and economic potential of HESC, the strategies adapted by China aim to develop an effective competition in the scientific, commercial and clinical application of HESC research worldwide.[1] Driven by the market pursuit of high technology interventions, the number of clinics and hospitals in China offered stem cell therapy to patients is rapidly increasing. Under the political environment of socialism with Chinese characteristics, China seems to offer a liberal and favourable environment for HESC research and its application. However, the culture response, business practice and regulation mode of HESC research are yet unclear. This Chapter will first explore HESC research environment, including HESC research funding in China and HESC industry in China. Then the legal framework of HESC research, which mainly refers to the Patent law of People's Republic of China (P.R.C), the Guideline for patent

* Section 5.3, 5.4 and 5.6 was abstracted from my paper entitled 'Between Scylla and Charybdis: Patentability and Morality related to HESC' 6 (2014) 1 American University Intellectual Property Brief.

[1] Brian Salter, 'state strategies and the geopolitics of the global knowledge economy: China, india and the case of regenerative medicine' (2009) 14 Geopolitics 47-78.

examination of P.R.C and the Ethical Guideline for HESC Research, will be examined.

In Patent Law of P.R.C. 2008, Article 5 states that '[n]o patent right shall be granted for any invention-creation that is contrary to the laws of the State or social morality or that is detrimental to public interest'.[2] The Patent Law grants exemption to patent infringement for experimental and research purposes.[3] And in the Guideline for examination of patent application, it further explains the concept that 'social morality' is 'based on certain cultural background, continuously changing with the time and social progresses, and many vary from region to region'.[4] The guideline also gives an example of inventions that use human embryos for industrial or commercial purposes and states that they may be treated as "contrary to social morality".[5]

Likewise, some exemplary cases concerning whether the inventions are related to HESC were excluded from the patent based on Article 5 of patent law and the issue of whether adult stem cells have a practical applicability under Article 22 of patent law are discussed hereto. Regarding the increase of stem cell tourism, there is a question as to whether stem cell therapy can be used for patient treatment in the absence of clear evidence about the safety of clinical applications. People are divided into two completely different groups of opinion: some in favour, some against. In the end, from two aspects, this chapter offers some recommendations to the HESC research regulations in China. One aspect is that moral exclusion should not be regulated in China. Three related issue will be analysed herein, including whether the moral standard in China is similar to that in Western countries, whether moral exclusion is proper on the premise that the moral standard in China is significantly different from that of Western countries and whether moral

[2] The Article 5 of patent law, People's Republic of China, promulgated by the Standing Committee, National People's Congress December 27 2008 <http://www.wipo.int/wipolex/en/details.jsp?id=6511> accessed August 1 2013.
[3] The Article 69 (4) of patent law, People's Republic of China,
[4] The Article 3.1.2 of Guideline for examination of patent application
[5] *ibid*

exclusion is proper in patent law. The other aspect refers to China's regulatory approach to stem cell research and its transfer. The issue is whether the Chinese government should exert their legal control over stem cell research and its transfer and there will be an exploration of which aspect of government control over stem cell research and its transfer should be detailed.

3.2 HESC Research Environment in China

Compared to the EUROPE, China's policy on HESC-related research and applications is relatively liberal and supported by Chinese culture and values. Since the Chinese people have reached a consensus that abortion is legal, in China, embryos are not typically treated as people.[6] Generally, human embryo use is not considered immoral by the Chinese.[7] In an interview by Dominique S McMahon, one Chinese expert stated, 'When we draft our Guideline, we always need to think about our culture as well. For Chinese people, we have not so strong religious ideas about the [embryo]... This is not a person, we don't think so...so we accept'.[8] And the majority finds 'the Chinese people incapable, unsuitable or uninterested' in participating in a public debate on moral issues related to HESC.[9] Therefore, China seems to enjoy a considerable advantage in conducting HESC research and protecting the intellectual property right of relevant inventions.[10] Moreover, the general public's acceptance of HESC research is a great benefit to the application of stem cell therapy in clinic and the development of the stem cell industry.

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[6] Fu Jun ying and Zhao Yun Hua, 'analysis of related policy, funds and outputs on stem cells in China' (2011) 15 Journal of Clinical rehabilitative tissue engineering research 9256.

[7] Liu lidong, 'analysis of the possibility apply for patent of HESC' (2013) 30 Hospital management forum 9-11.

[8] Dominique S McMahor, Halla Thorsteinsdottir, Peter A Singer and Abdallah S Daar,'cultivating regenerative medicine innovation in China' (2010) 5 regenerative medicine 35.

[9] Margaret Elizabeth Sleeboom Faulkner, 'boundary making and good stem cell research in mainland China: including bioethics, excluding debate' (2010) 4 East Asian science, technology and society an international journal 31.

[10] *ibid*.

3.2.1 HESC Research Funding in China

The major funding of HESC research in China is obtained from governmental organisations, ranging from the Ministry of Science and Technology, the National Natural Science Foundation to the Chinese Academy of Sciences. The 973 programmes[11] and the major scientific research project programme[12] are the two main sources of HESC research funding. The supporting priorities depend on the China national Five Year plan for National Economic and Social Development. During the eleventh Five-Year Plan, 29 stem cell research projects were funded by the 973 programmes and the major scientific research project programmes.[13] The money from these programmes exceeded 832 million RMB. Over 50 research centres throughout the country obtained sponsorship from these programmes.

Generally speaking, the funding strategy was successful, particularly in the following three areas. First, the research field of funded programmes is within the popular areas of world stem cell research.[14] Of the funded programmes, there are five programmes which refer to the regulatory network of stem cells, seven are involved with the IPS and HESC and ten are concerned with embryo differentiation and transplant. The remaining programmes mainly focus on tumour stem cells and the stem cell research platform.[15] Second, China's stem cell research consisted of experts, most of whom have either obtained an overseas university degree or have spent some time training overseas.[16] The China Global Expert Recruitment programme is highly attractive with a variety of financial and research incentives.[17] Third, some

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[11] The 973 programs, also called the national basic research program, were established in June 1997 in order to promote creativity and the sustainable development of China. Stem cell research is one supporting priority project by the 973 programs.

[12] The major scientific research project mainly sponsor four areas: Protein research, research on quantum control, Nanotechnology research and research on development and reproduction.

[13] Chen tao, Jiang haiyan and Qian wangqiang, 'the funding mode of stem cell research in China' (2011) 4 China Basic Science 31.

[14] The hot research area in the world stem cell research is the embryo differentiation and transplant, ips, HESC, tumor stem cell, neural stem cell, regulatory network of stem cell, stem cell used in heart disease treatment and core blood stem cell. See *Ibid.*

[15] *ibid.*

[16] *ibid.*

[17] *ibid.*

results of the funded programme considered to be pioneering research worldwide. For example, Chinese scientists were the first to verify the totipotent of ips cell,[18] as well as the first to find a way of generating the induced pluripotent cell.[19]

3.2.2 HESC Industry in China

The HESC research development to some extent depends on economic progress. Although the Chinese economy has grown in recent years, there is still a tremendous gap between China and Western countries. With regard to HESC research, the fundamental facilities in some laboratories such as those in Beijing or Shanghai are considered world class.[20] The environmental facilities and equipment of some laboratories are even envied by the world leading experts.[21] For average, Chinese laboratory facilities still lag behind those in developed countries. However, the stem cell industry in China, both with regard to technology and business models is in a rapid development phrase and this bodes well for future prosperity.

Focusing on therapy, stem cell research in China is in the rapid process of being transferred from basic scientific research to practicable diagnostic procedures. Shen Zhen Beike (Beike) is one such company that has won world renown for its stem cell therapy. From the laboratory to hospital application, Beike's highly reputable therapy is attracting patients from all over the world to undergo treatment in China. With the benefit of the first special economic zone of China, Beike combined laboratories and hospitals to establish treatment centres.[22] As the president of Beike Hu Xiang said, '[i]nitially, we

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[18] Zhao Xiaoyang, li wei, lv zhao, liu lei, tong man, hai tang, hao jie, guo changlong, ma qingwen, wang liu, zeng fanyi and zhou qi, 'ips cells produce viable mice through tetraploid complementation' (2009) 461 Nature 7260.

[19] Esteban M A et al, 'vitamin C enhances the generation of mouse and human induced pluripotent' (2009) 6 Cell stem cell 71.

[20] *ibid*.

[21] Xv Guotong, 'the challenge and opportunity of stem cell research in China' (2007) 4 Frontier Science 36.

[22] The city Shen Zhen was benefit of the "opening and reform" policy by the Chinese leader Deng Xiaoping. As the first "special economic zone", Shenzhen attracted many foreign investments as well as tax deductions. See Priscilla Song, 'the proliferation of stem cell therapies in post-Mao China:

only cooperated with laboratories and hospitals which offered a good standard of equipment, excellent environment and a high level team'.[23] In order to promote the interaction, 'Beike creatively launched a stem cell public technical service platform and constructed a stem cell clinical research network'. [24] So far, Beike has announced the world's largest clinical application security evaluation of allogeneic human umbilical cord blood-derived stem cells, as well as publishing the research data of effective treatment in systemic lupus erythematosus, hereditary ataxia and muscular dystrophywait.[25]

Hoping to grasp the opportunities brought by stem cell research, the city of Tianjin set up China's first stem cell industry alliance that included 22 biotech companies and research institutions such as the National Industrial base of Stem Cell Technology and the National Centre of Stem Cell Engineering and Technology.[26] The alliance aims to cure complicated diseases, create new stem cell technology, establish a public service platform and accelerate the transfer of scientific results to clinical products. [27] However, from the viewpoint of some academics, 'the issue of healthcare system and physician–patient relationship, the intellectual property and other commercial conflicts of interest produce obstacles for translational medicine'.[28]

Even in the capital market, it is possible to find companies whose main business relays on the stem cell industry. As the only one in the Shanghai and Shenzhen market, Zhongyuan Union Stem Cell Bio-engineering Corporation successfully operates three famous stem cell enterprises: Union Stem Cell Genetic Co. Ltd, Union East China Stem Cell Gene Engineering Co. Ltd. and

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problematizing ethical regulation' (2011) 30 New Genetics and Society 141.

[23] Yong yue, 'Beike biotech: win the respect and appraise by the stem cell frontier technology' (The Chinese economic, June 2nd 2011) <http://district.ce.cn/zg/201106/02/t20110602_22458434.shtml> accessed November 20 2013.

[24] *ibid*.

[25] The Beike Biotech website. <http://beikebiotech.com/> accessed 20 November 2012.

[26] *ibid*.

[27] Li Xiang, 'The beginning of stem cell industry' (Binhai newspaper, September 26, 2010).

[28] Haidan Chen, 'stem cell governance in China: from bench to bedside' (2009) 28 New Genetics and Society 267.

HeZe biotechnology Co. Ltd.[29] The company holds certain important patents such as umbilical cord tissue derived mesenchymal seeded separation method, human umbilical cord mesenchymal stem cell the antifibrotic injection and its preparation method, human adipose adult stem cell acquisition method and construction of the stem cell bank.[30] From the above, we can conclude that Chinese companies have already entered the downstream market of the stem cell industry.

3.3 The Legal Framework of HESC Research in China

It has been argued that developing countries profit from the legal and bioethical vacuum.[31] In particular, with regard to international collaboration which has increased in the areas of HESC research, China is determined to grasp the promise of regenerative medicine. Although China has established the moral based HESC regulation framework, the implementation of these regulations in research and clinic has not been carried out well.[32] Not only were poorly educated people unable to understand the relevant regulations, but also some medical staff and researchers have not been properly trained.[33] Thus, the application of HESC research in practice, to some extent, still faces many moral, political and material risks under the current legal framework in China.[34]

3.3.1 The Patent law of China and Its Guideline for Patent Examination

Like the EUROPE patent convention, the patent law of the People's Republic of China does not contain a moral exclusion either. Article 5 of the patent law states 'no patent right should be granted for any invention-creation that is

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[29] *ibid*.

[30] Ruan Xiaoqin, 'The patents granted to Heze Biotechnology' (Shanghai Stock Newspaper, August 25, 2011)

[31] *Supra* note 27; see also *Supra* note 20.

[32] Wolfgang Hennig, 'Bioethics in China-although national Guideline are in place, their implementation remains difficult' (2006) 7 EMBO reports 850.

[33] *ibid*.

[34] Moral risks refer to 'The violation of cultural values'; political risks is related to 'the political economy of bioethics and public debate'; material risks is involved with 'the distribution of material resources and wealth'. See Margaret E Sleeboom Faulkner, 'national risk signatures and HESC Research in

contrary to the laws of the State or social morality or that is detrimental to public interest'.[35] According to the explanation by the Commission of legislative affairs[36], the social morality standard depends on its acceptability by the public. If the invention is accepted by the public as well as being allowed by the moral standard, it may be granted a patent.[37] For example, artificial human organs for non-medical purposes and human-animal hybrid embryo are non-patentable due to the consideration of morality. Furthermore, the Guideline for patent examination (Guideline) indicates the following:

> The connotation of the laws, administrative regulations, social morality and public interest is quite broad, which may vary with time and from region to region. Sometimes certain restrictions may be added or removed because of enactment and implementation of a new law or administrative regulation or amendment to or abolishment of a preceding law or administrative regulation. Therefore, the examiner shall pay special attention to this point in conducting examination according to Article 5.[38]

The Guideline also provides the definition of social morality which refers to 'ethical or moral norms and rules generally recognized as justifiable and accepted by the public'.[39] It reemphasised the fact that social morality is based on 'certain cultural background, continuously changes with time and social progress, and varies from region to region'.[40]

In addition, the Guideline touches on some specific regulations related to HESC. First, Article 3.1.2 in part II chapter 1 of the Guideline states that the use of human embryos for industrial or commercial purposes is

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Mainland China' (2010) 12 Health, Risk & Society 1.

[35] *Supra* note 2.

[36] The commission of legislative affairs is affiliated to the National People's Congress of the People's Republic of China. The explanation of patent law of China aims to provide the explanations by the authority.

[37] *ibid.*

[38] Part II Chapter 1 of Guideline for patent examination by the State Intellectual Property Office of China.

[39] *ibid.*

contrary to social morality and therefore should be excluded from patenting. Second, Article 4.3.2.1 in part II chapter 1 lists 'methods of fertilization, contraception, increasing the number of sperm, adosculation, or embryonic transfer for the purpose of treatment' falls under 'methods of treatment' and therefore its subject matter should be excluded from patent protection under Article 25.[41] Third, Article 9.1.1.1 in Part II chapter ten of the Guideline states that 'both an embryonic stem cell of human beings and a preparation method thereof shall not be granted the patent right in accordance with the provisions of Article 5.1'.[42] Fourth, Article 9.1.1.2 points out 'the human body, at the various stages of its formation and development, including a germ cell, an onsperm, an embryo and an entire human body shall not be granted the patent right in accordance with the provisions of Article 5.1'.[43] Fifth, Article 9.1.2.3 reads 'an embryonic stem cell of an animal, an animal at the various stages of its formation and development, such as a germ cell, an oosperm, an embryo and so on, belong to the category of the animal variety…they are unpatentable in accordance with the provisions of Article 25 1(4).'[44]

From the above we may conclude that neither inventions related to "use human embryo for industrial or commercial use" nor creations referred to "HESC and a preparing method" are allowed to be patented under the Patent laws of China. But, in terms of the differentiation, use and preservation of HESC, both patent law and its guideline do not provide any prohibitive provisions.

3.3.2 The Ethical Guideline for HESC Research

In order to promote the development of HESC research in China, the Ministry of Science and Technology jointly with the Ministry of Health released the

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40 *ibid.*
41 *ibid.*
42 *ibid.*
43 *ibid.*
44 *ibid.*

Ethical Guideline for HESC research (Ethical Guideline) in December 2003.[45] The Ethical Guideline directly defined the justified source of HESC and regulated how to conduct research legally. Meanwhile, the Ethical Guideline declared that it is illegal to perform any productive cloning research and any embryo sale.[46] This was the first time to issue a guideline to clarify the illegitimate issues of reproductive cloning research. Undeniably, the Ethical Guideline has been of great significance to the rapid and healthy development of HESC research.

However, the Ethical Guideline contains some serious flaws and has received much criticism.[47]For example, Article 5 of the Ethical Guideline claimed HESC could be only obtained from: '(1) embryos that are left unused after in vitro fertilisation procedures; (2) foetus cells from spontaneous abortion or voluntary abortion; (3) embryos created by means of somatic cell nuclear transfer technique; (4) voluntarily donated germ cells.'[48] Obviously, the creation of a human embryo utilising sperm and egg is not allowed for research purposes. However, the Ethical Guideline ignored the main source of HESC- already existing embryonic stem cell lines. In Western countries such as Germany, the UK and the US, already existing embryonic stem cell lines are a very popular source of HESC.

Another argument is focused on the Article 6: 'use embryos from In Vitro Fertilisation, somatic nuclear transfer, a single replication technology or genetic modification blastocysts obtained in vitro, only embryos for a maximum of 14 days could be used in research'.[49] This article is similar to the Article 36, clause 4 of the Human Fertilisation and Embryology Bill.[50] The 14 days restriction is also regulated in many other countries such as Germany

[45] The Ethical Guideline for HESC research, 2003<http://www.cncbd.org.cn/News/Detail/3376> accessed February 2, 2014.
[46] *ibid*.
[47] Xiao Xianjing, 'The ethical guideline lacks morality' (China Science Daily, July 23 2004).
[48] The Ethical Guideline for HESC research, 2003.
[49] *ibid*.
[50] The Human Fertilisation and Embryology Bill 2008.

and Japan.[51] It seems reasonable because we use the restriction that is popular in other countries. The problem is the restriction cannot be applied well to the situation in China. The reason is that, unlike in western countries, abortion is considered legal in China. Therefore, considering moral and culture difference, it may be pragmatically meaningful for the regulators to rethink whether the 14 days restriction should be adopted in China.[52] Moreover, the Ethical Guideline should justify the necessity for 'transplanting' the regulations of Western countries.

In addition, one fatal problem pointed out by the ethicists is that the Ethical Guideline lacks the relevant moral definition as well as the relevant moral objection. From article 5 to article 10, the regulation places its focus on the code of conduct instead of moral behaviour.[53] Thus, the Ethical Guideline is lacking in moral connotation and appears monotonous and mechanical. In fact, it is necessary to express moral connotation and moral reasons in an appropriate form in order to let people deeply understand and accept the Ethical Guideline. In addition, it is noticeable that article 9 states 'the Ethical Committee should consist of the biologists, the doctors, the lawyers and the socialists. The responsibility of committee is to examine, supervise and provide consultation to HESC research.'[54] The clause did not mention the ethicists, who should play a critical role in the Ethical Committee. It is no exaggeration to say that whether the Ethical Committee can reach its aim depends largely on the participation of the ethicists.[55]

3.4 Case Studies

Most disputes over HESC are gathered in patent granting beyond the article 5 of the patent law: 'no patent right should be granted for any

[51] Sven Pompe, Michael Bader and Christof Tannert, 'Stem cell research: the state of the art' (2005) 6 EMBO Rep 297.
[52] Qiu Renzong, 'The review of the ethical guideline of HESC research' (2004) 4 Medical and philosophy 275.
[53] *Supra* note 32.
[54] *Supra* note 37.
[55] *Supra* note 32.

invention-creation that is contrary to the laws of the State or social morality'.[56]

3.4.1 Whether Article 5 of the Patent Law Excludes Inventions Related to HESC?

As shown by the following analysis, HESC differentiation and culturing methods are both prohibited by patent law in China. In addition, preparations of pre-implantation embryo for therapeutic cloning use are not patentable. However, in judicial practice, inventions related to existing HESC lines do not contrary to morality under the Article 5 of Patent Law.[57]

Case Advanced Cell Technology Related to the Differentiation of HESC and its Culture Method: Lacking the Explanation of "Embryo" and "Industrial or Commercial Purpose"

Advanced Cell Technology's[58] patent application on January 24, 2005 covers methods for improved cell-based therapies for retinal degeneration and for differentiating HESC.[59] Its publication date was May 23, 2007. Initially, the claims covered the differentiation of HESC into retinal pigment epithelial cells used to treat retinal degeneration.[60] Under Article 5, the patent could not be granted unless it deleted that claim.[61]

A similar situation also occurred in the context of Beijing University's patent application on May 17, 2006 related to a method for culturing HESC in a special culturing medium.[62] The patent application deleted claims involving HESC culturing before the patent was granted.[63] Likewise, the authorisation of a patent application covering methods of preparing feeder-cell-free, xeno-free HESC and stem-cell cultures specified the elimination of the HESC

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56 *Supra* note 2.
57 *Supra* note 56.
58 Advanced Cell Technology, Inc., is a biotechnology company that specializes in the development of cellular therapies for the treatment of diseases and conditions that impact tens of millions of people worldwide. The company applies stem cell-based technologies (both for adult and "embryo-safe" HESCs)
59 CN 1968608 A (Improved modalities for the treatment of degenerative diseases of the retina.)
60 *ibid.*
61 *ibid.*
62 CN 1844374 A (Culture method for HESC and special culture medium thereof.)
63 *ibid.*

culturing methods that had been included in the applicant's public specification.[64]

It is well established in this case that patent could not be granted to the differentiation of HESC and its culture method. However, neither "embryo" nor "industrial or commercial purpose" were defined in this case.[65] Although the Chinese patent office encountered the same problems as the European office[66], it neither provided any explicit explanation nor offered any judging approach.

Case Shanghai Genon Biological Product Related to the Preparation of Pre-implantation Embryo for Therapeutic Cloning Use：HESC with the Possibility of Developing into Human Being is within the Scope of Human Embryo

Shanghai Genon Biological Product Co. Ltd.'s (Genon) November 2, 1999, patent application referred to the preparation of pre-implantation embryos for therapeutic cloning use.[67] The publication date of the patent application was July 11, 2001. In 2003, the China's Intellectual Property Office (IPO) rejected the application pursuant to Article 5. The decision was made for the following reasons: First, the method used in the invention involves mixing a donor nuclear cell and non-mammal cytoplasm derived from donor oocytes. The reconstructed cell is stimulated and transplanted into non-human mammals.[68]

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[64] CN 100549163C (Methods of preparing feeder cells-free, xeno-free HESCs and stem cell cultures prepared using same); CN 1748025A (Methods of preparing feeder cells-free, xeno-free HESCs and stem cell cultures prepared using same.)

[65] *Supra* note 56.

[66] Brian Salter, 'Governing stem cell science in China and India: emerging economics and the global politics of innovation' (2008)27 New Genetics & Society 145, 154 (stating that with its accession to the World Trade Organization (WTO) in 2001, China agreed to conform to the requirements of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Since then China has cooperated frequently with the World Intellectual Property Organization (WIPO) and the European Patent Office (EPO) on personnel training and promoted IPR teaching and research in over 70 universities; see also Tang huadong and Wang dapeng, 'the analysis of the patentability of HESC' (2013) 5 Intellectual Property 52,54.

[67] Shanghai Genon Biological Product Co. Ltd. become the high and new technology enterprise in Shanghai, Little Giant Breeding enterprise, important enterprise of feed industry in Shanghai and the main unit which drafts out the national standard of "Spray dried globin protein powder for feed." The company has taken large number of special government projects such as industrialization project of high and new technologies from National Development and Reform Commission, National Spark Plan, innovation fund for medium and small enterprise, domestic cooperation projects in Shanghai, "develop agriculture by science and technology projects" in Shanghai and "four news" technology projects in Shanghai.

[68] See the 5972 re-examination decision by the patent review committee.

Finally, the cell is developed into early embryos. The IPO held that because the cell contains complete genetic information, the early embryo should be identified as a human embryo. The preparation method of an early embryo is equivalent to human cloning. Therefore, the invention falls within the moral exclusion of Article 5.[69] Second, the IPO held that the invention was for industrial and commercial purposes and therefore, it violated Article 5.[70] Third, as stated in the patent claim, the resulting embryo would be a human-animal hybrid, which is forbidden by the patent-examination Guideline.[71]

In 2004, Genon appealed to the Patent Review Committee making the following arguments: First, although the embryo includes human genetic information, it is a human-animal hybrid, not a human embryo. Thus, the invention is not related to the industrial or commercial use of a human embryo.[72] Second, the embryo created by this method has no possibility of becoming human because claims 1-10 of the application contain no human-cloning steps.[73] Third, the invention represents one aspect of human organ transplantation technology.[74] Therefore, the invention is properly classified as therapeutic cloning. Neither its aim nor its method involves human cloning. In conclusion, the invention is not against the law, social morality or the public interest.[75]

The committee reexamined the patent application and concluded that the invention is unlawful based on Article 5 for two reasons.[76] First, the nuclei donor's genetic information has a decisive impact on the cell's overall performance. Genon's patent application contains human nuclei materials

[69] *ibid.*
[70] *ibid.*
[71] *ibid.*
[72] *ibid.*
[73] *ibid.*
[74] *ibid.*
[75] *ibid.* see also Liu lidong, 'Analysis of the possibility apply for patent of HESC' (2013) 30 Hospital Management Forum 9, 11.
[76] *ibid.*

that possess the characteristics of human cells.[77] As claimed in the patent application, the invention is primarily used for the purpose of tissue or organ transplantation. If so, the invention could not exclude the possibility of developing into a human being. However, the committee did not ignore the possibility that the embryonic cells would exhibit the characteristics of an animal.[78] In that situation, the method still violates public morality because it changes the genetic identity of a human germ line. Second, the claim does not exclude the possibility of the early embryos developing into humans. Genon did not provide any evidence to prove that the embryos could not develop into human beings.[79]

It has been speculated that HESC comes with the possibility of developing into human being are against public morality under Article 5 of patent law. The argument in this case seems to provide the interpretation of human embryo. However, there are many extant ambiguous aspects, especially how broadly or narrowly to construe the possibility of developing into human being.

Case the Regents of the University of California related to the Oligodendrocytes Derived from Already Established HES Cell Lines for Remyelination and Treatment of Spinal Cord Injury: it is Improper to Trace the Origin of the World's First HESC Lines

The next patent application that we consider was filed by the Regents of the University of California in 2003 and covered oligodendrocytes derived from HESC for remylination and the treatment of spinal-cord injuries.[80] The IPO held that this invention violated Articles 5 and 22 of the Patent Law of China.[81] The committee believed that the patent specification and claims in

[77] *ibid.*
[78] *ibid.*
[79] *ibid.*
[80] See the 42698 re-examination decision of the patent review committee.
[81] Patent Law of China (promulgated by the Standing Comm. of the Seventh Nat'l People's Cong., Sept. 4, 1992, effective January 1, 1993) the Article 5 <http://www.chinatrademarkoffice.com/about/laws2.html#2> accessed September 2014 (providing that "No patent right shall be granted for any invention-creation that is contrary to the laws of the State or social morality or that is detrimental to public interest."); Patent Law of the People's Republic of China (promulgated by the Standing Comm. of the Seventh Nat'l People's Cong., Sept. 4, 1992, effective

their entirety related to HESC obtained from human embryos, thus violating social morality through the use of human embryos for industrial or commercial purposes. In addition, the pluripotent cell derived from non-embryo tissue required bone marrow or other human or animal tissues through a surgical method for non-therapeutic purposes. Thus, the invention could not satisfy the utility standard set forth in Article 22.[82]

The applicant appealed to the Patent Review Committee on the following two grounds: First, the HESC aspect of the invention had been removed from the patent specification, and the cell lines used in the invention belong to established, mature, already-commercialised HESC lines. Second, the application's claims explicitly excluded direct decomposition from the human-embryo or HESC-related technology solution. In addition, the application had deleted all industrial or commercial uses of human embryos.[83]

With respect to Article 5, the applicant argued that the origin of HESC should not be traced in perpetuity. The starting material of the application consisted of established HESC lines capable of unlimited in vitro proliferation. In the prior art, there are many ways to obtain mature and stable HESC lines. Moreover, it is improper to trace the origin of the world's first HESC lines. Using established HESC lines could decrease human-embryo abuse and in turn, limit the use of HESC to mature strains. Therefore, the application does

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January 1, 1993) the Article 22 <http://www.chinatrademarkoffice.com/about/laws2.html#2> accessed September 2014 (providing that "Any invention or utility model for which patent right may be granted must possess novelty, inventiveness and practical applicability. 'Novelty' means that, before the date of filing, no identical invention or utility model has been publicly disclosed in publications in the country or abroad or has been publicly used or made known to the public by any other means in the country, nor has any other person filed previously with the patent office an application which described the identical invention or utility model and was published after the said date of filing. 'Inventiveness' means that, as compared with the technology existing before the date of filing the invention has prominent substantive features and represents a notable progress and that the utility model has substantive features and represents progress. 'Practical Applicability' means that the invention or utility model can be made or used and can produce effective results.")

[82] *Supra* note 77.

[83] *ibid*.

not violate Article 5's social-morality provision.[84]

Recognising that it is inappropriate to trace the origin of HESC lines, using established stem cell lines is allowed by the morality provisions in the patent law. However, in the following decision 24343 made by the Patent Review Committee, the Committee held that although HESC could be obtained from commercial channel, the source of HESC still lay on the destruction of the human embryo.[85] More definitively, the culture of HESC featured problems like being time-consuming, difficulty to operation, and easy to contaminate. As a result, established cell lines are not the steady and long-term source of HESC. Subsequencely, the argument that HESC could get rid of the destructing human embryo is unrealistic.[86]

The uncertain decision made by the Patent Office is due to the misunderstanding of the moral provision.[87] The moral standard as well as the relevant definition should be clarified and developed as soon as possible.

3.4.2 Whether Adult Stem Cell Has the Practical Applicability Under Article 22 of Patent Law?

There are no specific clauses either in the patent law or the guideline for patent examination towards the practical applicability of adult stem cell. According to the article 22 of patent law, 'practical applicability means that the invention or utility model can be made or used and can produce effective results'.[88] If you apply a patent for the product, the invention must be able to manufacture in industry. Or if the patent application is referred to the method, the invention must be able to utilise in industry. In the section 4.3 of guideline for patent examination, 'methods of surgery for non-treatment purposes do

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[84] *ibid.*

[85] The 24343 re-examination decision of the patent review committee.

[86] See NIH fact sheet on human pluripotent stem cell research Guideline, <http://stemcells.nih.gov/news/newsarchives/stemfactsheet.asp> accessed October 28 2013.

[87] *Supra* note 57 (observing that the lack of consensus in the supplication of the morality provision suggests that there is a fundamental misunderstanding regarding the nature of the provision. The closer this analysis has gone to achieving an operative understanding of the provision, the greater recourse to commentators has been required in order bridge the gaps in practice.)

not have practical applicability because these methods are practiced on the living human or animal body and cannot be used industrially'.[89] In practice, this provision is widely used in examining adult stem cell patent application. Because the preparation method for adult stem cell includes the surgical procedure, the adult stem cell inventions for non-treatment purposes do not have practical applicability.

The Natural Killer T cell by Kirin Brewery Company: Lacking Practical Applicability due to the Step Involved with Human Body

The patent application by the Kirin Brewery company in 2001 claimed the culture method of natural killer T Cells as well as the relevant Reagent.[90] The method includes the mononuclear cell from the peripheral blood and the steps using granulocyte colony stimulate stem cells in the peripheral.[91]

The substantive examination department of the State IPO objected the patent application on the grounds of Article 22 of the patent law. The IPO held that according to the description in the specification of the patent application, the invention must have the step of collecting peripheral blood from human body and injecting granulocyte colony stimulating factor.[92] This step is involved human body as objectives therefore cannot be used in the industry. As a result, the invention lacking practical applicability does not comply with Article 22 of patent law. Accordingly, the relevant Reagent that does not have practical applicability cannot be patented either.[93]

The Culture and Growth Method by Da An Gene Co. Ltd. of Sun Yat-Sen University: Lacks Practical Applicability Because it Contains the Surgical Method

The patent application by the Da An Gene Company in 2003 claimed the

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88 The Article 22 of patent law of the People's Republic of China.
89 Section 3.2.4 in Part II of Guideline for patent examination by state intellectual property office of the People's Republic of China.
90 The CN1444648A patent application.
91 *ibid*.
92 *ibid*.
93 *ibid*.

culture and proliferation method of stem cell derived from adipose tissue.[94] The claimed method comprising:

> (1) [T]he collection of healthy human adipose tissue from the 3-18 years old boy and the preparation of conditions to produce the culture medium; (2) the isolation and purification of stem cells provided by a human adult adipose tissue; (3) the further purification of the products from claim 1 and 2; (4) the purification of stem cells obtained from step 3 and directed differentiation of the cultured stem cells.[95]

The substantive examination department of the State IPO rejected the application on the grounds of Article 22 of the patent law. The legitimate reason is: although the pluripotent stem cell culture method cannot be identified as the "surgical method for non-therapeutic purposes" under guideline for patent examination.[96] But the claim contains the step of fetch samples from the human body that belongs to the typical surgery for non-therapeutic purposes. Therefore, the patent application lacks practical applicability because it contains the surgical method.

3.5 Can Stem Cell Therapy be Used in Patient before Clinic Testing?

China practices high-quality but morally questionable stem cell therapy, which has raised concerns that stem cell therapy used in patients prior to clinic trials introduces certain safety problems. The direct to consumer advertising on a website that provides stem cell therapy is typically overly optimistic and inaccurate, which might mislead patients. In China, most stem cell therapies are not approved by the State Food and Drug Administration.[97] Without close monitoring and proper guidance, there is the question of whether the safety and efficiency of stem cell therapy can be guaranteed.

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[94] The CN1597936A patent application.
[95] *ibid*.
[96] Section 3.2.4 in Part II of Guideline for patent examination by state intellectual property office of the People's Republic of China.
[97] Lianming Liao and Robert Chunhua Zhao, 'An overview of stem cell based clinical trials in China' (2008) 17 stem cells and development 613.

3.5.1 From the Bench to Bedside: Stem Cell Therapy should not be Used in Patient Before Clinic Trials

Certain scholars in China believe that unproven therapies could yield negative consequences in patients.[98] Although most researchers believe it is too early to translate the HESC research to therapeutic application,[99] stem cell therapy is performed in many developing countries. Stem cell therapy does introduce a safety risk. For example, according to one report, neural stem cells may induce gliomagenesis.[100] The first report of a donor-derived brain tumour was related to a neural stem cell transplant in an Ataxia Telangiectasia patient.[101] The scientists found that 'tumor cells actually behave very much like stem cells—they divide indefinitely and they tend to be undifferentiated'.[102] Many stem cell therapies that have only been tested on animals are performed on humans in certain clinics, companies or hospitals for commercial purposes. However, because the physiology of humans is more complex than that of animals, effective stem cell therapy for animals may not be suitable for humans due to such differences.

Thus, there is an urgent need for the safety of such therapies to be assessed. Jing Naihe, the Deputy Director of the Shanghai Institute of Biochemistry and Cell Biology, stated that we should answer three questions before performing stem cell therapy.

First, whether the injected stem cell can survive; second, whether the

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98 Qiu Xiang Xing, Gao Zhi Yan, Wang De Yan, Wang Ming Xu, Shen Ming Xian and Chen Ren Biao, 'A Survey and Disscussion on Ethical Issues of HESC Research' (2004) 25 Medicine and Philosophy 8-11.

99 Ole Doring, 'life science in translation-a Sino-European Dialogue on ethical governance of the life sciences', (2009) report from ethical governance of biological and biomedical research: Chinese-European cooperation.

100 Ninette Amariglio, Abraham Hirshberg, Bernd W Scheithauer, Yoram Cohen, Ron Loewenthal, Luba Trakhtenbrot, Nurit Paz, Maya Koren Michowitz, Dalia Waldman, Leonor Leider Trejo, Amos Toren, Shlomi Constantini and Gldeon Rechavi, 'Donor-derived brain tumor following neural stem cell transplantation in an ataxia telangiectasia patient' (2009) PLOS Medicine <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.100002> accessed online November 20, 2013.

101 *ibid.*

102 *ibid.*

injected stem cells are capable of differentiating into the functional compensation neurons, for example, to differentiate into neurons treating diseases; third, whether the neuron could establish the real link with the nervous system of the body.[103]

Therefore, because the safety of stem cells has only been demonstrated through drug evaluation experiments, the scientific evidence is insufficient, and clinic testing is imperative.

3.5.2 From the Bedside to the Bench: Stem Cell Therapy Should Be Used in Patient Before Clinic Trials

However, certain scholars hold the opposite opinion.[104] Such scholars believe that, for stem cell therapy, we should follow scientific evidence from the bedside to the bench.[105] The debates and argument over using stem cells in patients before clinical trials often stimulates arguments from scholars who are unfamiliar with this area.[106] When they see patients expressing gratitude, they may well cease their debate.[107] The primary dispute over stem cell therapy is that strict evidence is unavailable, but in certain clinics, stem cell therapy could aid in treating many incurable diseases.[108] A case study on a university that began using such treatments on patients showed that, from the bench to the bedside, stem cell therapy should undergo a complicated process for acceptance and legitimacy under Chinese regulations.[109] The company Beike Biotechnology, which

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[103] Whether stem cell therapy can be used in patients prior to clinical testing? <http://www.bioon.com/biology/bioenginering/310200.shtml> accessed online November 23, 2012

[104] Chen Haidan, 'stem cell governance in China: from bench to bedside?' (2009) 28 New Genetic and Society 267-282.

[105] *ibid.* (some interviews state that since stem cells are there and might bring patients some hope, is it ethical not to treat patients with stem cells when they suffer from incurable diseases and are dying; also some interviews view that controversies raised by experts focus on the fact that there is no strict evidence theoretically, but in my personal view, this is a scientific chauvinism. In reality, they have helped to treat many incurable diseases, but in theory, we can't disprove it or prove it, there is something science can never solve…we think at least it is good for society and solves people's real pain.)

[106] *ibid.*

[107] Chen Haidan, 'The governance of stem cell translational research: an analysis based on case studies' (2009) Zhejiang University, doctoral thesis.

[108] *ibid.*

[109] *ibid.*

attempted to use stem cell research for clinic treatments, held that 'since stem cells are there and might bring patients some hope, is it ethical not to treat patients with stem cells when they suffer from incurable diseases and are dying?'[110] For untreatable debilitating diseases, 'many patients aren't willing to wait and are making their way to far-flung places, where clinics are administering unproven cell therapies to patients who can pay for them'.[111] For the importance of hope in a patient's quest for a cure, stem cell therapy may be reasonable.

However, the author believes that stem cell therapy should not be used in patients before clinical trials have been performed. Thus far, we have little information on the mechanisms of action underlying stem cell repair and regeneration of damaged human organs and tissues.[112] Moreover, to provide reliable treatment, standardisation and clinical grade quality stem cell therapy is necessary from the laboratory to the clinic.[113] Currently, most stem cell therapies do not satisfy such requirements. Therefore, a clinic, company or hospital could not guarantee the safety grade of the stem cells injected into patients.

3.6 Moral exclusion in or out patent law?

As shown in section 6.3 of the HESC legal framework in China, both Patent law in the China and the Examination Guideline relate to moral exclusion of patents for an HESC invention. Article 5 of the patent law provides that 'patent rights shall not be granted for invention-creations that violate the law or social ethics, or harm public interests'.[114]

The Examination Guideline further states that the definition of social morality is 'ethical or moral norms and rules generally recognized as justifiable and

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[110] *ibid.*
[111] *ibid.*
[112] *ibid.*
[113] *ibid.*
[114] The patent law of China, 2008 < http://www.gov.cn/flfg/2008-12/28/content_1189755.htm> accessed October 10 2014.

accepted by the public'.[115] However, neither the patent applicants nor the patent examiners clearly understand the meaning of social morality. Because the moral definition is abstract, we should not rely on the principle or standard as the measure. Cases are helpful in understanding the specifics and scope of protection by such regulations. In practice, many patent applicants modify their claims for consistency with the moral exclusion requirements.

3.6.1 Low Moral Status of Human Embryo in Practical Application

The first question is whether the moral standard in China is similar to the moral standard in Western countries. Contrary to popular assumption, Chinese people do not place too much value on life.[116] Based on Confucian philosophy, life begins at birth.[117] A human embryo holds the status of a pre-human being. Accordingly, the moral status of a human embryo is not equal that of a human being. Moreover, abortion is not prohibited and is sometimes compulsory under China's "one-child policy."[118] A survey about the moral status of HESC carried out in hospitals shows that more than 50% of doctors believe that human embryos are not human beings and that more than 70% of doctors support HESC research.[119] Moreover, under China's civil law, civil rights begin at birth.[120] A fetus is not a legal entity: in other words, fetuses are not human beings.

Therefore, China's moral standards are very different from those of Western countries. Even considering the existence of varying local circumstance, China has a much different moral standard related to HESC research than do

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115 *ibid.*

116 Achim Roseman, 'Life without value? Voices of embryo donors for HESC research in China' (2009) 52 IIAS Newsletter 17, 17 (concluding that equally flawed appears the assumption that due to the high number of abortions carried out in the context of the one-child policy, the value of early forms of human life are generally of low regard among Chinese people.)

117 Qiu Renzong, 'The historical, social and philosophical background of Chinese policies regarding HESC research' presentation at BIONET workshop on bio-ethical governance of stem cell research, October 9-11 2007.

118 Nie Jing Bao, *Behind the Silence: Chinese Voices on Abortion* (1st ed., Rowman & Littlefield Publishers 2005) 105.

119 *Supra* note 113

120 See the Article 9 of the Chinese Civil Law (providing 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

Westerncountries.[121]

3.6.2 High Moral Status of the Human Embryo in Patent Law

The next question is whether the moral exclusion is proper on the premise that the moral standard in China is much different from western countries. Although China's moral standards are much different from those of Western countries in practical application, according to the patent-examination Guideline, it is forbidden to patent the use of embryos for commercial or industrial purposes.[122] As in the EUROPE, the Chinese patent regulations contain no direct definition of "embryo" or "commercial or industrial purpose". Thus, the Chinese patent office has encountered the same problems as the EUROPE patent office. However, unlike the EUROPE, Chinese regulators have not needed to consider the issue of conflicting moral standards among member states. Practically, the moral standard in China is much different from the EUROPE.[123] Therefore, it is the author's firm belief that it is improper for China to introduce the moral exclusion provision from the EUROPE.

