

CONTENTS

<i>Acknowledgments</i>	v	
Introduction	1	
PART 1.		
TRADITIONAL MEDICAL KNOWLEDGE, BIOLOGICAL DIVERSITY AND INTELLECTUAL PROPERTY RIGHTS		9
Chapter 1.		
The Concept of Traditional Medical Knowledge and the Impact of Biotechnology		11
1.1. A Definition of Traditional Medical Knowledge	11	
1.1.1. Traditional and Indigenous Knowledge	11	
1.1.2. Traditional Medical Knowledge	13	
1.1.3. General Characteristics of Traditional Medical Knowledge	14	
1.1.3.1. Traditional Knowledge Holders	15	
1.1.3.2. Creation and Preservation	15	
1.1.3.3. Ownership	15	
1.2. The Role of Natural Resources in Pharmaceutical R&D	16	
1.2.1. Overview	16	
1.2.2. Pharmaceutical Biotechnology	17	
1.2.3. Bioprospecting Research Project	19	
1.3. The Value of Pharmaceutical Biotechnology and Traditional Medical Knowledge	21	
1.3.1. The Value of Pharmaceutical Biotechnological R&D	21	
1.3.2. The Value of Traditional Medical Knowledge	22	
Chapter 2.		
The Convention on Biological Diversity		25
2.1. Biological Diversity	25	
2.1.1. Loss of Biodiversity	25	
2.1.2. Consequences of Biodiversity Loss	26	
2.2. Main Objectives of the CBD	27	
2.2.1. Conservation and Sustainable Use	28	

2.2.2.	Access to Biological Resources and Benefit Sharing.....	30
2.2.2.1.	National Sovereignty.....	31
2.2.2.2.	The Tragedy of the Commons.....	32
2.2.2.3.	The Role of Property Rights in Access and Benefit-Sharing Regulation.....	33
2.3.	Article 8 (j) CBD.....	35
2.3.1.	The Elements of Traditional Knowledge Protection.....	35
2.3.2.	Relationship with the Objectives.....	35
2.3.3.	Form of Protection.....	37
2.3.3.1.	Protection by Intellectual Property Rights.....	37
2.3.3.2.	Positive and Negative Approaches to Protection.....	38
 Chapter 3.		
	Trade-Related Intellectual Property Rights and Traditional Medical Knowledge.....	39
3.1.	The TRIPS Agreement.....	39
3.1.1.	Introduction.....	40
3.1.1.1.	The International Legal Developments.....	40
3.1.1.2.	The Economic Rationale of Intellectual Property Protection.....	41
3.1.2.	Objectives of the TRIPS Agreement.....	43
3.1.2.1.	Promotion of Free Trade.....	44
3.1.2.2.	Promotion of Economic Development.....	45
3.1.2.3.	Intellectual Property Rights and Developing Countries.....	47
3.1.3.	General Principles of Non-Discrimination.....	52
3.1.3.1.	National Treatment.....	52
3.1.3.2.	Most-Favoured-Nation Clause.....	52
3.2.	The International Legal and Economic Framework of Patents.....	53
3.2.1.	Historical Development of Today's Patent Laws.....	54
3.2.2.	Overview on TRIPS Rules on Patents.....	54
3.2.2.1.	Patentable Subject Matter.....	55
3.2.2.2.	Rules on Biotechnological Inventions and Biological Resources.....	56
3.2.2.3.	Disclosure.....	57
3.2.3.	The Economic Underlyings of Patenting.....	57
3.2.3.1.	The Incentive-to-Invent Theory.....	57
3.2.3.2.	Patent Scope.....	59
3.3.	The Interaction Between Traditional Medical Knowledge, the TRIPS Agreement and the CBD.....	61
3.3.1.	Traditional Knowledge in the TRIPS Context.....	61
3.3.2.	Intellectual Property Rights and the CBD.....	62

3.3.2.1. Article 8 (j) CBD – Preservation of and Respect for the Knowledge, Innovations and Practices of Traditional Communities	62
3.3.2.2. Conservation and Sustainable Use of Biodiversity	63
3.3.2.3. Article 15 CBD – Access to Genetic Resources and Fair and Equitable Benefit Sharing	63
3.3.2.4. Article 16 CBD – Access to and Transfer of Technology	63
3.4. Summary of the Main Results of Part 1	64

PART 2.

