IPRs for Agricultural Biotechnological Inventions: A Case of Malaysia

Patent and Plant Variety Rights for Agricultural Biotechnology
Suzi Fadhilah Ismail

IPRs for Agricultural Biotechnological Inventions: A Case of Malaysia

Patent and Plant Variety Rights for Agricultural Biotechnology

LAP LAMBERT Academic Publishing
Acknowledgement

I owe a great many thanks to a great many people who helped and supported me during the writing of this thesis. First and foremost, my utmost gratitude to my supervisors, Prof. Paul Torremans and Prof. Dr. Ida Madieha Abd Ghani Azmi, whose sincerity and encouragement I will never forget. Prof. Paul Torremans, my principal supervisor, has been guiding me during all phases of this research. I am also indebted to my co-supervisor, Prof. Dr. Ida Madieha Abdul Ghani Azmi for the valuable guidance and constant advice. She has been my inspiration as I hurdle all the obstacles in the completion this research work particularly during semi-structured interviews and data collection for chapters on Malaysian biotechnology.

Thanks and appreciation to the helpful people at various research institutions in Malaysia (MARDI, FRIM, MPOB, MRB, MCB) for their support and co-operation during the interview sessions. Particular thanks are due to officials at Biotech Corp, MyIPO, MOSTI and DOA for the assistance in data collection relating to patents and plant breeders’ rights in Malaysia. I would also thank my faculty members, both in the University of Nottingham and International Islamic University Malaysia, for their support and encouragement throughout the study.

An honourable mention goes to my beloved parents and family for their care, support and strength along the way. I would like to express a sense of gratitude to my husband, Mr. Ronisham Mamat for his unending love, support, understanding and patience throughout my study. Last but not least, my deepest thanks and regards to my beloved late father, Mr Ismail Awang Besar, who supported me in any respect and built a strong foundation on me. Indeed, he has a place of honour, deep within my heart.
## Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBD</td>
<td>Convention of Biodiversity</td>
</tr>
<tr>
<td>DNA</td>
<td>Deoxyribonucleic Acid</td>
</tr>
<tr>
<td>DOA</td>
<td>Department of Agriculture</td>
</tr>
<tr>
<td>DUS</td>
<td>Distinct Uniform and Stable</td>
</tr>
<tr>
<td>EPC</td>
<td>European Patent Convention</td>
</tr>
<tr>
<td>EPO</td>
<td>European Patent Office</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FRIM</td>
<td>Forest Research Institute of Malaysia</td>
</tr>
<tr>
<td>MARDI</td>
<td>Malaysian Agricultural Research and Development Institute</td>
</tr>
<tr>
<td>MCB</td>
<td>Malaysian Cocoa Board</td>
</tr>
<tr>
<td>MPOB</td>
<td>Malaysia Palm Oil Board</td>
</tr>
<tr>
<td>MRB</td>
<td>Malaysian Rubber Board</td>
</tr>
<tr>
<td>MyIPO</td>
<td>Malaysian Intellectual Property Office</td>
</tr>
<tr>
<td>PBR</td>
<td>Plant Breeders' Right</td>
</tr>
<tr>
<td>PCT</td>
<td>Patent Cooperation Treaty</td>
</tr>
<tr>
<td>PLT</td>
<td>Patent Law Treaty</td>
</tr>
<tr>
<td>PPA</td>
<td>Plant Protection Act</td>
</tr>
<tr>
<td>PVP</td>
<td>plant variety protection</td>
</tr>
<tr>
<td>PVPA</td>
<td>Plant Varieties Protection Act</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
</tr>
<tr>
<td>RI</td>
<td>Research Institute</td>
</tr>
<tr>
<td>TRIPS</td>
<td>Trade Related Aspects of Intellectual Property Rights</td>
</tr>
<tr>
<td>UPA</td>
<td>Utility Patent Act</td>
</tr>
<tr>
<td>UPOV</td>
<td>International Convention for the Protection of New Varieties of Plants</td>
</tr>
<tr>
<td>USPTO</td>
<td>United States of Patent and Trademark Office</td>
</tr>
<tr>
<td>WIPO</td>
<td>World Intellectual Property Organization</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organization</td>
</tr>
</tbody>
</table>
# Table of Contents