Since China's moral standards are practically much different from those in the EUROPE,[124] it is understandable that Chinese regulators have adopted the moral exclusion in patent law and this is primarily due to the belief that the moral exclusion represents an international custom.[125]In response to pressures from stem cell markets, some scientists from countries with restrictive policies will rush areas that have permissive policies or alternatively, some might

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the law.)

[121] Margaret E Sleeboom Faulkner, 'National risk signatures and HESC research in Mainland China' (2010) 12 Health, Risk & Society 1-46 (describing that when in 2001 President Bush announced a moratorium on the federal funding of stem cell research, China, as some other countries in Asia (India, Singapore, South Korea, Japan and Taiwan), denied any engagement with the ethics that had informed the decision. In fact, they were ready to jump into the bioethical vacuum it had created. This vacuum was alleged to be a result of western moral scruples about using fertilized human cells, alleged absent in the East.)

[122] Part II Chapter 1 of Guideline for patent examination by the State Intellectual Property Office of China.

[123] Liu Li Dong, 'Analysis of the possibility apply for patent of HESC' (2013) 20 Hospital Management Forum 9.

[124] *ibid.*

engage in the activities conducted in more permissive areas. Likewise, Chinese scientists and doctors will blur what can and cannot be done due to a lack of medical risks or moral concerns. HESC research involving therapeutic cloning and other sensitive procedures cannot be effectively monitored, resulting in biomedical adventurism[126] that could create a nightmare for the entire legal and social infrastructure. Therefore, the author believes that moral exclusion is a necessity in the circumstance that human embryo is not treated as human being.

3.6.3 Whether the Moral Exclusion is Proper in China's Patent Law?

The next question is whether the moral exclusion in patent law is proper? The first edition of China's patent law was drafted with reference to the patent law of other countries, particularly the UK.[127] The China's Article 5 is the same as Article 53 of the EUROPE Directive. Additionally, in the later revision to the patent law, Article 5 was not substantially modified. Is it proper to include a moral exclusion in the patent law though? In my view, patent law should not be used as a tool to prohibit unethical research because the law's primary goals are to protect inventions and encourage creativity. Because the core aim of the patent law is to protect invention and encourage creation. The principles and clauses contained in the patent law should represent the spirit of that law. With respect to moral exclusions, HESC research could still be continued or sponsored in the absence of patent protection for the resulting products.[128] For example, in China, unverified stem cell therapy could be carried out in the clinics and hospitals.[129]

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125 *Supra* note 93.

126 Doring Ole, 'Chinese researchers promote biomedical regulations: what are the motives of the Biopolitical Daw in China and where are they heading?' (2004) 14 Kennedy Inst. Ethics Journal 39-42 (commenting that the positivistic principle "if an action is not illegal, by definition, it is legal" does not apply in China. Taking advantage of the fact that policymaking lags behind scientific and economic development, in terms of the entire legal and social infrastructure, amounts to biomedical adventurism.)

127 Wei Dong, 'Study on patentability of HESC related inventions' (2011) East China University of Political Science and law, master thesis.

128 See Graeme Laurie, *supra* note 2 at 64.

129 Lianming Liao and Robert Chunhua Zhao, 'An overview of stem cell based clinical trials in China' (2008) 17 Stem Cells & Dev. 613-615. (reporting that at the Fourth Military Medical University of China

Therefore, it would be more proper to issue a specific regulation related to moral standards for HESC research. Any invention permitted by that specific law should be patentable. Immoral research should be forbidden from the beginning instead of at the patent-application stage.[130] Moreover, from an economic point of view, restricting immoral research from the beginning could save a tremendous amount of time and money. It seems to be better to implement specific legal regulations applicable to HESC research than to include a general moral exclusion in the patent law.

3.7 Conclusion

This chapter three has examined the regulation of HESC research in China. Although HESC funding strategy is successful, we could also conclude that the legal framework of China on HESC is still unprepared for this comprehensive issue. Regarding the differentiation, use and preservation of HESC, both patent law and its guideline do not provide any prohibitive provisions. Moreover, the Ethical Guideline for HESC research lacks the relevant moral ground for definition as well as the relevant moral objection reason. The prohibition of the transfer of the embryo into the uterus in Ethical Guideline could not clearly demarcate the line between moral research and immoral research.

As the above passage demonstrates, public debate on HESC research might be considered a political risk due to its potential in undermining HESC research.[131] Due to the lack of the public debate on HESC research, the legal framework of China on HESC is still far from perfect. Neither China's patent law nor the Ethical Guideline by the Ethic Committee provided any

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further used peripherall blood monocytes that had been induced to differentiate into functional hepatocytes in vitro to treat patients with hepatitis B virus (HBV)-related decompensated liver cirrhosis.); see also *supra* note 861 (reporting that Beike Biotech was set up in Shenzhen, the first special economic zone of China on 18 July 2005. It collaborates with hospitals and treats patients in the hospitals and then shares the resulting profit. Until 2008 Beike cooperated with 13 hospitals; six centers were added in 2008, and five new centers will be initiated in 2009.)

[130] Zhu Huan, 'Patentability of embryonic stem cells related inventions' (2008) East China University of Political Science and law, Master's thesis.

[131] *Supra* note 114

prohibitive provisions towards the differentiation, use and preservation of HESC. Although the Ethical Guideline forbid to transfer the embryo into the uterus, due to the lack of relevant moral definition and moral ground for objection reasons, the line between moral research and immoral research is blurred. In addition, there are mainly two disputes in patent law: one is whether the Article 5 of patent law is the legitimate reason to exclude HESC research to be patented; the other is whether adult stem cell has the practical applicability under the Article 22 of patent law. Practically, many cases testified that moral objection in Article 5 is allowed for patent exclusion. Patent application involved with adult stem cell is insufficient in practical applicability and therefore could not be patented. However, China has appeared to be a powerhouse in HESC transfer. Despite that the government concerns with the safety and quality of transferring stem cell research from laboratories into the clinics, stem cell therapy is booming in clinics and hospitals. Lacking transparent legal framework and proper supervision, hospitals and companies could easily carry out stem cell therapy in patients and collaborate with each other on any level. In general, based on the previous analysis, the author proposed that China should establish specific legal documents on HESC research instead of putting moral exclusion in the patent law. The specific legal document should clear the lines between allowed research and prohibited research. Moreover, in terms of HESC research transfer, state legislation is more proper than the ethical guideline considering the different execution.

Referring to patent law in China, there are two core issues. One focus is on whether the inventions related to HESC are excluded from patents based on Article 5 of patent law - 'no patent right should be granted for any invention-creation that is contrary to the laws of the State or social morality'.[132] Based on case analysis, the author found that most patent applications involving HESC have been refused due to moral reasons. But,

[132] The Article 5 of patent law of the People's Republic of China.

many such applications have been granted after they have deleted the human element in their claims.[133] The other core issue contemplates whether adult stem cells have the practical applicability under Article 22 of patent law - 'practical applicability which means that the invention or utility model can be made or used and can produce effective results'.[134] In practice, such patent application lacks a practical applicability due to the fact that it comprises the surgical method.

In this chapter, the author has proposed three recommendations. First, moral exclusion should not be concluded in patent law where the inadequacies of China's HESC regulation are exposed. Since China has a very different moral standard compared with Western countries, Chinese researchers or clinicians tend to be vague on what is allowed and what is prohibited. The author argues that it is better to have the specific legal documents on HESC research rather than putting the moral exclusion in the patent law. Second, referring to the application and transfer of HESC research, it seems to be better regulated by the state legislation rather than by the guideline. Specific regulation on stem cell research by the government is urgently needed, in particular concerning the implementation clauses in the government control towards stem cell research and its transfer, the detailed issues of the ethic committee and the establishment of an effective and reasonable system for applying stem cell research transfer.

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[133] Tang Hua dong and Wang Da Peng, 'The analysis of the legal protection on HESC patent in China' (2013) 5 Intellectual Property 52.
[134] The Article 22 of patent law of the People's Republic of China.

CHAPTER FOUR: THE US MODE ABOUT MORAL-BASED REGULATIONS OF HESC RESEARCH: INCONSISTENT POLICIES ON FEDERAL FUNDING CONTROL OF HESC RESEARCH

4.1 Introduction

The question of the morality of HESC related invention and the inadequate HESC regulation in China has been widely addressed in previous chapter. This chapter will address how the US effectively deals with the patentability and morality disputes on HESC. In the US, regulation of HESC research primarily centres on federal-funding control, not moral control.[1] The story of HESC regulations in the US involves a battle between the executive and judicial branches, along with a battle between federal and state government. For decades, the primary moral concern addressed by HESC regulation involved whether an embryo is a legal person.[2] Unlike in the EUROPE and China, US patent law does not contain a moral exclusion. However, Law is not only a moral reflection of ethics but also involves governmental authority. Law shapes and provides a mechanism to balance the relationship among curing diseases, scientific advances and human dignity. The regulation of HESC is not a simple permission or prohibition. In previous years, the complexity of this issue has been implied by the federal government's strategies. Nevertheless, HESC research is worthy of attention from the White House and Congress.

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* It is acknowledged that section 4.3 was abstracted from my journal article entitled 'Between Scylla and Charybdis: Patentability and Morality related to HESC' 6 (2014) 1 American University Intellectual Property Brief (forthcoming); section 4.2 and 4.4 was abstracted from my article entitled 'Will Diversity Regulations Disadvantage HESC Research: A Comparison Between EUROPE and US' 25 (2014) Depaul Journal of Art, Technology and Intellectual Property Law (forthcoming)

[1] David B Resnik, 'Embryonic Stem Cell Patents and Human Dignity' (2007) 15 Health Care Anal 211-222 (observing that patent examiners focus on technical questions concerning novelty, non-obviousness, utility, and disclosure, while the courts focus on policy questions related to economic development, competition, and scientific and technical innovation.)

[2] See Chapter Two.

It is necessary to have an overview of the core of US political system—the social contract—before looking into the specific issue of HESC.[3] According to Jean Jacques Rousseau, the social contract can be described as follows: 'each of us puts his person and all his power in common under the supreme direction of the general will; and in a body we receive each member as an indivisible part of the whole'.[4] As for HESC research, there is a question of whether stem cells are suitable for us? In fact, this question is not deeply debated in the US. Instead of this, whether federal funding should be used in HESC research becomes the focus of argument.

This chapter examines HESC regulations at both the federal and the state levels, including the federal Bayh-Dole Act regime for licensing patents, the Dickey-Wicker Amendment prohibiting federal funding on research related to the destruction human embryos, Proposition 71 and the California Institute for Regenerative Medicine (CIRM) licensing patents regime.[5] Comparing various regulations and policies allows further analysis of the jurisdictional conflicts on HESC research. In addition, it discusses the roles and relationships among institutions, government and business in the US, especially the Wisconsin Alumni Research Foundation (WARF).[6] It currently holds some fundamental HESC patents, such as the patent related to isolating stem cells.

The approach adapted by the US government is that federal funding control of HESC research rather than patent control. This 'patent first, question later' strategy inevitably brought some problems, for example the legal consistency. Different administrations made various policies towards HESC research, for instance, over past years, President Clinton was permissive towards HESC research but President Bush was negative. As a result, many researches were left unfinished. Due to the negative policies, HESC researches had to rely on

[3] Jean Jacques Rousseau, The Social Contract (1st ed., Create Space Independent Publishing Platform2010) 1-138

[4] *ibid.*

[5] See <http://www.cirm.ca.gov> accessed October 28 2013.

private funding resulting in the stagnant researches. In order to proceed with research, the laboratory relied on private funding and bought extra equipment to distinguish federal funding research form non-federal funding research, which is a big waste. Although President Obama tries to lift the ban on federal funding on HESC research, it seems that research standards are still blur neither in his speech nor in NIH Guideline.[7] It could be say that the Obama policy was not as meaningful as it seems to be. Moreover, the regulations in state level also made their contribution to the development of HESC research especially the California Proposition 71.

In the US, the Government apparently favours intellectual property protection with technology advance. As stated in case *Diamond v Chakrabarty*, 'everything under the sun made by man is patentable'.[8] According to US patent law, an invention should satisfy the requirement of newness, non-obviousness, utility and disclosure to be eligible to be patented.[9] However, the Board of Patent Appeals and interferences (BPAI) hold the view that 'a claim directed to or including within its scope a human being will not be considered to be patentable subject matter under section 101 of US 35 Code'.[10] This is also traceable in case *Lowell v. Lewis* that requires patentable invention should not be 'injurious to the well-being, good policy or sound morals of society'.[11] Despite of these prior rulings, the United States Patent and Trademark Office (USPTO) grant three patents to the Wisconsin Alumni Research Foundation (WARF).[12] The first patent NO.5, 843, 780 on primate ES cells was issued on December 1, 1998.[13] On 13 March 2001, the second

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[6] See <http://www.warf.org> accessed October 28 2013.

[7] See Sheryl Gay Stolberg, 'Obama is leaving some stem cell issues to Congress' (2009) New York Times, March 8 2009 <http://www.nytimes.com/2009/03/09/us/politics/09stem.html> accessed October 28 2013.

[8] *Diamond v Chakrabarty* [1980] 447 US 303, <http://supreme.justia.com/us/447/303/> accessed October 28 2013.

[9] Section 101-103 United State Code Title 35-Patents

[10] US Patent and Trademark off Notice: Animals-Patentability, reprinted in 1077 Official Gazette Patent and Trademark off. 24 (April,7, 1987), <http://www.jstor.org/pss/797469> accessed 28 October 2012

[11] Lowell v Lewis [1817] 15 F Cas 1019

[12] U. S. Patent No.5, 843,780, U. S. Patent No.6, 200,806 and U. S. Patent No.7, 029,913.

[13] Primate Embryonic Stem Cell, U. S. Patent No.5, 843,780 (filed Jan.18,1996)(issued Dec.1,1998)

granted patent NO.6, 200, 806 directed attention to human ES cells.[14] Then on April 28 2006, the third patent NO.7, 029, 913 is related the culture and discovery human or primate embryonic stem cells.[15]However, these three patents were challenged by the Public Patent Foundation (PUBPAT) and California-based Foundation for Taxpayer and Consumer Rights (FTCR).[16]

4.2 "First Patent, Then Questioned"-the Approach of Patentability of Research Involving HESC Research under Moral Concerns

Although there is no particular clause on prohibiting patent on the grounds of morality in US patent law, general moral concerns do exist when considering patentability of inventions. The ruling of case *Lowell v Lewis* in 1817, which is the origin of modern usefulness doctrine, stated that 'the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society'.[17] An invention must meet the standards of morality before it satisfies the requirement of the usefulness. Section 101 of 35 U.S.C. regulates 'to be patentable, an invention must be useful. This requirement is known in patent law as utility'.[18] Therefore, the word "moral" integrated into the word "useful". Thus, moral violation could be one possible situation of lacking utility. In *Ex parte Latimer* 1889, the patent office stated that patenting living organism is "unreasonable and impossible".[19]

To pursue a competitive position in the HESC market, the legislation at the federal level is a vacuum in fact. Moral opposition seems to have little impact on patenting inventions related to HESC research in the US. In light of prior rulings, HESC could not be patented due to morality issues; however, in 1980, the Supreme Court of the US opened the door to granting patents on

[14] Primate Embryonic Stem Cell, U. S. Patent No.6, 200,806 (filed Jan.26,1998)(issued Mar 13,2001)
[15] Primate Embryonic Stem Cell, U. S. Patent No.7, 029,913 (filed Oct 18,2001)(issued Apr 18,2006)
[16] McDermott Elleen, 'USPTO backs WARF stem cell patents' (2008) 178 Managing Intellectual Property 62.
[17] *Lowell v Lewis,* 15 F.Cas.1019 (1817)
[18] United State Patent Law

"non-naturally occurring living substances" in *Diamond v. Chakrabarty.*[20] Since the *Diamond* ruling, thousands of genes, animals and living materials were granted patents. In 1987, the US Patent Office issued a notice clarifying that living organisms are patentable subject matter.[21] The US Patent and Trademark Office Board (USPTO) of Patent Appeals and Interferences (BPAI) then shed further light on patenting human beings, explaining that 'a claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C § 101'.[22] The rationale behind the USPTO's explanation is that patenting human life is similar to slavery. In 1998, the first HESC patent was granted with little moral objection.[23] Nevertheless, the USPTO declared in a statement that 'inventions directed towards human/non-human chimeras could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement'.[24] According to *Juicy Whip, Inc. v. Orange Bang*[25], the United States Court of Appeals for the Federal Circuit held that the Patent Office should not play a role in determining whether an invention is moral.[26]

4.2.1 "Bayh-Dole Model" in HESC Research-Allow Universities to Patent on Research by Federal Funding

Adopted in 1980, the Bayh-Dole Act addressed the low utilisation rate of government-owned patents.[27] This Act, sponsored by two senators, Birch

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19 Dec. Com. Pat.123, 126 (1889).
20 *Diamond v. Chakrabarty*, 447 US 303 (1980).
21 US Patent and Trademark office Notice: Animals Patentability, reprinted in 1077 Official Gazette Patent and Trademark Office, 7 April 1987 <http://www.uspto.gov/web/offices/pac/mpep/s2105.html> accessed 24 July 2014.
22 *Ibid*.
23 David B Resnik, 'Embryonic Stem Cell Patents and Human Dignity'(2007) 15 Health Care Anal 211.
24 Media Advisory, 'Facts on Patenting Life Forms Having a relationship to Human' US Patent and Trademark Office, April 1 1998 <http://www.uspto.gov/news/pr/1998/98-06.jsp> accessed 14 July 2014.
25 Juicy Whip, Inc. v. Orange Bang, 185 F.3d 1364 (Fed. Cir.1999)
26 *ibid*. (involving with a dispute on a patent. This patent owner is a beverage dispenser called post-mix beverage dispenser with an associated simulated display of beverage, Juicy Whip sued Orange Bang for patent infringement. The court held that patent lacked utility and was therefore unpatentable.)
27 Wendy H. Schacht, 'The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology' (2005) CRS Report for Congress Order Code RL32076

Bayh of Indiana and Bob Dole of Kansas, was codified at 35 U.S.C. § 200-212.The aim of this Act is to use

> '[T]he patent system to promote the utilization of inventions arising from federally supported research or development, ...and to promote collaboration between commercial concerns and non-profit organizations, including universities…'[28]

The Bayh-Dole Act contains march-in provisions that could assure the commercial rights of grantees.[29]

Aided by the Bayh-Dole Act, universities and small businesses rapidly established technology transfer groups and introduced experts in patenting inventions.[30] The Bayh-Dole Act was widely viewed as a success in bringing new technologies to the public.[31] The Act aims to 'give grantee inventors and those with whom they contract a reasonable degree of certainty'.[32] In terms of HESC research, a system based on the "Bayh-Dole Model" was created following the successes of California and Wisconsin.[33] In this system, there were attempts to place in the public domain, which made them accessible to

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<https://www.autm.net/Bayh_Dole_Act_Report.htm> accessed 24 July 2014.

[28] The Bayh-Dole Act, P.L.96-517, Section 200.

[29] 35 U.S.C. §203(a) states that "[w]ith respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees; (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements arenot reasonably satisfied by the contractor, assignee, or licensees; or (4) action is necessary because the agreement required by section has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section."

[30] Michael S Mireles, 'States as innovation system laboratories: California, patents and stem cell technology' (2006) 28 Cardozo L. REV. 1133-1159.

[31] See Ann L. Gisolfi and Anthony M. Insogna, "States fund stem cell research' (2005) the national law journal; see also *supra* note 18.

[32] Owen C B Hughes, Alan L Jakimo and Michael J Malinowski, 'United States regulation of stem cell research: recasting government's role and questions to be resolved' (2008) 37 HOFSTRA LAW REVIEW 383, 419.

stem cell repositories or banks.

Despite of huge success, it was argued that the Bayh-Dole Act did not significantly lower the treatment price.[34] As showed by US granted biotechnology patents, the Bayh-Dole received sharply criticisms for promoting patent on fundamental research. As professor Rebecca Eisenberg pointed out, 'proprietary claims have increasingly moved upstream' and universities rushed to patent discoveries instead of waiting further scientific studies.[35]

4.2.2 Patent on Embryo: the Opening of "Human Embryo Farms"

Based on the "Bayh Dole Model", there was patent inflation in the HESC area. In a 2002 speech, President George W. Bush conveyed his worry over" human embryo farms"[36] and urged the US Senate to approve a total ban on the cloning of human embryos.[37] When the USPTO faced an application for a patent on a cloned or genetically modified human embryo, it applied the substantive part of the US Patent Law, Title 35 of the United State Code, under which an invention is patentable if it satisfies patentable subject matter, which requires a showing the subject matter is novel, non-obvious and utilitatrian.[38] Back in 1980, however, the United States Supreme Court opened the door to granting patents on "non-naturally occurring living substances" in *Diamond v. Chakrabarty.*[39] Since then, thousands of genes,

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[33] *ibid*.

[34] See NIH Response to the Conference Report Request for a plan to ensure Taxpayers' Interests are Protected, the study of National Institutes of health conducted in July 2001, <http://www.ott.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf> accessed 24 July 2014.

[35] Arti K.Rai and Rebecca S. Eisenberg, 'Bayh-Dole reform and the Progress of Biomedicine' (2003) 66 Law and contemporary problems 289

[36] Using cloning technology, scientists could create billions of unfertilized human embryos for research or therapeutic use, called "human embryo farms".

[37] President Bush on cloning, April 10, 2002 <http://www.pbs.org/newshour/updates/april02/bush-cloning_4-10.html> accessed 12 December 2011

[38] Section 101, 102, 103 of Title 35 of the United State Code.

[39] *Diamond v. Chakrabarty*, 447 US 303 (1980). (The application asserted 36 claims related to

animals and other living materials have been the subjects of patent protection. Some scientists hope that patents will be granted for human embryos so that the scientists will have the exclusive right to license others and collect royalty fees. Alta Charo, a support of human embryo patent from University of Wisconsin, highlighted the fact that 'investors hope for a return on their original investment with the basic research, but with no patent, there is no return'.[40]

Meanwhile, other experts hold differing views from Charo. Congressman Dave Weldon, for example, believes that 'no one should be able to own a human being at any stage of development'.[41] Similarly, the National Right to Life Committee (NRLC) chairman Douglas Johnson commented that 'a member of the human family can never be regarded as a mere invention, or as intellectual property'.[42] With their support, in 2004, the Weldon Amendment, contained in annual Commerce, Justice and Science Appropriation bills, was enacted, banning patents on human embryos for the first time.[43] Section 518 of the Weldon Amendment states '[n]one of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism'.[44] On September 16, 2011, the Weldon Amendment, which was included in the America Invents Act (AIA) became an integral part of US patent law.[45] Granting a patent for a

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Chakrabarty's invention of a bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids. The patent examiner allowed the claims falling into the first two categories, but rejected claims for the bacteria. His decision rested on two grounds: (1) that mircro-organisms are products of nature and (2) that as living things they are not patentable subject matter under 35 U.S.C. § 101)

[40] Congress bans patents on human embryos NRLC-backed Weldon Amendment survive BIO attacks, NRLC Federal legislation 2004 <http://www.nrlc.org/killing_embryos/Human_Patenting/WeldonAmendmentEnacted.pdf> accessed 11 December 2011.

[41] *ibid*.

[42] *ibid*.

[43] *ibid*.

[44] Alan Fram, 'Panel Oks Anti-Abortion Provision' (the Washington post, July 14 2004) <http://www.washingtonpost.com/wp-dyn/articles/A49778-2004Jul14.html> accessed 10 December 2011.

[45] Jeremy Kryn, 'Amendment banning human embryo patents becomes permanent US law' (LifeSiteNews.com, September 20 2011) <http://www.lifesitenews.com/news/congress-makes-amendment-banning-human-embryo-patents-permanent/> accessed 13 December 2011.

human embryo is permanently prohibited in the US under section 33 of the AIA which states that 'no patent may issue on a claim directed to or encompassing a human organism'.[46]

However, according to Dr Weldon's explanation on the House floor, the Weldon patent ban was only restricted to human embryos or fetuses, not including HES cells.[47] HESC regulation at the federal level remains a vacuum under the Bayh-Dole regime and the Weldon Amendment. The US position toward HESC is liberal in regard to patent protection. There is no uniform regulation of procurement of embryos or the use of HESC lines at the federal level. A vacuum in HESC funding is also noticeable at the federal level.

4.2.3 HESC Patents Challenges: From Technical Criterion to Moral Concerns

Second to none, inventions related to HESC in US is extremely widely patented and protected. The focal points of world debate on the issue of HESC are three fundamental patents held by the Wisconsin Alumni Research Foundation (WARF). In 1998, after James Thomson published work on the isolation of embryonic stem cell lines, WARF (as his representative) applied to the USPTO to patent that work.[48] Three basic patents, known as 780, 806 and 913 patents, were issued to WARF. These patents are said to be some of 'the strongest intellectual property holdings in the whole stem cell field, establishing control at the very root of all possible lineages of cellular differentiation'.[49]The claims of these patents are quite broad. Patent 780 issued in 1998 covers 'a purified preparation of primate embryonic stem cells'.[50] Patent 806 issued in 2001 contains 'a purified preparation of

[46] America Invents Act of 2011, <http://judiciary.house.gov/issues/issues_patentreformact2011.html> accessed 15 December 2011.
[47] *Supra* note 9.
[48] United States Patent, 5,843,780, United States Patent, 6,200,806 and United States Patent, 7,029,913.
[49] Bergman K and Graff GD, 'the global stem cell patent landscape: implications for efficient technology transfer and commercial development' (2007) 5 Nature Biotechnology 419
[50] United States Patent, 5,843,780, December 1 1998

pluripotent HESC'.[51] Patent 913 issued in 2006 includes 'a replicating in vitro cell culture of HESCs comprising cells'.[52]Patent 780 and 806 claim the product embryonic cells. Patent 913 claims both product embryonic stem cells and the method of obtain them.

WARF holds a fee-based and royalty-bearing license to make, use and sell HESC lines. WARF has been widely criticised for its restrictive policy towards educational and scientific institutions because it 'slowed distribution of cell lines and cast a shadow over the ability of researchers to advance knowledge'.[53]In the commercial area, WARF transferred an exclusive license to Geron to develop products derived from the patents. Because the patents cover broad HESC technology, any commercial potential is restricted to exploitation by Geron.[54] Rovert Lanza from Advanced Cell Technology in Worecester, Massachusetts said that 'we would be sued if we even tried to develop insulin-producing cells to treat diabetes.'[55]

Although the three patent applications were refused for reasons of moral concern by the EUROPE, in the US, they were challenged for technical reasons. The Foundation for the Taxpayer and Consumer Rights, in conjunction with the New York-based Public Patent Foundation, challenged the patents on grounds of obviousness over prior art.[56] In addition, biomedical researchers worried that the USPTO's lax practices could stifle scientific innovation by granting patent holders overly broad rights over basic knowledge and research tools.[57] In response to concerns related to the adverse scientific and economic impact of the lack of Guideline for its patenting criteria, the USPTO received both oppositions.

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[51] United States Patent, 6,200,806, March 13 2001

[52] United States Patent, 7,029,913, April 18 2006

[53] Aurora Plomer, Kenneth S Taymor and Christopher Thomas Scott, 'Challenges to HESC Patents' (2008) 2 Cell Stem Cell 13-17.

[54] Constance Holden, 'US patent office casts doubt on Wisconsin Stem Cell Patents' (2007) 316 Science 182. (Rovert Lanza, from Advanced Cell Technology in Worcester, Massachusetts, claimed that we would be sued if we even tried to develop insulin-producing cells to treat diabetes.)

[55]*Ibid*.

[56] Request for Ex Parte Reexamination of US Patent No. 5,843,780, Request for Ex Parte Reexamination

Subsequently, WARF's patent application was appealed amidst intense criticism. One objection related to the cost and restrictiveness imposed on researchers by WARF's licensing practices. However, in my opinion, the reason for the high cost of HESC research is the patent licensing fee of patent. For example, the Thomson patents allow WARF to demand money from anyone who wants to use its stem cells, thus increasing the cost of research and restricting that research to those who can afford to pay.[58] WARF's approach to licensing by WARF has been verified to "be overly costly, cumbersome and restrictive."[59] Although opponents of HESC research have attempted to use the patent system to stop what they consider unethical research, there is little basis in the US patent law for moral barriers against the WARF patents.[60] The fundamental reason that no explicit morality clause exists in US patent law is the lack of a fiery debate in the US over whether HESC should be considered patent-eligible subject matter.

These three patents aroused much controversy in scientific community. Many Scientists were on the opposite side and argued that these patents were too broad.[61] As Tim Friend indicated, WARF is claiming intellectual property rights in every human ES cell line that qualifies for federal funding under President Bush's plan.[62] It is no exaggeration to say that patent 806 and 780 reference almost the whole field of stem cell research.[63] In July 2007, the Foundation for Taxpayer and Consumer Rights (FTCR) and the Public Patent

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of US Patent No 6,200,806 and Request for Inter Parties Reexamination of US Patent No 7,029,913.

[57] *Supra* note 51.

[58] Joseph Itskovitz, *Wisconsin Scientists Culture Elusive Embryonic Stem Cells*, November 6, 1998 <http://www.sciencedaily.com/ releases/1998/11/981109085437.htm> accessed 2 November 2013.

[59] John M Golden, 'WARF's stem cell patents and tensions between public and private sector approaches to research' (2010) 38 Journal Law Medicine and Ethics 314-315. (pointing out that WARF's patents cover all use of long-lasting hESC lines in the United States has been criticized as overly aggressive. WARF has been accused of improperly asserting control over hESCs and methods of maintaining them that extends far beyond the particular kinds of hESCs and methods developed by Thomson.)

[60] *ibid.* (analyzing that United States patent law provides comparatively little basis for such a morality-oriented barrier to WARF's patents. Instead, challenges to WARF's patents in the United States have attacked the value of Thomson's scientific contribution.)

[61] Friend T, 'Free Stem-Cell Lines Will Be Offered to Researcher' *USA TODAY* (Mclean 22 August 2001) D10; see also Beardsley D, 'A Two-Front Assault On The Stem Cell Patents' (2007) The John Marshall Review Of Intellectual Property Law 501

[62] *ibid.*

[63] *ibid.*

Foundation (PUBPAT) applied to re-examine the patents on the basis of prior art and obviousness.[64] Also there were some notions that these patents were too broad and might become the obstacle to the stem cell research.[65]

The key point of obviousness to be examined is whether the prior art which applied to species such as mouse and pig can obviously extend to humans. According to the plentiful previous experiments, the inference is that the method applied to animal cannot certainly suit to human. The complexities of living organism lead to the uncertainty of the outcome. Thus, I support the viewpoint that these patents are non-obvious.

The main argument for stifling the stem cell research is that the monopoly of WARF is driving both research and money out of the United States. However, WARF had not prohibited the application of these patents in stem cell research. WARF has changed their policies and distributes HESC in a cheap price to researchers.[66] Perhaps the bad funding policies of government should responsible for the flow.

After revoking three patents on 3 April 2007, the United States Patent and Trademark Office finally upheld them in 2008.[67] The WARF stem cell patents were ruled non-obviousness under the light of prior art; however, the claims were restricted to damages which beginning when the patent challenge is complete.[68]

4.2.4 Stem Cell Patent: Impediment or Not?

Patent law is designed to 'added the fuel of interest to the fire of genius'.[69]

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64 Foundation for Taxpayer and Consumer Rights.
65 Washburn J, 'The legal Lock on Stem Cells' *L.A.TIMES* (Los Angeles 12 April 2006) 13
66 Madison WI, Wisconsin Alumni Research Fundation Changes Stem Cell Policies to Encourage Greater Collaboration, (Willcell research institution, 22 Jan 2007) <http://www.wicell.org/index.php?option=com_content&task=view&id=166&Itemid=170> accessed online 10 October 2011
67 McDermott E, 'USPTO backs WARF stem cell patents' (2008) 178 Managing Intellectual Property 62.
68 *ibid*.
69 Abraham Lincoln, 'who was the only US president to hold a

However, because licensing is not compulsory, many patent holders may choose to license on their own or never license instead of licensing others to use the patented invention.[70] In terms of human stem cell research, the Wisconsin Alumni Research Foundation (WARF) holds three ground-breaking patents that cover methods for separating primate embryonic stem cells and HESCs as well as purified preparations of these two cells.[71] These patents are so broad that many people are concerned about their potential to hinder stem cell research.[72] In the Loring and Campbell study, WARF imposed unreasonable restraints on the patents.[73] The result of this rigid restriction is that research activities might be construed as infringement. Furthermore, to some beginning and small biotechnology companies, a high licensing fee is a nightmare. The report provided an instance where 'even if the company's research is noncommercial, WARF still requires a commercial license, which costs an upfront fee (typically 125,000 dollars), with 40,000 dollars annual maintenance fees to retain the license'.[74] In addition, Jeanne Loring, who is an embryologist at the Burnham Institute in California, is unable to run her company because she could not obtain a license from WARF for a reasonable fee. She said that 'the greatest roadblock to the development of HESC research in the United States is WARF's fundamental patent'.[75]

Some scholars have offered some resolutions. For instance, Merrill Goozner suggested using "patent pooling" to solve this paradox.[76] This proposed

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patent',<http://inventors.about.com/od/lstartinventors/a/Abraham_Lincoln.htm> accessed 28 October 2012.

[70] Loring F Jeanne and Campbell Cathryn, 'Intellectual Property and HESC Research' (2006) 311 Science 1716-1717

[71] Wisconsin Alumni Research Foundation <http://www.warf.org/index.jsp> accessed 28 October 2012

[72] See Knowles P Lori, 'Stem Cell Patent' [2008] Stem Cell Network <http://www.stemcellnetwork.ca/uploads/File/whitepapers/Stem-Cell-Patents.pdf> accessed July 23 2011; Also see *supra* note 81.

[73] *Supra* note 67.

[74] *ibid*.

[75] See Wadman Meredith 'Licensing fees slow advance of stem cells' (2005) Nature 18 May 2005 <http://www.nature.com/nature/journal/v435/n7040/pdf/435272a.pdf> accessed 23 July 2011.

[76] Goozner M, 'innovation in biomedicine: can stem cell research lead the way to affordability' (2006) 3 PloS Medicine <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030126 >

"patent pool" requires that 'all grant recipients agree to donate the exclusive license to any insights, materials, and technologies that they patent to a common patent pool supervised by a new, non-profit organisation set up for that purpose.[77] A patent pool serves as a one-stop shop where investigators can obtain no-cost or low-cost licenses for subsequent research'.[78] To prevent conflicts involving commercial benefit, the patent pool is coupled with a prize system, which is consistent with the intellectual property system. In this prize system, '[i]nventors and their institutions would retain the IP rights to their inventions. Any revenues generated from the prize could be shared with the inventor and reinvested in research and education. Though the rights to the invention would be turned over to the pool, the technology-transfer officials at an institution would still have an incentive (their share of the prize) to aggressively pursue its use by downstream scientists in the public or private sectors if they feel their invention is not being properly utilized'.[79] This community pool concept seems to be feasible.[80]

4.2.5 The Public's "Right to Know" Right

One of the most important financial sources of HESC research is from the government. Thus, some scholars believe that the fruit of HESC research should be shared with the public and be available to anyone who wishes to exploit it.[81] This belief inevitably raises the issue of the lack of balance between private intellectual property rights and public access rights. Under the Bayh-Dole Act, small businesses and non-profit entities, such as WARF, have the right to be granted patents created with federal support.[82]

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accessed August 2 2013.

[77] *ibid*.

[78] Goozner Merrill, 'Innovation in Biomedicine: Can Stem Cell Research Lead the Way to Affordability?' [2006] 3 PLoS Medicine <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030126> accessed 2 August 2011

[79] *Ibid*.

[80] Frazier B H, *New Perspectives on Human Embryonic Stemcell Research: what you need to know about the legal, moral &ethical issues* (Vandeplas Publishing,Lake Mary2009) 342-344

[81] Eisenberg Rebecca, 'Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research' (1996) 82 Virginia Law Review 1663-1691

[82] Bayh-Dole Act, 35 United States Code, 2000, http://uscode.house.gov/download/pls/35C18.txt (last

According to the study by Rebecca Eisenberg, 'both the pharmaceutical industry and the biotechnology industry are heavily dependent on patents'.[83] Therefore, the issue is whether the public benefit created by the patent outweighs the public investment cost.

Two factors need to be considered as to the cost of producing the invention and the cost of commercialising it.[84] First, in most circumstances, government funds only pay the salaries and research costs of scientists. Even if the public funds pay the cost of invention, a patent is still a significant motivation for commercialising the invention. In addition, before an invention goes to market, the research has already incurred costs in the millions of dollars. What is worse, taking such an invention to market is very risky.[85] No one would be willing to accept that the public should take responsibility for the fee.

However, despite of the negative effect of patents in technological innovation, to some extent, patents still promote technology transfer and encourage scientific advance.[86]

4.3 Political Interventions - the Federal Funding Control of HESC Research under Moral Concerns

With respect to HESC research, the question of whether stem cells are persons is not hotly debated in the US. Instead, the focus of the argument is whether federal funding should be granted for HESC research. Indeed, there are no federal regulations in the US that restrict HESC research. On the contrary, control over HESC research relates to the allocation of federal funding.[87]

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visited 09/07/2011)

[83] *Supra* note 89.

[84] Korobkin Russell and Stephen R Munzer, *Stem Cell Century-law and policy for a breakthrough technology* (Yale University Press, New haven and London2007) 135

[85] If the licensee is unable to either satisfy Food and Drug Administration requirements or create a technology able to reliably mass-produce the necessary raw material, the investment will earn no return at all. *See supra* note 92.

[86] *Supra* note 89.

[87] Christine Vestal and Staff Writer, 'Stem cell research at the crossroads of religion and politics',Pew Forum paper, July 17, 2008 available at

Generally speaking, there are three levels of federal funding of HESC research: complete prohibition, limited prohibition and permission. For a long time, the government banned federal funding of any research that involved human embryos.[88] In early cases, the court seemed to outweigh the protection of experimental subjects over the protection of research.[89] Until the 1930s, the attitudes of society towards human subjects research began to change. In case *Stammer v Board of Regents of the University of New York,* the court held that the initiative and originality of experimental treatments 'should not be thus effectively stifled, especially when undertaken with the patient's full knowledge and consent and as a last resort'.[90] Then the Second World War broke out. It was an unpredictable fact to accelerating some developments in human research subjects, notably by the Nazi medical experiments concentration camps.

As time flew to early 20th century, with the development of scientific technology and growth of public concerns, HESC research was regulated by various documents.[91] The transition of democratic governments with changing nature of scientific knowledge required more involvement of government in HESC research. In 1974, the Secretary of Health, Education and Welfare approved the support for the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research (CPHS) established according to the National Research Act.[92] CPHS is the first national institution that shaped the conduct of bioethics policy in the US.[93]

<http://pewforum.org/Science-and-Bioethics/Stem-Cell-Research-at-the-Crossroads-of-Religion-and-Politics.aspx> accessed 24 July 2014.

[88] See Paul Murray McNeill, *The ethics and politics of human experimentation* (Cambridge university press, 1993) 119; also see Kyla Dunn, 'The politics of Stem cells' (NOVA science NOW, January 4th 2005) <http://www.pbs.org/wgbh/nova/body/stem-cells-politics.html> accessed 8 September 2011.

[89] See e.g. case *Jackson v Burnham* (1895); *Sawdey v Spokane Falls* (1902); *Allen v Voje* (1902); *Owens v McCleary* (1926).

[90] Jesse A Goldner, 'An overview of legal controls on human experimentation and the regulatory implications of taking professor katz seriously' (1993) 38 SAINT LOUIS UNIVERSITY LAW JOURNAL 63, 67.

[91] See e.g. Nuremberg Code, Thalidomide, Tuskegee Syphilis Study, Declaration of Helsinki and National Research Act.

[92] David W Louisell, 'National commission for the protection of Human Subjects of Biomedical and Behavioral research: research on the Fetus' (1977) 22 Villanova Law Review 300.

[93] *ibid*.

One significant work of CPHS is to launch the Institutional Review Board (IRB) report. IRB governed by Title 45 Code of Federal regulation aims to examine the experiments involving with human subjects.[94]

Then, in 1996, pursuant to Executive Order 12975, the National Bioethics Advisory Commission (NBAC) was established to protect 'the rights and welfare of human research subjects, issues in the management and use of genetic information'.[95]The NBAC's establishment was a profound historical event in the regulation of HES research because it 'has increased the awareness of US and foreign governments, international groups, the research community, and the public about complex bioethical issues, thereby helping to provide a forum for public debate of those issues'.[96]In the meantime, President Clinton required relevant executive agencies within the NBAC to report their opinions on developing human-subject-protection policies.[97]Based on an NBAC report, President Clinton signed the "Cloning Prohibition Act of 1997" to ban the creation of babies through somatic cell nuclear transfer cloning.[98]Although the history of federal involvement in HESC research is quite complex, these events are distinguishable from the jurisdictional battle over federal regulation of HESC research.

4.3.1 The National Institutes of Health Revitalization Act: Allow Federal Funding of Research Related to Embryos at the Early Stage

The Department of Health and Human Services (DHHS) is the chief US government agency providing human services, granting federal research

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94 *ibid*.

95 Executive Order 12975, October 3 1995.

96 Eiseman Elisa, The National Bioethics Advisory Commission: contributing to public policy (RAND, 2003) 130.

97 Mary Leinhos, 'The US National Bioethics Advisory Commission as a boundary organism' (2005)32 Science and Public Policy 423-426. (The Commission was granted the authority to deliberate on additional issues raised by the general public, other federal bodies and organizations, or NBAC itself.)

