

Utilisation of Traditional Medicinal Knowledge in the Industry – Legal Aspects and Protection in International Law

Thèse de doctorat soutenue à la Faculté de droit
de l'Université de Neuchâtel le 14 mars 2017

Par

LEILA GHASSEMI FARRERAS

Jury :

Prof. OLIVIER GUILLOD

Faculté de droit de l'Université de Neuchâtel
Directeur de thèse

Prof. DANIEL KRAUS

Faculté de droit de l'Université de Neuchâtel
Rapporteur interne

Dr MARTIN GIRSBERGER

Swiss Federal Institute of Intellectual Property, Head Sustainable
Development & International Cooperation,
Legal and International Affairs Division
Rapporteur externe

To Bâbâ

To Àlex, Kiyana, Ariya and Armin

Acknowledgements

Writing is a solitary endeavour but I did not feel lonely during these years. The finalisation of this thesis would not have been possible without contributions from a large number of people. Sincere thanks to all of them for their support through this long journey.

First and foremost, I would like to express my gratitude to my supervisor Professor Olivier Guillod, for his great sense of humanity, his guidance and stimulating discussions. I would also like to sincerely thank Professor Daniel Kraus, who kept me inspired and for his very courage-boosting words during these years. I want to express my profound appreciations and gratitude to Dr Martin Girsberger from whom I received invaluable expertise. I owe a special debt to Professor Philippe Cullet who made me discover this fascinating subject matter.

My colleagues at the Faculty of Law and the Institute of Health Law must be sincerely thanked for their patience and support. I would like to specially thank Mrs Dominique Mengisen, Mrs Viviane Perratone, Mrs Nathalie Brunner, Mrs Beatrice Stirner, Dr Johanne Gagnebin, Mr Gaël Schaffter, Mrs Valérie Wyssbrod, Mr Anaic Cordoba, Mrs Marlène Collette, Dr Stéfanie Kurt, Mr Pascal Jeanin and Dr Olivier Riske, who one way or another have been present by my side with their good humour and friendship in the University of Neuchâtel. I owe a great debt of gratitude to my friend, Mr Greg Mayne, international human rights' expert, for his valuable insights, comments and infinite patience. I want to express my profound gratitude to Christiane Johannot-Gradis and Diego Gradis of Traditions for Tomorrow for their trust and for helping me to assist the sessions of the WIPO-IGC. I am also very grateful to Mr Jean Perrenoud for his invaluable help and diligence in reviewing the technical aspects of this work and for his goodwill. I also want to extend my gratitude to Mr Slim Ben Younes, head of the library of the Law Faculty in Neuchâtel and all the Faculty staff who kindly helped me in my research.

Without the moral support of my dear husband, my everything, Àlex, this research would not have seen the light. I am truly grateful for your love, support, and patience. Thank you to our three little bundles of joy, Kiyana, Ariya and Armin who accompanied me through this adventure from their birth. Lastly, I want to thank Shila the cat for staying up late into the night on my side and giving me a sense of comfort with her gentle purr.

Abstract

The development of new organisms through modification of biological resources is the basis of modern biotechnology. One of the most straightforward means to target a biological resource with bioactive compounds, which is of interest to the industry, is through traditional medicinal knowledge. This thesis provides an in-depth analysis of some of the legal problems that arise when traditional medicinal knowledge is captured into a patented invention without the consent of its holders. The first Part examines the diverse concepts and distinctive characteristics of traditional medicinal knowledge, the role traditional medicinal knowledge plays in the drug industry and the international legal framework relevant to the use of traditional medicinal knowledge. The second Part addresses the legal gaps that result in the legal protection of traditional medicinal knowledge when it meets the patent system by providing an in-depth legal analysis of the conditions of patentability. Finally, the third Part proposes and analyses long and short term solutions to the legal protection of traditional medicinal knowledge.

Résumé

Le développement de nouveaux organismes obtenus par la modification des ressources biologiques constituent un des piliers de la biotechnologie. Un moyen sûr et rapide de découvrir des principes actifs des ressources biologiques, utilisé dans l'industrie, est de recourir aux savoirs traditionnels médicinaux. Cette thèse analyse de manière détaillée un certain nombre de problèmes qui surgissent lorsque le savoir traditionnel médicinal est incorporé dans une invention brevetée sans que le consentement du détenteur du savoir ait été au préalable. La première partie donne un aperçu de la diversité des concepts liés aux caractères distinctifs des savoirs traditionnels médicinaux, leur rôle dans l'industrie pharmaceutique ainsi que le cadre légal international régissant leur utilisation. La seconde partie examine la situation juridique qui résulte de l'intersection entre les savoirs traditionnels et le système des brevets en analysant de manière approfondie les conditions de la brevetabilité. Pour conclure, la dernière partie propose et analyse quelques solutions à court et à long terme pour la protection des savoirs traditionnels médicinaux.

.

Keywords

Access and Benefit-sharing; Biological resources; Biotechnology; Customary law; Databases; Discoveries; Disclosure Requirement; Genetic resources; Indigenous Peoples; Invention; Inventiveness; Intellectual property rights; Ordre public; Origin; Ownership; Misappropriation; Morality; New medical uses; Non-obviousness; Novelty; Patent; Preservation; Prior informed consent; Protection; Public domain; Self-determination; Source; Sovereignty; *Sui generis*; Utilisation; Traditional medicinal knowledge; Transparency.

Mots-clés

Accès et partage des bénéfices; Activité inventive; Appropriation illégitime; Autodétermination; Base de données; Biotechnologie; Brevet; Consentement préalable éclairé; Découverte; Domaine public; Droits de la propriété intellectuelle; Invention; L'exigence de divulgation; Lois coutumières; Moralité; Nouveauté; Nouvelle indication thérapeutique; Ordre public; Origine; Populations autochtones; Préservation; Propriété; Protection; Ressources biologiques; Ressources génétiques; Savoirs traditionnels médicaux; Source; Souveraineté; *Sui generis*; Transparence; Utilisation.

CONTENTS

Contents.....	I
Introduction	1
PART I CONCEPTUAL AND LEGAL ISSUES RELATED TO TRADITIONAL MEDICINAL KNOWLEDGE	13
Chapter 1 Terms and Definitions – Areas of Uncertainty.....	13
1 Traditional knowledge and Related Terms	13
1.1 Terminological Pluralism and Definitions	15
1.2 Definition of Traditional Medicinal Knowledge and Related Concepts.....	20
1.3 Indigenous Peoples’ Knowledge.....	23
2 Characteristics	30
2.1 What is “Traditional”?	31
2.2 Scientific Knowledge – Commensurability of Traditional Knowledge (knowledge pluralism).....	33
2.3 Entitlement to Knowledge – Ownership Claims? Collective Stewardship and Guardianship	37
Chapter 2 The Role of Traditional Medicinal Knowledge in Drug Industries.....	43
1 A Historical Perspective of Drug Discovery	44
2 The Drugs Research and Development Process today	45
3 Plant-derived drugs	47
4 Traditional Medicinal Knowledge-derived Drugs	50
Chapter 3 Selected International Legal Framework Relevant to Traditional Medicinal Knowledge	55
1 Conservation of Biological Diversity.....	56
1.1 The Convention on Biodiversity	56
1.1.1 Scope of the Convention on Biological Diversity for Traditional Medicinal Knowledge.....	58

1.1.2	The Follow-up Implementation Process of the Convention on Biodiversity	63
1.2	The Nagoya Protocol to the Convention on Biological Diversity	65
1.2.1	Scope of the Protocol with Regard to Traditional Knowledge	67
1.2.2	Prior Informed Consent as it relates to Traditional Knowledge	75
1.2.3	Customary Laws of Indigenous Peoples	84
2	Intellectual Property Rights	87
2.1	TRIPS	88
2.1.1	Patentable Subject Matter	91
2.1.2	Justifications for Patent Protection and Competing Values – Legitimizing Narratives	95
2.2	Doha Trade Round of the WTO	100
2.3	World Intellectual Property Organisation (WIPO)	101
2.3.1	The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC)	103
2.3.2	WIPO Development Agenda	107
3	Human Rights	108
3.1	The United Nations Declaration on the Rights of Indigenous Peoples	114
3.1.1	The Evolution of the Rights to Self-determination under the UN Declaration	116
3.1.2	“Free, Prior and Informed Consent”: from a Principle to a Right	121
3.1.3	Intellectual Property Rights of Indigenous Peoples	125
3.2	Human Rights, Intellectual Property Rights and Traditional Knowledge	129
Chapter 4	Conclusion	135
PART II	IDENTIFYING THE LEGAL PROBLEMS	137
Chapter 1	Utilisation of traditional medicinal knowledge beyond its traditional community	139

1	From Bioprospecting to “Biopiracy” – Free Riding or Bioprospecting without Prior Informed Consent!.....	139
1.1	Utilisation of Traditional Medicinal Knowledge without Authorisation or Prior Informed Consent (PIC) – TRIPS Agreement v. CBD	143
1.2	Utilisation of Traditional Medicinal Knowledge in Patent claims.....	144
2	Selected Case Studies: Utilisation of TMK beyond Traditional Communities	144
2.1	The Turmeric “Bad Patent”.....	145
2.2	The “Morality” of the Neem Patent / Neem patent and prior art	148
2.1	The <i>Ayahuasca</i> Case / Prior Art Printed Publication	151
2.2	Hoodia Case: Challenging a Patent or Entering into an Access and Benefit-Sharing Agreement?	153
2.2.1	Towards an Agreement on Benefit-Sharing	153
2.2.2	Was the Patent Inventive?.....	157
2.3	The Pelargonium Case: Solely a Question of Patentability ?.....	159
3	Concluding Remarks	162
Chapter 2 Incorporating Traditional Medicinal Knowledge into Patentable Inventions		
1	Inventions or Man-Made Living Things <i>versus</i> Discoveries	165
2	“ <i>Ordre Public</i> and Morality” as an Exception to Patentability	170
3	Substantive Requirements for Patentability and Traditional Medicinal Knowledge.....	179
3.1	Novelty – prior art	180
3.2	New Medical Uses of Known Substances.....	186
3.3	Inventive Step.....	191
3.3.1	Problem-Solution Approach	192
3.3.2	Non-Obviousness Approach	199
3.4	Industrial Application.....	208

4	Formal Requirements for Patentability and Traditional Medicinal Knowledge.....	210
4.1	Patent Claim / Traditional Medicinal Knowledge within a Patent claim.....	210
4.2	The Disclosure Requirement.....	214
5	Conclusion.....	217
Chapter 3	One Public Domain <i>versus</i> Different Knowledge Systems.....	221
1	Public Domain: An Overview	221
2	Public Domain and Intellectual Property Rights: What about Traditional Medicinal Knowledge?	227
3	Publicly Available Traditional Medicinal Knowledge and Prior Informed Consent	234
Chapter 4	Conclusion	237
PART III	DEFINING A LEGAL REGIME OF PROTECTION.....	241
Chapter 1	Towards an International <i>sui generis</i> System of Protection	242
1	WIPO-IGC and the CBD Working Group on Article 8(j)	243
2	An International Binding Treaty	246
3	Protection according to Policy Objectives	252
4	The Voice of Indigenous Peoples in the International Debate.....	255
Chapter 2	“Draft Articles” of the WIPO IGC for the Protection of Traditional Knowledge	259
1	Subject Matter of Protection	259
2	Beneficiaries.....	265
3	Scope of Protection: From a Defensive to a Differential Approach - Reconsidering the Boundaries of Public Domain?	272
4	Fundamental Role of Customary Laws in a <i>Sui Generis</i> System of Protection of Traditional Knowledge.....	277
Chapter 3	Toward Concrete Means of Protection of Traditional Knowledge	289
1	Databases as a Defensive Protection of Traditional Knowledge	290

2	Disclosing the Use / Origin of TK and PIC in Patent Descriptions or Claims	297
2.1	The Background – From the Ministerial Declaration at Doha to the Disclosure Requirement Debate	298
2.2	Member States’ Positions and Types of Disclosure Requirements.....	302
2.2.1	The TRIPS Disclosure Proposal	302
2.2.2	The Mandatory Disclosure Proposal.....	305
2.2.3	The Patent Cooperation Treaty Disclosure Proposal	306
2.2.4	From No Need for a Disclosure Requirement towards an Unexpected Coalition	308
2.3	Disclosure of Traditional Knowledge	312
2.3.1	Compliance, Monitoring and Disclosure	312
2.3.2	WIPO IGC Draft Articles on Requirements for the Disclosure of Traditional Knowledge	314
2.3.3	Concluding Remarks on the Disclosure of Traditional Knowledge	322
3	Selected National Approaches	324
3.1	The Transparent and Pragmatic Approach of Switzerland	325
3.1.1	The Swiss Patent Act	325
3.1.2	The Swiss Federal Act on the Protection of Nature and Cultural Heritage	328
3.2	The Peruvian <i>Sui Generis</i> Law.....	332
3.2.1	Disclosure Requirement.....	333
3.2.2	Law 27811	335
	• Subject matter of protection	337
	• Beneficiaries	339
	• Scope of protection.....	339
3.3	New Zealand’s Case-by-Case Approach.....	342
3.3.1	The Wai 262 Claim and the Tribunal of Waitangi’s Report.....	345
3.3.2	The Patent Act and the Māori Patents Advisory Committee.....	352

Chapter 4	Final Reflections	357
1	International Minimum Standards.....	357
2	Subject Matter, Beneficiaries of Protection and Scope of Rights	358
3	Transparency, Prior Informed Consent and Monitoring	362
CONCLUSION		367
REFERENCES.....		371
Books and Articles		371
United Nations / UN Agencies' Documents		416
International Treaties, Conventions, Agreements and Declarations		435
Statutes and Legislations		439
Case Law		441
ABBREVIATIONS.....		447

INTRODUCTION

Over the last few years, the recognition and use of traditional medicinal knowledge (TMK) has progressively gained in prominence. For instance, it is estimated that 80 per cent of the population in most Asian and African countries depend upon traditional medicinal knowledge as the main source of care. This reliance on TMK is either due to cost factors and/or due to cultural choices. In these countries, access to modern health care services and medicine is generally restricted due to economic, social and cultural factors.¹

However interest in traditional medicinal knowledge is not solely confined to the developing or emerging world. Equally, in the developed world, it has gained renewed interest in a variety of industrial sectors, particularly the pharmaceutical, food and cosmetic industries.² In particular, traditional knowledge of the healing properties of plants has constituted the basis of many bioprospecting activities³ aiming at the development of new promising drugs. This knowledge extraction from its original holders and its further use by third parties triggers legal questions in need of legal answers.

It is generally assumed that the holders of, and those that continue to perpetuate, traditional knowledge are indigenous peoples or local communities living in a given territory, whether this territory is delimited by a state or spread over different states. In its report on Intellectual Property Needs and Expectations of Traditional Knowledge Holders, the World Intellectual Property Organisation (WIPO) noted that holders of traditional knowledge may broadly refer to “all persons who create, originate, develop and practice traditional knowledge in a traditional setting and context”.⁴

¹ WHO, ‘WHO Traditional Medicine Strategy 2002-2005, 2002, p. 1; see also, WHO, ‘WHO Traditional Medicine Strategy 2014-2023, 2013, p. 16.

² CORREA, *Protection and Promotion of Traditional Medicine*, 2002, p. 9; FARNSWORTH et al., “Medicinal-Plants in Therapy”, 1985, p. 966.

³ The Oxford Dictionary of Biomedicine, online version, 2015 defines bioprospecting as “[a] shorthand term for investigations carried out with the aim of discovering biological materials (e.g. pharmacologically active plant substances) that can be commercially exploited. The term biopiracy has been used when local inhabitants are not rewarded” [accessed August 2016].

⁴ WIPO, ‘WIPO Report on Intellectual Property Needs and Expectations of Traditional Knowledge Holders’, 2001, p. 26.

Furthermore, a number of countries do not accommodate or may not recognise indigenous peoples or local communities, although they still possess traditional knowledge. This raises the controversial question whether States can be considered as holders of traditional knowledge.

Beyond this, some scholars also make a differentiation between the terms traditional knowledge and indigenous knowledge.⁵ According to the WIPO report, “indigenous knowledge is used to describe knowledge held and used by communities, peoples and nations that are indigenous”.⁶ In other words, indigenous knowledge constitutes the traditional knowledge of indigenous peoples, but traditional knowledge is not necessarily indigenous.⁷ However, some other scholars consider this distinction as being irrelevant and use these terms in an interchangeable way or opt to use other working concepts such as “community resources”.⁸

The emergence of the discourse related to traditional knowledge is due to four main factors, namely, the recognition of indigenous peoples and their intangible cultural heritage;⁹ the concern about the loss of biodiversity; the advancement of modern biotechnology; and the adherence to strong intellectual property agreements implemented internationally.¹⁰ The

⁵ See for instance, ANAYA, *Indigenous Peoples in International Law*, 1996; BLAKENEY, “The Protection of Traditional Knowledge under Intellectual Property Law”, 2000.

⁶ WIPO, ‘Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge 1998-1999’, 2001, p. 23.

⁷ OGUAMANAM, *International Law and Indigenous Knowledge*, 2006, p. 20.

⁸ GIBSON, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, 2005, p. 31.

⁹ Convention for the Safeguarding of the Intangible Cultural Heritage, UNESCO, Paris, 17 October 2003, 2368 UNTS 3 (UNESCO Convention 2003), Article 2 (intangible cultural heritage is defined as “the practices, representations, expressions, knowledge, skills — as well as the instruments, objects, artefacts and cultural spaces associated therewith — that communities, groups and, in some cases, individuals recognize as part of their cultural heritage”); See also, Human Rights Council, ‘Promotion and Protection of the Rights of Indigenous Peoples with Respect to their Cultural Heritage’, 2015, UN Doc. A/HRC/30/53, para. 4 (the Special Rapporteur in the field of cultural rights refers to tangible cultural heritage, intangible cultural heritage and natural cultural heritage. She adds that “Cultural heritage should be understood as resources enabling the cultural identification and development processes of individuals and communities which they, implicitly or explicitly, wish to transmit to future generations”).

¹⁰ Dutfield, “TRIPS-Related Aspects of Traditional Knowledge”, 2001, p. 235; BRADFORD, “Intellectual Property and Traditional Knowledge”, 2005, p. 1636.

regaining of interest by consumers for traditional and natural products shall not be underestimated. However, whilst so-called “ethnic” products have become fashionable, there is also evidence of an increasing interest in preserving the diversity of traditional knowledge systems, in general, far beyond so called "scientific" knowledge.¹¹

A comprehensive study on the situation of indigenous peoples goes far beyond the subject matter of this work. However it is essential to give an overview of the international context relating to them given the close interrelationship between traditional knowledge and indigenous peoples’ issues. The recognition by international law of indigenous peoples and the recovery of indigenous knowledge has been a direct consequence of the decolonisation process.¹² In this context and using human rights frame, the International Labour Organisation (ILO) adopted the ILO Convention Concerning the Protection and Integration of Indigenous and other Tribal and Semi-Tribal Populations in Independent Countries of 1957 (ILO Convention No 107 or ILO 107).¹³ The underlying philosophy of ILO 107 was to promote integration of indigenous peoples into the larger social and political order.¹⁴ It was, however, not until the early 1970s that the United Nations addressed the issue of indigenous peoples, when the Economic and Social Council of the United Nations (ECOSOC)¹⁵ mandated the Sub-Commission on Prevention of Discrimination and Protection of Minorities to carry out a study on the problem of discrimination against indigenous peoples. The voluminous report was finalised and issued in 1986 by José R. Martínez Cobo.¹⁶ Three years later, ILO Convention Concerning Indigenous and Tribal Peoples in Independent Countries was adopted

¹¹ BLAKENEY, “The Protection of Traditional Knowledge under Intellectual Property Law”, 2000, p. 255.

¹² See generally WAZIYATAWIN, “Indigenous knowledge recovery is indigenous empowerment”, 2004, p. 359 (the author exposes the impacts of centuries of colonialism’s efforts to eradicate indigenous peoples’ way of seeing, being and interacting with the world).

¹³ International Labour Organisation Convention Concerning the Protection and Integration of Indigenous and Other Tribal and Semi-Tribal Populations in Independent Countries, Geneva, 26 June 1957, 328 UNTS 247 (ILO Convention No 107).

¹⁴ On the ILO Convention No 107, see ANAYA, *Indigenous Peoples in International Law*, 1996, p. 44-45.

¹⁵ On the mandate and functions of the UN Economic and Social Council (ECOSOC), see UN site at: <http://www.un.org/en/ecosoc/about/> [accessed August 2016].

¹⁶ Commission on Human Rights, ‘Study of the Problem of Discrimination Against Indigenous Populations’, Special Rapporteur José Martínez Cobo, 1986, vol. I-V, UN Doc E/CN. 4/Sub.2/1986/7 and Add. 1-4.

(ILO Convention No 169 or ILO 169),¹⁷ in which the need for special protection of indigenous peoples' values and practices was finally emphasised. Thus, for the first time, international law acknowledged the rights of indigenous peoples as tribes that “distinguish them from other sections of the national community, and whose status is regulated wholly or partially by their own customs or traditions or by special laws or regulations”.¹⁸

In 2007, and after more than twenty years of negotiation, the General Assembly of the United Nations adopted the Declaration on the Rights of Indigenous Peoples (UNDRIP) that entered into force in May 2008. Article 31 of the Declaration expressly recognises the right of Indigenous Peoples “to maintain, control, protect and develop [...] their traditional knowledge”.¹⁹

The increased awareness of the need to improve the preservation of biological diversity has been expressly linked to the increased interest in equally preserving traditional knowledge.²⁰ Indeed, the role of indigenous and local communities in the management of the environment is being better acknowledged, and in particular their knowledge and traditional practices have been essential for the conservation and sustainable use of natural resources. Indigenous peoples' needs and interests in conserving their traditional lifestyle and activities have also been acknowledged in the framework of the Rio process, particularly in the Agenda 21 concerned with a series of recommendations about the relevance of traditional knowledge for the implementation of sustainable development policies and programmes.²¹ Since the beginning of the discourse on the interrelation between traditional knowledge and biodiversity conservation, organisations of indigenous peoples have pointed out the inextricable link

¹⁷ International Labour Organisation Convention Concerning Indigenous and Tribal Peoples in Independent Countries, Geneva, 27 June 1989, 1650 UNTS 383 (ILO Convention No 169).

¹⁸ ILO Convention No 169, Article 1.1.

¹⁹ United Nations Declaration on the Rights of Indigenous Peoples, UN GA Res, 2 October 2007, UN Doc A/RES/61/295, (UNDRIP).

²⁰ OVIEDO et al., *Indigenous and Traditional Peoples of the World and Ecoregion Conservation*, 2000, pp. 7-8.

²¹ Rio Declaration on Environment and Development, proclaimed 13 June 1992, Agenda 21, Rio de Janeiro, 3-14 June 1992, UN Doc., A/CONF.151/26 (vol. I), 31 ILM 874 (Rio Declaration), paras. 26.1-26.9, chapter 26 is titled “Recognizing and strengthening the role of indigenous people and their communities”.

between biological and cultural diversity.²² It has been recognised that the lifestyle and activities of indigenous peoples, far from being damaging, sustain rather positively nature conservation and its biodiversity.²³ Indeed, it has been observed that it is not realistic to protect nature and species by prohibiting any human interference. The solution is a compromise between human welfare and nature preservation. The concept of “sustainable development” represents this compromise. Traditional lifestyles became a key element of this concept, as they developed and adapted to the surrounding environment. Among the legal instruments presented for signature at the Rio Conference was the Convention on the Biological Diversity (CBD).²⁴ As is widely known, the three core objectives of the Convention are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilisation of genetic resources.²⁵ Furthermore, the CBD is the first international binding instrument on biological resources that links the conservation of biodiversity with its use and recognises the importance of traditional knowledge. However, the Convention is often subject to scepticism and circumspection mainly because it promotes the commercialisation of biological resources. The regime of genetic resources prior to the CBD was characterised as one of common property, thus essentially of freedom of access and reasonable exploitation.²⁶ Hence, there has been a major change from a system favouring free exchanges to a system that privileges sovereign appropriation by States and private appropriation through intellectual property rights.²⁷ Indeed, the Convention’s goals are not limited to the conservation of biological diversity and the sustainable use of biological resources. It further embraces issues such as

²² POSEY, “Biological and Cultural Diversity: The Inextricable, Linked by Language and Politics”, 2001, p. 382.

²³ LAIRD et al., “The Interweave of People and Place: Biocultural Diversity in Migrant and Indigenous Livelihoods around Mount Cameroon”, 2011, p. 288 (the author stresses that “[i]n many areas, these [traditional knowledge] systems have been shown to actually enhance rather than reduce biological diversity, and although it was not the subject of this study, seasonal and highly varied diets and traditional medicinal plant use would also appear to support local health and nutrition”)

²⁴ Convention on Biological Diversity, adopted 5 June 1992, 1760 UNTS 79 (Convention on Biodiversity or CBD).

²⁵ CBD, Article 1.

²⁶ THOMAS, “Biodiversité, biotechnologies et savoirs traditionnels. Du patrimoine commun de l’humanité aux ABS”, 2006, p. 835.

²⁷ CULLET, *Intellectual Property Protection and Sustainable Development*, 2005, p. 2.

access to genetic resources, sharing of benefits from the use of genetic material and access to technology and biotechnology.²⁸

Nowadays, the development of new organisms through modification of life forms constitutes the basis of modern biotechnology. Intellectual property rights and specifically patents constitute the instrument of protection sought for these types of inventions. The raw materials for these biotechnological developments are genetic resources. Successful research and development on this raw material will eventually lead to a myriad of biotechnological applications in a variety of sectors such as pharmaceuticals, foodstuffs and agriculture. This search for potentially valuable biological resources, mostly located in the tropical and subtropical regions of the world,²⁹ is often referred to as bioprospecting. One of the most straightforward means to target a valuable genetic resource in terms of its therapeutic utility is through traditional medicinal knowledge. As a matter of fact, the traditional knowledge associated with a biological resource is an intangible part of the resource itself and has the potential of being commercially exploited by providing valuable research direction for the development of useful products.³⁰ Thus, one can assume that knowledge of the medicinal properties of a plant will save time, money and investment of biotech firms in their research and development of new drugs.³¹ Some biotechnological innovations, particularly in the sector of drug discovery, already draw substantial value from this knowledge.³² Indeed, as demonstrated by biochemist Norman Farnsworth, it is estimated that of “the 119 plant-based extracts used in drugs worldwide, over 74 percent were discovered by chemists attempting to identify the chemical substances in plants used in traditional medicine”.³³ In turn, the strengthening of intellectual property protection all over the world can be attributed in part to

²⁸ GLOWKA, “A Guide to the Convention on Biological Diversity”, p. 1.

²⁹ GLOWKA, “A Guide to the Convention on Biological Diversity”, p. 1.

³⁰ TAUBMAN and LEISTNER, “Analysis of different areas of indigenous resources”, 2008, p.62.

³¹ POSEY, DUTFIELD, et al., *Traditional Resource Rights: International Instruments for Protection and Compensation for Indigenous Peoples and Local Communities*, 1996, p. 14.

³² DUTFIELD, “A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-Bases Biopiracy”, 2011, p. 238 (the author notes “the continued relevance of traditional knowledge at a time when the industry is broadening its range of drug discovery strategies in the face of a persisting failure to increase the rate of developing new molecular entities, which includes taking an intensified interest in natural products”).

³³ FARNSWORTH, “Medicinal Plants in Therapy”, 1985, p. 967.

the increasing reliance by developed countries on knowledge-based economies,³⁴ including the rapid evolution of the genetic engineering industry. It is not surprising that some branches of industry have increased their research efforts on these complex systems of traditional knowledge. For instance, in the case of ethnobotanical knowledge,³⁵ pharmaceutical, chemical and other relevant industries have increased their efforts to gain intellectual property rights, mainly patents, through exploration primarily in biodiversity-rich but often economically-poor countries.³⁶ In other words, the knowledge accumulated by indigenous peoples and local communities over generations is serving as low-cost or even free inputs into the proprietary industrial information production process. This also enables users of traditional knowledge to claim protection, such as patents on "purified" natural substances, by using expensive technology usually not available in developing states.³⁷

Thus, the concerns related to the protection of these knowledge systems have to be partly found in their relationship with intellectual property rights and it can be summarised as follows. First, intellectual property rights might adversely affect traditional knowledge and particularly the holders of this knowledge, when elements of the knowledge are extracted and used by third parties beyond its traditional context, often referred to as "misappropriation of traditional knowledge". Others do not hesitate to call it "biopiracy"- a term that is politically and emotionally charged but that has not yet received a defined meaning in the context of neither intellectual property rights nor property rights.³⁸ Second, intellectual property rights have received extensive attention as a mean for the protection of some aspects of traditional knowledge. However, the initial impulse has been to protect traditional knowledge from intellectual property rights rather than through intellectual property rights. Third, at the other end of the spectrum of protection proposed for traditional knowledge, there is the issue of protecting intellectual property rights in traditional knowledge development.

³⁴ CULLET Philippe, *Intellectual Property Protection and Sustainable Development*, 2005, p. 9.

³⁵ BALICK Michael, "Ethnobotany and the Identification of Therapeutic Agents from the Rainforest", 1990, p. 25 ("this approach employs local people's knowledge about the medicinal uses of the plant and their environment").

³⁶ POSEY and DUTFIELD, *Beyond Intellectual Property – Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*, 1996, p. 53.

³⁷ BRADFORD, "Intellectual Property and Traditional Knowledge", 2005, p. 1618.

³⁸ The Oxford Dictionary of Biomedicine, online version, 2015: "The term biopiracy has been used when local inhabitants are not rewarded" [accessed August 2016]; See generally ROBINSON, *Confronting Biopiracy – Challenges, Cases and International Debates*, 2010.

However, the impetus for the protection of traditional knowledge cannot be solely reduced to mitigating the *undue utilisation* of traditional knowledge in patentable subject matter or elsewhere. Indeed, a wider concern relates to the very preservation of the distinctive cultural identity of communities and their survival as such.³⁹ Preservation concerns are fundamentally linked to an interest in preserving the world's cultural diversity. Globalisation progressively, but surely puts at risk the community cultural heritage of indigenous peoples and local communities that are recognised as being part of humanity's cultural heritage.⁴⁰ Thus, the value of traditional knowledge in the advancement and improvement of science is undeniable and its erosion should be regarded as a common concern of mankind. In the same manner, traditional knowledge of indigenous peoples and local communities related to their environmental resources are acknowledged to play an essential role in the conservation of biodiversity and its sustainable use.⁴¹ Both cultural diversity and biological diversity are, thus, common concerns of mankind. However, what about the interests of the generators and custodians of traditional knowledge? This is where the discourse on the protection of traditional knowledge takes all its sense. In order to refine the diverse discourse around the concerns, needs and expectations of traditional knowledge holders, this work should be confined to the legal issues surrounding the protection of traditional knowledge. Legally speaking, concerns have been expressed on the relationship between intellectual property and traditional knowledge within the full context of the law of human rights, environmental protection and related ethical issues.

Generally speaking, "intellectual property" refers to any creations of the mind. When these creations of the human mind are recognised to possess a potential commercial value, they are vested with ownership rights.⁴² According to this principle and assuming that traditional knowledge does potentially have a commercial value one may assume that it might be

³⁹ Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, 'Discrimination against indigenous peoples - Report of the Working Group on Indigenous Populations on its ninth session, by Special Rapporteur Erica-Irene Daes, 3 October 1991, UN Doc E/CN.4/Sub.2/1991/40/Rev.1, para. 50, p. 31.

⁴⁰ See UNESCO Universal Declaration 2001 and UNESCO Convention 2003; see also PARDO-DE-SANTAYANA and MACIA, "Biodiversity: The Benefits of Traditional Knowledge", 2015, pp. 487-488.

⁴¹ CBD, Article 8(j).

⁴² CORNISH, LLEWELYN & ALPIN, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 2013, para. 1-04, p. 6; CULLET et al., "Intellectual property rights, plant genetic resources and traditional knowledge", 2006, p. 112.

protected through intellectual property rights. Notwithstanding this assumption, intellectual property protection is extremely well developed in certain areas while others have been largely left aside, such as traditional knowledge. This is due to the fact that developed countries, in general, ensured the adaptability of the intellectual property system to the different stages of their economic and technological development before the adoption of the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter, TRIPS Agreement or TRIPS).⁴³ On the other side, developing countries did not have this possibility. Thus, the latter are bound to apply the minimum standards of protection that are often deemed to be more suitable for advanced levels of economic development. In other words, the current system of intellectual property rights is characterised by the fact that only inventions in the most advanced fields of technology or commercially useful knowledge are protected whereas other areas have been left vulnerable, such as traditional knowledge.⁴⁴ This dichotomy between protectable knowledge and non-protectable knowledge finds its clearest expression in the discussion concerning the concept of public domain.⁴⁵ This contrast can be illustrated by means of two concrete situations: when a new drug is made on the basis of a previously existing patented invention and when a new drug is made on the basis of a previously existing traditional discovery that does not benefit from the patent protection because it is deemed to be in the public domain.

Many scholars consider that the protection of traditional knowledge is a question of equity, if the use of traditional knowledge enables third parties' users to profit in a commercial sense. However, there is a great controversy as to the means of protecting the holders of this knowledge. Diverse approaches have been proposed. Part III will analyse some of them in greater details.

⁴³ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1 C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125, 1197 (1994) (TRIPS Agreement or TRIPS).

⁴⁴ DUTFIELD, "The public and private domains – Intellectual property rights in traditional knowledge", 2000, p. 288; CHANDER and SUNDER, "The Romance of the Public Domain", 2004, p. 1331.

⁴⁵ Berne Convention for the Protection of Literary and Artistic Works, opened for signature Sept. 9, 1886, revised at Paris in 1979, 828 UNTS 221, Article 18(1); See also, WIPO IGC, 'Note on the Meaning of the Term "Public Domain" in the Intellectual Property System with Special Reference to the Protection of Traditional Knowledge and Traditional Cultural Expressions/Expressions of Folklore', 6-10 December 2010, WIPO/GRTKF/IC/17/INF/8.

Before moving onto a legal analysis of the issues surrounding the protection of traditional medicinal knowledge and its inherent linkage to intellectual property rights (IPRs) in, Part I, Chapter One, will first examine the diverse concepts and distinctive characteristics of traditional knowledge, generally, and traditional medicinal knowledge, specifically. The second chapter will give an overview of the important role traditional medicinal knowledge has played, and continues to play, as of today, in the drug industry. The third chapter will then turn to an analysis of a selection of international treaties and frameworks where the discussion on the protection of traditional knowledge takes place.

Once the concepts and the sources have been settled, Part II will get to the heart of the issue that is the subject matter of this thesis. The analysis will address the legal gaps that result in the protection of traditional medicinal knowledge when it meets the patent system. The first chapter of Part II will illustrate this point of convergence by analysing a selection of case studies, which will shed a light on the imbalance between both systems of knowledge. The second chapter's objective will be to demonstrate how traditional medicinal knowledge can be quite easily incorporated in inventions that are later granted patents. For this, the chapter will endeavour to conduct an in-depth legal analysis of the conditions of patentability. The theoretical study will be backed up by examples of case law in Europe and in the United States. Finally, Chapter Three of this second part will examine the concept of public domain and its implications for traditional medicinal knowledge.

Once the legal problem have been identified, Part III, Chapters One and Two will present the latest draft articles on a *sui generis* system of protection of traditional knowledge that are being currently negotiated within the World Intellectual Property Organisation. The analysis will focus upon the very first provisions of the Draft, as they constitute the central thread of the negotiations. These concern the subject matter of protection, the beneficiaries of protection and the scope of protection of the international instrument. Finally, the last chapter will present the main proposals for additional measures that are currently being discussed in WIPO. These concern, first, the compilation and recording of traditional knowledge in databases and, second, the requirement from the patent applicant to disclose the origin and/or source of traditional knowledge. While the first proposal is a purely defensive approach, the second proposal may include positive rights for the beneficiaries or holders of traditional knowledge.

Finally, the reason why I have chosen to focus my analysis on traditional medicinal knowledge rather than traditional knowledge in general resides in practical or pragmatic considerations. As we will see the definition of traditional knowledge is not an easy task, if at all possible. In addition, traditional knowledge may cover many different sectors of activities. For the purpose of this research, the focus is mainly upon the medicinal component of traditional knowledge, given its contribution to useful products in the pharmaceutical industry, namely drugs, as well as its importance in other industries, including the cosmetic and food sectors.

At this point, it is equally important to state that resorting to categorisation, for utility purposes, does not equate to a statement in favour or not of a categorisation of traditional knowledge in the sense of its legal protection.

PART I CONCEPTUAL AND LEGAL ISSUES RELATED TO TRADITIONAL MEDICINAL KNOWLEDGE

Chapter 1 Terms and Definitions – Areas of Uncertainty

1 Traditional Knowledge and Related Terms

From the emergence of the concept of traditional knowledge (TK) in the international framework in 1980s, neither the international institutions or organisations nor the authors dealing with the issue of TK have agreed upon a commonly settled definition. The reasons for this are diverse and some of them are explained below.