Acknowledgements ........................................................................................................ iii

Abbreviations and Acronyms ........................................................................................ iv

Table of contents ............................................................................................................. v

Chapter 1: Introduction ...................................................................................................... 1

1.1 Agricultural Biotechnology: An overview of current development .................... 1

1.1.1 Biotechnology in general .................................................................................... 1

1.1.2 Plant biotechnology ............................................................................................ 2

1.1.3 Legal mechanism: Protection via patent and plant variety rights ....................... 3

1.1.4 Global IPR regime ............................................................................................... 5

1.2 Scope of study ........................................................................................................... 7

1.2.1 Research questions ............................................................................................. 7

1.3 Methodology ............................................................................................................ 8

1.4 Division of chapters .................................................................................................. 9

(i) Chapter 1 .............................................................................................................. 9

(ii) Chapter 2 ............................................................................................................. 10

(iii) Chapter 3 .......................................................................................................... 13

(iv) Chapter 4 .......................................................................................................... 14

(v) Chapter 5 .......................................................................................................... 15

(vi) Chapter 6 .......................................................................................................... 15

(vii) Chapter 7 ......................................................................................................... 16

1.5 Defining the Terminology ....................................................................................... 17

(i) Agriculture .......................................................................................................... 18

(ii) Biological process, microbiological process ....................................................... 19

(iii) Genetic engineering ........................................................................................... 23

(iv) Invention (as opposed to discovery) .................................................................... 24

(v) Patent .................................................................................................................. 26

(vi) Utility models for innovation .............................................................................. 29

(vii) Plant, plant variety, crops, seed ........................................................................ 31

(viii) Plant variety rights, plant breeders' rights, farmers' rights ............................... 35

(viii) Sui generis protection ....................................................................................... 40

1.6 Conclusion & Contribution ..................................................................................... 42
Chapter 2: The International and European Legal Background

2.1 Background

2.2 The Paris Convention on the Protection of Industrial Property

2.2.1 The origin and background

2.2.2 The relevant provisions

2.2.3 The implementation

2.2.4 The significance

2.3 The Role of the World Intellectual Property Organization (WIPO)

2.3.1 Background

2.3.2 Administration of national treaties

(i) Patent Co-operation Treaty (PCT)

(ii) Patent Law Treaty (PLT)

2.3.3 Recent development

2.4 The International Convention for the Protection of New Plant Varieties (UPOV)

2.4.1 Background

2.4.2 Purpose of adoption

2.4.3 Criteria for a plant breeder’s rights

2.4.4 Definition of ‘plant variety’

2.4.5 Definition of ‘breeder’

2.4.6 The issue of ‘dual protection’

2.4.7 Limitation of rights

(i) Research exemption

(ii) Insertion of the term ‘essentially derived variety’