98 *ibid*. at 427 (Consistent with the NBAC's recommendation, the President's legislative proposal prohibits for five years the use of somatic cell nuclear transfer to create a human being and directs the NBAC to report to the President in four and a half years on whether to continue the ban.)

funds and providing health insurance. DHHS consists of eleven operating divisions. Among these divisions, the National Institutes of Health (NIH) is responsible for funding biomedical and health-related research. Initially, research related to human subjects was prohibited from receiving federal funds. In September 1988, the NIH Advisory Committee voted to lift the moratorium on the use of federal funds for fetal-tissue transplantation research.[99] In 1993, President Clinton, supported by the NIH review panel, lifted the moratorium; a congressional hearing followed.[100]

Next, the National Institutes of Health Revitalization Act authorized federal funding of research involving human fetal tissue transplantation.[101] This Act also paved the way for federal funding of research related to early-stage embryos.One federal judge Peter J Messitte commented the Act as follows:

> This law [the Revitalization Act] amended existing federal regulations governing research on human embryos, which required such research to be reviewed by an EAB before such research might proceed. Because prior presidential administrations apparently chose not to appoint an EAB, no funding for such research had in fact been approved. What the new law did was to reverse the conditions for in vitro fertilization research: it could go forward unless disapproved. Previously it could not go forward unless approved.[102]

With the endorsement of the National Institutes of Health Revitalization Act, in 1994, the NIH set up the Human Embryo Research Panel to develop policies for the use of embryos and the moral scope of that research.

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[99] The National Institutes of Health, Human Fetal Tissue Transplantation Research, report of the Advisory Committee to the Director, December 14, 1988.
[100] Helen M Maroney, 'Bioethical catch-22: the moratorium on federal funding of fetal tissue transplantation research and the NIH revitalization amendments' (1993) 9 Journal Contemporary Health Law and Policy 485-487.
[101] Research on Human Fetal Tissue Amendments Act of 1993, March 2, 1993.
[102] Case *Mary Doe v Donna Shalala*, September 26, 1994.

4.3.2 Dickey-Wicker Amendment: No Federal Funding on HESC Research Involving Destruction Embryo

Contrary to his previous position, President Clinton issued an executive order to ban federal funding of HESC research in the wake of a resounding Democratic electoral defeat.[103] In 1995, consistent with President Clinton's declaration, Congress overrode the decision to sponsor some types of stem-cell research. The Dickey-Wicker Amendment, named for Representatives Jay Dickey and Roger Wicker, was approved by Congress.[104] The Dickey-Wicker Amendment is a rider to other legislation pertaining to DHHS. It is the first regulation to focus specifically on embryo research and is also the US's most important regulation of HESC research.[105]

Subpart A of the Dickey-Wicker Amendment reflects an endorsement of the existing prohibition on embryo creation. Parallel to subpart A, subpart B adds a ban on federal funding of any research involving embryos obtained from in vitro fertilization (IVF) procedures. The Dickey-Wicker Amendment requires that:

> (a) None of the funds made available in this Act may be used for—
>
> (1) The creation of a human embryo or embryos for research purposes;
>
> (2) Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero
>
> (b) For purposes of this section, the term 'human embryo or embryos'

[103] Heather J Meeker, 'Issues of property, ethics and Consent in the transplantation of fetal reproductive tissue' (1994) 9 Berkeley Technology Law Journal 185-187 (citing profound ethical and moral questions associated with the subject, refused to follow the contrary recommendation of a National Institutes of Health panel.)

[104] The Dickey Wicker Amendment 1996.

[105] *Supra* note 100.

> includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.[106]

It is clear that research involving with destruction of embryos is excluded from federal funding. However, the problem of research using already-destroyed embryos from IVF is still unsettled, which has led to debate.

Despite the lack of federal funding, HESC research has developed and flourished with private support. In 1998, scientists claimed that they had successfully derived stem cells from human embryos and emphasized the potential of stem cells to grow into specific cells.[107] Following this landmark development, on January 15, 1999, top DHHS lawyer Harriet Rabb declared that the Dickey Amendment should not apply to derived stem cell because such cell "are not a human embryo within the statutory definition".[108] Therefore, DHHS took the position that the NIH could provide federal funding to HESC research on the ground that a stem cell could not become an organism because it had not been implanted into a uterus.[109]An NIH official said 'this opinion allows us to proceed carefully and thoughtfully with a line of research that has enormous potential for the treatment of almost every disease and condition'.[110]

In response to DHHS opinion, the NIH appointed a group of experts to

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[106] The Dickey Amendment 1996 section 509.

[107] James A Thomson, 'Embryonic stem cell lines derived from human blastocysts' (1998) 282 Science 1145.

[108] See Letter from HHS Gen. Counsel Harriet Rabb to Harold Varmus, Director, NIH, January 15, 1999. (General Counsel Rabb determined that the statutory ban on human embryonic research defined an embryo as an "organism" that, when implanted in the uterus, is capable of becoming a human being); see also Judith A Johnson and Erin D Williams, *Stem cell research: Federal research funding and oversight,* CRS report to Congress 2007 <http://www.fas.org/sgp/crs/misc/RL33540.pdf> accessed 10 October, 2012.

[109] Meredith Wadman, 'Embryonic stem cell research exempt from ban, NIH is told' (1999) 397 Nature 185-886. (According to an NIH official, This opinion allows us to proceed carefully and thoughtfully with a line of research that has enormous potential for the treatment of almost every disease and condition.)

develop appropriate Guideline.[111] Meanwhile, the notion that federal funds could be used for HESC research was backed by the Clinton administration.[112]However, seventy-seven Congressional opponents wrote two letters to the Secretary of Health and Human Services to criticize the provision of federal funding to HESC research. The writers claimed that 'Rabb makes a specious distinction by reading the law narrowly to apply only to the act of destroying embryos, and not more broadly to include any research that depends on their destruction'.[113] Jay Dickey, the author of the existing ban, also stated that stem cells derivation is 'precisely the kind of research for which we intended to ban, and did ban, federal funding'.[114]

4.3.3 NIH Guideline 2000

Regardless of the National Institutes of Health Revitalization Act and the Dickey-Wicker Amendment's contradictory interpretations, the NIH published a Guideline outlining funding-ineligible types of HESC research. The Guideline stated that the following research areas were ineligible for NIH funding:

> A. The derivation of pluripotent stem cells from human embryos; B. Research in which human pluripotent stem cells are utilized to create or contribute to a human embryo; C. Research utilizing pluripotent stem cells that were derived from human embryos created for research purposes, rather than for fertility treatment; D. Research in which human pluripotent stem cells are derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; E. Research utilizing human pluripotent stem cells that were derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg;

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110 *ibid.*
111 *ibid.*
112 Marshall E, 'Ethicists back stem cell research, white house treads cautiously' (1999) 285 Science 502.
113 Meredith Wadman, 'Congress may block stem cell research' (1999) 397 Nature 639.
114 *ibid.*

F. Research in which human pluripotent stem cells are combined with an animal embryo; and G. Research in which human pluripotent stem cells are used in combination with somatic cell nuclear transfer for the purposes of reproductive cloning of a human.[115]

The Guideline restricts the scope of federal funds to stem cells derived from 'human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment'.[116] The Guideline also established a national review panel, the NIH Human Pluripotent Stem Cell Review Group. President Clinton commented the Guideline was a proper government action because 'we cannot walk away from the potential to save lives and improve lives, to help people literally to get up and walk, to do all kinds of things we could never have imagined'.[117]

However, before the NIH could provide funding, the Bush Administration took power and conducted a legal review of Clinton-era policy. Implementation of the Guideline was halted and federal funding was never granted. Nevertheless, the Clinton Administration had already opened the door for federal funding of HESC research.[118]

4.3.4 The Bush Compromise:Accepted the Narrow Explanation of Dickey-Wicker Amendment but Exercised the Executive Power Instead of Legal Power to Allocate Funding

Immediately after President Bush took office in January 2001, he ordered 'another look at the options regarding HESC research policy', including a

[115] The Clinton administration NIH Guideline for embryonic stem cell funding, 65 Fed Reg. 51,975,Aug. 25,2000 <https://bioethicsarchive.georgetown.edu/pcbe/reports/stemcell/appendix_d.html> accessed 24 July 2014.
[116] Ibid.
[117] Nicholas Wade, 'new rules on use of human embryos in cell research' The New York Times (New York, August 24, 2000) <http://www.nytimes.com/2000/08/24/us/new-rules-on-use-of-human-embryos-in-cell-research.html?pagewanted=all&src=pm> accessed 20 October 2011.
[118] Kyla Dunn, The politics of stem cells, NOVA Science Now, April 1 2005

review of Rabb's decision.[119] Next, President Bush articulated his own policy by suspending the NIH's implementation of funding and repealing the NIH guideline. Some scientists and patients expressed anger and frustration. One unanimous member of NIH believed that 'it certainly is holding up research that could potentially affect a lot of people with a number of different diseases'.[120] Nobel laureate Paul Berg feared that 'We have a major part of the world's science talent pool, but our hands are tied behind our backs in this area'.[121]

On August 9, 2001, President Bush launched his newly crafted policy for HESC research in a national television speech. He announced that to avoid sanctioning or encouraging further destruction of human embryos, federal grants would only be available for research using the 64 stem cell lines that were already in existence.[122] The new policy claimed that

> Federal funds will only be used for research on existing stem cell lines that were derived: (1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any financial inducements to the donors. No federal funds will be used for: (1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose.[123]

President Bush's view on the ethics of HESC research appears quite different from that of President Clinton. In President Bush's speech, he

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<http://www.pbs.org/wgbh/nova/body/stem-cells-politics.html> accessed 23 July 2014.

[119] The President's Council on Bioethics, the administration's HESC research funding policy: moral and political foundations, the President's Council on Bioethics, September 2003 <https://bioethicsarchive.georgetown.edu/pcbe/background/es_moralfoundations.html> accessed 25 July 2014.

[120] Rick Weiss, 'Bush administration Order halts stem cell meeting; NIH planned session to review fund requests' The Washington Post (Washington, 21 April 2001) A02

[121] *Ibid.*

[122] See <http://www.presidency.ucsb.edu/ws/?pid=79025 > accessed October 7 2013.

[123] White house fact sheet embryonic stem cell research, August 9 2001, <http://usgovinfo.about.com/blwhrelease17.htm> accessed October 7 2013.

described the embryo as a snowflake that 'each of these embryos is unique, with the unique genetic potential of an individual human being'.[124]Stem-cell separation results in the deprivation of the embryo's human potential because it destroys the embryo. Thus, President Bush decided to 'allow federal funds to be used for research on these existing stem cell lines, where the life-and-death decision has already been made'.[125]

After the new policy was implemented, its moral, legal and political implications were hotly debated among the media, politicians, scientists and organizations. The Bush policy was known as the "Bush compromise". One reason for that characterisation is that the policy apparently straddles the line between the conservative and liberal views on the question of governing federal funding. Another possible reason is that the policy tried to satisfy both the scientific and pro-life communities.[126] In Bush policy, a five-day-old cluster of stem cells is 'not an embryo, not yet an individual, but a pre-embryo'.[127] To some extent, the Bush policy accepted the narrow view exemplified by the Dickey-Wicker Amendment. However, the Bush policy also adopted a new, broad concept embryonic human life. In addition, the Bush policy changed the executive and legislative branches' positions on the question of federal funding for HESC research. The Bush policy not only acknowledged Congress's sole authority but also exercised executive power to allocate funding.[128] This new policy inevitably raised many concerns that scientists might move to other countries. For example, due to 'the possibility of carrying out my research on HESC(s) with public support', Roger Pedersen

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[124] President George W.Bush's address on stem cell research, August 9 2001, CNN TV <http://edition.cnn.com/2001/ALLPOLITICS/08/09/bush.transcript/index.html> accessed 24 July 2014.

[125] *Ibid*.

[126] Patrick Walsh, 'Stemming the tide of stem cell research: the Bush compromise' (2005) 38 The John Marshall Law Review 1061-1068

[127] *Supra* note 79.

[128] Carter O. Snead, 'The pedagogical significance of the Bush Stem cell policy: A window into Bioethical regulation in the United States' (2005) 5 Yale Journal of Health policy, Law and Ethics 491-497 (demonstrating both an acknowledgement of congress's sole authority to appropriate federal funds and a robust exercise of the President's authority as head of the executive branch to allocate the appropriated funding according to the administration's priorities.)

who discovered the development of stem cells turn into internal organs in fish, moved to Britain.[129]

4.3.5 The Report from President Council on Bioethics Clarified that the Enforcement Law was Dickey Amendment

Following the public announcement, Bush Administration established the Presidential Council on Bioethics to provide 'an adequate moral and ethical lens through which to view particular developments in their proper scope and depth'.[130]The Council was headed by Leon Kass.[131] It was quite different from previous councils because the White House was in charge of appointing its members. Chairman Kass proclaimed that the Council would listen to both religious and secular voices in its consideration of HESC research.[132]

Following its proceedings, in January 2004, the Council published a report on monitoring stem-cell research. The report summarises ethical, legal and policy issues around applications of stem cell research. It summarizes ethical, legal and policy issues around applications of stem cell research. According to the letter of Chairman Kass, the report has four basic aims: 'sought to clarify and explain the current federal policy', 'provide an overview of the ethical and policy debates', 'enable readers to appreciate the reasons for the excitement' and 'convey the moral and social importance of the issue at hand'.[133] The report concluded that the Dickey Amendment was enforceable law. Federal money should not be used to 'encourage the exploitation or destruction of nascent human life, even if scientific and medical benefits might come from

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[129]Tom Abate, 'Scientist fears that political uncertainty threatens his research' (SFGate, 17 July 2001) <http://www.sfgate.com/cgi-bin/article.cgi?f=/Chronicle/a/2001/07/17/MN153775.DTL#ixzz1ZfVOVkOj> accessed 2 October 2011.

[130] Monitoring Stem Cell Research,<http://bioethics.georgetown.edu/pcbe/index.html> accessed 1 November 2011.

[131]*ibid.*

[132]*ibid.*

[133] Letter of Transmittal to the President of the United State, <http://bioethics.georgetown.edu/pcbe/reports/reproductionandresponsibility/transmittal.html> accessed 2 November 2011.

such acts'.[134] The research should aim to cure deadly diseases provided it respects important moral boundaries. Meanwhile, the award of federal funding is a significant issue to be handled with care.[135]

The council also announced reports on alternative sources of stem cells, human cloning, human dignity, bioethics and so on. However, these reports did not have a substantial effect on public debate in the US.[136] The Council's approach was criticised as 'entertains with the spectacle of enhanced bodies and immortal lives but offers little meaningful and substantive ethical analysis'.[137]

4.3.6 Executive Order by President Obama: Reverse the Bush Policy

Its practical import aside, the Bush policy had pedagogical significance for legal developments in regulating HESC research. The General Council of the President's Council on Bioethics evaluated the Bush policy as 'provides an unparalleled window into the nature and substance of "bioethical regulation" within the unique framework of the American system of government'.[138] However, President Obama has expressed dissatisfaction with the policy restricting federal funding of HESC research. This is what President Obama said, 'In recent years, when it comes to stem cell research, rather than furthering discovery, our government has forced what I believe is a false choice between sound science and moral values'.[139]

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[134] Patrick Walsh, 'stemming the tide of stem cell research: the Bush Compromise' (2005) 38 John Marshall Law Review 1061-1077.

[135] *ibid.*

[136] Leigh Turner, 'Science, politics and the President's Council on Bioethics'(2004) 22 Nature Biotech. 509-510. (analyzing that though the reports produced by the US President's Council on Bioethics have not yet had a dramatic effect on public debates in the United States, the Council itself is back in the limelight following the departures of Elizabeth Blackbrun and William E. May and the additions of Benjamin Carson, Peter Lawler and Diana Schaub.)

[137] Leigh Turner, 'Has the President's Council on Bioethics missed the boat?' (2003) 327 bmj 629

[138] *Supra* note 91.

[139] Obama overturns Bush policy on stem cells, CNN Politics (Washington, March 9 2009) <http://articles.cnn.com/2009-03-09/politics/obama.stem.cells_1_cancer-and-spinal-cord-embryonic-cell-research?_s=PM:POLITICS > accessed 4 November 2011; see also The White House, Executive Order:

On March 9, 2009, President Obama signed an executive order to lift the ban on HESC funding. Research related to embryonic stem cell lines created after August 2001 was allowed to receive federal funding. Privately funded research was not affected. However, the creation of stem cell lines involving destruction embryos was still prohibited from receiving federal funds. Section 1 of the executive order provides that:

> Research involving HESCs and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds.[140]

The order did not clearly describe standards for which stem-cell lines would be eligible for federal funds. The rule unlocking federal funding was challenged by the Dickey-Wicker Amendment, which prohibited funding of HESC research involving the destruction of embryos. The NIH attempted to finish the job of answering a host of morally and politically complicated questions within 120 days.[141] Because the order was challenged by the Dickey-Wicker Amendment, the president let Congress to decide whether overturn the statutory ban on federal funding involving embryos.[142] Despite some weaknesses in the order, it is still a remarkable milestone in HESC research. As President Obama commented:

Removing barriers to responsible scientific research involving human stem cells, March 9, 2009, <http://www.whitehouse.gov/the_press_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-Cells/> accessed October 12 2013.

[140] Executive Order: Removing barriers to responsible scientific research involving human stem cells, March 9, 2009 <http://www.whitehouse.gov/the_press_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-Cells/> accessed 7 November 2011.

[141] Rob Stein, 'Obama's Order on Stem Cells Leaves Key Questions to NIH' The Washington Post (Washington, March 10 2009) <http://www.washingtonpost.com/wp-dyn/content/article/2009/03/09/AR2009030903156.html> accessed 8 November 2011.

[142] Sheryl Gay Stolberg, 'Obama is leaving some stem cell issues to Congress' The New York Times (NEW York, March 8 2009) <http://www.nytimes.com/2009/03/09/us/politics/09stem.html> accessed 8 November 2011.

> Today, with the Executive Order I am about to sign, we will bring the change that so many scientists and researchers; doctors and innovators; patients and loved ones have hoped for, and fought for, these past eight years: we will lift the ban on federal funding for promising embryonic stem cell research. We will vigorously support scientists who pursue this research. And we will aim for America to lead the world in the discoveries it one day may yield.[143]

4.3.7 The Result of Battle Over the Dickey-Wicker Amendment: the Funding Policy of HESC Research by Obama Administration could Go Ahead

NIH planned to implement new Guideline to suggest how federal funds should be used for HESC research.[144] This was welcome news to scientists who had applauded President Obama's new policy.[145] However, in a shocking case that issued on August 23, 2010, a federal district judge ruled against the Obama executive order.[146] In *Sherley v. Sebelius*, the court held that federal funding for HESC research clearly violated the Dickey-Wicker Amendment.[147] He also stated that the New NIH Guideline 'allow federal funding of HESC research, which involves the destruction of embryos'.[148]

Because of the judgment's potential to block federal funding of HESC research, on the very day of the ruling, the Obama administration decided to appeal. The Directive of NIH, Dr. Francis S. Collins criticised that the ruling could 'cause irreparable damage and delay potential breakthroughs to

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[143] A debt of gratitude to so many tireless advocates, the White House Blog, March 9 2009 <http://www.whitehouse.gov/blog/09/03/09/A-debt-of-gratitude-to-so-many-tireless-advocates/> accessed 8 November 2011.

[144] See generally Devin Dwyer, 'NIH Issues new stem cell research Guideline as Obama Administration prepares to Appeal court ruling', ABC News, Aug. 31, 2010, <http://abcnews.go.com/blogs/politics/2010/08/nih-issues-new-stem-cell-research-Guideline-as-obama-administration-prepares-to-appeal-court-ruling/> accessed October 23 2013.

[145] *ibid.*

[146] *Sherley v. Sebelius*, 2010 U.S. Dist. LEXIS 86441 (D.D.C. August 23, 2010).

[147] *ibid.*

[148] *ibid.*

improve care for people living with serious diseases and condition…the injunction threatens to stop progress in one of the most encouraging areas of biomedical research'[149] On September 9, 2010, the United States Court of Appeals for the District of Columbia issued temporary permission for federal funding of HESC research.[150] The decision 'has just poured sand into that engine of discovery'.[151] A few months later, at the request of federal government, a federal appellate court reinstated the presidential policy and suspended the injunction issued by the district court.[152]

The court dispute over the Dickey-Wicker Amendment flared up again on April 29, 2011, when the appellate court permanently overturned the district court's injunction, holding that the Dickey-Wicker Amendment was ambiguous.[153] The NIH applauded the ruling, with a spokesperson stating, 'I am delighted and relieved to learn of the decision of the Court of Appeals'.[154]The ruling was reconfirmed on July 27, 2011, when a federal judge dismissed the legal challenge to government funding of HESC research.[155] Ultimately, President Obama's policy of funding HESC research was allowed to proceed.

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[149] Ariane de Vogue, 'NIH Issues new stem cell research Guideline as Obama Administration prepares to Appeal court ruling' ABC NEWS, August 31, 2010 <http://abcnews.go.com/blogs/politics/2010/08/nih-issues-new-stem-cell-research-Guideline-as-obama-administration-prepares-to-appeal-court-ruling/> accessed 9 November 2011. (criticizing that the ruling as one that could 'cause irreparable damage and delay potential breakthroughs to improve care for people living with serious diseases and conditions… the injunction threatens to stop progress in one of the most encouraging areas of biomedical research)

[150] Janice Hopkins Tanne, 'US court temporarily lifts ban imposed in August on HESC research' (2010) 341 BMJ 579 <http://www.bmj.com/content/341/bmj.c4981> accessed October 4 2013.

[151] *ibid*. (Stating that the ruling threw the field into disarray, immediately halting some projects and causing the US National Institutes of Health (NIH) to put a hold on many research grants.)

[152] Ubaka Ogbogu, 'US Appeal Court reinstates Obama's funding policy on stem cell research' Stem Cell Network, 2 May 2011 <http://scnblog.typepad.com/scnblog/2011/05/us-appeal-court-obama-funding-policy-stem-cell-research.html> accessed 9 November 2011.

[153] Bill Mears, 'Appeal court lifts ban on federal funding for stem cell research' CNN April 29, 2011 <http://articles.cnn.com/2011-04-29/us/stem.cells_1_stem-cell-research-cell-types-ban-research?_s=PM:US> accessed 9 November 2011.

[154] Maggie Fox, 'Appeals court hands Obama a stem cell victory' National Journal, April 29, 2011 <http://www.nationaljournal.com/healthcare/appeals-court-hands-obama-a-stem-cell-victory-20110429> accessed 9 November 2011.

[155] *Supra* note 104.

4.4 Conflict between Federal Law and State Law

Regulation of HESC operates at the federal and state levels of government. In general, the US has a liberal environment and has no uniform HESC regulation at the federal level.[156] Because the federal government has precluded coordinated efforts in this area, each state has developed its own regulations.[157] The HESC legal framework varies on one fundamental dimension:[158] Whether to permit or prohibit HESC research. Some states widely permit HESC research, including somatic cell transfer.[159] Others do not explicitly prohibit reproductive cloning.[160] A small handful of states have restrictive policies on HESC research.[161] Therefore, harmonizing the divergent HESC laws among the federal and state governments became important. The federal restrictions in the United States on funding of HESC research led to the phenomenon that the state funding mechanisms for HESC research was in a very inconsistent and perhaps economically costly manner.

4.4.1 Proposition 71 in California: Success or Failure?

The California Stem Cell Research and Cures Bond Act of 2004 (Proposition 71) by the state California is worth to be deeply read, not only because it was the biggest world's largest single backer of HESC research, but also it received strong moral oppositions from Christian religious represents.

California Stem Cell Research and Cures Bond Act of 2004 (Proposition 71)

On November 2, 2004, California voters passed the California Stem Cell Research and Cures Bond Act of 2004.[162] This Act, known as Proposition 71,

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[156] Arif Jamil, "Human stem cell research in Europe and the USA: post Brustle and Sherley, ethics issues and patent quagmire," NTUT J. of Intell. Prop. L. & Mgmt (2013): 145.
[157] Geoffrey P Lomax, Erik J Forsberg, Dan Gincel, Debra S Grega, Melissa J Lopes, Caroline J Marshall, Stefan Winkler and Warren Wollschlager, "policy harmonization through collaboration: The Interstate Alliance on Stem Cell Research," World Stem Cell Report (2010): 100.
[158] Owen C B Hughes, Alan L Jakimo and Michael J Malinowski, "United States regulation of stem cell research: recasting government's role and questions to be resolved," Hofstra Law Review 37 (2008): 383.
[159] E.g., New Jersey, California, Illinois.
[160] E.g., Arkansas, Virginia.
[161] E.g., Oklahoma.
[162] Proposition 71, California Stem Cell Research and Cures Initiative,

seemed to be a victory for scientists and research funding. Proposition 71 was proposed as a response to Bush administration's restrictive policy on HESC research. Proposition 71 is the outcome of direct democracy which was supported by 59% of voters.[163] In 2004, 59.1 percent of the California electorate endorsed Proposition 71, also known as the Stem Cell Research and Cures Act 2004 (California).

This Act appeared to be a victory for scientists and research funding. This new legal model challenged the standard way in which public policy was made. It warranted a close examination and enable voters to amend law directly. The approval of proposition 71 mainly due to the effort of Robert Klein, a California real estate developer whose son suffered pains of juvenile diabetes.[164] Although many people believe that more direct democracy always leads to better policy, Proposition 71 might not accord to that. There are many lessons could be learned from Proposition 71.[165] For example it resulted in the circumvention of critical basic policy processes and the balkanization of research. It also concentrated too much power in a small group.[166]

Proposition 71 is belong to the state constitution rather than the state law. The purpose of Proposition 71 is to 'protect and benefit the California budge by funding scientific medical research that will significantly reduce state health care costs in the future and provide an opportunity for the state to benefit

<http://www.assembly.ca.gov/acs/committee/c15/Publications/Stem%20Cell%20background.doc.> accessed September 11 2013.

[163] Eileen Burgin, 'embryonic stem cell research and Proposition 71' (2010) 29 Politics and Life Science 73-78

[164] Klein used his huge wealth to underwrite Proposition 71's campaign. Klein made tremendous effort on drafting and financing Proposition 71. See Elle Dolgin, 'Stem cells: The impatient advocate' (2010) 468 Nature 620

[165] Donna Gerardi Riordan, 'Research funding via direct democracy: is it good for science?' (2008) Issues in science and technology <http://www.issues.org/24.4/p_riordan.html> accessed November 1 2013.

[166] *ibid.*

from royalties, patents and licensing fees that result from the research'.[167] Four key provisions consist of Proposition 71:

> (1) The California Institute for Regenerative Medicine (CIRM) was established to regulate stem cell research and funding, and the Independent Citizen's Oversight Committee (ICOC) was established to govern CIRM; (2) Loans up to 3 million dollars were provided for CIRM's initial administration and implementation costs and bonds to annually finance CIRM were authorized (an annual limit of 350 million dollars up to a total of 3 billion; (3) A constitutional right to conduct stem cell research but one that prohibits funding of human reproductive cloning was established; (4) No amendments are allowed to statutes for the first three years and any repeal or amendment thereafter requires a legislative supermajority (70%).[168]

In general, Proposition 71 successfully fills the gap left by the lack of US federal funding. It uses an approach called obligation bonds, which is normally used in funding brick and mortar projects, to finance the research. HESC research is conducted by the state constitutional right under Proposition 71. Although Proposition 71 makes a huge success, it has significant deficiencies especially lacking the clarity. For instance, it does not state an adequate return on investment for taxpayers. It does not specify social benefit for the citizens and public from research.[169] What is worse, it leaves blank of the evaluation system after 3 billion dollars is spent.

California Institute for Regenerative Medicine (CIRM)

Proposition 71 was proposed as a response to the Bush administration's restrictive policy on HESC research. Based on this Act, a new state medical

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[167] Proposition 71, California Stem Cell Research and Cures Initiative, Section 3, available from Senate Informational Hearing Background Paper, "Implementation of Proposition 71: Options for Handling Intellectual Property Associated with Stem Cell Research Grants," <http://www.assembly.ca.gov/acs/committee/c15/Publications/Stem%20Cell%20background.doc.> accessed November 7 2013.

[168] *ibid.*

[169] *Supra* note 113.

research institute, the Californian Institute for Regenerative Medicine, was established and the issuance of $3 billion in state general obligation bonds authorized to fund stem cell research and research facilities in California. According to Proposition 71, the California Institute for Regenerative Medicine was created to making 'grants and loads for stem cell research, for research facilities, and for other vital research opportunities to realize therapies' and establishing 'the appropriate regulatory standards of oversight bodies for research and facilities development'.[170]

Klein served as chairman of CIRM and personally donated around 1.2 million dollars to start.[171] This action was criticised by Peter Can Etten, former director of Juvenile Diabetes Research Foundation International (JDRF) as "bob's show almost entirely".[172] It was even pointed out that Klein 'wrote the initiative for him to be chairman'.[173]

However, Klein defended for his competence in the statue. He claimed that he is trained in law and finance, therefore he could think both legally and financially towards the project.[174] Klein also pointed out that 'the purpose of CIRM is medical science with a plan to drive that science all the way through to therapies'.[175] CIRM aims to bring a lab discovery to clinical use. For example, in a project treating sickle cell disease, the grant not only covered laboratory experiments but also clinical trials.[176] However, it inevitably arose concerns about moving stem cells too quickly to the clinic. Arnold Kriegstein from University of California, believed that CIRM ignored huge amount of basic research that needs to be done instead put on higher risk preclinical studies.[177]

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170 The California Institute for Regenerative Medicine, <http://www.cirm.ca.gov/> accessed 6 November, 2011
171 *Supra* note 161.
172 *ibid.*
173 *ibid.*
174 *ibid.*
175 *ibid.*
176 Jocelyn Kaiser, 'CIRM Awards Seek to move cell therapies to the Clinic' (2009) 326 Science 780
177 *ibid.*

Initially, research funding was delayed due to the constitutionality of CIRM challenged by anti-stem cell research groups. Until May 16 2007, the California Supreme Court refused to hear the appeal in the litigation challenging the constitutionality of Proposition 71, was made by the California Family Bioethics Council, along with the Peoples Advocate and National Tax Limitation Foundation.[178] The immediate result of this decision is funding flowing. The first 250 million dollars bond to fund research was finally sold out and up to 48.5 million dollars was allowed to move by the state agency.[179]

The California Stem Cell Research and Cures Bond Act of 2004 (Proposition 71) is worth reading closely, not only because California was the world's largest single backer of HESC research but also because it received strong moral opposition from religious Christian representatives.[180] This new legal model challenged the standard way in which public policy was formulated in federal level. It warranted a close examination and enabled voters to amend the law directly. Although many people believe that more direct democracy always leads to better policy, Proposition 71 might not support that belief.[181]There are many lessons that could be learned from Proposition 71.[182]For example, it resulted in the circumvention of critical basic policy processes and the balkanization of research. It also concentrated too much power in a small group.[183]

The lack of federal funding has discouraged scientists from entering HESC research. Proposition 71 successfully fills the gap left by the lack of US federal

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[178] California stem cell project prevails: appellate court affirms constitutionality of proposition 71, February 27, 2007 <http://www.cirm.ca.gov/PressRelease_022707b> accessed 9 November 2011.

[179] Joyce E Cutler, 'State supreme court rejects challenge clearing way for stem cell bond initiative' Center for Genetics and Society, May 17 2007, <http://www.geneticsandsociety.org/article.php?id=3834> accessed 9 November 2011.

[180]On November 2, 2004, California voters passed the California Stem Cell Research and Cures Bond Act of 2004

[181] Eileen Burgin, 'Embryonic stem cell research and Proposition 71,' (2010) 29 Politics and Life Science 73.
(noting that Proposition 71 is the outcome of direct democracy that was supported by 59% of voters.)

[182] Donna Gerardi Riordan, 'Research funding via direct democracy: is it good for science?' (2008) Issues in science and technology, accessed November 1, 2011 http://www.issues.org/24.4/p_riordan.html.

[183]*Ibid*.

funding. It uses an approach called obligation bonds, which are normally used in funding brick and mortar projects, to finance the research. HESC research is supported through a right under the state constitution through Proposition 71.[184]Proposition 71 created the California Institute for Regenerative Medicine (CIRM).[185] CIRM expanded the licensing authority under the Bayh-Dole regime, which is limited to 'any contractor who is a non-profit research institution or a small business'.[186] Based on Bayh-Dole, CIRM reserved the right of the funding agency and the march-in right. This new method has attracted both national and international researchers.[187]

Although Proposition 71 is a huge success, it has significant deficiencies, especially its lack of clarity. For example, it does not state an adequate return on investment for taxpayers. Proposition 71 does not specify any social benefit for the citizens and public from HESC research.[188] Worse, Proposition 71 authorises the spending of 3 million dollars but does not specify any evaluation system. There is also a growing concern over the conflict between the licensing regime under Bayh-Dole and CIRM regulations. Moreover, the federal restrictions in the United States on funding HESC research led to

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[184]Proposition 71, California Stem Cell Research and Cures Initiative, Section 3, Accessed November 7, 2011,
http://www.assembly.ca.gov/acs/committee/c15/Publications/Stem%20Cell%20background.doc.
(stating that Proposition 71 is part of the state constitution rather than the state law and that the purpose of Proposition 71 is to protect and benefit the California budget by funding scientific medical research that will significantly reduce future state health care costs and provide an opportunity for the state to benefit from royalties, patents and licensing fees that result from the research. Proposition 71 has four key provisions: (1) The California Institute for Regenerative Medicine (CIRM) was established to regulate stem cell research and funding, and the Independent Citizen's Oversight Committee (ICOC) was established to govern CIRM; (2) Loans of up to 3 million dollars were provided for CIRM's initial administration and implementation costs, and bonds to annually finance CIRM were authorized (an annual limit of 350 million dollars up to a total of 3 billion; (3) A constitutional right to conduct stem cell research but one that prohibits funding of human reproductive cloning was established; (4) No amendments are allowed to statutes for the first three years and any repeal or amendment thereafter requires a legislative supermajority (70%).)

[185] The California Institute for Regenerative Medicine, accessed 6 November, 2011, http://www.cirm.ca.gov/
(providing grants and loads for stem cell research, research facilities, and other vital research opportunities to realize therapies and establishing the appropriate regulatory standards of oversight bodies for research and facilities development.)

[186] See Bayh-Dole Act , NO. 96-1307, pt. 1, at 5 (1980).

[187] *Supra* note 178.

[188] *Supra* note 130.

inconsistent and perhaps unduly costly state funding mechanisms for HESC research.

However, Proposition 71 is California's answer to the federal restriction, developing policies to ensure that HESC research is conducted under the highest medical and moral standards.[189] An economic analysis concluded that Proposition 71 could generate economic benefits for California and the global society.[190] In the context of the vacuum at the federal level, Proposition 71 attempts to fill the gap between science and politics at the state level.

Economic Analysis of Proposition 71 and CIRM

Before its implementing, Dr. Laurence Baker, an associate professor of the Stanford University of School of Medicine, and Bruce Deal, managing partner of the Analysis Group, a consulting firm based in Menlo Park, made an economic analysis of Proposition 71 and CIRM. They analyzed the economic costs and benefits of Proposition 71 through four primary areas.[191] Based on the assumption, the conclusion of their analysis was that Proposition 71 could generate economic benefits to California and the global society.[192]

Several days later, Dr. Stephen Shmanske, Professor of Economics of California State University, commented that their analysis is actually 'an advocacy paper paid for by and tailored to the Proposition 71 force'.[193] He pointed out that Baker and Deal analysis totally ignored massive borrowing and high cost of obtaining eggs in the research. In terms of benefits from Proposition 71 and CIRM, Baker and Deal analysis addressed to the job created rather than the benefits from improved health status might bring.

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189 Zach W Hall, 'Stem cell research in California: the intersection of science, politics, culture and law' (2008) 10 Minni. Journal Law Science & Technology 1-18.

190 Laurence Baker and Bruce Deal, "Economic Impact Analysis Proposition 71 California Stem Cell Research and Cures Initiative," analysis group economic financial and strategy consultants (2004).

191 Laurence Baker and Bruce Deal, 'Economic Impact Analysis Proposition 71 California Stem Cell Research and Cures Initiative' (2004) analysis group economic financial and strategy consultants <http://www.analysisgroup.com/uploadedFiles/News_and_Events/News/Proposition_71_report.pdf> accessed 14 July 2014.

192 *Ibid.*

193 Stephen Shmanske, 'Comment on Baker and Deal's analysis of Proposition 71' September 19, 2004 <http://www.humanebiotech.com/images/prop71econimpact.pdf> accessed 10 November 2011

However, new jobs created in stem cell research would be at the expense of lost jobs in areas where the funds would alternatively invest.[194] Therefore, he believed that 'the potential cost is no less real than the potential benefits sought in stem cell research'.[195]

About one year after it implementation, People's Advocate, National Tax Limitation Foundation and the California Family Bioethics Council appealed that Proposition 71 is unconstitutional and CIRM is unable to manage the funding under state control.[196] They claimed Proposition 71 should be overturned because Proposition 71 misrepresented the financial returns to the state and the researches to be funded.[197] After careful considerations, the judge of California Supreme Court held that 'our view of the various constitutional and other objections appellants have addressed to the stem cell involves no normative evaluation of the merit of the measure'.[198] The decision upheld the legal validity of Proposition 71.

Then in 2007, Michael T. Longaker and Laurence C. Baker, both from Stanford School of Medicine, gave an assessment of returns on investing Proposition 71 and CIRM.[199] They first compared the benefits from funding in HESC research as a pie. Then they developed the analysis about how big is the pie, whether the pie is worth baking and how to divide the pie? Finally, they discussed patent issues as part of the pie. They made the conclusion that 'assessing the benefits of stem cell research is likely to be a complex undertaking'.[200]

Five years after CIRM established, Investor's Business Daily (IBD) evaluated

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194 *ibid.*

195 *ibid.*

196 Independent citizen's oversight committee v California Institute for Regenerative Medicine, People's Advocates, <http://www.cirm.ca.gov/board-and-meetings/our-governing-board> accessed 24 July 2013.

197 Steven N.H.Wood, 'Beeson et al Amicus brief' November 4, 2005 <http://www.geneticsandsociety.org/article.php?id=2994>accessed 11 November, 2001.

198 *ibid.*

199 Michael T Longaker, Laurence C Baker and Henry T Greely, 'Proposition 71 and CIRM-assessing the return on investment'(2007) 25 COMMENTARY 513

200 *ibid.*

Proposition 71 was a "failure" amid worries about fruitless of huge investments on HESC research allocated by CIRM. The IBD further assessed, instead of expected high return from research, there seemed to no cures, no therapies and little progress. IBD insisted adult stem cell research held the promise of curing disease rather than HESC. Therefore, Proposition 71 was misleading public funds to actual therapies.[201] This opinion received many supporters. For example, Wesley J Smith stated the IBD speaks is truth. He described Proposition 71 even as a disaster. 'California is dying and can no longer afford the reckless financial boondoggle that goes by the names of CIRM'.[202]

4.4.2 Other States

In January 2004, after California passed Proposition 71, New Jersey signed the New Jersey bill, S1909, into law by Governor James E. McGreevy.[203] This regulation not only provided supports for HESC research but also sponsored the cloning of HESC for therapeutic purposes. However, unlike California Proposition 71, the New Jersey bill did not involve with the state funding for HESC research. Nevertheless, Governor McGreevy still allocated 6.5 million dollars to establish HESC institute.[204] This move strongly backed by patient groups but opposed by religious groups. For instance, the US Conference of Catholic Bishops claimed it would create "government sanctioned human fetus farms".[205] New Jersey voters wisely rejected an initiative to borrow 450 million dollars to fund state-run stem cell research when seeing the fruit of California high funding is quite little.[206]

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[201] California Proposition 71 Failure, December 1, 2010 <http://www.investors.com/NewsAndAnalysis/Article.aspx?id=517870> accessed 12 November 2011

[202] Wesley J. Smith, Proposition 71 a failure, Jan 13 2010, <http://www.firstthings.com/blogs/secondhandsmoke/2010/01/13/proposition-71-a-failure/> accessed 12 November 2011

[203] See < http://www.bionity.com/en/encyclopedia/S1909/A2840.html> accessed November 22 2013.

[204] Ella Detrizio and Chris Brennan, 'The New Jersey Stem Cell Research law' (2004) 3 New Jersey life science technology 2.

[205] David Malakoff, 'Stem Cell Studies Backed By New Jersey Law' (2004) 303 SCIENCE 153.

[206] Revere F S and Elgin M, 'Public Stem Cell Research Funding Boon or Boondoggle?' (2008) 4 Advancing Liberty From the Economy to Ecology 1-26.