THE STATUS QUO – PROTECTION OF TRADITIONAL MEDICAL KNOWLEDGE AND BIOTECHNOLOGICAL INVENTIONS UNDER CURRENT PATENT LAW	67
--	-----------

Chapter 1.

Patentability Criteria in the US and the EU	71
--	-----------

1.1. Legal Foundations for (Biotechnological) Patents in the US and the EU	72
1.1.1. Sources of US Patent Law	72
1.1.1.1. The Constitution	72
1.1.1.2. Federal Statutes and Regulations	72
1.1.1.3. Case Law	73
1.1.2. European Patent Law	74
1.1.2.1. The European Patent Convention	74
1.1.2.2. The Biotechnology Directive	75
1.1.2.3. National Laws and Court Decisions	76
1.2. Substantive Patent Requirements	76
1.2.1. Products of Nature	76
1.2.1.1. US Patent Law	77
1.2.1.2. European Patent Law	79
1.2.2. Novelty	82
1.2.2.1. The State of the Art in US Patent Law	82
1.2.2.2. The European Approach to Novelty	84
1.2.3. Inventive Step and Non-Obviousness	85
1.2.3.1. US Patent Law – Non-Obviousness	86
1.2.3.2. European Patent Law – Inventive Step	89
1.2.4. Utility and Industrial Application	91
1.2.4.1. US – Utility	91
1.2.4.2. EU – Industrial Application	93
1.3. Specification	94
1.3.1. Disclosure of the Invention	94

1.3.1.1.	US Patent Law	94
1.3.1.2.	Europe	96
1.3.2.	Patent Claims	98
1.3.2.1.	Claim Categories	98
1.3.2.2.	Claim Drafting	98
1.4.	Concluding Remarks	100
Chapter 2.		
Biotechnological Patents on Pharmaceutical Drugs Developed in Bioprospecting Research Projects		
		101
2.1.	The Patentability of Biotechnological Inventions Using Traditional Medical Knowledge	101
2.1.1.	Natural Products Doctrine	101
2.1.2.	Traditional Medical Knowledge as Invalidating Prior Art	102
2.1.2.1.	The <i>Neem</i> Patents	103
2.1.2.2.	Analysis of the Prior Art Assessment in the <i>Neem</i> Proceedings	104
2.1.2.3.	The Standard of Disclosure	105
2.1.3.	Non-Obviousness in Bioprospecting Research Projects	106
2.1.3.1.	US Patent Law: The Standard of Non-Obviousness in the Aftermath of <i>KSR</i>	107
2.1.3.2.	The Inventive Step Requirement in Europe: <i>Neem</i> and <i>Hoodia</i>	109
2.2.	Analysis of the Results	112
2.2.1.	The Importance of Patents for Pharmaceutical R&D	112
2.2.2.	The Predictability of the Outcomes of Patent Proceedings	114
Chapter 3.		
The Rights of the Providers of Traditional Medical Knowledge		
		117
3.1.	The Patentability of Traditional Medical Knowledge	117
3.1.1.	Products of Nature	117
3.1.2.	Novelty and Non-Obviousness	118
3.1.3.	Formal Requirements	120
3.2.	The Owner of the Patent: The Concept of Joint Inventorship	120
3.2.1.	Legal Definition of Joint Inventorship	121
3.2.1.1.	Requirements for Joint Inventorship in US Patent Law	121
3.2.1.2.	Joint Inventorship Under the EPC	122
3.2.2.	Joint Inventorship of Traditional Knowledge Groups and Pharmaceutical Companies	124
3.3.	Analysis of the Results	127
3.3.1.	The Public Good Problem	127