The challenge of defining and understanding TK starts with the difficult task of settling on how it should be named. In the relevant literature, different formulations (idiomatic expressions) are used interchangeably depending on the context, including but not limited to traditional knowledge, traditional ecological knowledge (TEK), local knowledge and indigenous knowledge. Each of these terms presents significant normative and policy implications, whether used in sociological, anthropological, historical or legal terms, and there is no consensus as which one is the most appropriate.

This terminological diversity is based on the fact that the discussions related to the issue of traditional knowledge can be found in a wide variety of disciplines ranging from food, agriculture, medicinal remedies or biotech innovation, biological diversity to human rights or trade and development. It can also arise as an issue in traditional forms of dispute-settlement resolution and methods of governance. As such the concept of traditional knowledge will accordingly be shaped by the context in which it arises. Therefore, terms might be used for the same or overlapping subjects but, equally, the choice of terminology might result from or denote a more political or ideological objective. In other words, the terminological pluralism essentially stems from the fact that the working concepts of traditional knowledge in each forum tend to be in accordance with the policy framework and objectives of that forum.⁴⁶

⁴⁶ TAUBMAN and LEISTNER, “Analysis of different areas of indigenous resources”, 2008, p. 72.

There is also a conceptual difficulty arising when we try to define this concept by defining each term in turn. Traditional knowledge is extremely ambiguous and vague since the words composing the concept of TK are themselves vague and ambiguous. According to the Concise Oxford Dictionary,⁴⁷ traditional refers to the concept of cultural continuity transmitted over a long period of time and derived from experience. Because societies continuously adapt themselves by adopting new practices and know-how, it makes it difficult to define to what extent these changes affect the cataloguing of a practice as traditional. Furthermore, “traditional” may have a negative connotation if by traditional it is meant non-modern, non-scientific or non-Western.

As far as the concept of knowledge is concerned, it is a contested one. Indeed, a whole branch of philosophy, epistemology, is dedicated to the definition of knowledge. The Black’s Law Dictionary defines knowledge as “An awareness or understanding of a fact or circumstance; a state of mind in which a person has no substantial doubt about the existence of a fact.”⁴⁸

The Cambridge Dictionary provides the following definition of knowledge: “understanding of or information about a subject which a person gets by experience or study, and which is either in a person’s mind or known by people generally.”⁴⁹

Thus, it can be deduced that TK might refer to the understanding of facts and circumstances derived from experience, which takes place over a long period of time. This does not really help to grasp the inherent conceptual meaning of TK, because it can broadly refer to all kinds of knowledge. However, it is at this point that the link between the concepts of traditional knowledge and intellectual property can be made. Broadly speaking, the concept of “intellectual property” refers to any creation of the mind, such as knowledge, information, know-how, concepts or ideas. In turn, intellectual property rights are the legal rights conferred to the owners of the intellectual property to exclude others from using them. In that sense, traditional knowledge should easily and logically be viewed as an intellectual property, but without rights conferred to its owners.

⁴⁷ Concise Oxford Dictionary, 8th edition, 2004.

⁴⁸ Black’s Law Dictionary, 9th edition, 2009.

⁴⁹ Cambridge Dictionary Online Version available at:
<http://dictionary.cambridge.org/dictionary/british/knowledge>, [accessed September 2016].

The following sections will provide an updated overview of the various expressions used in the literature and other relevant fora. Subsequently, the various concepts related to the issue of traditional knowledge will be discussed. This endeavour will help extract the essence of what is meant by traditional knowledge, and consequently what is intended to be protected. Eventually, a few analytical distinctions have to be made in order to delineate the subject matter of the underlying work that is traditional medicinal knowledge.

1.1 Terminological Pluralism and Definitions

Traditional knowledge encompasses an extraordinary broad range of subject matters and of policy fields – such as medicinal remedies and practices, biodiversity-related knowledge and agricultural knowledge related to plant genetic resources for food and agriculture. Berkes proposes to define traditional ecological knowledge (TEK) broadly enough to encompass not purely ecology as defined narrowly as a branch of biology in the domain of “Western”⁵⁰ science, but also the knowledge acquired in the interaction of living beings with one another and with their surrounding environment. Thus, he defines TEK as “a cumulative body of knowledge and beliefs, handed down through generation by cultural transmission, about the relationship of living beings (including humans) with one another and with their environment. Further, TEK is an attribute of societies with historical continuity in resource use practices; by and large, these are not industrial or less technologically advanced societies, many of them indigenous or tribal”.⁵¹

Along the same lines, the Canadian anthropologist Martha Johnson has opted for the term traditional environmental knowledge and defines it “as a body of knowledge built by a group of people through generations living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment, and a system of self-management that governs resource use”.⁵²

⁵⁰ KURTH, “Western Civilization, our tradition”, pp. 5-6 (for the author, the concept “western” refers to common values shared by European and Anglo-American countries, including the classical culture of Greece and Rome, Western Christianity, and the Enlightenment of the modern era).

⁵¹ BERKES, “Traditional Ecological Knowledge in Perspective”, 1993, p. 3.

⁵² JOHNSON, *LORE: Capturing Traditional Ecological Knowledge*, 1992, p. 3.

Others have opted to avoid this terminology and have rather opted for the term “indigenous knowledge.”⁵³ However, this choice shifts the problem to another level that poses definitional dilemma of its own. The advantage of this terminological option resides in the fact that it explicitly targets the group of peoples most concerned, i.e. indigenous peoples as stated in the Universal Declaration of Indigenous Peoples Rights (UNDRIP).⁵⁴ However, there is still no consensus as to who is indigenous and who is excluded from this category. The term indigenous is very much related to the colonial history of the country in question. For instance, this term is inappropriate to the realities of the Asian and African continents, where all peoples are considered to be native but with diverse ethnicities.

For some of the reasons identified above, the expression local knowledge is often preferred. It has the advantage of not excluding the non-indigenous communities, also called local communities, encompassing farmers, fishers or health practitioners whose knowledge is also the result of the development of a deep understanding and practice transmitted through generations. Again, this term despite this advantage has the disadvantage of being a very broad and blurred term, as most knowledge can be tagged as local.

On the other hand, some authors define traditional knowledge according to considerations related to specific policy objectives, such as the susceptibility of the relevant subject matter to commercial utilisation and the protection of it through intellectual property rights. Accordingly, Cottier opts for the term “Traditional Intellectual Property Rights” and defines it as “the ways and means by which individuals or communities identify and improve genetic resources over time, including processes related to their extraction from nature and their preparation for human usage. Also implicated by the term are methods and techniques for preserving the communities’ accumulated information about genetic resources for future generation”.⁵⁵

Similarly, in international fora no terminological uniformity has been decided on, let alone a consensus concerning the definition of traditional knowledge. For instance, the issue of traditional knowledge, in the sense of cultural heritage, is addressed by the United Nations

⁵³ TAUBMAN and LEISTNER, “Analysis of different areas of indigenous resources”, 2008, p. 79.

⁵⁴ United Nations Declaration on the Rights of Indigenous Peoples, Resolution 61/295 adopted by the UN GA Res., 61st session, 13 September 2007, UN Doc. A/RES/61/295 (UNDRIP).

⁵⁵ COTTIER and PANIZZON, “Legal perspectives on traditional knowledge: The case for intellectual property protection”, 2005, p. 566.

Educational, Scientific and cultural Organisation (UNESCO).⁵⁶ With respect to intellectual property rights and the protection of traditional knowledge, the World Intellectual Property Organisation (WIPO) is extensively dealing with the issue. From the perspective of health and traditional medicine, traditional medicinal knowledge is dealt by the World Health Organisation (WHO).⁵⁷ In this last case, traditional knowledge subject matter is limited according to health policy goals.

The Convention on Biological Diversity (Convention on Biodiversity or CBD), in turn, refers to traditional knowledge in the context of conservation and sustainable use of biological diversity.⁵⁸ Art. 8(j) of the CBD refers to traditional knowledge as “the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity [...]”.⁵⁹

According to this definition, the scope of traditional knowledge covered by the CBD is solely confined to the conservation and sustainable use of biological diversity. The newly adopted Nagoya Protocol to the CBD additionally refers to “traditional knowledge associated with genetic resources” without providing a definition for it.⁶⁰ It only requires that traditional knowledge be associated with genetic resources.

⁵⁶ WIPO IGC, ‘Report of the First ICG Session, 30 April- 3 May 2001, WIPO/GRTKF/IC/1/13, para. 73, p. 51 (The Representative of UNESCO stated that “UNESCO was closely involved in identifying, preserving and promoting this cultural heritage”).

⁵⁷ WIPO IGC, ‘Report of the First ICG Session, 30 April- 3 May 2001, WIPO/GRTKF/IC/1/13, para. 72, p. 50 (“The Representative WHO referred to the increased worldwide interest in the health and economic development aspects of traditional medicine and recognition of its potential value to trade giving rise to the need to protect it and to secure fair and equitable sharing of any benefits derived from it. [...] Several recommendations were made including the need to formulate a national policy on traditional medicine as part of the national health policy of countries”).

⁵⁸ Convention on Biological Diversity, adopted 5 June 1992, 1760 UNTS 79 (Convention on Biodiversity or CBD), Article 8(j), Preamble.

⁵⁹ CBD, Article 8(j); see also CBD, ‘Traditional Knowledge and Biological Diversity’, Madrid, 24-28 November 1997, UNEP/CBD/TKBD/1/2, p. 2.

⁶⁰ The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity, Decision adopted by the COP at its tenth meeting, Nagoya, 29 October 2010, UNEP/CBD/COP/DEC/X/1 (Nagoya Protocol), Preamble 20-24 and Article 5 bis.

Given the enormous range of subject matters that could potentially be embraced by the term traditional knowledge, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO IGC on IPGRTKF or IGC in order to better target the scope of the subject matter with regard to the application of intellectual property protection, has suggested that traditional knowledge be understood as “technical traditional knowledge”.⁶¹ The working definition “technical traditional knowledge” provided by the IGC includes the kinds of traditional knowledge, innovations and practices referred to in the Convention on Biological Diversity.⁶²

The practice of the WIPO IGC’s secretariat of distinguishing traditional knowledge in a descriptive broader concept (*lato sensu*) from traditional knowledge in a narrow legal and policy sense (*stricto sensu*) has gathered considerable support.⁶³ A broad description of traditional knowledge embraces the content of knowledge itself as well as the traditional cultural expressions (songs, rituals, dances, handicrafts, etc.),⁶⁴ including distinctive signs and symbols associated with it. In other words, it embraces the intangible cultural heritage,⁶⁵ practices and the knowledge systems of traditional communities, whether indigenous or not.⁶⁶

In contrast traditional knowledge in a narrow sense refers to “knowledge as such”, that is the content or substance of knowledge resulting from intellectual activity in a traditional context, the know-how, skills, innovations, practices and learning that form part of traditional

⁶¹ WIPO IGC, ‘Operational Terms and Definitions’, 13-21 June 2002, WIPO/GRTKF/IC/3/9.

⁶² Art. 8 (j) CBD ; See Extracts covering the evolution of the issue of definitions within the *sui generis* agenda item from the working group on article 8(j) and related provisions, Note by the Executive Secretary, UNEP/CBD/WG8j/7/INF/1/Add.1, 6 July 2011, p. 5.

⁶³ TAUBMAN and LEISTNER, “Analysis of different areas of indigenous resources”, 2008, p. 69.

⁶⁴ WIPO IGC, ‘The Protection of Traditional Cultural Expressions: Draft Gap Analysis’, 13-17 October 2008, WIPO/GRTKF/IC/13/4(b) Rev.

⁶⁵ UNESCO Convention 2003, Article 2 defines “intangible cultural heritage” as “the practices, representations, expressions, knowledge, skills – as well as the instruments, objects, artefacts and cultural spaces associated therewith – that communities, groups and, in some cases, individuals recognize as part of their cultural heritage. This intangible cultural heritage, transmitted from generation to generation, is constantly recreated by communities and groups in response to their environment, their interaction with nature and their history, and provides them with a sense of identity and continuity, thus promoting respect for cultural diversity and human creativity”).

⁶⁶ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Gap Analysis’, 13-17 October 2008, WIPO/GRTKF/IC/13/5(b) Rev, para. 67, p. 23.

knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources”.⁶⁷

By making this distinction, the WIPO Secretariat has broken the holistic working concept of traditional knowledge as articulated by indigenous communities themselves.⁶⁸ WIPO has justified this categorisation because it appears to have conceptual and practical advantages in defining the subject matter of traditional knowledge suitable for legal protection. WIPO’s approach essentially relates to the legal protection of traditional knowledge by means of intellectual property rights.⁶⁹ Furthermore, it makes a distinction between traditional knowledge “as such” and traditional knowledge-based innovations and creations. This distinction is especially relevant for the protection of traditional knowledge, from an intellectual property perspective, as traditional knowledge-based innovations and creations can refer to innovations and creations based on traditional knowledge beyond a traditional context.⁷⁰ The subsequent innovators may be indigenous and local communities, or certain members thereof, but they can also be third parties beyond such communities.

This section has shown that neither the scholars nor the specialised fora dealing with the subject matter of traditional knowledge have succeeded in reaching a unanimous definition of traditional knowledge. The next paragraphs will try to narrow the broad concept of traditional knowledge to only target the traditional knowledge related to the therapeutic properties of plants.

⁶⁷ WIPO IGC, ‘Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions’, 19-23 September 2016, WIPO/GRTKF/IC/31/INF/7, p. 40; see also WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Gap Analysis’, 13-17 October 2008, WIPO/GRTKF/IC/13/5(b) Rev., para. 67, p. 23.

⁶⁸ JOHNSON, *Capturing Traditional Ecological Knowledge*, 1992, p. 5 (Amongst the characteristics of TK, the author cites that it is holistic rather than reductionist, intuitive rather than analytical. “For TEK, all elements of matter are viewed as interconnected and cannot be understood in isolation”).

⁶⁹ WIPO IGC, ‘Traditional Knowledge – Operational Terms and Definitions’, 13-21 June 2002, WIPO/GRTKF/IC/3/9, p. 2.

⁷⁰ WIPO IGC, ‘List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found’, 6-10 December 2010, WIPO/GRTKF/IC/17/INF/9, p. 12.

1.2 Definition of Traditional Medicinal Knowledge and Related Concepts

Traditional medicinal knowledge (TMK) is a subset of traditional knowledge. It includes a diversity of health practices, approaches, knowledge and beliefs incorporating plants, animals and minerals-based medicines. Traditional medicinal knowledge can be broadly divided in two branches: medication based therapies and non-medication based therapies.⁷¹

Medication based therapies mainly involve the use of herbal material (or medicinal plants), but may also involve use of other living and non-living organisms such as animals and minerals. The traditional use of herbal medicines encompasses herbs,⁷² herbal materials,⁷³ herbal preparations,⁷⁴ and finished herbal products⁷⁵ that contain as active ingredients⁷⁶ parts

⁷¹ See generally, CORREA, *Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries*, 2002; see also LI and LI, “Inadequacy of patent regime on traditional medicinal knowledge – A diagnosis of 13-year traditional medicinal knowledge patent experience in China”, 2007, p. 129.

⁷² WHO, ‘General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine’, 2000, WHO/EDM/TRM/2000.1, p. 3 (“Herbs” is defined to “crude plant material such as leaves, flowers, fruits, seed, stems, wood, bark, roots, rhizomes or other plants parts, which may be entire, fragmented or powdered”).

⁷³ WHO, ‘General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine’, 2000, WHO/EDM/TRM/2000.1, p. 3 (“Herbal materials include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting, or stir-baking with honey, alcoholic beverages or other materials”).

⁷⁴ WHO, ‘General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine’, 2000, WHO/EDM/TRM/2000.1, p. 3 (“Herbal preparations are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials”).

⁷⁵ WHO, ‘General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine’, 2000, WHO/EDM/TRM/2000.1, pp. 3-4 (“Finished herbal products consist of herbal preparations made from one or more herbs. If more than one herb is used, the term mixture herbal product can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal”).

of plants, or other plant materials, or combinations thereof”.⁷⁷ Traditional knowledge of the therapeutic activity⁷⁸ of plant is thus encompassed in traditional knowledge defined in the strict sense by the IGC. As mentioned earlier, the term traditional knowledge *stricto sensu* is defined by the WIPO Secretariat as “the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes know-how, skills, innovations, practices and traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any technical field”.⁷⁹

The second branch involves all therapies that do not entail the use of medication, as in the case of acupuncture, manual therapies and other techniques to maintain well-being as well as to treat, diagnose and prevent illnesses. Furthermore, this branch encompasses less technical approaches such as spiritual therapies. Examples that are familiar and often termed as complementary or alternative medicine include acupuncture, yoga, naturopathy, aroma therapy or tai xi, and other physical, mental, spiritual and mind-body therapies.⁸⁰

Specific to the role of traditional medicine in health care systems has been the work of the World Health Organisation (WHO), to which WIPO refers in its glossary of terms, which has defined traditional medicine as “the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not,

⁷⁶ WHO, ‘General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine’, 2000, WHO/EDM/TRM/2000.1, p. 4 (“Active ingredients refer to ingredients of herbal medicines with therapeutic activity. In herbal medicines where the active ingredients have been identified, the preparation of these medicines should be standardized to contain a defined amount of the active ingredients, if adequate analytical methods are available. In cases where it is not possible to identify the active ingredients, the whole herbal medicine may be considered as one active ingredient”).

⁷⁷ WHO, ‘General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine’, 2000, WHO/EDM/TRM/2000.1, p. 4.

⁷⁸ WHO, ‘General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine’, 2000, WHO/EDM/TRM/2000.1, p. 4 (“therapeutic activity refers to the successful prevention, diagnosis and treatment of physical and mental illness; improvement of symptoms of illnesses; as well as beneficial alteration or regulation of the physical and mental status of the body”).

⁷⁹ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Gap Analysis’, 13-17 October 2008, WIPO/GRTFK/IC/13/5(b) Rev., p. 4.

⁸⁰ CORREA, *Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries*, 2002, p. 9.

used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illness.”⁸¹ In summary, WHO specifically refers to the medical role of this knowledge that is indigenous to different cultures. In this sense, it can be argued that “indigenous” may equate to the concept of “traditional”.

Even though the WHO considers that a precise and concise definition of TMK is not conceivable at this stage, it admits that a working definition would be useful if it is comprehensive and inclusive. Thus, the organisation defines TMK as including “diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness”.⁸²

According to Carlos Correa, “TMK includes materials, processes and methods of treatment, individually or collectively held, constituted by old and recently developed knowledge, largely but not totally disclosed and capable of generating commercial value at different points of the value added chain. Most importantly, TMK has “great value in many developing countries where it plays a crucial role in health care systems.”⁸³ According to this definition, TMK relates to both products and processes. In this definition, the author captures the most essential features of TMK common to most traditional medicinal systems and different cultures.

A significant part of TMK relates to the properties of natural materials used in their wild form, or as a part of preparation or mixture. This is concerned mainly with “traditional” knowledge related to plants for medicinal purposes often referred to as indigenous ethno-biological knowledge, traditional knowledge of plant-based therapy,⁸⁴ or traditional pharmacopoeia.⁸⁵ It is also referred to as the ethnobotanical approach to drug discovery and it

⁸¹ WHO, ‘WHO Traditional Medicine Strategy 2014-2023’, 2013, p. 15; see also, WIPO IGC, ‘Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions’, 19-23 September 2016, WIPO/GRTKF/IC/31/INF/7, p. 41.

⁸² WHO, ‘WHO Traditional Medicine Strategy 2014-2023’, 2013, p. 15.

⁸³ CORREA, *Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries*, 2002, p. 108.

⁸⁴ OGUAMANAM, *International Law and Indigenous Knowledge*, 2006, p. 28.

⁸⁵ BARSH, “The Epistemology of Traditional Healing Systems”, 1997, p. 28.

covers the use of people’s knowledge and experiences of the medicinal properties of plants and other genetic resources to guide drug discovery.⁸⁶ In other words, it focuses on the knowledge related to plant genetic resources for medicinal purposes as opposed, firstly, to therapies and methods or ceremonies of therapies and, secondly, to agriculture or food. Although, herbal products are considered to be part of traditional medicine in most developing countries, they are often classified as foodstuffs in the Western legal traditions.⁸⁷

Throughout this work, traditional medicinal knowledge will solely refer to the traditional knowledge of the therapeutic properties of plants. Furthermore, the terms “traditional medicinal knowledge,” “plant-based traditional knowledge” and “traditional pharmacopoeia” will be used in an interchangeable way. This taxonomic understanding of traditional knowledge has a purpose oriented objective. Such categorisation is criticised by some authors.⁸⁸ These divisions and categorisations are mainly done for practical reasons and in reality, a traditional medicinal therapist will use them interdependently.

Finally, the term “traditional knowledge associated with genetic resources”, as it is used in the CBD, Nagoya Protocol and WIPO framework, will be analysed in Chapter 3 of this Part. Broadly speaking, traditional knowledge associated with genetic resources is a sub-category of traditional knowledge that encompasses plant-based traditional knowledge.

1.3 Indigenous Peoples’ Knowledge

As previously mentioned in the Introduction, some authors prefer the term indigenous knowledge to traditional knowledge because it places the importance on the people or group of peoples possessing, creating and wishing to protect traditional knowledge. In addition, determining who pursues the protection of traditional knowledge helps to grasp what traditional knowledge is and the scope of protection that is sought.⁸⁹ This means that the choice of terms for the subject of protection exceeds the nature of the knowledge itself, which shall include the cultural and the legal identity of the community. In other words, this

⁸⁶ BALICK Michael, “Ethnobotany and the Identification of Therapeutic Agents from the Rainforest”, 1990, p. 25.

⁸⁷ ETKIN and ROSS, “Recasting Malaria, Medicine, and Meals: A perspective on Disease Adaptation”, 199, p. 230.

⁸⁸ See, for example, GIBSON, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, 2005, pp. 26 and 187.

⁸⁹ FRANKEL and GERVAIS, *Advanced Introduction to International Intellectual Property*, 2016, p. 121.

terminological option focuses upon the highly sensitive issues related to the legal recognition of indigenous peoples under international law including the self-determination rhetoric that has been the subject of considerable debates well beyond the issue of traditional knowledge protection. It is undeniable that the definition and the scope of traditional knowledge will fluctuate according to the identity of the community that holds the knowledge. Similarly, the use of the terms traditional knowledge, indigenous knowledge, or indigenous and local communities' knowledge will vary according to the fora that use them.

While the expression "indigenous and local communities" is used in environmental context,⁹⁰ the terms "indigenous peoples", which specifically refer to the subjects protected by international human rights instruments is used in human rights' institutions.⁹¹ On the other hand, WIPO and WTO preferably use the term traditional knowledge without necessarily making reference or difference between the terms indigenous peoples or local communities as holders.

There are still on-going policy debates in various international fora as to the question, whether or not to limit the scope of protection of traditional knowledge to the communities identified as indigenous or not. This brings us to a further fundamental question which is what distinguishes a people as "indigenous".⁹²

Although defining "indigenous peoples" has proven difficult, some scholars and international organisations have ventured into this task. At the United Nations, a first attempt was made by the United Nations Special Rapporteur Martinez Cobo in 1982.⁹³ According to this definition,

⁹⁰ Namely in the CBD and the NP.

⁹¹ See UN ECOSOC, Permanent Forum on Indigenous Issues, 'Report on the Ninth Session', 19-30 April 2010, UN Doc. E/2010/43-E/C.19/2010/15, para. 112, p. 18 (The UNPFII calls upon the parties to the CBD to adopt the more human rights-oriented terminology "indigenous peoples and local communities"); see also MEYER, "International Environmental Law and Human Rights: Towards the Explicit Recognition of Traditional Knowledge", p. 38.

⁹² Commission on Human Rights, 'Study of the Problem of Discrimination Against Indigenous Populations', Special Rapporteur José Martínez Cobo, 1986, vol. II, UN Doc E/CN. 4/Sub.2/1986/7/Add.1, Chapter 5, p. 3 (On the definition of "indigenous populations", the Rapporteur states that "[t]he basic question is how to determine which groups should be considered as indigenous populations in the various countries covered by the study").

⁹³ See Commission on Human Rights, 'Study of the Problem of Discrimination Against Indigenous Populations', Special Rapporteur José Martínez Cobo, 1986, vol. II, UN Doc E/CN. 4/Sub.2/1986/7/Add.1,

“[i]ndigenous communities, peoples and nations are those which, having a *historical continuity with pre-invasion and pre-colonial societies that developed on their territories*, consider themselves *distinct* from other sectors of the societies now prevailing on those territories, or parts of them. They form at present non-dominant sectors of society and are determined to preserve, develop and transmit to future generations their ancestral territories, and their ethnic identity, as the basis of their continued existence as peoples, in accordance with their own cultural patterns, social institutions and legal system”.⁹⁴ This approach has the disadvantage of rendering conquest and colonisation an almost exclusive criterion for being indigenous. Thus it has been criticised because many indigenous peoples in Africa and Asia are *de facto* excluded.⁹⁵ This is equally the case for Saami people even though they did not suffer from colonial oppression.⁹⁶

A definition of indigenous peoples that has gained wide international acceptance is that of the International Labour Organisation Convention on Indigenous and Tribal Peoples in Independent Countries (ILO 169),⁹⁷ which takes a step further in the definition by embracing all tribal and indigenous peoples “in independent countries who are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonization or the establishment of present State boundaries and who, irrespective of their legal status, retain

pp. 3-70 (the Special Rapporteur listed various criteria, adopted in diverse countries, that help to determine the indigenousness of some groups: (i) Occupation of ancestral lands, or at least of part of them; (ii) Common ancestry with the original occupants of these lands; (iii) Culture in general, or in specific manifestations (such as religion, living under a tribal system, acceptance by the indigenous community, dress, means of livelihood, lifestyle, etc.); (iv) Language (whether used as the only language, as mother-tongue, as the habitual means of communication at home or in the family, or as the main, preferred, habitual, general or normal language); (v) Residence on certain parts of the country, or in certain regions of the world; (vi) legal definitions established by governments).

⁹⁴ Commission on Human Rights, ‘Study of the Problem of Discrimination Against Indigenous Populations – Conclusions, Proposals and Recommendation’, Special Rapporteur José Martínez Cobo, 1986, vol. V, UN Doc E/CN. 4/Sub.2/1986/7/Add.4, para. 379-382, p. 29.

⁹⁵ BRUSH, “Whose knowledge, Whose Genes, Whose Rights?”, 1996, p. 5.

⁹⁶ VAN DEN DRIEST, *Remedial Secession: A Right to External Self-Determination as a Remedy to Serious Injustices?*, 2013, p. 77.

⁹⁷ International Labour Organisation Convention Concerning Indigenous and Tribal Peoples in Independent Countries, Geneva, 27 June 1989, 1650 UNTS 383 (ILO Convention No 169).

some or all of their own social, economic, cultural and political institutions”⁹⁸. This would mean that indigenous should retain some form of autonomy vis-à-vis the nation State. However the reality of State practice differs considerably from this broad definition and the ILO Convention has only received the ratification of twenty-two States, since its promulgation.

The CBD, the Nagoya Protocol and the Convention to Combat Desertification (UNCCD)⁹⁹ refer to the holders of traditional knowledge as being, respectively, “indigenous and local communities”, “local populations” and “local communities”, but do not define them. This way of proceeding considerably enlarges the scope of the holders of traditional knowledge,¹⁰⁰ embracing two types of communities, one being indigenous peoples and the other being local communities. According to Meyer, “it is not the exact nature of the group itself, but the nature of the economic system which is relevant [for local communities]”.¹⁰¹ Indeed “local communities”, in contrast to indigenous groups, identify themselves through their economic mode of subsistence, and encompass the traditional farming communities, peasants, hunters, shamans¹⁰² or rural and nomadic groups. While this might be true, indigenous peoples are those that are usually active within the environmental framework. In the environmental context, a strict distinction between both groups is not yet settled.¹⁰³

By contrast, in the human rights’ framework, there is a distinction between both groups. While the rights of indigenous groups to their traditional knowledge have been recognised

⁹⁸ ILO Convention No 169, Article 1(b).

⁹⁹ United Nations Convention to Combat Desertification in Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa, 14 October 1994, Paris, 1954 UNTS 3 (UNCCD).

¹⁰⁰ WIPO IGC, ‘Traditional Knowledge – Operational Terms and Definitions’, the Secretariat, 20 May 2002, WIPO/GRTKF/IC/3/9, p. 15 (WIPO uses the “term traditional knowledge holder to refer to all persons who create, originate, develop and practice traditional knowledge in a traditional setting and context. Indigenous communities, peoples and nations are traditional knowledge holders, but not all traditional knowledge holders are indigenous”).

¹⁰¹ Meyer, “International Environmental Law and Human Rights: Towards the Explicit Recognition of Traditional Knowledge”, p. 38.

¹⁰² For an in-depth discussion on shamanism, see, NARBY and HUXLEY, *Anthologie du chamanisme – Cinq cents ans sur la piste du savoir*, 2002.

¹⁰³ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, pp. 38-39.

under international human rights law, this is not the case for local communities.¹⁰⁴ However, on a case-by-case analysis, local communities may be granted with those rights that are bestowed upon indigenous groups. This will be the case when local communities share characteristics with indigenous peoples.¹⁰⁵ For instance, holders might be indigenous peoples, local communities whose knowledge is inherently linked to a particular geographical place. However, this has the disadvantage of recognising some rights to a community through the requirement of some connection to a geographical area or place.¹⁰⁶ Setting aside the differences between indigenous peoples and other concepts such as local communities, seeking to define traditional knowledge often implies the following question: How eligible are the relevant communities?

Broadly speaking, we can identify two tendencies. The first tendency is one of a broad definition of indigenous peoples permitting a wide interpretation of who is indigenous. This tendency is by and large preferred by indigenous groups and local communities because it does not exclude any particular group.¹⁰⁷ Thus, the power to determine identity is neither vested in the State nor the individual, but in the community through its representative bodies based on their customary practices.¹⁰⁸ Indeed, a formal definition of indigenous peoples has been rejected by representatives of indigenous organisations¹⁰⁹ preferring a self-identification

¹⁰⁴ MEYER, “International Environmental Law and Human Rights: Towards the Explicit Recognition of Traditional Knowledge”, p. 38.

¹⁰⁵ See Inter-American Court of Human Rights (IACHR), *Saramaka People v. Suriname*, Preliminary Objections, Merits, Reparations, and Costs Judgement of 28 November 2007, Series C No. 172, IACHR 5, para. 80-85 (for instance, the “distinct social, cultural and economic group with a special relationship with its ancestral territory”); for an in-depth analysis of the status of non-indigenous local communities, see generally BESSA, *Traditional Local Communities in International Law*, 2013.

¹⁰⁶ WIPO IGC, ‘Traditional Knowledge – Operational Terms and Definitions’, the Secretariat, 20 May 2002, WIPO/GRTKF/IC/3/9, p. 2

¹⁰⁷ DAES, ‘On the concept of “indigenous people”’, Working Paper by the Chairperson-Rapporteur, 10 July 1996, UN Doc. E/CN.4/Sub.2/AC.4/1996/2, p. 13.

¹⁰⁸ RINGELHEIM, “L’appréhension juridique de l’identité culturelle – Entre autodéfinition et objectivation”, 2013, p. 180.

¹⁰⁹ Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, Report of the Working Group on Indigenous Populations, chairperson-Rapporteur Erica-Irene Daes, 29 July- 2 August 1996, UN Doc. E/CN.4/Sub.2/1996/21, para. 23, p. 13.

approach instead.¹¹⁰ The second tendency favoured by some States is that of a strict definition. Indeed, by adopting the broad definition, States would remove their ability to decide on the existence of indigenous peoples within their territory and the claim of those groups to specific rights granted by international norms.¹¹¹ In this regard, the International Law Association (ILA) has been supportive of a broad definition in order to prevent certain States, while supporting the United Nations Declaration on the Rights of Indigenous Peoples, to claim the inapplicability of the Declaration in their territory in light of the assumed absence of indigenous communities within their borders.¹¹²

For Erica-Irene Daes, the Chairperson-Rapporteur of the UN Working Group on Indigenous Populations, an accurate and inclusive definition capable of encompassing the particularities of indigenous peoples was hardly feasible and not desirable.¹¹³ Thus, instead of offering a definition, Article 33 of the recently adopted United Nations Declaration on the Rights of Indigenous Peoples underlines the importance of self-identification, that indigenous peoples themselves define their own identity as indigenous. This article reads as follows:

“1. Indigenous peoples have the right to determine their own identity or membership in accordance with their customs and traditions. This does not impair the right of indigenous individuals to obtain citizenship of the States in which they live.

2. Indigenous peoples have the right to determine the structures and to select the membership of their institutions in accordance with their own procedures.”¹¹⁴

The right to self-identification is viewed as a direct consequence of the right to self-determination, as provided in Article 3 of the UN Declaration, which reads: “Indigenous peoples have the right to self-determination. By virtue of that right they freely determine their

¹¹⁰ International Law Association (ILA), ‘Rights of Indigenous Peoples’, Interim Report, The Hague Conference, 2010, p. 6; see also ILA, ‘Rights of Indigenous Peoples’, Final Report, The Sofia Conference, 2012, p. 2.

¹¹¹ SCHILLHORN, “Kulturelle Rechte indigener Völker und Umweltvölkerrecht – Verhältnis und Vereinbarkeit”, 2000, p. 25.

¹¹² ILA, ‘Rights of Indigenous Peoples’, Interim Report, The Hague Conference, 2010, p. 7.

¹¹³ DAES, ‘On the concept of “indigenous people”’, Working Paper by the Chairperson-Rapporteur, 10 July 1996, UN Doc. E/CN.4/Sub.2/AC.4/1996/2, p. 21.

¹¹⁴ UNDRIP, Article 33.

political status and freely pursue their economic, social and cultural development.”¹¹⁵ While the UN Declaration is not a binding instrument, it is a reference text of high political and moral authority.¹¹⁶

The “s” on indigenous peoples is significant and has been the subject of tumultuous debate and controversy relating to the right of self-determination.¹¹⁷ Generally speaking, this right allows all “peoples” to freely determine their political status and pursue their economic, social and cultural development. Thus, governments have generally been reluctant to concede on this issue, fearing secession or substantial internal autonomy demands. It has to be noted that the understanding of the term self-determination has changed in the post-colonial era. Nowadays, the emphasis lies on the right of internal self-determination rather than external self-determination, which is related to the very controversial right to an independent statehood.

The International Law Association’s Committee on the Rights of Indigenous Peoples has proposed the following characteristics for determining whether a given traditional community can be considered as an indigenous people:

- “self-identification: self-identification as both indigenous and as people;
- historical continuity: common ancestry and historical continuity with pre-colonial and/or pre-settler societies;
- special relationship with ancestral lands: having a strong and special link with the territories occupied by their ancestors before colonial domination and surrounding natural resources. Such a link will often form the basis of the cultural distinctiveness of indigenous peoples;
- distinctiveness: having distinct social, economic or political systems; having distinct language, culture, beliefs and customary law;
- non-dominance: forming non-dominant groups within the current society;

¹¹⁵ UNDRIP, Article 3.

¹¹⁶ RINGELHEIM, “L’appréhension juridique de l’identité culturelle – Entre autodéfinition et objectivation”, 2013, p. 171.

¹¹⁷ For an in-depth discussion of this issue, see ANAYA, *Indigenous peoples in international law*, 1996, p. 77.

- perpetuation: perseverance to maintain and reproduce their ancestral environments, social and legal systems and culture as distinct peoples and communities”.¹¹⁸

In conclusion, the formulation of a single definition will inevitably exclude some groups that do not fulfil the *rationae personae* of indigenous rights norms.¹¹⁹ Thus, while no definition has been agreed upon internationally, the *distinctive* nature of their rights has been recognised¹²⁰ and inherent to any consideration of indigenous claims to distinctiveness is the concept of internal self-determination.¹²¹ Hence, national, regional and international courts when confronted with indigenous peoples’ claims shall take their decision in accordance with ILA indicia mentioned above.

2 Characteristics

Because defining TK is difficult, some authors have tried to clarify its meaning by describing what it is not, or by identifying certain characteristics that distinguish it from knowledge as understood in westernised or secular knowledge, i.e., that is commonly referred to as Western or modern science. For instance, Dutfield has identified the following characteristics of traditional knowledge: oral transmission; holistic nature; developed through observation and

¹¹⁸ ILA, ‘Rights of Indigenous Peoples’, Interim Report, The Hague Conference, 2010, pp. 7-8.

¹¹⁹ Commission on Human Rights, ‘Study of the Problem of Discrimination Against Indigenous Populations – Conclusions, Proposals and Recommendation’, Special Rapporteur José Martínez Cobo, 1986, vol. V, UN Doc E/CN. 4/Sub.2/1986/7/Add.4.