In the state of Louisiana, embryo was recognised as a juridical person. 'An in vitro fertilized human ovum is a juridical person which cannot be owned by the in vitro fertilization patients who owe it a high duty of care and prudent administration'.[207] Furthermore, it was pointed out that an embryo is 'a biological *human being* which is not the property of the physician which acts as an agent of fertilization, or the facility which employs him or the donors of the sperm and ovum'.[208]

4.4.3 The Interstate Alliance on Stem Cell Research (IASCR): A Venue for the States to Cooperate

The varying policies on the derivation and use HESC lines threaten the cooperative attempts between states. The IASCR was established to 'advance stem cell research by fostering effective interstate collaboration, by assisting states in developing research programs, and by promoting efficient and responsible use of public funds has achieved important milestones', the IASCR was established.[209] The IASCR aims to 'identify and increase opportunities for interstate collaboration; identify and decrease obstacles to collaborative research across state lines; and assist state that wish to develop or improve upon public funding programs in this area'.[210]

Efforts by the IASCR center on two areas: (1) 'identify policies that spur economic development" and (2) "facilitate inter-jurisdictional collaborative partnerships".[211] As described, the IASCR may vertically integrate relevant regulations and blunt some sharp differences in research policies.[212] For

[207] La. Rev. Stat. Ann. § 9:130.
[208] La. Rev. Stat. Ann. § 9:125.
[209] Geoffrey P Lomax, Erik J Forsberg, Dan Gincel, Debra S Grega, Melissa J Lopes, Caroline J Marshall, Stefan Winkler and Warren Wollschlager, 'policy harmonization through collaboration: the Interstate Alliance on Stem Cell Research' World Stem Cell Report 2010, accessed 17 December, 2011 http://www.iascr.org/about.shtml
[210] *Ibid.*
[211] *ibid.*
[212] Insoo Hyun, 'The bioethics of stem cell research and therapy' (2010) 71 the Journal of Clinical Investigation 120.

example, the IASCR is crucial to the cooperation of Ohio and Maryland.[213] The IASCR also supports the development of private-public partnerships, such as the New York Stem Cell Foundation (NYSCF).[214]

Moreover, the IASCR promotes state investment in HESC research. State policy makers in Connecticut, for example, approved a ten-year, one hundred million dollar funding program in June 2005, and lawmakers in New Jersey, Illinois, and Maryland have allocated state funds to support research in the field.[215] Altogether, policy makers from at least fifteen states have expressed interest in supporting stem cell research.[216]

4.4.4 Conflicts between the Federal and State Regulation

Considering the sizeable tax and other benefits from the HESC industry, some states have stepped in to fill the vacuum. In the US, each state can have its own sets of definitions, rules, and regulations to a certain extent. Certain states draw distinctions based on the source of the stem cells or add restrictions based on the purpose for which the research is conducted, while other states have yet to decide what HESC research to allow and what research to restrict. Many states are proposing new regulations; however, in states that appear to have already settled on a position, HESC policies are still in considerable flux.

There is growing concern that 'inconsistent regimes within legal jurisdictions have the potential to put researchers in unusually precarious positions with respect to their research methodology and output.'[217] However, it is worth considering whether inconsistent regulations truly hamper technological advances. The diversity may have costs but can also 'enable systems to find novel and breakthrough solutions, and it can add to their value and

[213] Roger Brownsword, 'Stem Cells, Superman, and the Report of the Select Committee' (2002) 65 the Modern Law Review 568.
[214] *ibid.*
[215] *ibid.*
[216] *Quintavalle v. Secretary of State for Health* [2001] 4 All E.R. 1013.
[217] Murdoch C J, 'intraoperability problems: inconsistent stem cell IP and Research regimes within nations' (2011) 3 Stanford Journal of Law Science & Policy 49-55.

robustness'.[218] Therefore, governmental policymaker in US that allows hundreds of opinions to be heard on multiple jurisdictional levels in the field of HESC research. In my opinion, it to some extent might be good for the improvement of HESC regulation.

4.5 Conclusion

From the above discussion, this chapter concludes that federal funding control is not a effective way to monitor HESC research. It could be said that using federal control approach has not eliminated the moral concerns associated with HESC research. We can observe that in the event that federal funding is prohibited from being used in HESC research, private funds still could be invested. In this situation, unethical research could still proceed. The moral objections by its opponent have not decreased. Moreover, the research may be easily omitted from ethic monitoring by the government since private research is potentially unknown and unregulated. On the contrary, allowing federal funding on HESC research is beneficial for the development of independent research organisations as well as meaning less reliance on private funds.[219] It is also in favour of monitoring and regulating by the Government to ensure that the research conforms to the ethical Guideline. In addition, the Government seems to be more attractive to the top scientists.

From accepted medical ethics and scientific knowledge, this chapter has attempted to draw some lessons from the above analysis. Although numerous attempts had been made to restrict patent law, the approach adapted by the US government is meant to be federal funding control instead of patent control.[220] Since the morality issue is not the core of the controversy, the focal point for much discussion is whether federal funding could be used in HESC

[218] Owen C.B. Hughes, Alan L.Jakimo and Michael J. Malinowski, "United States Regulation of Stem cell research: recasting government's role and questions to be resolved," Hofstra law review 37 (2008): 383.

[219] Gabriel S Gross, 'Federally funding HESC research: an administrative analysis' (2000) 4 Wisconsin Law Review 855-84.

[220] Annas G J, Caplan A and Elias S, 'stem cell politics, Ethics and Medical Progress' (1999) 5 Natural

research. It can be said that the US government takes the approach of patenting first and asking questions later. This hands-off approach is market oriented.[221] Opponents have strongly criticised this approach for its lack of ethical and social considerations.[222] Scientific research can be conducted with little public oversight. Since there are limited moral concerns, the inventions related to HESC research are patentable in US. In general, it is reasonable to withdraw the moral review of HESC from the patent law.

However, the different administrations adapted different policies in HESC domain. President Clinton was enthusiastic about this research and dedicated himself to establishing the Advisory Committee. The policy President Clinton used is permissive in that it allows federal funding for HESC research. By contrast, President Bush opposed to this research. The policy President Bush developed was relatively unsuitable and was opposed by many scientists. Bush restricted the federal funding on HESC research on already derived stem cell lines. But the existing stem cell lines might not be able to meet the NIH criterion and satisfy the demands of research.[223] The HESC research relied on private funding, which inevitably impeded scientific progress. Meanwhile, the cost of HESC research is increasing because the laboratory needed to buy an extra set of equipment in order to distinguish machines used in federal funding research from those used in non-federal funding research.

Unlike the preceding administrations, President Obama's policy seems to be rather broad and permissive. However, three criterions "responsibly conduct", "scientific worth" and "permit by law" in his speech are unclear and remain to be clarified. The same situation occurred in the following NIH Guideline. Therefore, despite the fact that that Obama ordered an executive order to lift

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Medicine 1339.

[221] The report of the US national Bioethics Advisory Committee, Ethical Issues on Human Stem Cell Research, September 13 1999.

[222] Littlefield N, 'transformation of a research platform into commercial products: the impact of US federal policy on Biotechnology' in Caulfield and Jones Williams (ed.), the Commercialisation of Genetic research: ethical, legal and policy Issues (Kluwer International 1999) 80.

the ban on federal funding on HESC research, he did not solve the real problem. Instead, he left and passed the problem to the NIH. In this aspect, the Obama policy was not as meaningful as it appears. As for the state level in the US, regulations especially California Proposition 71 have all made their contribution to the development of HESC regulations. From my point of view, proposition 71 could be said to fail economically, but it might be considered a success in promoting HESC research.

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[223] Holden C, 'stem cell lines: NIH's list of 64 leaves questions' (2001) 293 Science 1567.

CHAPTER FIVE: THE EUROPE MODE ABOUT MORAL-BASED REGULATIONS OF HESC RESEARCH : INCONSISTENT INTERPRETATIONS OF MORAL PROVISIONS IN PATENT LAW

5.1 Introduction

In the previous chapters, the moral maze, the failure of HESC regulation in China and US legalframwork around HESC have been thoroughly discussed and analysed. As it has been illustrated throughout chapter one of this thesis, the scope of this thesis will cover the patentability and morality of HESC related invention in regulation reconciliation, which is probably the most controversial issues around HESC. In order to fully illustrate it, this chapter will analyse specific regional regulation for HESC. In the EUROPE, morality is deeply rooted in regulation.[1] The EUROPE regulation of HESC research related to moral concerns has adopted an approach which is to infuse patent examination with a moral assessment.[2] Although many scholars and legal practitioners have agreed that patent law is not the proper vehicle for enforcing morality and that patent examiners are not experts on moral issues[3],

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* It is acknowledged that section 4.5 was abstracted from my paper entitled 'Space for Flexibility: Lessons from the European Union Harmonisation Model in HESC Regulation' 97 (2014) Intellectual Property forum 63-68; Section 4.3 was abstracted from my paper entitled 'Between Scylla and Charybdis: Patentability and Morality related to HESC' 6 (2014) 1 American University Intellectual Property Brief (forthcoming); section 4.2 and 4.4 was abstracted from my paper entitled 'Will Diversity Regulations disadvantage HESC Research: A Comparison Between EUROPE and US' 25 (2014) Depaul Journal of Art, Technology and Intellectual property Law (forthcoming).

[1] Brian Salter, *Bioethics, politics and the moral economy of HESC science: the case of the European Union's Sixth Framework Programme*, 26 New Genetics & Soc'y 269-288 (2007). (indicating that the EUROPE modes of ethics engagement become a political technology that constitutes a permanent feature of the new cultural politics as mechanisms are sought that will enable the refining, manipulating, resolving and legitimating of cultural differences.)

[2] The Article 53(a) of European Patent Convention: 'European patents shall not be granted in respect of (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality.

[3] See Bentham J, *The Principles Of Morals And Legislation* (Dover Publications 1907) 317 (stating that technical, commercial tool with little or nothing to do with questions of morality); see also Cornish W, Llewelyn, and Aplin T, I*ntellectual Property: Patents, Copyright, Trademarks And Allied Rights* (7th ed., Sweet & Maxwell 2010) 881 (pointing out that morality and patent law should be divided because patent system is not an appropriated arena for moral discussion); see also Black Julia, 'regulation as

the patent-granting agencies in the EUROPE are responsible for interpreting moral provisions.[4] At the EUROPE level, the European Patent Convention contains a morality clause to exclude patenting immoral inventions, whereas the morality standard developed in case laws established two inconsistent standards ("abhorrence" and "unacceptability"). The European Biotechnology Directive 98/44/EC, in an effort to harmonise the biotechnology patent law, explicitly stated that inventions that involve the "uses of human embryos for industrial or commercial purpose" cannot be patented. There are two core questions : first, what is a human embryo? Second, what can be considered industrial or commercial purposes? These two questions are fully discussed in the case *Edinburgh* and the case *WARF*. The statue regulation in conjunction with case law, completely ban the patent on HESC involving the destruction of human embryos.

The answers to these questions are implied in the *Howard Florey*, *Harvard Onco-mouse*, case *Plant Genetic Systems*, *University of Edinburgh*, *WARF* and *Oliver Brüstle* cases. Furthermore, in respect of HESC research, member states have adopted different regulatory approaches, some are prone to being restrictive, some tend to be liberal and some prefer an intermediate policy.[5] In particular, the current regulatory framework in the UK is worth mentioning. The UK Human Fertilisation and Embryology Authority (HFEA), established in 1991, was the first statutory body responsible for licensing and monitoring human embryo research.[6] Therefore, the jurisdiction of HFEA to award licenses is explored in this chapter. Public consultants have a profound

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facilitation: negotiating the genetic revolution' (1998) 61 Modern Law Review 621, 635 (stating that The objective, technical and legal' nature of patent law is contrary to the morality that is inherently malleable, subjective and emotive); see Leland Stanford/MODIFIED ANIMALS, 2002 EPOR 2, at point 51(The Opposition Division of European Patent Office has noticed this difference and commented that 'it cannot be the role of the EPO to act as a moral censor and invoke the provisions of the Article 53(a) EPC to refuse on ethical grounds to grant a patent on legal research and directed to an invention indisputably associated with medical benefits').

[4] See *Relaxin/Howard Florey Institute*, T 0272/95 [2002] E.P.O.R.; see also *HARVARD/Onco-mouse*, T19/90, [1990]; see also *Plant Genetic Systems/Glutamine Synthetase Inhibitors* (T356/93) [1995] E.P.O.R. 361 (TBA)

[5] For example, the UK adopted the liberal policy; the German adopted the restrictive policy; the Dutch adopted the intermediate policy.

[6] Aurora Plomer, 'Beyond the HFE Act 1990:the regulation of stem cell research in the UK' (2002) 10

influence on the regulatory environment and legal reforms. In the end, this chapter will conclude with a discussion of the European experience of reconciling HESC regulations in the EUROPE. We find that the Biotechnology Directive is a giant step towards reconciling the European patent law on biotechnology. Although no uniform moral definition and legal status of human embryo could be traced in EUROPE regulations, the uniform concept of human embryo is accepted in the EUROPE and there is a total ban on patenting inventions involving destruction of human embryos.[7] We can also see the attempt of infusing moral control with patent regulation in the EUROPE.

The EUROPE funds HESC research[8] but its results cannot be patented because 'such research has great therapeutic potential with respect to a wide range of life-threatening diseases'.[9] It is wasteful that the results of EUROPE-funded HESC research are excluded from patenting. Immoral HESC research should be prohibited at the beginning stead of being prohibited from patenting. In addition, the diversity of regulatory approaches to HESC is mirrored in national policies in the EUROPE. The restrictive, intermediate and liberal approaches are distinguished according to difference in degree to which HESC researches are permitted. This chapter will explore the HESC regulation and case law to find out whether consistency and harmonised regulation is formulated within the EUROPE framework.

5.2 The Legal Framework of HESC Research in the EUROPE

Before assessing the patentability and morality of HESC in Europe, it is necessary to

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[7] See chapter 3, experience from the EUROPE.

[8] See Sarah Laitner, 'EUROPE to fund embryonic stem cell research' (2006) Financial Times, July 24 <http://208.71.46.190/search/srpcache?ei=UTF-8&p=EUROPE+fund+human+embryonic+stem+cell&xa=AuCXBKRS2n5UUW37M8utxA--%2C1410765392&fr=aaplw&u=http://cc.bingj.com/cache.aspx?q=EUROPE+fund+human+embryonic+stem+cell&d=5031774546040122&mkt=en-US&setlang=en-US&w=6cBPKZ_WZ_7wL7QhRLi5bnMTYhu8iPec&icp=1&.intl=us&sig=pDZ4WqfgBuCAXkH4QlrK_Q--#axzz3DGwIveaC > accessed October 13 2013. (stating that the Brussels agreement allow scientists in countries where human embryo experiments are legal to apply for funding from the EUROPE's Framework Seven research programme).

[9] European Commission Memo, May 28 2014

examine the Europe Patent system. The EPO established by the European Patent Convention in 1973 is not a EU institution, which is the executive body of granting patent for the pan-European patent system. Accordingly, the EPO has its own schemes like pension and retirement.[10] The EPO is governed by the EPC which is a council of Europe Treaty. There is no institutional relationship between the EPO and the EU. Since the EPO is not an operating organ of the EU, the decision made by the EPO do not produce legal effects to the member states under EU law. On the contrary, the CJEU do not have the authority to review the EPO decision. Considering the tension between the EU and member states, the EPO recognize the coexistence of European and national patent systems. In other words, the operation of EPO is parallel to the national patent offices. The determination of substantive decision is made by the national patent offices. The EPC also has no binding force to the national patent law.[11]

Although the EPO remarks a huge success, it also received many negative comments. It is criticized that 'although the EPO is well-established and appears to be necessary to a practical EU patent system, the roles it can and should play are not entirely clear because it is not an EU institution and has non-EU members'.[12] Also there is the complaint that the EPO system cannot kept up with the development of the EU.[13] Since EU law supersedes national law, 'the disjunction between the EU and EPC can potentially place an EPO patent applicant in a position of double jeopardy within EU member states'.[14] In terms of HESC, the EU Directive is also incorporated into the EPC in order to eliminate inconsistency.

The Rule 28 Europe Patent Convention 2010 indicated that 'Under Article 53(a) European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic

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<Europa.Europe/rapid/press-release_MEMO-14-385_en.doc> accessed June 21 2014.

[10] *Simone Gardella v Istituto nazionale* Case C-233/12

[11] Aurora Plomer, 'Stem cell patents: European Patent law and Ethics Report' (2006) reports for FP6 life sciences, genomics and biotechnology for health 87.

[12] John B Pegram, 'An American View of the Patent System in Europe in 2009' (2009) 91 Journal of Patent and Trademark Office Society 594

[13] *ibid.*

[14] Mark Nickas, 'Discordant Harmonization: Did the European Court of Justice Interpret the Biotechnology Directives Exclusions to Patentability Too Broadly in Brustle v Greenpeace' (2012) 40

identity of human beings; (c) uses of human embryos for industrial or commercial purposes.'[15]According to the case WARF, clause "uses of human embryos for industrial or commercial purposes" includes any claimed step that involves the destruction of human embryos.[16] In addition, the European Parliament and the Council launched Directive 98/44/EC of the legal Protection of Biotechnological Inventions (the Directive). Article 6 (1) provides that 'inventions shall be considered unable to be patented where their commercial exploitation would be contrary to public order or morality'.[17]Meanwhile, Article 6 (2), provides some specific exclusions from patentability on moral grounds:

> '(1) [P]rocesses for cloning human beings; (2) processes for modifying the germ line genetic identity of human beings; (3) uses of human embryos for industrial or commercial purposes; (4) 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'.[18]

The Advocate General of the European Court of Justice recently suggested that inventions involving HESC should be prohibited from being granted a patent.[19] This news immediately gave rise to much responses and debate.[20] On March 16 2011, Nature reported that some scientists feared that 'the opinion could also prompt European countries to tighten their legislation on such research, or ban it altogether.'[21]

American Intellectual Property Law Association 517.

[15] Rule 28 of European Patent Convention

[16] G-02/06 of the Enlarged Board of Appeal of the European Patent Office

[17] See the Article 6(1) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions <http://ec.Europa.Europe/internal_market/indprop/invent/index_en.htm> accessed November 18 2013.

[18] See the Article 6(2) of Directive 98/44/EC

[19] Lain Brassington, 'stem cells: to patent or not?' (2011) Journal of Medical Ethics <http://blogs.bmj.com/medical-ethics/2011/05/08/stem-cells-to-patent-or-not/> accessed 28 October 2012.

[20] Fergus Walsh, 'ban on stem cell patents wrong' *The BBC* (London, 27 April 2011) <http://www.bbc.co.uk/news/health-13214036> accessed 28 October 2012.

[21] Abbott Alison, 'Europe rules against stem cell patents-work with HESCs is contrary to ethics' (2011) 471 Nature 280 <http://www.nature.com/news/2011/110316/full/471280a.html?WT.ec_id=NATUREjobs-20110317>

However, European countries take different approaches towards the HESC patenting.

5.2.1 Moral Criterion of the European Patent Convention (EPC)

The patent protection of HESC research also stemmed from the EPC, which is an intergovernmental agreement between 38 European states for the purpose of harmonising patent law throughout the EUROPE.[22] Notably, the members of the EPC not only include EUROPE members but also non-EUROPE members.[23] The European Patent Office established by the EPC is responsible for granting European patents. The European patent is 'a bundle of national patent' which is valid among the countries where patent application is sought.[24]

Unlike the patent laws in the US, the EPC contains a clause related to the morality of the claimed invention.[25]Article 53(a) of the EPC provides that:

> European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.[26]

Under this provision, even if an invention fulfills the requirements of novelty, inventiveness and sufficient disclosure, a patent can still not be granted if it is contrary to the "order public" or morality. This moral

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accessed October 28 2013.

[22] The European Patent Convention is the Convention on the Grant of European Patents. <http://www.epo.org/law-practice/legal-texts/epc.html> accessed March 5 2014.

[23] The European Patent Convention, <http://www.epo.org/law-practice/legal-texts/epc.html> accessed 29 February 2012.

[24] The Article 64(1) of the EPC provides that 'a European patent shall, subject to the provisions of paragraph 2, confer on its proprietor from the date on which the mention of its grant is published in the European Patent Bulletin, in each contracting state in respect of which it is granted, the same rights as would be conferred by a national patent granted in that state'.

[25] The Article 53(a) of the EPC provides that: European patents shall not be granted for: (a) inventions the publication or exploitation of which would be contrary to 'order public' or morality, provided that exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

exclusion is often utilised by animal rights campaigners, Greenpeace or other similar institutions to oppose certain biotechnology patents granted by the EPO.[27]

After Directive 98/44/EC of the European Parliament and of the Council of July 6 1998 on the legal protection of biotechnological inventions (the Directive) was issued, the EPC introduced a new chapter to accord with the Directive.[28] Rule 23(d) EPC stated that 'under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: (c) uses of human embryos for industrial or commercial purposes'.[29] Also 23(e) EPC provides that:

> (1) The human body, at the various stages of its formation and development ... cannot constitute patentable inventions. (2) An element isolated from the human body or otherwise produced by means of a technical process ... may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.[30]

5.2.2 The Directive 98/44/EC Excludes "Uses Human Embryos for Industrial or Commercial Purpose" from Patenting

With the purpose for harmonising the patentability of biotechnological products and process throughout Europe, the July 6, 1998 Directive 98/44/EC was launched and enunciated that morality is an evaluative criterion for granting a patent. The Directive was the result of ten years of difficult negotiations, providing general principles in dealing with a

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[26] The Article 53(a) of the EPC.
[27] Walters Leroy, 'HESC research: an intercultural perspective' (2004) 14 kennedy institute of ethics journal 3-38.
[28] Rule 23(b) of EPC provides that 'for European patent applications and patents concerning biotechnological inventions, 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 for biotechnological inventions shall be used as supplementary means of interpretation'. accordance with the provisions of this chapter.
[29] Rule 23(d) of the EPC.
[30] Rule 23(e) of the EPC.

biotechnological patent.[31] In 1988, the European Parliament rejected the proposed Directive because it lacked moral aspects, particularly the patentability of materials derived from human beings.[32] However, the purpose of the Directive, as stated by the European Commission, is to 'foster the overall innovatory potential and competitiveness of Community science and industry in this important field of modern technology'.[33]

The EUROPE Commission believed that the Directive, as a uniform biotechnology regulation, was important to the development of biotechnology in the internal market.[34] The commission also recognised that harmonisation of biotechnology patenting is not confined to the technical dimension but also presents ethical concerns.[35] Therefore, from 1989-1995, the draft Directive introduced ethical elements, such as respect for animal suffering, the non-patentability of human beings, and the safety of genetically engineered products.[36] Among these ethical elements, Parliament was particularly concerned by the patentability of the human body and its components; consequently, an amendment was added to exclusively prohibit the grant of patents to the human body or its components.[37] In the face of competition from the US and Japan, the Directive was finally sent to the EUROPE Council and the Parliament in 1996.[38]

The Parliament reviewed the amended Directive and affirmed its

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31 Aurora Plomer and Paul Torremans, *Embryonic stem cell patents European patent law and ethics* (1st edn, Oxford University Press 2009) 6.
32 Proposal for a Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, COM(88),17 October 1988.
33 *ibid.*
34 *ibid*
35 *ibid.*
36 Richard E Gold and Alain Gallochat, 'The European Biotech Directive: Past as Prologue' (200) 7 European Law Journal 331.
37 *ibid.*
38 European Commission, Opinion of the Economic and Social Committee on the Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions, [1996] OJ C295/1.

amendments. The Directive was eventually approved in 1998.[39] The Directive stressed the importance of both patents and morality. Article 6(1) provides that

> Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.[40]

This provision is similar to Article 53(a) of the EPC. After the Directive was issued, the EPC introduced a new chapter to accord with the Directive. Rule 23(d) of the EPC stated that 'under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: (c) uses of human embryos for industrial or commercial purposes'.[41]

The Directive first excluded 'uses of human embryos for industrial or commercial purposes' from patenting.[42] Although the original intention of listing unpatentable inventions was to clarify the regulation[43], its practical ramifications are ambiguous and misleading.[44] The moral provisions set out in the Directive also created some discomfort among member states, for example, in the case *The Netherlands (Italy and Norway, intervening) v. European Parliament and E.U. Council (E.C. Commission, intervening)*.[45]The Netherlands presented six arguments to revoke the

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[39] Press Release, Environmental Council, 2106th session, 16 June 1998.
[40] The Article 6(1) of the Directive.
[41] Rule 23 of the EPC. The Article 23(e) EPC provides that:(1) The human body, at the various stages of its formation and development ... cannot constitute patentable inventions. (2) An element isolated from the human body or otherwise produced by means of a technical process ... may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
[42] Article 6(2) of the Directive.
[43] The EPO Guideline said the purpose of this provision is to 'deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour', EPO Guideline C-IV. 4.1.
[44] Amina Agovic, 'Stem cell patents on a knife edge' (2008) 3 Journal of Intellectual Property Law & Practice 718.
[45] Case *The Netherlands (Italy and Norway, intervening) v European Parliament and E.U. Council (E.C. Commission, intervening)*, C-377/98, [2001] 3 C.M.L.R.49.

Directive.[46] The argument 'it infringes the principle of legal certainty' was discussed in Chapter three.[47]The claim is related to morality that 'the Directive violates fundamental rights'.[48] The Netherlands insisted that 'not provide for the free and informed consent of the donor of human biological material to patenting of inventions developed from or using this material' violated the fundamental right and value.[49] The CJEU holds that Recital 26 of the Directive confirmed:

> Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.[50]

Therefore, the CJEU concluded that the appellant claim on this point obviously failed. The CJEU stated that member states are responsible for assessing the morality of patents in the terms of 'the ethical, sociological, or philosophical context of each country'.[51]The court also affirmed that the Directive is a necessary harmonisation measure to eliminate biotechnology regulation disparities among member states. However, the intention of the EPC and the Directive is merely to make uniform the pre-grant phase.[52]No formal harmonisation of HESC regulation was achieved by the EPC and the Directive.[53]

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46 *ibid*.
47 *ibid*.
48 *ibid*.
49 *ibid*.
50 Recital 26 of the Directive.
51 Richard E Gold and Alain Gallochat, 'The European Biotech Directive: Past as Prologue' (2007) 7 European Law Journal 331.
52 Aurora Plomer, 'Stem cell patents: European Patent law and Ethics Report' (2006) reports for FP6 life sciences, genomics and biotechnology for health 88.
53 *ibid*.

5.2.3 The European Group on Ethics in Science and New Technologies (EGE) Supply Authoritative Opinions to Legislation

Although the EPC and Directive set out many moral provisions, neither the EPC nor Directive was specifically regulated with HESC. With the emergence of HESC technology, many legal issues related to it have become extremely urgent. The EGE was established in order to provide clear and predictable advice on the looming advance of this technology.[54] The EGE began as the Group of Advisers to the European Commission on the Ethical Implications of Biotechnology (GAEIB) supporting the regulatory process.[55] Compared to GAEIB which only belongs to the Commission, the EGE plays the role of "European decision makers".[56] However, the EGE as one example of "grey government" as it is an informal body.[57]

Before the Directive was implemented, two opinions given by the GAEIB influenced its development. One opinion, No. 3, concerned questions from the proposed Directive, ranging from patenting living organism, transgenic animals, the issue of human dignity through to biodiversity.[58] The opinion recommended clarifying the scope of previsions and the definition in the Directive, as well as harmonising biotechnology patent law within the community.[59] The other Opinion No. 8 covered the patenting issues on elements of human origin. The opinion advised that essential criteria such as novelty, inventive steps and industrial application should be examined under the moral framework that provides the protection of human dignity.[60] The opinion ascertained that citizens' rights in the EUROPE imply that 'the

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54 The European Group on Ethics in Science and New Technology, <http://ec.Europa.Europe/bepa/European-group-ethics/welcome/index_en.htm> accessed 7 March 2012.

55 *ibid*.

56 Helen Busby, Tamara Hervey and Alison Mohr, 'Ethical EUROPE law? The influence of the European Group on Ethics in Science and New Technologies' (2008) 33 European Law Review 803.

57 *ibid*.

58 *ibid*.

59 Opinion No 3 of the EGE, at 9.

60 Opinion No.8 of the EGE, at para.2.1.

economic advantages derived from biotechnological developments should in no way affect the respect of ethical requirements'.[61]

Reference to unsettled issues such as therapeutic diagnostic inventions involving the embryo and already established HESC lines, were separately reasoned by the EGE in opinion No. 16. The opinion suggested that research should be facilitated with human embryos and foetal tissues that remained after IVF. The creation of embryos for research must not be allowed.[62] The EGE affirmed that unmodified isolated stem cells accord with the patent requirements even if it refers to industrial applications.[63] Many patent authorities disagreed with this and believed no patent should be granted to unmodified isolated stem cells.[64] The EGE also held that 'no ethical obstacle to patentability attached to processes involving HESC, whatever their source…'[65] With the moral consideration of restrict patenting HESC, the opinion advocated either embryonic or non-embryonic stem cells were to be provided with no patent protection, except on the condition that they had been genetically modified in IVF treatments.[66] To some extent, the EGE enhanced 'the legitimacy, transparency, accountability, representativeness, effectiveness and efficiency of the European Union's legislative and executive decision-making'.[67]

In the adaption of Directive 98/44 on the legal protection of biotechnological invention, the EGE published many opinions involving ethical aspects of biotechnology inventions. According to Article 6 of the Biotechnology Directive, the use of human embryos for industrial or commercial purposes cannot be patented because it is contrary to morality. In opinion No. 12, the EGE argued to 'respect different philosophical, moral or legal approaches and

[61] *ibid* at para 2.5.
[62] Opinion No. 16 of the EGE.
[63] *ibid*.
[64] *Supra* note 7.
[65] *Supra note 42.*
[66] *ibid*.
[67] *Supra note 39.*

diverse national cultures' under the prohibition EUROPE-level funding for research that results in the destruction of human embryos.[68] Furthermore, opinion No. 15 distinguished between the types of human embryo and types of stem cell, particularly between "supernumerary" embryos and those created for research.[69] The implementation measures which assured the consistency of ethical rules and requirements were detailed in Opinion No. 22. In this opinion, the EGE suggested that 'applicants must provide information that the HESCs to be used result from non-implanted IVF embryos'.[70] The EGE, as a "grey governance" body plays a significant role in the moral right of stem cell research.

5.3 Cases Studies

The EUROPE modes of ethics engagement have become 'a political technology that constitutes a permanent feature of the new cultural politics as mechanisms are sought that will enable the refining, manipulating, resolving and legitimating of cultural differences'.[71]

5.3.1 How to Assess the Morality?

At the EUROPE level, the European Patent Convention contains a morality clause that excludes patenting immoral inventions[72], whereas the morality standard developed in the case law has established inconsistent standards (i.e., "abhorrence" and "unacceptability").

Case Howard Florey/Relaxin: the "abhorrence" standard with rebuttable presumption approach

The "abhorrence" standard is essentially implied from the case of Howard

[68] Opinion No.12 para.2.8
[69] Opinion No.15 para.1.12
[70] Opinion No.22 para.IV.2.2
[71] Brian Salter, 'Bioethics, politics and the moral economy of HESC science: the case of the European Union's Sixth Framework Programme' (2007) 26 New Genetics and Society 269.
[72] The Article 53 of European Patent Convention states that European patents shall not be granted in respect of: inventions the commercial exploitation of which would be contrary to "ordre public" or morality.

Florey/Relaxin, which relates to a patent application related to the DNA sequence coding for relaxin, the unexpected second form of human hormone that helps to reduce the need for Cesarean sections.[73] The patent was initially granted in 1991, but the Green party opposed it in the European Parliament. [74]One of the Green Party's primary objections was issuance of the patent was contrary to morality.[75] The Opposition Division (OD) first cited the "abhorrence" standard established in the *Hybrid plants* case. It stated that 'an invention will be excluded from patent protection only where the public in general would regard the invention as so abhorrent that the grant of a patent would be inconceivable'.[76] The OD used a "rebuttable presumption"[77] approach to develop the "abhorrence" standard:

> [A] fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that this is the case, objection should be raised under Article 53(a); otherwise not.[78]

Based on this standard, no overwhelming consensus has been reached that *Relaxin* patent involves the patenting of human life; therefore, the Green Party's morality objection is invalid.[79]

This EPO decision applies the general principle of narrowly interpreting the exclusion of patentability.[80] When the opponent requested to conduct a public survey of "what would be patentable", the OD refused and indicated that the EPO is not a proper organisation to determine fundamental moral

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[73] Howard Florey/Relaxin, EPO 6/1995 388.
[74] *ibid*
[75] Case *Relaxin/Howard Florey Institute*, T 0272/95 [2002] E.P.O.R. (The Green Party opposed European patent 112.149 granted to the Howard Florey Institute of Experimental Physiology and Medicine for human H-2 relaxin, a hormone involved in reproduction, and a DNA sequence coding for the hormone.)
[76] Case *Lubrizol/Hybrid plants*, T320/87 [1990] E.P.O.R. 173.
[77] Yan Min, 'Morality-an equivocal area in the patent system' (2012) 34 European Intellectual Property Review 261.
[78] Case *Howard Florey/Relaxin* [1995] E.P.O.R. at 549.
[79] *ibid*. at 378.

questions.[81] Therefore, to some extent, the "abhorrence" standard is much different from the "unacceptability" standard discussed below.

Case Harvard/ Onco-mouse: the "unacceptability" standard

The "abhorrence" standard is mainly implied in the *Onco-mouse* case, which involves the patentability of genetically modified mice, which are useful in cancer research.[82] In 1992, the Examining Division granted the patent,[83] which was then challenged on the ground that the invention violates the morality requirement of Article 53(a) of the EPC. The Technical Appeal Board (TBA) cites the "unacceptability" definition in the case *Plant Genetic Systems v. Greenpeace*, which states that '[t]he concept of morality is related to the belief that some behavior is right and acceptable, whereas other behavior is wrong, this belief being founded on the totality of the accepted norms that are deeply rooted in a particular culture'. [84] The TBA has developed the "unacceptability" standard by balancing "acceptable suffering" and "unacceptable suffering".[85] Specifically, the TBA weighs 'the suffering of animals and possible risks to the environment' and 'the invention's usefulness to mankind'.[86] The use of this balancing test resulted in the patent being upheld based on its huge benefits.

The EPO has developed two moral standards for its tests: a balancing test to determine whether the "unacceptability" standard applies and a rebuttable presumption that the "abhorrence" standard applies. The "abhorrence" standard provides minimum morality-based protections. [87] The "unacceptability" standard is frequently implicated in patent applications

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[80] The rational of the Directive, see *Supra* note 135.
[81] Case *Howard Florey/Relaxin* [1995] E.P.O.R. at 552.
[82] *HARVARD/Onco-mouse,*T19/90, [1990].
[83] For the method for producing transgenic animals, see EPO0169672.
[84] *Plant Genetic System/Glutamine synthetase inhibitors*, T356/93 [1995] E.P.O.R.
[85] *Harvard/Transgenic animal* T-315/03 [2005] E.P.O.R.
[86] *ibid.*
[87] See Margo A Bagley, 'A global controversy: the role of morality in biotechnology patent law' (2007) 57 University of Virginia Law school Public law and legal theory 317-346 (commenting that this "unacceptability" standard is certainly a lower hurdle for an invention to overcome than the balancing test); See also *supra* note 599 at 265.

related to life.[88] The EPO can adopt different moral standards during the initial examination and the appeal stages of a human biotechnology patent application.[89] The two above-mentioned methodologies are fundamentally different: 'the "balancing exercise" incorporates direct competition between diverse issues; conversely, the " rebuttable presumption" examines a raft of issues to determine if any one of them constitutes an "abhorrence".[90] The distinction between these two standards is significant because 'under the "balancing exercise" all of the issues considered form part of the reason why the invention is or is not patentable, whereas the "rebuttable presumption" approach identifies a single issue upon which the decision rests'.[91]In the foreseeable future, the equivocal of the moral provision in patent law is a barrier to the great medical potential.[92]

Case Plant Genetic Systems v Greenpeace: the Conflict between "Abhorrence" Standard and "Unacceptability" Standard

The case of *Plant Genetic Systems* involves an application to patent the glutamine synthetase inhibitors that help plants and seeds to resist weeds and fungal diseases.[93] The granted patent was challenged by Greenpeace, which argued that it created serious environmental risks.[94] The application was first rejected by the OD; Greenpeace then appealed to the Technological Board of Appeal (TBA). Both the "abhorrence" and "unacceptability" standards were discussed and applied in this case.

The OD initially refused to exercise the balancing test established in the

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[88] For example, the invention is related to animal and plant biotechnology.
[89] *Supra* note 54.
[90] *ibid.*
[91] *ibid.*
[92] *ibid.* (commenting that this is because, on one hand, the so-called morality exception is favored by the Greens, animal welfare activists and environmentalists as a powerful weapon against biotechnology inventions, and consequently they prefer a stricter moral standard which is in stark contrast to the proponents of genetic engineering who prefer a loose standard; and on the other hand, in contemporary society there are few, if any, inventions so obviously immoral as to raise little difficulty in denying a grant of patent on the grounds of morality.)
[93] *Plant Genetic System/Glutamine synthetase inhibitors*, T356/93 [1995] E.P.O.R. (TBA)
[94] *ibid.* at 8 (the exploitation of the present invention resulted in serious, irreversible environmental risks: the treated plants themselves could become weeds; Herbicide-resistance could spread to other plants; the ecosystems could be damaged).

Onco-mouse case.[95] By claiming that the "unacceptability" standard is 'not the only way of assessing patentability'[96], the OD found that 'the invention did not belong to the category of inventions that the public in general would have regarded as being so abhorrent or so dangerous that the grant of patent rights should have been inconceivable'.[97] Because the moral provision acts as an emergency safeguard, the OD further stated that patents should not be granted for inventions that are universally regarded as outrageous.[98] The reason that OD adopted the "abhorrence" standard instead of the "unacceptability" balancing test was that 'balancing does not even come into play unless concrete societal disadvantages of the invention are presented'.[99] Therefore, the OD held that 'in those very limited cases in which there is an overwhelming consensus that the exploitation of an invention would be immoral, an invention may be excluded from patentability under Article 53(a)'.[100]

However, by contrast, the TBA seems to apply the "unacceptability" rather than the "abhorrence" standard. Due to the nature of the EPC, the TBA historically explained the concept of morality relates to the belief 'that some behavior is right and acceptable, whereas other behavior is wrong, this belief being founded on the totality of the accepted norms that are deeply rooted in a particular culture'.[101] Based on this norm, an assessment of morality cannot possibly be achieved by balancing benefits and disadvantages because there is no sufficient evidence of true benefits or disadvantages.[102] However, the possibility remains that a morality assessment could involve assessing

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95 *Supra note 59* at 373

96 *Supra note 62. at 12.*

97 *ibid.*

98 Amanda Warren Jones, 'Vital parameters for patent morality-a question of form' (2008) 2 Journal of Intellectual Property Law & Practice 832.

99 *Supra* note 59.

100 *Supra* note 54.

101 *Plant Genetic System/Glutamine synthetase inhibitors*, T356/93 [1995] TBA. at 373.

102 *ibid*. (In the present case, since no sufficient evidence of actual disadvantages has been adduced, the assessment of patentability with regard to the Article 53(a) EPC may not be based on the so-called "balancing exercise" of benefits and disadvantages, as submitted by the Appellants. The Board observes that such a "balancing exercise" is not the only way of assessing patentability with regard to the Article 53(a) EPC, but just one possible way, perhaps useful in situations in which an actual damage and/or disadvantage (e.g. suffering of animals as in the case of decision T 19/90 supra) exists.

potential benefits and disadvantages. In the *Plant Genetic Systems* case, TBA held that the invention was not patentable after considering the potential environmental risk.[103]

The above analysis shows that the EPO conducts moral assessments inconsistently, which leads to a cycle of misapplication. Even in the EPO's decisions, two competing standards "abhorrence" and "unacceptability" standards may be applied. Moreover, this dual system provides no clear guidance on which approach is appropriate in any particular case.[104] Amanda Warren Jones has fully analyzed this issue and argues that 'only one defensible approach could offer cohesion in the European patent system'.[105] This case would apply the "rebuttable presumption" approach to the "abhorrence" standard.

The only remaining issue would be 'how this standard and methodology are to operate in practice, which would require an analysis of the evidence that forms the basis of the decision'.[106] Jones advances three arguments to support her view. First, unlike the "unacceptability" standard, which covering all issues related to whether a patent should be granted, the "abhorrence" standard focuses on a single issue on which to base a decision relied.[107] Second, 'it is not possible to weigh competing issues to determine "abhorrence" because that concept is an absolute that does not permit fine logical distinctions in the way that "unacceptability" does'.[108] In the case of *WARF*, the president of EPO observed that 'adopting a balancing exercise at the initial examination stage imposes an ethical assessment beyond the ability and mandate of patent offices'.[109] Third, the EPO has already identified cases involving "abhorrent" inventions. Only when such examinations are

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[103] *ibid*. at 40.
[104] *Supra note 54.* (analysing this issue and argues that only one defensible approach could offers cohesion in the European patent system.)
[105] *Supra* note 75.
[106] *ibid.*
[107] *ibid.*
[108] *ibid.*
[109] G2/06, comments by the President of the EPO, 28 September 2006 at 53-54.

appealed based on that issue might a decision be reversed.[110] Therefore, Jones believes that it is improper to balance issues involving human beings from either an ethical or an evidentiary perspective.

5.3.2 Whether HESC should be Included in "Human Embryo"? What is the Scope of "Industrial or Commercial Use"?

Another enduring ambiguous aspect of morality is commercial exploitation. The scope of the industrial or commercial use in Article 53(a) of EPC determines the arena for the moral assessment. In patent examination, morality is capable of being determined only if commercial exploitation has been assured.[111]

Case University of Edinburgh: a broad approach by the Opposition Division (OD) on the interpretation of "human embryos"

The scope of the exclusion of the "use of human embryos for industrial or commercial use" was first addressed in *University of Edinburgh/Stem Cell Isolation*. That case involved a European patent held by the University of Edinburgh's Austin Smith and Peter Mountford addressed methods of selecting for animal stem cells (including HESC).[112] To further complicate matters, a term used in the patent claim referred to animals, not excluding humans.[113] Accordingly, the patent was opposed by fourteen parties, including Germany and the Netherlands, because it might cover HESC, not just animal stem cells. Those parties filed in the OD[114] on the ground that granting the patent would violate Article 53(a) of the EPC[115].

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[110] Amina Agovic, 'Stem cell patents on a knife edge' (2008) 3 Journal of Intellectual Property Law & Practice 718.

[111] Amanda Warren Jones, *A mouse in sheep's clothing* 20 European Intellectual Property Review 445, 448 (1999) (observing that examination at the patenting stage requires that morality be determined before exploitation has become assured. Therefore it is inevitable that any assessment at such an early stage in the invention's commercial development will entail some considerations which will consequentially prove superfluous.)

[112] EP0695351, Edinburgh University.

[113] *ibid*.

