

# Contents

<b>1 Stem Cell Tourism Phenomenon in China: An Introduction</b> . . . . .	1
1.1 Reasons for Stem Cell Tourism Phenomenon . . . . .	1
1.1.1 Values of Human Embryonic Stem Cell (HESC) Research . . . . .	1
1.1.2 Inconsistency HESC Related Regulations Across Jurisdictions Leads to Stem Cell Tourism in China . . . . .	3
1.1.3 TRIPS Agreement Cannot Assure Symmetrical Coherence Between Moral Provision Within Patent Law and Moral Provision Outside Patent Law . . . . .	6
1.1.4 Inadequate Regulation of HESC Research in China . . . . .	7
1.2 Purpose and Focus of the Book. . . . .	7
1.3 Conceptual Framework. . . . .	11
1.4 The Framework of the Book. . . . .	17
<b>2 The Legal Framework of Stem Cell Science and Medicine in China: An Overview</b> . . . . .	19
2.1 HESC Research Environment in China. . . . .	20
2.1.1 HESC Research Funding in China. . . . .	21
2.1.2 HESC Industry in China . . . . .	22
2.2 The Legal Framework of HESC Research in China . . . . .	23
2.2.1 The Patent Law of China and Its Guideline for Patent Examination . . . . .	24
2.2.2 The Ethical Guideline for HESC Research . . . . .	25
2.3 Case Studies . . . . .	27
2.3.1 Whether Article 5 of the Patent Law Excludes Inventions Related to HESC?. . . . .	27
2.3.2 Whether Adult Stem Cell Has the Practical Applicability Under Article 22 of Patent Law?. . . . .	31
2.4 Conclusion . . . . .	33

- 3 The Moral Dilemma of Stem Cell Science and Medicine . . . . . 35**
  - 3.1 Overview of Moral Issues on HESC Research. . . . . 36
    - 3.1.1 Human Dignity and the Rights of Human Embryo . . . . . 38
    - 3.1.2 Create Embryos for Research . . . . . 39
    - 3.1.3 Moral Issues in Embryo Donation . . . . . 40
  - 3.2 The Moral Status of Human Embryo . . . . . 41
    - 3.2.1 Human Embryos Are Individual Human Beings . . . . . 41
    - 3.2.2 Human Embryos Are Human Beings, but They Are not Human Persons. . . . . 45
    - 3.2.3 Human Embryos Are not Human Beings . . . . . 48
  - 3.3 What Is the Moral Source of Human Embryos: Use the Discard Human Embryos or Create Human Embryos for Research?. . . . . 51
    - 3.3.1 Use the Spare Human Embryos from IVF . . . . . 51
    - 3.3.2 Create Human Embryos for Research . . . . . 54
  - 3.4 Will Therapeutic Cloning Use Lead to Reproductive Cloning Use? . . . . . 56
    - 3.4.1 Will Therapeutic Cloning Use Turn to Commercial Use? . . . . . 56
    - 3.4.2 Will the Distinction Between Therapeutic Cloning Use and Reproductive Cloning Use Be Impossible to Police?. . . . . 58
  - 3.5 Whether Adult Stem Cell Could Be Fully Used as an Alternate to Embryonic Stem Cell? . . . . . 59
    - 3.5.1 Adult Stem Cell Can Be Fully Used as an Alternate to Embryonic Stem Cell. . . . . 60
    - 3.5.2 Adult Stem Cell Cannot Be Fully Used as Alternate Embryonic Stem Cell. . . . . 60
  - 3.6 Conclusion . . . . . 61
- 4 Stem Cells, Patents and Regulation in China: Inadequacy . . . . . 63**
  - 4.1 The Critical Issues of First Administration Measure on Clinical Stem Cell Research 2015 . . . . . 64
    - 4.1.1 Clarifying the Qualifications of Institution Conducting Clinical Stem Cell Research . . . . . 65
    - 4.1.2 Establishing the Initial Review, Record Filing Mechanism, and the Research Project Reporting System . . . . . 66
    - 4.1.3 Reporting the Unsafe Event in Clinical Stem Cell Research . . . . . 66
  - 4.2 The First Administrative Measure Cannot Effectively Control Stem Cell Therapy in China . . . . . 67
    - 4.2.1 Lacking Liability Clause . . . . . 67
    - 4.2.2 Lacking Traceability System. . . . . 68
    - 4.2.3 Lacking Expert Responsible Authorities. . . . . 69
    - 4.2.4 Non-applicable to Military Hospital. . . . . 69