¹²⁰ Human Rights Council, ‘Report of the Special Rapporteur on the Situation of Human Rights and Fundamental Freedoms of Indigenous Peoples’, James Anaya, 15 August 2008, UN Doc. A/HRC/9/9/Add.1, paragraph 40 (“[t]he Declaration does not affirm or create special rights separate from the fundamental human rights that are deemed of universal application, but rather elaborates upon these fundamental rights in the specific cultural, historical, social and economic circumstances of indigenous peoples”); see also, IACHR, *Saramaka People v. Suriname*, Preliminary Objections, Merits, Reparations, and Costs Judgement of 28 November 2007, Series C No. 172, IACHR 5, paras. 80-84 and 164 (“[...] the Court has already declared that the Saramaka people can be defined as a distinct tribal group, whose members enjoy and exercise certain rights, such as the right to property, in a distinctly collective manner. The fact that some individual members of the Saramaka people may live outside of the traditional Saramaka territory and in a way that may differ from other Saramakas who live within the traditional territory and in accordance with Saramaka customs does not affect the distinctiveness of this tribal group nor its communal use and enjoyment of their property”).

¹²¹ VAN COTT, “A Political Analysis of Legal Pluralism in Bolivia and Colombia”, 2000, p. 211.

hands-on experience.¹²² However, as already mentioned, traditional knowledge is highly diverse. Therefore, one has to be cautious with any kind of generalisation.

2.1 What is “Traditional”?

The first and foremost characteristic of TK is that it is traditional. An external observer to this field might assume that traditional is synonymous with outdated, fixed, closed or archaic knowledge. Such characteristics may indeed be true for TK as for any other knowledge. However, TK as any other knowledge is also constantly evolving. Thus, “traditional” does not necessarily mean ancient; it refers to the fact that its creation and use form part of the cultural traditions of communities. In other words, what makes this knowledge traditional is the manner in which it has been created, preserved, transmitted and developed within a community.¹²³

The glossary of key terms related to intellectual property and TK prepared for the WIPO IGC provides the following clarification: “The adjective “traditional” qualifies the method of creating traditional knowledge and not the knowledge itself”.¹²⁴ Along the same lines, Posey states that the essential feature of traditional knowledge consists of its constant evolution and adaptation to changing social and environmental conditions.¹²⁵

Beyond this, traditional knowledge is often assumed to have certain characteristics. It is stated that TK is a form of knowledge that is transferred between generations or that is inter-generational. However, according to De Carvalho, the sole notion of “tradition” eliminates the need to refer to the way it is transmitted because the adjective already encompasses the concept of cultural continuity transmitted over a long period of time.¹²⁶ It is also often assumed that TK is transmitted orally. However, it is also true that a vast amount of TK is in a written form, i.e., documented or codified TK. Traditional knowledge is codified when it is in

¹²² DUTFIELD, “TRIPS-Related Aspects of Traditional Knowledge”, p. 241.

¹²³ WIPO IGC, ‘Elements of a *Sui Generis* System for the Protection of Traditional Knowledge’, the Secretariat, 9-19 December 2002, WIPO/GRTKF/IC/4/8, para. 25, p. 10.

¹²⁴ WIPO IGC, ‘Elements of a *Sui Generis* System for the Protection of Traditional Knowledge’, the Secretariat, 9-19 December 2002, WIPO/GRTKF/IC/4/8, para. 27, p. 11.

¹²⁵ POSEY, “Biological and Cultural Diversity: The Inextricable, Linked by Language and Politics”, 2001, p. 381.

¹²⁶ CARVALHO, “From the Shaman’s hut to the Patent Office: In search of effective protection for traditional knowledge, 2003, p. 8.

some systematic and structured form and the knowledge is organised and classified in some manner. This is particularly the case with codified traditional medicinal knowledge. The World Health Organisation makes a distinction between (i) codified systems of traditional medicine, which have been disclosed in writing in ancient texts and are in the public domain, such as for instance the traditional Chinese medicine disclosed in ancient Chinese medical texts; and (ii) non-codified traditional medicinal knowledge which has not been fixed in any written text, and often remains undisclosed by its holders and is passed orally from one generation to the next.¹²⁷ Finally, it is further argued that because TK is transmitted from one generation to another, it is cumulative. But it is also argued that such transfer does not occur systematically and it does not necessarily imply that TK will last more than one generation.¹²⁸ The intergenerational transmission of the knowledge implies that the knowledge is enhanced because each generation brings its input. Hence, traditional knowledge presents innovative features.¹²⁹

Amongst the characteristics of traditional knowledge, the relationship between the knowledge and the indigenous community constitutes one of the core elements characterising traditional knowledge. The knowledge is inherently bound to the community within which it has been created and evolves.¹³⁰ Traditional knowledge is thus an instrument of cultural identification of its holders and that the cultural identity and integrity of the community depends upon its preservation and protection.¹³¹

¹²⁷ WHO, 'WHO Traditional Medicine Strategy 2002-2005', 2002, p. 7.

¹²⁸ WHO, 'WHO Traditional Medicine Strategy 2002-2005', 2002, p. 7.

¹²⁹ CBD, Article 8(j) defines traditional knowledge as "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles".

¹³⁰ WIPO IGC, 'Traditional Knowledge – Operational Terms and Definitions', the Secretariat, 20 May 2002, WIPO/GRTKF/IC/3/9, paras. 33-35, pp. 13-14 ("The relationship may entail a positive sense of responsibility on the part of the community or collective group, an active sense of obligation to preserve TK and to use it in certain defined, appropriate ways; or it may entail a negative sense, in that the misuse or pejorative misappropriation of traditional knowledge may be seen as harmful or offensive to the community or a set of collective values").

¹³¹ Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, 'Discrimination against indigenous peoples - Report of the Working Group on Indigenous Populations on its ninth session, by Special Rapporteur Erica-Irene Daes, 3 October 1991, UN Doc E/CN.4/Sub.2/1991/40/Rev.1, para. 50, p. 31.

While the scope of our present analysis is exclusively limited to indigenous peoples as previously defined, determining the common characteristics of traditional knowledge is not an easy task, if not feasible. Indeed, indigenous peoples are present in Latin America, the Pacific, Siberia, Europe, and in Asia. Hence, the way of living is extremely diverse from one place to another or from a community to another. The common characteristics developed by the WIPO IGC and human rights' bodies are essentially based on a rich anthropological literature developed over time.¹³²

2.2 Scientific Knowledge – Commensurability of Traditional Knowledge (knowledge pluralism)

Any attempt to list the characteristics of traditional knowledge places us within the debate over whether there is a principal difference between modern or “Western” science or Western scientific traditions and traditional knowledge at all. The issue of traditional or indigenous knowledge, when analysed from an Occidental perspective, encounters sooner or later the recurrent question of the validity of this form of knowledge and presupposes that scientific knowledge is hierarchically superior to the body of traditional knowledge.¹³³

The reasons for this assumption are mainly twofold. First, scientific knowledge is the dominant knowledge in the sense that it benefits from an international infrastructure of “networks” including laboratories, publications, public and private funding institutions, museums, libraries, universities, and so on.¹³⁴ Second, the dominance of this knowledge is given further authority by means of the global system of intellectual property rights. This

¹³² See for instance, BROWN, *Who owns native culture?* 2004; COOMBE, “Comments”, 1998, pp. 207-208; POSEY and DUTFIELD, *Beyond Intellectual Property – Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*, 1996; BLAKENEY Michel, “The Protection of Traditional Knowledge under Intellectual Property Law”, 2000; SILLITOE Paul, “The development of indigenous knowledge: A new applied anthropology”, 1998; GREENE Shane, “Indigenous People Incorporated? Culture as Politics, Culture as Property in Pharmaceutical Bioprospecting”, 2004; TSOSIE Rebecca, “Indigenous Peoples’ Claims to Cultural Property: A Legal Perspective”, 1997.

¹³³ See generally BRADFORD, “Intellectual Property and Traditional Knowledge: A Psychological Approach to Conflicting Claims of Creativity in International Law” (the author explores the competing claims regarding the “nature” of creativity and innovation, which is central to the IP and TK discourses through the lenses of discourse analysis and social and cognitive psychology).

¹³⁴ CHAMBERS and GILLESPIE, “Locality in the History of Science: Colonial Science, Technoscience, and Indigenous Knowledge”, 2000, p. 239.

leads us to the heart of the controversy and sheds light on the reason why we make a distinction between traditional knowledge systems and scientific knowledge systems from the perspective of the protection of the former. The legal controversy surrounding the protection of traditional knowledge demonstrates that knowledge evolved over centuries is not treated as a candidate of conventional intellectual property rights, but is protected when the same knowledge is validated through the network of modern scientific institutions. This comparison method seems inappropriate for the reasons developed below.

The process of comparing traditional knowledge to “Western” knowledge encompasses a risk that traditional knowledge will be reduced to practical knowledge that is mainly based on experience and practical application as opposed to theoretical knowledge that is developed through inductive and deductive reasoning and benefits from a universal validity.¹³⁵ Indeed, it is often assumed that knowledge developed by these communities is essentially directed to a basic subsistence mode. Lévi-Strauss, a philosopher and anthropologist, has argued that the knowledge developed by indigenous peoples or local communities is motivated by considerations that go far beyond utility purposes.¹³⁶ From the early work of Lévi-Strauss and until today, numerous observers have examined these knowledge systems. Some have suggested that the use of the term “science” should be broadened to encompass traditional knowledge systems.¹³⁷

Another risk for traditional knowledge is also to be considered as pseudo-science in comparison to science. The International Council for Science (ICSU) has discussed the relationship between science, pseudo-science and traditional knowledge. What basically differentiates traditional knowledge from science is that the former originates “independently

¹³⁵ SILLITOE, “The Development of Indigenous Knowledge: A new Applied Anthropology”, 1998, p. 227 (the author notes that “ethnocentrism remains common. The lack of respect for other’s knowledge traditions manifested by many Western scientist, underpinned by the assumption that technological superiority implies answers to all difficulties, is a considerable barrier to development”).

¹³⁶ LÉVI-STRAUSS, *La Pensée Sauvage*, Chapter one, titled “la science du concret” (“chaque civilisation a tendance à surestimer l’orientation objective de sa pensée [...] Quand nous commettons l’erreur de croire le sauvage exclusivement gouverné par ses besoins organiques ou économiques, nous ne prenons pas garde qu’il nous adresse le même reproche, et qu’à lui, son propre désir de savoir paraît mieux équilibré que le nôtre”).

¹³⁷ See generally, SILLITOE, “Local Science vs. Global Science: an Overview”, 2007, pp. 1-22.

of science in a particular cultural setting, mostly also quite independently of western culture".¹³⁸

Therefore, the failure to fairly compare traditional knowledge to non-traditional knowledge has resulted in a definition of traditional knowledge in a negative way, i.e., what indigenous knowledge is not rather than what it is. For instance, science as it is understood in western, westernised or secular societies, defines itself as experimental (deduction from hypotheses that are tested), systematic (replication of the results) and universal (abstracting capacity and independent from context).¹³⁹ In contrast, TK is context-dependant, practical (determined by utility) and inherently linked to community identity. The very legitimacy of a community will derive from the stability of tradition, narratives (its history) and the interdependence between the community and the land.¹⁴⁰

According to Dutfield, there is a category of knowledge that may be called traditional knowledge, which in turn is sub-divided into various sub-categories such as, for instance, traditional medicinal knowledge.¹⁴¹ Under this classification system, what really differentiates TK from what we have called westernised scientific knowledge or non-indigenous knowledge is the “form of expression” of each knowledge system.

The process of creating and enhancing traditional knowledge is inherently linked with the identity and cultural context of the creators of this knowledge. For instance, a traditional

¹³⁸ ICSU, ‘Science and Traditional Knowledge’, 2002, p. 11 (While Traditional Knowledge does not intend to be in competition with science, it has informed science from its very beginnings and it continues to do so until today. In contrast to traditional knowledge, pseudo-science is an endeavour that is systematically in competition with science. Whereas in science all sort of statistical testing procedures are involved, in the pseudo-scientific movement anecdotic evidence prevails).

¹³⁹ ZANDERS, *The Science and Business of Drug Discovery – Demystifying the Jargon*, 2011, p. 60 (the author states that “despite the successes with herbal extracts, the theoretical foundations of drug discovery were still based to a large extent upon the old ideas of correcting imbalances in the body. Slowly, however, these gave way to new theories based on the application of scientific method: perform experiments to produce data upon which to form a hypothesis and then repeat the process by performing further experiments to confirm, reject or modify the hypothesis and so on”).

¹⁴⁰ POSEY, *Indigenous Knowledge and Ethics: A Darrell Posey Reader*, 2004, pp. 18, 30-31 (for the author, ecological knowledge represents the relationship between narration, transmission of knowledge and identity); for an indigenous community perspective, see Alaska Native Science Commission, at: http://www.nativescience.org/html/traditional_knowledge.html [accessed in September 2016].

¹⁴¹ DUTFIELD, “TRIPS-Related Aspects of Traditional Knowledge”, 2001, p. 242.

healer will have an accurate understanding and knowledge of the medicinal plants composing within their habitat. But this knowledge is also closely linked with the religious and spiritual beliefs of its community. Thus, the causes of the illness will be looked for in, what we would probably call supernatural forces. By contrast, a Western medical practitioner, wherever its activity may be, will prescribe the same treatment to patients presenting the same symptoms. Thus, it is often argued that scientific knowledge is reductionist in nature, whereas TK is conceived in fully holistic terms.¹⁴² Indeed, for indigenous peoples and local communities, the relationship between their knowledge, cultural identity and surrounding environment are fundamentally inseparable and constitute a whole. This is what fundamentally distinguishes traditional knowledge from non-traditional knowledge that is currently acknowledged to be scientific. A historian of science, Thomas Kuhn, suggested that it was impossible to make the comparison needed to judge which body of knowledge was better or more advanced.¹⁴³ Thus, we can assume that traditional knowledge is a body of knowledge that is autonomous and possesses its own paradigm.

Precisely because TK could be taken to cover an enormous field, i.e., the knowledge of indigenous and local communities, it is not realistic to define TK as scientific or non-scientific as compared to the Western scientific system. Even though some categories of traditional medicinal knowledge might be commensurable to the Western body of scientific knowledge, it is misleading to compare it to or contrast it solely with science. The reasons are mainly twofold. Firstly, traditional medicinal knowledge cannot be compared to scientific knowledge, because a taxonomy or categorisation of traditional knowledge is foreign to traditional communities. Strictly speaking, it is inaccurate to identify traditional medicinal knowledge as a sub-category of traditional knowledge. Secondly, this body of knowledge is rooted in the interconnection of elements such as spirituality, language and culture of the people.¹⁴⁴

¹⁴² JOHNSON, *LORE: Capturing Traditional Ecological Knowledge*, 1992, p. 3 (the author has listed the characteristics distinguishing TK from western scientific knowledge); see also Wai 262 Report I, p. 70 (The Tribunal of Waitangi in New Zealand compares the Māori traditional knowledge on the use of plants and Western science).

¹⁴³ KUHN, *The Structure of Scientific Revolutions*, 2012 (for an original discussion in relation to the history of science and its evolution not as development by accumulation process but as successive paradigm shifts).

¹⁴⁴ Alaska Native Science Commission, at: http://www.nativescience.org/html/traditional_knowledge.html (“Whereas scientific practice generally excludes the humanistic perspective, traditional understanding

Ultimately, despite all of these uncertainties, it can be ascertained that knowledge is an attribute of human beings whether they are native, indigenous, form part of local communities, rich, poor, academics or not, living in developed countries or developing countries. Traditional knowledge is a set of knowledge of its own with a proper legitimacy and credibility. The problem arises when one system of knowledge can freely or at low-cost assert ownership over another body of knowledge.

2.3 Entitlement to Knowledge – Collective Stewardship and Guardianship

The following paragraphs will neither expound on the origins of the concept of property rights and ownership, nor on the philosophical discussions surrounding it. I will limit this section to the naturalistic theory and the utilitarian theory of intellectual property rights. This section will help to further understand the concept of public domain that will be discussed and analysed in Chapter 3 of Part II.

The concept of property and the justification of rights attached to it have evolved through history of mankind, from ancient civilisations, passing through ancient, medieval and modern philosophers to contemporary attitudes, thus generating numerous theories, mainly contingent upon the political, economic and societal context at the time. According to Drahos, “[P]roperty rules, more than most rules, are rooted in the fundamental morality of a given society”.¹⁴⁵

Whilst possession is a fact, property constitutes a right to possess. Thus, property is the right of possessing something. The contemporary approach of Western legal system to property originates in Roman private law and incorporates a fundamental distinction between corporeal or physical objects, and incorporeal or abstract objects such as intellectual endeavour.¹⁴⁶ Intellectual endeavour may in turn be divided into creations and discoveries. While creations are defined as a human invention, discoveries are abstract objects that exist independently of a

assumes a holistic view including language, culture, practice, spirituality, mythology, customs and even the social organization of the local communities”).

¹⁴⁵ DRAHOS, *A philosophy of Intellectual Property*, 1996, p. 15.

¹⁴⁶ See generally, DUNAND, SCHMIDLIN and WINIGER, *Droit privé romain*, 2012; see, however, DRAHOS Peter, “Indigenous Knowledge and the Duties of Intellectual Property Owners”, 1997, p. 198 (stating that “intellectual property rights are not like other property rights. Patents and copyrights have their origin in privilege [...] they interfered in the negative liberties of others and were tolerated only to the extent that they promoted the welfare of all in the longer term”).

person's will but are nevertheless discovered by one. While corporeal objects are the subject matter of property rights, incorporeal objects are the subject of intellectual property rights. In other words, intellectual property rights are property rights in abstract objects. The fundamental distinction between physical objects and abstract objects is that whereas the former are consumed when used, the latter are not. They can be used by an infinite number of persons at the same time.

One of the main theories of intellectual property rights has been linked back predominantly to the English philosopher John Locke. He stated that "whatsoever [a man] removes out of the state that nature hath provided and left it in, he hath mixed his labour with, and joined to it something that is his own, and thereby makes it his property".¹⁴⁷ This statement entails that property rights are natural rights in the sense that human beings, by means of labour, can legitimately exert ownership over the commons or natural resources. The necessary precondition being that there should be "enough, and as good, left in common for others".¹⁴⁸ For Locke, labour constitutes the basis of a natural property right. Applied to intellectual property rights, Locke's theory would be: intellectual property rights are natural rights in the sense that human beings, by means of an intellectual labour, can legitimately exert ownership over an intellectual commons that are abstract objects to be discovered. Through the identification or discovery process a person can acquire property on abstract objects. However, the extraction of the abstract object out of the intellectual common does not hinder their accessibility. Anyone interested in accessing the subject matter of these rights will have to pay the owner of the right an agreed licence fee. Thus, intellectual property rights provide a right to exclude others from the use of the knowledge.

As discussed earlier, traditional knowledge and particularly the issue of its protection, are repeatedly discussed in international fora and amongst authors with reference to proprietary schemes and intellectual property rules.¹⁴⁹ However, indigenous peoples do not perceive their knowledge, their resources, their land, - in other words their cultural heritage, in terms of property rights, in the sense that they might be commodified. They rather view their heritage

¹⁴⁷ LOCKE and SHERMAN, *Treatise of Civil Government and A Letter Concerning Toleration*, 1937, p. 19.

¹⁴⁸ LOCKE and SHERMAN, *Treatise of Civil Government and A Letter Concerning Toleration*, 1937, p. 19.

¹⁴⁹ See, for instance, the large amount of working documents produced by the WIPO IGC at each of its meetings.

in terms of community responsibility or stewardship under the umbrella of the right to cultural integrity or the right to self-determination.¹⁵⁰

It is generally assumed that traditional knowledge is collective in nature as opposed to the individualistic and commercial based paradigm of the Western institution of formal property. Some authors argue that stating that “in the case of traditional knowledge, no such individual “owner” exists”, as opposed to conventional intellectual property rights, is an oversimplification.¹⁵¹ Within the diversity of indigenous traditions existing in the world, not all of them follow a model of community ownership. Thus, in a specific indigenous community, both individual and collective rights might be present. In other words, not in every traditional or indigenous community is “everything shared with everybody” and concepts of property and ownership do exist in traditional societies.

While this is certainly true, the concept of ownership should be used loosely to denote the right of a person or a group over an object. Based on some field studies, WIPO has identified that traditional knowledge belongs, in general, to the whole community or to groups of individuals within such a community.¹⁵² In the specific case of TMK, an individual member of a community, for instance a healer (commonly referred to as being the Shaman) might hold specific knowledge. More precisely, rather than holding in a property right sense, they have the power due to their position within the community to restrict access to their knowledge for safety reasons, because the knowledge is considered to be dangerous for the uninitiated, or because the knowledge is deemed to be sacred as opposed to secular TK.¹⁵³ Similarly, while individuals may bear specific responsibilities with regard to the use and management of traditional knowledge, their authority is not unlimited, and they are required to conform to the rules imposed upon the members of the community. For instance, they will not be allowed to

¹⁵⁰ See generally, SIMPSON, *Indigenous heritage and Self-Determination: The Cultural and Intellectual Property Rights of Indigenous Peoples*, 1997.

¹⁵¹ Study of Directorate-General For External Policies of the Union, Intellectual Property Rights on Genetic Resources and the Fight against Poverty, December 2011, p. 45, available at : <http://www.europarl.europa.eu/committees/fr/studiesdownload.html?languageDocument=EN&file=66771> (accessed September 2016).

¹⁵² WIPO IGC, ‘List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found’, 6-10 December 2010, WIPO/GRTKF/IC/17/INF/9, p. 13.

¹⁵³ WIPO IGC, ‘List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found’, 6-10 December 2010, WIPO/GRTKF/IC/17/INF/9, p. 10.

transfer traditional knowledge to another person because that knowledge is part of their collective identity.¹⁵⁴

These points are fundamental in terms of the protection of traditional knowledge, which will be discussed in more depth in Part III, but it is essential, at this point, to clarify the nature of the interaction of the community with the knowledge that forms part of its cultural heritage.

The expression of traditional heritage that encompasses, amongst others, songs, dances, stories and medicinal and spiritual knowledge, is not automatically viewed as a form of control over that expression that would lead to some sort of a collective or individual property claim. Thus, even though some forms of individual or communal control or ownership can be found in traditional communities, the regulation of those entitlements are managed according to customary laws¹⁵⁵ and principles shared by the community. The community is formed by individuals who are the nominee “experts” or custodians of songs, dances or medicinal knowledge. These experts are in charge of acting in the best interest of the community.

According to Erica-Irene Daes, former Chairperson-Rapporteur on the Working Group on Indigenous Populations, individual custodianships or responsibilities are not equivalent to ownership or property rights. Legally speaking, it is inaccurate to assume that some traditional communities do possess individual and collective property rights. Each traditional community retains control and manages its traditional heritage or culture according to its own customary laws and regulations. Daes states that “although heritage is communal, there is usually an individual who can best be described as a custodian or caretaker of each song, story, name, medicine, sacred place and other aspect of a people’s heritage. Such individual responsibilities should not be confused with ownership or property rights”.¹⁵⁶

¹⁵⁴ SIMPSON, *Indigenous heritage and Self-Determination: The Cultural and Intellectual Property Rights of Indigenous Peoples*, 1997, p. 19.

¹⁵⁵ Black’s Law Dictionary, 9th edition, 2009 defines customary law as “law consisting of customs that are accepted as legal requirements or obligatory rules of conduct; practices and beliefs that are so vital and intrinsic a part of a social and economic system that they are treated as if they were laws”. In turn, customs is defined as “a practice that by its common adoption and long, unvarying habit has come to have the force of law”.

¹⁵⁶ Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, ‘Discrimination against indigenous peoples - Study on the protection of the cultural and intellectual property of indigenous peoples, by Erica-Irene Daes’, Special Rapporteur of the Sub-

Along the same lines, the following quotation denotes indigenous peoples' relationship to the components of their cultural identity, be it land, natural resources or traditional knowledge. "Ownership in our community, in our way, is different from a white man's ownership and view. We believe that we don't own things. They belong to the Creator and bundles are given to our people for specific purposes. These things are sacred. One is not the owner of them".¹⁵⁷

Indeed, the linkage between traditional knowledge and its holders is broader than conventionally recognised forms of tangible and intangible property rights. It rather refers to concepts such as stewardship and custodianship, where there is a sense of obligation to preserve and transmit knowledge in accordance with rules (customary laws) consented to by the community.¹⁵⁸ Similarly, the Glossary of the Key Terms of the WIPO IGC defined the concept of "custodian" with reference to traditional knowledge as referring to "those communities, peoples, individuals and other entities, which, according to customary laws and other practices, maintain, use and develop the traditional knowledge. It expresses a notion that is different from ownership as such, since it conveys a sense of responsibility to ensure that traditional knowledge is used in a way that is consistent with community values and customary laws".¹⁵⁹

Thus, while there is a general recognition that the control and management of traditional knowledge of indigenous communities does not equate to the legal forms of ownership used in non-indigenous communities, most solutions proposed to protect their "intangible cultural property" are essentially based on paradigms of property rights foreign to indigenous

Commission on Prevention of Discrimination and Protection of Minorities and Chairperson of the Working Group on Indigenous Populations, 28 July 1993, UN Doc. E/CN.4/Sub.2/1993/28, para. 29, p. 9.

¹⁵⁷ WEASEL Frank, Head, quoted in BELL, STATT and the Mookakin Cultural Society, "Repatriation and Heritage Protection: Reflections on the Kainai Experience", 2008, pp. 224-225.

¹⁵⁸ CARPENTER et al., "In Defense of Property", 2009, pp. 1022-1125 (they argue that the concept of property should be broadened to integrate the principle of stewardship as well in order to be more compatible with indigenous peoples world view); See also BROWN, "Culture, Property, and Peoplehood: A Comment on Carpenter, Katyal, and Riley's "In Defense of Property", 2010, pp. 569-579 (while the author acknowledges the significant contribution of Carpenter et al. to the ongoing global debate, he criticises some of their assertions that impede the development of pragmatic, cost-effective solutions to the problem of cultural appropriation).

¹⁵⁹ WIPO IGC, 'Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions', 19-23 September 2016, WIPO/GRTKF/IC/31/INF/7, p. 8.

communities' practices. For instance, Drahos considers that while those who hold privileges, in other words owners of intellectual property rights, are subject to duties, *sui generis* "indigenous intellectual property forms should be linked to the protection of personality, both collective and individual".¹⁶⁰ Hence, it is a reality that where justice takes place, the indigenous communities are vulnerable without property laws.

Before examining the legal protection of traditional medicinal knowledge, the following chapter gives an insight of the role and value of traditional medicinal knowledge in the drug industry.

¹⁶⁰ DRAHOS Peter, "Indigenous Knowledge and the Duties of Intellectual Property Owners", 1997, p. 180.

Chapter 2 The Role of Traditional Medicinal Knowledge in Drug Industries

“Everything on the earth has a purpose, every disease an herb to cure it, and every person a mission. This is the Indian theory of existence”.¹⁶¹

The World Health Organisation has listed plant species with known medicinal properties in four volumes, where each volume contains more than twenty monographs.¹⁶² From the 380,800 estimated plant species in the world, only 25 to 30 per cent have been tested. Worldwide demand for medicinal plant tissues and extracts for use in pharmaceuticals, foods, dietary supplements, cosmetics, and veterinary products has been increasing at an estimated rate of 3 to 7 per cent per year over the past several years.¹⁶³ This significant growth can easily lead to an unsustainable overcollecting of wild species by individuals and organized groups motivated by the opportunity for financial profit with no apparent concern about the loss of plant species.

This chapter is important in two senses. First, it gives an overall view of the importance of traditional medicinal knowledge in the drug discovery process.¹⁶⁴ Second, the correlation between TMK and the drug discovery process creates the basis for a discussion of the legal protection of TMK. However, the drug industry is only one industry amongst others using TMK. Others industries, to name a few, such as the phytopharmaceuticals, cosmetics or food also rely on TMK for innovative new developments.

The pharmaceutical industry, as we know it today, is sixty years old. Indeed, the discovery of sulfamides, antibiotics and their role in the treatment of tuberculosis, between 1935 and 1945, constitutes the turning point in the history of drug discovery. The same period also witnessed an outbreak of products developed by means of chemical synthesis and fermentation processes, thus diminishing the interest for plant-derived drugs.

¹⁶¹ Christal Quintasket, native American author 'Mourning Dove' quoted in ARAB FERNANDEZ, *Cultural Identity Revisited: Early Twentieth-Century Women's Work of Cultural Preservation*, 2007, p. 70.

¹⁶² WHO Monographs on Selected Medicinal Plants, vol. 1, 2, 3 and 4, published in 1999, 2003, 2007 and 2009, available at: <http://apps.who.int/medicinedocs/fr/d/Js2200e/> [accessed September 2016].

¹⁶³ TAYLOR, *The Healing Power of Rainforest Herbs: A Guide to Understanding and Using Herbal Medicinal*, 2005.

¹⁶⁴ For the purpose of this work, drug discovery broadly encompasses the identification of a lead, which includes the process by which a lead is identified and the acquisition of material for screening (the source of a drug), and the identification of a disease and the relevant target of interest.

1 **A Historical Perspective of Drug Discovery**

The roots of drug discovery can probably be traced back to the origins of human being. Ancient populations reported the medicinal properties of plant extracts, all of which were the result of a trial and error process. Historically, whole plants or extracts of them were used as remedies to administer several active substances or chemical entities at once. The appearance of new techniques, in the 19th century, for partitioning and fractioning some of these extracts into individual compounds made the creation of single entity drugs possible.¹⁶⁵ Indeed, one of the greatest advances in the drug discovery process was the isolation of active principles from plants.¹⁶⁶ By 1990, the vast majority of drugs were either natural products or analogues inspired by them.

Thus, after the Second World War, the pharmaceutical industry's interest shifted away from plant-derived drugs to concentrate on two emerging areas: synthetic pharmaceutical chemistry and microbial fermentation. During the first half of the 20th century, drug research was revolutionised by several new technologies. Indeed, drug development was no longer done exclusively by chemists, but it stemmed from a necessary collaboration between biologists and chemists. The alliance between these two fields led to the identification of the biochemical mechanism of action (MoA)¹⁶⁷ that results from an understanding of biological structure and function and gives rise to the creation of a novel chemical structure. The resulting drugs are often referred to as “biotech” drugs. The main promise of this new approach (often referred to as rational drug design) lies in its potential to understand disease

¹⁶⁵ See generally, SNEADER Walter, *Drug Discovery: A History*, John Wiley & Sons, West Sussex, 2005, pp. 88 ff.; see also, ZANDERS, *The Science and Business of Drug Discovery – Demystifying the Jargon*, 2011, p. 61 (the author states that Paracelsus, a Swiss physician, a major figure in the history of drug discovery, in the 16th century, was one of the first to advocate the use of pure chemical compounds as medicines rather than the herbal mixtures used for centuries previously).

¹⁶⁶ The dawn of the modern pharmaceutical research and development is to be traced back to Bayer's work on aspirin.

¹⁶⁷ Dictionary: Refers to the specific biochemical interaction through which a drug substance produces its pharmacological effect. It includes mention of the specific molecular targets to which the drug binds, such as enzyme or receptor. As an example, the mechanism of action of aspirin involves irreversible inhibition of the enzyme cyclooxygenase, therefore suppressing the production of prostaglandins and thromboxanes, thereby reducing pain and inflammation.

processes at molecular (genetic) level and to determine the optimal molecular targets for the drug invention.¹⁶⁸

2 **The Drugs Research and Development Process today**

The process of drug discovery has become a complex and heterogeneous field (above all for a legal practitioner). Whereas, three decades ago drug research and development was mainly based on chemistry, today it draws on a broad range of scientific disciplines, tools and approaches. Today, drug discovery is excessively referred to as “rational” by contrast to the random approach. In this section, I will describe both approaches.

The rational approach, otherwise known as modern drug discovery is essentially based on a target approach. What is central to this approach is that it is based on the interaction between the human body and the potential new drug. Indeed, since the dawn of the genomics era in the 1990s, the main focus of the drug discovery process and research efforts has been on drug targets, which are proteins that appear to have a key role in disease development.¹⁶⁹

This approach is divided into five principal stages that are: (i) target identification; (ii) target validation; (iii) lead identification; (iv) lead optimisation; and (v) preclinical pharmacology and toxicology. The following paragraphs will not address the final stage concerning clinical trials, as the purpose of this section is to focus upon the discovery and design phases of the process.¹⁷⁰

Once they have a sufficient understanding of the underlying cause of a disease, researchers select a “target” for a potential new medicine. A target is a single molecule – either a gene or a protein – which is involved in a particular disease. At this early stage, what is essential for researchers is that they try to pick a target that is “drugable”, i.e., one that can potentially interact with and be affected by a drug molecule. This stage is called target identification. An analogy to this approach is the key and lock comparison, with the key representing the drug and the lock being the disease target.¹⁷¹ The target validation stage, as the name itself suggests, tries to validate the target that has previously been identified. Its crucial role is to help scientists avoid research paths that look very promising but that could ultimately lead to

¹⁶⁸ DREWS, “Drug Discovery: A Historical Perspective”, 2000, pp. 1960-1964.

¹⁶⁹ LINDSAY, “Target Discovery”, 2003, pp. 831-838.

¹⁷⁰ LINDSAY, “Target Discovery”, 2003, pp. 831-838.

¹⁷¹ DUCOR, “New Drug Discovery Technologies and Patents”, 1996, p. 379.

a dead end. At this point, it has to be added that, for complex diseases, such as cancer or diabetes, there are so many possible target to explore that researchers often do not know where to start.¹⁷²

The third stage constitutes the cornerstone of the process of drug discovery for the purposes of this research. What is sought at this stage is to find a molecule or “lead compound” that may act on the identified target to alter the disease course. In the final stage of the “drug discovery process” (lead optimisation), the lead compound is altered to make it more effective and safer. But before this final stage, the appropriate lead compound has to be identified. Various approaches are relevant for identifying the lead compound. The next section will focus on natural plants and traditional medicinal knowledge as the principal means for identifying the lead compound.

The second approach known as the irrational approach or random approach (often tagged as the historical method of drug discovery) involves empirical observations of the pharmacological effects from the screening of many chemical compounds, mainly those from natural products (trial-and-error testing). Once the relevant active substance is isolated, the chemical formula is elaborated, called new chemical entity (NCE), and modifications are made to improve its properties. The majority of drugs available today stemmed from this technique. Indeed, before the advent of the rational drug design, the search for novel drugs was mainly empirical and in-built through the screening of plausible alternative molecules.¹⁷³

For instance, the screens were narrow where similar molecules had already shown therapeutic activity. In that case, investigators tried to identify comparable effects from “me too”¹⁷⁴ molecular variants. On the other hand, when new molecules had no clear therapeutic backgrounds, the screens were broad, i.e., “covering panoply of possible diseases”.¹⁷⁵ Due to these random screenings, the pharmaceutical industry built extensive libraries of molecules.

¹⁷² ZANDERS, *The Science and Business of Drug Discovery – Demystifying the Jargon*, 2011, p. 102.

¹⁷³ DUCOR, “New Drug Discovery Technologies and Patents”, 1996, p. 390; see also, SHERER, “Pharmaceutical Innovation”, 2007, p. 8.

¹⁷⁴ See DIMASI and PAQUETTE, “The Economics of Follow-on Drug Research and Development: Trends in Entry Rates and the Timing of Development”, 2004, p. 2 (Although the term ‘me too’ has come to be used in different ways, historically it has most often referred to a new drug entity with a similar chemical structure or the same mechanism of action as that of a drug already on the market).

¹⁷⁵ SHERER, “Pharmaceutical Innovation”, 2007, p. 8.

The key point to be made here is that if so many “new” drugs are in reality not new molecular entities (NMEs), it is very likely that the sources of a high proportion of drugs that are on the market can be traced back to the knowledge of local healers on the medicinal properties of plants.¹⁷⁶

3 Plant-derived drugs

It is widely accepted that natural products have been the source of most of the active ingredients of medicines, for example morphine, quinine, aspirin or artemisinin.¹⁷⁷ During the twentieth century, the interest in plants as a source of new drugs has evaporated due to the development of chemical synthesis and processes for the fermentation of microorganisms’ fermentation process.¹⁷⁸ It seems that natural products are not as much of interest for the pharmaceutical industry as in the past. This is mainly due to the industry embracing promising new technologies, particularly combinatorial chemistry and genomics. However, the tide may be turning for several reasons.¹⁷⁹ One is that combinatorial chemistry’s promise to enhance drug development with *de novo* synthetic small-molecule drug candidates is unfulfilled. Indeed, the chemical diversity found in synthetic combinatorial chemical libraries is not comparable to the overwhelming chemical diversity contained in the plants kingdom, resulting from the natural evolution of the plants over centuries.¹⁸⁰ In addition, the practical difficulties of drug discoveries from natural products are being overcome by advances in separation or fraction technologies and in the speed and sensitivity of structure elucidation.

¹⁷⁶ See generally, FARNSWORTH and FABRICANT, “The Value of Plants Used in Traditional Medicine for Drug Discovery”, 2001, pp. 69-75.

¹⁷⁷ See generally, FARNSWORTH Norman et al, “Medicinal Plants in Therapy”, 1985, pp. 965-981; FARNSWORTH and FABRICANT, “The Value of Plants Used in Traditional Medicine for Drug Discovery”, 2001, pp. 69-75; HARVEY, “Natural Products in Drug Discovery”, 2008, p. 894-901; HAMBURGER Matthias and HOSTETTMAN Kurt, “Bioactivity in Plants: The Link between Phytochemistry and Medicine”, 1991, pp. 3864-3874.