[114] *University of Edinburgh/Stem Cell Isolation (Edinburgh),* T-1079/03 EP 949131742 unreported, July 21, 2003, Opposition Division.

[115] Under the Article 53(a), European patents should not be granted for inventions involving 'uses of

The OD distinguished between fact and opinion and finally concluded that based on the Biotechnology Directive, HESC derived from destruction of human embryos are not patentable.[116] First, the OD acknowledged the existence of two primary views of the scope of the term "human embryo" as used in Article 53(a) of the EPC: the narrow interpretation understood it to mean "human embryos"; and the broad interpretation understood it to mean "human embryos together with the cells retrieved from the destruction of those embryos—namely, human ES cells".[117] Next, the OD noted that Article 53(a) of the EPC is equivalent to Article 6(2) of the Directive. The original purpose of the Directive, as set forth in its recitals, is that HESC fall within the scope of the term "human embryo".[118] Thus, the OD held that the broad interpretation was appropriate.

With regard to the term "industrial or commercial use", the OD stressed that "use" should be considered in the event that an invention is morally acceptable. 'If the patenting of a product is ethically unacceptable it is hardly conceivable that the patenting of "uses" of this product could be judged differently'.[119] In the *University of Edinburgh/Stem Cell Isolation* case, the invention was obtained by destroying human embryos; thus, moral scrutiny of the "use" of that invention would be unnecessary. Ultimately, the OD ruled that the scope of the exclusion related to the use of human embryos for industrial or commercial purposes '…must be interpreted broadly to encompass not only the industrial or commercial use of human embryos but also the use of human ES cells retrieved from the destruction of human

human embryos for industrial or commercial purposes'.

116 *ibid.*

117 Walters Leroy, 'HESC research: an intercultural perspective' (2004) 14 Kennedy Institute of Ethics Journal 3-38.

118 Recital 16 of the Directive provides that 'it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented'.

119 Aurora Plomer, 'Stem cell patents: European Patent law and Ethics Report' (2006) reports for FP6 life sciences, genomics and biotechnology for health 88.

embryos'.[120]

However, a former board of Appeal Member at the EPO, Claudio Germinario, expressed a different opinion; specifically, that to conform to a previous TAB ruling, the term "human embryo" in Article 6(2) of the Directive should be interpreted narrowly.[121] He further stated that if human ES cells are 'available through importation or from many other sources', there is no moral obstacle to using them.[122] Under the OD's ruling, it is contrary to morality to use either spare embryos from IVF procedures or embryos created for research. Although the OD's ruling is controversial, it is not binding on other divisions such as the EBA. Therefore, the EPO's interpretation of Article 53(a) stands.

Case Use of embryos /WARF/Stem cells (G2/06): the Landmark Ruling by the EPO of Patenting HESC

The case of *WARF* seamlessly addressed the same questions as *University of Edinburgh*.[123]*WARF* involved a European patent application by the Wisconsin Alumni Research Foundation (WARF) titled "Primate embryonic stem cells", covering the derivation and cultures of pluripotent embryonic stem cell lines.[124] The patent description shows that WARF's claims address inventions obtained through a method that involves the destruction of human embryos.[125] Although the application does not directly claim that method, human embryos are inevitably destroyed because the method is the only way to obtain the invention. In 2004, the EPO's Examining Division denied the application.[126] The examiners held that the claims violated Article 53(a), in

120 *ibid.*
121 Germinario C, 'The Value of Life' (2004) Patent World 16-18.
122 *Supra* note 96.
123 WARF/Stem cells (G2/06) [2009] E.P.O.R. 15 (EPO Enlarged Broad of Appeal).
124 WARF's European patent application, App.No.96903521, claims 'a cell culture comprising primate embryonic stem cells that (i) are capable of proliferation in an *in vitro* culture for over one year, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and are not noticeably altered by the culturing, (iii) maintain the potential throughout the culture to differentiate into derivatives of endoderm, mesoderm, and ectoderm tissues, and (iv) are prevented from differentiating when cultured on a fibroblast feeder layer'.
125 Eur. Pat. App. No.96,903,521 published as EP0770125.
126 European Patent application, NO. 96 903 521.1, published as WO 96/22362 (EP Nr. 0 770 125).

conjunction with Rule 28(c) of EPC 2000,[127] because 'as regards the generation of HESC cultures, the use of human embryos as starting material is described as indispensable in the application as originally filed.'[128] Although the patent application did not directly claim human embryos, the invention is related to them and exclusively relies on them.[129] The examiners also ascertained that the use of human embryos as a starting material is a use for industrial purposes within the scope of Rule 28(c) of the EPC 2000, which concerns "uses of human embryos for industrial or commercial purpose", and the invention therefore could not be patented.[130]

The decision was appealed and turned to the Board of Appeal in 2004.[131] However, the Broad did not rectify the decision and referred four questions to the Enlarge Board of Appeal (EBA):

> 1) Does Rule 28(c) EPC extend to patent applications whose claimed subject-matter comprises a product derived from human embryos? 2) If the answer to question 1 is yes, does Rule 23d(c) [now 28(c)] EPC forbid the patenting of claims directed to products (here: HESC cultures) which – as described in the application - at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims? 3) If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims? 4) In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human

[127] Rule 28(c) of EPC 2000 provides that 'Under the Article 53(a), European patents shall not be granted in respect of biotechnological Inventions which, in particular, concern the following: … c) uses of human embryos for industrial or commercial purposes'.
[128] WARF/Stem Cells T1374/04 [2006] E.P.O.R.
[129] *ibid*.
[130] *ibid*.

embryos (here: e.g. derivation from available human embryonic cell lines)?[132]

The *WARF* case required the EBA to perform a brief analysis of four questions. The first question is procedural and concerns the effective time of Rule 28(c). Regardless of the answer to that question, the requirements of Article 53(a) should be met beyond Rule 28(c).[133] The second and third questions refer to the main issue in the case: the patentability of inventions involving the destruction of human embryos. The core argument in the case relates to the proper approach for interpreting the phrase "use human embryos for industrial or commercial use".[134] The fourth question relates to whether the decision in this case is binding when the method for which the patent was sought was capable of being accomplished without destroying human embryos as of the filing date.[135]

In 2008, by answering the four questions set forth above, the EBA decided that no patent would be granted on inventions related to the destruction of human embryos.[136] First, the EBA affirmed that Rule 28(c) is retroactive to patent applications prior to enforcement.[137] Second, the EBA stated that the rationale underlying Rule 28(c) is 'the prohibition of the misuse or commodification of embryos'.[138] The exclusion of Rule 28(c) listed in Recital 42 of the Directive applies only when human embryos are used for a "therapeutic or diagnostic purpose".[139] The EBA further held that legislators deliberately declined to provide either a precise definition or a restricted

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131 *ibid*.
132 *ibid*.
133 Rule 23d(c) contains the same wording as the Article 53(a) EPC, which took effect in 1973. See note 13.
134 Ewan Nettleton, 'EPO's Enlarged Board rules on patenting stem cell inventions' (2009) 4 Journal of Intellectual Property Law & Practice 306.
135 *Supra* note 117.
136 *ibid*.
137 *ibid*.
138 *ibid*.
139 Recital 42 of the Directive provides that 'whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes that are applied to the human embryo and are useful to it'.

interpretation of the term "embryo".[140] With respect to the appellant's allegation that the claim does not cover human-embryo destruction, the EBA identified the term used in rule 28(c) as "invention", not "claim". The HESC derivation method disclosed in the description is an "essential and integral" part of the invention.[141] Since the destruction of the embryo is an "essential and integral" part of the invention, then the use of the human embryos is for "industrial or commercial exploitation". However, the appellant defended its destruction of human embryos as not for "industrial or commercial use".[142] The EBA disagreed and noted that human-embryo destruction is one step of the manufacturing procedure described in the claim.[143] Performing an invention that inevitably destroys human embryos is one type of commercial exploitation. Because the patent application involved with the destruction of human embryo, the patentability criterion applies to all steps of inventions.[144] Fourth, the EBA indicated its decision has no influence over the patentability of 'general inventions relating to human stem cells or human stem-cell cultures'.[145]

This case represents a rare instance in which an appellant has requested the EPO to refer a patent question to the European Court of Justice (CJEU) because Rule 28((c) is the same as Article 6(2)(c) of the Directive.[146] However, the EBA held that neither the EPC nor the Implementing Regulations grant any authority to refer questions of law to the ECJ.[147] The conjunction of Rule

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140 *Supra note 117.*

141 *ibid. at 25* (finding that the destruction of the human embryo under the derivation method is an integral and essential part of the industrial or commercial exploitation of the claimed invention, and thus violates the prohibition of Rule 28(c) (formerly 23d(c)) of EPC 2000).

142 *ibid.* at 24.

143 *ibid.* at 29. ("[I]t is important to point out that it is not the fact of the patenting itself that is considered to be against the *ordre public* or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravenethose concepts.")

144 *ibid.*

145 *ibid.* at 35.

146 *ibid.* Rule 28 of EPC (providing that "under the Article53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: (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").

147 *ibid.*

28(c) of EPC with Article 6(2)(c) of the Directive does not compel the conclusion that 'the CJEU now has jurisdiction to decide matters for the EPO under the EPC'.[148] The Biotechnology Directive should be used by the EPO only as a supplementary method of interpretation, not as a direct source.[149] Moreover, the decision noted that national patent bodies, such as the UK Intellectual Property Office, are to some extent out of step and should consider EPO's the view on patenting HESC.[150] Therefore, the EBA believes that the EPO could not seek CJEU guidance.

The rejection decision seems not fully clarified the law. According to Dr Paul Chapman, partner at Marks and Clerk UK, '[i]t's very specific in what it says, which means it's very non-specific in what it doesn't say. At the time when Warf were filing there was no way they could carry out research without harming the embryo'.[151] He further indicated that the Enlarge Board of Appeal had not given clear answer to the circumstance in which the applicants use stem cells as the starting point without themselves destroying an embryo. What is worse, these situations such as derived from stem cell lines are very common among the applications. The uncertainty of law, which is the greatest enemy to patent law, might be inevitable due to this grey area.[152]

Another challenging phenomenon is that most patent applicants file not only at the EUROPE level but also the national level. It is a well-known fact that the Europe reveals the ethical diversity. The standards of patentability of HESC vary greatly form stated to state. For instance, the UK Patent Office

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148 *ibid.*
149 *ibid.*
150 *ibid.*

151 Sigrid Sterckc and Julian Cockbain, 'Assessing the morality of the commercial exploitation of inventions concerning ses of human embryos and the relevance of moral complicit: comments on the EPO's WARF decision' (2010) 7 Scripted 83.
152 Chapman P, 'Rejection of controversial stem cell patent fails to fully clarify law' (M&C, 28 November 2008) <http://www.marks-clerk.com/uk/attorneys/news/newsitem.aspx?item=228> accessed online 17 October 2011.

tends to narrowly explain their counterpart of 28(c) EPC.[153] In UK, HESC derivation and nuclear transfer of human somatic cell are both permitted and licensed by the Human Fertilisation and Embryology Authority (HFEA).[154] On the contrary, in a civil law jurisdiction such as Germany, the majority point of the research on human stem cell is immoral. Scientists are merely allowed to use HESC lines derived from the labs in foreign country. Besides, HESC lines could only be obtained before 2002 outside German.[155]

Obviously, different perspectives on HESC research between countries lead to the inconsistent interpretations of the moral provision. Thus, the decision had not eliminated the uncertainty of the scope of moral exclusion. Currently, embryo stem cell research has become one of the key areas in biotechnology. The concern that the moral rejection would hinder the development of stem cell research in Europe is reasonable. It might lead to the lag of Europe in contrast to other economic areas such as United State and Japan.

However, the EBA's decision has had a significant and profound influence in the field of HESC. It has removed doubt on some fundamental issues and built a foundation of legal certainty for Rule 28(c). It unveiled the moral dilemma in patentability of HESC and leaves space for evaluating the scope of Rule 28(c).[156] Some scientists predicted that the decision would encourage European companies to develop new HESC technology because the old technology is not patentable.[157] However, the decision does not resolve all controversies around HESC and many important questions remain unsettled,

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153 Owen C.B. Hughes, Alan L.Jakimo and Michael J. Malinowski, 'United States Regulation of Stem cell research: recasting government's role and questions to be resolved'(2008) 37 Hofstra law review 383-443.

154 Minger S, 'Introduction to Stem Cell research in the UK', August 2007 <http://ukChina.fco.gov.uk/en/working-with-China/science-innovation/pis2/stemcell/intro-stemcell> accessed online 14 October 2011.

155 Russo E, 'Follow the Money-The Politics of Embryonic Stem Cell Research' (2005) 3 PLOS Biol 234

156 For instance, for an interpretation of prohibiting patents for 'all the possible variants of the prohibited inventions in different circumstances', see Pierre Treichel, 'Case comment G2/06 and the verdict of immorality' 40 (2009) 450.

157 James Randerson, 'Europe rejects patent governing use of embryonic stem cells' *The Guardian* (London, 27 November 2008) <http://www.guardian.co.uk/science/2008/nov/27/embryonic-stem-cells-patent> accessed 24

including those that involve inventions using HESC as starting material. 'It is very specific in what it says, which means that it is very non-specific in what it does not say'.[158]

Although the decision did not thoroughly clarify the scope of moral exception, it did unambiguously preclude the patent related to the destruction of human embryo. So many homologous applications will not be protected. This prohibition will press scientists to draw more attention to nondestructive embryo stem cell research. To some extent, the destruction of human embryo could be reduced. Second, the decision is in favor of the stem cell research in Europe. The claims of WARF were relevant to the basis of stem cell research. If the relevant basic work patents granted to the inventors, expensive royalty and unnecessary restraints would hinder the subsequent stem cell research in this area. With the increase cost of research and development, the investment to this area will be correspondingly shrinking. Obviously, many disease researches that based on embryo stem cell could be influenced by the declining investment. Third, the sanctity of human embryos can be developed into human life should be respected. In spite of the fact that many researches use the human embryos that are discarded as medical waste from IVF (Vitro fertilisation) clinics, those embryos still have the right to be respectful treated instead of being destructed. The human embryo stem cell instrumentalisation damages the integrity of life and violation of human dignity. The consequence of abuse of human embryo would be inconceivable.

Case Oliver Brüstle v Greenpeace: the Decision by CJEU on Patenting HESC

The ECJ and the EPO have similar concerns regarding the patentability of inventions involving human-embryo destruction. In *Oliver Brüstle v.*

February 2012.

[158] Chapman P, 'Rejection of controversial stem cell patent fails to fully clarify law' (M&C, 28 November 2008) <http://www.marks-clerk.com/uk/attorneys/news/newsitem.aspx?item=228> accessed 25 February 2012.

Greenpeace[159] the ECJ addressed the same two questions as the WARF case — namely the definition of the term "human embryos" and the scope of "industrial or commercial use" under Article 6(2) of the Directive — before concluding that the invention was not patentable.[160] The CJEU and the EPO seem to have similar concerns about this issue. The case involved a patent that had been overturned by the German Federal Patent Court (Germany's restrictive approach to the generation of mammalian embryonic stem cells, including HESC, is discussed below).[161] The patent claims did not cover the production of HESC, but its methods of obtaining the cells were inevitably related to human-embryo destruction.[162] However, unlike the situation in the WARF case, the HESC in this case had been obtained from existing HESC lines, consistent with German law.[163]

On March 10, 2011, the court concluded that, regardless of whether the description contained any reference to the use of embryos, the invention is not patentable since the patent 'necessitates the prior destruction of human embryos'.[164] The decision, which was authored by Advocate General Bot, appears to bring trouble beyond the patentability issue.[165] Some scholars commented the decision is too restrictive.[166] The letter further stated that the opinion placed too much emphasis on cell-line origin, ignoring the time at which a line has been established.[167] Another commenter opined that the ruling might encourage 'vacillating countries to introduce restrictive laws or

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159 Case C-34/10, Brüstle v. Greenpeace e.V (October 18, 2011), http://curia.Europa.Europe/juris/document/document.jsf?text=&docid=111402&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=98844.

160 *Oliver Brustle v Greenpeace* C-34/10.

161 German Patent DE 197 56 864

162 *ibid.*

163 German allows HESC research based on the existing HESC lines. Supra note 148.

164 The decision is fully discussed in the section on European regulatory approaches to national jurisdiction in HESC research. See supra note 148.

165 *ibid.* (the court states that the exclusion from patentability concerning the use of human embryos for industrial or commercial purpose set out in the Article 6(2)(c) of the Directive 98/44 also covers the use of human embryos for purposes of scientific research, only use of therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable.)

166 Alison Abbott, 'Europe rules against stem cell patents-work with HESCs is contrary to ethics' (2011) 471 Nature 280

167 *ibid.*

complete bans on the research'.[168]

Immediately after the opinion was published, leaders of twelve major stem-cell projects wrote an open letter addressing the potential effect the prohibition on patent protection for embryonic stem cells would have on the entire field of stem-cell-related inventions. [169] That letter stated that embryonic stem-cell lines are not embryos: '[b]ecause more than 100 established lines are now available through national and international cell banks, concerns about commercialization of human embryos are misplaced'.[170] It further states that without patent protection, the medical stem-cell industry will lose its will to develop HESC-based therapies.[171] Moreover, the letter states, that some existing achievements developed through research under the European Commission and various EUROPE member states, would also be nullified by a ban on patentability.[172] Finally, the letter states a hope that the CJEU's Grand Chamber would 'deliberate on the full implications before making a legally binding ruling'.[173]

Disappointing the authors of the letter, the CJEU's Grand Chamber eventually ruled against patentability on October 18, 2011.[174] The CJEU held that even already-existing HESC have been harvested from human embryos. Therefore, inventions involving either newly derived HESC or HESC obtained from established stem cell lines are excluded from patentability. Moreover, "use for industrial or commercial purposes" under Article 6(2) includes the use of human embryos for scientific research.[175] Austin Smith[176], who wrote the letter criticising the March 10 decision, complained that 'we

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168 *ibid.*
169 Austin Smith, 'No to ban on stem cell patents' (2011) 472 Nature 418.
170 *ibid.*
171 *ibid.*
172 *ibid.*(listing drug development and cell-replacement therapy as examples of achievements that would be nullified by a ban on patentability).
173 *ibid.*
174 Judgment of the Court (Grand Chamber) in *Oliver Brüstle v Greenpeace* C-34/10, referencing a preliminary German ruling under the Article 267 of the TFEU, 18th October 2011.
175 According to a recital in the Directive, only uses for therapeutic or diagnostic purposes are not covered by the Article 6(2), see *supra note 680*.
176 Austin Smith is affiliated with the Wellcome Trust Centre for Stem Cell Research at the University of

are funded to do research for the public good, yet prevented from taking our discoveries to the market place where they could be developed into new medicines'.[177] The verdict might have the unfortunate effect of driving stem-cell scientists out of Europe and blocking the development of some therapies derived from stem cells.

After the *Brüstle* ruling, we could conclude that the EUROPE has erected a barrier to patenting HESC-related inventions. Moral considerations are deeply rooted in the EUROPE—even in the UK, which has liberal policies towards HESC research.[178] Despite the huge efforts made in the HESC regulations, there remains an inconsistency related to whether a moral examination is properly an element of patent law.[179] The CJEU and the EPO have different system of assessing morality standards, which resulted in legal uncertainty. Therefore, from my point of view, the Patent Office should not take the responsibility of examining the morality of HESC inventions: it would be better to leave such decisions to the Ethics Committee.

5.4 Regulatory Approaches of National Jurisdiction in HESC Research in EUROPE

Based on their different scientific, economic and moral ambitions, Member states have adopted different approaches in interpreting Article 53(a) of the EPC. In the plurality view, some states have heightened moral concerns, while others focus on the commercial applications. Member states such as France, Italy and the UK use the same wording in their own laws as the EPC's

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Cambridge.

177 Emma, 'A Court bans stem cell patents' (Europerostemcell, October 18th 2011) <http://www.Eurostemcell.org/node/21554> accessed February 27 2012.

178 See Department of Health & Social Security, Report of the Committee of Inquiry into Human Fertilisation and Embryology ("The Warnock Report") (1984), <http://www.hfea.gov.uk/2068.html > accessed January 24 2014 (providing a dissenting view from those in the UK who believe the human embryo has a special status and should not be used for research,). But see Aurora Plomer, 'Beyond the HFE Act 1990: The Regulation of Stem Cell Research in the UK' (2002) 10 Medical Law Review 132, 133 (The UK currently stands alone in Europe in permitting the creation of human embryos specifically for research purposes, including the use of cloning techniques.).

179 See Graeme Laurie, 'patenting stem cells of human origin' (2005) 26 European Intellectual Property Review at 61 ((stating that it has taken the advent of embryonic stem cell technology to expose the weakness of the system and the hopelessly confused state in which we now find ourselves..)

Directive.[180] However, some states use the wording to broaden the Directive's moral exclusion.[181] Nevertheless, the overview of policies in member states reveals a patchwork of disparate regulations on the patentability of HESC.

5.4.1 Permissive Policy: UK Approach

The rational reason for a permissive policy is to advance scientific study that enables society to conquer diseases, benefitting all of society.[182] In the EUROPE, Sweden, Spain, Belgium, Denmark and so on all adopted a liberal policy towards HESC research. Despite these countries' permissive policies, some core ethical principles such as human cloning are not allowed. Similarly, human reproductive materials should not be commercialised are all agreed in these countries.

As this thesis will analyze in the following section, this liberal policy is well articulated in the UK's regulations and in funds for and the permitted range of stem cell research.

From Warnock Report to Human Fertilisation and Embryology Act 1990: License Up to the Formation of the Primitive Streak (14 Days after the Mixing of the Gametes)

The UK's regulatory system on HESC research is considered one of the best in the world.[183]Professor Anne Mclaren of the Wellcome Trust Gurdon Institute remarked that the 'UK has a sensible and scientifically based regulatory system that has functioned with few major problems for the past sixteen years'.[184]Although both the US and the UK adopt permissive regulatory approaches to HESC research, the US mode does not seem appropriate for the

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[180] Åsa Hellstadius, 'A comparative analysis of the National implementation of the Directive's Morality Clause', in Aurora Plomer and Paul Torremans eds, *Embryonic stem cell patents: European Patent Law and ethics*, (1st edn, Oxford University Press 2009) 96-148.

[181] *ibid*.

[182] Bartha Maria Knopper, 'Genetic Technologies: Commercialization of Genetic Research and Public Policy' (1999) 286 Science 2277.

[183] UK Government proposals for the regulation of hybrid and chimera embryos, House of Commons Science and Technology Committee, March 2007, <http://www.publications.parliament.uk/pa/cm200607/cmselect/cmsctech/272/27202.htm> accessed 19 January 2012.

UK's moral atmosphere.[185]Within the EUROPE, the UK's liberal approach was strongly criticized by opponents.[186]

The Warnock report widely discussed two extreme views: (1) religious members of the Catholic Church who believe that the human embryo has human status and (2) utilitarians who insist that the human embryo has no moral status.[187]Bypassing the fundamental question of whether an embryo is a human being, the highlight of the Warnock report is its endorsement of the view that a human embryo has a special moral status and that its particular status depends on its stage of development.[188]The Warnock report suggests that HESC research should be prohibited when cell differentiation has occurred after 14 days and the appearance of the primitive streak.[189]The UK legislature generally accepted HESC research using either embryos created for research or IVF waste embryos[190] and agreed that embryos used in research should be no older than 14 days.[191]

Based on the Warnock report, the Human Fertilisation and Embryology Act (HFE Act) was passed in 1990. The HFE Act was revised considerably in 2008. Because the huge potential of HESC was not foreseen at the time of passage of the HFE Act, it could be judged as accidental rather than by design that

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184 *ibid*.

185 Aurora Plomer, 'Beyond the HFE Act 1990:the regulation of stem cell research in the UK' (2002) 10 Medical Law Review 132.

186 Jan Deckers, 'Why Eberl is Wrong: reflections on the Beginning of Personhood' (2007) 21 Bioethics 270.

187 *Supra note 152*.

188 Warnock Report 1984, <http://www.hfea.gov.uk/2068.html> accessed 19 January 2012.

189 *Supra note 152*.

190 Because the proportion of successful IVF is normally at best 20-25%, doctors must produce many surplus embryos. These embryos are byproducts of IVF and are usually discarded or destroyed.

191 There are four main views accepted by UK legislators: "argument from suffering justifies embryo research because of its potential to assist the development of treatments for disease"; "argument from twinning asserts that early embryos cannot be considered human individuals because blastocysts can develop into two human beings"; "the argument from capacities suggests that since embryos lack the ability to think, act and communicate they cannot be accorded full status as human beings"; "argument from potentiality accepts that though the embryo has the potential to develop into a human being, this can only occur under specific circumstances and therefore it cannot be considered a human being in itself". Erica Haimes, Rouven Porz, Jackie Scully and Christoph Rehmann Sutter, 'So what is an embryo? A comparative study of the views of those asked to donate embryos for hESC research in the UK and Switzerland' (2008) 27 New Genetics and Society 113.

embryo research is permitted under the Act.[192] According to Schedule 2, section 3 (1), the legitimate purposes for which research could be licensed:

> (a)[P]romoting advances in the treatment of infertility, (b) increasing knowledge about the causes of congenital disease, (c) increasing knowledge about the causes of miscarriages, (d) developing more effective techniques of contraception, or (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.[193]

The Human Fertilisation and Embryology Authority (HFEA) was created by the HFE Act.[194] HFEA is one of five critical regulatory bodies that make up the integral HESC regulatory framework in the UK.[195] HFEA licenses and regulates embryo research and UK fertility clinics.[196] Additionally, the Human Tissue Authority (HTA) and UK Stem Cell Bank (UKSCB) are mainly responsible for overseeing the deposit and use of embryos and stem cell lines.[197] The Gene Therapy Advisory Committee (GTAC) and Medicine and Healthcare Products Regulatory Agency (MHRA) are in charge of conducting clinical trials and investigating harmful accidents.[198] In light of the HFE Act of 1990, the UK is the only country in the EUROPE that allows embryos to be created for research purposes.

Whether Human Embryo Created by Cell Nuclear Replacement (CNR) is an Embryo Defined by the HFE Act 1990?

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[192] Ryan Morgan, 'A tight fit? Deficiencies in the Human Fertilisation and Embryology Regulations 2001' (2007) 28 Statute Law Review 199.

[193] Schedule 2, section 3 (1) of Human Fertilisation and Embryology Act 1990.

[194] Human Fertilisation and Embryology Act 1990, <http://www.legislation.gov.uk/ukpga/1990/37/contents> accessed 20 January, 2012.

[195] Human Fertilisation and Embryology Authority (HFEA), Human Tissue Authority (HTA), Medicines and Healthcare Products Regulatory Agency (MHRA), Gene Therapy Advisory Committee (GTAC) and UK Stem Cell Bank Steering Committee (UKSCB)

[196] Human Fertilisation and Embryology Authority, <http://www.hfea.gov.uk/> accessed 20 January 2012.

[197] Human Tissue Authority, <http://www.hta.gov.uk/> accessed 20 January 20 2012; UK Stem Cell Bank, <http://www.ukstemcellbank.org.uk/> accessed 20 January 2012.

[198] Gene Therapy Advisory Committee, <http://www.dh.gov.uk/ab/GTAC/index.htm> accessed 20 January 2012; Medicines and Healthcare Products Regulatory Agency, <http://www.mhra.gov.uk/#page=DynamicListMedicines> accessed 20 January 2012.

The HFE Act of 1990 was initially passed to settle the dispute over In Vitro Fertilisation (IVF).[199] However, Dolly's birth prompted questions about whether HESC research in Cell Nuclear Replacement (CNR) fell within the scope of the HFE Act.[200] Faced with the possibilities of human cloning and tissue factories, the HFEA collaborated with the Human Genetics Advisory Commission (HGAC) to address these questions. A joint report by the two organisations stated that the HFE Act of 1990 was effective in research involving CNR.[201] The nuclear replacement of eggs is permitted because it is not listed in the HFE Act, it is permitted, and the monitoring of NCR is under the jurisdiction of the HFEA.[202] During the same period, Chief Medical Officer Professor Donaldson was commissioned by the government and also reported beyond the legal scope of the HFE Act of 1990. In the Donaldson Report, research involving NCR is allowed under the HFE Act of 1990 provided that 'it is for one of the existing specified research purpose'.[203] Compared with the joint report, the Donaldson report indicated that embryos created for research generate more moral objections than spare embryos.[204] The report further proposed to "enact new legislation to ban CNR for reproductive purposes.[205]

Following these reports, Parliament approved the 2001 Human Fertilisation and Embryology (Research Purpose) Regulations to extend the legitimate purposes under Schedule 2, Section 3(1) of the HFE Act. Three conditions were added to obtain a license for research: '(a) increasing knowledge about

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[199] Aurora Plomer, 'Beyond the HFE Act of 1990: the regulation of stem cell research in the UK' (2002) 10 Medical Law Review 132-264.

[200] Dolly was the first mammal to be cloned from an adult somatic cell, using the process of nuclear transfer. <http://en.wikipedia.org/wiki/Dolly_(sheep)> accessed July 6 2014; see also *Supra* note 98.

[201] Cloning issues in reproduction, science and medicine, <http://www.dh.gov.uk/ab/Archive/HGAC/index.htm> accessed 22 January 2012.

[202] *ibid.*

[203] Stem Cell Research: Medical Progress with Responsibility, a report from the Chief Medical Officer's Expert Group reviewing the potential of developments in stem cell research and cell nuclear replacement to benefit human health, Department of Health, June 2000, <http://www.lifecellinternational.com/downloads/whitepapers/stemcell_research_22.pdf> accessed 22 January 2012.

[204] *ibid.*

[205] CNR for reproductive purposes means that a cloned embryo could be implanted in a womb and cloned fetus allowed to born.

the development of embryos; (b) increasing knowledge about serious disease; or (c) enabling any such knowledge to be applied in developing treatments for serious disease'.[206] The regulation presents two clear deficiencies. First, according to the HFE Act of 1990, human cloning could potentially be permitted in the UK.[207] The public is uneasy about cloning humans and believes that it should have been strictly banned by regulation.[208] However, the 2001 regulation does not clearly outlaw the cloning of human embryos. Second, the definition of "serious disease" under Section 2(2)(c) might be narrowly read to preclude conditions such as injury or trauma.[209] Thus, some important therapeutic cloning, such as production of skin tissue, brain trauma or spinal cord injury, would not be allowed to develop in the UK.

Because the 2001 Regulation only extended the legitimate license purposes and did not answer the question of whether human embryos created by CNR fell within the definition of "embryo" under the HFE Act of 1990, the group Pro-life Alliance brought a claim for judicial review.[210] In *Quintavalle v. Secretary of State for Health*, Judge Crane of the High Court held that fertilisation is essential to the definition of an embryo[211], and that an organism produced by CNR does not have complete fertilisation; therefore, the creation of human embryos through CNR falls outside the meaning of embryo in section 1 of the HFE Act of 1990.[212] Judge Crane also denied that section 3(3)(d) is effective in licensing of CNR by reason of fertilisation.[213]

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[206] Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (S.I. 2001 No. 188), <http://www.legislation.gov.uk/uksi/2001/188/contents/made> accessed 24 January 2012.

[207] Wellcome Trust, Public Perspective on human cloning, <http://www.wellcome.ac.uk/About-us/Publications/Reports/Public-engagement/wtd003422.htm> accessed 26 January 2012.

[208] *ibid*.

[209] Roger Brownsword, 'Stem Cells, Superman, and the Report of the Select Committee' (2002) 65 the Modern Law Review 568.

[210] Lee Robert Gregory, *Human Fertilisation and embryology: regulating the reproductive revolution*, (1ST edn, Blackstone Press 2001)

[211] Section 1(1)(b) of HFE Act 1990 provides that: "the meaning of embryo, gamete and associated expressions in this Act, expect where otherwise stated, references to an embryo include an egg in the process of fertilisation".

[212] *Quintavalle v. Secretary of State for Health* [2001] 4 All E.R. 1013.

[213] Section 3(3)(d) of HFE Act 1990 provides that: "a license cannot authorise replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person embryo or subsequent development of

Although *Quintavalle*'s narrow interpretation of the HFE Act of 1990 seemed to be an exemplary judgment, it was reversed by the Court of Appeal.[214] First, the lords explained the consistency between the rules that 'statutory language retain the meaning' and that 'a statute is always speaking" through the analogy that '[i]f Parliament, passed an Act applicable to dogs, it could not properly be interpreted to apply to cats; but it could properly be held to apply to animals which were not regarded as dogs when the Act was passed but are so regarded now'.[215]Additionally, the lords referred to the ruling in *Royal College of Nursing v. Department of Health and Social Security*[216] that 'when a new state of affairs, or a fresh set of facts bearing on policy, comes into existence, the courts have to consider whether they fall within the Parliamentary intention'.[217] The lords also noted that the HFE Act was passed when embryos could only be created by fertilisation and that the definition of embryo should be extended with the advance of technology. Finally, the court of appeal held that embryos created by CNR were within the ambit of the HFE Act.[218] Aurora Plomer concluded that the judicial attempts to control HESC research under the HFE Act of 1990 exhibit 'the weaknesses and deficiencies of precipitated legal intervention'.[219] She suggested that the government rather than the court should be responsible for reviewing the HFE Act.[220] Plomer's opinion was cited in the legal challenge to the patentability of research involved human embryos.[221]

Inventions Related HESC: Patentable or Non-Patentable?

One main difficulty faced by the UK is the creation of a rule regarding the patentability of inventions involving HESC. The UK Patent Act of 1977 was

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an embryo".

214 *Quintavalle v. Secretary of State for health* [2003] UKHL 13.

215 *ibid.*

216 *Royal College of Nursing of the United Kingdom v. Department of Health and Social Secutity* [1981] AC 800, [1981] 1 ALL ER 545 CA and HL (E), [1981] 2 WLR 279, [1980] UKHL 10.

217 *ibid.*

218 *ibid.*

219 *Supra* note 191.

220 *ibid.*

221 *ibid.*

amended in 2000 to implement Article 1-11 of the Directive.[222] The 1995 Patent Rule and Plant Variety rights regulation was also changed to accord with Article 12-14 of the Directive.[223] In terms of HESC research, the question of how to interpret Article 6(2) of the Directive was left to the legislators. However, the 2000 UK patent regulation simply copied the wording of Article 6(2)(c) of the Directive and did not expressly list the patentable inventions related to HESC. In 2003, the United Kingdom Intellectual Property Office (UKIPO) issued a practice statement to clarify this Act, prohibiting patents on human embryos or processes for deriving stem cells from a human being.[224]

Additionally, the approach adopted by the UKIPO is to exclude totipotent cells[225] from patenting but to allow pluripotent cells[226] to be patented.[227] The UKIPO noted that pluripotent cells have no potential to develop into human beings; therefore, inventions involving these cells are not within the scope of moral violation.[228] Aided by this narrow interpretation of the Directive, many inventions related to HESC were granted patents in the UK. According to a survey, the UKIPO played a pioneering role in granting downstream HESC derivatives.[229] Considering the permissive moral and legal culture in the UK, the UKIPO's interpretation of Article 6(2)(c) seems proper and effective.

5.4.2 Prohibition Policy: German Approach

Countries that adopted policies of prohibition often hold the opinion that

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[222] The Patent Regulation 2000 (SI 2000/2037)

[223] The Patent Amendment Rules 2001 (SI 2001/1412) related to the deposit, access and re-deposit of biological material implemented the Article 13-14 of the EUROPE Directive; The Patents and Plant Variety Rights Regulations 2002 (SI2002/247) implemented the Article 12 of the EUROPE Directive.

[224] Inventions involving HESCs, the United Kingdom Intellectual Property Office, <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm> accessed 28 January 2012

[225] Totipotent stem cells are one of the most important stem cells types because they have the potential to develop into any cell found in the human body, <http://www.explorestemcells.co.uk/TotipotentStemCells.html> accessed June 8 2013.

[226] Pluripotent stem cells have the potential to differentiate into almost any cell in the body, available at <http://www.explorestemcells.co.uk/PluripotentStemCells.html> accessed June 8 2013.

[227] *ibid*.

[228] Paragraph 3 (a) of Schedule A2 to the Patent Act 1977.

[229] In a survey made by A Plomer in 2009 showed that almost 100 patents were granted to UK or non-UK residences by UKIPO. See Aurora Plomer and Paul Torremans, *Embryonic stem cell patents: European Patent Law and ethics*, (1st edn, Oxford University Press 2009) 196.

human embryos have the status of human beings, conveying their skepticism toward biotechnology development through strict regulations. However, these strict regulations do not necessarily prevent all HESC research in these countries. In countries adopting restrictive policies, inconsistency between regulations and moral objectives might occur.[230] In the EUROPE, this approach is widely accepted by Austria, Ireland, Italy and Germany.[231] Among these countries, Germany offers a specific example of the prohibitive approach. Influenced by the devaluation of life during the Nazi era, the German constitution contains two provisions expressing the importance of human dignity.[232] These provisions could be viewed as the moral basis of the restrictive policy in Germany.[233]

Protect the Human Embryo but Allow Importation of Embryo Stem Cell from Abroad

German law is extremely restrictive of HESC research, as demonstrated by the definition of embryo in the German Embryo Protection Act (ESchG), which provides that 'the fertilized human ovum which is capable of development after the nuclei have merged, also any totipotent cell extracted from an embryo capable – under the right circumstances – of dividing and developing into an individual'.[234] According to the ESchG, to protect human embryos, egg donation, pre-implantation genetic diagnosis (PGD)[235] and cultivation of more than three embryos are all prohibited.[236] However, the ESchG does not prohibit research on already harvested HESC because it is pluripotent. Interestingly, because embryo stem cells can only be obtained by destroying embryos, it is paradoxical that the destruction of embryos is

[230] For instance scientist in Italy are allowed to use cell lines obtained from abroad, which is against its moral value of the human embryo.
[231] Rosario M Isasi & Bartha M Knoppers, 'Mind the Gap: policy approaches to Embryonic Stem Cell and Cloning research in 50 Countries' (2006) 13 European Journal of Health Law 9-26.
[232] The Protection of human dignity and the right to life.
[233] Jan P Beckmann, 'on the German Debate on HESC Research' 29 Journal of Medicine & Philosophy 603-621 (stating that Germany presents a rather special case in that the law strictly forbids any manipulation of the human embryo that does not contribute to its development).
[234] Section 8 of the German Embryo Protection Act.
[235] Pre-implantation genetic diagnosis (PGD) is "a technique that enables people with a specific inherited condition in their family to avoid passing it on to their children. It involves checking the genes of embryos created through IVF for this genetic condition". See PGD on Human Fertilisation and Embryology authority.

ethically forbidden while embryo stem cells are legal. Consequently, the German Research Foundation (DFG) recommended importing pluripotent embryonic stem cells from abroad.[237] The DFG believes that doing so is "in principle admissible" because German constitutional law has no legal force outside of Germany.[238]

The main remaining dispute concerns whether importing HESC from abroad is allowable. A report by the Parliamentary Study Commission on the Law and Ethics of Modern Medicine suggested that embryonic stem cells should be completely prohibited even if they are imported from abroad.[239]However, the National Ethics Council proposed that imports of embryonic stem cells should be permitted for a period of three years under the condition that they are strictly regulated.[240]

In 2002, Germany's legislature passed the Stem Cell Act (StZG) to 'ensure the protection of embryos in connection with the importation and use of HESCs'.[241] StZG provides the basic principle that importation and use of embryonic stem cells is forbidden. However, the StZG also decreed that imported stem cells meeting the following conditions could be licensed:

> (1) [T]he stem cell lines were extracted from surplus embryos from in vitro fertilisations in the country of origin before 1 January 2002; (2) the persons entitled to disposal under the law of the country of origin

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[236] The German embryo protection act, Federal Law Gazette, December 1990.
[237] *Supra* note 226.
[238] Jan P Beckmann, 'On the German debate on HESC research' (2004) 29 Journal of Medicine and Philosophy 603.
[239] Parliamentary Study Commission on the law and Ethics of Modern Medicine's report (n.103) at 102.
[240] The National Council on Ethics which had been established by Chancellor Gerhard Schroder in May 2001, offered four options: Option A (which would entail a change in the Embryo Protection Act held the importing, the use, and even he derivation of embryonic stem cells from super numerous embryos to be ethically admissible, provided the research goals attainable by means of these embryonic stem cell were not attainable by other, less questionable means. Option B also favored the importing and use of HESC but opposed the derivation of stem cells in Germany. Option C favored a moratorium in order to clarify important questions. Option D held the importing and use of HESC to be an illegitimate instrumentalization of human life and hence ethically inadmissible, see National Ethics Council's Opinion (n.103) at 17.
[241] The official title of the Stem Cell Act is "Act to Secure the Protection of Embryos in Connection with the Importing and Use of HESCs". See Jan P Beckmann, 'On the German debate on HESC research' (2004) 29 Journal of Medicine and Philosophy 603.

have properly consented to the extraction of stem cells; (3) no remuneration or benefit in kind has been granted; (4) no other regulations, especially those of the ESchG, are violated.[242]

Without a license, importation or use of embryonic stem cells may be treated as a criminal offense.[243] Through setting limitations with a ban on importation and use of embryonic stem cells[244], German HESC research can be conducted without the destruction of embryos. German scientists need not move abroad to conduct their research, and German companies can invest money in this research. It is noteworthy that President George W. Bush also borrowed this regulatory mode in his policy.[245]

Nevertheless, the StZG was criticised as adding problems in practice rather than resolving the controversies related to HESC research.[246] One problem with the StZG is that the difference in policy within and outside of Germany's geographical boundaries may be viewed as a double standard. Importing HESC could be viewed as 'a convenient solution allowing for the protection of the life of German embryos to remain undiminished while German scientists are enabled to act in an opportunistic manner, profiting from the destruction of embryos in other countries'.[247]Another problem is that the StZG's rule that embryonic stem cells must have been extracted before January 2002 introduced the risk of contamination with mouse viruses.[248]

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242 Section 4, Para 2 of the Stem Cell Act.