3.3.1.1. Suboptimal Rate of Innovation	128
3.3.1.2. Free-Riding	129
3.3.2. Allocation of Resources	129
3.3.3. Implementation of the CBD	131
3.3.3.1. Prior Informed Consent	131
3.3.3.2. Benefit Sharing	131
3.3.3.3. Disclosure of the Origin of the Source	132
3.4. Summary of the Main Results of Part 2	132
PART 3.	
PROTECTING AND REWARDING TRADITIONAL MEDICAL KNOWLEDGE CONTRIBUTIONS UNDER PROPERTY AND LIABILITY REGIMES.....	
	135
Chapter 1.	
The Property Rights-based Approach to Protection	
	139
1.1. The Construction of Traditional Knowledge Rights	139
1.1.1. Novel Interpretation of Existing Norms.....	139
1.1.1.1. Invention	140
1.1.1.2. Novelty and Inventive Step	140
1.1.2. Sui Generis Systems – Definition of New Rights for Indigenous Peoples	141
1.2. Implementation of Article 8 (j) CBD Through Traditional Knowledge Rights	144
1.2.1. Interpretation and Infringement	144
1.2.1.1. Literal Infringement.....	145
1.2.1.2. The Doctrine of Equivalents.....	145
1.2.1.3. Implications for the Right of Traditional Knowledge Providers	148
1.2.2. Economic Analysis – The Effects of Patents in Cumulative Innovation Scenarios	149
1.2.2.1. Optimal Allocation of Rights and Division of Profits ..	149
1.2.2.2. Hold-Up and Anticommons.....	151
1.2.2.3. Conclusion.....	153
1.3. Co-Operation Between Indigenous Groups and Pharmaceutical Companies and Joint Inventorship	154
1.3.1. Modification of the Requirements.....	154
1.3.2. The Rights of Joint Inventors	155
1.3.2.1. Use of the Patented Invention.....	155
1.3.2.2. Sharing of Profits	156
1.3.2.3. Discussion	156
1.4. Conclusion on the Property Rights Approach.....	157

Chapter 2.	
Benefit-Sharing Agreements and Liability Rules	159
2.1. Mandatory Benefit-Sharing Agreements as Conditions to Patentability.....	160
2.2. Benefit Sharing Under a Liability-Based Approach.....	161
2.2.1. Conditions of a Compensatory Liability Regime	162
2.2.2. Determination of the Value.....	163
2.2.2.1. Statutory Rules	164
2.2.2.2. Collective Rights Organizations	164
2.2.3. Impact of Benefit Sharing on Retail Costs of Pharmaceuticals... ..	165
2.3. Conclusion on Benefit Sharing	167
Chapter 3.	
Prior Informed Consent and Disclosure Requirements	169
3.1. The Content and Scope of the Requirements	169
3.1.1. Prior Informed Consent Requirement	169
3.1.2. Disclosure Requirements.....	170
3.1.3. Effects and Costs of Prior Informed Consent and Disclosure Requirements.....	170
3.1.3.1. The Sanction in Case of Non-Compliance.....	170
3.1.3.2. The Effects of Disclosure Requirements	171
3.1.3.3. The Effects of Prior Informed Consent.....	172
3.2.. Compatibility with TRIPS.....	172
3.2.1. Prior Informed Consent	173
3.2.2. Disclosure Requirements.....	173
3.2.2.1. Substantive or Formal Requirements	173
3.2.2.2. Article 29 TRIPS.....	173
3.2.2.3. Article 62 TRIPS.....	174
3.3. Conclusion on Disclosure and Prior Informed Consent Requirements.....	175
3.4. Summary of the Results of Part 3.....	175
Conclusion. The Results of the Analysis and the Implications for Future Discussions	177
<i>Bibliography</i>	185
<i>List of Cases</i>	193
<i>About the author</i>	197
<i>About the series</i>	199