¹⁷⁸ LI et al., “Drug discovery and Natural Products: End of an Era or an Endless Frontier?”, 2009, p. 162.

¹⁷⁹ See generally CRAGG and NEWMAN, “Natural Products as sources of new drugs over the last 25 years”, 2007, pp. 461-477.

¹⁸⁰ HARVEY, “Medicines from nature: are natural products still relevant to drug discovery?”, 1999, pp. 196-198; see also FEHER and SCHMIDT, “Property distributions: Differences between Drugs, Natural Products, and Molecules from Combinatorial Chemistry”, 2003, pp. 218-227; DUCOR, “New Drug Discovery Technologies and Patents”, 1996, p. 373.

Eventually, a compelling case is being made for the intrinsic utility of natural products as sources of drug leads.¹⁸¹ According to several recent reviews, the major advantage of natural products resides in their structural diversity, which is greater than what is provided by most existing combinatorial approaches.¹⁸²

In addition, emerging and re-emerging infectious diseases, partly because of the growth in antibiotic resistance, provides impetus to the need to discover new cures. At least 29 previously unknown diseases have appeared globally since 1973 and 20 well-known ones have re-emerged.¹⁸³ As a result, there is a revived interest in natural products, such as plant-derived drugs, as a basis for drug candidates.¹⁸⁴

One has to bear in mind that the concept of “plant-derived drugs” may be very broadly defined or not. Some fundamental conceptual distinctions should be drawn before entering in any legal analysis on the patentability of plant and TMK-derived drugs.

A first distinction has to be made as to the collection strategies of natural products, which include the random method, the targeted plant families’ method, and the ethnobotanical approach. While the random method involves the complete collection of plants found in a specific geographical area, the targeted plant families’ method targets for collection of those plant families known to be rich in biologically active compounds. The third approach is based on local or indigenous people’s knowledge about medicinal activities of the plants.¹⁸⁵

¹⁸¹ HARVEY, “Natural Products in Drug Discovery”, 2008, p. 897; LI et al., “Drug discovery and Natural Products: End of an Era or an Endless Frontier?”, 2009, p. 163.

¹⁸² CRAGG and NEWMAN, “Natural Products: A Continuing Source of Novel Drug Leads”, 2013, pp. 3679-3681; see also DUCOR, “New Drug Discovery Technologies and Patents”, 1996, p. 375 (For the author, “it is hardly surprising that natural products have pharmacological effects. According to evolution theory, a natural product which has been inherited throughout evolution must have had some effect on biological systems; if not, it probably would have disappeared”).

¹⁸³ NOJI, “The Global Resurgence of Infectious Diseases”, 2001, p. 224.

¹⁸⁴ See generally, CRAGG and NEWMAN, “Natural Products: A Continuing Source of Novel Drug Leads”, 2013, pp. 3679-3681; see also, GUPTA et al., “Nature’s Medicines: Traditional Knowledge and Intellectual Property Management. Case Studies from the National Institutes of Health (NIH), USA”, 2005, p. 206.

¹⁸⁵ BALICK, “Ethnobotany and the Identification of Therapeutic Agents from the Rainforest”, 1990, pp. 24-25.

A second distinction has to be made as to the utilisation of plants having therapeutic activities. First, it refers to the direct utilisation of crude herbal material without any manipulations, such as, for instance the direct application of the plant or extract on the skin or its oral intake. Second, this herbal material may be processed by various local procedures or phytopharmaceutical preparation,¹⁸⁶ such as steaming, roasting, or stir-baking with honey or vinegar. The resulting products comprise many diverse forms, such as tinctures, fluid extracts, powder, pills and capsules. Third, plants may undergo successive extraction and purification processes to isolate the chemical compound. Once the chemical compound has been isolated, the researchers have two distinct choices. First, the same pure active compound can be directly used as a drug. Second, the pure compound may be subjected to further synthetic manipulations such as structure elucidation or structure modification resulting in a synthetic drug.¹⁸⁷ In other words, the synthetic drug is the replication of the structure of the natural compound permitting its mass-production in the form of a drug.¹⁸⁸

It has been argued that synthetic pharmaceutical products possess relevant advantages over natural products. These advantages mainly refer to the criteria that pharmaceutical drug requirements must comply with safety, effectiveness and quality. Nevertheless, while scientists recognise that it may be hazardous and challenging to derive pharmaceutically relevant compounds from nature, it is even more difficult to discover complex molecules with therapeutic properties from synthetic chemistry alone.¹⁸⁹ For instance, “complex compounds such as paclitaxel (taxol) would never have been synthesized in the laboratory, if they had not been identified initially from nature and discovered to contain anti-cancer properties”.¹⁹⁰ In addition, according to the National Cancer Institute (NCI), one of the main institutes of the US National Institutes of Health (NIH), the diversity of chemical compounds that can be derived from natural sources presents a higher probability of drug leads.

¹⁸⁶ A phytopharmaceutical is any manufactured medicine that is exclusively produced by means of plants.

¹⁸⁷ RATES, “Plants as Source of Drugs”, *Toxicon*, 2001, vol. 39(5), pp. 603-613, p. 605; HAMBURGER and HOSTETTMAN, “Bioactivity in Plants: The Link between Phytochemistry and Medicine”, 1991, p. 3865.

¹⁸⁸ LAIRD and TEN KATE, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, 1991, p. 40.

¹⁸⁹ GUPTA et al., “Nature’s Medicines: Traditional Knowledge and Intellectual Property Management. Case Studies from the National Institutes of Health (NIH), USA”, 2005, p. 206.

¹⁹⁰ GUPTA et al., “Nature’s Medicines: Traditional Knowledge and Intellectual Property Management. Case Studies from the National Institutes of Health (NIH), USA”, 2005, p. 206.

According to the scientific literature, plant-derived drugs and synthetic drugs are not in competition, but rather complementary. Indeed, the combination of traditional approaches to drug discovery with new techniques involving combinatorial chemistry, high-throughput screenings (HTS), natural product genomics,¹⁹¹ and synthetic biology have boosted the interest of the pharmaceutical industry in plants, specifically, and, natural products in general.¹⁹²

Parallel to a regaining of interest in natural products, traditional medicinal knowledge is not being left behind as a means of discovering lead compounds.¹⁹³

4 **Traditional Medicinal Knowledge-derived Drugs**

Traditional knowledge's contribution to the drug discovery process is mainly twofold.¹⁹⁴ First, it constitutes a cost-effective method for screening material because it provides the researchers with a very valuable short cut to species of plants with bioactive compounds.¹⁹⁵ Second, the utilisation of the traditional medicinal knowledge of indigenous communities may

¹⁹¹ See generally, MONKS et al, "Natural Products Genomics: A novel approach for the discovery of anti-cancer therapeutics", *Journal of Pharmacological and Toxicological Methods*, 2011, vol. 64(3), p. 217.

¹⁹² WANG, "Needs for New Plant-derived Pharmaceuticals in the Post-genome Era: An Industrial view in Drug Research and Development", 2008, p. 403; see also, BAGLEY and RAI, "The Nagoya Protocol and Synthetic Biology Research: A Look at the Potential Impacts", 2014; see also, KINGSTON, "Modern Natural Products Drug Discovery and its Relevance to Biodiversity Conservation?", 2011, p. 497.

¹⁹³ See recently adopted European Union Regulation No 511/2014 of the European Parliament and of the Council of 16 April 2014 on Compliance Measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (EU Regulation 511/2014), Official Journal of the European Union, L 150/59, 20 May 2014, Preamble Paragraph 5 states that "traditional knowledge that is held by indigenous and local communities could provide important lead information for the scientific discovery of interesting genetic or biochemical properties of genetic resources".

¹⁹⁴ Also called Ethnopharmacology and ethnobotanical approach to drug discovery.

¹⁹⁵ PLOTKIN, M., "Traditional Knowledge of Medicinal Plants – The Search For New Jungle Medicines", 1991, p. 53-64; ROBINSON, *Confronting Biopiracy – Challenges, Cases and International Debates*, 2010, p. 25 ("Researchers accessing the materials has often used the knowledge of indigenous or local peoples over specific traits relating to plants to shortcut the many steps involved in the chain of invention resulting in commercially viable drugs).

considerably shorten preclinical pharmacological and toxicological tests.¹⁹⁶ In addition, some authors argue that traditional medicinal knowledge, in the pharmaceutical sector, has been found to increase the success ratio of bioprospecting by 400 per cent,¹⁹⁷ while others suggest that the pharmaceutical sector is moving towards genes, and away from organisms.¹⁹⁸

The utilisation of traditional medicinal knowledge as a guide to biological active compounds covers two situations. First, the traditional medical use of the plant serves as a direct source of information for the new drug development process. The essential information encompassed in the specific traditional medicinal knowledge is constituted by plant A with therapeutic effect X. The final drug results from the isolation of the active principle of the biological compound A that has the same pharmacological action X. In other words the final drug is a copy of the traditional medicinal knowledge with the particularity of the former being isolated and synthesised. Second, traditional medicinal knowledge may be used indirectly to produce a final drug. In this case, the traditional knowledge of the therapeutic properties of a plant may constitute an interesting starting point in the sense that new therapeutic uses (different from the TMK use) may be discovered.¹⁹⁹

According to the Director-General of the World Health Organisation, traditional medicinal knowledge has provided and still provides researchers with a direction (with a lead) to isolate valuable active compounds within biological (genetic) resources.²⁰⁰ Numerous journals are

¹⁹⁶ WANG Ying, “Needs for New Plant-derived Pharmaceuticals in the Post-genome Era: An Industrial view in Drug Research and Development”, 2008, p. 397.

¹⁹⁷ OBTERTHÜR Sebastian and ROSENDAL Kristin, “Global Governance of Genetic Resources: Background and Analytical Framework”, 2014, p. 3 (the authors notes that “in many cases, especially within the medicinal sector, traditional knowledge about characteristics, effects and possible uses of particular plants that is held by ILC is crucial for efforts to utilize and exploit related GRs in biotechnology and the life sciences”); See also REID, “Gene Co-ops and the Biotrade: Translating Genetic Resource Rights into Sustainable Development”, 1996, pp. 75-92.

¹⁹⁸ LAIRD Sarah, *Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Pharmaceutical Industry*, 2013, p. 10.

¹⁹⁹ FARNSWORTH and FABRICANT, “The Value of Plants Used in Traditional Medicine for Drug Discovery”, 2001, pp. 69-75 (providing an overview of examples documenting the value of using traditional knowledge to initiate drug discovery process).

²⁰⁰ The Director-General of the World Health Organisation stated that “The time is also right to view traditional medicine as a precious resource. It needs to be respected and supported as a valuable source of leads for therapeutic advances and the discovery of new classes of drugs. I need mention only artemisinin

published on the knowledge of indigenous peoples and local communities on the use of plants, such as the Journal of Ethnopharmacology, the Journal of Chinese Medicine, Pharmaceutical Biology, Planta Medica, Phytotherapy Research, and Phytochemistry to name a few.²⁰¹ The role of traditional knowledge of the therapeutic properties of plants as a rich source of therapeutic leads for drug discovery is also acknowledged by experts active in health sectors.²⁰² They draw upon successful stories related to Artemisinin,²⁰³ aspirin,²⁰⁴ morphine, saffron,²⁰⁵ quinine,²⁰⁶ tubocurarine,²⁰⁷ and Turmeric.²⁰⁸ All of these traditional

for malaria to make this point.” Dr CHAN, available at :

<http://www.who.int/dg/speeches/2008/20081107/en/index.html> [accessed September 2016].

²⁰¹ WIPO PCT Union, ‘PCT Minimum Documentation: Traditional Knowledge’, the International Bureau, 21-25 February 2005, PCT/MIA/11/5 (These journals have been listed by WIPO as constituting the minimum documentation list of the Patent Cooperation Treaty (PCT). The objective is to include traditional knowledge documentation in the searchable prior art within the defensive protection approach).

²⁰² CORSON and CREWS, “Molecular Understanding and Modern Application of Traditional Medicines: Triumphs and Trials”, 2007, p.773 (Ethnopharmacologists must identify a medicine, its uses, and active components. These efforts are urgent, as traditional knowledge— and traditional plant species—are being lost at an alarming rate”); see generally, BAUD and GHASARIAN, *Des plantes psychotropes - Initiations, thérapies et quêtes de soi*, 2013.

²⁰³ CORSON and CREWS, “Molecular Understanding and Modern Application of Traditional Medicines: Triumphs and Trials”, 2007, p. 770 (Artemisinin has been found in 1972 by the Chinese military after research into medicinal plants. However, until now, its mode of action has not been fully established. This is mainly due to the fact that “the artemisinin content in plant extracts varies widely due to the environmental conditions. Currently, it constitutes the most effective antimalarial available).

²⁰⁴ CORSON and CREWS, “Molecular Understanding and Modern Application of Traditional Medicines: Triumphs and Trials”, 2007, p. 770 (the active ingredient in aspirin, acetyl salicylic acid, is a synthetic derivative of a compound, salicin, which occurs naturally in plants, notably the willow tree. Extracts of willow were traditionally used in folk medicine and as early as 400 BC the Greek physician Hippocrates recommended a brew made from willow leaves to treat labour pains. Later in 1763 an English clergyman, Reverend Edward Stone carried out the first proper scientific study of the herbal medicine when he described the benefits he observed after giving ground up willow bark to 50 parishioners suffering from rheumatic fever).

²⁰⁵ See GOHARI et al., “An Overview on Saffron, Phytochemicals, and Medicinal Properties”, 2013, pp. 61-66 (Saffron is the most valuable medicinal food product because of its importance in Iran's agricultural economy. It is also been used in folk medicine and Ayurvedic health system as a sedative, expectorant, anti-asthma, emmenagogue, and adaptogenic agent); see also AKHONDZADEH et al., “*Crocus sativus* L. in the treatment of mild to moderate depression: a double-blind, randomized and placebo-controlled trial”, 2005, p. 148 (The ancient Persian word for Saffron was Karkum and it was used for depression in Persian traditional medicine. Akhondzadeh assessed the efficacy of the stigmas of *Crocus sativus* (saffron) in the

medicine-related new drugs are currently being used by non-indigenous or non-traditional medicine in modern hospitals all over the world.

This section has provided a broad overview of the importance of natural products and traditional knowledge, as pharmaceutical products in themselves and/or as guides to bioactive molecules. New techniques in the drug discovery process will help to speed up the process of identification of novel lead structures. While some scientists would argue that the interest in natural products, and the traditional knowledge related to it, is slowing down, others “believe that a very significant portion of these leads will continue to be natural product derived”. They recall that “Mother Nature has had three billion years to refine her chemistry and we are only now scratching the surface in exploring Nature’s molecular diversity!”²⁰⁹ In addition, consumers’ regaining of interest in the products of nature seems to indicate other future perspectives.

Finally, while the use of the traditional knowledge of indigenous peoples for curing fatal diseases is essential and praiseworthy, what is rather questionable is when patented drugs are

treatment of mild to moderate depression in a 6-week double-blind, placebo-controlled and randomized trial).

²⁰⁶ GREENWOOD, “The Quinine Connection”, 1992, p. 417 (Quinine, an alkaloid derived from the bark of the cinchona tree was brought to Europe from Peru in the 17th century. It has been used by Peruvian Indians to suppress shivering. Isolation of quinine and other cinchona alkaloids was achieved in France in the early part of the 19th century and uncertainties of supply of the bark stimulated efforts to synthesize quinine).

²⁰⁷ CRAGG and NEWMAN, “Natural Products: A Continuing Source of Novel Drug Leads”, 2013, p. 3671 (tubocurarine, the principal muscle relaxant known today, has been isolated from *Chondrodendron* and *Curarea* species used by indigenous groups in the Amazon as the basis for the arrow poison).

²⁰⁸ NASRI Hamid et al., “Turmeric: A Spice with Multifunctional Medicinal Properties”, 2014, p. 5 (the article provide a brief summary of the new and current knowledge of the effects of curcumin); RINGMAN et al., “Oral Curcumin for Alzheimer’s disease: tolerability and efficacy in a 24-week randomised, double blind, placebo-controlled study”, 2012, p. 43 (Investigators at the University of California at Los Angeles, studying a mouse model of Alzheimer’s, reported that the brains of animals fed curcumin had up to 80 percent fewer of the protein plaques associated with the disease than those of mice given a normal diet); see also AGGARWAL et al., “Synthesis, characterization and in vitro anticancer activity of C-5 curcumin analogues with potential to inhibit TNF-alpha-induced NF-kappaB activation”, 2014, pp. 1-10 (Bharat Aggarwal, a professor of cancer medicine at the University of Texas M.D states that evidence is mounting that curcumin may help fight many cancers).

²⁰⁹ CRAGG and NEWMAN, “Natural Products: A Continuing Source of Novel Drug Leads”, 2013, p. 3690.

derived from that same traditional knowledge and sold at a high price. This question will be further analysed in Part II of this work.

Chapter 3 Selected International Legal Framework Relevant to Traditional Medicinal Knowledge

As discussed earlier, traditional knowledge, in general, and traditional medicinal knowledge in particular, has not yet become a specific field of legal study at the international level. Indeed, there are few express provisions on traditional medicinal knowledge in relevant international instruments, and in most of the relevant international organisations, the issue of traditional medicinal knowledge is integrated into the broader discussion related to traditional knowledge. The issue of traditional knowledge as intangible cultural heritage²¹⁰ is addressed by the United Nations Educational, Scientific and Cultural Organisation (UNESCO) for the purpose of its safeguarding, and, with respect to healthcare, by the World Health Organisation (WHO). From the perspective of intellectual property, the World Intellectual Property Organisation (WIPO) is dealing with the issue of the protection of TK through intellectual property. TK is addressed by the United Nations Environment Programme (UNEP) in the context of the Convention on Biodiversity (CBD), and by the United Nations Conference on Trade and Development (UNCTAD) in the context of trade and development. With respect to agriculture, it is dealt with by the Food and Agriculture Organisation (FAO) and the Consultative Group on International Agricultural Research (CGIAR).²¹¹ Within the WTO in the context of TRIPS, Paragraph 19 of the Doha Declaration expressly addresses traditional knowledge. In other words, the concept of traditional knowledge finds its place in a wide variety of debates with objectives ranging from the preservation of cultural diversity, poverty eradication, biodiversity management and the protection of intellectual property.

In the following paragraphs, the analysis will be limited to a selection of international fora discussing the legal protection of traditional medicinal knowledge.

²¹⁰ UNESCO Convention 2003, Article 2 (“The intangible cultural heritage means the practices, representations, expressions, knowledge, skills – as well as the instruments, objects, artefacts and cultural spaces associated therewith – that communities, groups and, in some cases, individuals recognize as part of their cultural heritage. This intangible cultural heritage, transmitted from generation to generation, is constantly recreated by communities and groups in response to their environment, their interaction with nature and their history, and provides them with a sense of identity and continuity, thus promoting respect for cultural diversity and human creativity”).

²¹¹ International Treaty on Plant Genetic Resources for Food and Agriculture, adopted Nov. 3, 2001, Rome, S. Treaty Doc. No. 110–19 (International Treaty or ITPGRFA), Article 9.2(a) defines traditional knowledge as “traditional knowledge relevant to plant genetic resources for food and agriculture”.

1 Conservation of Biological Diversity

“Only when the last tree has died and the last river has been poisoned and the last fish has been poisoned we will realise we cannot eat money”.²¹²

The link between traditional knowledge and the conservation of biodiversity can be reduced to the worldwide recognition of the essential role that the holders of these knowledge systems play in the conservation and sustainable use of biological diversity.²¹³ The following paragraphs will briefly describe two important international agreements relating to the conservation of biodiversity, and analyse their provisions related to traditional knowledge.

As a first step, the main provisions related to traditional knowledge in the CBD will be analysed. Then, the analysis will extend to the Nagoya Protocol and its provisions related to traditional knowledge, given that the Protocol constitutes the international regime on the issue of access to, and benefit sharing of, genetic resources and the associated traditional knowledge, including the knowledge related to the therapeutic properties of these natural occurring resources.

1.1 The Convention on Biodiversity

The Convention on Biological Diversity (CBD, the Convention on Biodiversity or the Biodiversity Convention) was adopted in 1992 under the United Nations Environment Programme (UNEP), in Rio de Janeiro, Brazil. It entered into force on 29 December, 1993.²¹⁴ It currently has 193 Contracting Parties.²¹⁵ It is both an international binding treaty and an institutional framework for the development of further legal and policy initiatives on biological diversity.

²¹² Cree Indian proverb quoted by the European Union Commissioner, Janez Potocnik in Our Planet, the Magazine of the United Nations Environment Programme, ‘Natural Capital – The Economics of Ecosystems and Biodiversity’, September 2010, p. 24, available at: http://www.unep.org/pdf/OP_sept/2010/EN/OP-2010-09-EN-FULLVERSION.pdf [accessed September 2016].

²¹³ See generally, BURELLI, “De la conservation de la biodiversité à l’émergence des droits de la propriété intellectuelle autochtones : la reconnaissance progressive de l’apport des savoirs autochtones et leur protection en droit international”, 2015, pp. 181-199.

²¹⁴ Convention on Biological Diversity, adopted 5 June 1992, 1760 UNTS 79 (Convention on Biodiversity or CBD).

²¹⁵ See www.cbd.int/information/parties.shtml, last visited September 2016.

Recognising "the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural, [...] values of biological diversity and its components",²¹⁶ the CBD lays down the foundations of a market related to biodiversity.²¹⁷ Practically, sustainable use of the biodiversity components means finding new drugs, crops, and industrial products, while conserving the resources for future studies. In other words, this market aims to stimulate the innovations in the field of biotechnology, and to finance the conservation of genetic resources²¹⁸ and, as a subsidiary matter, the associated traditional knowledge. It deals not only with the conservation of biological diversity *in situ*²¹⁹ and *ex situ*²²⁰, but also with its sustainable use and the sharing of its benefits.

Like other multilateral agreements, the CBD creates rights and obligations among its sovereign Contracting Parties. Under the CBD, even though genetic resources are subject to the State sovereignty²²¹ – and no longer part of the world heritage – States are obliged to facilitate access to them.²²² In other words, establishing sovereign rights over natural resources and the associated traditional knowledge is the opposite of considering them as the common heritage of mankind. Notwithstanding this, States are required to preserve and use genetic resources in a manner compatible with the common interest of mankind. Additionally, institutions such as universities, gene banks and botanic gardens are also obliged to comply

²¹⁶ CBD, Preamble, paragraph one.

²¹⁷ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 11.

²¹⁸ CBD, Article 2 ("genetic resources" is defined as "genetic material of actual or potential value". Genetic material is in turn defined as "any material of plant, animal or other origin containing functional units of heredity". The broader related concept of biological resources encompasses "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity", but by definition need not contain functional units of heredity; See also, UNEP/CBD/COP/2/19, p. 22 (The CBD COP clarified that "human genetic resources are not included within the framework of the Convention").

²¹⁹ CBD, Articles 2 and 8 (*in-situ* refers to the place where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties).

²²⁰ CBD, Article 2 and 9 (*ex situ* refers to the place where genetic resources exist outside their natural habitats, i.e. Gene banks, botanical gardens, etc.).

²²¹ See preambular paragraph 4, Article 3 and 15 of the Convention on Biological Diversity (CBD).

²²² CBD, Article 15.

with the objectives of the CBD. As for other private actors, their rights and responsibilities will depend on the provisions of national laws.

The three objectives of the Convention are (i) the conservation of biological diversity; (ii) the sustainable use of its components; and (iii) the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.²²³ As already mentioned, the CBD obliges Parties to facilitate access to genetic resources. According to the Convention, such access shall be subject to the Parties' prior informed consent (PIC),²²⁴ and on mutually agreed terms (MAT)²²⁵ that promote the fair and equitable sharing of benefits.²²⁶ The Convention on Biodiversity, therefore, has favoured a contractual approach to the access and benefit-sharing system. However, the obligations and rights of the Parties, including the obligation to facilitate access and to share benefits, have to be read in the light of the primary obligation, that is, to ensure the conservation of biodiversity. In this context, the role of traditional knowledge has been recognised and directly linked to the objectives of the CBD.

1.1.1 Scope of the Convention on Biological Diversity for Traditional Medicinal Knowledge

The CBD does not refer to the term “traditional medicinal knowledge”²²⁷ as such, but gives some regard to the issue of traditional knowledge, recognising that indigenous and local communities play an essential role in the conservation of biodiversity.²²⁸

The Convention contains provisions relevant to the issue of traditional knowledge in five (six with the preambular paragraph) distinct Articles. Relevant provisions begin with paragraph 12 of the Preamble, which recognises “the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge,

²²³ CBD, Article 1.

²²⁴ CBD, Article 15.5.

²²⁵ CBD, Article 15.4.

²²⁶ CBD, Article 15.7.

²²⁷ As already settled in definitions in Chapter 1, 1.1, traditional medicinal knowledge refers to the traditional of the therapeutic properties of plants.

²²⁸ The link between indigenous and local communities is stated several times in the CBD. Preambular paragraph 12 and 13, Articles 8(j) and 10(c); see also GLOWKA, “A Guide to the Convention on Biological Diversity”, p. 48.

innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components”.²²⁹

Article 8(j) of the CBD encompasses the main provisions relevant to traditional knowledge for *in situ* conservation. It encapsulates the Convention's approach to traditional knowledge in accordance with the preamble and its main objectives under Article 1.²³⁰ Being the key provision of the CBD relating to traditional knowledge, it deserves quotation in full:

“Each Contracting Party shall, as far as possible and as appropriate: [...] (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote wider application with the approval and involvement of holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices”.²³¹

The importance of this article stems from the fact that it explicitly mentions the holders of traditional knowledge and recognises their active contribution to the conservation of biodiversity. It is through this argumentation that the protection of traditional knowledge was first raised in the context of biodiversity discussions. This article raises a number of issues.

First, Article 8(j) does not define traditional knowledge. It only outlines some of its characteristics and provides an indication of how the concept should be understood in the framework of the CBD. It specifically links such “knowledge, innovations and practices” to “indigenous and local communities.” It also refers to traditional lifestyles that are “relevant for the conservation and sustainable use of biological diversity,” i.e. in conformity with the CBD’s objectives. However, it is questionable whether the term “traditional lifestyles” is equivalent to a complete conception of TK or whether its linking with biodiversity adds a new condition for the traditional knowledge to deserve protection.²³² One of the legal effects of

²²⁹ CBD, paragraph 12 of the Preamble.

²³⁰ CBD, Article one.

²³¹ CBD, Article 8(j).

²³² GLOWKA, “Guide to the Convention on Biological Diversity”, 1994, p. 48 (the author interprets the terms “traditional lifestyles” as excluding the knowledge of groups that are descendent of indigenous communities but, who have “assimilated into mainstream, non-traditional economy and society”).

this article is that non-traditional knowledge, innovations and practices will be excluded from the scope of the Convention. Further, aspects of traditional knowledge that are not environmentally sound are equally excluded.

Second, article 8(j) does not provide any property-like rights to traditional knowledge holders compared to the sovereignty granted to States over biological resources. Thus, indigenous peoples and local communities are “only entitled to have a piece of the pie.”²³³ Rather than establishing a real obligation, it is more a statement of guidelines insofar as the provision is qualified by terms that encourage states to implement specific obligations “as far as possible and as appropriate.”²³⁴

On the whole, Article 8(j) contains three different recommendations directed to States Parties. First, Contracting Parties “*shall* respect, preserve and maintain” such knowledge, innovations and practices. Second, it requests States to “promote wider application with the approval and involvement of the holders of such knowledge, innovations and practices”. Third, the article calls for the encouragement of “the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices”.

Under this provision, the underlying rationale for benefit-sharing is as a reward for the custodians of biodiversity, i.e. indigenous and local communities.²³⁵ As opposed to the use of genetic resources,²³⁶ the utilisation of traditional knowledge is not expressly linked to the obligation of Access and Benefit-sharing. However, the interpretation of the CBD in relation to traditional knowledge has considerably evolved during the discussions in the context of Access and Benefit-sharing negotiations.²³⁷ This interpretation, which goes beyond a strict interpretation of the CBD, has resulted in a combined reading of Articles 8(j) and 15 of the CBD.²³⁸

²³³ KOOPMAN, “Amidst Peril and Progress: Conservation of Diversity and Patent Law”, 2006, p. 138.

²³⁴ See, for example, CBD, Articles 7, 8, 9, 10 and 11.

²³⁵ SCHROEDER Doris, “Justice in Benefit-Sharing”, 2009, p. 24.

²³⁶ CBD, Article 15(7).

²³⁷ See generally, MORGERA, TSIOUNMANI, “The Evolution of Benefit-Sharing”, 2010, pp. 150-173.

²³⁸ CBD, Article 15(7) reads as follows: “Each Contracting Party shall take legislative, administrative or policy measures, [...] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms”.

Similarly, the CBD does not require prior informed consent²³⁹ of indigenous traditional knowledge holders in contrast to the regime for genetic resources. It only encourages States to “promote wider application with the *approval and involvement of holders of such knowledge, innovations and practices*”.

As mentioned previously, Article 8(j) covers *all traditional knowledge of indigenous and local communities*, including traditional knowledge associated with genetic resources, which is relevant for biodiversity conservation.²⁴⁰ Indeed, conservation and sustainable use of biological resources constitute the overall mandate of the Convention on Biodiversity. Thus, traditional cultural expressions, as defined within WIPO, are not included in this concept. In the report of the meeting of the group of technical and legal experts on traditional knowledge associated with genetic resources, the experts stated that “associated traditional knowledge does not necessarily have to be associated with genetic resources, as it can also include the use of traditional knowledge associated with biological resources, i.e. traditional biodiversity-related knowledge”.²⁴¹

Several other articles of the CBD are relevant to the knowledge of indigenous and local communities, namely Articles 10(c), 16(5), 17 and 18(4). These provisions have to be read in conjunction with Article 8(j) in order to understand their requirements and thereby mutually reinforce each other.

Article 10(c) calls upon Parties to “protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements”. Traditional knowledge, and particularly traditional medicinal knowledge, is the direct result of the “traditional cultural” use of biological resources. In other words, Contracting Parties would have to secure indigenous

²³⁹ The concept of “prior informed consent” (PIC) will be analysed within the framework of the Nagoya Protocol and the United Nations Declaration of the Rights of Indigenous Peoples.

²⁴⁰ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 30.

²⁴¹ CBD WG-ABS, ‘Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing’, 9-15 November 2009, UNEP/CBD/WG-ABS/8/2, p. 8.

peoples access to the land and its biological resources.²⁴² For instance, Cotula and Mayers highlight the gap between what is written and what occurs in practice in terms of local land tenure and projects aiming at reducing emissions from deforestation and forest degradation. Indeed, despite a growing international recognition of communities' rights to self-determination and to manage their natural resources, international rights are far from a panacea against the denial of procedural and substantive justice.²⁴³

Article 16(5) constitutes an important provision for the purpose of the present analysis although it does not address the issue of traditional knowledge. It recognises that “patents and other intellectual property rights may have an influence on the implementation of this Convention”. It thus requires that Contracting Parties “shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.” This provision is highly controversial and forms the basis of the continuous discussions in the TRIPS Council regarding the relationship between intellectual property rights and the objective of the CBD.²⁴⁴

Article 17 requires Parties to facilitate the exchange of information. The word “facilitate” implies that the Parties are expected to remove barriers that may hinder the exchange of information. This obligation is qualified in two ways. First, the information has to be “relevant to the conservation and sustainable use of biological diversity”. Second, this article applies to information from “publicly available sources.”²⁴⁵ Accordingly, it “excludes all confidential information held by a Contracting Party's public or private sectors, such as trade secrets.”²⁴⁶

Finally, Article 18.4 sets forth the requirements for technical and scientific cooperation, and states that “Parties shall encourage and develop methods of cooperation for the development

²⁴² BARSH, “How do you patent a landscape? The perils of dichotomizing cultural and intellectual property”, p. 33.

²⁴³ COTULA Lorenzo and MAYERS James, *Tenure in REDD: Start-Point or Afterthought?*, 2009, p. 23.

²⁴⁴ See WTO News Items: Nagoya gives new context to old views in intellectual property council, available at: https://www.wto.org/english/news_e/news11_e/trip_01mar11_e.htm, 1 March 2011, [accessed August 2016]; see also, WTO TRIPS Council, ‘The Relationship between the TRIPS Agreement and the Convention on Biological Diversity’, 8 February 2006, IP/C/W/368/Rev.1 (provides with a comprehensive summary on the relationship between the TRIPS Agreement and the CBD).

²⁴⁵ The terms publicly available, publicly accessible and public domain will be discussed in Part II, chapter 3.

²⁴⁶ GLOWKA, “Guide to the Convention on Biological Diversity”, 1994, p. 92.

and use of technologies, including indigenous and traditional technologies, in pursuance of the objectives of this Convention.”²⁴⁷ Thus, the exchange of information is not limited to the most advanced fields of technologies, often developed within industrialised countries, but it also includes relevant traditional and indigenous knowledge systems. However, it is also worth mentioning that much traditional knowledge is likely to be most valuable as a means to achieve on site sustainable economic management.²⁴⁸

As seen from the provisions discussed above, Article 8(j) is the sole provision of the CBD expressly mentioning traditional knowledge. It is important to emphasise several points in this regard. First, the provision does not create any enforceable rights for holders of traditional knowledge. Second, it imposes no explicit obligation on Member States to ensure that the use of their indigenous peoples’ traditional knowledge has taken place with fair and equitable benefit-sharing. In all likelihood, neither consent nor any involvement of indigenous or local communities in granting access to their traditional knowledge and the genetic resources associated to it is required. While recognising the role traditional knowledge custodians play in the conservation of biodiversity, the Convention does not acknowledge that indigenous peoples and local communities are entitled to be considered as the owners of traditional knowledge and the genetic resources associated with it, or to claim any control over their traditional knowledge.²⁴⁹

1.1.2 The Follow-up Implementation Process of the Convention on Biodiversity

The issue of traditional knowledge has been on the agenda of the Conference of the Parties (COP)²⁵⁰ since its third meeting in 1996. This meeting resulted in the adoption of Decision III/14 titled “Implementation of Article 8(j)”, whereby Parties agreed on the need to “develop national legislation and corresponding strategies for the implementation of Article 8(j) in

²⁴⁷ CBD, Article 18.4.

²⁴⁸ This would be particularly the case for TK that is, for instance, relevant for combating desertification or land degradation.

²⁴⁹ NIJAR, “Incorporating Traditional Knowledge in an International Regime on Access to Genetic Resources and Benefit Sharing: Problems and Prospects”, 210, pp. 457-475.

²⁵⁰ The Conference of the Parties (COP) is the governing body of the CBD. Its main role is to carry out the implementation of the Convention through the decisions it takes at its periodic meetings. To date, COP has held 13 ordinary meetings from which around 300 procedural and substantive decisions have seen the light.

consultation particularly with representatives of their indigenous and local communities".²⁵¹ The establishment by the fourth COP of the *Ad Hoc* Open-ended Working Group on Art. 8(j) and Related Provisions of the Convention (WG-8J), is one of the most significant accomplishments for the protection of traditional knowledge.²⁵² It was established in 1998 to further implement the CBD's provision on traditional knowledge, innovations and practices of indigenous and local communities. The Parties recognised "the importance of making intellectual property-related provisions of Article 8(j) and related provisions of the Convention on Biological Diversity and provisions of international agreements relating to intellectual property mutually supportive, and the desirability of undertaking further cooperation and consultation with the World Intellectual Property Organization."²⁵³ Apart from being open to all Parties, the Working Group has also invited representatives of indigenous peoples and local communities in order for them to play a full and proactive role in its work. It mainly performs an advisory function to ensure the effective protection of traditional knowledge, including the assessment of existing supranational, regional or national norms on traditional knowledge protection. It further seeks to find opportunities of collaboration with other international fora.

In parallel to WG-8J, the Conference of the Parties (COP) established the *Ad Hoc* Open-ended Working Group on Access and Benefit-Sharing (WG-ABS) with the mandate to develop guidelines and further discuss the implementation of the CBD provisions. Amongst its decisions, the WG-ABS adopted the Bonn Guidelines, in 2002, on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation (the "Bonn Guidelines").²⁵⁴ This step was mainly due to the insufficient and almost non-existent efforts at the domestic level to accomplish "fair and equitable benefit-sharing". The objective

²⁵¹ CBD COP 3, 'Report of the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity', 4-15 November 1996, U.N. Doc. UNEP/CBD/COP/3/38, p. 90-91.

²⁵² In the context of the CBD, the protection of traditional knowledge, innovations and practices refers to a *sui generis* system of protection.

²⁵³ CBD COP, 'Report of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity', 4-15 May 1998, UNEP/CBD/COP/4/27, p. 111.

