

Leila Ghassemi Farreras

Dr en droit, avocate

Utilisation of Traditional Medicinal Knowledge in the Industry

Legal Aspects and Protection in
International Law



COLLECTION NEUCHÂTELOISE

Helbing Lichtenhahn

CONTENTS

Contents	I
Introduction	1
PART I CONCEPTUAL AND LEGAL ISSUES RELATED TO TRADITIONAL MEDICINAL KNOWLEDGE	11
Chapter 1 Terms and Definitions – Areas of Uncertainty	11
1 Traditional Knowledge and Related Terms	11
1.1 Terminological Pluralism and Definitions.....	13
1.2 Definition of Traditional Medicinal Knowledge and Related Concepts	17
1.3 Indigenous Peoples’ Knowledge	21
2 Characteristics	27
2.1 What is “Traditional”?.....	28
2.2 Scientific Knowledge – Commensurability of Traditional Knowledge (knowledge pluralism)	30
2.3 Entitlement to Knowledge – Collective Stewardship and Guardianship.....	34
Chapter 2 The Role of Traditional Medicinal Knowledge in Drug Industries.....	39
1 A Historical Perspective of Drug Discovery	40
2 The Drugs Research and Development Process today	41
3 Plant-derived drugs.....	43
4 Traditional Medicinal Knowledge-derived Drugs.....	46
Chapter 3 Selected International Legal Framework Relevant to Traditional Medicinal Knowledge	51
1 Conservation of Biological Diversity	52
1.1 The Convention on Biodiversity.....	52
1.1.1 Scope of the Convention on Biological Diversity for Traditional Medicinal Knowledge	54

1.1.2	The Follow-up Implementation Process of the Convention on Biodiversity.....	59
1.2	The Nagoya Protocol to the Convention on Biological Diversity.....	61
1.2.1	Scope of the Protocol with Regard to Traditional Knowledge.....	62
1.2.2	Prior Informed Consent as it relates to Traditional Knowledge.....	70
1.2.3	Customary Laws of Indigenous Peoples	78
2	Intellectual Property Rights	81
2.1	TRIPS	82
2.1.1	Patentable Subject Matter.....	85
2.1.2	Justifications for Patent Protection and Competing Values – Legitimizing Narratives	89
2.2	Doha Trade Round of the WTO	94
2.3	World Intellectual Property Organisation (WIPO).....	95
2.3.1	The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC).....	97
2.3.2	WIPO Development Agenda.....	101
3	Human Rights.....	102
3.1	The United Nations Declaration on the Rights of Indigenous Peoples	108
3.1.1	The Evolution of the Rights to Self-determination under the UN Declaration.....	110
3.1.2	“Free, Prior and Informed Consent”: from a Principle to a Right	115
3.1.3	Intellectual Property Rights of Indigenous Peoples.....	119
3.2	Human Rights, Intellectual Property Rights and Traditional Knowledge	123
Chapter 4	Conclusion.....	127

PART II	IDENTIFYING THE LEGAL PROBLEMS	129
Chapter 1	Utilisation of traditional medicinal knowledge beyond its traditional community	131
1	From Bioprospecting to “Biopiracy” – Free Riding or Bioprospecting without Prior Informed Consent!	131
1.1	Utilisation of Traditional Medicinal Knowledge without Authorisation or Prior Informed Consent (PIC) – TRIPS Agreement v. CBD.....	135
1.2	Utilisation of Traditional Medicinal Knowledge in Patent claims.....	136
2	Selected Case Studies: Utilisation of TMK beyond Traditional Communities	136
2.1	The Turmeric “Bad Patent”	137
2.2	The “Morality” of the Neem Patent / Neem patent and prior art	140
2.1	The <i>Ayahuasca</i> Case / Prior Art Printed Publication.....	143
2.2	Hoodia Case: Challenging a Patent or Entering into an Access and Benefit-Sharing Agreement?	145
2.2.1	Towards an Agreement on Benefit-Sharing	145
2.2.2	Was the Patent Inventive?	149
2.3	The Pelargonium Case: Solely a Question of Patentability ?	150
3	Concluding Remarks	153
Chapter 2	Incorporating Traditional Medicinal Knowledge into Patentable Inventions	155
1	Inventions or Man-Made Living Things <i>versus</i> Discoveries.....	155
2	“ <i>Ordre Public</i> and Morality” as an Exception to Patentability	160
3	Substantive Requirements for Patentability and Traditional Medicinal Knowledge	168
3.1	Novelty – prior art	169
3.2	New Medical Uses of Known Substances.....	175
3.3	Inventive Step.....	179