(iii) Farmer’s privilege

2.4.8 UPOV revision

2.4.8.1 Comparison of UPOV 1978 Act and UPOV 1991 Act

(i) Number of protected varieties

(ii) Expansion of the exclusive rights

2.4.9 Expansion of UPOV

2.4.9.1 UPOV Impact Study

2.4.9.2 Resistance to the 1991 Act

2.5 Trade-Related Aspects of Intellectual Property Rights (TRIPS)

2.5.1 Background

2.5.2 Patentable subject matter under TRIPS

2.5.3 Sui generis concept

2.5.4 Review of Article 27(3)(b) TRIPS Agreement
Chapter 2: Intellectual Property Rights Protection

2.5.5 Important role of TRIPS .......................................................... 86
2.6 The co-existence of UPOV and TRIPS in protecting plant-related inventions ......................................................... 86
2.7 The European Patent Laws ....................................................... 92
   2.7.1 European Patent Convention (EPC) ...................................... 92
      2.7.1.1 Background .................................................................. 92
      2.7.1.2 Important provisions of EPC .......................................... 94
   2.7.2 The Biotechnology Directive (the Directive 98/44) ................. 100
      2.7.2.1 Background .................................................................. 100
      2.7.2.2 Relevant provisions ...................................................... 102
   2.7.3 Some recent developments .................................................. 106
2.8 Patenable Subject Matter: The EPO’s Case Law....................... 107
   (i) Ciba-Geigy/Propagating Material (Case T-49/83) ..................... 108
   (ii) Lubrizol/Hybrid Plants (Case T-320/87) ................................. 111
   (iii) Plant Genetic Systems (Case T-356/93) ................................. 114
   (iv) Novartis/Transgenic Plant (Case G01/98) .............................. 120
   (v) Plant Bioscience Limited (Case T83/05) ................................. 135
   (vi) Monsanto Canada Inc. v Schmeiser ...................................... 138
2.9 Patentability of transgenic plant in Europe: the current position ... 147
2.10 The interface between patent and plant variety protection ...... 150
   2.10.1 Patent system provides a better protection for agricultural biotechnology inventions ............................................. 159
2.11 Conclusion & Contribution ...................................................... 162

3.1 Introduction .............................................................................. 163
3.2 Brief History and Background of U.S. Statutory Laws for Agricultural Biotechnological Inventions .................................. 165
3.3 Current IPR legislation in the U.S. ............................................ 170
   3.3.1 The PPA ........................................................................... 170
   3.3.2 The PVP Certificates ......................................................... 174
   3.3.3 Utility Patents (UPA) ........................................................... 177
   3.3.4 The issue of joint protection .............................................. 182
   3.3.5 How Utility Patents and PVP differ, and Why One Would Be Preferable ................................................................. 190
3.4 Development of the Legal Protection For Agricultural Biotechnological Inventions ......................................................... 196
   3.4.1 Case-law ........................................................................... 197
3.4.1.1 The significance of the case-law in shaping the current position of laws on plant patents in the U.S. ........................................ 214

3.4.2 Some Controversies over Plant Patents in the U.S. .................. 216

3.4.3 Recent development in plant biotechnology and possible effects on the U.S. current laws on plant-related inventions .................. 219

3.5 Comparison of the U.S. and European approaches ...................... 221

3.6 How relevant is the U.S. system to Malaysian IP laws on agricultural biotechnological inventions ........................................ 225

3.7 Conclusion & Contribution ................................................ 229

Chapter 4: Malaysian Agricultural Biotechnology: An Outlook on Recent Developments, Regulatory Framework and Impediments .................................................. 232

4.1 Introduction ........................................................................ 232

4.2 The National Biotechnology Policy ..................................... 234

4.2.1 BioNexus Status ......................................................... 237

4.3 Legal and Regulatory Framework ....................................... 240

4.3.1 The International Treaties ............................................. 240

4.3.2 IP protection for agricultural biotechnological inventions in Malaysia: Patent and PVP ........................................ 243

4.3.2.1 Patents Act 1983 .................................................. 244

(i) Patent Registration Process ........................................... 245

(ii) Scope of Patentability .................................................. 247

(iii) Patenting Activities in Malaysia .................................... 249

(iv) Patent Registration Procedure ...................................... 253

(v) Patent Classification ..................................................... 255

4.3.2.2 Protection of New Plant Varieties Act 2004 .................... 257

(i) Salient Features of the Protection of New Plant Varieties Act 2004 .......................................................... 260

(a) Threshold of registrability ............................................ 260

(b) Essentially derived varieties ......................................... 261

(c) Limitation of Breeder's rights ........................................ 262
(d) Farmers’ Privilege ................................................................. 263
(e) Traditional Variety ............................................................... 265
(f) Process of Application ........................................................ 266

(ii) The implementation of the Protection of New Plant Varieties Act 2004 ................................................................. 269

(iii) Towards UPOV accession ..................................................... 273

4.4 The Impediments to the Success of Biotechnology ................. 278
(i) Weak scientific critical mass ................................................... 279
(ii) Linkages between the biotechnology industry and the R&D ...... 280
(iii) Time factor in patent application ........................................... 281
(iv) Vagueness in the interpretation of some patent provisions ..... 281
   (a) Lack of clarity in determining the exclusion from patentability
   .................................................................................................. 282
   (b) Problems in ascertaining ‘inventive step’ ......................... 283
   (c) Problems in determining ‘industrial application’ .......... 284
   (v) Issue on commercialization ................................................. 285
   (vi) Low percentage of global players .................................. 286