²⁵⁴ Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation, CBD COP 6 Decision VI/24, "Access and Benefit-Sharing as Related to Genetic Resources", in 'Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity', 7-9 April 2002, UN Doc. UNEP/CBD/COP/6/20, 2002, Annex I, pp. 253-269 (Bonn Guidelines).

of the Bonn Guidelines was to guide users and providers in developing mechanisms and arrangements for ABS with the participation of relevant stakeholder, including indigenous and local communities, based on their prior informed consent (PIC) and upon mutually agreed terms (MAT). As the implementation of the Bonn Guidelines was on a voluntary basis, it did not achieve its intended goal.

Also relevant in the context of traditional knowledge, the WG-ABS was given a new mandate at the 7th meeting of the COP to work jointly with the Working Group on Article 8(j) and Related Provisions to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing in order to effectively implement Article 8(j) and Article 15 of the CBD.²⁵⁵ Eventually, after several meetings held between 2009 and 2010, the finally negotiated text of the draft Protocol was adopted by the COP Plenary on 29 October 2010 at Aichi-Nagoya, Japan.²⁵⁶

1.2 The Nagoya Protocol to the Convention on Biological Diversity

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (hereinafter the Nagoya Protocol, the Protocol or NP), was adopted at the 10th session of the Conference of the Parties (COP), and ultimately entered into force on 12 October 2014.

The Nagoya Protocol is a legally binding text adopted by consensus, and constitutes a complementary agreement to the Convention on Biological Diversity (CBD).²⁵⁷ According to scholars, its adoption by consensus provides it with a “powerful law-making effect, even

²⁵⁵ CBD COP Decision IV/9, “Implementation of Article 8(j) and Related Provisions”, in ‘Report of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity’, 4-15 May 1998, UN Doc. UNEP/CBD/COP/4/27, pp. 111-115.

²⁵⁶ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity, CBD COP Decision X/1, “Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation”, in ‘Report of the Tenth Meeting of the Conference of the Parties to the Convention on Biological Diversity’ Nagoya, 18-19 October 2010, UN Doc. UNEP/CBD/COP/10/27 pp. 82 ff (Nagoya Protocol or NP).

²⁵⁷ The Protocol contains 27 preambular paragraphs, 36 articles and one annex that encompass a non-exhaustive list of monetary and non-monetary compensation means. The text of the Nagoya Protocol is available at: <https://www.cbd.int/abs/text/> [accessed September 2016].

before the treaty enters into force”.²⁵⁸ Article 1 of the Protocol sets out its objective and some of its core functions, which is to further develop the CBD provisions on benefit-sharing, particularly Article 15 CBD dealing with the obligations concerning prior informed consent (PIC) and benefit sharing.²⁵⁹ It establishes rules for the use of genetic material of animals, plants and microbes and the associated traditional knowledge for food, medicines, cosmetics and other possible applications so that both users and providers²⁶⁰ can benefit in a fair and equitable way. The negotiation of the material, temporal and geographical scope of the Protocol was one of the most arduous issues in the drafting process. Article 3 reflects the final agreed scope of the Protocol, which applies: (i) to genetic resources within the scope of Article 15 CBD; (ii) to the benefits arising out of the utilisation of these resources; (iii) to traditional knowledge associated with genetic resources within the scope of the CBD; and (iv) to the benefits arising from the utilisation of such knowledge.

As opposed to the Convention on Biological Diversity, the Protocol expressly links traditional knowledge and Access and Benefit-Sharing (ABS) obligations and specifically recognises indigenous peoples’ rights to engage in negotiations with regard to ABS.²⁶¹ In addition, while access to the genetic resources of indigenous and local communities is not even mentioned in the CBD, the Nagoya Protocol explicitly refers to genetic resources held by indigenous and local communities, although in a prudent manner.²⁶² This issue will be only briefly mentioned as it makes a reference to the “customary laws of indigenous peoples” as referred to in Article 12 of the Nagoya Protocol.

²⁵⁸ BOYLE and CHINKIN, *The Making of International Law*, 2007, p. 160.

²⁵⁹ CBD, Article 28 (“[t]he Contracting Parties shall cooperate in the formulation and adoption of protocols to this Convention”).

²⁶⁰ Nagoya Protocol, Article 6(1) (“[t]he providing party is either the country of origin of the resources or the party that has acquired the genetic resources in accordance with the CBD. The providing party may also be otherwise determined by a Party”).

²⁶¹ Nagoya Protocol, Article 5(5) (“Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms”).

²⁶² Nagoya Protocol, Articles 5(2) and 6(2).

The following paragraphs will analyse the subject of traditional knowledge associated with genetic resources within the provisions of the Protocol. Accordingly, they will not analyse the subject of genetic resources in general or those held by indigenous and local communities.

1.2.1 Scope of the Protocol with Regard to Traditional Knowledge

Traditional medicinal knowledge, as has been previously defined as traditional knowledge of the properties of plant resources, is not dealt with as such in the Nagoya Protocol. The Protocol rather uses the terms “traditional knowledge associated with genetic resources” without providing a definition of these terms. As stated, traditional knowledge associated to genetic resources may encompass traditional knowledge for food, medicines, cosmetics and other possible applications.

As far as the scope of the Protocol is concerned, Article 3 distinguishes between two subject-matters: genetic resources and traditional knowledge associated with genetic resources. The provision reads as follows: “[t]his Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.”²⁶³

The article raises a number of issues with regard to traditional knowledge. First, the Nagoya Protocol only uses the terms “traditional knowledge associated with genetic resources.” Indeed, in contrast to the CBD,²⁶⁴ the Nagoya Protocol has explicitly enshrined “the interrelationship between genetic resources and traditional knowledge [and] their inseparable nature in its preamble”.²⁶⁵ However, this link does not necessarily imply that traditional knowledge needs to be always *accessed* or *used* in combination with a genetic resource. The Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources attempted to clarify the relationship between traditional knowledge and genetic resources. Some experts of the Group have noted that it is “traditional knowledge that inspires

²⁶³ Nagoya Protocol, Article 3.

²⁶⁴ TAUBMAN and LEISTNER, “Analysis of Different Areas of Indigenous Resources”, 2008, p. 152 (The relationship between traditional knowledge and genetic resources is implicitly recognised in the Convention on Biological Diversity (CBD) for the purpose of biodiversity conservation).

²⁶⁵ Nagoya Protocol, Preamble, para. 22.

the process or provides the lead to the properties of a genetic resource although it may not be reflected in the end product, it remains associated to that product”.²⁶⁶ It has also been highlighted by Greiber et al., that a potential user might be only interested in the traditional knowledge and not in the genetic resources associated with it.²⁶⁷ This will be the case, for instance, when laboratories are already in possession of a genetic resource but wish to know the therapeutic applications used by indigenous communities.

Another fundamental point needs to be made in relation to the use of the phrase “traditional knowledge associated with genetic resources” in opposition to “associated traditional knowledge.” The latter expression permits a broader interpretation in the sense that traditional knowledge does not necessarily have to be associated with genetic resources, as it can also refer to the use of traditional knowledge associated with biological resources, which would also include such things as biochemical properties and organic extracts, amongst others. While both terms were considered during the negotiation of the Nagoya Protocol, preference was given to “traditional knowledge associated with genetic resources.”²⁶⁸

However, ongoing negotiations under the auspices WIPO-IGC are considering both terminologies. As will be seen in more depth later, despite the inherent linkages between

²⁶⁶ CBD WG-ABS, ‘Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing’, 9-15 November 2009, UNEP/CBD/WG-ABS/8/2, p. 8 (traditional knowledge might help to discover a genetic resource with interesting therapeutic properties. Two situations are given. Situation A refers to the premise where the traditional knowledge on the properties of the plant is equivalent to the therapeutic properties of the end product that is a drug. Situation B refers to the case where traditional knowledge has been a mere indicator of the genetic resource. In this case, the end product uses differ from the use made by the traditional knowledge holders. Thus, according to the experts group, situation A and B will both trigger benefit-sharing obligations for the party that has resorted to the traditional knowledge. However, determining whether one case falls in situation A or B will not be given at the time of access to the traditional knowledge and the genetic resource, but rather at the time of use, which is during the whole process of research and development).

²⁶⁷ GREIBER et al., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing*, 2012, Article 7, p. 110; MORGERA et al., *Unravelling the Nagoya Protocol - A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 31.

²⁶⁸ See CBD COP 10, ‘the Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity’, Nagoya, 17 October 2010, UNEP/CBD/COP/10/5/Add.5, p. 9, Article 3

traditional knowledge and genetic resources, these two areas are being discussed quite separately in the debates taking place within the WIPO IGC framework, albeit with confusing overlap.

For instance, the WIPO IGC, at the conclusion of its 20th session, in 2013, submitted to the WIPO General Assembly, the draft Articles on “Intellectual Property and the Protection of Genetic Resources [their Derivatives] and Associated Traditional Knowledge,” which referred to “associated traditional knowledge” and “traditional knowledge related to genetic resources”.²⁶⁹

In 2016, the draft Articles entitled, “Consolidated Document Relating to Intellectual Property and Genetic Resources” refers to “associated traditional knowledge” and “traditional knowledge associated with genetic resources” in its list of terms. Throughout the Articles, both terminologies are inserted into brackets.²⁷⁰ For example, Article 1 reads “[This international legal instrument shall/should apply to any [IP] [patent] right or [application] [claimed invention] [derived from] [the utilization of] [directly based on] genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources]. [This instrument applies to genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources]].”²⁷¹

²⁶⁹ WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, the Secretariat, 4-8 February 2013, WIPO/GRTKF/IC/23/4, p. 3 (“associated traditional knowledge means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, *that subsist in genetic resources*. In its turn, “traditional knowledge related to genetic resources as it is understood in the CBD and related instruments and the ITPGRFA”).

²⁷⁰ WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, the Secretariat, 30 May – 3 June 2016, WIPO/GRTKF/IC/30/4, p. 2 (While “the definition provided to “associated traditional knowledge” has not changed, “traditional knowledge associated with genetic resources” now refers to “substantive knowledge of the properties and uses of genetic resources [and their derivatives] held by indigenous [people[s]] and local communities [and which directly leads to a claimed [invention] [intellectual property]]”).

²⁷¹ WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, the Secretariat, 30 May – 3 June 2016, WIPO/GRTKF/IC/30/4, p. 7.

Second, as far as the *utilisation* of traditional knowledge is concerned, while Article 2(c) provides a definition of the “utilization of genetic resources,”²⁷² it does not do so for the utilisation of traditional knowledge. It is, however, commonly accepted that the *use* of traditional knowledge associated with genetic resources can be interpreted analogously with the “utilisation of genetic resources,” as equally meaning research and development on traditional knowledge.²⁷³

Third, as opposed to the CBD,²⁷⁴ the Protocol deals with the rights of indigenous and local communities regarding both their genetic resources and the traditional knowledge associated to it²⁷⁵, although in an uneven way. Nevertheless, under the Nagoya Protocol, there is now a clear international obligation to share the benefits arising from the use of traditional knowledge associated with genetic resources. Whilst genetic resources are, in principle, subject to national sovereignty,²⁷⁶ traditional knowledge belongs to indigenous

²⁷² Nagoya Protocol, Article 2 (c) (the Article reads: “utilisation of genetic resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology and defined in Article 2 of the Convention”. In turn, “biotechnology” is defined as “any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use” and “derivative” as “a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity”. These natural biochemical compounds contain genetic material, i.e. functional units of heredity. Nevertheless, biochemical compounds can also be produced by human intervention by means of methods such as extraction, dilution or concentration. They may or may not hold genetic material. For instance, essential oils and fragrances do not retain functional units of heredity); see also, TVEDT and SCHEI, ‘Genetic Resources’ in the CBD: The Wording, the Past, the Present and the Future, 2010, p. 9 (suggesting that the concept “functional units of heredity” is not solely confined in genes (a segment of DNA) but may also be present in other part of a cell, such as the RNA and proteins. As our understanding of molecular biology progresses, there is a growing awareness that the Central Dogma may not be as valid as scientists thought a decade ago); see generally, TVEDT and SCHEI, “The term ‘Genetic Resources’: Flexible and Dynamic While Providing Legal Certainty”, 2014, pp 18-32.

²⁷³ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 74.

²⁷⁴ The CBD only deals with TK of ILCs under its article 8(j).

²⁷⁵ Nagoya Protocol, Article 6.2; NIJAR, “The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries”, 2011, p. 24.

²⁷⁶ Nagoya Protocol, Articles 5(2) and 6(2) (under these articles, indigenous communities are not only beneficiaries of their knowledge associated to genetic resources but also of the genetic resources per se, if

communities.²⁷⁷ This brings a new breadth to the access and benefit-sharing setting. The relationship is no longer solely between a provider State and a user State (inter-States) but also between the State and the indigenous communities located within its borders (intra-State).²⁷⁸

Finally, although Article 3 determines the scope of the Protocol in relation to its subject-matter, it contains uncertainties on questions concerning its temporal scope. This silence is the direct result of a lack of consensus during the negotiations with regard to the temporal scope of the Nagoya Protocol. It is clear that the Protocol will apply to situations where genetic resources and TK are accessed and utilised after the entry into force of the Protocol. In other words, traditional knowledge that has been accessed before the entry into force of the Protocol cannot retroactively be made subject to the prior informed consent requirement.²⁷⁹ Similarly, any benefits resulted before that date cannot be retroactively subject to sharing obligations.

However, what about situations where genetic resources and traditional knowledge, while having been accessed after the entry into force of the CBD, but before the entry into force of the Nagoya Protocol, continue to be used or have been newly used after the entry into force of the Nagoya Protocol? Without an express solution in the Nagoya Protocol, one has to answer this question by referring to general rules of international law. According to Article 28 of the Vienna Convention, the provisions of a Treaty “do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party.”²⁸⁰ Consequently, the argument according to which any new use of traditional knowledge associated to genetic resources amounts to a situation that has not ceased to exist, is a valid one.²⁸¹ In other words, the generation of new

so provided by national laws. In addition, some national laws recognise ownership prerogatives to indigenous communities.

²⁷⁷ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, pp. 29-30.

²⁷⁸ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 25.

²⁷⁹ Nagoya Protocol, Article 5.

²⁸⁰ Vienna Convention on the law of Treaties, Vienna, 23 May 1969, 1155 UNTS 331, 1980 (Vienna Convention), Article 28.

²⁸¹ KAMAU, “The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and What are the Implications for Provider and User Countries and the Scientific Community”, 2010, p. 255.

benefits - arising from the utilisation of traditional knowledge - after the entry into force of the Nagoya Protocol constitutes a new act or situation. It is very probable that without a clear solution in the text of the Nagoya Protocol, State Parties may require, in their national laws, the sharing of benefits arising from new and continuing uses of traditional knowledge accessed before the entry into force of the Protocol, but after the entry into force of the Convention on Biological Diversity.²⁸²

It is not clear whether the same is true for the requirement of prior informed consent and, the question remains open whether traditional knowledge that has been accessed before that date, but that is newly used, is still subject to the prior informed consent of the holders of knowledge. According to Article 7, it seems that prior informed consent is required only at the time of access.²⁸³ However, it can also be argued that any new use of traditional knowledge is equivalent to a new access, and thus, the requirement of prior informed consent should also be fulfilled.

While the CBD expressly refers to traditional knowledge in only one Article,²⁸⁴ several articles are directly relevant to traditional knowledge in the Nagoya Protocol, including Articles 5(5), 7, 12(2) and 16. Other provisions are also relevant as they concern access and use of genetic resources that are being held by indigenous and local communities.²⁸⁵

Article 5(5) requires Parties to take appropriate legislative, administrative or policy measures, “as appropriate”²⁸⁶ to ensure that benefits generated from the utilisation of traditional knowledge associated with genetic resources are shared in a fair and equitable way with the indigenous and local communities holding such knowledge. This provision clearly goes

²⁸² GREIBER et al., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing*, 2012, p. 90; see also, MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 77.

²⁸³ Nagoya Protocol, Article 7.

²⁸⁴ CBD, Article 8(j).

²⁸⁵ Nagoya Protocol, Articles 5(2) and 6(2) (the provisions concern respectively the utilisation and the access to genetic resources that are “held by indigenous and local communities”).

²⁸⁶ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 127 (the authors note that while the terms “as appropriate” leaves discretion in relation to the type of implementing measures that parties have to adopt, it does not mean that State Parties are free to adopt these measures or not).

beyond the obligation of sharing the benefits as provided for in Article 15(7) of the CBD.²⁸⁷ It is a new obligation with regard to share the benefits arising from the utilisation of traditional knowledge. However, one of the principal difficulties with this will be, in practice, determining who the holders of traditional knowledge are in an access and benefit-sharing transaction.²⁸⁸

Article 7 of the Nagoya Protocol requires Parties to "take measures to ensure that associated traditional knowledge is accessed with prior informed consent (PIC) or "approval and involvement"²⁸⁹ of indigenous peoples and local communities, and that mutually agreed terms (MAT) are established.

Thus, it seems that the Protocol brings traditional knowledge to an almost equal footing with genetic resources by establishing a straightforward link between access/use, benefit-sharing/prior informed consent and traditional knowledge. However, a careful reading of the provisions of the Protocol proves the contrary. The provisions relating to traditional knowledge are formulated in a language that is less binding and is subject to the national law of provider countries.²⁹⁰

Most importantly, Article 16 of the Protocol specifically sets out a number of obligations that State Parties have to implement in order to ensure compliance with the Protocol by users of traditional knowledge.²⁹¹ These inter-state obligations with regard to the users' compliance with domestic national laws in the provider state are concretised through monitoring activities, provided for in Article 17 of the Nagoya Protocol. This monitoring system is based on both checkpoints and an international system for the certification of compliance.²⁹²

²⁸⁷ CBD, Article 15.7.

²⁸⁸ See however, the Preamble of the Nagoya Protocol, which states: "*Mindful* that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities".

²⁸⁹ CBD, Article 15.5.

²⁹⁰ Nagoya Protocol, Article 7 starts with the following wording: "In accordance with domestic law" and "as appropriate".

²⁹¹ The same provision is provided for in Article 15 of the NP with regard to genetic resources.

²⁹² Nagoya Protocol, Article 17; see, KAMAU, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and What are the Implications for Provider and User Countries and the

However, while the Protocol establishes a monitoring system for when genetic resources are utilised, it does not envisage a system for the certification of origin nor the existence of PIC for the utilisation of traditional knowledge.²⁹³ The capacity of the Protocol to serve as a tool for monitoring and enforcing traditional knowledge rights is therefore considerably reduced.²⁹⁴

With regard to the benefit-sharing regime for genetic resources, the protocol envisages an *inter-State* relationship, whereas for traditional knowledge, the benefit-sharing regime is based on an *intra-state* relationship.²⁹⁵ As far as the Protocol does not solve these issues, they are left to national legislation to be dealt with.²⁹⁶

The following paragraphs will analyse in further detail two key measures that have been adopted by the Nagoya Protocol to secure the rights of indigenous communities over their traditional knowledge and genetic resources and to define States obligations to protect these rights. First, as discussed above, Article 7 of the Protocol requires that prior informed consent

Scientific Community”, 2010, p. 252 ; For an in-depth discussion on certification systems see also, TOBIN et al., *Certificates of Clarity or Confusion*, 2008.

²⁹³ CBD, Article 16 (the provision reads: “Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located”).

²⁹⁴ European Parliament Resolution, ‘Development Aspects of Intellectual Property Rights on Genetic Resources: The Impact on Poverty Reduction in Developing Countries’, 15 January 2013, para. 19 (“Notes with [...] regrets in this context that traditional knowledge associated with genetic resources is not covered by any of the Nagoya Protocol’s monitoring measures, given that there is no obligation to disclose to the ‘checkpoint’ information on the TK used, while the internationally recognised certificate of compliance does not cover TK associated with GR, which limits the possibility of tracing biopiracy related to such TK; takes the view that the EU should grant traditional knowledge at least the same level of protection as genetic resources when implementing the Nagoya Protocol”).

²⁹⁵ HELLIO, “Le Protocole de Nagoya: reconnaissance internationale du droit des communautés autochtones et locales aux ressources génétiques de leur environnement ou pis-aller à l’impossible application équitable?”, 2012, p. 582.

²⁹⁶ KOUTOUKI, “The Nagoya Protocol: Status of Indigenous and Local Communities”, 2011, p. 16.

(PIC) is obtained when traditional knowledge associated with genetic resources is accessed.²⁹⁷ Second, Article 12 which calls upon States to “take into consideration the customary laws and protocols” of Indigenous peoples and local communities in implementing the Nagoya Protocol. By integrating these two concepts in relation to indigenous communities, some scholars have argued that the Protocol makes a direct link with relevant international human rights law, namely the Universal Declaration on the Rights of Indigenous Peoples.²⁹⁸

1.2.2 Prior Informed Consent as it relates to Traditional Knowledge

The key provisions with regard to prior informed consent in relation to traditional knowledge associated with genetic resources are provided by Articles 7 and 16 of the Nagoya Protocol.

According to Article 7 of the Nagoya Protocol, “each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities *is accessed* with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established”.

Article 16 of the Nagoya Protocol, in its turn, calls upon State Parties to “take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction *has been accessed* in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been

²⁹⁷ Nagoya Protocol, Article 7. This Article further requires that mutually agreed terms be established for access to traditional knowledge.

²⁹⁸ See generally, SAVARESI, “The International Human Rights Law Implications of the Nagoya Protocol”, 2013, pp. 53-81; see equally, HELLIO, “Le Protocole de Nagoya: reconnaissance internationale du droit des communautés autochtones et locales aux ressources génétiques de leur environnement ou pis-aller à l’impossible application équitable?” 2012, p. 583; MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, pp. 37-38; see also, Nagoya Protocol the Preamble, para. 26, which reads as follows: “Noting the United Nations Declaration on the Rights of Indigenous Peoples and Affirming that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities”.

established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located”.²⁹⁹

The Protocol does not provide a definition of the concept of prior informed consent. The origin of the concept of PIC, however, can be traced back to the medical field in the relationship between the practitioner and the patient. Thus, in this field, PIC guarantees that the practitioner discloses to the patient sufficient information to allow its patient to take an informed decision regarding a medical intervention.³⁰⁰ In international law, prior informed consent is also crucial in the relationship between States with regard to hazardous and toxic materials,³⁰¹ and in this context, States have a right to prior informed consent before those materials are imported within their territories.³⁰² Under both the CBD and the Nagoya Protocol, States also have an established right to prior informed consent when genetic resources are exported from their territories. Eventually, under the latter treaties, indigenous peoples’ prior informed consent is also recognised with regard to their genetic resources³⁰³ and traditional knowledge.³⁰⁴ Indigenous peoples consider PIC to be a core element with respect to their rights to self-determination, as recognised by international human rights treaties, in various situations, including mining, resettlement, dam building, genetic resources and their traditional knowledge. For instance, in March 2003, the Committee on the Elimination of Racial Discrimination (CERD) considered that “merely consulting indigenous communities prior to exploiting resources on their traditional lands” was insufficient, and that Ecuador “had fallen short of meeting the requirements set out in the Committee’s General Recommendation XXIII³⁰⁵ on the rights of indigenous peoples”.³⁰⁶ In one of its recent reports,

²⁹⁹ Nagoya Protocol, Article 16.

³⁰⁰ PERRAULT, “Facilitating Prior Informed Consent in the Context of Genetic Resources and Traditional Knowledge”, 2004, p. 21.

³⁰¹ The Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal, adopted 22 March 1989, 1673 UNTS 126, (hereafter, “Basel Convention”).

³⁰² HEY, *Advanced Introduction to International Environmental Law*, 2016, p. 40.

³⁰³ Nagoya Protocol, Article 6(2).

³⁰⁴ Nagoya Protocol, Article 7.

³⁰⁵ Committee on the Elimination of Racial Discrimination (CERD), ‘General Recommendation XXIII on the Rights of Indigenous Peoples’, adopted 22 August 1997, in *Report of the Committee on the Elimination of Racial Discrimination*, GA Official Records, 52nd Session, Supplement No. 18, UN Doc. A/52/18, Annex V, pp. 122-123.

CERD also censured the United States for a “lack of concrete progress to guarantee, in law and in practice, the free, prior and informed consent of indigenous peoples in policy-making and decisions that affect them”.³⁰⁷

While the Nagoya Protocol does not directly establish ‘the right’ of indigenous peoples to prior informed consent with regard to their traditional knowledge, it does it indirectly by obliging States to adopt measures ensuring that access to traditional knowledge will be conditional on having obtained “prior informed consent” or “approval and involvement” of indigenous peoples.³⁰⁸

The wording “approval and involvement” does not entail the same obligations as “prior informed consent.”³⁰⁹ Indeed, while “approval” is synonymous with the term consent, the term does not entail a requirement that such approval has to be based on the full disclosure of relevant information in anticipation of any further utilisation of traditional knowledge.³¹⁰ Greiber et al., has also pointed out that the inclusion of the concept “prior informed consent” in the Nagoya Protocol, as opposed to the CBD,³¹¹ could also indicate that PIC has acquired a particular status under international law, and especially, under international human rights laws.³¹²

Even though the language of the Nagoya Protocol is stronger than that of the CBD with regard to the requirement of PIC, its wording ‘in accordance with domestic law’, ‘shall’, and ‘as appropriate’ leave Members States quite free to implement this provision in national

³⁰⁶ CERD ‘Consideration of Reports Submitted by States Parties under Article 9 of the Convention: Concluding Observations on Ecuador, Committee on the Elimination of Racial Discrimination’, 3-21 March 2003, UN Doc. CERD/C/62/CO/2.

³⁰⁷ CERD, Concluding Observations on the Combined seventh to ninth Periodic Reports of the United States of America’, 25 September 2014, UN Doc. CERD/C/USA/CO/7-9, p. 11.

³⁰⁸ CBD COP 5 Decision V/16, “Article 8(j) and Related Provisions”, in Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity, 15-26 May 2000, UN Doc. UNEP/CBD/COP/5/23, p. 143 (the decision stated that “[a]ccess to traditional knowledge [...] should be subject to prior informed consent or prior informed approval from the holders of such knowledge”).

³⁰⁹ DUTFIELD, “Protecting the Rights of Indigenous Peoples: Can Prior Informed Consent Help?”, 2009, p. 59.

³¹⁰ DUTFIELD, “Protecting the Rights of Indigenous Peoples: Can Prior Informed Consent Help?”, 2009, p. 59.

³¹¹ CBD, Article 8(j) (this article only refers to the term “approval” with regard to traditional knowledge).

³¹² GREIBER et al., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing*, 2012, p. 111.

legislation. According to this provision, while the obligation to take measures is mandatory, Member States enjoy a degree of flexibility as to the kind of measures to take.³¹³ This is potentially wherein a problem lies.³¹⁴

The difficulty in implementing the PIC requirement in domestic legislative measures stems from the fact that countries have differing approaches to traditional knowledge, and the rights of its holders, i.e. indigenous peoples and local communities. For instance, during the negotiation of the UNDRIP, the African regional grouping affirmed that their entire population is constituted by indigenous and local communities. Other countries, including India, consider that indigenous communities are distinct, but form an integral part of the population. Thus, they should be subject to the common law of the country and abide by it.³¹⁵ Finally, some countries view indigenous peoples as holding rights that must be respected and implemented in national laws.³¹⁶ Additionally, while some Latin American countries have adopted legislation on access and benefit-sharing in relation to genetic resources and associated traditional knowledge (Peru, Brazil, Colombia), others have enacted specific legislation that guarantees the rights of indigenous peoples over their knowledge and genetic resources located on their lands (Peru, Panama, Ecuador, Bolivia, Colombia, Venezuela).³¹⁷ In other words, States having implemented national laws on ABS and/or on the protection of traditional knowledge have required the prior informed consent of indigenous communities at various stages, including prior to the grant of access, the commencement of the activity (utilisation) or at the stage of the benefit-sharing transaction.³¹⁸ This situation, while very

³¹³ GREIBER et al., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing*, 2012, p. 113.

³¹⁴ NIJAR, “Traditional Knowledge Systems, International Law and National Challenges: Marginalization or Emancipation”, 2013, p. 1210.

³¹⁵ TOBIN, *Indigenous Peoples, Customary Law and Human Rights – Why Living Law Matters*, 2014, p. 43.

³¹⁶ See, for example, in Peru, *Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos, Ley 27811* (Protection of Indigenous Peoples’ Collective Knowledge Associated with Biological Resources, Peruvian Law 27811), 24 July 2002.

³¹⁷ CABRERA MEDAGLIA, “The Implementation of the Nagoya Protocol in Latin America and the Caribbean”, 2013, p. 361; see also, see also KISHI, “PIC in Access to TK in Brazil”, 2009, p. 312 (In Brazil, Article 7 of Medida Provisória (MP) 2186-16/2001 requires PIC from traditional communities for the authorisation of access to traditional knowledge).

³¹⁸ NIJAR et al., *Framework Study on Food Security and Access and Benefit-sharing for Genetic Resources for Food and Agriculture*, 2009, p.53; see also, KUEI-JUNG, “Legal Aspects of Prior Informed Consent on

flexible, is problematic as it does not contribute to legal certainty. To date, no international agreement has been reached as to the procedural and substantive requirements for indigenous communities' PIC over their traditional knowledge associated with genetic resources. Without an international instrument that would settle the minimum standards for each Member State to implement, the sole enactment of national laws by some countries may prove to be ineffective protecting traditional knowledge.

Within the framework of the Working Group on Article 8(j), CBD Parties have reached a “soft” consensus with regard to this issue by adopting the CBD *Akwé: Kon* Guidelines³¹⁹ and the *Tkarihwaïé: Ri* Code of Ethical Conduct.³²⁰ Both set out the requirements for community PIC and respect for the customary laws of indigenous peoples. Along the same lines, the 2002 Bonn Guidelines states that the consent of relevant holders should be obtained “as appropriate to the circumstances and subject to domestic law.”³²¹ Under these voluntary instruments, the requirements for effective community PIC involve: (i) respect of customary laws governing ownership, access, control, use and dissemination of traditional knowledge, innovations and practices; (ii) the use of appropriate language and process; (iii) the allocation of sufficient

Access to Genetic Resources”, 2009, p. 273 (the author states that Member States enjoy, under international law, the option to adopt either a single- or a double- or multiple-consent system of PIC).

³¹⁹ CBD COP 7 Decision VII/16, “Article 8(j) and Related Provisions: Akwé: Kon Voluntary Guidelines for the Conduct of Cultural, Environmental and Social Impact Assessment regarding Developments Proposed to Take Place on, or which are Likely to Impact on, Sacred Sites and on Lands and Waters Traditionally Occupied or Used by Indigenous and Local Communities”, in Report of the Seventh Meeting of the Conference of the Parties to the Convention on Biological Diversity, 9-20 and 27 February 2004, UN Doc. UNEP/CBD/COP/7/21, section F, p. 177 (CBD *Akwé: Kon* Guidelines).

³²⁰ CBD COP 10 Decision X/42, “The Tkarihwaïé:ri Code of Ethical Conduct to Ensure Respect for the Cultural and Intellectual Heritage of Indigenous and Local Communities”, in ‘Report of the Tenth Meeting of the Conference of the Parties to the Convention on Biological Diversity’, 18-19 October 2010, UNEP/CBD/COP/10/27, pp. 311-319 (CBD *Tkarihwaïé:ri* Code of Ethical Conduct).

³²¹ See CBD COP 5 Decision V/16, ‘Article 8(j) and Related Provisions, 15-16 May 2000, UNEP/CBD/COP/5/23, p. 143; CBD COP 6 Decision VI/24, ‘Bonn Guidelines’, UN Doc. UNEP/CBD/COP/6/20, p. 260 (parties to the CBD decided that they shall take measures to enhance and strengthen the capacity of indigenous and local communities to be effectively involved in decision-making related to the use of their traditional knowledge, innovations and practices relevant to the conservation and sustainable use of biological diversity subject to their prior informed approval and effective involvement).

time for consent to be given or not; (iv) accurate, factual and legally correct information;³²² and (v) non-coerced, forced or manipulated consent.³²³

An authoritative study conducted by Darrell Posey and Graham Dutfield also identified the various elements that comprise the notion of prior informed consent. According to them, “prior informed consent is consent to an activity that is given after receiving full disclosure regarding the reasons for the activity, the specific procedures the activity would entail, the potential risks involved, and the full implications that can realistically be foreseen. Prior informed consent implies the right to stop the activity from proceeding, and for it to be halted if it is already underway.”³²⁴

Authors generally agree on the two core elements necessary for prior informed consent, namely: (i) full disclosure (all the information related to the project, including the disclosure of the objectives of the activity, the potential consequences of the project on the community, and the duration of the activity); and (ii) a right to veto.³²⁵ Doris Shroeder has completed the concept by noting that full disclosure is not sufficient for a decision to be made, “the disclosed information must also be comprehended by the recipient.”³²⁶ Finally, consent must encompass several values, including the recognition of the autonomy of individuals or groups to render a decision based on freedom of choice.³²⁷

³²² CBD Tkarihwaïé:ri Code of Ethical Conduct, para. 53; CBD Tkarihwaïé:ri Code of Ethical Conduct, para. 11.

³²³ CBD Tkarihwaïé:ri Code of Ethical Conduct, para. 11 reads: “Any activities/interactions related to traditional knowledge associated with the conservation and sustainable use of biological diversity, occurring on or likely to impact on sacred sites and on lands and waters traditionally occupied or used by indigenous and local communities and impacting upon specific groups, should be carried out with the prior informed consent and/or approval and involvement of indigenous and local communities. Such consent or approval should not be coerced, forced or manipulated”.

³²⁴ POSEY and DUTFIELD, “Beyond Intellectual Property – Toward Traditional Resource Rights for Indigenous Peoples and Local Communities”, 1996, pp. 46ff.

³²⁵ PERRAULT, “Facilitating Prior Informed Consent in the Context of Genetic Resources and Traditional Knowledge”, 2004, p. 21; see also, SCHROEDER, “Informed Consent : From Medical Research to Traditional Knowledge” 2009, pp. 27-52.

³²⁶ SCHROEDER Doris, “Informed Consent: From Medical Research to Traditional Knowledge”, p. 39.

³²⁷ NIJAR, “An Asian Developing Country’s View on Implementation Challenges”, 2013, p. 258.

Given the flexibility enjoyed by States under the Nagoya Protocol, indigenous peoples consider that the Protocol seals their fate by leaving full discretion to Parties to interpret and implement the provisions with regard to prior informed consent as they wish. However, this position can be challenged for several reasons. First, the Nagoya Protocol clearly distinguishes between two forms of prior informed consent. The requirement for ‘indigenous peoples’ prior informed consent’ with regard to traditional knowledge as opposed to ‘State prior informed consent’ for access to genetic resources, which is based on the principle of state sovereignty over genetic resources.³²⁸ Prior informed consent of indigenous peoples has to be understood in the broader context of human rights standards.³²⁹ As in this case, by requiring the prior informed consent of indigenous peoples, the Nagoya Protocol makes a direct link to human rights standards regarding indigenous peoples’ rights.³³⁰ The Preamble of the Nagoya Protocol expressly refers to the UN Declaration on the Rights of Indigenous Peoples and the concept of PIC clearly overlaps with that of “free prior informed consent” (FPIC).³³¹ According to the general rules of treaty interpretation, PIC “shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”³³² Furthermore, due regard shall be paid to “the context for the purpose of the interpretation of a treaty [...], in addition to the text, including its preamble and annexes.”³³³ Recommendations under international human rights law require Member States to protect the rights of indigenous peoples over their resources and knowledge.³³⁴ Accordingly, Parties to international human rights instruments

³²⁸ Nagoya Protocol, Article 6(1).

³²⁹ ICCPR, Articles 1 and 27; ILO Convention No 169, Article 2(b); and UNDRIP Articles 3, 4, 32.

³³⁰ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 171.

³³¹ Provisions of FPIC are both present in international human rights and environmental law treaties, decisions of human rights treaty bodies and jurisprudence of regional human rights organisations, and increasingly incorporated into national laws. The concept of Free prior informed consent will be later analysed in the context of the UN Declaration on the Rights of Indigenous Peoples (UNDRIP).

³³² Vienna Convention on the Law of Treaties, Vienna, 23 May 1969, entered into force 27 January 1980 1155 UNTS 331, (VCLT), Article 31(1).

³³³ VCLT, Article 31(2).

³³⁴ UNDRIP, Articles 26, 27, 31 and 34; ILO Conventions 169, Articles 8, 15 and 16.

should use human rights standards to interpret the prior informed consent requirement under the Nagoya Protocol.³³⁵

Second, the obligation to implement procedures for indigenous peoples' PIC seems to be limited to traditional knowledge "held" by indigenous peoples.³³⁶ This requirement might be undermined where traditional knowledge is held by the State Party, such as for instance in registries or databases. The recording of traditional knowledge makes it generally publicly available, depending on who is authorised to access the databases. Furthermore, traditional knowledge may not have been obtained from traditional peoples directly, that is *ex situ* traditional knowledge.³³⁷ Under these hypotheses, traditional knowledge may have lost its link with its originator community. While the issue of publicly available traditional knowledge was discussed during the negotiations and incorporated into the draft of the Nagoya Protocol, with regard to the obligation of sharing benefits resulting from the utilisation of traditional knowledge, the final version of the Protocol is silent on this issue.³³⁸ As a result, the question remains open as to whether benefit-sharing and prior informed consent requirement still applies to traditional knowledge that is publicly available. It can be argued that even if the traditional knowledge is publicly available, traditional communities still hold this knowledge under human rights principles.³³⁹ In addition, the concept of "public availability" partly

³³⁵ SAVARESI, "The International Human Rights Law Implications of the Nagoya Protocol", 2013, p. 68.