3.3.1	Problem-Solution Approach.....	181
3.3.2	Non-Obviousness Approach.....	188
3.4	Industrial Application.....	196
4	Formal Requirements for Patentability and Traditional Medicinal Knowledge	198
4.1	Patent Claim / Traditional Medicinal Knowledge within a Patent claim	199
4.2	The Disclosure Requirement	202
5	Conclusion.....	205
Chapter 3	One Public Domain <i>versus</i> Different Knowledge Systems.....	209
1	Public Domain: An Overview	209
2	Public Domain and Intellectual Property Rights: What about Traditional Medicinal Knowledge?.....	215
3	Publicly Available Traditional Medicinal Knowledge and Prior Informed Consent.....	222
Chapter 4	Conclusion.....	225
PART III	DEFINING A LEGAL REGIME OF PROTECTION	229
Chapter 1	Towards an International <i>sui generis</i> System of Protection.....	230
1	WIPO-IGC and the CBD Working Group on Article 8(j).....	230
2	An International Binding Treaty.....	234
3	Protection according to Policy Objectives.....	239
4	The Voice of Indigenous Peoples in the International Debate	242
Chapter 2	“Draft Articles” of the WIPO IGC for the Protection of Traditional Knowledge.....	245
1	Subject Matter of Protection.....	245
2	Beneficiaries.....	251
3	Scope of Protection: From a Defensive to a Differential Approach - Reconsidering the Boundaries of Public Domain?.....	257

4	Fundamental Role of Customary Laws in a <i>Sui Generis</i> System of Protection of Traditional Knowledge	262
Chapter 3	Toward Concrete Means of Protection of Traditional Knowledge	275
1	Databases as a Defensive Protection of Traditional Knowledge	276
2	Disclosing the Use / Origin of TK and PIC in Patent Descriptions or Claims	283
2.1	The Background – From the Ministerial Declaration at Doha to the Disclosure Requirement Debate.....	283
2.2	Member States' Positions and Types of Disclosure Requirements.....	288
2.2.1	The TRIPS Disclosure Proposal	288
2.2.2	The Mandatory Disclosure Proposal	290
2.2.3	The Patent Cooperation Treaty Disclosure Proposal....	291
2.2.4	From No Need for a Disclosure Requirement towards an Unexpected Coalition.....	293
2.3	Disclosure of Traditional Knowledge.....	296
2.3.1	Compliance, Monitoring and Disclosure.....	297
2.3.2	WIPO IGC Draft Articles on Requirements for the Disclosure of Traditional Knowledge	299
2.3.3	Concluding Remarks on the Disclosure of Traditional Knowledge.....	306
3	Selected National Approaches	308
3.1	The Transparent and Pragmatic Approach of Switzerland.....	309
3.1.1	The Swiss Patent Act.....	309
3.1.2	The Swiss Federal Act on the Protection of Nature and Cultural Heritage	312
3.2	The Peruvian <i>Sui Generis</i> Law	316
3.2.1	Disclosure Requirement	317
3.2.2	Law 27811	319

3.3	New Zealand’s Case-by-Case Approach.....	326
3.3.1	The Wai 262 Claim and the Tribunal of Waitangi’s Report	329
3.3.2	The Patent Act and the Māori Patents Advisory Committee	335
Chapter 4	Final Reflections	339
1	International Minimum Standards	339
2	Subject Matter, Beneficiaries of Protection and Scope of Rights.....	340
3	Transparency, Prior Informed Consent and Monitoring.....	344
	CONCLUSION	349
	REFERENCES	353
	Books and Articles.....	353
	United Nations / UN Agencies’ Documents	392
	International Treaties, Conventions, Agreements and Declarations.....	409
	Statutes and Legislations	413
	Case Law	415
	ABBREVIATIONS	419