243 Section 13 of the Stem Cell Act provides that 'any person who imports or uses embryonic stem cells without having obtained approved pursuant to para 1 of section 6 obove shall be punished with imprisonment of up to three years or shall be fined'.

244 *Supra* note 230.

245 On August 9th, 2001, President Bush announce federal funds could only be used: 'the derivation process (which begins with the destruction of the embryo) was initiated prior to 9:00 P.M. EDT on August 9, 2001; the stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed; Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements', HESC policy under former President Bush, <http://stemcells.nih.gov/policy/2001policy.htm> accessed 4 February 2012.

246 Minou Bernadette Friele, 'The case of German Stem Cell Laws' (2005) Transnational cooperation and national legislation <http://www.hinxtongroup.org/au_trans_refs.html> accessed 4 February 2012.

247 Samantha Halliday, 'a comparative approach to the regulation of HESC research in Europe' (2004) 12 Medical Law Review 40.

248 Because successful culturing of human stem cells without mouse contamination is in 2003, but German scientists are only allowed to use human stem cells that created before 2002. See Minou

Additionally, allowing derivation of imported HESC is still, to some extent, condoning the destruction of the embryos.[249]Considering these restrictive clauses, StZG could merely be a temporary buffer in this scientific and moral conflict.

Case Oliver Brüstle v Greenpeace - the Patentability of Neuronal Precursor Cells

The case *Oliver Brüstle v. Greenpeace* involved the validity of a patent regarding the Neuronal Precursor Cell.[250] In 1997, the patent granted to German neuroscientist Brüstle claimed that the invention 'isolated and purified neural precursor cells, processes for their production from embryonic stem cells and the use of neural precursor cells for the treatment of neural defects'.[251] After the Directive was issued, in 2004, Greenpeace sued for the revocation of the patent because neural precursor cells are harvested from HESCs and that based on section 2 of the German Patent Law (GPL), the patent should be withdrawn.[252] In 2005, German patent law was changed to maintain consistency with the Directive. Thus, the core issue of this case changed to clearly elucidate Article 6(2) of the Directive in the German jurisdiction. The German Federal Patent Court (GFPC) ruled that the national patent conflicted with Article 6(2)(c) of the Directive, which prohibited patents on human embryos for industrial or commercial use.[253] Notably, the corresponding patent filed in the EUROPE was granted by the EPO before this ruling.[254]The German patent was dismissed, and Mr. Brüstle then

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Bernadette Friele, 'The case of German Stem Cell Laws' (2005) Transnational cooperation and national legislation, <www.hinxtongroup.org/references/Germanlaw.doc> accessed 24 July 2014.

[249] *Supra* note *195.*

[250] Defined by Mr Brustle in written observation, Neuronal Precursor Cells are 'immature cells which are capable of forming mature nervous system cells, such as neurons', case *Oliver Brustle v Greenpeace* C-34/10.

[251] The German Patent DE 197 56 864; case *Oliver Brustle v Greenpeace* C-34/10.

[252] Section 2(2) of German Patent Act provides that 'patents are especially not granted for…the use of human embryos for industrial or commercial purposed'. This provision is transferred from the Article 6(2)(c) of EUROPE Directive.

[253] Martin Grund, Erik Richly and Stacey J Farmer, 'the German Federal Patent Court Confronts the patentability of HESCs' (2007) 8 Bioscience law review 1-4.

[254] Schneider Ingrid, 'Das EuGH-Urteil, Brustle versus Greenpeace (Rs. C-34/10) BedEutung und Imlokationen fur Eruopa' (2011) 3 Intellectual Property Journal 475.

appealed to the German Federal High Court of Justice (GFHCJ).[255]

The GFHCJ decided to submit the case to the CJEU and specifically asked for an interpretation of Article 6 of the Directive:

> 1. What is meant by the term "human embryos" in Article 6(2)(c) of Directive 98/44...? 2. What is meant by the expression "uses of human embryos for industrial or commercial purposes"? Does it include any commercial exploitation within the meaning of Article 6(1) of [Directive 98/44], especially use for the purposes of scientific research? 3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching.[256]

Answering the first question, the CJEU, referred to the preceding case *Monsanto v. Cefetra*[257], which held that the Directive left almost no room for the discretion of national law.[258] According to Recital 16 of the Directive[259], "human embryos" cover all stages 'from the fertilisation stage to the initial totipotent cells and to the entire ensuing process of the development and formation of the human body'.[260] The blastocyst and unfertilized ova are both included in the concept of "human embryos".[261] However, pluripotent embryonic stem cells, with no potential to become human beings, are excluded from the definition of "human embryos" under Article 6(2)(c).[262] In terms of the second question, in accordance with the human dignity principle

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255 *ibid*.
256 Case *Oliver Brustle v Greenpeace* C-34/10, at 35.
257 In case *Monsanto v Cefetra* C-428/08, para. 48 provides that 'the body of rules laid soen in Directive 98/44 is not complete, but must be deemed to be exhaustive in the area with which it deals: the corollary being that, in those areas, national legislation cannot provide for a level of patent protection which is wider than that provided for under the directive'.
258 *Supra* note 248.
259 Recital 16 of the Directive provides that 'it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented'.
260 *Supra note 754*, at 119.
261 *ibid.*

of the Directive, therapeutic or diagnostic uses are legitimate exceptions to non-patentable "uses of human embryos for industrial or commercial purposes".[263] With regard to the last question, the CJEU took the view that the description should be treated as an integral part. If obtaining neuron precursor cells entails the inevitable destruction of human embryos, patents must not be granted to the invention even if its claims do not contain any use of human embryos.[264]

As discussed in the previous case studies, the CJEU's ruling is undeniably similar to that of the EBA in terms of problems with patentability. Christopher Heath explained that if the CJEU has a different interpretation from that of the EBA, this would bring an uncomfortable situation, namely 'the national courts would be bound by the CJEU in interpreting the patentability of national patents, whilst EBA would be bound by the EBA decision in determining patentability of a European patent application or European patent in appeal proceedings'.[265]

5.4.3 Intermediate approach: Netherland policy

An intermediate approach between permissiveness and prohibition is usually the result of political and commercial balancing. One significant characteristic of this approach is that while embryos created for research are forbidden, surplus embryos from IVF are allowed. This approach to some extent has the effects of protecting human dignity and providing a safe environment for HESC research. Therefore, most European countries have formally adopted this approach.[266] However, policies made based upon this approach are 'at

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[262] *ibid.*

[263] *ibid.*

[264] *ibid.*

[265] Christopher Heath, 'case comment Germany: German Patent Act, sec.2; European Directive on the legal protection of biotechnological inventions, art.6(2)(c)-"Neural Precursor Cells/Brustle's Patent" (NEuroperale Vorlauferzellen)' (2010) 41 International Review of Intellectual Property and Competition Law 853.

[266] Charles Kessler, 'European Policies and Priorities for stem cell research' (2009) Remedie Project, 7-8 May 2009 <http://www.york.ac.uk/res/sci/events/FinalConfPres/Kessler.pdf> accessed 24 June 2013.

risk of being ambiguous and internally inconsistent'.[267] This approach is well developed in the Netherlands.

From Health Council Report to the Dutch embryo Act: Embryo Created for Research was not Allowed

Similar to the Warnock report in the UK, a report by the Health Council provided advice on emerging IVF. Compared with the Warnock report, the Council agreed with the fourteen-day limit on permissible embryos in research.[268] However, the Council distinguished "the spare embryo" from IVF with embryos created for research.[269] Then, in a discussion about instrumental and non-instrumental uses of human embryos[270], the council expressed the view that human embryos could not be used or created for research.[271] The Christian Democratic Party (CDA) published a report entitled "Meaningful Life" that opposed any instrumental uses of human embryos.[272]The report stated that 'respect and protection of human life, irrespective of its developmental stage or manifestation, should be the cornerstone of our [Dutch] legal order'.[273]

This issue was hotly debated and the Dutch Embryos Act was ultimately passed in 2002. In the Act, the research use of supernumerary embryos is permitted within a three- to five-year moratorium.[274] As with the new technology CNR, an embryo is described as 'a cell or a complex of cells with

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[267] Rosario M Isasi and Bartha M Knoppers, 'Towards commonality? Policy approaches to HESC research in Europe' in Plomer Aurora and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethic* (Oxford university press 2009).

[268] Gezondheidsraad (The Health Council), Interimadviesinzake IVF (s'-Gravenhage: Gezondheldsraad, 1984)

[269] *ibid.*

[270] In this debate, instrumental use referred to use for research whereas non-instrumental use was use for reproductive aims (such as IVF).

[271] Marta Kirejczyk, 'Parliamentary cultures and human embryos: the Dutch and British debates compared' (1999) 29 Social Studies of Science 889.

[272] CDA, Wetenschappelijk Instituut voor het, Zinvol leven, Een christen-democratische bijdrage aan de discussie over draagmoederschap, kunstmatige inseminatie, gift en in vitro fertilisatie (Deventer: Van Loghum Slaterus, 1988).

[273] *ibid.*

[274] Section 32 of the Dutch Embryo Act 2002 provides that 'within three years of this Act entering into force, and every four years there-after, our Minister shall send a report to Parliament concerning its effectiveness and impact in practice'.

the capacity to develop into a human being'.[275] Due to a declaration that only cloning of a person is forbidden, CNR is permitted by the Dutch Embryos Act provided that it satisfied all other provisions in the Act.[276] Additionally, the Dutch Embryos Act specifically listed legitimate purposes for research involving human embryos.[277] The Dutch Embryos Act was viewed as a compromise between moral objections to creating embryos for research use and potential benefits to certain categories of research.[278]

5.5 The Conclusion

This chapter has aimed to highlight the patentability and morality of HESC related invention in the EUROPE. It draws the conclusion that patent control is not an effective way to monitoring HESC research. It discusses whether patent law is proper to include moral examination. It has observed that, so far, the barrier to the patentability of HESC is impossible to breach. Moral considerations are deeply rooted in the EUROPE, even in the UK, which has applied liberal policies to HESC research. Despite huge efforts being made in harmonsing biotechnology patent regulations, inconsistency still exists. For instance, the dual system of assessing the morality standard leaves an uncertainty with regard to the Law. Contrary to its original intention, the Directive has also inevitably given rise to uncertainty when it is implemented by member states under national jurisdiction. As has been seen, the member states retain certain decision-making rights in the EUROPE HESC regulation harmonisation. Although the EPC provides uniform substantive principles and procedures of patent application, the EUROPE did not have a uniform legal status of human embryo and moral definition. However the EUROPE reached a consensus on the human embryo concept. In terms of cloning and destroying human embryos, the EUROPE imposed a total ban.

The author believes that the infusion of moral control and patent law in the

[275] Section 1 of the Dutch Embryo Act 2002.
[276] *Supra note 225*.
[277] Section 8 of the Dutch Embryo Act 2002.

EUROPE mode might not be an appropriate strategy. Generally, the EUROPE mode in HESC regulation provides clear guidance for member states, as well as leaving enough room for adaption. The Member States retain certain decision-making rights in the EUROPE for the harmonisation of HESC regulations. Although the EPC provides uniform substantive principles and procedures for patent applications, the EUROPE has not uniformly defined the legal and moral status of human embryos. However, the EUROPE has reached a consensus on human embryos; the EUROPE has imposed a total ban on cloning and destroying human embryos. In the author's opinion, the EUROPE's infusion of moral control and patent law is not an appropriate strategy. Typically, for HESC regulation, the EUROPE provides clear guidance for Member States and provides sufficient opportunity for adoption. The space for flexibility, which aids in relieving the tension underlying moral conflicts in different countries, may be at the heart of harmonising HESC regulations.

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[278] *Supra note 225.*

CHAPTER SIX: THE RECONCILING ATTEMPTS FOR MORAL BASED HESC REGULATION IN THE INTERNATIONAL REGIME

6.1 Introduction

It has been examined in previous Chapters that moral issues arouse in the field of HESC challenge the regulators and policy makers. And it has been observed in previous Chapters, both federal funding control and patent control are not effective way to monitoring HESC research. In order to tackle the topic of the best solution to stem cell tourism in China, there is a need to analyse two closely related issues from the international HESC reconciled regulation: lessons from other reconciliation attempts and the degree of reconciliation attempt. Indeed, it might be fruitless to carry out a proper analysis on the patentability and morality of HESC related invention without building up a general understanding about the reconciliation attempt which has already made. As far as the jurisdiction and applicable law issues in HESC are concerned, giving sufficient significance to highlighting the scope of international HESC reconciled regulation should come first because it might lead to fruitful results later in discussing patentability and morality of HESC related invention in the following chapters of this thesis. Accordingly, this chapter will aim to examine lessons from reconciliation attempts which has already made and reconciliation attempt degree regarding international HESC regulation.

No comparison between legal regimes will be carried out in this chapter but a deep critical analysis of lessons from reconciled attempts will be sought instead. This chapter will be divided into five sections: the section following this introduction will briefly attempt to highlight issues of the economic, scientific and legal pressures for reconciliation in HESC regulations. Section three will attempt to draw lessons from harmonising HESC regulations in the

EUROPE. This section explores the particular challenges to harmonising HESC regulations and investigates the EUROPE solutions to conquering such challenges by addressing the ancillary question: what are the lessons learned from the EUROPE harmonisation attempt? It finds that lawmakers should preserve space for flexibility when generating uniformity in HESC research, especially the moral definitions and the moral statues of human embryos. In the EUROPE unitary substantive patent regulation, considerable freedom is still given to national legislations.[1] The margin of appreciation principle, developed considering the conflict between member states and the European Patent Convention, allows national courts to interpret the Convention differently based on various cultural, philosophical and cultural circumstances. Although the EUROPE reached a broadly interpretation of human embryo which includes HESC lines, no uniform legal status of human embryos or human dignity was provided under the requirement for wide margin discretion. It concludes that the adequate flexibility and diversity in the field of HESC regulation are beneficial to HESC research.

In section four, two important international initiatives are considered: international drug agreements and regulation of the environmental and human safety aspects of international trade. In section five, the author will introduce two international organisations that are important for their effort in determining the scope of reconciliation for HESC research regulations, the International Society for Stem Cell research (ISSCR) and the Hinxdon Group. The practical mode for HESC regulation reconciliation will be discussed in section six. Finally, section seven will summarise the main conclusions that the writer has drawn.

[1] Avgi Kaisi, 'Finally a single European right for the EUROPE? An analysis of the substantive provisions of the European patent with unitary effect' (2014) 36 European Intellectual Property Review 170-180 (concluding that the regulation on the Unitary Patent leaves many crucial issues on the national patent laws of the Member States, such as prior user right and compulsory licensing).

6.2 Reasons for attempts of HESC Regulations Reconciliation at International Level?

HESC research regulations can encourage or stifle technology innovation through research. Variations that influence HESC research regulations are not only limited to the legal elements but many other facets, such as morality, political history, social norms and commercial capacity. Generally, reconciliation is defined as 'making the regulatory requirements or governmental policies of different jurisdictions identical or at least more similar'.[2] Reconciliation is an attempt to implement a standardized approach within different areas. With judicial bounding, reconciliation seems to be a prospective measure rather than the negative or corrective means. The international regulatory framework, which facilitates scientific advances and clinical applications, would be vital to future developments in biomedicine.

The reasoning behind attempting to reconcile the regulation of HESC research are primarily from economic, scientific and legal pressures. In the money-oriented global market, HESC research in some commercial area is lacking in proper moral standard and legal guidance. The argument is that the consensus within the international community is strongly needed to prohibit the invalidated and unsafe treatment for commercial gain. But we must distinguish the reasonable medical innovation attempt from objective stem cell tourism. Under the tighten regulations, stem cell therapy tourism might be controlled and monitored. Here the author also argues that the national differences in regulations of HESC research affect the quality and quantity of research as well as impact cross-border collaborations. According to the lessons from harmonising drug agreement and harmonising the regulation of environmental and human safety aspects of international trade, it seems to be premature to harmonise relevant HESC regulations at international level. But reconciling relevant standard and norms for scientific

[2] David W Leebron, 'Claims for harmonisation: a theoretical framework' (1996) 27 Canadian Business Law Journal 63.

innovation appears to be appropriate. The author believes that the reconciled regulation and the establishment of a central international authority would facilitate scientific progress and public benefit. The EUROPE biotechnology Directive is a successful attempt. Considering the ethical aspects of HESC research, the flexible, widely applicable, no binding rules as well as some uniform norms and principles might be appropriate for reconciling regulations of HESC research. Although some international organisations already made efforts to establish standards for HESC research, for instance, the ISSCR set a guideline for technical standard in practice and the Hinxdon Group made the consensus statement, remaining issues have been brought to light. The ISSCR guideline only focused on technical standard instead of policy reconciliation, and the consensus statement ignored the moral dimension of HESC research.

6.2.1 The Economic Source of Pressure for Reconciliation

Economists believe that scientific research using HESC is a worthwhile investment. Further, they insist that products from such research are commodities with public goods characteristics.[3] Therefore, in the opinion of economists, results from HESC research should flow freely and be accessible to patients worldwide, which is difficult due to the different HESC regulations in various countries. Without a global reconciliation regulation to supervise stem cell therapy, "stem cell tourism" is unsafe.

Follow the Money: National Interests in a Global Market

Many scientists believe that HESC may cure a patchwork of unprecedented diseases, such as diabetes, cancer, Parkinson's, Alzheimer's and heart diseases.[4] The boundless potential of HESC motivates countries to rebuild their current regulatory frameworks, facilitate HESC research and maintain a competitive position in the global health market. In the US, statistics from the

[3] Brian Salter, 'The global politics of HESC science' (2007) 13 Global governance 277.
[4] Cynthia Robbinsroth, *from alchemy to IPO-The business of biotechnology* (Perseus Publishing 2001) 91.

NIH website showed that the federal government invested nearly 143 million dollars in HESC research; 137 million dollars and 126 million dollars was invested in 2010 and 2011, respectively.[5] In the EUROPE, 54 billion Euros were budgeted for HESC research from 2007 to 2013.[6] China was no exception to HESC research promotion and provided approximately 320 million dollars per year.[7] Certain health markets for luxury treatments have already matured around the world, such as for PGD, IVF, cancer treatment and sex selection. The question is why such governments have invested so heavily in HESC research.

First, it should be noted that such nations use public money allocated by governments instead of market support through venture capital to encourage the HESC industry. According to a report from a biomedical consultancy group, Biophoenix, in the UK, the primary commercial incentives for HESC research are focused on cord blood banking, drug screening, cartilage regeneration and skin modification.[8] Because the results from HESC research are uncertain, the influx of venture capital has slowly developed.[9] Without high levels of capital investment, it will be difficult for HESC biotechnology applications to transition into the market.[10] However, in business, 'products not science will make these companies profitable and provide returns to investor'.[11] Lacking a natural connection between HESC science and market support, 'promoters of science will pressure governments and state authorities to introduce arrangements that allow public money to assume at least some of the development risk associated with this novel science and so

[5] US National Institutes of Health, <http://www.nih.gov/> accessed online 25 June 2012.
[6] Nicholas Watt, 'EUROPE reaches deal on stem cell research' The *Guardian* (London, 24 July 2006) <http://www.guardian.co.uk/world/2006/jul/24/Europe.research> accessed online 25 June 2012.
[7] Natasha Khan, 'China to halt stem cell trial applications in effort to tighten regulation' Bloomberg <http://www.bloomberg.com/news/2012-01-10/China-to-halt-stem-cell-trial-applications-in-effort-to-tighten-regulation.html> accessed online 25 June 2012.
[8] Opportunities in stem cell research and commercialization-technology advances, regulatory impact and key players, reports by Biophoenix,2006 <http://www.researchandmarkets.com/reports/328882/opportunities_in_stem_cell_research_and> accessed 22 July 2014.
[9] *Supra* note 2.
[10] *ibid*.
[11] Herper Matthew, 'hold off on investing in stem cells' *Forbes* (Washington, 13 August 2001) <http://www.forbes.com/2001/08/13/0813steminvest.html> accessed 25 June 2012.

reassure potential investors'.[12] Certainly, the national investment in basic HESC research could lay the foundation for development by companies,[13] which one reason governments are aggressively investing in HESC.

Another reason is that governments desire an international and transnational competitive advantage. HESC research is still at an early stage, and researchers are developing the basic technologies for this area. To a secure a competitive position in future commercial development, countries seem provide equivalent state funding-oriented stem cell research networks.[14] Governmental funding has become a core characteristic of HESC research.

However, because governmental funding is focused on the gain provided by the technology, HESC might be mistakenly and prematurely used in a commercial manner without proper moral or legal consideration.[15] As Brian Salter noted, the nature of international competition in the HESC field generated 'a dynamic that does not always resonate easily with the tenets of cautious rationalism'.[16] For example, stem cell therapy that should be further studied is already available to clinics in China and Thailand, among others.[17] Many patients have ventured to such countries to accept expensive, unproven, likely risky and ineffective stem cell treatments.[18] This phenomenon is "stem cell therapy tourism".[19]

"Stem Cell Therapy Tourism": Should it be Allowed or Not?

The International Society for Stem Cell Research (ISSCR) warned patients to be cautious with "claims based on patient testimonials"[20], "multiple

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12 *Supra* note 2.
13 *ibid*.
14 *ibid*.
15 Eugene Russo, 'follow the money-the politics of embryonic stem cell research' (2005) 3 Plos biology 324.
16 *Supra* note 2.
17 Carolyn Brown, 'stem cell tourism poses risks' (2012) 184 CMAJ E121 <http://www.cmaj.ca/content/184/2/E121.full.pdf+html> accessed 25 June 2012.
18 *ibid*.
19 *ibid*.
20 "Claims based on patient testimonials" means 'patients want to believe so much that a treatment is helping them that they can convince themselves that it has. They may even have experienced some recovery unrelated to the treatment. Unless there has been carefully evaluated clinical research it is very

diseases treated with the same cells"[21], "the source of the cells or how the treatment will be done is not clearly documented"[22], "claims there is no risk"[23] and the "high cost of treatment or hidden costs"[24]. It is argued that one solution is to tighten regulations on the offending authorities through propositions from international regulatory bodies.

The question is whether we should demonise all medical travel based on certain stem cell therapies that are unjustified and unsafe. The answer is obviously no. Because medical travel is often related to highly innovative interventions at a high cost to desperate patients, medical travel might be such patients' last grasp at hope.[25] Thus, the remaining issue is to distinguish between stem cell tourism and reasonable attempts at medical innovation.[26] This complex issue relates to research, the clinical trial process and medical innovation. First, we could draw a clear line between research and medical innovation; research is aimed at scientific results, while medical innovations are focused on patient care.[27] Thus, patients care more about survival and curing disease than expanding knowledge,

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difficult to know what is true effect of the treatment and what you can expect', Patient Handbook on stem cell therapies, International Society for Stem Cell Research, 3 December 2008 <http://www.isscr.org/clinical_trans/pdfs/ISSCRPatientHandbook.pdf> accessed 25 June 2012.

[21] "Multiple diseases treated with the same cells" means 'unless the diseases are related, such as all being diseases of the blood, different diseases, such as Parkinson's disease and heart disease, would be expected to have very different treatments. Also, you want to be treated by a doctor that is a specialist in your disease'. See *ibid.*

[22] "The sources of the cells or how the treatment will be done is not clearly documented" means 'this should be clearly explained to you in a treatment consent form. In addition, there should be a protocol that outlines the treatment in detail to the medical practitioner. The protocol is the operating manual for the procedure. While it may not be made available to you automatically, you should be able to request this. For a clinical trial or experimental treatment, protocols should have been reviewed for scientific merit by independent experts and approved by an ethics committee to ensure that the rights and well-being of the participants will be respected. Ask who has approved this protocol and when the approval expires'. See *ibid.*

[23] "Claims there is no risk" means 'there is always risk involved with treatment. Information about the possible risks should be available from preclinical or earlier clinical research'. See *Ibid*.

[24] "High cost of treatment or hidden costs" means 'it is not customary for someone to pay to be in a clinical trial other than perhaps travel and other personal expenses. Consider whether you should pay for a treatment that is unproven. Furthermore, ask about the costs of emergency medical care if something goes wrong, particularly if you are outside your own country. Find out what costs your national health program or health insurance provider will cover, in what circumstances and in what countries'. See *ibid*.

[25] Olle Lindvall and Insoo Hyun, 'Medical innovation versus stem cell tourism' (2009) 324 Science 1664.

[26] *ibid*.

[27] Agich G J, 'ethics and innovation in medicine' (2001) 27 J Med Ethics 295; see also Margo C E, 'when is surgery research? Towards an operating definition of human research' (2001) 27 Journal Medicine Ethics 40.

and compared with clinical trial participation, patients prefer to enroll in medically innovative care.[28] Based on the principle of humanitarianism, seriously ill patients must be provided acceptable channels to receive aid.[29] Moreover, for treatment advances, medically innovative care may be an additional path for developing proven therapies instead of clinical trials.[30] Given the current regulations governing stem cells, there is much work ahead for international regulators and researchers.

6.2.2 International Stem Cell Collaboration: Disparate Policies Impact Research

Ethical and policy disparities under different policy regimes in HESC research currently challenge international collaborations in HESC research. Case studies from 50 scientists, lawyers, ethicists and policy makers in 14 countries[31] indicate that law can facilitate or restrict HESC research. 'Even apparently well-crafted laws can have unintended consequences as science progress'.[32] Unclear regulations, including ambiguous technical language, may lead to time-consuming or costly problems for international collaborations.[33] The question of international jurisdiction over HESC research is also noteworthy. To answer this question, the Hinxton Group examined two cases; one case is involved Italian scientists that move to the UK to pursue development of nuclear transfer HESC lines,[34] and the other

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[28] *Supra* note 19.
[29] *ibid*.
[30] *ibid*.
[31] They developed a new international and interdisciplinary group called "the Hinxton group" to 'explore the ethical and policy challenges of transnational scientific collaboration raised by variations in national regulations governing embryo research and stem cell science', <http://www.hinxtongroup.org/au.html> accessed July 1 2012.
[32] Derbra J H Mathews, Peter Donovan, John Harris, Robin Lovell Badge, Julian Savulescu and Ruth Faden, 'integrity in international stem cell research collaborations' (2006) 313 Science 921.
[33] Hansen B, 'Embryonic stem cell research: terminological ambiguity may lead to legal obscurity' (2004) 23 Medicine and Law 19.
[34] Nuclear transfer is a form of cloning. 'the steps involve removing the DNA from an oocyte, and injecting the nucleus which contains the DNA to be cloned. In rare instances, the newly constructed cell will divide normally, replicating the new DNA while remaining in a pluripotent state. If the cloned cells are placed in the uterus of a female mammal, a cloned organism develops to term in rare instances. This is how Dolly the Sheep and many other species were cloned. Cows are commonly cloned to select those that have the best milk production', <http://en.wikipedia.org/wiki/Nuclear_transfer> accessed July 2

case is related to German scientists that travel to the US to investigate whether IVF embryos can generate HESC lines.[35] The Hinxton Group concluded that scientists should be free to engage in international collaborations on HESC without fear of prosecution or discrimination, and lawmakers should be careful when restricting citizen participation in international collaborations on HESC.[36]

Although reconciling regulations may be too premature for emerging HESC research, regulators are considering various policies across borders.[37] The nature of HESC research highlights the difficulties lawmakers and scientists face with international collaborations that involve various researchers under conflicting policy regimes. Although HESC research is young, the intrinsic nature of this area has generated a high level of international collaboration from its conception.[38] Therefore, HESC research is an ideal area for studying global regulations because it is governed by tremendously different regulations across borders. Through a statistical analysis of articles, the overall citation rates for international papers in the US and UK related to HESC are significantly higher than HESC papers with a single author or country.[39] One primary reason for this observation is that international collaboration is advantageous due to 'the sharing of resources, ideas, expertise and institutions'.[40] Additionally, it is notable that certain well-established researchers in this area tend to pursue international collaborations.[41]

This investigation might indicate that products of international collaborations are typically better than single-country research. However, in my opinion, this conclusion is not fully supported. To determine the quality of

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35 Supra note 309.

36 *ibid*.

37 The International Society for Stem Cell Research Committee Forum, Stem cell therapies in Clinical Trials: *workshop on Best Practices and the need for harmonization* (Cell Stem Cell 7, 451 2010).

38 *Supra* note 29.

39 *ibid*.

40 *ibid*.

publications related to HESC, the citation rate is important, but it is not the only measure. For example, self-citation has not been examined. Furthermore, in determining the significance of HESC research, publication is a key test but not the only test. For instance, research awards, patents and scientific honours should also be considered when judging HESC research.[42]

Case Study: Indian Adjustments to the International Collaboration Linked with HESC Research

India's ambition in this fast-developing biotechnology is to establish an advantageous position in global HESC research. To achieve this goal, an important question is what type of policies or interventions are beneficial for expanding such promising research in a developing country, such as India. A global bio-politics research group from the UK produced a special report that unveiled Indian policies and patterns for facing challenges.[43] In this report, the Indian strategies may be divided into science intervention and policy intervention.[44] For science intervention, India highlights domestic scientific training to sustain researchers because most postgraduate students with a Ph.D. work abroad.[45] To recruit a scientific workforce to develop this field, India also encourages trading national or international intellectual property rights.[46] Notably, the healthcare sector accounts for a large portion of international collaboration in this field.[47]

For policy intervention, the Department of Biotechnology (DBT) adopted new strategies, such as promoting use of easily obtained stem cell sources and establishing stem cell research centres for excellence. In addition to the public sector, private companies, such as Dr Reddy's Laboratory, also increased

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41 *ibid*.
42 *ibid*.
43 Brian Salter, Melinda Cooper, Amanda Dickins and Valentin Cardo, 'Stem cell science in India: emerging economies and the politics of globalization' (2007) 2 Regenerative Medicine 75.
44 *ibid*.
45 *ibid*.
46 *ibid*.
47 Almost 70 alliances out of 129 (54%) are belong to healthcare sector. See Chaturvedi S, 'Dynamics of biotechnology research and industry in India: statistics, perspectives and key policy issues' (2005) 6

research and develop investment in HESC research.[48] As the Patent Act excludes stem cells from patenting, national support was used to stimulate this new technology.[49] For example, the Technology Development Board launched 103 projects to support HESC research in 2003.[50] Moreover, the Biotech Consortium India Limited (BCIL) was created to 'provide the linkages amongst research institutions, industry, government and funding institutions, to facilitate accelerated commercialisation of biotechnology'.[51] To shape the stem cell market environment, the state government provides benefits, such as tax concessions, cheap credit and a subsidised industrial infrastructure.[52] In my opinion, although measures adopted by India remain weak, India did discover a feasible way to maintain a competitive global position in HESC research.

6.3 Lessons from EUROPE HESC Regulation Reconciliation

Interestingly, the problems of legislating for reconciling HESC regulation at the international level have been well rehearsed in the EUROPE. HESCs have virtually limitless use and enormous potential for therapeutic medicine. The lack of common technical standards and uniform patent criteria has hampered further technology progress in EUROPE. For HESC research in the EUROPE, the divergent regulations among member states have generated unequal access to treatment and an imbalance in distribution of benefits and duties.[53]

Directorate for science, technology and industry 19.

[48] The proportion of research and develop expenditure in sales was 4.4% in 2003 but was estimated at 12% in 2005. See *Ibid*.

[49] Section 3 of the Patent Act of India 2005 states that 'technological inventions include any living entity of artificial origin, such as transgenic animals or plants; biological materials such as organs, tissues, cells, viruses and the process of preparing them; and processes for cloning human being or animals are not considered patentable'.

[50] Supra note 49.

[51] Kumar Shanti and Wilson Neeti, 'biotechnology in the limelight' (2006) Managing Intellectual Property <http://www.managingip.com/Article/1321387/Biotechnology-in-the-limelight.html> accessed 3 July 2012.

[52] Chaturvedi S, 'Dynamics of biotechnology research and industry in India: statistics, perspectives and key policy issues' (2005) Directorate for science, technology and industry 19.

[53] See Human stem cell research and regenerative medicine, a European perspective on Scientific, Ethic and Legal issue.2010. Science Policy briefing,

As the European Research Commissioner Philippe Busquin has commented,'[i]n Europe, we have a legitimate diversity of rules and ethical frameworks in the field of HESC research'.[54] Hence, the EUROPE received the continuing push by scientists and biotechnology companies for harmonising HESC regulation. The lack of common technical standard and uniform patent criterion had hampered further technology progress.

The EUROPE, in order to promote technology advance in the community, made many efforts to reach a consensus on HESC research regulations.[55] It is commented that 'the EUROPE can be instrumental in setting a broad consensus and can establish tangible limits that are likely to be followed by existing and new states'.[56] 'This harmonised legislation, at the least at the national level, can have a norm-setting function thus declaring minimal values and interests, providing international sanctions, and have a declarative function'.[57] This session explores the particular challenges when HESC regulations face harmonisation, as well as investigate the solutions as to how the EUROPE conquers these challenges. By drawing four main aspects of regulatory harmonisation attempts, namely: establishing the Biotechnology Directive, allowing different moral definition and various legal status of human embryos in the EUROPE, providing uniform concept of human embryo and total ban on patenting involving destruction of human embryo in the EUROPE, and infusing moral control with the patent law, this section tries

<http://www.esf.org/publications/science-policy-briefings.html> accessed 28 October 2012.

[54] See European Commission publishes background paper on stem cell research, the Public Health Genetics Unit <http://genome.wellcome.ac.uk/doc_WTD020783S.html> accessed 28 October 2012.

[55] The EUROPE proposed many Direcitves on setting standards of HESC researh and regulations. For example: the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (1998); the Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells; and the Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious aderse reactions and events and certain technical requirement for the coding, processing, preservation, storage and distribution of human tissue and cells.

[56] Nielsen Linda, 'Legal Consensus and Divergence in Europe in the Area of Human Embryology-Room for Harmonisation' in Evans Donald and Neil Pickering (ed) Conceiving the Embryo: Ethics Law and Practice in Human Embryology (Kluwer Law International, Netherlands1996) 325.

[57] Benjamin J Capps, 'Proposals for the Ethical Grounding of Future Regulation' (2003) PHD Dissertation, the University of Bristol.

to explore the particular challenges when HESC regulations face harmonization as well as investigate the solutions as to how the EUROPE should conquers these challenges.

6.3.1 Unitary Substantive Patent Law in the EUROPE: Considerable Freedom Still Given to National Legislations

Based on the Article 118 of the European Union Treaty, the European Council adapted EUROPE Patent Package including the unitary patent, the language regime and an international agreement on the Unitary Patent Court in 2012.[58] Certain improvement was brought by the regulation. The unitary patent protection aims to 'improve the level of patent protection by making it possible to obtain uniform patent protection in the participating member states'.[59] In the field of biotechnology, the patentability criterions in the Biotechnology Directive are applicable to a European patent in the participating Member States. The decision by the Court of Justice of the European Union (CJEUROPE) has the binding force on the Unified Patent Court.[60] However, during an opposition procedure, the interpretation of the definition of human embryo should be in a procedure before the Unified Patent Court instead of the CJEUROPE.[61]

Spain v Council of the European Union: the First Spanish Challenges to Single Patent Cooperation

The Council of the EUROPE authorised 25 member states to exercises themselves in line with the unitary patent protection because the unitary patent and the language regime could not be established within a reasonable

[58] The Article 118 provides that the Union law-makers shall establish measures for the creation of European Intellectual Property rights to provide uniform protection of intellectual property rights throughout the Union.
[59] Regulation 1257/2012 on implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L361/1-8, Preamble 4.
[60] Rob J. Aerts, 'the unitary patent and the biotechnology Directive: is a uniform protection of biotechnological inventions ensured' (2014) 36 European Intellectual Property Review 584-587.
[61] *ibid*.

period.[62] However, Spain claimed that 'the contested decision was vitiated by misuse of powers, namely an attempt to circumvent the requirement of unanimity laid down by the second paragraph of Article 118'.[63] Spain argued as follows:

> (1) [T]he creation of European intellectual property rights providing uniform protection as referred to in art.118 did not fall within the ambit of competences shared by the Member States, but within the exclusive competence of the EUROPE; (2) the true object of the contested decision was not to contribute to the process of integration but to exclude Spain and Italy from negotiations about language arrangements for the unitary patent; (3) the possibility of negotiations on the language arrangements had not been exhausted; (4) the Council had failed to specify the judicial rules applicable when adopting the contested decision.[64]

However, the court refused the application. First, the court held that 'although rules on intellectual property were essential in order to maintain undistorted competition on the internal market, they did not constitute "competition rules" for the purposes of article 3(1)(b)'.[65] Falling within the scope of the functioning the internal market, the Council had competence to authorise the enhanced co-operation in question.[66] Second, the court observed that 'in the instant case, the Council had found that the unitary patent and its language arrangements could not be established by the

[62] Spain v Council of the European Union (C-274/11) Unreported April 16, 2013.
[63] *ibid*.
[64] *ibid*.
[65] *ibid*.
[66] The scope of, and arrangements for, exercising the EUROPE's competences in the area of "competition rules necessary for the functioning of the internal market" were determined in art.101 to art.109; therefore, to regard art.118 as forming part of that area would be contrary to art. 2(6) and would extend unduly the scope of art.3 (1)(b). It followed that the competences conferred by art.118 fell within an area of shared competences for the purposes of art. 4(2) and were non-exclusive for the purpose of the first paragraph of TEU art. 20(1). See *ibid*.

EUROPE as a whole within a reasonable period'.[67] Therefore, its decision to authorise enhanced co-operation did not amount to misuse of powers, but rather contributed to the process of integration.[68] Third, the court pointed out that 'the process of integration would not be protected if all fruitless negotiations could lead to enhanced co-operation….the court had to ascertain whether the Council had carefully and impartially examined the relevant aspects and given adequate reasons'.[69] The Spain's argument lacks specific evidence, which is capable of disproving the Council's assertion that there was insufficient support.[70] Fourth, the court argued that 'the Council was not obliged to provide, in the contested decision, information concerning the possible content of the judicial system adopted by the participants in the enhanced co-operation in question'.[71] It was for those Member States to establish co-operation, exercise their competences and rights or shouldering their obligations.

The Unitary Patent Protection for a Unitary Market: Enhanced Cooperation and Market Integration

It is argued that integrated regulation promotes the free movement of goods within the EUROPE.[72] One essential principle of intellectual property is territoriality.[73] 'National, independent patents isolate the national markets and thus lead to obstacles to the free movement of goods'.[74] In the fact that intellectual property right is a competence to the member states, the unitary regulation could provide the equivalent protection within the EUROPE. Furthermore, the unitary regulation is benefit to the legal certainty, technological progress and cross-border.[75] However, the unitary patent

[67] *ibid.*
[68] *ibid.*
[69] *ibid.*
[70] *ibid.*
[71] *ibid.*
[72] Katharina Kaesling, 'The European Patent with unitary effect- a unitary patent protection for a unitary market' (2013) 2 UCL Journal of Law and Jurisprudence 87-111.
[73] See *ibid.* The sovereign's power to attribute exclusive rights is limited to its respective territory.
[74] *ibid.*
[75] *ibid.*

system is not a self-contained or autonomous system. It is much rely on EPC and the member state law.[76]

As some scholar reviewed, 'the creation of a unitary patent will not solve all problems arising from a geographically distributed use of patented inventions. Unitary patents, too, will be subject to the territoriality principle'.[77] From the member state perspective, such as Polish, the unitary regulation is not perfect. It lacks the Poland's participation in the regulating unitary regulation. Spain and Italy also not accede to the unitary system. 'The legitimacy of the European patent with unitary effect seems dubious, and instead of leading to the unification of protection and a strengthening of the common market, it will deepen already existing divisions'.[78]

But Only through harmonising substantive patent law and creating a unitary patent court, the uniform patent protection in the entire EUROPE could be achieved.[79] Compared with EPC, the substantive patent law has achieved high level harmonisation in patentability criterions and patent validity.[80] However, considerable freedom is still given to national legislations. Issues such as pre-grant substantive provisions were still ruled out of the regulation. As a result, the disputes like the grace period, the doctrine of equivalence and employees' inventions were left unsolved.[81] The uncertainty aroused by the equivalence provision has negative influence on the patent holder, the competitors and the public.[82] In addition, the regulation failed to tackle issues

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[76] *ibid*.

[77] Roberto Romandini and Alexander Klicznik, 'The territoriality principle and transnational use of patented inventions-the wider reach of a unitary patent and the role of the CJEU' (2013) 44 International Review of Intellectual Property and Competition Law 524-540.

[78] Zofia Zawadska, 'The unitary patent protection-a voice in the discussion from the polish perspective' (2014) 45 International Review of Intellectual Property and Competition Law 383-398.

[79] Avgi Kaisi, 'Finally a single European right for the EUROPE? An analysis of the substantive of the European patent with unitary effect', 36 European Intellectual Property Review 170-180.

[80] *ibid*.

[81] *ibid*.