³³⁶ Nagoya Protocol, Article 7.

³³⁷ While holders of traditional knowledge refer to indigenous communities practicing and transmitting their knowledge, providers of traditional knowledge could be any third party in possession of that knowledge but outside the traditional community context. The terms *in situ* and *ex situ* traditional knowledge are also used to distinguish both situations.

³³⁸ See CBD COP 10 "Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity" in 'Report of the third part of the ninth meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-sharing', 17 October 2010, UNEP/CBD/COP/10/5/Add.5, p. 16 (Nagoya Draft). Article 9(5) reads: "Parties shall [encourage][require] the users of [publicly available] traditional knowledge associated with genetic resources [which has been lawfully obtained by that user from a source other than an indigenous and local community] to take reasonable measures to enter into fair and equitable benefit-sharing arrangements with the [rightful] holders of [such] knowledge." Note that bracketed text in international negotiating documents refers to text proposed but not yet agreed upon by negotiators.

³³⁹ NIJAR, "An Asian Developing Country's View on Implementation Challenges", 2013, p. 263 (the author provides the example of the Royal Botanic Gardens at Kew that possess more than 2000 species of plant genetic resources from the oldest rainforest in the world, located in Malaysia. He argues that when the use

overlaps with the concept of “public domain” without having the same implications. Part II will more extensively analyse the situation of traditional knowledge that is publicly available or in the public domain, and Part III will study some national laws trying to address this particularly contentious issue.

In conclusion, the need for prior informed consent is paramount in the overall discussion relating to the protection of traditional medicinal knowledge. The ethical rationale for prior informed consent is twofold.

First, from an ethical perspective, both the CBD and the Nagoya Protocol recognise the role of traditional knowledge holders in biodiversity conservation³⁴⁰ and the protection and just compensation of their role is expressed as an issue of fairness. It is also a recognition of the rights of indigenous peoples to self-determination as provided for by Article 1 of the International Covenant on Economic, Social and Cultural Rights (ICESCR 1996) and the UNDRIP.³⁴¹

Second, also founded upon ethical considerations, prior informed consent is a key element in the proposals to protect traditional knowledge through a *sui generis* system. This makes a direct link with intellectual property rights, and the question is whether PIC should be disclosed in a claimed invention based on traditional knowledge. The proposal for a *sui generis* protection of traditional knowledge requires prior informed consent as a condition for access to, and use of, traditional knowledge. By doing so, the objective is to enable indigenous peoples to exercise control over their knowledge, with due respect to their customary laws governing the use and transfer of their knowledge.

of genetic resources “is informed by traditional knowledge, the PIC and MAT requirements to the Protocol should apply. [...]. If PIC is not possible, the benefit-sharing provisions should apply”. The very last solution is to resort to the global multilateral fund provided for in the Protocol).

³⁴⁰ SWIDERSKA, “Could things for biodiversity go from bad to worse?”, BBC News, 13 July 2010, available at: <http://news.bbc.co.uk/2/hi/science/nature/8810627.stm> [accessed September 2016] (she stressed on the critical role that traditional knowledge farmers and healer play in sustaining and enhancing genetic diversity).

³⁴¹ SCHROEDER, “Informed Consent: From Medical Research to Traditional Knowledge”, 2009, p. 39.

1.2.3 Customary Laws of Indigenous Peoples

Article 12 of the Nagoya Protocol expressly refers to indigenous peoples' customary laws and stipulates that "[i]n implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources".³⁴²

While the provision leaves an extensive degree of discretion to Member States, it does oblige Parties to take into account the customary laws of indigenous peoples in the development and implementation of national access and benefit-sharing (ABS) obligations. This implies that the competent national authorities should identify relevant customary laws and understand them. This endeavour necessitates, therefore, the effective involvement of indigenous communities at the stage of identification, understanding, and the implementation of ABS measures at the national level. Article 12 of the Nagoya Protocol is the sole article referring to the customary laws of indigenous communities.

Whilst it is not mentioned in Article 3, the provisions of Articles 5(2) and 6(2) also explicitly address the issue of genetic resources held by indigenous and local communities with regard to access and benefit-sharing, respectively. This is, however, seriously undermined, both by references to cases where indigenous communities have "the established rights"³⁴³ to grant access to such resources and by reference to "in accordance with national legislation" or "domestic laws."

However, this formulation can be interpreted either broadly or narrowly. A narrow interpretation of these provisions would suggest that genetic resources are deemed to be held by indigenous people only where their rights over these resources are enshrined in domestic laws or affirmed by judicial decisions. In the absence of such national legal recognition, indigenous communities are not entitled to any rights deriving from the Protocol, including prior informed consent. A broad interpretation of these provisions would require an interpretation of the provision in conformity with international human rights standards, as well as Article 12 of the Protocol. Accordingly, "established rights" would refer to customary

³⁴² Nagoya Protocol, Article 12.

³⁴³ The terms "established rights" appears only in Articles 5(2) and 6(2) of the Nagoya Protocol.

rights of indigenous and local communities as explicitly referred in that said article.³⁴⁴ In connection with this, the Human Rights Council has pointed out that, even in the absence of recognition in domestic legislations, indigenous peoples have rights over natural resources.³⁴⁵ This interpretation has received the full support of the UN Permanent Forum on Indigenous Issues (UNPFII).³⁴⁶

Recently, the European Parliament also passed a strong resolution stating that an effective protection of traditional knowledge of indigenous and local communities' rights has to reflect their customary laws and practices.³⁴⁷ This resolution was adopted in the broader context of a discussion on the development aspects of intellectual property rights on genetic resources. Surprisingly however, subsequent to the adoption of this resolution, the newly adopted European Regulation implementing the Nagoya Protocol ("Regulation 511/2014") failed to mention customary laws and affords no guidance to Member States as to how to meet their obligations under Article 12 of the Nagoya Protocol.³⁴⁸ Above all, Regulation 511/2014 seems to recognise the protection of only that traditional knowledge which is the subject of access and benefit-sharing agreements.³⁴⁹ Thus, if traditional knowledge has been accessed

³⁴⁴ MORGERA et al., *Unravelling the Nagoya Protocol– A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 171.

³⁴⁵ Human Rights Council, 'Report of the Special Rapporteur of indigenous peoples' rights by James Anaya', 1st July 2013, UN Doc. A/HRC/24/41, paras 9, 12 and 35.

³⁴⁶ The United Nations Permanent Forum on Indigenous Issues (UNPFII), 'Report on the tenth session', 16-27 May 2011, UN Doc. E/2011/43-E/C.19/2011/14, para. 27, p. 6. The UNPFII is an advisory body to the ECOSOC, with a mandate to discuss indigenous issues related to economic and social development, culture, environment, education, health and human rights.

³⁴⁷ European Parliament Resolution, 'Development Aspects of Intellectual Property Rights on Genetic Resources: The Impact on Poverty Reduction in Developing Countries', 15 January 2013, para. 18.

³⁴⁸ European Union Regulation No 511/2014 of the European Parliament and of the Council of 16 April 2014 on Compliance Measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (EU Regulation 511/2014), Official Journal of the European Union, L 150/59, 20 May 2014.

³⁴⁹ EU Regulation 511/2014, Preamble Paragraph 20 and Article 3(7) ("[...] in order to ensure flexibility and legal certainty for providers and users, this Regulation should make reference to traditional knowledge associated with genetic resources as described in benefit-sharing agreements").

without an access and benefit-sharing agreement, there is no obligation for EU Member States to protect that traditional knowledge.³⁵⁰

The introduction of indigenous customary laws within a national legal order implies that the State should adopt an approach that is supportive of intercultural or multicultural legal pluralism.³⁵¹ Indeed, the recognition of customary laws is not sufficient to protect traditional knowledge beyond the context where the knowledge is practiced.³⁵² While the term ‘legal pluralism’ is frequently used, especially with regard to indigenous law in Latin American countries, it is not always accompanied in practice by the meaning Griffiths attributes to the term, but is rather a refutation of legal centralism.³⁵³ However, it can be stated that an approach based upon legal pluralism promotes respect for diversity in general, a diverse legal system in particular, and the drawing upon of a wide range of legal sources, including national and international laws, as well as the customary laws and practices of indigenous peoples.³⁵⁴ A failure to pay due regard to the customary practices of indigenous peoples will render Article 12 of the Nagoya Protocol meaningless.

In conclusion, the adoption of the Nagoya Protocol has cemented the international recognition of indigenous peoples’ rights over their knowledge by making a direct reference to the UN Declaration on the Rights of Indigenous Peoples. The main criticism that can be directed at the Protocol is the lack of obligations for States to establish a monitoring system with regard to the utilisation of traditional knowledge. As is the case for the use of genetic resources, this monitoring system would include checkpoints where compliance with the requirement for

³⁵⁰ TOBIN, “Biopiracy by Law: EU Draft Law Threatens Indigenous Peoples’ Rights over their Traditional Knowledge and Genetic Resources”, 2014, p. 127.

³⁵¹ TOBIN, “Bridging the Nagoya Compliance”, 2013, vol. 9(2), p. 147.

³⁵² FRANKEL, “Using intellectual property rules to support the self-determination goals of indigenous peoples”, 2015, p. 635.

³⁵³ Legal centralism refers to the idea that state law, in positivist tradition, is coherent, unitary and universal in its neutral and cultural application; see GRIFFITHS, “What is Legal Pluralism?”, 1986, p. 3 (legal scholars broadly distinguish between ‘hard’ pluralism and ‘weak’ pluralism. While the former assumes that both sets of laws, state and customary, are equal, the latter considers that customary law is hierarchically inferior to the law of the State. Thus, it is wholly operated by the State without a direct involvement of indigenous peoples).

³⁵⁴ For an in-depth discussion on legal pluralism, see GRIFFITHS, “What is Legal Pluralism?”, 1986; see also, DIAZ-POLANCO, *Elogio de la diversidad: globalización, multiculturalismo y etnofagia*, 2002, p. 62.

prior informed consent may be demonstrated by means of an international certificate of compliance.³⁵⁵

However, importantly, the Nagoya Protocol makes a clear link with human rights principles without losing sight of the economics behind the use of traditional knowledge, which tends to seek the protection of traditional knowledge through intellectual property rights.³⁵⁶

2 Intellectual Property Rights

Broadly speaking, intellectual property rights are ownership rights on knowledge or on intangible objects as opposed to property rights on tangible objects. Under the current intellectual property system, whilst all knowledge is deemed to be protected, in practice only that which fulfils the criteria established by the different categories of intellectual property rights is.³⁵⁷

In the WTO context, intellectual property rights (IPRs), in a broad sense, are defined as “the rights given to persons over the creations of their minds. They usually give the creator an

³⁵⁵ For a general discussion on the certificate of origin, see TOBIN et al., “The feasibility, practicality and cost of a certificate of origin system for genetic resources – Preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme”, 2005, UN doc. UNEP/CBD/WG-ABS/3/INF/5, p. 3 (The term certificate of origin has been first used to describe a proposal for use “of patent applications procedures as a means for ensuring the existence of PIC for use of genetic resources. The original concept was that the patent offices should require the disclosure of the origin of genetic resources and associated traditional knowledge as a condition for receiving applications for grant of patents”).

³⁵⁶ HELLIO, “Le Protocole de Nagoya”, 2012, p. 585.

³⁵⁷ For a broader approach of the concept, see, See GEORGE, *Constructing Intellectual Property*, 2014, p. 143 (in order to understand intellectual property it is necessary to look for the core criteria that characterise it. These criteria fall in two categories, first, conceptual criteria (ideational object, a documented form, creatorship, and originality) and rights (these vary according to the intellectual property doctrine in question, but they include rights to use or exploit a patented invention, and to authorise others to do these things). From this, it can be ascertained that traditional medicinal knowledge is an intellectual endeavour and so can fall in the broad definition of intellectual property; this does not mean that it should necessarily be protected by the categories of rights as set up in the TRIPS Agreement. Intellectual property, in broad terms, encompasses any rights relating to intellectual activity in the scientific, industrial, literary and artistic fields. Intellectual property rights are the rights given to persons over the creations of their minds.)

exclusive right over the use of his/her creation for a certain period of time.”³⁵⁸ Intellectual property laws, therefore, aim at conferring exclusive rights on individuals to enable owners to appropriate the full market value of the protected subject matter for a limited period of time. In this regard, traditional medicinal knowledge shares certain similar characteristics with the subject matter considered to be an issue of intellectual property rights.³⁵⁹

The next paragraphs will discuss the main international agreement providing a strong protection of intellectual property rights, the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter, TRIPS Agreement or TRIPS),³⁶⁰ which is administered by the World Trade Organisation (WTO). Other regional intellectual property instruments will not be specifically analysed in this Chapter, but will be referred to in Part II, Chapter Two, specifically the European Patent Convention (EPC).³⁶¹

2.1 TRIPS

Six months after the CBD entered into force, the members of the WTO adopted the TRIPS Agreement. Both TRIPS and the WTO are outcomes of the Uruguay Round of trade negotiations under the General Agreement on Tariffs and Trade (GATT). Before intellectual property rights entered in the realm of the WTO, the tasks of promoting and implementing intellectual property rights under the Paris and Berne Conventions were undertaken by the World Intellectual Property Organisation,³⁶² necessitating the new role of the WTO in relation to intellectual property rights' matters to be formalised through the adoption of an agreement

³⁵⁸ See definition given by the World Trade Organisation (WTO), available at: http://www.wto.org/english/tratop_e/trips_e/intell_e.htm [accessed August 2016].

³⁵⁹ EBERMANN, *Patents as Protection of Traditional Medicinal Knowledge? A Law and Economic Analysis*, 2012, p. 37.

³⁶⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1 C, Legal Instruments – Results of the Uruguay Round, 1869 UNTS 229 (TRIPS Agreement or TRIPS).

³⁶¹ Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000, OJ EPO 2001, Special edition No. 4, p.55 and OJ EPO 2007, Special edition No. 4, synoptic presentation (EPC).

³⁶² Before the establishment of the WIPO, in 1967, the United International bureaux for the Protection of Intellectual Property Rights had been mandated to carry out the implementation of the Paris and Berne Convention.

between WIPO and the latter.³⁶³ This forum shift was pursued mainly by industrialised countries for two reasons. First, due to the lack of an enforcement mechanism in WIPO as compared to the WTO system. Second, because the decision-making process within WIPO is based upon the one-State, one-vote principle, developing countries are perceived to come out as winners in negotiations in that forum.³⁶⁴ Thus, it is argued that the main objective of the proponents of the TRIPS Agreement was to guarantee the ability of intellectual property rights holders to secure their protected assets in the jurisdictions of all Member States to the WTO.

The path towards the adoption of the TRIPS Agreement can be broadly traced back to the 1880s. Before the adoption of the TRIPS Agreement, intellectual property laws were mainly within the discretion of States. Indeed, States were free to define intellectual property, the scope of the rights attached to it, and the ways to enforce these rights, even though States were party to many agreements and unions, in particular those administered by the World Intellectual Property Organisation, namely the Paris³⁶⁵ and Berne³⁶⁶ Conventions. This lack of harmonisation and the principle of territoriality inherent to the intellectual property system resulted in States gathering in a number of fora, including WIPO, WTO and regional fora such as the European Union (EU), in order to define common standards of protection.³⁶⁷ Since the passage of the TRIPS Agreement, the WTO has become the main actor in the globalisation of intellectual property rights. There are two key elements in this success. Firstly, the TRIPS Agreement only imposes minimum standards of protection and does not prevent its Member States from adopting higher standards of intellectual property

³⁶³ Agreement between the World Intellectual Property Organisation and the World Trade Organisation, Geneva, 22 December 1995 (WTO-WIPO Agreement), available at: https://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm [accessed September 2016].

³⁶⁴ ABBOTT, “Protecting the First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework”, 1989, p. 713.

³⁶⁵ The Paris Convention for the Protection of Industrial Property, adopted in 1883, and revised at Stockholm in 1967, 828 UNTS 305 (Paris Convention). The Paris Convention is the multilateral agreement regarding the protection of industrial property. It addresses both patents and trademarks, and encompasses some articles relating to industrial designs, trade names, appellations of origins and indications of source, and unfair competition law.

³⁶⁶ Berne Convention for the Protection of Literary and Artistic Works, opened for signature Sept. 9, 1886, revised at Paris in 1979, 828 UNTS 221 (Berne Convention).

³⁶⁷ ABBOTT et al., *The international intellectual property system: commentary and materials*, 1999, p. 24.

protection³⁶⁸ or the signing of supplementary bilateral treaties, referred to as "TRIPS-plus."³⁶⁹ Secondly, the agreement possesses efficacious formal dispute mechanisms within the WTO system to assure compliance with the agreements.

The TRIPS Agreement is not a stand-alone treaty, but constitutes one element of a complex legal text. Indeed, it imports requirements of previous multilateral conventions regarding copyright and industrial property, and embraces rights and obligations under the Berne and Paris Conventions, thus essentially rendering their standards mandatory for WTO members. As far as patents are concerned, the TRIPS Agreement only complements the Paris Convention with specific substantive rules.³⁷⁰ Thus, the imported provisions of these Conventions apply directly as an integral part of TRIPS. Furthermore, as the provisions of TRIPS and the imported provisions of the Conventions entered into force at the same time, there is no legal hierarchy between these two sets of provisions.³⁷¹ The TRIPS Agreement also adds additional requirements regarding domestic intellectual property enforcement mechanisms and brings disputes relating to intellectual property matters into the WTO system of dispute resolution.

Furthermore, the TRIPS Agreement possesses a special status within the framework of the WTO. TRIPS is the only agreement that directly deals with the rights of private entities, whilst the WTO deals with governmental measures. According to two commentators, “the agreement is unique in the WTO context in that it imposes obligations upon governments to adopt a set of substantive rules in an area that traditionally has been regarded to be in the purview of domestic regulation.”³⁷²

The multilateral TRIPS Agreement encompasses a preamble and seven parts and sets out the general principles that govern the intellectual property system and the substantive provisions

³⁶⁸ CULLET et al., “Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge”, 2006, p. 140.

³⁶⁹ HAUNSS, *Conflicts in the Knowledge Society – The Contentious Politics of Intellectual Property*, 2013, pp. 47-48.

³⁷⁰ ABBOTT et al., *The international intellectual property system: commentary and materials*, 1999, p. 634.

³⁷¹ US – Section 110(5) Copyright Act, WT/DS160/R, p. 86 ff, available at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds160_e.htm [accessed September 2016].

³⁷² HOEKMAN and KOSTECKI, *The Political Economy of the World Trading System: The WTO and Beyond*, 2009, p. 370.

concerning their protection. In addition, it requires Member States to undertake to provide rules guaranteeing the procedures and remedies for the effective enforcement of intellectual property rights in their domestic legislation.

Article 1 of the TRIPS Agreement, entitled “Nature and Scope of Obligations,” defines the term “intellectual property” as referring to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II, namely copyright, trademarks and service marks, geographical indications, industrial designs, patents for inventions, topographies of integrated circuits and trade secrets. Intellectual property rights are not defined *per se*.

These rights all include the exclusive right to make, use, sell, offer to sell, and import subject matter protected by intellectual property rights. While almost all of the IP categories have an impact on traditional knowledge in a broad sense, it is essentially the patent system that concentrates the full debates and concerns relative to the protection and/or misappropriation of traditional medicinal knowledge associated with the plant genetic resources.³⁷³

How this global agreement responds to the challenges with respect to the protection of traditional knowledge has become a matter of increasing discussion and debate in the post-TRIPS era.³⁷⁴ It contains material and formal standards for the protection of intellectual property rights based on well-established concepts.

2.1.1 Patentable Subject Matter

The principal achievement of the TRIPS Agreement has been the internationalisation of the patent system, which has been built on the already existing patent standards in the WIPO Paris Convention. As it will be shown in the following paragraphs, this has not gone hand in hand with the establishment of an overall uniform or single patent system. Indeed, TRIPS only sets out minimum standards of protection to be provided by each WTO Member State. Thus, according to Article 1.1, Member States may implement higher thresholds of protection than provided for in the Agreement.³⁷⁵

³⁷³ For instance, copyrights are of interest for Traditional Cultural Expressions (TCEs).

³⁷⁴ COTTIER and PANIZZON, “Legal perspectives on traditional knowledge: The case for intellectual property protection”, 2005, pp. 565-594, p. 566 (suggesting the adaptation of the intellectual property system to accommodate a suitable form of protection for traditional knowledge);

³⁷⁵ TRIPS Agreement, Article 1.1.

Article 27 of the TRIPS agreement requires that “patents shall be available for any inventions, whether products or processes, in all fields of technology.”³⁷⁶ However, what is not defined is the term “invention.” This omission leaves considerable room for national legislation to identify what actually constitutes a patentable subject matter. The criteria of patentability are incorporated into article 27.1 of TRIPS, namely, novelty, non-obviousness and industrial applicability and these criteria apply equally to all fields of technologies. Again, the TRIPS Agreement does not precisely define the content of each of these patentability requirements. Thus, this article clearly establishes a very broad space for national laws to articulate patentability conditions. An advantage of his very broad definition is to allow patents to adapt to constant technological advances, like the ones witnessed in the last decades. This explains the smooth manner in which the patent system has endorsed natural product-based inventions within the realm of chemical and biotechnological inventions.

Technically, a patent is a title provided by the national competent authority to the creator of an invention – either a product or a process – that offers a new technical solution to a specific problem. Exclusive or monopoly rights are granted to an inventor who has put into practice his knowledge and skills in producing a product or process that is new, involves an inventive step and is capable of industrial application. In addition, the grant of a patent is contingent upon the public disclosure of the invention in order for other potential inventors to build on the disclosed invention with further innovations.

The right to exclude others from using the invention does not equate with the right to exploit the invention.³⁷⁷ These exclusive or monopoly rights are limited to a specific period of time and States have generally opted for a twenty year protection term. Once the protection has elapsed, the invention falls into the public domain and is freely available to anyone. It is not an exaggeration to state that the public-interest role of the patent system is to nourish the existing pool of knowledge within the public domain.³⁷⁸ This concept is essential to the

³⁷⁶ TRIPS Agreement, Article 27; see, for example, Swiss Patent Act, Article 1; see also, ABBOTT et al., *The international intellectual property system: commentary and materials*, 1999, p. 25.

³⁷⁷ The patentee’s will to exploit the invention may be limited by national rules and procedures being independent from the patent legislation. For instance, even if a patent is granted for a drug, the right-holder must first obtain the due authorisation from the competent health authority before bringing it on the market.

³⁷⁸ BOYLE, “the Second Enclosure Movement and the Construction of the Public Domain”, 2003, pp. 33-74 (who argues that the expansion of intellectual property systems is unwise and that a large public domain is vital to creativity more than the intellectual property system. There is a lack of economic evidence

understanding of the intricacies related to the protection and preservation of traditional knowledge. This will be dealt with in Chapter 3 of the present Part.

Despite the fact that the TRIPS Agreement makes no reference to traditional knowledge, there are some provisions that are of relevance for the issue of traditional knowledge, whether for its protection or for its appropriation.³⁷⁹ Indeed, Part I of the Agreement, entitled “General Provisions and Basic Principles” encompasses two articles that may prove to be of potential value for the issue of traditional knowledge.³⁸⁰ These articles may prove to be interesting for framing national laws in conformity with the public interest.

Article 7 of TRIPS, in reference to its objectives, states: “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”³⁸¹ Broadly speaking, it reflects the concerns of developing countries that strong intellectual property rights may have negative impacts on their economic and social development.³⁸²

Another provision that is relevant to the issue of traditional knowledge, and particularly, traditional medicinal knowledge, is Article 8 of the TRIPS Agreement. Firstly, this provision provides some flexibility to Member States by allowing them to adopt “measures necessary to protect public health and nutrition and to promote the public interest in the sectors of vital importance to their socio-economic and technological development.”³⁸³ However, the

supporting the argument that more intellectual property rights mean more innovation); see generally, DOSI and STIGLITZ, “The Role of Intellectual Property Rights in the Development Process, with Some Lessons from Developed Countries: An Introduction”, 2014, p. 5 (the authors state that “intellectual property rights are social constructions whose objective is to promote the well-being of society [and] all institutions need to be adapted to the circumstances and objectives of each country”).

³⁷⁹ BOKEDER, “A Public Health Agenda for Traditional Complementary, and Alternative Medicine”, 2002, p. 1586.

³⁸⁰ BIBER-KLEMM et al., “The current law of plant genetic resources and traditional knowledge”, 2006, p. 75.

³⁸¹ TRIPS Agreement, Article 7.

³⁸² CORREA, *Trade related aspects of intellectual property rights : a commentary on the TRIPS Agreement*, 2007, pp. 91 ff.

³⁸³ TRIPS Agreement, Art. 8.1.

constraints imposed by this article are that such measures must be consistent with the provisions of the Agreement. As with Article 7, this article is based on developing countries' proposals.³⁸⁴ Secondly, Article 8(2) allows countries to adopt appropriate measures in order to circumvent the abuses that may be caused by intellectual property rights' holders. It refers to three types of behaviours, namely (i) abuse of intellectual property rights by right-holders; (ii) practices which unreasonably restrain trade; or (iii) practices which adversely affect the international transfer of technology. Under Article 8(2), WTO Members recognise that some intellectual property rights-related anti-competitive practices need to be prevented and Members are empowered to deal with such practices at the national level. This article opens up a space to address the overall issue of traditional knowledge and its misappropriation. Even though misappropriation as such is not addressed in an express manner, it allows its integration into the broader principle of honest business practices.³⁸⁵

As briefly mentioned, under the system of intellectual property rights, traditional knowledge is not distinct from any other sort of knowledge that has fallen into the public domain. This principle is enshrined in Article 70, paragraph 3 of the TRIPS Agreement, entitled "Protection of Existing Subject Matter." This provision reads as follows: "There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain."³⁸⁶ However, by stating that "[t]here shall be no obligation" means that Members are able, if they elect to do so, to restore protection to subject matter in the public domain.³⁸⁷ Is traditional knowledge a subject matter that has fallen in the public domain? The relationship between traditional knowledge and the public domain will be discussed in Part II, chapter 3.

³⁸⁴ Multilateral Trade Negotiations, The Uruguay Round, 'Negotiating Group on Trade-Related Aspects of Intellectual Property Rights', Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, 14 May 1990, GATT Doc. MTN.GNG/NG11/W/71, pp. 7-8.

³⁸⁵ COTTIER and PANIZZON, "A new generation of IPR for the protection of traditional knowledge in PGR for food, agricultural and pharmaceutical uses", 2006, p. 209.

³⁸⁶ TRIPS Agreement, Article 70(3).

³⁸⁷ JUSTIN et al., *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights: A Commentary*, 2014, Article 70, page 770.

2.1.2 Justifications for Patent Protection and Competing Values – Legitimizing Narratives

The concept “intellectual property” hints at a defined set of intangible assets of human activity. These intangible products often refer to an idea, an expression of an idea, knowledge or information resulting from the human mind, even though they are embodied in tangible or material support.³⁸⁸ Thus, it would not be wrong to state that intellectual property covers information or knowledge.

From an economic point of view, information shares some of the main characteristics that define public goods. Public goods are those goods that have to be managed collectively because they are important to the human community at large. Like public goods, information is characterised by two features: it is “non-rival” and “non-excludable.” These two features constitute the fundamental distinction between property rights on tangible things and property rights in information. Information or an idea or knowledge is non-rival because it can be used and reproduced without depriving its owner of its ability to use it or to possess it. One person using the good would not affect the availability of the good to the others. Information is non-excludable because once revealed or disclosed, it is available to all because it is not possible to exclude anyone anymore from the good.³⁸⁹

The intuitive question that comes to mind is why should this information be protected if its use by one person does not reduce its availability to others?³⁹⁰ According to the classical economic view, the best way to produce new knowledge is to reward creators by granting

³⁸⁸ ABBOTT et al., *The international intellectual property system: commentary and materials*, 1999, p. 22.

³⁸⁹ See generally BOYLE, “the Second Enclosure Movement and the Construction of the Public Domain”, 2003, p. 42.

³⁹⁰ LEMLEY et al., *Intellectual Property in the New Technological Age: 2016 - Volume I: Perspectives, Trade Secrets and Patents*, 2016, pp. 2-30 (there are essentially three school of thoughts justifying property rights in information: (i) the natural rights approach is based on John Locke’s labour theory, which states that people are entitled to the fruits of their own labour. In the IP context, the theory assumes that the creator has a natural property rights on his intellectual creativity and that an unauthorised appropriation of that knowledge is equivalent to stealing; (ii) Hegelian philosophy justifies the protection of IP on the basis that property is inherently linked to the identity of the free individual in society; (iii) the utilitarian paradigm requires that the creator receives compensation or reward, by means of limited monopoly rights, for the services rendered to the society at large); see also generally, MAY, *The Global Political Economy of Intellectual Property Rights: The New Enclosures*, 2010.

them some exclusive rights on the information produced.³⁹¹ Indeed, according to one of the main principles of the intellectual property economic justification is that costless copying of innovation drives its *ex post* price to zero in the absence of intellectual property rights.³⁹²

Similarly, from a legal point of view, intellectual property rights refer to a set of legally enforceable rights that the owner may exercise with respect to their intellectual creativity.³⁹³ According to a known argument, if everyone had free access to this knowledge and could use it without restrictions, inventors and creators would have no incentive to spend their time and money in further elaborating new knowledge without a resulting profit.³⁹⁴ Indeed, the extent of the patent exclusiveness should be proportionate to the technical contribution to the art. This justification for IP protection encompasses moral rights in favour of the owner of the newly developed knowledge. It refers to the natural rights-based narrative. In addition to this, there is a broader justification, upon which the origins of TRIPS are founded, which is the strengthening of the international system of unimpeded trade.³⁹⁵

A more contemporary approach to the rationale for intellectual property rights considers both the interests of the rights holders and the interests of society at large. Generally speaking, IP policy making attempts, in essence, to undertake a measured balancing of opposing values. In

³⁹¹ For a classical analysis, see generally DEMSETZ, “Towards a theory of property rights”, 1967, pp. 347-359; see also, PLOMER, “Human Dignity and patents”, 2015, p. 493 (arguing that “the real work in securing appropriate legal controls over potentially socially and economically damaging patent should primarily be done within patent law through the delineation of patentability criteria and outside patent law through the tightening of antitrust and competition law and research exemptions”); for a more inclusive view of intellectual property rights, see KUHLEN, “Knowledge and Information – Private Property or Common Good? A Global Perspective”, 2009, pp. 213-230.

³⁹² For a challenge to the classical argument, see, BOLDRIN and LEVINE, “The Case Against Intellectual Property”, 2002, pp. 209-212; BOLDRIN and LEVINE, “Perfectly Competitive Innovation”, 2008, pp. 435-453 (they argue that the cost of copying is not without cost. Between the time the innovation takes place and when it is copied, innovators have time to capture enough rents to recoup their costs. They state that innovation survives in a perfectly competitive market).

³⁹³ CORNISH et al., *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 2013, p. 3; ABBOTT et al., *The international intellectual property system: commentary and materials*, 1999, pp. 22ff.

³⁹⁴ This argument has come under criticism from some authors. See particularly, BOYLE, “the Second Enclosure Movement and the Construction of the Public Domain”, 2003, pp. 42 ff.

³⁹⁵ CLIFT, “Why IPR Issues were Brought to GATT: A Historical Perspective on the Origin of TRIPS”, 2010, pp. 3-21.

particular, patent protection is justified as long as the benefits to society exceed its costs. The benefits are the creation of information, whilst the costs are the monopoly patents create. In other words, the objective of this approach is to strike a balance between benefits and costs. The already mentioned Article 7 of the TRIPS Agreement defines the objectives of intellectual property rights protection in development-friendly words:

“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”³⁹⁶

Intellectual property rights, in general, and the patent system in particular, are based on a compromise. Indeed, it is commonly stated that a patent is a contract between the rights-holder of the patent and the society, where the rights-holder is granted a monopoly limited in time at the cost of public disclosure. The ideal goal of an intellectual property system is to strike a balance between commercial profitability (return on investment) and public-interest concerns (production and dissemination of knowledge). An imbalance would be generated when one interest is disproportionately favoured over another, thus rendering the system unjust.³⁹⁷ According to Taubman, “the IP system is ostensibly a means of ordering and producing certain public goods, and of promoting overall public welfare, through precisely crafted exclusions from the public domain.”³⁹⁸ As overall public welfare is the ultimate goal, the decision maker is faced with a dilemma: which value³⁹⁹ better promotes overall welfare? For instance, while some will fiercely defend a robust intellectual property system, others will

³⁹⁶ TRIPS Agreement, Article 7.

³⁹⁷ TAUBMAN, “TRIPS Jurisprudence in the Balance: Between the Realist Defense of Policy Space and a Shared Utilitarian Ethic”, 2007, p. 91 (the author stresses that while the balance of rights principle is “a naïve and simplistic caricature of a complex and subtle debate, it may have some analytical utility. In the current debate over ethics, policy and law of IP, the very complexity and range of issues covered can promote a tendency to vacate the middle ground, and to categorize view and to construct analysis in terms of opposing polarities”).

³⁹⁸ TAUBMAN, “TRIPS Jurisprudence in the Balance: Between the Realist Defense of Policy Space and a Shared Utilitarian Ethic”, 2007, p. 90.

³⁹⁹ The opposing values can range from public as against private interest; consumer as against producer interest; the interest of developed as against developing countries; economic growth as against sustainable development; human rights and environmental laws as against trade-law; and individual innovation as against the collective and sharing ethos of indigenous communities.

defend a rich public domain. The objective of both groups is the overall public welfare through innovation and economic growth. The former consider that economic development will be better served through a regime based on exclusivity of rights. In the particular case of patents, the argument is that there would be fewer inventions without patenting and an important loss to society overall.⁴⁰⁰ In contrast, the latter will argue that overall public welfare will be better served either through a regime based on non-exclusivity or “inclusivity,”⁴⁰¹ including open access and a sharing ethos or through a more rigorous application of patent conditions.⁴⁰² Others also argue for an intellectual property regime that embraces social and cultural functions.⁴⁰³ For instance, Markus and Reichman argue that “the proliferation of exclusive rights could raise fundamental road-blocks for the national and global provision of numerous public goods, including scientific research, education, health care, biodiversity, environmental and some human rights’ protection.”⁴⁰⁴ Finally, an intellectual property expert makes the following remark: “part of the problem is that we may never be able to know exactly what sparks a thought or a creative idea in somebody’s mind.”⁴⁰⁵

⁴⁰⁰ LENK, “Exclusive Property Rights in the Biosciences: An Ethical Discussion”, 2007, p. 127.

⁴⁰¹ See generally, DOSI and STIGLITZ, “The Role of Intellectual Property Rights in the Development Process”, 2014, pp. 1-53; BRADFORD, “Intellectual Property and Traditional Knowledge: A Psychological Approach to Conflicting Claims of Creativity in International Law”, 2005, p. 1683 (arguing that “[t]he TK discourse provides an important and unique critique of the IP regime. [...] The longer-range task is an inclusive international legal regime that is as informed by diverse local practices and norms as by fundamental human attributes of creativity.”); DUSOLIER, “Inclusivity in intellectual property”, 2015, p. 104 (the author notes that “whereas exclusivity of property has been defined by exclusion (only me and not you) and individuality (solely me), inclusivity can be described by (i) the absence of power to exclude others, which leads to inclusion of others in the use (me and others), and (ii) the collectiveness of uses, as opposed to the individuality of exclusive rights (me with others)”).

⁴⁰² See also, ARORA et al., “Markets for technology, intellectual property rights, and development”, 2005, p. 328 (the author argues that in the current debate, the available evidence on the link between intellectual property rights and innovation, transfer of technology and economic growth is not straightforward, but rather mixed among experts); BOLDRIN and LEVINE, “Perfectly Competitive Innovation”, 2008, pp. 435-453.

⁴⁰³ See for example, SUNDER, *From Goods to A Good Life: Intellectual Property and Global Justice*, 2012, p. 98 (the author argues that while economic efficiency is an important goal, the fair access to culture is also a crucial component of global justice).

⁴⁰⁴ MASKUS and REICHMAN, “The Globalisation of Private Knowledge Goods and the Privatisation of Global Public Goods”, 2004, p. 283.

⁴⁰⁵ LEMLEY, “Reconceiving Patents in the Age of Venture Capital”, 2000, p. 139.