4.4.1 Some efforts in tackling the impediments ......................... 287

4.5 Conclusion & Contribution .................................................... 288

Chapter 5: The Views of Malaysian Plant Breeder ....................... 290
5.1 Introduction ........................................................................... 291
5.2 Brief background of the research institutes and agencies ...... 291
   5.2.1 MARDI ................................................................. 292
   5.2.2 FRIM ................................................................. 293
   5.2.3 MPOB ................................................................. 293
   5.2.4 MRB ................................................................. 294
   5.2.5 MCB ................................................................. 295
   5.2.6 BiotechCorp ......................................................... 296
   5.2.7 MOSTI ............................................................... 296
   5.2.8 Crop Quality Control Division, Department of Agriculture .. 297
   5.2.9 Patent Division, MyIPO ............................................. 298

5.3 Assessing the Views of Malaysian Plant Breeders ............... 298
   5.3.1 Biotechnology research activities: The current status and focus
   ............................................................................................. 298
   5.3.2 The significance of agricultural biotechnology R&D activities .. 301
   5.3.3 Patenting Activities ..................................................... 304
   5.3.4 Issues on Patents ......................................................... 309

VII
5.3.4.1 Problems in Patents Application ........................................ 309
5.3.4.2 Patents in Agricultural Biotechnology ................................. 310
5.3.5 Plant Variety Protection: An Alternative ................................ 312
5.3.5.1 Issues on patenting of new plant variety ............................ 314
5.4 Patent Law versus Plant Breeder's Rights .................................. 319
5.5 Commercialization of agricultural biotechnological inventions in Malaysia: Issues and Challenges .................................................. 322
5.6 Conclusion & Contribution ....................................................... 327

Chapter 6: Towards A Better Intellectual Property Legal System in Malaysia: A Proposed IPR Model ......................................................... 329
6.1 Introduction .............................................................................. 329
6.2 Background ............................................................................ 330
6.2.1 Overview of current IPR legislation in Malaysia ....................... 330
6.2.2 Agricultural Biotechnology Research in Malaysia: Persisting Challenges ...................................................................................... 332
6.2.3 Why there is a need for an enhanced IPR regime in Malaysia .... 334
6.3 Some recent developments .......................................................... 335
6.3.1 Draft manual of examination guidelines for biotechnology patents ........................................................................................................ 336
6.3.2 Review of existing IPR statute by a special committee .............. 337
6.3.3 Accession to UPOV ................................................................ 338
6.4 The proposed IP model for Malaysia .......................................... 339
6.4.1 Lessons from existing models .................................................. 339
6.4.1.1 First model: Europe & UK .................................................. 340
(i) Lessons learnt from European model ........................................ 340
6.4.1.2 Second model: the U.S ....................................................... 344
(ii) Lessons learnt from the American model ................................. 345
6.4.2 The model for Malaysia: a two way approach ......................... 348
6.4.2.1 Features of model of IP system for Malaysia ....................... 349
(i) The enhancement of existing Patents Act 1983 ......................... 349
(a) Clearer provisions and interpretation .................................... 349
(b) The utility innovations is to be made available for plant
innovations ................................................................................. 351
(c) The ban on patenting of plant varieties is to be retained ......... 353
(d) The utilization of research exemption under patent laws is to be optimized ................................................................. 355
(ii) Enhancement of PVP ................................................................ 357
Protection via PVP is to be encouraged as an option for interested plant breeders and inventors. 358

6.4.3 The IPR model for Malaysia in a nutshell 361
6.5 Conclusion 362

Chapter 7: Conclusion 366
7.1 Introduction 366
7.2 Journey revisited 366
7.2.1 Chapter summary 367
7.2.2 Questions and answers 369
7.3 Research limitations 370
7.4 Conclusion 372
7.5 Recommendations 373

Bibliography 374

Appendices 385