[82] *ibid*. (stating that this legal uncertainty has negative effects on all the players involved in the patent system: the proprietor of the patent, who cannot rely in one scope of protection given in one country; the competitors, who cannot know with certainty where it is legal and where it is illegal to commercialise their products; and finally the public, since such uncertainties have an impact on the free trade between the Member States.)

in the post grant phase neither. For instance, it did not provide a unitary character of protecting the prior user right.[83] In addition, it dismissed the use of common compulsory license considering that the coexistence of the national, European and unitary patents may result disuse of unitary patents by the applicants.[84]

The Unitary Patent Protection for Member States: a Successful Attempt

To retain experts and biotechnology industry funding, the EUROPE searched for a reconciling patent regime. Recognising the huge benefits of a uniform patent application process and granting system, the European Commission sought to create a patent policy that could be adopted by the entire community. The change commenced with a centralised registration system; if applicants are granted patents in one country, the patent is valid in the remaining member states.[85] This centralised registration system included a uniform procedure and evaluation standard for patent applications.[86] However, the key weakness of this centralised registration system was the contradiction between EUROPE and member state patent laws.[87] Especially for HESC research, the inconsistent EUROPE patent policy increased the cost and reduced efficiency. Not only does patentability of inventions depend on different nations, but patent enforceability in member states was not promised.[88] If the EUROPE patent laws were consistent, innovation would directly be encouraged and boosted because the patents would be respected throughout the European Common market.[89]

Notably, the EUROPE attempt was conservative with regard to moral restrictions on patent regulation.[90] The European attempt shows that 'it is

[83] *ibid*.
[84] *ibid*.
[85] See the Article 2 & the Article 4 of the European Patent Convention 1973.
[86] See the Article 100 of the European Patent Convention 1973.
[87] Gerald Paterson, A *concise guide to European patents: law and practice* (Sweet and Maxwell, 1995) 1.
[88] Robin Beck Skarstad, 'The European Union self-defeating policy: patent harmonisation and the ban on human cloning' (1997) 20 University of Pennsylvania Journal of International Economy Law 364.
[89] *ibid*.
[90] *ibid*.

possible to have a workable patent system that excludes many biotechnological inventions from patentability on the grounds that they are morally defensive'.[91] Certain scholars have suggested that the EUROPE regime provided neither well-articulated criterions nor a well-developed theoretical framework.[92] Nevertheless, in my opinion, the EUROPE reconciled patent regulation was a successful attempt. It unveiled the need for broad enunciation of moral issues considering the different cultures of the member states.

6.3.2 The Biotechnology Directive - a Giant Step towards Harmonising the European Patent Law on Biotechnology

With the fierce commercial competition, the EUROPE foresaw the enormous profits behind biotechnological innovation[93], especially using HESC in curing diseases. In addition, the EUROPE observed that a friendly environment in biotechnology research is crucial for the biotechnology industry's prosperity.[94] Although there was a uniform application process for the European patent within the EUROPE, this centralised registration framework coexists with national patent jurisdiction.[95] Therefore, where a European patent could not be acquired, a national patent could be granted among member states. This legal inconsistency and uncertainty might inevitably

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[91] Audrey R Chapman, 'the ethics of patenting HESCs' (2009) 19 Kennedy Institute of Ethics Journal 261.

[92] Brody Baruch, 'intellectual property and biotechnology: the European Debate' (2007) 17 Kennedy Institute of Ethics Journal 69.

[93] See the Commission of the European Communities Reports on HESC Research of 4 March 2003. In Chapter One, "Origin and Characteristics of Human Stem Cells and Potential Application for Stem Cell Research", it states the potential application of human stem cell research includes the development of novel stem cell based therapies, the understanding of human development, the understanding of the basic mechanisms of cell differentiation and proliferation, transplantation of differentiated cells derived from stem cells, stimulation of endogenous stem cells and direct administration of stem cells. It further provides some examples of stem cell applications for treating diseases such as neurological diseases and disorders, heart failure and diabetes.

[94] See FP6 life sciencce, genomics and biotechnology for health' reports on stem cell patents: European Patent Law and Ethics. It states that: "[the] EC needed to be strategically positioned in order to take maximum advantage of the opportunities for the generation of wealth and job-creation that the promised growth of the biotechnology industry presented. Patent law was to play a key role in this process". See also Winfried Kluth, 'Embryonic Stem Cell Research and European Law' (2010) World Stem Cell Report 134. The author concluded the uncertain legal framework in EUROPE has negative effects on research projects on Member States.

[95] *Supra* note 249.

yield additional cost for biotechnology business.

Beyond the ambition to provide the European biotechnology industry with a considerable advantage over US and Japan, the EUROPE drafted and issued the Directive 98/44/EC of the European Parliament and the Council on 6 July 1998 on the legal protection of biotechnological inventions (the Directive).[96] The Recital 3 of the Directive states that '[e]ffective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology'.[97]

The rationale of the Directive was a lag of Europerope compared with other economic areas.[98] Among three main areas of United States, Europerope and Japan, they all believe that patent system can increase investment activity and enable a patented technology to be protected worldwide. Thus they all retain pro-patenting attitudes and improve their patent system to promote development of economy. The United States Patent Office preferred the equal treatment of biotechnology and other technologies.[99] This led to a liberal attitude of United States towards patentability of biotechnological inventions. Consequently, if United States patent principles confer an advantage than European patent principles do, it put pressures to Europerope to reform patent system.[100] Under this structure, the Directive adapted in 1998 aimed to clearly express the patentability of biotechnological inventions.

The other was the non-uniformity of member states. Although the harmonisation of substantive patent law in the contracting states, the interpretation and application of these law are disagreeable.[101]Such as case

[96] Plomer Auroar and Paul Torremans (eds), *Embryonic stem cell patents: European Law and Ethics*, (Oxford University press 2009)
[97] Recital 3 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.
[98] MacQueen H, Waelde C and Laurie G, Contemporary Intellectual Property (Oxford 2008, New York)
[99] Morneault M, 'Stem Cell Research and Human Cloning: Where Do We Draw The Line?' (2005) New England Law Review 523
[100] Drahos P, 'Biotechnology patents, markets and morality' (1999) European Intellectual Property Review
[101] Braendli P, 'The future of the European patent system' (1995) International Review of Intellectual

Genentech v Welcome Foundation, the EPO and UK courts have different standards of obviousness.[102] In order to reinforce the research capability and promote economy in the whole Europerope, the uncertainty of patent law in member states should be avoided. The Directive held the promise of harmonising the rule of biotechnological patent throughout the EUROPE. All member states have the obligation to transpose or implement in their national law. However, Before July 2000, only 6 member states amend their national law to in line with the Directive. According to the second report of the Commission (2005)，21 Member States had apprised the Commission of their instruments implementing the Directive.[103]

Originally, the first draft of Directive 1988 was rejected by European Parliament for lacking moral consideration.[104] Some animal welfare groups and religious groups strongly protested against the Directive and suggested that ethical considerations should be added.[105] After ten years, the Directive 98/44 was finally adapted. However, a problem of potential conflict between legal systems arose. Because the EPC, which is the rules of an intergovernmental treaty, belongs to a non-EC instrument, the European Union (EUROPE) has no jurisdiction over the EPC. For the purpose of releasing the discrepancy, in 1999 the Administrative Council of the European Patent Office decided to make some changes to the rules in the implementing Regulations for adjusting the EPC to the Directive.[106] Moreover, Rule 23b(1) EPC provides that: "Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of

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Property and Competition Law

[102] *Genentech Inc.* v *Wellcome Foundation Ltd* (1989) 8 RPC 147; (1988) 15 IPR 423

[103] Report from the Commission to the Council and the European Parliament, development and implications of patent law in the field of biotechnology and genetic engineering, at 2

[104] Plomer Auroar and Paul Torremans (eds), *Embryonic stem cell patents: European Law and Ethics*, (Oxford University press 2009)

[105] Sommer T, 'Patenting the animal kingdom? From cross-breeding to genetic make-up and biomedical research' (2008) International Review of Intellectual Property and Competition Law

[106] *Supra* note 174.

interpretation".[107]These countermeasures basically bridged the gap between the EUROPE Biotechnology Directive and the EPC.

The Directive is an example where harmonisation is essential for clarifying legal inconsistency and uncertainty.[108] The Directive ordered member states should implement it before July 30 2000 to ensure harmonisation.[109] From the above analysis, it is concluded that the EUROPE had clearly realised the importance of harmonising HESC regulation within its community. However, the question as to whether the Directive benefits harmonisation of HESC regulations remains to be seen. The Directive intended to harmonise HESC regulations, but was crucially only a restatement and clarification of existing practice at the EPO.

The Kingdom of the Netherlands v Europer. Parliament &Council of the Europer. Union: Does the Directive Encourage Harmonisation within the EUROPE Community?

Immediately after the Directive adopted, the Kingdom of the Netherlands supported by Norway and Italy claimed the application to the European Court of Justice to violate the Directive. The petition consisted of six pleas:

> (1) [T]hat it is incorrectly based on Article 100a (now Article 95) of the Treaty; (2) that it is contrary to the principle of subsidiarity; (3) that it infringes the principle of legal certainty; (4) that it is incompatible with international obligations; (5) that it breaches

[107] Aerts R J, 'Biotechnological patents in Europe-functions of recombination DNA and expressed protein and satisfaction of the industrial applicability requirement' (2008) International Review of Intellectual Property and Competition Law

[108] Recital 9 of the Directive provides that 'whereas in certain cases, such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals, certain concepts in national laws based upon international patent and plant variety conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas harmonisation is necessary to clarify the said uncertainty'.

[109] The Article 15 of the Directive provides that 'Member states shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000. They shall forthwith inform the Commission thereof'.

fundamental rights; and (6) that the procedure for its adoption was incorrect.[110]

The plea, that the Directive is not benefit for the harmonisation of community market within EUROPE against Article 100a of Treaty of the Europerope Union, is the dominant argument.[111] The appellant first stated the different interpretations of the Directive in member states could create barriers to trade, which was contrary to the rational of the Directive-harmonisation.[112] The judges unanimously disagreed with this argument and believed that 'the differing interpretations to which those provisions are open as regards the patentability of biotechnological inventions are liable to give rise to divergences of practice and case-law prejudicial to the proper operation of the internal market'.[113] Considering that national patent jurisdiction is to 'prevent damage to the unity of the internal market which might result from the member states deciding unilaterally to grant or refuse such protection'[114], the court indicated that the intent of the Directive was to require that Member States protect biotechnological inventions.

Secondly, the appellant speculated the international legal instruments, not the Europe, should be responsibility of harmonisation.[115] The court held that the origin of the harmonisation did not matter. 'There is nothing in principle to prevent recourse to adoption of a Directive as a means of ensuring a uniform interpretation of such terms by the Member States'.[116] Finally, the appellant argued that the Directive went too far because it created a new property right certain aspects of which were covered by the patent law.[117] The court did not

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[110] Case *Kingdom of the Netherlands v Eur. Parliament &Council of the Eur. Union*, C-377/98 [2001] E.C.R. 1-7079

[111] See the Article 100a of the EC Treaty provides that 'the Council shall acting unanimously… issue directives for the approximation of such provisions laid down by law, regulation or administrative action in Member states as directly affect the establishment or functioning of the common market'.

[112] *Supra* note180, at para 14

[113] *ibid.* at para 16.

[114] *ibid,* at para 18.

[115] *ibid,* at para 19.

[116] *ibid,* at para 20.

[117] *ibid,* at para 23. (stating that 'by virtue of the Article 8 and 9, the protection it provides for applies not only to specific biological material but also to biological material obtained from it by reproduction

consider that the Directive created a new right. Alternatively, the court ruled that 'the Directive makes certain clarifications and provides for derogations from patent law as regards the scope of the protection'.[118]

The court finally affirmed that the Directive was correctly adopted based on Article 100a of the European Commission Treaty.[119] They not only confirmed the necessity of the Directive as a harmonisation measure for eliminating biotechnology regulation disparities between Member States, but also testified that the Directive is important to the EUROPE biotechnology business for reducing obstacles and enhancing their competitiveness position.

Disparities among Member States in Implementing the Directive Despite Efforts towards Harmonisation

With different social and legal cultures in the member states, it is unsurprising that the Directive did not produce real harmonisation. Simultaneously maintaining a uniform set of rules and reconciling different Member States regulations is not easy. The draft history of the Directive strongly hinted at such divergent views. After ten years debates and queries on whether moral principles were compatible with the Directive, the Directive finally portrayed itself as unified and competent for harmonising biotechnology patent laws in the EUROPE.[120]

During the ten years of discussion, France always played a role in supporting the Directive.[121] However, two years after implementing the Directive, the

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or multiplication, and that under the Article 11 the right of the holder of the patent, as against framers, is limited'.)

118 *ibid*, at para 25.

119 *ibid*, at para 27 and 29. The Court held that: "whilst it is common ground, in that regard, that the aim of the Directive is to promote research and development in the field of genetic engineering in the European Community, the way in which it does so is to remove the legal obstacles within the single market that are brought about by differences in national legislation and case-law and are likely to impede and disrupt research and development activity in that field." The Court concluded that: "the Directive was correctly adopted on the basis of the Article 100a of the Treaty".

120 *Supra* note 189, at 89.

121 H. Busby et al., 'Ethical EUROPE Law? The Influence of the European Group on Ethics in Science and new Technologies' (2008) 33 European Law Review 803. See also G. Maio, 'The Embryo in Relationships: A French Debate on Stem Cell Research' (2004) 29 A Forum for Bioethics and Philosophy of Medicine 583.

French National Advisory Committee of Ethics encouraged the French government to start a new discussion about the terms of the Directive.[122] The suggested discussion was primarily on 'the non-commercialisation of the human body, the free access of the knowledge of gene, and the sharing of this knowledge'. [123] The French Government made an effort to avoid implementing or delay implementation of the Directive. The UK acted similarly.[124] Due to the various concerns and divergent interpretations, the UK legislators spent more than two years implementing the patent exclusion provisions of the Directive.[125]

Apart from slowing down the Directive transition, the EUROPE Member States also showed immense discrepancies in their national implementing legislation.[126] What are the primary factors considered by the Member States when implementing the Directive into national law? Moral issues and national commerce interests could be two leading aspects. For example, the French National Ethics Committee's opinion was significant in drafting the French law related to the Directive.[127] Economic pressures expressed by the public are also considered in French policy.[128] However, why did the Member States differ in implementing the Directive? One reason may be the different weights for the two factors in each Member States. If the economic element outweighs the moral value, countries tend to adopt a permissive

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[122] Opinion No. 64 on the law proposal to implement the European Directive on the legal protection of biotechnological inventions, by the French national Advisory Committee of Ethics.
[123] *ibid.*
[124] *Supra* note 189, at 235. See also *Supra* note 152.
[125] *ibid.*
[126] Regulatory approaches of national jurisdiction in HESC research in EUROPE could be substantially divided into three categories: First is the permissive policy. The exemplary embodiment is UK where the Article 6(2) of the Directive was narrowly explained, such as pluripotent cells could be granted patent. See reports of the United Kingdom Intellectual Property Office on inventions involving HESCs: <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm.> accessed online September 9, 2012. Second is the restrict policy. The exemplary embodiment is German where only imported HESC lines could be used in research. See Jan P Beckmann, 'On the German Debate on HESC Research' (2004) 29 Journal of Medicine and Philosophy, 203. Third is the intermediate policy. The exemplary embodiment is Netherland where embryos created for research is forbidden but surplus embryos from IVF is allowed. See Marta Kirejczyk, 'Parliamentary Cultures and Human Embryos: the Dutch and British Debates Compared' (1999) 29 Social Studies of Science, 889.
[127] Martin W Bauer and Georage Gaskell (eds), *Biotechnology: the making of a global controversy* (london, Cambridge University press 2002)
[128] *ibid.*

policy and liberal interpretation of the Directive. In contrast, a restrictive policy might be applied in countries where the moral value outweighs commercial benefits.

Although the Directive was imperfects, we do not doubt its extraordinary achievements. We should also bear in mind that the Directive does not sacrifice any fundamental principle to moral objections or patent demands in business. Most importantly, the Directive clearly met its aim to harmonise biotechnology regulations in the EUROPE for scientific progress.

6.3.3 No Uniform Moral Definition and Legal Status of Human Embryo

Despite the tendency of the Directive towards harmonising biotechnology regulations in the community, the Directive provides neither a uniform moral definition nor a uniform legal status of human embryos. Significant deference has been left with Member States, which adopted different approaches in this area. Moreover, the human embryo is excluded from patent where the Directive lacks a uniform moral definition and human embryo legal status. Human embryos, as a part of the human body 'at the various stages of its formation and development', are not patentable.[129] Judicially, there have been cases in which non-patentability of human embryos had been pondered over.

Case Vo v France: Develop the Margin of Appreciation Principle, Different Interpretations Based on Various Cultural, Philosophical and Cultural Circumstances

This case is related to a criminal suit involving a six-months-fetus mistakenly removed from Mrs Thi-Nho Vo by a doctor in France.[130] The doctor was initially charged with involuntary injury. However, the crime was later changed to involuntary homicide by the Lyons Court of Appeal after the

[129] The Article 5(1) of the Directive provides that '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'.
[130] Case *Vo v France*, (Application No 53924/00) GC, 2004.

application appealed. Alternatively, the Court of Cassation revoked the Court of Appeal decision because the fetus was not a human being under criminal law.[131] Therefore, an involuntary homicide conviction could not be established.[132] Finally, Mrs Thi-Nho Vo complained to the European Court of Human Rights, alleging that France government should pass legislation characterising the unintentional killing of a fetus as involuntary homicide based on Article 2 of the European Convention of Human Rights.[133]

The Court noted that the different levels of protecting human life among member states results in a lack of both scientific and legal definitions for the beginning of human life.[134] The decision respected the traditions of Member States and held that the human right 'comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere'.[135] The Margin of Appreciation principle[136], which was developed considering the conflicts between Member States and the Convention, allows the national courts to interpret the Convention differently based on various cultural, philosophical and cultural circumstances.[137]

Evans v United Kingdom: No Uniform Legal Status of Human Embryo

This case referred to protect an IVF embryo owned by Miss Evans and her former husband. Miss Evans requested that the European Court of Appeal withdraw the ruling by the UK High Court to destroy the embryo from Miss Evans' ex-husband.[138] The petition was refused. At the European Court of Human Right, Strasbourg, Miss Evans then claimed that the UK Government should protect embryos from destruction by the clinic because the UK

131 *ibid.*
132 *ibid.*
133 The Article 2 of the European Convention of Human rights provides that '1 Everyone's right to life shall be protected by law. Noone shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime force which this penalty is provided by law'.
134 *Supra* note 130 at para. 83 and 40.
135 *ibid,* at para. 42.
136 Margin of appreciation is a long standing ECHR principle, which can be traced back to case Greece v United Kingdom.
137 Yuval Shany, 'Toward a General Margin of Appreciation Doctrine in International Law?' (2006) 16 The European Journal of International Law 907.
138 Case *Evans v UK* (Application No 6339/05) the European Court of Human rights, 2006.

regulation is contrary to the European Convention on human rights.[139]

The Court left the decision on whether destroying the human embryo opposes to the fundamental principle of Convention-human dignity to the Member States. According to the prior ruling in case *Vo v France*[140], the court held human rights fall within the margin of appreciation (i.e., when Member States have the right to provide explanations under the Convention).[141] Furthermore, the Court stated there is no legal basis for the uniform European ban because the intention was that the Directive is not within the scope of the ban.[142] The ruling unquestionably and unanimously met the requirements for wide-margin discretion to Member States in this morally sensitive area.[143] Moreover, the decision clarified the scope of restrictions on HESC research covered in the European Convention of Human Rights.[144]

6.3.4 Uniform Concept of Human Embryo and Ban on Patenting Inventions that Involve the Destruction of Human Embryos

Distinct from the margin of appreciation principle established in *Vo v France* and *Evans v United Kingdom*, the European Court of Justice held that an autonomous concept of EUROPE law must be applied when looking for the definition for the purposes of a uniform interpretation of law within the EUROPE in case *Oliver Brüstle v Greenpeace*.[145] The court distinctly stated that:

> The lack of a uniform definition of the concept of human embryo would create a risk for the authors of certain biotechnological inventions being tempted to seek their patentability in the Member

[139] *ibid*.
[140] *Supra* note 130.
[141] *Supra* note 137.
[142] Recital 14 of the Directive provides that 'substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialization of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards'.
[143] Aurora Plomer, 'the European Group on Ehics: Law, Politics and the Limits of Moral Integration in Europe' (2008) 14 European Law Journal 839.
[144] *Supra* note 90.
[145] Judgment of the Court (Grand Chamber) in case *Oliver Brustle v Greenpeace* C-34/10, referencing for

> States which have the narrowest concept of human embryo and are accordingly the most liberal as regards possible patentability, because those inventions would not be patentable in the other Member States. Such a situation would adversely affect the smooth functioning of the internal market, which is the aim of the Directive.[146]

The court notes that neither the Directive nor the EPC provided a uniform embryo definition. Considering that the definition of human embryo is "a very sensitive social issue" in many Member States, the Court must 'restrict itself to a legal interpretation of the relevant provisions of the Directive' instead of broaching 'questions of a medical or ethical nature'.[147] After considering the moral value and the industrial potential of human embryos, the Court ruled that the meaning and scope of human embryos should be broadly interpreted where embryos are formed and its intent underlying such formation.[148] But relevant to HESC whether they are capable of commencing the process of development of a human being or not, is subsidiary to the concept of a human embryo.[149]

Given this uniform definition of a human embryo, any research related to HESC including that to merely use already established cell lines funded by the EUROPE, is prohibited from patents. This complete ban on HESC patents involving the destruction of human embryo was criticised by scientists and legal scholars. For example, Aurora Plomer from Sheffield's Institute of Biotechnology, law and Ethics, articulated three serious flaws in legal dimension.[150] First, Plomer thought that the ruling betrayed the intention of the Directive given its drafting history because the Directive was 'never to

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a preliminary ruling under the Article 267 TFEUROPE from the Germany, 18th October 2011

[146] Judgment of the Court (Grand Chamber) in case *Oliver Brustle v Greenpeace* C-34/10, referencing for a preliminary ruling under the Article 267 TFEUROPE from the Germany, 18th October 2011, at para 28.

[147] *ibid*. at para 30.

[148] *ibid*. at para 31

[149] *ibid* at para 37.

[150] Aurora Plomer, 'EUROPE ban on stem cell patents is a threat both to science and the rule of law' the Guardian (London, 12 December 2011) <http://www.guardian.co.uk/science/blog/2011/dec/12/Europe-ban-stem-cell-patents> accessed 19 March 2012.

render unpatentable research that is lawful in member states'.[151]

Secondly, considering the fact that a European-wide ban was not imposed by the EUROPE Directive on human tissue and cells (2004),[152] as well as regulations on advanced therapies (2007), a EUROPE consensus on the degree of human dignity has not been reached. However, the ruling presumed that a uniform European view had developed despite the diversity of laws and moral cultures in Member States.[153] Thirdly, the ruling was inconsistent with the margin of appreciation principle in the preceding decision by the European Court of Human Rights.[154]

6.3.5 The Attempt of Infusing Moral Control with the Patent Regulation

Initially, biotechnology inventions were treated equally with other inventions in the patent application procedure. However, in contrast with other inventions, biotechnology inventions are coupled with morality issues.[155] Despite the strong impetus encouraging biotech advances, the EUROPE did not sacrifice moral standards for either legal harmonisation or industry benefit.

The Council of EUROPE first decided to add moral exclusion in patent law in the Strasbourg Convention 1963. Then it is preserved in the EPC and Biotechnology Directive. Article 6 (1) of Biotechnology Directive states that 'inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality'.[156] Article 6 (2) further lists 'uses of human embryos for industrial or commercial purposes' should be considered as unpatentable. From the history of HESC regulation in EUROPE, it was concluded that 'despite some initial hesitations about involvement in moral issues surrounding patentability, the European Patent

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151 *ibid.*
152 *Supra* note 35.
153 *Supra* note 290.
154 *ibid,* see case *Vo v France*, (Application No 53924/00) GC, 2004.
155 Other inventions refers to chemical related invention, technical related invention etc, which generally do not involve moral issues.

Office (EPO) finally accepted the necessity of addressing such issues'.[157] Therefore, the EUROPE development of HESC regulations infuses moral considerations into traditional patent regulations.

However, moral issues related to biotechnology patents could not be easily articulated. Certain inventions, such as cloning human beings and using human embryos for industrial or commercial purposes, could simply be excluded from patentability.[158] As Brody Baruch states, this experience demonstrates 'the need for well-articulated criteria for determining what should be excluded from patentability on those grounds in order to deal with newly emerging controversial inventions'.[159] However, certain issues, such as human dignity and commercialisation of the human body might be appropriate for alternative social mechanisms.[160] Brody Baruch suggests that such considerations should be understood under better theoretical circumstances.[161] Therefore, Baruch concludes that 'the European experience is an incomplete experiment in incorporating moral considerations into patent law'.[162]

The combined moral control and patent regime in EUROPE framework is strange to certain scholars, including certain legal positivist theories, such as Bentham, who stated that 'a technical, commercial tool with little or nothing to do with questions of morality'.[163] Using an alternative philosophy, Hart also claimed morality should play no part in patent law.[164] Certain academics, such as Cornish, Llewelyn and Aplin, have argued that morality and patent law should be divided because patent system is not an appropriated arena for

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156 The Biotechnology Directive 98/44/EC.
157 Brody Baruch, 'intellectual property and biotechnology: the European Debate' (2007) 17 Kennedy Institute of Ethics Journal 69.
158 *ibid.*
159 *ibid.*
160 *ibid.*
161 *ibid.*
162 *ibid.*
163 Bentham J, *the Principles of morals and legislation* (Oxford claredon press, London 1907) 317.
164 Hart H L A, *the concept of law* (2nd edn Oxford claredon press, London 1994).

moral discussions.[165] The objective, technical and legal nature of patent law is contrary to the morality because it is inherently malleable, subjective and emotive.[166] Certain scholars have even suggested removing the moral objections from the Directive.[167]

One reason for separating moral considerations from the EPO patent procedure is that the capability of the EPO in performing moral analysis is limited. The EPO was regarded as unqualified since their examiners are 'not sufficiently trained in philosophy or jurisprudence to tackle moral issues surrounding patent law'.[168] In fact, EPO examiners recognised that the Patent examiners are not an appropriate for measuring such moral issues. In *Europethanasia Composition*, the TBA further publicly pointed that 'morality is not a criterion to be determined by patent authorities'.[169] It is therefore to be concluded that the infusion of moral control and patent law in the EUROPE mode might not be an appropriate approach.

6.3.6 Space for flexibility on the Basis of Minimum Standards: Let States Decide Moral Provisions Instead of a Universal Moral Standard due to Culture Difference

The diversity may have costs but can also 'enable systems to find novel and breakthrough solutions, and it can add to their value and robustness'.[170] It is however worth considering the degree of diversity that would become a turning point in hampering technological advances. This section attempts to find regional and international solutions for similar roadblocks concerned with the scientific, legislative and ethical issues. The research specifically

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165 Cornish W, Llewelyn, and Aplin T, *Intellectual property: patents, copyright, trademarks and allied rights* (7th edn Sweet & Maxwell, London 2010) 881.

166 Black J, 'regulation as facilitation: negotiating the genetic revolution' (1998) 61 Modern Law Review 621.

167 Llewelyn M, 'the patentability of biological material: continuing contradiction and confusion' (2000) 22 European Intellectual Property Review 191.

168 Bentham J, *The Principles of morals and legislation* (Oxford Claredon Press, London 1907) 317.

169 Case *Euthanasia Composition*, T-866/01 Decision of Technical Board of Appeal, May 11 2005.

170 Owen C.B. Hughes, Alan L.Jakimo and Michael J. Malinowski, 'United States Regulation of Stem cell research: recasting government's role and questions to be resolved'(2008) 37 Hofstra law review 383-443.

draws on the lessons from an attempt to harmonise HESC regulations in the EUROPE.

As has been demonstrated, the member states retain certain decision-making rights in the EUROPE for HESC regulations harmonisation. Although the EPC provides uniform substantive principles and procedures for patent applications, the EUROPE did not uniformly define the legal and moral status of human embryos. However, the EUROPE reached a consensus on human embryos; the EUROPE imposed a total ban on cloning and destroying human embryos. The EUROPE adapted the unitary patent package including the unitary patent regulation, the language regime and an international agreement on the unitary patent court. It is the author's belief that the EUROPE infusion of moral control and patent law is not the appropriate strategy. Typically, for HESC regulation, the EUROPE provides clear guidance for member states and provides sufficient opportunity for adaption. The space for flexibility, which aids in relieving the tension underlying moral conflicts in different countries, might be at the heart of harmonising HESC regulations.

6.4 Lessons from Other Harmonising Regulations

From the above discussion, at least theoretically, we could conclude that reconciliation of HESC regulations could yield significant benefits either for national states or the entire world. However, international regulations related to the morally sensitive HESC research field might be justified and rationally acceptable for interested parties. Based on a full understanding of the related issues, the reconciled regulations might simultaneously include legitimising and acceptable principles. A legitimising principle includes 'what sorts of conduct may be the state rightly make criminal'.[171] The acceptable principle refers to 'the fact that the addresses of a prohibition can rationally agree to the

[171] Feinberg Joel, *The moral limits of the criminal law volume 4: harmless wrongdoing* (Oxford Scholarship Online, 2003)

curtailment of his or her liberties'.[172] Facing a wide range of moral differences and enforcement diversity at the international level, what is an effective way to reconcile international regulations and improve scientific progress in HESC research? Attempts at reconciling HESC research regulations should be cautious and thoughtful, and lessons should be considered from models aimed at reconciliation in other areas, such as international drug agreements as well as the human safety aspects of international trade, research and development.

6.4.1 Lessons Learned from Harmonised Drug Agreement

Similar to HESC research, the pharmaceutical industry is challenged by rapid technology advances and international cooperation. Regulatory bodies have attempted to harmonise drug regulations across national jurisdictions. Such harmonisation was attempted for three dominant areas: the US, the EUROPE and Japan. These countries established the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to standardise these areas.[173] The EUROPE Committee on Proprietary Medicinal Products (CPMP) made a similar effort to harmonise EUROPE drug regulations for centralisation.[174] From the EUROPE experience, the pharmaceutical industry can be viewed as a core driving force for economic development.[175]

One key lesson from the effort to harmonise international drug regulations is mutual recognition. One significant measure by the ICH was creation of the

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[172] Minou Friele, 'striving for harmonisation and living without it. Is international legislative harmonisation in morally problematic areas such as research on human embryos ethically justifiable?' (2009) 201 Legitimation ethischer Entsceidungen in Recht 331.

[173] The international Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), <http://www.ich.org/> accessed July 8 2012.

[174] The EUROPE Committee on Proprietary Medicinal Products (CPMP), <http://www.ema.Europa.Europe/ema/index.jsp?curl=pages/about_us/general/general_content_000094.jsp> accessed 8 July 2012.

[175] John Lee, 'what is past prologue: the international conference on harmonisation and lessons learned from European Drug Regulations on harmonisation' (2005) 26 University of Pennsylvania Journal of

Common Technical Document (CTD).[176] Assisting harmonisation efforts, the CTD served as 'an acceptable alternate form for drug marketing approval applications' in the US, the EUROPE and Japan.[177] Through the CTD, not only is the same set of information provided to these areas, but a common set of market approvals are required.[178] Most importantly, the CTD could indicate, to a certain extent, the willingness for mutual recognition in such jurisdictions.[179] The CTD, safety Guideline, quality Guideline and efficacy Guideline indicate the ICH's commitment to harmonising drug regulation.[180] Although mutual recognition was not a goal for the ICH, we can conclude that mutual recognition is the vital essence of harmonising drug regulations based on evidence from the CTD. Additionally, 'in all likelihood, mutual recognition must be the foundation on which the harmonised system is based'.[181]

Another significant lesson from the effort to harmonise international drug regulation is the importance of a strong central international authority. A sufficient centralised international authority is the foundation for success of mutual recognition in an international agreement.[182] A powerful centralised organised force can efficiently prevent a clash between national interests and harmonisation. From the EUROPE experience in harmonising drug regulations, member states could simply disagree with CPMP opinions due to a national interest.[183] Recognising the importance of centralisation, the CPMP adopted two measures to advance true harmonisation. One such measure was

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International Economy Law 151.

176 The Common Technical Document is included in ICH Multidisciplinary Guideline. ICH Guideline can be divided into four categories: quality Guideline, safety Guideline, efficacy Guideline and multidisciplinary Guideline. Multidisciplinary Guideline are 'the cross-cutting topics which do not fit uniquely into one of the quality, safety and efficacy categories.' <http://www.ich.org/products/Guideline.html> accessed 8 July 2012.

177 *ibid*.

178 The Multidisciplinary Guideline, <http://www.ich.org/products/Guideline/multidisciplinary/article/multidisciplinary-Guideline.html> accessed 8July 2012.

179 *Supra* note 80.

180 *ibid.*

181 *ibid.*

182 *ibid.*

183 John Abraham and Graham Lewis, *Regulating medicines in Europe* (London and New York press, 2000) 97.

that applications should be submitted to the European Agency for the Evaluation of Medicinal Products (EMEA)[184] instead of national regulatory agencies for authorisation.[185] The other measure was the binding force of EMEA and CPMP decisions on member states.[186] However, a national regulatory agency approval remains necessary for a drug company to enter the national market.

From the above analysis, we could discern many similarities between harmonising drug regulations and HESC regulations. First, both activities increase international collaboration and support for harmonising regulations across national boundaries. Second, both activities are governed by specific EUROPE Directives on drug regulations and biotechnology regulations to facilitate harmonisation in the internal market.[187] Third, both harmonising drug regulations and HESC research regulations carry morality concerns for different cultures. Thus, the precious lessons learned from harmonising drug regulations must be used in harmonising HESC regulations. Mutual recognition and a strong central international authority are also vital to harmonising HESC regulations.

6.4.2 Lessons from Harmonising the Regulation of Environmental and Human Safety Aspects of International Trade

Similar and important challenges for HESC have also been raised for harmonisation of the regulations governing the environmental and human safety aspects of international trade. For instance, these regulations produce an intense conflict between national interest in a competitive advantage on

[184] The European Agency for the Evaluation of Medicinal Products (EMEA) <http://www.ema.Europa.Europe/ema/> accessed July 15 2012.
[185] The Article 4, section 1 of Council Directive 93/39/EEC 1993 O.J.
[186] The Article 12, section 1 and section 2 of Council Directive 93/39/EEC 1993 O.J.
[187] The Council Directive 93/39/EEC 1993 O.J.; The Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

the global market and a moral claim to respect human dignity.[188] Further, the different cultures, policies and moralities of various nations have tremendously influenced such regulations. In other words, both regulations carry the risk that harmonisation will lack legitimacy and be impeded by cultural variations. Therefore, to a certain extent, harmonisation attempts in these areas must avoid similar pitfalls in the legal process.

One important lesson from harmonising the regulations governing the environmental and human safety aspects of international trade is the equivalence mode of harmonisation. The regulations governing the environmental and human safety aspects of international trade achieved were harmonised through two important agreements, the Technical Barriers to Trade Agreement (TBT) and the Sanitary and Phytosanitary Agreement (SPS). The purpose of the TBT is 'to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles, while also providing members with the right to implement measures to achieve legitimate policy objectives'.[189] The SPS Agreement sets out the basic rule for 'how governments can apply food safety and animal and plant health measures' and ensures 'strict health and safety regulations are not being used as an excuse for protecting domestic producers'.[190] These agreements both rely on the equivalence model to 'encourage member states to harmonise their standards with those of other member states by simply treating the foreign standards as though they were identical to domestic rules'.[191] Member states do not have the right to adjust their rules rather than accept the rules of another jurisdiction.[192] Certain international norms and standards laid out in

[188] Angela Campbell and Gillian Nycum, 'Harmonsing the international regulation of embryonic stem cell research: possibilities, promises and potential pitfalls' (2005) 7 Medical Law International 113.
[189] Technical barriers to trade of the World Trade Organisation, <http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm> accessed 18 July 2012.
[190] Sanitary and Phytosanitary measures of the World Trade Organisation, <http://www.wto.org/english/tratop_e/sps_e/sps_e.htm> accessed July 18 2012.
[191] Angela Campbell and Gillian Nycum, 'Harmonsing the international regulation of embryonic stem cell research: possibilities, promises and potential pitfalls' (2005) 7 Medical Law International 113.
[192] Alexander M Donahue, 'Equivalence: not quite close enough for the international harmonisation of environmental standards' 30 Environment law 363.

the TBT were formulated based on national rules.[193] Unlike the TBT Agreement to encourage harmonisation, the SPS Agreement requires that member states apply the international standard with the exception that a stricter national standard may be used with justification. Further, when a state that adopts the SPS measures provides equal protection as other member states, according to equivalent principle, the other member states must accept the SPS measures of the adopting state.[194]

The two apparent approaches of this equivalency mode can be discerned for the TBT and SPS Agreements. One such approach includes flexibility in harmonising principles because standards provided by an international regulatory agency or other state have no binding force in member states.[195] The other approach is a strict requirement for harmonising rules when certain norms set out by international bodies or other states must be applied under circumstances where certain conditions are satisfied.[196] In my understanding, the first approach should precede the second approach in harmonising HESC research regulations because the first approach allows nations' rules that adhere to international rules in the uncertain moral context of HESC research. In addition, as Herman noted, 'specificity in harmonisation agreements is seen as an impediment to free trade since in lacks flexibility to deal with future events, on some level a degree of rigidity is desirable'.[197] I personally believe that a strict agreement on HESC research is premature because this field may generate enormous unpredictable changes over the next decade. Currently, technical barriers include 'the limited functionality of public patent information databases, the lack of timeliness of published information, and the presumed knowledge of the patent system', and cultural barriers include 'scientist senses of alienation from the patent system and their belief that they

[193] Margaret Renee Herman, 'Are we learning for the mistakes of environmentalists? The Application of Environmental Harmonisation Models to the Automotive Industry' (1999) 16 Arizonal Journal International & Competition Law 543.
[194] *Supra* note 94.
[195] It is implied in the Technical Barriers to Trade Agreement (TBT).
[196] It is implied in the Sanitary and Phytosanitary Agreement (SPS).
[197] *Supra* note 97.

are safe from litigation', which demonstrates that a standard of rigid harmonisation is a long way off.[198]

Applying the lessons from regulations governing international drug agreements and the environmental and human safety aspects of international trade to reconciling HESC regulations, we should allow differences but seek to narrow such differences. Therefore, in my opinion, flexible, widely applicable and non-binding rules with certain uniform norms or principles is likely a good fit for reconciling HESC regulations.

6.4.3 Is the Universal Patenting Regime is a Good Candidate for the Extraterritorial Jurisdiction over HESC Research?

Currently, there are two primary international patent treaties; one treaty is the Paris Convention for the Protection of Industrial Property,[199] and the other is the Trade Related Intellectual Property Agreement[200]. For the HESC field, consistent patent regulations protecting innovations between extraterritorial jurisdictions are valuable.

Five basic legal principles govern cross-jurisdictions: 'the territorial principle, the nationality principle, the passive personality principle, the protective principle and the universality principle'.[201] Although the territorial principle is most commonly used in international public law, it has little chance for acceptance because morality-based regulation of embryo research differs

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[198] Aurora Plomer, 'Stem cell patents in a global economy: the legal challenges' (2010) 3 Stanford Journal of Law, Science & Policy 5; see also Zhen Lei, 'Patents versus patenting: implications of intellectual property protection for biological research' (2009) 27 Nauture Biotechnology 36.

[199] The Paris Convention for the Protection of Industrial Property signed on March 20 1883 was 'one of the first intellectual property treaties. It established a Union for the protection of industrial property', <http://en.wikipedia.org/wiki/Paris_Convention_for_the_Protection_of_Industrial_Property> accessed July 6 2012.

[200] The Agreement on Trade Related Aspects of Intellectual Property Rights is 'an international agreement administered by the World Trade Organization that sets down minimum standards for many forms of intellectual property regulation as applied to nationals of other WTO members', <http://en.wikipedia.org/wiki/Agreement_on_Trade-Related_Aspects_of_Intellectual_Property_Rights> accessed July 6 2012.

enormously between countries.[202] Where scientists move from an unlawful regime to a favourable regulatory scheme, the protective and passive personality principles are both unconvincing because they are involved with the restrictive and permissive countries.[203]

The question is which principles are better for extraterritorial jurisdiction over patenting HESC research, national or universal principles. According to international law, national jurisdiction can be extended beyond the physical territory of a country.[204] However, for HESC research, countries have not exercised national jurisdiction extraterritorially.[205] The nationality principle is typically adopted for military offences.[206] As a result, the universal principle is likely the best choice for extraterritorial jurisdiction over HESC. For HESC research, 'any successful patenting system must be flexible and adaptable to changing and unforeseen technologies'.[207] Clearly, a flexible patent regime is 'free from the shackles of a statutory moral utility doctrine, science and technology may be unnecessarily stunted'.[208]

Although significant advantages to reconciling patent law have been expressed, certain objectors believe that an inconsistent patent system benefits global society.[209] This argument is based on the notion that 'harmonisation is obviously desirable in the long term provided at the same time the world become egalitarian'. [210] Because the world is unequal, patent law

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201 Brownlie I, *Principles of public International Law* (Oxford: Oxford University Press, 5th ed 1998) 15-78.
202 Heidi Mertes and Guido Pennings, 'cross-border research on HESCs legal and ethical considerations' (2009) 5 Stem Cell Rev and Rep 10.
203 *ibid.*
204 Loane Skene, 'Undertaking research in other countries: national ethico-legal barometers and international ethical consensus statement' (2007) 4 PLos Medicine 10.
205 *ibid.*
206 Heidi Mertes and Guido Pennings, 'Cross-border research on HESCs legal and ethical considerations' (2009) 5 Stem Cell Rev and Rep 10.
207 Charles Hall, 'the lessons stem cells provide patents: working towards an international/universal patent regime' (2004) the Berkeley Electronic press 278.
208 *ibid.*
209 Sadaf Shariat, 'Response to global ethical concerns regarding patentability of HESC Research' (2011) International Conference on Management (ICM 2011) Proceding.
210 WIPO Open Forum on Draft SPLT reports by John Sulston, International patent law harmonisation, development and policy space for flexibility, 2006 <http://www.wipo.int/export/sites/www/meetings/en/2006/scp_of_ge_06/presentations/scp_of_ge_06_sulston1.pdf> accessed online 2 July 2012.

harmonisation is meaningless.[211] Addressing the concept of universal HESC patenting, Professor Yochal Benkler indicated 'the world need more emphasize on the cultural values, such as freedom and health, of a cooperative society rather than a totally commercialised society that successfully invade the institutions of learning and corporations'.[212] I agree with the above arguments and believe that regulatory harmonisation might be implausible in an unequal world. However, reconciling relevant regulations in a worldwide regime may be possible to a certain extent. I would defend this concept by noting that the EUROPE successfully attempted to reconcile patent regulations in an unequal world.