Within the context of the debate on the balance of rights and obligations, the following question arises: where is the debate over the legal protection of traditional knowledge and biopiracy situated? This issue neither fits within the narrative of a robust public domain nor that of strong intellectual property rights. Here again, the decision makers or treaty negotiators are faced with opposing values. Indigenous and local communities call for the limiting of the patenting of public domain resources and claim stewardship or a new set of rights to prevent the misappropriation of their knowledge, despite the fact that users assume that these resources are in the public domain.⁴⁰⁶

The foundations of the discourse relating to the protection of traditional knowledge are twofold. It has a human rights and environmental dimension to it, but also an economic justification to it, through the application of intellectual property rights to its protection.⁴⁰⁷ These apparently divergent values are not necessarily in opposition, but it will depend on the approach that treaty negotiators or decision makers embrace: an inclusive or “syncretic”⁴⁰⁸ approach or an approach based more on predictability and stability. Thus, according to one commentator in the field, the TRIPS Agreement has the potential to reconcile diverse values and this is principally “the role of the responsible interpreter of TRIPS”, that is, “the domestic policy maker or legislator.”⁴⁰⁹ A real reconciliation of these diverging values or the establishment of a balance between diverging interests will therefore be found in domestic implementation rather than in an international context.

While this is true, for the particular issue of the protection of traditional knowledge, the importance of an international regime is fundamental. Indeed, there are principally two groups who are seeking to protect traditional knowledge, and whose interests are often at odds. They include indigenous peoples but also some nation states like India or China that are also seeking to protect traditional knowledge and who do not necessarily recognise indigenous

⁴⁰⁶ TAUBMAN, “Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge”, 2005, pp. 521-564.

⁴⁰⁷ HELFER, “Human Rights and Intellectual Property: Conflict or Coexistence?”, 2003, p. 52 (the author argues that “trade and intellectual property negotiators should embrace rather than resist opening up these organizations to human rights influence”. This will strengthen “the legitimacy of these organisations”).

⁴⁰⁸ TAUBMAN, “TRIPS Jurisprudence in the Balance: Between the Realist Defense of Policy Space and a Shared Utilitarian Ethic”, 2007, p. 103.

⁴⁰⁹ TAUBMAN, “TRIPS Jurisprudence in the Balance: Between the Realist Defense of Policy Space and a Shared Utilitarian Ethic”, 2007, p. 108.

peoples as distinctive communities with distinctive rights. Furthermore, one has to admit that the international framework is also more inclined today to an inclusive and syncretic approach than it was when TRIPS was adopted.⁴¹⁰ One example is the Doha Trade Round adopted one decade after the entry into force of the TRIPS Agreement.

2.2 Doha Trade Round of the WTO

The issue of traditional knowledge was expressly mentioned in the Doha Ministerial Declaration. In paragraph 19 of the Declaration, the TRIPS Council was instructed to review, amongst others, the relationship between the TRIPS Agreement and the UN Convention on Biodiversity and the protection of traditional knowledge.⁴¹¹ In this regard, the Doha Declaration mentions TK as an aspect of the wider debate on intellectual property rights protection and the conservation of biological diversity. Generally speaking, the debate regarding both the protection of traditional knowledge and the relationship between TRIPS Agreement and the CBD have culminated in discussions on the implementation of a disclosure requirement.

The TRIPS Council commenced its reviews of Article 27.3(b) in 1999. A first review targeted Article 27.3(b) that deals with the patentability of plant and animals inventions, and the protection of plant varieties. The second was directed, generally, to the review of the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity. It was decided that the TRIPS Council should work with WIPO and CBD in addressing these issues.

⁴¹⁰ TAUBMAN, “TRIPS Jurisprudence in the Balance: Between the Realist Defense of Policy Space and a Shared Utilitarian Ethic”, 2007, p. 109 (the author notes that “it is well documented that the background political dynamics that led to TRIPS included bilateral trade negotiations and bilateral trade pressure, and that TRIPS formed part of a trade-off between sectorial interests in constructing a final deal in the Uruguay Round”).

⁴¹¹ WTO Ministerial Conference, ‘Ministerial Declaration’, adopted 14 November 2001, Fourth Ministerial Conference, Doha, 9-14 November 2001, WTO Doc. WT/MIN(01)/DEC/1 (Doha Declaration) (Paragraph 19 reads as follows: “We instruct the Council for TRIPS, in pursuing its work program including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, *inter alia*, [...] the protection of traditional knowledge and folklore [...]. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension”).

Until now, the examination foreseen in paragraph 19 has centred on issues related to the disclosure of the origin or source of traditional knowledge under patent law. In 2011, developing countries submitted a draft decision proposing to add a new article 29bis on the “Disclosure of Origin of Genetic Resources and/or Associated Traditional Knowledge” in the TRIPS Agreement,⁴¹² although they failed to include a similar provision in the Nagoya Protocol. Such disclosure requirements have long been a demand of many developing countries, supported by some developed countries. As in the past, this proposal ran into opposition from some developed countries. Part III of the present work will extensively address the issue of disclosure of origin.

2.3 World Intellectual Property Organisation (WIPO)

Historically, the World Intellectual Property Organisation (WIPO) has been the main institution in the United Nations system related to intellectual property. The major roles of this institution have been both to promote the protection of intellectual property through the world, and to perform the administration of intellectual property rights treaties. Although the adoption of the TRIPS agreement in 1994 brought considerable changes in the institutional scene in relation to intellectual property rights at the international level, WIPO continues to maintain its central role concerning the administration of intellectual property rights treaties and the promotion of these rights.

Since 1998, WIPO has been mandated by its Member States to take a lead on the question of traditional knowledge protection, specifically the intellectual property aspects of it. It is clear that WIPO has shifted from its traditional emphasis on the promotion and expansion of intellectual property rights towards a more development-oriented approach.⁴¹³ Indeed, the enforcement side of intellectual property rights has been left to the WTO.⁴¹⁴

⁴¹² WTO Trade Negotiations Committee, ‘Draft Decision to Enhance Mutual Supportiveness between the TRIPS Agreement and the Convention on Biological Diversity’, Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, ACP Group, and the African Group, 19 April 2011, WTO Doc. TN/C/w/59.

⁴¹³ WIPO General Assembly (WIPO GA), ‘Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore’, the Secretariat, 25 September -3 October 2000, WO/GA/26/6, para 11; see also MAY, “The World Intellectual Property Organisation and the Development Agenda”, 2008, pp. 97-113.

⁴¹⁴ MAY, *The World Intellectual Property Organisation: Resurgence and the Development Agenda*, Routledge, London, p. 92.

The consideration of tradition-based forms of innovation, as opposed to the types of innovation and creativity that had been generally dealt with by intellectual property law, began when UNESCO and WIPO jointly elaborated the 1982 “Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions”⁴¹⁵ (the Model Provisions). This collaboration constitutes the beginning of WIPO’s work on cultural heritage through the prism of intellectual property rights. While the Model Provisions focus upon traditional cultural expressions, they laid down the bases for the subsequent comprehensive work of WIPO with regard to traditional knowledge. Even at that time, there was an awareness of a situation of unbalance and inequity taking place between the original holders of traditional cultural expressions and the innovators using traditional cultural expressions.⁴¹⁶ Seven years later, in 1989, WIPO established the Global Intellectual Property Rights Issues Division (hereafter, GIPID), which tackled both traditional cultural expressions and traditional knowledge. While the CBD and the TRIPS Agreement were only adopted in 1992 and 1994, respectively, the mandate of the GIPID already consisted of assessing the feasibility of protecting new subject matters under an intellectual property rights system and the relationship between intellectual property rights and biodiversity.⁴¹⁷ The categorisation of traditional knowledge into two sub-groups also started at this time, whereas traditional knowledge started to be discussed in terms of patent law and biodiversity law, cultural expressions were related to copyright law. This distinction has remained until today.

The cornerstone activity of the GIPID has been the nine “fact finding missions” (hereafter, the FFM) conducted by WIPO between 1998 and 1999 in 28 countries to identify the intellectual property related needs and expectations of traditional knowledge holders in order to guide the future work of WIPO on the protection of traditional knowledge.⁴¹⁸ The FFMs reached the following conclusions: (i) traditional knowledge is constantly evolving; and (ii) it constitutes a rich and diverse source of innovation and creativity in a wide variety of fields, including traditional medicine, agriculture, music, and design. Importantly, the FFMs acknowledged

⁴¹⁵ WIPO/UNESCO, ‘Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions’ (WIPO/UNESCO, Model Provision 1985).

⁴¹⁶ WIPO/UNESCO, Model Provision 1985), para. 9.

⁴¹⁷ WIPO, ‘Protection of Traditional Knowledge: A Global Intellectual Property Issue’, by the International Bureau, Geneva, 1-2 November 1999, WIPO/IPTK/RT/99/2.

⁴¹⁸ WIPO, ‘Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge 1998-1999’, 2001.

that the distinction between traditional knowledge and traditional cultural expressions in accordance with the conventional branches of intellectual property law, does not correspond to the holistic view of the holders,⁴¹⁹ who “do not separate “artistic” from “useful” aspects of their intellectual creations and innovations; [...] both emanate from a single belief system which is expressed in daily life and ritual.”⁴²⁰

Subsequent to the FFMs, the WIPO General Assembly decided to establish the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC) as a multilateral policy forum.⁴²¹

2.3.1 The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC)

In 2000, at the 26th session of the WIPO General Assembly, Member States decided to create the WIPO-IGC. The origins of the IGC can be traced back to the negotiations that led to the adoption of the Patent Law Treaty (PLT) in 2000 under the auspices of the WIPO Standing Committee on Patents (SCP). During the discussions, Colombia presented a proposal indicating that “[a]ll industrial property protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of heritage shall be subject to their having been acquired legally.”⁴²² Some developed countries rejected the proposal, arguing that the SCP was not the right forum for such an issue. Eventually, Member States agreed upon the creation of an intergovernmental body that would broadly address intellectual property matters that arise in the context of access to genetic resources, traditional knowledge and benefit-sharing.

⁴¹⁹ WIPO, ‘Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge 1998-1999’, 2001, p. 26 (“WIPO uses the term “traditional knowledge holder” to refer to all persons who create, originate, develop and practice traditional knowledge in a traditional setting and context. Indigenous communities, peoples and nations are traditional knowledge holders, but not all traditional knowledge holders are indigenous”).

⁴²⁰ WIPO, ‘Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge 1998-1999’, 2001, p. 213.

⁴²¹ WIPO GA, ‘Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore’, the Secretariat, 25 September – 3 October 2000, WO/GA/26/6, p. 4.

⁴²² WIPO SCP, ‘Protection of Biological and Genetic Resources’, the Delegation of Colombia, 6 to 14 September 1999, WIPO/SCP/3/10.

The three main topics for this special body to discuss are: (i) the development of model clauses for genetic resources contracts; (ii) work on a *sui generis* system for the protection of traditional knowledge and traditional cultural expressions against misappropriation⁴²³ and misuse;⁴²⁴ and (iii) the creation of a framework to address the intellectual property aspects of access and benefit-sharing in genetic resources. The IGC is currently negotiating draft of international legal instruments on the protection of traditional knowledge (TK), traditional cultural expression (TCE) and genetic resources (GR).⁴²⁵

⁴²³ CHIAROLLA, “The Role of Private International Law under the Nagoya Protocol”, 2013, pp. 428 (the author defines “misappropriation of genetic resources and traditional knowledge [...] as the appropriation (and subsequent utilisation) of such resources and knowledge, which occurs in violation of the applicable domestic ABS legislation or regulatory requirements of a Party to the Protocol”); see also, WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Objectives and Principles’, the Secretariat, 30 November – 8 December 2006, WIPO/GRTKF/IC/10/5, p. 6 (the IGC has identified five specific aspects of misappropriation, which are: (i) direct acts of deliberate misappropriation; (i) misappropriation through the breach of legal arrangements for prior informed consent and benefit-sharing; (iii) misappropriation through attempts to obtain illegitimate intellectual property rights over traditional knowledge; (iv) misappropriation in the form of unfair competition or unjust enrichment, deriving commercial benefit when this is manifestly inequitable; and (v) certain forms of wilful misuse and offensive behaviour regarding traditional knowledge).

⁴²⁴ Black’s Law Dictionary, 9th edition, 2009 defines “misuse” as “the use of a patent either to improperly extend the granted monopoly to non-patented goods or to violate antitrust laws.” Dictionaries generally refer to misuse as an incorrect or improper use or a wrong; see also, CHIAROLLA, “The Role of Private International Law under the Nagoya Protocol”, 2013, pp. 427-428 (the author notes that the term “misuse” of genetic resources and traditional knowledge may be generally understood as a use that violates the MAT between the user and the provider(s) or holder(s) of such resources and knowledge, assuming a contractual relationship between the parties); see also, WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, the Secretariat, 9-13 May 2011, WIPO/GRTKF/IC/18/5, FN 86, p. 35 (The Delegation of Australia noted that “misuse was a term that was used in the CBD context within the draft negotiating text for an international regime on access and benefit sharing of GR and associated TK. It was used to refer to acts that were contrary to mutually agreed terms, while misappropriation referred specifically to acquisition without prior informed consent. It called for further discussion as to the meaning of these terms in the context of this Committee and in relation to IP rather than access to TK associated with GR”).

⁴²⁵ WIPO GA, ‘Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore’, the Secretariat, 25 September – 3 October 2000, WO/GA/26/6; see also WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Objectives and Principles’, the Secretariat, 30 November – 8

In contrast to the conclusions reached by the Fact-Finding Missions (FFMs), the IGC's mandate continued to subdivide traditional knowledge into sub-groups (TK and TCEs) in order to fit into the branches of intellectual property law, namely patent and copyright laws.

The WIPO-IGC is open to all WIPO Member States and intergovernmental organisations, and non-governmental organisations may assist deliberations if invited to participate as accredited observers.⁴²⁶ The creation of the WIPO-IGC was extensively supported by Member States, especially among Latin American, African and Asian countries. Group B countries including the European Union Member States⁴²⁷ stressed the importance of not prejudging any outcome of the IGC, which should primarily constitute a forum for discussions on issues that could not be dealt within the existing WIPO bodies.⁴²⁸

Broadly speaking, since 2000 until now, two tendencies can be underlined. While some delegations stress the urgent need for an international instrument protecting traditional knowledge,⁴²⁹ others maintain that any outcome should be carefully considered in order to ensure the consistency of potential solutions with existing intellectual property rights.⁴³⁰

While the mandate of the IGC has been renewed on a two years basis since its beginning, at the 46th session the WIPO General Assembly, in 2014, no decision on the work programme of the IGC for the biennium 2015-2016 was made.⁴³¹ This failure to agree on a way forward for the IGC was due to a significant lack of consensus on fundamental issues, such as the legal nature of the international instrument, objectives and principles of the IGC, subject matter of protection, scope of rights, and beneficiaries. In October 2015, at the 47th session of the WIPO General Assembly, while some members, including Switzerland, were in favour of renewing

December 2006, WIPO/GRTKF/IC/10/5, p. 6 (the IGC extends on the specific characteristics of protection of traditional knowledge).

⁴²⁶ WIPO GA, 'Report', adopted by the Assembly, Geneva, 25 September – 3 October 2000, WO/GA/26/10, para. 30, 31 and 32.

⁴²⁷ Group of Industrialised Countries.

⁴²⁸ WIPO GA, 'Report', 25 September – 3 October 2000, WO/GA/26/10, para. 34 (statement of Japan on behalf of Group B) and para. 41 (statement of France on behalf of the Members of the European Union).

⁴²⁹ WIPO IGC, 'Report of the First ICG Session, 30 April – 3 May 2001, WIPO/GRTKF/IC/1/13, para. 62 (statement of the Delegation of Panama supporting the Delegation of Uruguay on behalf of GRULAC)

⁴³⁰ WIPO IGC, 'Report of the First ICG Session, 30 April – 3 May 2001, WIPO/GRTKF/IC/1/13, para. 132 (statement of the Delegation of Sweden on behalf of the European Union Member States).

⁴³¹ WIPO GA, 'Report', 22– 30 September 2014, WO/GA/46/12, para. 173, p. 46.

the IGC mandate,⁴³² others proposed a structural change to the IGC through the conversion of the IGC into a standing committee.⁴³³ Out of all member states, the delegations of US, Japan and the Korea were alone in questioning the very existence of the Committee and its objective by recommending that “the mandate of the IGC should not be renewed. An *ad hoc*, cross regional group of experts should be established to determine what, if any problems, existed and what, if anything, could be done at the international level to address any such problems”.⁴³⁴

Eventually, at the end of October 2015, the WIPO General Assembly decided to renew the IGC mandate for the next biennium 2016-2017. The mandate stipulates that “[t]he Committee will, during the next budgetary biennium 2016/2017, continue to expedite its work, with a focus on narrowing existing gaps, with open and full engagement, including text-based negotiations, with the objective of reaching an agreement on an international legal instrument(s), without prejudging the nature of outcome(s), relating to intellectual property which will ensure the balanced and effective protection of genetic resources (GRs), traditional knowledge (TK) and traditional cultural expressions (TCEs).”⁴³⁵

At the time of writing, the IGC will meet again from the 19th to the 23rd of September 2016, at its 31st session, for addressing and reviewing the draft international legal instrument on the protection of traditional knowledge.

Finally, it can be said that while WIPO is fundamentally an organisation devoted to intellectual property rights, its vision has evolved towards development policy goals. In relation to traditional knowledge, WIPO draft text denotes that even though the protection of traditional knowledge forms an integral part of policies concerning the promotion and protection of innovation, the protection of traditional knowledge touches upon other policy

⁴³² WIPO GA, ‘Matters concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) : Proposal of the Holy See, Kenya, Mozambique, New Zealand, Norway and Switzerland to the WPO GA, 5- 14 October 2015, WO/GA/47/18.

⁴³³ WIPO General Assembly, ‘Conversion of WIPO IGC into a Standing Committee: Proposal by the African Group to the 2015 GA’, 5- 14 October 2015, WO/GA/47/16.

⁴³⁴ WIPO GA, ‘Matters concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) : Proposal of the United States of America to the WPO GA’, 5- 14 October 2015, WO/GA/47/17.

⁴³⁵ WIPO GA, ‘Report’, 5 – 14 October 2015, WO/GA/47/19, para. 289, p. 56; see also, WIPO agenda for 2016-2017 at: www.wipo.int/tk/en/igc/ [accessed September 2016].

domains. These include the safeguarding and preservation of diverse knowledge systems and the intellectual and cultural heritage of communities; respect for the rights, interests and claims of indigenous peoples; conservation of the components of biodiversity and associated traditional knowledge, and mechanisms for prior informed consent and equitable benefit-sharing; access to knowledge and the scope of the “public domain;” addressing the challenges of multiculturalism; and the promotion of cultural diversity and the distinctive character, values and beliefs of diverse knowledge systems.⁴³⁶

The WIPO Development Agenda (DA) is evidence of the efforts to integrate development considerations within the organisation.

2.3.2 WIPO Development Agenda

The Development Agenda was adopted in October 2007, based upon a proposal that was originally tabled by Argentina and Brazil at the 2004 WIPO General Assembly, and was later supported by other developing countries, called the Group of Friends of Development. The DA emphasises the need for social, cultural, economic, and technological development. Its main objective is to aims to reach a balance between the rights and obligations of producers and users of knowledge-based goods, always bearing at mind the costs and benefits of intellectual property protection in relation to the public interest. The spirit of the DA is in essence that the intellectual property regime should be viewed as means for achieving sustainable development and serving the socio-economic needs of society, rather than promoting the private enrichment of a few.

The WIPO Development Agenda includes 45 recommendations that aim to enhance the development role of the organisation. The recommendations are divided into six clusters: Cluster A relates to technical assistance and capacity building; Cluster B refers to norm-setting, flexibilities, public policy and public domain; Cluster C concerns technology transfer, information and communication technologies (ICT) and access to knowledge; Cluster D relates to assessment, evaluation and impact studies; Cluster E addresses institutional matters, such as mandate and governance; and Cluster F covers other issues. Cluster F contains a single recommendation which involves the idea of approaching “intellectual property enforcement in the context of broader social interests and especially development-

⁴³⁶ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Objectives and Principles’, 30 November – 8 December 2006, WIPO/GRTKF/IC/10/5, para. 15, p. 5.

oriented concerns, with a view that ‘the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations’, in accordance with Article 7 of the TRIPS Agreement.”⁴³⁷

As far as the specific issue of the protection of traditional knowledge is concerned, recommendation number 18 of Cluster B urges “the IGC to accelerate the process on the protection of genetic resources, traditional knowledge and folklore, without prejudice to any outcome, including the possible development of an international instrument or instruments.”⁴³⁸

3 Human Rights

The preceding sections have explored and identified the interface between, on one side, environmental laws and the protection of traditional knowledge, and on the other side, the intellectual property regime and the protection of traditional knowledge. The present section will examine the issue of the protection of traditional knowledge from a human rights perspective. Hence the following analysis will be broken into two sub-sections, whereas the first will analyse the issue of the protection of traditional knowledge under the United Nations Declaration on the Rights of Indigenous Peoples, the second will question the relationship between intellectual property rights and human rights.

Before getting into the heart of our analysis, it is worth raising the issue of the equality between various categories of human rights. While it is beyond the scope of this work to undertake a detailed analysis of this subject matter, which is highly complex on its own, some distinctions related to first-generation rights, i.e. civil and political rights, and to second-generation rights, i.e. economic, social and cultural rights or to the hierarchy of human rights, in general, are necessary to better grasp conflicts that may arise between human rights and intellectual property laws, and traditional knowledge protection.

⁴³⁷ WIPO, ‘The 45 Adopted Recommendations under the WIPO Development Agenda’ at: www.wipo.int/ip-development/en/agenda/recommendations.html#b [accessed September 2016]; see also, BIRKBECK, *The World Intellectual Property Organization (WIPO) – A Reference Guide*, 2016, pp. 60ff.

⁴³⁸ WIPO, ‘The 45 Adopted Recommendations under the WIPO Development Agenda’ at: www.wipo.int/ip-development/en/agenda/recommendations.html#b [accessed September 2016].

The official thesis is that there is no hierarchy between first- and second-generation rights.⁴³⁹ However, and as is often the case, the theory and the reality do not always follow the same path. In other words, there is a hierarchy between human rights, in practice. This hierarchy can be observed at two levels. First, first- and second-generation rights are protected by separate instruments, which are not equal in strength. A striking example can be seen in the rights encoded in the European Convention on Human Rights (ECHR)⁴⁴⁰ regarded as the most effective instrument in transnational judicial protection of human rights around the world.⁴⁴¹ Indeed, the Court's case law seems to demonstrate that the rights enshrined in the Convention are given more weight than rights enshrined in other non-Convention instruments.⁴⁴² Second, there are also inequalities between rights enshrined within the same instrument. Indeed, while some rights are absolute and non-derogable, i.e. the core human rights or *jus cogens* norms, others may be subject to legitimate limitations and derogations.⁴⁴³ For instance, in both the ECHR and the International Covenant on Civil and Political Rights (ICCPR),⁴⁴⁴ the following rights - the right to life; the prohibition of torture and other cruel, inhuman or degrading treatment or punishment; the prohibition of slavery; the principle of legality in criminal law; or the prohibition of medical or scientific experimentation without consent - are universally considered to be at the top of the hierarchy amongst human rights. One of the main differences between derogable and non-derogable rights resides in the fact that while for the

⁴³⁹ Universal Declaration of Human Rights, Paris, 10 Dec. 1948, U.N.G.A. Res. 217 A (III) (UDHR) (The Declaration recognises both first and second-generation rights as worthy of protection).

⁴⁴⁰ European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by substantive and procedural additional protocols, Council of Europe, Rome, 4 November 1950, ETS 5, 213 UNTS 221 (ECHR).

⁴⁴¹ GREER, "What's Wrong with the European Convention on Human Rights?", 2008, p. 680.

⁴⁴² See a leading case on this matter, ECtHR, *Chassagnou and Others v. France* [GC], nos. 25088/94, 28331/95 and 28443/95, 20 April 1999, Reports of Judgments and Decisions 1999-III, para. 113 ("[...] where restrictions are imposed on a right or freedom guaranteed by the Convention in order to protect 'rights and freedoms' not, as such, enunciated therein. In such a case only indisputable imperatives can justify interference with enjoyment of a Convention right. In the present case the Government pleaded the need to protect or encourage democratic participation in hunting. Even supposing that French law enshrines a 'right' or 'freedom' to hunt, the Court notes [...] that such a right or freedom is not one of those set forth in the Convention, which does, however, expressly guarantee the freedom of association").

⁴⁴³ For an in-depth discussion on the issue of *Jus Cogens* and obligations *Erga Omnes* see, TRINDADE, *International Law for Humankind – Toward a New Jus Gentium*, 2013, pp. 291ff.

⁴⁴⁴ International Covenant on Civil and Political Rights, 16 December 1966, GA Resolution 2200 (XXI), entered into force 23 March 1976, 999 UNTS 171 (ICCPR).

former the margin of appreciation of States is wide, in the case of the latter, it is almost non-existent. For instance, with respect to the right to property in Article 1 of the Protocol 1 to the ECHR, the margin of appreciation of States is deployed to its full effect.⁴⁴⁵ In a nutshell, the hierarchy of rights constitutes a first step in the overall balancing exercise to resolve conflicts arising from the interaction between human rights. However, it is not an absolute, in the sense that its existence will not automatically result in the prevalence of rights at the top of the hierarchy over those located at a lower level. Other circumstances, such as the status of rights-holders or the gravity of the interference have to be taken into account when solving conflicting interactions between human rights.⁴⁴⁶

This brief introduction to issues around the hierarchy of rights is important in the light of the analysis that will follow. The following paragraphs will try to answer some questions that are particularly relevant in the context of this study. These questions can be listed as follows.

First, does the protection of traditional knowledge stand in the realm of international human rights? In trying to answer this question, the following discussion will be limited to the analysis of certain aspects that are relevant to the protection of traditional knowledge. These are: the right to self-determination, the concept of “free, prior, informed consent” and the intellectual property rights of indigenous peoples.

Second, can we assert that intellectual property rights are human rights as defined by Article 15(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR)?⁴⁴⁷ If the answer to this second question is positive, then the question is whether there is a hierarchy between the intellectual property rights of indigenous peoples under UN Declaration on the Rights of Indigenous Peoples (hereafter, the “UNDRIP”), and intellectual property rights under ICESCR? And if the answer is negative, is there still a hierarchy between intellectual property rights under the international human rights treaties and those under TRIPS?

The following paragraphs will discuss whether the protection of traditional knowledge stands in the realm of international human rights. As mentioned earlier, before the adoption of UNDRIP, the International Labour Conventions No. 107 and No. 169 were the only

⁴⁴⁵ DUCOULOMBIER Peggy, “Interaction between human rights: Are all human rights equal?”, 2015, p. 46.

⁴⁴⁶ DUCOULOMBIER Peggy, “Interaction between human rights: Are all human rights equal?”, 2015, p. 50.

⁴⁴⁷ International Covenant on Economic, Social and Cultural Rights, 16 December 1966, GA Resolution 2200 A (XXI), entered into force 3 January 1976, 993 UNTS 3 (ICESCR).

international instruments specifically dealing with indigenous peoples' rights within the ambit of international human rights. While the ILO 107 was the first international instrument to place indigenous peoples' concerns within the ambit of international human rights, it had two main shortcomings. First, indigenous peoples were not consulted in its development. Second, the Convention was mainly constructed upon assimilationist and integrationist elements.⁴⁴⁸ The ILO 169 was adopted three years later to remediate these shortcomings. At present, the majority of indigenous peoples are deprived of the protection provided by the legal framework of ILO 169, as it has been only ratified by twenty-two States.⁴⁴⁹ In addition, ILO 169 has a principal shortcoming in that it fails to confer on indigenous peoples the right to self-determination. Additionally, it specifically fails to address the protection of traditional knowledge in relation to a conflict with intellectual property rights.

Apart from these two conventions, there are several other international human rights treaties that are relevant to the protection of indigenous peoples' rights.⁴⁵⁰ The International Covenant on Civil and Political Rights⁴⁵¹ protects rights that are important to indigenous peoples, such as the right to self-determination⁴⁵² and the rights of persons belonging to minorities to enjoy

⁴⁴⁸ ANAYA, *Indigenous Peoples in International Law*, 1996, pp. 155ff.

⁴⁴⁹ The list of ratification is available at: <http://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:1:0::NO::> [accessed September 2016].

⁴⁵⁰ For example, there exist diverse international monitoring procedures under the auspices of universal human rights instruments that encourage States Parties to comply with their obligations under their international human rights obligations. These treaties require State Parties to submit periodic reports on implementation of treaty provisions. Apart from these two conventions, there are several other international human rights treaties that are relevant to the protection of indigenous peoples' rights. The reports are reviewed and commented by the respective Committee. The International Covenant on Civil and Political Rights (ICCPR) and the Convention on the Elimination of All Forms of Racial Discrimination (ICERD) have respectively established the Human Rights Committee (HRC) and the Committee on the Elimination of Racial Discrimination; see, International Covenant on Civil and Political Rights, 16 December 1966, GA Resolution 2200 (XXI), entered into force 23 March 1976, 999 UNTS 171, (ICCPR), Article 40 establishes the reporting procedure under the Covenant; International Convention on the Elimination of All Forms of Racial Discrimination, 21 December 1966, GA Resolution 2106A (XX), entered into force 4 January 1969, 660 UNTS 195, (ICERD), Article 9 establishes the reporting procedure under the Convention.

⁴⁵¹ International Covenant on Civil and Political Rights, 16 December 1966, GA Resolution 2200 (XXI), entered into force 23 March 1976, 999 UNTS 171, Article 40 establishes the reporting procedure under the Covenant (ICCPR).

⁴⁵² ICCPR, Article 1.

their own culture, to profess and practise their own religion or to use their own language.⁴⁵³ The Human Rights Committee has interpreted “the right to self-determination as applying not only to colonial situations but to other situations as well and that the people of a given territory should be allowed to determine their political and economic destiny.”⁴⁵⁴ Similarly, it has interpreted the right to culture of persons belonging to minorities to encompass indigenous peoples’ rights in relation to their customary activities, their lands, territories and resources, and their right to participate in political decisions that affect their cultural rights.⁴⁵⁵

The Committee established by the International Convention on the Elimination of All Forms of Racial Discrimination (ICERD) has also addressed a number of indigenous peoples’ concerns, particularly in the last 15 years. Its approach is reflected in its General Recommendation No. 23 on indigenous peoples, which calls on States, *inter alia*, to:

- (i) ensure indigenous peoples have equal rights in respect of *effective participation in public life* and that no decisions directly relating to their rights and interests are taken without *their informed consent*; [...]
- (ii) recognize and protect the rights of indigenous peoples to own, develop, control and use their communal lands, territories and resources and, where they have been deprived of their lands and territories traditionally owned or otherwise inhabited or used *without their free and informed consent*, to take steps to return those lands and territories. Only when this is for factual reasons not possible, the right to restitution should be substituted by the right to just, fair and prompt compensation. Such compensation should as far as possible take the form of lands and territories.⁴⁵⁶

⁴⁵³ ICCPR, Article 27.

⁴⁵⁴ Human Rights Committee, ‘General Comment adopted by the Human Rights Committee under Article 40, paragraph 4, of the International Covenant on Civil and Political Rights: General Comment No. 23(50), Article 27’, 26 April 1994, UN Doc. CCPR/C/21/Rev.1/Add.5 (the General Comment discuss the extend of coverage of Article 27 and its link with other Articles of the Covenant).

⁴⁵⁵ Human Rights Committee, ‘General Comment adopted by the Human Rights Committee under Article 40, paragraph 4, of the International Covenant on Civil and Political Rights: General Comment No. 23(50), Article 27’, 26 April 1994, UN Doc. CCPR/C/21/Rev.1/Add.5, para. 3.2 (the General Comment discuss the extend of coverage of Article 27 and its link with other Articles of the Covenant).

⁴⁵⁶ CERD, ‘General Recommendation XXIII on the Rights of Indigenous Peoples, General Recommendation 23, 22 August 1997, 51st Session, annex V, at 122, U.N. Doc. A/52/18, reprinted in “Compilation of

What stands out from the general recommendation is the requirement that indigenous peoples shall participate actively in matters that concern them, and that their informed consent shall be obtained before taking any decisions affecting them. The following paragraphs will analyse the close relationship between the right to effectively participate in public life and the right to self-determination. Beyond the right to informed consent, the recommendation also endorses the collective nature of rights in lands and resources for indigenous peoples.⁴⁵⁷ It goes as far as to place the right to restitution before the right to compensation without providing any limits in time. In contrast to the rights to land and resources, however, the recommendation fails to address the issue of indigenous peoples' intellectual creativity.

Beyond the work of the UN Treaty Bodies, the United Nations human rights system provides three additional procedures that are highly relevant for indigenous peoples' voices. These are: the Expert Mechanism;⁴⁵⁸ the Special Rapporteur on the Rights of Indigenous Peoples;⁴⁵⁹ and the UN Permanent Forum on Indigenous Issues (UNPFII).⁴⁶⁰ The mandates of the Expert Mechanism, the Special Rapporteur and the UN Permanent Forum are all mutually supportive. While the Expert Mechanism undertakes thematic

General Comments and General Recommendations Adopted by Human Rights Treaty Bodies", the Secretariat, 12 May 2003, U.N. Doc. HRI/GEN/1/Rev.6, p. 212.

⁴⁵⁷ THORNBERRY, "Integrating the UN Declaration on the Rights of Indigenous Peoples into CERD Practice", 2011, p. 88.

⁴⁵⁸ The Expert Mechanism on the Rights of Indigenous Peoples was established in 2007 by the Human Rights Council, 'Expert mechanism on the rights of indigenous peoples', Resolution 6/36, 6th Session, 14 December 2007, UN Doc. A/HRC/RES/6/36.

⁴⁵⁹ Human Rights Council, 'Human rights and indigenous peoples: mandate of the Special Rapporteur on the rights of indigenous peoples', Resolution 15/14, 15th Session, 6 October 2010, UN Doc. A/HRC/RES/15/14 (the mandate of the Special Rapporteur was established in 2001 by the Commission on Human Rights and continued by the Human Rights Council in 2007. Rodolfo Stavenhagen (Mexico) held the mandate between 2001 and 2008 and James Anaya (United States) held the mandate between 2008 and 2014 and Victoria Tauli Corpuz (Philippines) has held the mandate since 2014).

⁴⁶⁰ UN ECOSOC, 'Establishment of a Permanent Forum on Indigenous Issues', Resolution 2000/22, 45th Plenary Meeting, 28 July 2000, UN Doc E/2000/22, in "Resolutions and Decisions Adopted by the Economic and Social Council at its substantive session of 2000", 5 to 28 July 2000, E/2000/INF/2/Add.2, pp. 50-52 (the PFII was established by ECOSOC Resolution 2000/22, in response to demands from indigenous peoples for a high-level body that could promote dialogue and cooperation among Member States, United Nations agencies and indigenous peoples).

studies, the Special Rapporteur undertakes country visits, addresses cases of alleged human rights' violations through communications with Governments and carries out or contributes to thematic studies. For instance, the last thematic report submitted by the Special Rapporteur concerned the impacts of international investment and free trade on the vulnerable situation of indigenous peoples.⁴⁶¹ The UN Permanent Forum focuses on advice on and coordination of indigenous issues within the United Nations system and raises awareness about such issues. The significance of the Forum lies in the fact that for the first time representatives of States and non-State actors have been accorded parity in a permanent representative body within the organisations of the United Nations.⁴⁶²

According to the former Special Rapporteur on the Rights of Indigenous Peoples, James Anaya, while these procedures within the United Nations human rights system have played and still play an important role in developing international standards and in enhancing awareness amongst Member States on the issue of indigenous rights, they “are not devised specifically to address the historically rooted grievances of indigenous peoples.”⁴⁶³ In addition, their functioning is mostly dependent on State consent.

Against this background, on 12 September 2007, the UN General Assembly adopted the UN Declaration on the Rights of Indigenous Peoples in a striking vote of 144 States in favour of and 4 against.⁴⁶⁴ As the following section will demonstrate, the Declaration brings a new breath of life to the rights of indigenous peoples, particularly with reference to their right to self-determination.

3.1 The United Nations Declaration on the Rights of Indigenous Peoples

More than 20 years of arduous negotiations between nation states and indigenous peoples eventually led to the adoption of the United Nations Declaration on the Rights of Indigenous

⁴⁶¹ UN GA, ‘Report of the Special Rapporteur of the Human Rights Council on the Rights of Indigenous Peoples on the Impact of International Investment and Free Trade on the Human Rights of Indigenous Peoples’, Victoria Tauli Corpuz, 7 August 2015, UN Doc. A/70/301, pp. 9ff.

⁴⁶² See generally, WIESSNER Siegfried and CAREY John, “A New United Nations Subsidiary Organ: The Permanent Forum on Indigenous Issues”, 2001.

⁴⁶³ ANAYA, *Indigenous Peoples in International Law*, 1996, p. 184.

⁴⁶⁴ UN GA, ‘United Nations Declaration on the Rights of Indigenous Peoples’, Resolution 61/295 adopted by the UN GA Res., 61st session, 13 September 2007, UN Doc. A/RES/61/295; see also FN No 56.