- 4.3 Can Stem Cell Therapy Be Used in Patient Before Clinic Testing? . . . . . 70
  - 4.3.1 From the Bench to Bedside: Stem Cell Therapy Should not Be Used in Patient Before Clinic Trials . . . . . 70
  - 4.3.2 From the Bedside to the Bench: Stem Cell Therapy Should Be Used in Patient Before Clinic Trials. . . . . 71
- 4.4 Moral Exclusion In or Out Patent Law? . . . . . 72
  - 4.4.1 Low Moral Status of Human Embryo in Practical Application . . . . . 73
  - 4.4.2 High Moral Status of the Human Embryo in Patent Law . . . . . 74
  - 4.4.3 Whether the Moral Exclusion Is Proper in China’s Patent Law? . . . . . 75
- 4.5 Conclusion . . . . . 76
- 5 Stem Cells, Patents and Policy in the US: Inefficiency . . . . . 77**
  - 5.1 The Political Background of HESC Regulation . . . . . 77
  - 5.2 “First Patent, then Questioned”—The Approach of Patentability of Research Involving HESC Research Under Moral Concerns. . . . . 79
    - 5.2.1 “Bayh-Dole Model” in HESC Research-Allow Universities to Patent on Research by Federal Funding . . . . . 80
    - 5.2.2 Patent on Embryo: The Opening of “Human Embryo Farms”. . . . . 82
    - 5.2.3 HESC Patents Challenges: From Technical Criterion to Moral Concerns . . . . . 83
    - 5.2.4 Stem Cell Patent: Impediment or not? . . . . . 86
    - 5.2.5 The Public’s “Right to Know” Right . . . . . 87
  - 5.3 Political Interventions the Federal Funding Control of HESC Research Under Moral Concerns . . . . . 88
    - 5.3.1 The National Institutes of Health Revitalization Act: Allow Federal Funding of Research Related to Embryos at the Early Stage . . . . . 90
    - 5.3.2 Dickey-Wicker Amendment: No Federal Funding on HESC Research Involving Destruction Embryo . . . . . 91
    - 5.3.3 NIH Guideline 2000 . . . . . 93
    - 5.3.4 The Bush Compromise: Accepted the Narrow Explanation of Dickey-Wicker Amendment but Exercised the Executive Power Instead of Legal Power to Allocate Funding. . . . . 94
    - 5.3.5 The Report from President Council on Bioethics Clarified that the Enforcement Law Was Dickey Amendment . . . . . 95
    - 5.3.6 Executive Order by President Obama: Reverse the Bush Policy . . . . . 96