6.5 Lessons from Reconciliation Efforts by Some Institutions

The success of reconciling HESC regulations depends on the institutions involved. The momentum of HESC research is outpacing the speed of regulation. [213] As Professor David Leebron observed, '[i]nternational institutions serving as the forum for harmonization sometimes have narrow competencies or mandates'.[214] In fact, certain academic, public sector and private sector organisations are already committed to building a framework and laying the foundation for harmonising HESC regulations.

6.5.1 The International Society for Stem Cell Research (ISSCR): Setting a Guideline for Technical Standardisation

The ISSCR is an independent, non-profit organisation that seeks to encourage global governance of international collaboration in HESC research. It aims to

[211] Sadaf Shariat, 'response to global ethical concerns regarding patentability of HESC Research' (2011) International Conference on Management (ICM 2011) <http://www.internationalconference.com.my/proceeding/icm2011_proceeding/115_324_ICM2011_PG1675_1684_STEM_CELL.pdf> accessed 22 July 2014.

[212] Yochal Benkler, *The wealth of networks how social production transforms markets and freedom* (New Haven and London: Yale University press, 2006) 14.

[213] David W Leebron, 'claims for harmonisaton: a theoretical framework' (1996) 27 Canadia Business

> [P]romote and foster the exchange and dissemination of information and ideas relating to stem cells, to encourage the general field of research involving stem cells and to promote professional and public education in all areas of stem cell research and application.[215]

The ISSCR seeks to reconcile policies, core ethical principles, safety requirements and technical standards to promote international collaboration and foster global governance over HESC research.[216]

One significant contribution of the ISSCR is the "Guideline for the conduct of HESC Research", which address responsible, uniform and transparent clinical trials in the international context.[217] The ISSCR Guideline attempt to clarify legitimate interventions by clinicians on behalf of patients in stem cell tourism and separate the legitimate clinicians from medical opportunists.[218] The ISSCR Guideline establish an independent panel to review the fundamental moral requirements and approve projects.[219] Further, the ISSCR Guideline define 'categories of research that are non-permissible, that are permissible under currently mandated review process, and research that is permissible yet should be subjected to an added level of oversight'.[220] Nevertheless, such aspects are related to bioethics and are scientific technicalities.[221] In other words, these aspects address the term "standardisation", which is involved in 'the processes of scientific guidance in the adoption of uniform scientific and technical requirements and common Guideline'.[222] However, the

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Law Journal 63.

214 *ibid*.

215 Mission statement of the international Society for Stem Cell Research, <http://www.isscr.org/Mission_Statement/2810.htm> accessed 20 July 2012.

216 *ibid*.

217 Guideline for the Conduct of HESC Research, <http://www.isscr.org/GuidelineforhESCResearch/2917.htm> accessed 1 August 2012.

218 Bryn Nelson, 'Stem cell researchers face down stem cell tourism' (2008) Nature Reports Stem Cells 89.

219 *Supra* note 105.

220 *ibid*.

221 Insoo Hyun, 'the bioethics of stem cell research and therapy' (2010) 120 The Journal of Clinical Investigation 71.

222 Rosario M Isasi and Bartha M Knoppers, 'Governing stem cell banks and registries: emerging issues'

term "harmonisation" is related to 'the process in which diverse elements are combined or adapted to each other to form a coherent whole'.[223] For HESC research, either technical standardisation or policy convergence is important for promoting scientific advances. However, the ISSCR Guideline are restricted to technical standardisation and ignore policy reconciliation.

Despite of certain drawbacks, in my view, the ISSCR Guideline are a good initial attempt at reconciling HESC regulations for a worldwide regime. Particularly in the stem cell banking context, the ISSCR Guideline propose a "Registry of HESC Lines Provenance" to facilitate HESC exchange and dissemination throughout the world.[224] The ISSCR Guideline also highlight the moral use of HESC lines in various rules.[225] James Wilson believed that the ISSCR could 'play an important role in steering this young discipline in the right direction'[226], especially by discouraging 'overselling the clinical reality of stem cell therapeutics' and 'effectively communicating how long it takes to go from laboratory bench to bedside'.[227] Using the standards in the ISSCR Guideline, we can easily 'identify the shortcomings of some clinics and call into question the legitimacy of their purported claims of providing innovative care to patients'.[228]

(2009) 3 Stem Cell Research 96.

[223] Boodman M, 'The myth of harmonisation of laws' (1991) 39 American Journal Contemporary Law 699.

[224] Bernard Lo, Arnold Kriegstein and Deborach Grady, 'Clinical Trials in stem cell transplantation: Guideline for scientific and ethical review' (2008) 5 Clinical Trials 517.

[225] Jeremy Sugarman and Andrew Siegel, ' How to determine whether existing HESC lines can be used ethically' (2008) 3 Cell Stem Cell 238; see also Emma L Stephenson, Peter R Braude and Chris Mason, 'international community consensus standard for reporting derivation of HESC lines' (2007) 2 Future Medicine 349.

[226] James M Wilson, 'A history lesson for stem cells' (2009) 324 Science 727.

[227] *ibid*.

[228] *Supra* note 124.

6.5.2 The Hinxdon Group: the Consensus Statement Lack Moral Consideration

The Hinxton Group is 'a clearing house, facilitating communication among scientists, policymakers, journal editors and the public about international scientific collaboration in the area of stem cell research'.[229] Through its consensus statements on ethical principles, the Hinxton Group attempts to facilitate international HESC collaboration and guide global HESC research.[230] The fundamental moral value underlying the consensus statements is that 'both the possibility of advancing knowledge and the value of relieving suffering and promoting human welfare' should be simultaneously respected.[231] In the updated version of the consensus statement in 2010, the Hinxton Group produced five specific recommendations to address the challenges raised by HESC harmonisation:

> 1) Establish a central hub for accessing global stem cell registry information and establish a central hub for accessing information about stem cell patents; 2) Encourage support and coordinate international human stem cell banks and human tissue and cell repositories; 3) Develop and Institute incentives for data and materials sharing through publication, participation in information hubs, and other mechanisms; 4) Explore options for formal collaborative networks, patent brokering, and formation of patent pools when those mechanisms for collective management of intellectual property can move the field forward; 5) Adopt licensing practices and patent policies that promote fair, reasonable, and nondiscriminatory (equitable) access to knowledge and health care

[229] The Hinxton Group, <http://www.hinxtongroup.org/> accessed 8 August 2012.
[230] Alan C Regenberg, Lauren A Hutchinson, Benjamin Schanker and Debra J H Mathews, 'Medicine on the Fringe: Stem cell-based interventions in advance of evidence' (2009) 27 Stem Cells 2312-2319.
[231] The Hinxton Group, an international Consortium on Stem Cells, Ethics and Law Consensus Statement, 2006 <http://www.hinxtongroup.org/au_trans_cs.html> accessed 8 August 2012.

applications.[232]

The consensus statement recommendations ambitiously seek prosperity in both technology innovation and commercial transaction.[233]

One important feature of the consensus statement is establishment of a centralised hub to govern issues related to international HESC collaboration research. The recommendation to establish a centralised hub to access relevant data is related to concerns over accessing cell lines and certain related critical information.[234] However, as Debra Mathew noted, such a hub must face certain substantial challenges, such as 'who will fund it, who will do the work, what the resource will look like, where it will reside administratively, and how the various blurred distinctions will be facilitated and managed in practice'.[235] Further, the design of data architectures requires certain restrictions and formal legal agreements.[236] In the consensus statement, these relevant issues are phrased in general terms.

However, to a certain extent, the consensus statement lacks moral considerations for human embryos. Although the Hinxton Group aims to develop an international consensus on moral and scientific issues involved in HESC, from this statement's phrasing, the group is silent on using embryos created for research.[237] The Hinxton Group simply believes that a 'scientist should be free to participate in that research without fear of being liable to prosecution, restriction, or discrimination in other jurisdiction' without considering circumstances where scientists move abroad to conduct HESC

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[232] The Hinxton Group, statement on Policies and Practices Governing data and materials sharing and intellectual Property in stem cell science 2010 <http://www.hinxtongroup.org/Consensus_HG10_FINAL.pdf>accessed 8 August 2012.

[233] Rosario Isasi and Bartha M Knoppers, 'From banking to international governance: fostering innovation in stem cell research' (2011) Stem Cells International 1-8.

[234] Debra J H Mathew, 'Access to stem cells and data: persons, property rights and scientific progress' (2011) 331 Science 725.

[235] *ibid*.

[236] *ibid*.

[237] Rosario M Isasi, 'Policy interoperability in stem cell research: demystifying harmonisation' (2009) 5 Stem Cell Review and Reports 108; also see Loane Skene, 'Undertaking research in other countries: national ethico-legal barometers and international ethical consensus statements' (2007) 4 PLoS Medicine 10.

research that is considered unmoral.[238] Therefore, the consensus statement recommendations are useless and impractical both for nations and researchers in reconciling HESC regulations.[239] Where moral values differ among countries and morally rejected HESC research is conducted in another country, the consensus statement should include certain recommendations to ensure that studies are scientifically and morally monitored.

Despite certain scholars' doubt on the utility of the consensus statement[240], in my opinion, the consensus statement is valuable for reconciling HESC regulations. It opened a dialogue between nations on this complex area. It advocates that scientists, researchers, ethicists, policy makers and legal experts discuss, analyse and share their opinions. Its suggested regulatory mode inspired and triggered the international considerations for HESC regulations.

6.6 Conclusion

It is argued that the reconciled HESC regulation at international level is the best solution to the inadequacy in China. Reconciling regulations of HESC research at international level is motivated by economic, scientific and legal factors. National countries compete to take advantage role in global HESC market. Disparate policies to some extent encountered international stem cell collaboration research that took a big portion of HESC research. Drawing lessons from the EUROPE, in the reconciliation of HESC regulation, adequate flexibility and diversity in the field of HESC regulation is beneficial to HESC research. It finds that in the EUROPE unitary substantive patent regulation, considerable freedom is still given to national legislators.[241] The margin of

[238] Heidi Mertes and Guido Pennings, 'Cross-border research on HESCs: legal and ethical considerations' (2009) 5 Stem Cell Review and Reports 10.
[239] *ibid.*
[240] Loane Skene, 'Undertaking research in other countries: national ethico-legal barometers and international ethical consensus statements' (2007) 4 PLoS Medicine 10.
[241] Avgi Kaisi, 'Finally a single European right for the EUROPE? An analysis of the substantive provisions of the European patent with unitary effect' (2014) 36 European Intellectual Property Review 170-180 (concluding that the regulation on the Unitary Patent leaves many crucial issues on the national patent laws of the Member States, such as prior user right and compulsory licensing).

appreciation principle, developed considering the conflict between member states and the European Patent Convention, allows national courts to interpret the Convention differently based on various cultural, philosophical and cultural circumstances. Although the EUROPE reached a broadly interpretation of human embryo which includes HESC lines, no uniform legal status of human embryos or human dignity was provided under the requirement for wide margin discretion.

After taking lessons from the reconciled drug agreement and the regulation of environmental and human safety aspects of international trade, this section demonstrates that reconciling HESC regulations should base on mutual recognition, establish a strong central international authority and use the equivalence mode. However, the guideline for technical standardisation in practice by ISSCR is focused on "standardisation", not reconciling regulations because it merely addressed absent technical standards by combining relevant diverse elements. The consensus statement from the Hinxton Group established a centralised hub to govern relevant issues. A weakness of the consensus statement is that it ignored the moral dimension of HESC research.

This chapter analysis the feasible HESC reconciliation approach which aims to provide minimum standards of HESC research. Minimum standards are significant for the stability and credibility of scientific progress. Through establishing the specific authority to monitor the reproductive research and setting a central stem cell bank, HESC research are monitored to compliance with harmonised regulations. The international attitude towards HESC research should point at providing the minimal standards and achieving practical benefits. The international reconciled regulation should not attempt to control national endeavours except that the national policies are against the fundamental human rights. Moreover, the international reconciled regulation should aim to promote the public health.

CHAPTER SEVEN: CONCLUSION

This thesis has addressed the research question of *what is a better way to regulate HESC research in China?* The aim of this thesis is to provide a best way to regulate HESC research. This study has been motivated by the recent developments in the HESC technology. Based on the above analysis in previous chapters, the Law faces problems from HESC technology that are still being questioned. The Law is struggling to keep up with and make reflexive responses to these developments. Factors such as moral culture, commercial interest, technological standard, patent policy, public right and clinic ethics have all affected HESC research.[1] Being an area of heavily financial and political investment, it seems to be essential to make the law facilitate technology change in China. If HESC technology develops in a legal vacuum or in a legislation rash, HESC technology might be a threat to human society. It is only when HESC technology is monitored by the law that it can develop a better understanding for human beings.

When tacking such a topic, moral exclusion has been examined and discussed. To achieve the purpose of the research, the thesis also examines the 'moral maze' in HESC research and the reconciliation attempts of HESC regulations. The failure of current legal framework of HESC regulation in China is observed. In this context, two areas have been scrutinised: the EUROPE (moral exclusion within the patent law) and the US (moral exclusion without the patent law) to find a better way to regulate HESC research. These two different legal systems were chosen due to the distinctive approach of each regime in dealing with the patentability and morality of HESC related invention. A comparative analysis has been carried out relying mainly on case law, statutes and scholarly views. It has been concluded that the law in each of these jurisdictions has dealt differently with cases involving the patentability and morality of HESC related inventions.

[1] Chapter Two and Three.

7.1 The Comparative Analysis of HESC Regulations in the US and the EUROPE

In order to provide a comprehensive answer to the research question raised, a comparative critical analysis approach has been adopted which offers a clear framework for the subject matter and sensible research outcomes. As discussed, in HESC, hundreds of flowers bloom on multiple jurisdictional levels. In particular, there is a difference in dealing with HESC related regulation across borders. The invention that obtains patent protection in one area might be objected to in other areas.[2] This regulatory inconsistency leads to the phenomenon whereby scientists, research funding and patients flow to the area that has a liberal policy in HESC research.[3] The problem of unequal access to therapies resulting from HESC is likely to arise due to the disparities in regulatory conditions.[4]

This thesis observed that the EUROPE and China patent regulations both contain moral opposition to the HESC, while the US has no such clause. The EUROPE tradition values bioethics and is rooted in moral values,[5] whereas the US tradition does not share these characteristics.[6] The EUROPE patent regulations contain moral opposition to HESC, while the US has no such clause. Chinese regulators have adopted the idea that moral exclusion in patent law is merely due to the belief that moral exclusion represents an international custom. Although the moral-exclusion-fits-all approach of the EUROPE Directive is not likely to yield the best result in the member states which differ widely in social and cultural realities, to ensure efficiency and effectiveness, cultural, ethical and legal reconciliation is indispensable. Legal diversity is inevitable, whereas Legal reconciliation is essential in order to assure research could be morally carried out in China.

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[2] Chapter Four and Five. (WARF patent application related to differentiate HESC was granted in US, but rejected in EUROPE).
[3] Chapter Three. (For example stem cell therapy).
[4] Chapter Three.

When we view the HESC regulation regime in a long-term historical background in EUROPE, it is concluded that infusing morality insider patent law is not an effective way to control HESC research. According to the ruling of case *WARF* and case *Brüstle*[7], HESC related inventions can not be patented in the presence of morality objections. This moral exclusion in patent law seems to be unreasonable.[8] First, although the results of HESC related inventions can not be patented, the HESC research has already been carried out. If the research is prohibited from being patented for the reason that the research is immoral, this research should not be carried out. Second, many pieces of HESC research are funded by the EUROPE.[9] It would appear to be a waste of money and time since their results cannot be patented. Third, the moral-exclusion-fits-all approach of the EUROPE Directive is not likely to yield the best results in the member states, which differ widely in social and cultural realities. In the EUROPE, even if member states reach a compromise at the EUROPE level, inevitably member states interpret diversely in national jurisdiction. The harmonisation attempt at the EUROPE level remains a case of divergent interpretations in member sates. For example, according to case Onco-mouse, case Relaxin, case Plant Genetic Systems, case University of Edinburgh and case WARF, the member states had different interpretations towards moral definition, human embryo definition and industrial or commercial use definition. This inconsistency does not conform to the harmonisation aims of the EUROPE Unitary Patent Regulation, EPC and Biotechnology Directive.

This thesis observes that federal funding control on HESC research is also not a effective way to control HESC research. Although there is moral concern concerning HESC research, the patent regulation in US does not preclude the patentability of inventions for reasons of morality. The US position on HESC

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[5] Chapter Five.
[6] Chapter Four.
[7] Chapter Five.
[8] Chapter Five.
[9] Chapter Five.

is a liberal one on patent protection. Some quite important patents in the field of HESC, such as patent WARF 780, 806 and 913, have been granted.[10] Instead, the US government uses the federal funding control to monitor HESC research. [11] For instance, the Dickey-Wicker Amendment in Clinton Administration prohibited federal funding on HESC research. During the Bush Administration, research using 64 existing stem cell lines was allowed to use federal funding. While in Obama Administration, the executive order which allowed federal funding for HESC research was ruled against the Dickey-Wicker Amendment in case *Sherley v Sebelius*.[12] The US approach is market-oriented. Although opponents have worried that the patent on HESC might lead to the opening of human embryo farms, from the economical perspective, the results of research should be patented. If the research is immoral, it should be prohibited from receiving funding. Disallowing immoral research at its initial stage both saves time and money. However, in the circustamce of lacking federal funding, private funding is still allowed in HESC research. Also, from an economic persepective, it is waste time, money, manpower and material resource to end some federal funding research that is already conducted, and use private funding to redo the aforesaid research.

Under the circumstances that moral exclusion is outside patent law, there is a question of whether immoral HESC research can be controlled. Through comparative analysis of Europe and US regulation, it is concluded that the moral exclusion in patent law and federal funding seem to be ineffective at controlling immoral research. In China, based on Article 5 of patent law and the Examination Guideline of State Intellectual Property Office of the P.R.C, the use of human embryos for industrial or commercial purposes is contrary to social morality therefore should be excluded from patenting. However, the main sources of HESC research funding are from the Chinese government, for example, the 973 program and the 863 program.[13] Many instances of risky

[10] Chapter Four.
[11] Chapter Four.
[12] Chapter Four.
[13] Chapter Three.

and unproven stem cell therapy have been carried out in hospitals, clinics and companies for commercial purposes. For instance, Shen Zhen Beike was renowned for their stem cell therapy.[14] Beike claimed to be one of the largest clinical application centers.[15] Pieces of immoral HESC research were carried out despite the moral exclusion in patent law. Therefore, it is urgently needed to find a better way to control HESC research in China.

7.2 A Best Way to control HESC Research in China: Regulate Research itself in a International Regime

7.2.1 Moral Exclusion should not be Regulated by the Patent Law

Based on comparative, historical and doctrinal analysis, this thesis argues that moral control should be outside patent law in the reconciliation of HESC regulation. In the context of HESC regulations, scant attention is paid to the moral exclusion in patenting HESC. Inventions related to HESC invention as a patentable subject matter are in considerable flux.[16] In most circumstances, morality and law do not coincide. However, moral obstacles are significant issues to inventions related to HESC research. Patent examiners inevitably encounter moral issues when examining applications related to HESC. Some consider the marriage of law and morality in this area to be in a hopelessly confused state.[17] As morality plays a more important role in patent law, we must ask whether it is reasonable to reject HESC invention on moral grounds. Therefore, to some extent, clarifying the ethical dimensions of patent law seems to be necessary.[18] It concludes that excluding HESC-related inventions from patentability based on moral provisions is not appropriate.

Compared with the EUROPE mode with the US mode, we could easily observe that the EUROPE patent regulations provide a moral opposition while in the US, such a clause does not exist. In the EUROPE, the research

[14] Chapter Three.
[15] Chapter Three
[16] Chapter Four, Chapter Five and Chapter Six.
[17] Chapter Five.

involving HESC could be eligible for funding under the Seventh Framework Programme. The EUROPE tradition of valued bioethics and cultural disputes has become routine. Whereas a strong moral opposition has arisen from the granted patent in US, patent law still outlaws the moral clause. It is observed that patent examiners focus on technical patentability criterions, while the courts focus on policy considerations such as scientific and technical innovation, economic development and competition.[19]

The Patent Office shall not play the role of moral censor and shall not reject to grant a patent based on ethical grounds. Because it is impossible for the patent law to accommodate such controversy issues since HESC technology is fast-developing. Moreover, society divided and confused towards HESC technology.[20] From another perspective, the morality clause in patent law aims to reduce the adverse impact of broad patents that might develop unbearable drugs and therapies.[21] But in terms of funds invested in the research, the reward of the patent seems to be overvalued. Since funds are allowed to be invested in HESC research, we should be clear that the moral concerns towards HESC research cannot be solved through prohibiting the patent. On the contrary, it is a waste that the results of funded research are not protected. Therefore, it is vitally important to understand that moral exclusion in the patent law cannot reduce immoral research.

No one can deny the intrinsic link between HESC and morality. We should effectively control and monitor this questionable technology. The problem is whether such control should be within the patent law system. The approach taken by the EUROPE and China is to insert moral provisions into their patent law to limit the patentability of inventions related to HESC, whereas the US has not. The US government's approach uses federal-funding control instead of patent control. Taken together the role of ethical provisions

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18 Chapter One.
19 Chapter Six.
20 Chapter Three, Chapter Four and Chapter Five.
21 Chapter Five

towards HESC in those areas, it is concluded that morality should play the role of initial filtering mechanism instead of fundamental regulatory.[22] Because even if the results of HESC research cannot be patented, HESC research could still be performed and funded. However, immoral research should be prohibited at the beginning instead of at the patent-application stage. In addition, although the EUROPE and China consider morality in granting patents, there is no direct moral standard, moral definition or defined meaning of industrial or commercial use, which inevitably results in legal inconsistency.

Morality is not a criterion that should be determinable by patent authorities. Even if the results of HESC research cannot be patented, HESC research could still be performed and funded. However, immoral research should be prohibited from the outset instead of at the patent-application stage. Moreover, from an economic point of view, restricting immoral research from the beginning could save a tremendous amount of time and money. In terms of funds invested into research, the reward of a patent seems to have been overvalued. A weak patent system without a moral clause would be more beneficial for moving HESC research forward. The Patent Office should not take on the responsibility of examining the morality of HESC inventions and it would be better to leave such decisions to the Ethics Committee. It is therefore the author's belief that it would be more economically viable to implement specific legal regulations applicable to HESC research than to include a general moral exclusion in the patent law.

It seems better to establish the specific authority to monitor HESC research pursuant to specific regulations before such research is conducted. Moreover, morality clauses in patent law aim to reduce the adverse impact of broad patents that might develop insupportable drugs and therapies. In terms of funds invested into such research, the reward represented by patent seems overvalued. Therefore, the author believes, a weak-patent system without a

[22] Chapter Five.

moral clause would be a critical step forward for HESC research. Infusing moral exclusions into patent law is both inefficient and ineffective.

7.2.2 China's Regulatory Approach on Stem Cell Research and Transfer: State Legislations is more Appropriate than Guideline

It is not an exaggeration to state that China is entering stem cell therapy more quickly and easily than many other countries. Catering to foreign patients, clinics and hospitals are increasingly offering stem cell therapies. Many patients, who are deemed incurable in the US, claim that they may be healed in Chinese hospitals.[23] Additionally, medical tourists are not restricted by the regulatory regimes of their home and receiving countries.[24] To explore stem cell therapy, scientists or clinics are operating in the dark in China because HESC policies are uncertain. Two extremes are practiced in stem cell research and therapy: on one hand, certain researchers insist on following the procedures and requirements for drug approval, and on the other hand, certain doctors and companies exaggerate the effects of stem cell therapy to treat patients.[25]

Should the Chinese Government Emphasis Their Legal Control over Stem Cell Research and Transfer?

Lacking a sound economic and scientific infrastructure, Chinese clinics are pioneering direct stem cell research transfer and immediate treatment of patients in need. Certain scholars argue that to collect clinic data, HESC research policy requires flexibility.[26] Alternatively, the clinic data could contribute to stem cell therapy development.[27] However, certain ethics scholars believe that strict regulations should be adopted to protect patient

[23] Sorapop Kiatpongsan and Douglas Sipp, 'Monitoring and regulating offshore stem cell clinics' (2009) 323 Science 1564-1565.
[24] Priscilla Song, 'The proliferation of stem cell therapies in post-mao China: problematizing ethical regulation' (2011) 30 New Genetics and Society 141.
[25] *Supra* note 100.
[26] Charles E Murdoch and Christopher Thomas Scott, 'Stem cell tourism and the power of hope' (2010) 10 the American Journal of Bioethics 16.
[27] Fiona Murray, 'Bit player or powerhouse? China and stem cell research' (2006) 355 New England

interests.[28]

The Chinese government proposed the Ethic Guideline for stem cell research in 2003. The guideline delineates certain prohibited areas of research including 'transfer a human embryo into the uterus after IVF, implant human blastocysts by SCNT into a human uterus and so on'.[29] However, there is no clause that relates to the qualification of research institutions or licensing, monitoring and supervising researchers. As a result, the balance between freedom and monitoring research was not reached.[30] Chinese scientists are free to make their own decisions and consult their own consciences.[31]

Thereafter, the question becomes whether the vague guideline could be used to monitor and supervise HESC research and clinic use compared with regulation? The answer is obvious in light of previous experience. Forbidden experiments have been conducted in renowned hospitals or research institutions over moral objections and safety concerns.[32] Furthermore, according to one report, 'it is the scientist themselves who have been the main initiators in setting up institutional review board, and who have personally facilitated or put efforts into the creation of written bioethics Guideline'.[33] Apparently, such researchers do not favour restricting stem cell research and transfer. Therefore, in my opinion, specific regulations on stem cell research by the government are necessary. The regulatory strategy of China should rely on state legislation, not Guideline.

What Aspect of Government Should Control Stem Cell Research and Transfer?

Journal of Medicine 1191.

[28] Brian Salter, 'Governing stem cell science in China and India: emerging economies and the global politics of innovation' (2008) 27 New Genetics and Society 145.

[29] The Ethical Guideline for HESC research, 2003.

[30] Qiu renzong and Qu Xiaomei, 'The overview and the future of stem cell related research and the ethical clinic use' (2009) 22 Chinese Medical Ethics 3.

[31] Brian Salter, 'China and the global stem cell bioeconomy: an emerging political strategy?' (2006) 1 Regenerative Medicine 671.

[32] Peter Glasner, 'Banking on immortality? Exploring the stem cell supply chain from embryo to therapeutic application' (2005) 53 Current SOCIOLOGY 355.

[33] Margaret Sleeboom Faulkner and Seyoung Hwang, 'Governance of stem cell research: public participation and decision making in China, Japan, South Korea and Taiwan' (2012) 42 Social Studies of Science 684.

Although China has accepted many international declarations, such as the Guideline on Ethics in Medical Genetics by the World Health Organisation[34], Universal Declaration on Human Rights and Biomedicine by the United Nation's Educational, Cultural and Scientific Organization[35], there is a large gap between the international requirements and domestic implementation in China. The ethical guideline for stem cell research from 2003, by analogy, introduces a wide gap between the phasing and implementation. To a certain extent, the Guideline lost political credibility because they were not properly implemented. Therefore, I believe implementation clauses are necessary for government control over stem cell research and transfer, for example, establishing a licensing system for HESC research. Without a license, institutions could not conduct HESC research. Penalties and fines for non-compliance is another example. For those that refuse to enforce the regulations, a relevant punishment should be in place to prevent repeat offenders. Likewise, such a regulation could require that the individual institution have ethical expertise in guiding such research.

Additionally, despite the stipulation that HESC research must be examined and approved by the ethics committee, the ethical Guideline from 2003 introduces no additional implementation clauses. How many people engage in HESC research and how many people are qualified for such research are unknown.[36] Even where research is examined and monitored by the ethics committee, the quality of the examination has no measure. Moreover, the majority of ethics committee members are scientists, not a variety of persons, including ethics advocates, patients, legal experts, doctors and scientists. Certain scientists on the ethics committee do not have a good grasp of ethics; therefore, the capacity of the ethics committee is not guaranteed. Thus, the ethics committee and relevant issues should be further articulated in detail

[34] Guideline on Ethics in Medical Genetics, reports by the World Health Organisation 1998.
[35] Universal Declaration on Human rights and Biomedicine, reports by the United Nation's Educational, Cultural And Scientific Organization 2005.
[36] Qiu renzong and Qu Xiaomei, 'The overview and the future of stem cell related research and the ethical clinic use' (2009) 22 Chinese Medical Ethics 3.

through the specific legislation.

Further, certain academics appreciate that the lack of effective management will eventually impede the research advancement.[37] In China, the ministry of health oversees medical institutions, not research institutions.[38] However, the majority of stem cell research funding has been from the Ministry of Science and Technology.[39] In practice, most researchers are scientists, not clinical doctors. However, clinical applications for stem cell research are examined and approved by the Ministry of Health. This system produces an obstacle in stem cell research management.[40] In particular, the Guideline from the Ministry of Health state that an applicant of clinic use is limited to the medical institution. While the embryonic stem cell transfer researches are preferably conducted by the enterprises and research institutions, stem cell research transfer is challenged by the relationship between hospitals, enterprises and research institutions.[41] Therefore, specific regulation should be provided to clarify such relationships as well as establish an effective and reasonable system for applying stem cell research transfer.

7.2.3 A International Reconciled Regime: Minimum Moral Standard for HESC Research

From above attempts situated in previous section, it is concluded that the practical mode for HESC regulation reconciliation is to provide minimum standards. The purpose of the reconciled regulation is to establish clear, efficient and reconciled standards on HESC research. The minimum standard should reflect on ethic and scientific standards instead of the controversial issues. Because I have argued that reconciled regulation should provide minimum standards in HESC research, here I argue that member states

[37] Supra note 100.
[38] The Ministry of Health of the People's Republic of China, <http://www.moh.gov.cn/> accessed 3 January 2013.
[39] The ministry of science and technology of the people's republic of China, <http://www.most.gov.cn/> accessed 3 January 2013.
[40] *Ibid.*

should reserve some discretionary power. The reconciled legislation would establish tangible limits at international level as well as declare the minimal values and interest of HESC. In response to the globalisation of HESC research, norm setting and international sanction should be provided by the reconciled legislation. Meanwhile, beyond the international board, the structured legislation should also include a micro scale that national ethic culture should be considered.

The minimal standards should cover the exporting and importing of HESC lines, the rules for procedure and arbitration, scientific standards for derivation, characterisation and evaluation of HESC, the principles for monitoring research finding. The minimum standard for protecting human embryo should also be provided, such as the prohibition of human cloning. It is worthy noting that since reconciled regulation aims to gain practical benefits, general theoretical controversial issues such as the status of embryo should not be necessarily agreed on the reconciled regulation.

In order to guarantee the morality of HESC research, the reconciled system should include the minimum standard for reviewing procedure. The option for international HESC regulation might be the strategy put in Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement set out the minimum standard of protection from member state, 'which allows members to provide more extensive protection of intellectual property if they wish', while retaining certain flexibility.[42] For example, the types of rights and protection, the minimum duration of rights and the methods of enforcement are designed in regulation.[43] However, member states are 'left free to determine the appropriate method of implementing the provisions of Agreement within their own legal system and practice'.[44]

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[41] *Ibid.*

[42] The World Trade Organisation <http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 2 December 2013.

[43] *ibid.*

[44] *ibid.*

In terms of patenting HESC inventions, the successful patenting system needs to be flexible and adaptable to the developing biotechnology. As Charles F Hall pointed out, 'without a flexible patent system that is free from the shackles of a statutory moral utility doctrine, science and technology may be unnecessarily stunted'.[45] It is better to let the individual nation decide whether inventions related HESC could be granted patents or denied. However, the reconciled regulation might facilitate the harmonised administration of patent applications. Generally speaking, a uniform set of principles for HESC related patent applications are established in the reconciled regulation, which will not hinder the biotechnology progress.

Accordingly, the minimum standard imposed on the reconciled regulation must be reasonable and avoid any unintentionally enlargement, exaggeration, devaluation and underplay of the moral protection of HESC. For example, with respect to the moral status of human embryo, a universal standard might be too restrictive for some countries.[46] Because there are many different opinions in this issue, it is inappropriate to impose one will. However, as to the reproductive cloning that is universally rejected, it could set a clear prohibition in reconciled regulation. In the case that the prohibition setting is problematic, the reconciled regulation should focus on distinguishing the unacceptable research from acceptable research.

7.2.4 The United Nation (UN) is an Appropriate Platform for International HESC Regulation

In 2005, the UN has already launched the UN Declaration on Human Cloning by the UN General Assembly.[47] Reproductive cloning was banned by this international Declaration. However, regarding HESC regulations, more

[45] Charles F Hall, 'The lessons stem cells provide Vis-à-vis Patents: working towards an international/Universal Patent regime' (2004) bepress legal series 278.
[46] Angela Campbell and Gillian Nycum, 'harmonizing the international regulation of Embryonic Stem Cell Research: Possibilities, Promises and Potnetial Pitfalls' (2005) 7 Medical Law International 113.
[47] The UN Declaration on Human Cloning, <http://www.un.org/law/cloning/> accessed 2 December 2013.

relevant fields need to be ruled, such as stem cell therapy, human-animal chimeras. The UN planned to fulfill these following tasks that are supported by most countries of the convention.[48] Due to the rifts in detailed rules between different groups, these tasks are not yet finished. Some scholars commented that 'it is very difficult, if not impossible, for the world to agree on any issue involving research on human embryos, at least without the active support and leadership of the us'.[49] But some academics conveyed 'the UN, as a political entity, is an inappropriate place for decision-making related to the ethics of science and biomedicine'.[50]

The UN could bear to reconciling HESC regulation at international level. In fact, it is undoubted that the UN had played a pioneering role in legislating such international treaty.[51] Although the prior work seems to be not fruitful, the UN might still be the best place for addressing this issue. The UN could initially commit on a draft of the proposed regulation that then is amended by the member states.

According to some academics' theory, there are several models for international reconciliation[52]: a) Minimum standards are to 'set a regulatory floor below which no jurisdiction can go'.[53] This model ensures that all countries require at least a baseline level protection. b) Multitier standards allow 'parties to a multilateral agreement to adopt different standards for economies of different strengths'.[54] c) Converging standards are designed to 'essentially take the mean of the high and low standards and make that the

[48] Rosario M Isasi and George J Annas, 'Arbitrage, Bioethics and Cloning: The ABCs of Gestating a United Nations Cloning Convention' (2003) 35 Case W. Res. Journal International Law 414.
[49] *ibid*.
[50] Angela Campbell and Gillian Nycum, 'Harmonizing the international regulation of embryonic stem cell research: possibilities, promises and potential pitfalls' (2005) 7 Medical Law International 113.
[51] Piotr Rewerski, 'the need for a new US stem cell research policy: a comparative look at international stem cell research laws' (2007) III Journal of Law, Technology & Policy 415.
[52] Daniel C Esty and Damien Geradin, 'Market access, Competitiveness, and harmonization: environmental protection in regional trade agreements' (1997) 21 Harvard Environmental Law Review 265; see also Margaret Renee Herman, 'Are we learning from the mistakes of environmentalists? The application of environmental harmonization models to the automotive industry' (1999) 16 Arizona Journal of International and Comparative Law 544.
[53] *ibid*.
[54] *ibid*.

new standard'.[55] Convergence standards seem to be the most realistic approach since it considers the existing circumstance rather than merely assuming. d) Goal reconciliation does not 'delineate specific standards and regulatory measures. Instead, goal harmonisation looks less at the specific means and only standardizes the ends'.[56] The goal reconciliation approach is extremely flexible and has little enforcement as it lacks specified standards. f) System reconciliation requires that 'certain protocols [be] adopted without requiring uniformity of all substantive requirements'.[57] This approach is administratively efficient since the processes are reconciled rather than the results.

Among the variety of identified reconciliation approaches, the minimum standards strategy seems to be more proper than any other approaches. The minimum standards approach is the most effective way to ensure that HESC research are morally conducted. Other approaches might be too flexible for the member states to adapt the regulations. The detailed rules that are not limited the core standards of reconciled regulation could be developed in nations. Moreover, as Catherine Waldby and Brian Salter observed, 'stem cell lines are inherently prone to artifactual distortions and contaminations'.[58] Therefore, the minimum standard is significant for the stability and credibility of scientific progress.

7.2.5 An Established Framework of Human Rights is the Mainstay of a Reconciled International Policy

In the international regulatory scheme, the possibility of implementing HESC policy should be philosophically formalised in line with the Principle of Generic Consistency. According to Alan Gewirth, morality should consider

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55 *ibid.*
56 *ibid.*
57 *ibid.*
58 Catherine Waldby and Brian Salter, 'Global Governance in HESC Science' (2008) 2 studies in Ethics, law and Technology 1-23.

whose interest and which interest are worth protecting.[59] It requires that 'act in accord with the generic rights of your recipients as well as of yourself'.[60] In other words, the Principle of Generic Consistency demands that 'all prospective purposive agents be granted rights to the generic features of action'.[61] In addition, 'the fundamental principles of political science can be established within the framework of the Principle of Generic Consistency without inconsistency or contradiction'.[62] Therefore, the Principle of Generic Consistency is construed as the foundation for human right.

In international policies, human right is an important instrument to protect human being and promote the equality in the world. Human right has supreme importance in HESC regulation since HESC researches are related to moral dilemma. Some philosophers argued that human right is the *prima facie* right in the international law.[63] It is observed that 'human rights have been used as a tool against systematic and brutal regimes that are a threat to world peace and stability, or guilty of domestic violations; through them, state conduct and internal affairs can be monitored, condemned and influenced'.[64] Since different countries might not accord the equal significance to human rights, the international policies should direct attention to the enforcement of human right clause.

7.2.6 Establish the Authority to Monitor the Reproductive Treatment and Research

Despite of the reconciled regulation, it should facilitate a central enforcement

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[59] Gewirth Alan, *Reason and Morality* (University of Chicago Press, Chicago 1981) 131.
[60] *ibid*.
[61] Catarina Rodrigues, 'Who's the patient? Ethics in and around maternal-fetal surgery' (Ipskamp Drukkers, Enschede 2012) 62.
[62] Robert A Montana, 'the Gewirthian Principle of Generic Consistency as a Foundation for Human Fulfillment: unveiling a Rational Path for Moral and Political Hope' (2009) 3 Kritike 24 <http://www.kritike.org/journal/issue_5/montana_june2009.pdf> accessed1 December 2013.
[63] Gewirth A, *self-fulfillment* (Princeton University Press, Princeton 1998); see also Beyleveld D, 'the concept of a human rights and incorporation of the European Convention on Human rights' (1995) Public Law Winter 577.
[64] Benjamin J Capps, UK and European Policy in Stem Cell Research: Proposals for the Ethical Grounding of future regulation, Ph.D. dissertation, University of Bristol (2003).

system. The structured enforcement system could be monitored to ensure compliance with reconciled regulation. The Authority established in the international level could overlook the uniform requirements. Through the available literature, the central Authority could be an *ad hoc* committee that consists in a number of other groups.[65] These groups might be the permanent national ethic advisory institutions. They could link each other and should be blindly contacted. In other words, the final say right is retained in the Authority rather than the each country.

Furthermore, the central Authority could secure the legitimacy of standards. Considering the poor implementation of international regulation, the legitimacy of standards is difficult to achieve. The reason for this might be in lack of local consideration since international standards are made to ensure objectivity and equity in international regulation. [66] Thus, procedural legitimacy is significant to assure the inclusive regulations. The central Authority takes responsibility for developing unified or compatible relevant standards in order to let these international rules accepted at the national level. The central Authority might also be in charge of authorising HESC researches.

In order to assure the justice, open and fair decisions made by the central Authority, it should be consisted of diverse cross-section members. Any countries where HESC research is carried out should have presenters in the central Authority. The presenters could be citizens affected by HESC research. The committee of central Authority should include experts from philosophic, legal, ethical and scientific areas. Theoretically, the central Authority serves all citizens of the nations in the world. Therefore, it is important that citizens have relevant ways to express their opinions. Members of committee in central Authority should be performed in rotation so as to guarantee the fresh of the committee.

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[65] Angela Campbell and Gillian Nycum, 'Harmonizing the international regulation of embryonic stem

Many countries established their own national governance organisations, such as the UK Stem Cell Bank (UKSCB).[67]As HESC researches are morally concerned, setting a central stem cell bank to oversight them seems to be indispensable. The central stem cell bank is in charge of protecting HESC lines, licensing HESC researches and monitoring HESC purity and use. Depositing HESC line in central stem cell bank might be the basis of obtaining the research license. The central stem cell bank is affiliated to the Authority. The Authority might oversee the running of central stem cell bank. And only research within the scope of the reconciled regulation could be allowed in member states. Like UK stem cell bank, stem cells lines could be classified as "research grade" and "clinical grade". [68] However, the ownership of intellectual property rights still belongs to the originator.[69]

In the light of all relevant circumstances, the central stem cell bank is a key institution in standardisation of the scientific process and the market process at international level. Laboratory standards and bioethical standards for HESC that are disparate among national legislation system could become comparatively consensual. The central stem cell bank provides a platform for assessing, storing and disseminating the research finding in the worldwide. The collection and use of HESC could also be uniform and standardised to meet the minimum protection under the reconciled regulation.

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cell research: possibilities, promises and potential pitfalls' (2005) 7 Medical Law International 113.

66 *ibid*.

67 See, for example, the US stem cell bank (USCB), Swiss stem cell bank (SSCB), Jeevan stem cell Bank (JSCB)

68 UK stem cell bank steering committee, Code of Practice for the UK stem cell bank (2010) <http://www.ukstemcellbank.org.uk/pdf/Code_of_Practice_for_the_Use_of_Human_Stem_Cell_Lines_(2010).pdf > accessed 12 December 2013.

69 *ibid*.

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