- 5.3.7 The Result of Battle Over the Dickey-Wicker Amendment: The Funding Policy of HESC Research by Obama Administration Could Go Ahead . . . . . 98
- 5.4 Conflict Between Federal Law and State Law . . . . . 99
  - 5.4.1 Proposition 71 in California: Success or Failure?. . . . . 100
  - 5.4.2 Other States . . . . . 106
  - 5.4.3 The Interstate Alliance on Stem Cell Research (IASCR): A Venue for the States to Cooperate . . . . . 106
  - 5.4.4 Conflicts Between the Federal and State Regulation. . . . . 107
- 5.5 Conclusion . . . . . 108
- 6 Stem Cells, Patents and Morality in the EU: Inconsistency . . . . . 111**
  - 6.1 The Legal Framework of HESC Research in the EUROPE. . . . . 113
    - 6.1.1 Moral Criterion of the European Patent Convention (EPC) . . . . . 115
    - 6.1.2 The Directive 98/44/EC Excludes “Uses Human Embryos for Industrial or Commercial Purpose” from Patenting . . . . . 116
    - 6.1.3 The European Group on Ethics in Science and New Technologies (EGE) Supply Authoritative Opinions to Legislation . . . . . 118
  - 6.2 Cases Studies . . . . . 120
    - 6.2.1 How to Assess the Morality? . . . . . 120
    - 6.2.2 Whether HESC Should Be Included in “Human Embryo”? What Is the Scope of “Industrial or Commercial Use”? . . . . . 125
  - 6.3 Regulatory Approaches of National Jurisdiction in HESC Research in EUROPE . . . . . 133
    - 6.3.1 Permissive Policy: UK Approach . . . . . 134
    - 6.3.2 Prohibition Policy: German Approach . . . . . 139
    - 6.3.3 Intermediate Approach: Netherland Policy . . . . . 144
  - 6.4 Lessons from EUROPE HESC Regulation Reconciliation. . . . . 145
    - 6.4.1 Unitary Substantive Patent Law in the EUROPE: Considerable Freedom Still Given to National Legislations . . . . . 146
    - 6.4.2 The Biotechnology Directive—A Giant Step Towards Harmonising the European Patent Law on Biotechnology . . . . . 150
    - 6.4.3 No Uniform Moral Definition and Legal Status of Human Embryo . . . . . 155
    - 6.4.4 Uniform Concept of Human Embryo and Ban on Patenting Inventions that Involve the Destruction of Human Embryos. . . . . 157

- 6.4.5 The Attempt of Infusing Moral Control with the Patent Regulation . . . . . 159
- 6.4.6 Space for Flexibility on the Basis of Minimum Standards: Let States Decide Moral Provisions Instead of a Universal Moral Standard Due to Culture Difference . . . . . 161
- 6.5 Conclusion . . . . . 161
- 7 Proposal for Controlling Stem Cell Science and Medicine in China: Internationalism . . . . . 163**
  - 7.1 The Comparative Analysis of HESC Regulations in the US and the EUROPE . . . . . 164
  - 7.2 A Better Way to Control HESC Research in China: Regulate Research Itself in a International Regime . . . . . 166
    - 7.2.1 Moral Exclusion Should not Be Regulated by the Patent Law. . . . . 166
    - 7.2.2 China’s Regulatory Approach on Stem Cell Research and Transfer: State Legislations is More Appropriate than Guideline. . . . . 167
    - 7.2.3 A International Reconciled Regime: Minimum Moral Standard for HESC Research . . . . . 170
    - 7.2.4 The United Nation (UN) is an Appropriate Platform for International HESC Regulation . . . . . 172
    - 7.2.5 An Established Framework of Human Rights is the Mainstay of a Reconciled International Policy . . . . . 173
    - 7.2.6 Establish the Authority to Monitor the Reproductive Treatment and Research. . . . . 174
  - 7.3 How Does International Agreement Push China to Regulate and Supervise Stem Cell Therapy?. . . . . 175
    - 7.3.1 Controlling the Increased Demands . . . . . 176
    - 7.3.2 Introducing New Rigorous Regulations . . . . . 176
    - 7.3.3 Creating a Watch List . . . . . 176
    - 7.3.4 Setting a Dispute Resolution Process . . . . . 177
  - 7.4 Conclusion . . . . . 177
- Bibliography. . . . . 179**



<http://www.springer.com/978-981-10-2100-8>

Regulating Human Embryonic Stem Cell in China  
A Comparative Study on Human Embryonic Stem Cell's  
Patentability and Morality in US and EU

Jiang, L.

2016, XVIII, 200 p. 2 illus., Hardcover

ISBN: 978-981-10-2100-8