Peoples by the UN General Assembly.⁴⁶⁵ At the outset, it should be noted that the Declaration is the direct result of the concerted efforts and demands of indigenous peoples regarding the recognition and the protection of their basic rights and fundamental freedoms.⁴⁶⁶ That being said, it remains no less true that is also the result of a drafting process involving both States and indigenous peoples. The final text is composed of a preamble and 46 articles. As a declaration, the UNDRIP is not a legally binding international instrument. Indeed, from a purely legal perspective, United Nations Declarations are of a mere hortatory nature. They are typified as recommendations without legally binding character.⁴⁶⁷ According to one author, “under the complexity and dynamism of contemporary international law-making, soft law cannot be simply dismissed as non-law.”⁴⁶⁸

Notwithstanding its non-binding nature, the Declaration articulates the most comprehensive standards of protection for all issues of relevance to indigenous peoples.⁴⁶⁹ UNDRIP strongly places emphasis upon principles of paramount importance for indigenous peoples, namely indigenous representation,⁴⁷⁰ cultural identity,⁴⁷¹ prior informed consent,⁴⁷² benefit sharing,⁴⁷³ lands and natural resources,⁴⁷⁴ and indigenous intellectual property in the exercise of their rights to collective identity, non-discrimination, and self-determination.⁴⁷⁵

⁴⁶⁵ Australia, Canada, New Zealand and the United States encompassing relatively large indigenous populations were initially opposed. See United Nations General Assembly (UNGA) Department of Public Information, “General Assembly Adopts Declaration on Rights of Indigenous Peoples. Major step forward towards human rights for all, says President”, UN Press release, 13 September 2007, available at: <http://www.un.org/press/en/2007/ga10612.doc.htm> [accessed September 2016].

⁴⁶⁶ DAES, “The Contribution of the Working Group on Indigenous Populations to the Genesis and Evolution of the UN Declaration on the Rights of Indigenous Peoples”, 2009, p. 73.

⁴⁶⁷ Charter of the United Nations, 24 October 1945, 1 UNTS XVI, Articles 10 and 11.

⁴⁶⁸ BARELLI, “The United Nations Declaration on the Rights of Indigenous Peoples: A Human Rights Framework for Intellectual Property Rights”, 2015, p. 52.

⁴⁶⁹ CHARTER and STAVENHAGE, “The UN Declaration on the Rights of Indigenous Peoples: How it Came to Be and What it Heralds”, 2009, p. 10.

⁴⁷⁰ UNDRIP, Article 18.

⁴⁷¹ UNDRIP, Article 8.

⁴⁷² UNDRIP, Articles 19, 32.0

⁴⁷³ UNDRIP, Article 28.

⁴⁷⁴ UNDRIP, Article 29.

⁴⁷⁵ RIMMER, “Introduction: Mapping Indigenous Intellectual Property”, 2015, p. 2.

According to the former Head of the Indigenous Peoples' Programme at the Office of the United Nations High Commissioner for Human Rights, the Declaration is largely under the umbrella of two principal rights: the right not to be discriminated against and the right to self-determination. The right not to be discriminated against results from the actions of States, assimilating indigenous peoples, denying them a right to equal treatment and reducing them to a state of dependency. The right of self-determination, in turn, is the consequence of the historical actions of colonising States to dispossess indigenous peoples of their lands and resources, and to dismantle their political, economic and spiritual authorities.⁴⁷⁶

The following analysis is broken down into three parts. The first section will address indigenous peoples' right to self-determination. The second section will focus on one of the components of the right to participate in public life, the right to free prior informed consent. The third section will specifically cover Article 31 of the Declaration related to intellectual property and the traditional knowledge of indigenous peoples.

3.1.1 The Evolution of the Rights to Self-determination under the UN Declaration

In international law, the right to self-determination signifies that “all people freely determine their political status and freely pursue their economic, social and cultural development. [They] may, for their own ends, freely dispose of their natural wealth and resources.”⁴⁷⁷ It is generally agreed that this right has two dimensions, internal and external, one being more controversial than the other. While the internal dimension broadly refers to the right of people to choose their own system of government and develop their own policies, the latter refers to the rights of people to determine their international status, including the decision to seek independence.⁴⁷⁸

⁴⁷⁶ BURGER, “The UN Declaration on the Rights of Indigenous Peoples: From Advocacy to Implementation”, 2010, p. 43.

⁴⁷⁷ ICCPR and ICESCR, common Article 1.

⁴⁷⁸ See generally, CASSESE, *Self-Determination of Peoples: A Legal Reappraisal*, 1995; see also ANAYA, *Indigenous Peoples in International Law*, 1996, pp. 80ff (this classical distinction has been questioned by the author, who suggests an alternative framework based on “constitutive and ongoing self-determination”).

While it is beyond the scope of the present study to perform an in-depth study on the evolution of the right to self-determination,⁴⁷⁹ an overview of this right under the Declaration proves to be essential. The right to self-determination has acquired a new breath under the Declaration for three main reasons. The Declaration has linked the right to self-determination and the right to participate in public life, and this relationship is suggested to be one of the innovations brought in by the Declaration.⁴⁸⁰

First, UNDRIP expressly recognises indigenous peoples' right to self-determination.⁴⁸¹ Second, it further recognises that the right is no longer limited to peoples organised as States or colonial peoples but extends to other categories of people. Indeed, it defines a people in relation to their distinct ethnic and cultural identity.⁴⁸² Third, it makes a link between the right to self-determination and the right to participate in public life or in decision-making for indigenous peoples. This relationship is suggested to be one of the innovations brought in by the Declaration.⁴⁸³ Finally, leading scholars in this field have argued that some provisions of

⁴⁷⁹ ENGLE, *The Elusive Promise of Indigenous Development – Rights, Culture and Strategy*, 2010, p. 96 ff. (the author describes how the basis of indigenous peoples' right to self-determination has evolved from a right to statehood to a human rights basis, namely human rights to culture and property).

⁴⁸⁰ QUANE, "The UN Declaration on the Rights of Indigenous Peoples: New Directions for Self-Determination and Participatory Rights?", 2010, p. 272.

⁴⁸¹ UNDRIP, Article 3.

⁴⁸² QUANE, "The UN Declaration on the Rights of Indigenous Peoples: New Directions for Self-Determination and Participatory Rights?", 2010, p. 285.

⁴⁸³ See generally, CLAVERO, "The Indigenous Rights of Participation and International Development Policies", 2005, p. 41 (the author affirms that "[u]nder the current international regime, policies that affect indigenous peoples, including those of development assistance and cooperation, are illegitimate if they are negotiated without indigenous participation".); see also, QUANE Helen, "The UN Declaration on the Rights of Indigenous Peoples: New Directions for Self-Determination and Participatory Rights?", 2010, pp. 276ff (the author classifies the right to participate in public life through the prism of the right of self-determination under the Declaration in three different possible categories. First, the participatory rights of indigenous peoples are dependent on the consent of the entire population of the State. This approach being consistent with the approach traditionally adopted by the Human Rights Committee to the right to self-determination. Second, the right to participate in public life is the expression of the right to self-determination of indigenous peoples. This approach recognises the very recognition of indigenous peoples' self-determination. This approach encompasses a conflict of rights between indigenous peoples and the entire population of a State that should be resolved according to the principles permitting the limitations of individual human rights. That is whether the restriction (i) is permitted by law; (ii) pursues a legitimate aim; (iii) is necessary to achieve that aim; and (iv) is not discriminatory. Third, the right to participate in public

the Declaration are becoming part of customary international law, mainly the right of indigenous peoples to self-determination.⁴⁸⁴

Article 3 of the UNDRIP expressly refers to the right of self-determination and reads as follows: “[i]ndigenous peoples have the right to self-determination by virtue of which they may freely determine their political status and pursue their economic, social and cultural development.”⁴⁸⁵ It can therefore be seen that indigenous peoples’ right to self-determination refers to the internal dimension of the right, as defined by general international law. Indeed, in most instances, indigenous peoples do not seek to become independent nation states.⁴⁸⁶ This interpretation is supported by two comments. First, the provision is immediately followed by article 4, which confines the exercise of this right within the structures of recognised states, thus practically referring to the “internal right of self-determination” and excluding the right to an independent statehood.⁴⁸⁷ Second, the recognition that the right to self-determination is not confined only to colonial situations but addresses the situation of indigenous peoples is proved by the overwhelming adoption of the Declaration by States.

life is not linked with the right to self-determination but rather with the concept of non-discriminatory participation in public life. The author adopts this third approach for its practical implications, and above all for separating the right of indigenous peoples to participate in public life from the contentious right of self-determination).

⁴⁸⁴ ANAYA, *Indigenous Peoples in International Law*, 1996, pp. 61 and 72; see also, PERRY, “Balancing Rights or Building Rights? Reconciling the Right to Use Customary Systems of Law with Competing Human Rights in Pursuit of Indigenous Sovereignty”, 2011, p. 98; In the same line, TOBIN, “Bridging the Nagoya Compliance Gap: the Fundamental Role of Customary Law in Protection of Indigenous Peoples’ Resources and Knowledge Rights”, 2013, p. 156 (the author argues that “the extensive body of state practice recognising Indigenous peoples’ rights to apply their own customary laws [...] supports claims that these rights have become norms of customary international law, applicable to all states whether or not they are parties to relevant international human rights instruments and the [NP]”).

⁴⁸⁵ UNDRIP, Article 3.

⁴⁸⁶ WIESSNER Siegfried, “Indigenous self-determination, culture, and land: a reassessment in light of the 2007 UN Declaration on the Rights of indigenous Peoples”, 2012, p. 45.

⁴⁸⁷ UNDRIP, Article 4 reads: “Indigenous peoples, in exercising their right to self-determination, have the right to autonomy or self-government in matters relating to their internal and local affairs, as well as ways and means for financing their autonomous functions. See also, Erica-Irene A. Daes, ‘An overview of the history of indigenous peoples self-determination and the United Nations’ (2008) 21 *Cambridge Review of International Affairs*, p. 8. See also Article 46 UNDRIP prohibiting any violations of the territorial integrity of states, thus referring to the “external self-determination right”.

Even though the scope and the content of indigenous peoples' right to self-determination is still very blurry⁴⁸⁸, it is without doubt the foundation stone of the whole instrument, around which different kinds of rights are built. Amongst them are the right for indigenous peoples to preserve their cultural identity,⁴⁸⁹ and to have collective authority over decision-making regarding their lands, natural resources and their traditional knowledge. Hence, the protection of indigenous peoples' traditional knowledge is closely linked to the right to cultural identity and the right to lands and resources more than a right associated with statehood's right in the sense of a right to secession.

Article 8 prohibits "the forced assimilation or destruction of [indigenous peoples'] culture." According to Wiessner, the Declaration constitutes the most comprehensive text regarding the safeguarding of indigenous peoples' culture. Indeed, during the lengthy negotiations, while the claims of indigenous peoples' representatives were often very diverse, one of their common aspirations was the preservation of their cultural identity.⁴⁹⁰ Cultural identity has a strong link with the history, culture and identities of indigenous peoples, and touches upon various areas, including traditional knowledge, lands and natural resources, languages, rituals and social practices. Fundamentally, the right to lands and natural resources is inextricably linked to their fundamental right to preserve their cultural identity. However, cultural identity is not solely limited to these various areas, but should be understood more broadly as encompassing "the culturally bounded right to property and the culturally grounded right to self-determination."⁴⁹¹ In other words, it seems that while cultural rights and self-determination claims share a very common ground, the justification for indigenous peoples'

⁴⁸⁸ See QUANE, "The UN Declaration on the Rights of Indigenous Peoples: New Directions for Self-Determination and Participatory Rights?", 2010, pp. 276ff; see also, ENGLE, *The Elusive Promise of Indigenous Development – Rights, Culture and Strategy*, 2010, p. 81 ("political participation, not secession would provide the substance for the rights").

⁴⁸⁹ ICCPR, Article 27 affirms the right of persons belonging to "ethnic, linguistic or religious minorities [...], in community with others embers of their group, to enjoy their own culture, to profess and practice their own religion [, and] to use their own language".

⁴⁹⁰ WIESSNER, "The Cultural Rights of Indigenous Peoples: Achievements and Continuing Challenges", 2011, p. 121.

⁴⁹¹ WIESSNER, "The Cultural Rights of Indigenous Peoples: Achievements and Continuing Challenges", 2011, p. 139; see also, BARELLI, "The United Nations Declaration on the Rights of Indigenous Peoples: A Human Rights Framework for Intellectual Property Rights", 2015, p. 58.

claims has evolved towards cultural rights claims. This is mainly due to the controversies that underline the right to self-determination, namely its external dimension.⁴⁹²

The group of provisions relating to lands and natural resources also recognise the “distinctive spiritual relationship” that indigenous peoples have within respect to their lands and natural resources,⁴⁹³ and identify a series of rights and standards for the conservation of their livelihoods.⁴⁹⁴ Amongst them are the right of ownership and use, the right of veto on development projects and a right to compensation in cases of loss of lands. For instance, Article 26 expressly recognises that indigenous peoples have the right to own the lands, territories and resources which they have traditionally owned, occupied or otherwise used or acquired. At this point, it is interesting to note that even before the adoption of the Declaration, the right of indigenous peoples to natural resources went hand in hand with the right to lands, which were both connected to the right to cultural identity.⁴⁹⁵ For instance, a decision of the Inter-American Court of Human Rights (IACHR), based on the American Convention on Human Rights (hereafter, ACHR), clearly settled the link between rights over lands, rights over natural resources and the right to cultural identity. The Court found that, according to Article 21 of the ACHR, the property rights of indigenous peoples to their customary lands had been violated by Nicaragua, which had granted concessions to third parties to exploit the property and the resources located in the lands of the *Awes Tingni* community. Hence, the Court affirmed that the international human right to property and its benefits covers the right of indigenous peoples to the protection of their traditional land and natural resources.⁴⁹⁶ The Court fundamentally noted that for indigenous communities, their relationship with their lands is not solely a question of possession and production but have a material and spiritual component, which they shall fully enjoy in order to preserve their

⁴⁹² For a detailed review of this evolution, see ENGLE, *The Elusive Promise of Indigenous Development – Rights, Culture and Strategy*, 2010, pp. 67 ff.

⁴⁹³ UNDRIP, Article 25.

⁴⁹⁴ UNDRIP, Articles 25-30 and 32.

⁴⁹⁵ See for example, Article 15 of ILO Convention 169 that provides: “The right of the peoples concerned to the natural resources pertaining to their lands shall be specially safeguarded”.

⁴⁹⁶ IACHR, *Mayagna (Sumo) Awes tingni Community v. Nicaragua*, Judgement of 31 August 2001, Series C No 79, IACHR 9, paragraph 153. See further on this matter James Anaya and Robert Williams, 'The protection of indigenous peoples land and resource rights under the Inter-American Human Rights System' (2001) 14 *Harvard Human Rights Journal* 33.

cultural legacy and transmit it to future generations.⁴⁹⁷ One of the former Special Rapporteur on the rights of indigenous peoples stated that the recognition of the right to land and natural resources is an essential step in the fulfilment of the right of indigenous peoples' to self-determination.⁴⁹⁸

However, the right to land, natural resources and cultural heritage would be emptied of its essence, if it was not underpinned by the free, prior and informed consent (FPIC) of indigenous peoples.

3.1.2 “Free, Prior and Informed Consent”: from a Principle to a Right

As mentioned before, the concept of FPIC is embedded in the discourse related to self-determination. While the principle of consent has been on the table in negotiations and agreements between States and indigenous communities far before the adoption of the ILO 169 and UNDRIP,⁴⁹⁹ its adoption as a general principle in negotiations has gained significant impulse in recent years. This results from the fact that references to FPIC are gaining importance in international fora and instruments ranging from the deliberations of the UN treaty bodies and comments and reports of the UN Special Rapporteur to jurisprudence of regional and national courts⁵⁰⁰ and in international treaties and national legislation.⁵⁰¹

For instance, as highlighted above, both the Human Rights Committee and the committee on the Elimination of all Forms of Racial Discrimination have stated that the right to self-

⁴⁹⁷ IACHR, *Mayagna (Sumo) Awas tingni Community v. Nicaragua*, Judgement of 31 August 2001, Series C No 79, IACHR 9, paragraph 149.

⁴⁹⁸ DAES, ‘Indigenous Peoples’ Permanent Sovereignty Over Natural Resources’, Final Report of the Special Rapporteur, Erica-Irene Daes, 12 July 2004, UN Doc. E/CN.4/Sub.2/2004/30/Add.1, para. 7.

⁴⁹⁹ *Western Sahara: Advisory Opinion* of 16 October 1975, IJC Rep 12, para. 55 (the ICJ advisory opinion refers to “freely expressed will and desire” of a people).

⁵⁰⁰ IACHR, *Saramaka People v. Suriname*, Preliminary Objections, Merits, Reparations, and Costs Judgement of 28 November 2007, Series C No. 172, IACHR 5; see also, IACHR, *Mayagna (Sumo) Awas tingni Community v. Nicaragua*, Judgement of 31 August 2001, Series C No 79, IACHR 9, para. 165.

⁵⁰¹ For instance, the International Labor Organization Indigenous and Tribal Peoples Convention, 1989 (No. 169) refers to the principle of free and informed consent in several of its provisions. In Articles 2, 6 and 15, the Convention requires that States fully consult with indigenous peoples and ensure their informed participation in the context of development, national institutions, lands and resources.

determination also applies to the category of indigenous peoples.⁵⁰² Consequently, the treaty bodies have repeatedly noted the State's obligation to obtain FPIC in decisions and activities implicating indigenous peoples' interests.⁵⁰³

The former Special Rapporteurs on the rights of indigenous peoples have also constantly stressed the high importance of FPIC.⁵⁰⁴ Some have chosen to stress that FPIC also includes a specific "right to say no", whilst others have affirmed that FPIC has become an international norm and that the extent of the obligation to obtain FPIC will increase when the activities of the State may have substantial impacts that could threaten the basic livelihoods and cultural integrity of indigenous peoples.⁵⁰⁵ The current Special Rapporteur, Victoria Tauli Corpuz, notes that she is "not aware of representatives of indigenous peoples and/or officials from recognized indigenous self-governing structures being invited to participate in the formal negotiation and drafting of investment and free trade agreements that will have direct impacts on them. Given that such agreements are formally binding on all levels of government and that many investment projects have significant impact on indigenous peoples, that situation is,

⁵⁰² CERD, 'General Recommendation XXIII on the Rights of Indigenous Peoples', 22 August 1997, U.N. Doc. HRI/GEN/1/Rev.6, para. 4(d) (the general recommendation implicitly recognised the right to self-determination to indigenous peoples by using the term "peoples". It further states that "no decisions directly relating to their rights and interests are to be taken without their informed consent").

⁵⁰³ See, for example, CERD, 'Concluding Observations on the Eighteenth to Twenty-first Periodic Reports of Peru', 25 September 2014, UN Doc. CERD/C/PER/CO/18-21, para. 14 ("the Committee recommends that the State party should [e]nsure that all projects on the development and exploitation of natural resources, including mining operations, are submitted to the consultation process with a view to obtaining the free, prior and informed consent of communities that may be affected").

⁵⁰⁴ Commission on Human Rights, 'Report of the Special Rapporteur on the Situation of Human Rights and Fundamental Freedoms of Indigenous Peoples by Dr. Rudolfo Stavehagen', 21 January 2003, UN Doc. E/CN.4/2003/90, para. 66 (he asserted the relevance of FPIC, including "the right to say no" for the protection of indigenous peoples' human rights).

⁵⁰⁵ Human Rights Council, 'Report of the Special Rapporteur on the Situation of Human Rights and Fundamental Freedoms of Indigenous Peoples', James Anaya, 15 August 2008, UN Doc. A/HRC/9/9/Add.1, Annex 1, para 40, p. 100 ("los principios de la consulta y el consentimiento se sitúan en conformidad con lo que considera estar establecido en la normativa internacional aplicable").

in and of itself, a violation of the rights to free, informed and prior consent, participation, consultation and self-determination.”⁵⁰⁶

Another forum, namely the UN Permanent Forum on Indigenous Issues, has suggested the following definition of the concept free, prior and informed consent. First, the concept of “free” implies that consent has been given without coercion, intimidation or manipulation. In other words, it would mean that indigenous peoples shall be able to say ‘no’ and to not suffer threat if they do so. Second, “prior” has to be understood in the sense that consent has been sought sufficiently in advance of any authorization or commencement of activities, with regard to indigenous peoples’ traditional knowledge, for instance. Third, “informed” should imply that indigenous peoples have received satisfactory information with regard to a range of issues entailed by the activity. Finally, the term “consent” is fully realised where indigenous peoples have been both consulted and actively participated in any decision-making, for instance, concerning their traditional knowledge. The term “consultation” alone, would involve an exchange of views without implying a decision on the part of interested indigenous peoples. The mechanism used to reach agreement with indigenous peoples must be consistent with their decision-making rules and procedures, namely their customary laws.⁵⁰⁷

The importance of the requirement of free, prior and informed consent is equally stressed by an International Law Association report on the rights of indigenous peoples in 2010. The report affirmed that “the proper realization of this requirement may imply the need that indigenous peoples have all information – made available to the peoples concerned in an easily comprehensible form and language – that are necessary to arrive at a position on a policy proposal.”⁵⁰⁸

Under the UNDRIP, a range of provisions directly or indirectly refer to, and highlight the importance of, free, prior and informed consent for indigenous peoples.⁵⁰⁹ Indeed, the

⁵⁰⁶ UN GA, ‘Report of the Special Rapporteur of the Human Rights Council on the Rights of Indigenous Peoples on the Impact of International Investment and Free Trade on the Human Rights of Indigenous Peoples’, Victoria Tauli Corpuz, 7 August 2015, UN Doc. A/70/301, paras. 31 and 32, pp. 11 and 12.

⁵⁰⁷ UN ECOSOC, Permanent Forum on Indigenous Issues, ‘Report of the International Workshop on Methodologies regarding Free, Prior and Informed Consent and Indigenous Peoples’, 17 February 2005, E/C.19/2005/3, para. 46.

⁵⁰⁸ ILA, ‘Rights of Indigenous Peoples’, Interim Report, The Hague Conference, 2010, p. 14.

⁵⁰⁹ UNDRIP, Articles 5, 11(2), 13(2), 18, 19, 23, 27 *in fine*, 30(2), 31, 32, 36 and 38.

wording that makes reference to FPIC is “free, prior and informed consent” itself, but also, “States shall consult and cooperate in good faith with the indigenous peoples”, “States shall undertake effective consultation with the indigenous peoples”, or “indigenous peoples have the right to control their cultural heritage.” As an example, Article 19 UNDRIP reads:

“States shall consult and cooperate in good faith with the indigenous peoples concerned through their own representative institutions in order to obtain their free, prior and informed consent before adopting and implementing legislative or administrative measures that may affect them.”⁵¹⁰

This Article requires that States consult with indigenous peoples “in good faith” through their “own representative institutions”. Article 32(2) goes further in requiring their FPIC be obtained “for *any* project affecting their lands or territories and other resources.”⁵¹¹ The Declaration further states that indigenous peoples have the right to “determine the structures and to select the membership of their institutions in accordance with their own procedures.”⁵¹² This issue is highly important and is discussed in Part III, Chapter 2 in relation to the negotiations currently taking place within the World Intellectual Property Organisation.

In addition, in accordance with Article 11(2), “States shall provide redress through effective mechanisms, which may include restitution, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs”. Hence, this provision makes a direct reference to the appropriation of the intellectual property of indigenous peoples that has already taken place without their FPIC, and calls on States to provide redress through effective mechanisms.

⁵¹⁰ UNDRIP, Article 19.

⁵¹¹ UNDRIP, Article 32(2).

⁵¹² UNDRIP, Article 33; see also, IACHR, *Saramaka People v. Suriname*, Preliminary Objections, Merits, Reparations, and Costs Judgement of 28 November 2007, Series C No. 172, IACHR 5, para. 164 (“the question of whether certain self-identified members of the Saramaka people may assert certain communal rights on behalf of the juridical personality of such people is a question that must be resolved by the Saramaka people in accordance with their own traditional customs and norms, not by the State or this Court in this particular case. Accordingly, the lack of individual identification with the traditions and laws of the Saramaka by some alleged members of the community may not be used as a pretext to deny the Saramaka people their right to juridical personality”).

Ultimately, while the requirement to obtain FPIC in relation to development projects is commonly accepted, there are some divergences of position concerning the situations that trigger this requirement. According to one opinion, supported by many indigenous peoples, FPIC is required for *any* activity affecting their lands, resources, intellectual property and cultural identity, in general. On the other side, some argue that respect for FPIC is only essential when indigenous peoples property rights or their physical and cultural survival is threatened.⁵¹³

While the first position derives from the opinion that consent is fully embedded in the right to self-determination, the second position envisages the consent requirement on a case by case basis. According to this approach, UNDRIP has already classified the situations where FPIC is essential by expressly using the wording “free, prior and informed consent”, including situations where “cultural, intellectual, religious and spiritual property is taken.”⁵¹⁴

3.1.3 Intellectual Property Rights of Indigenous Peoples

The previous paragraphs have addressed the major significance of the UN Declaration for the Rights of Indigenous Peoples, despite its non-binding nature. It has been further noted that the instrument has linked two important rights, i.e. the right to self-determination and the right to participate in public life, particularly the requirement to obtain free prior informed consent. The present section will specifically focus upon the intellectual property rights of indigenous peoples under the Declaration.

Three Articles are of relevance for the intellectual property of indigenous peoples and traditional knowledge. These are Article 11(2) and Article 31. In addition, Article 24 specifically targets traditional medicinal knowledge.

Article 31 is the result of the many claims made by indigenous peoples for the recognition of, and control over, their physical and intellectual heritage, including their traditional knowledge

⁵¹³ Human Rights Council, ‘Report of the Special Rapporteur on the Situation of Human Rights and Fundamental Freedoms of Indigenous Peoples’, James Anaya, 15 August 2008, UN Doc. A/HRC/9/9/Add.1, Annex 1, paras. 39, p. 100 (“[e]n aquellas situaciones en que la medida tendría impactos substanciales que podrían poner en peligro el bienestar físico o cultural básico de la comunidad indígena interesada, el Estado sí tiene el deber de no adoptar la medida sin el consentimiento de la comunidad, tal como señaló la Corte Interamericana de Derechos Humanos en el caso *Saramaka c. Suriname*”).

⁵¹⁴ UNDRIP, Articles 28, 32, 10, 11(2) and 29(2).

relating to biodiversity and medicines.⁵¹⁵ It expressly targets the relationship between the cultural and intellectual property rights of indigenous peoples. It also brings into one provision the link between traditional knowledge and the intellectual property protection over such knowledge.⁵¹⁶ The provisions of Article 31 deserve full quotation as they expressly refer to the subject of the present analysis.

Article 31

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.

In conjunction with indigenous peoples, States shall take effective measures to recognise and protect the exercise of these rights.

Article 31 encompasses three elements of essential importance. It provides a description of what constitutes the subject matter of protection, the beneficiaries of protection and the scope of rights. The subject matter is constituted by a listing of indigenous peoples' resources that is very broad in scope, ranging from cultural and intellectual resources to real (tangible) resources such as human and genetic resources. In addition, not only does the use of the pronoun "their" suggest that there is some form of intellectual property belonging to indigenous peoples with regard to their knowledge, it also suggests that such protection shall be in line with the customary laws and regulations of indigenous peoples.

⁵¹⁵ SUNDER, "The invention of Traditional Knowledge", 2007, p. 100.

⁵¹⁶ UN GA, 61st Session, 13 September 2007, UN Doc. A/61/PV.107, Agenda item 68, p. 10 (Delegates of Member states that voted against the Declaration affirmed that the Declaration's provision on intellectual property were one of the reasons why they opposed the adoption of the instrument: "Australia stated that "with regard to intellectual property, Australia does not support the inclusion in the text of intellectual property rights for indigenous peoples. Australia extends protection to indigenous cultural heritage, traditional knowledge and traditional cultural expressions to the extent that it is consistent with Australian and international intellectual property law. However, Australia will not provide *sui generis* intellectual property rights for indigenous communities as envisaged in the declaration").

The second paragraph calls states to take effective measures to not only recognise, but also protect, the exercise of these rights. Importantly States are directed to do so “in conjunction with indigenous peoples.” Here again, the provision is in line with the importance placed upon self-determination in the Declaration. In other words, self-determination constitutes the normative rationale for protecting traditional knowledge.⁵¹⁷

Article 31 of the Declaration should be read in conjunction with Article 11(2), which calls upon states to “provide redress through effective mechanisms, [...] with respect to [...] intellectual [...] property [of indigenous peoples] taken without their free, prior and informed consent or in violation of their laws, traditions and customs.”⁵¹⁸ Here again, “free, prior and informed consent” recalls the right of indigenous peoples to actively control the utilisation of their intellectual resources.

In comparison to the wording of the adopted Article 31, the Draft Declaration on the Rights of Indigenous Peoples (hereafter, the Draft Declaration)⁵¹⁹ provided that “Indigenous Peoples [were] entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property” and that “they [had] the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, [and] knowledge of the properties of fauna and flora”.⁵²⁰ The resulting shift in the wording of the Draft article 29 is certainly due to the

⁵¹⁷ FRANKEL, “Using intellectual property rules to support the self-determination goals of indigenous peoples”, 2015, p. 631; CLAVERO, “The Indigenous Rights of Participation and International Development Policies”, 2005, p. 42; see also WIESSNER, *Indigenous Sovereignty: A Reassessment in Light of the UN Declaration on the Rights of Indigenous Peoples*, 2008, p. 1176 ; see also CARMEN, “The Right to Free, Prior, and informed Consent – A Framework for Harmonious Relations and New Process for Redress”, 2010, p. 120.

⁵¹⁸ UNDRIP, Article 11(2).

⁵¹⁹ See Working Group on the Draft Declaration on the Rights of Indigenous Peoples, available at: <http://www.ohchr.org/EN/Issues/IPeoples/Pages/WGDraftDeclaration.aspx> [accessed September 2016].

⁵²⁰ Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, ‘Discrimination Against Indigenous Peoples - Report of the Working Group on Indigenous Populations’, Special Rapporteur Erica-Irene Daes, 23 August 1993, UN Doc E/CN.4/Sub.2/1993/29, Annex I, p. 57, Article 29 of the Draft Declaration; see also Observations of the Indian Movement Tuaj Katari, Commission on Human Rights, ‘*Observaciones y enmiendas a los artículos examinados del proyecto de declaración sobre los derechos de los pueblos indígenas y la introducción de nuevos párrafos*

concerns expressed by some States⁵²¹ regarding the potential conflicts that may have arisen with other *fora* such as the World Intellectual Property Organisation.

Additionally, Article 24 makes explicit reference to the right of indigenous peoples to their “traditional medicines” and to maintain their health practices, including “the conservation of their vital medicinal plants, animals and minerals.”⁵²²

Finally, it should be noted that the Declaration expressly recognises the collective nature of the rights of indigenous peoples in addition to their human rights as individual members of their community. According to Article 1, indigenous peoples have the right to the full enjoyment, as a collective or as individuals, of all human rights and fundamental freedoms as recognized in the Charter of the United Nations, the Universal Declaration of Human Rights and international human rights law.⁵²³ However, under the Declaration, it is the community as such that is the subject of duties and rights, and this is in accordance with the way in which indigenous communities see themselves.⁵²⁴ As mentioned before, collective rights concern the possession of land, resources and traditional knowledge. For instance, Juan León, one of the founders of the National Front of Human Rights Organizations of Guatemala stressed “individualism is not part of the philosophy of indigenous peoples, that the indigenous peoples live in communities and not individually, and that individuals and communities, are inextricably linked for all indigenous societies.”⁵²⁵

In summary, the holistic determination of the subject matter of traditional knowledge, the express identification of indigenous peoples as beneficiaries of rights and the scope of protection of these rights under the Declaration constitutes a fair picture of indigenous

en la parte dispositiva, formuladas por el Movimiento Indio Tupaj Katari el Consejo Mundial por la Paz, 29 November 2005, UN Doc. E/CN.4/2005/WG.15/CRP.5, pp. 10-11, *Artículo 29*.

⁵²¹ See FN 513 above, UN GA, 61st Session, 13 September 2007, UN Doc. A/61/PV.107, Agenda item 68, p. 10.

⁵²² UNDRIP, Article 24.

⁵²³ UNDRIP, Article 1

⁵²⁴ See important passage of the UNDRIP Preamble that recognises that “indigenous peoples possess collective rights which are indispensable for their existence, well-being and integral development as peoples”.

⁵²⁵ Statement made by Juan León, Defensoria Maya, in MEIJKNECHT Anna, *Towards International Personality: The Position of Minorities and Indigenous Peoples in International Law*, 2001, p. 156.

people's worldview. According to an expert, self-determination constitutes the normative rationale for protecting traditional knowledge.⁵²⁶

This statement has important results. One of the results is that indigenous peoples will have the right, in conformity with their right to self-determination, to authorise or deny the use of their traditional knowledge, because the unauthorised use of their traditional knowledge may hinder the development of their culture and identity.⁵²⁷

Building on this, an appropriate protection regime for traditional knowledge must ally with the intellectual property system. The absence of any recognition from intellectual property will undeniably place traditional knowledge protection on an inferior level, or place the protection of TK at risk of defeat by intellectual property rights (Frankel).⁵²⁸ It remains to be seen whether the Draft proposal under discussion in the WIPO – IGC, discussed above, on the protection of traditional knowledge will be in line with these requirements. The WIPO Draft proposal will be extensively discussed in Part III of this study.

In conclusion, this section has demonstrated that the protection of traditional knowledge pertains to the realm of international human rights law. It has also demonstrated that international human rights norms require that indigenous peoples have the right to control the results of their intellectual activity, i.e. their traditional knowledge. The following section will analyse the link between human rights norms, intellectual property rights and traditional knowledge.

3.2 Human Rights, Intellectual Property Rights and Traditional Knowledge

Article 27(2) of the Universal Declaration of Human Rights (UDHR)⁵²⁹ recognises intellectual property as a universal human right, providing that “everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic protection of which he is the author.” The same guarantees are embedded in Article 15(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which

⁵²⁶ FRANKEL, “Using intellectual property rules to support the self-determination goals of indigenous peoples”, 2015, p. 631.

⁵²⁷ BARELLI, “The United Nations Declaration on the Rights of Indigenous Peoples: a human rights framework for intellectual property rights”, 2015, p. 58.

⁵²⁸ FRANKEL, “Traditional knowledge and innovation as a global concern”, 2015, p. 232.

⁵²⁹ Universal Declaration of Human Rights, Paris, 10 Dec. 1948, Resolution 217 A adopted by the UN GA Res, 10 December 1948, UN Doc. A/RES/3/217 A (UDHR).

provides that State Parties “recognize the right of everyone to take part in cultural life, to enjoy the benefits of scientific progress and its application and to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”⁵³⁰

Thus, these provisions clearly recognise a creator’s moral and material rights as “human rights.” This human rights approach to intellectual property calls for two comments with regard to the conventional intellectual property system.

First, a human rights approach to intellectual property may include the protection of traditional knowledge as the intellectual property of indigenous peoples. However, for some scholars this extension to the protection of traditional knowledge is far from being straightforward. They advance two reasons. At the outset, the right embedded in these provisions is “clearly tied to an individual author or inventor and cannot be held by a group” as is generally the case with international human rights standards.⁵³¹ This argument can be defeated by subsequent developments in international human rights law, as articulated in General Comment No. 17 and the UNDRIP. These developments encompass both an individual and a collective approach to intellectual property claims.⁵³² Additionally, they argue, the issue of traditional knowledge was neither a subject of discussion in the *travaux préparatoires* nor was it included when the articles were drafted.⁵³³ Again, this argument does not exclude, *per se*, a broader interpretation which includes traditional knowledge.

Along the same lines as the UNDRIP, with the adoption of General Comment No. 17, the Committee on Economic, Social and Cultural Rights (CESCR)⁵³⁴ has interpreted Article 15(1) ICESCR as encompassing the knowledge, innovations and practices of indigenous and local

⁵³⁰ ICESCR, Article 15(1).

⁵³¹ HAHN and STOLL, “Indigenous peoples, knowledge and resources in international law”, 2008, pp. 22-23.

⁵³² Collective rights of indigenous peoples shall be distinguished from the rights assigned to groups such as economic actors, i.e. moral persons.

⁵³³ HAHN and STOLL, “Indigenous peoples, knowledge and resources in international law”, 2008, pp. 22-23.

⁵³⁴ UN ECOSOC, CESCR, ‘General Comment No. 17 - The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, 7-25 November 2005, UN Doc. E/C.12/GC/17 (CESCR, ‘General Comment No. 17’).

communities.⁵³⁵ In other words, any type of intellectual contribution from any individual or group should fall within the scope of this article, including traditional knowledge.

The second comment that can be made is in relation to a comparison between intellectual property rights under human rights standards and intellectual property rights under the TRIPS Agreement. The CESCR clearly distinguishes a human rights approach to intellectual contribution recognised under article 15(1)(c) from “most legal entitlements recognized in intellectual property systems.”⁵³⁶ At this point, it is important to highlight that this second comment is enshrined in a broader discussion that is the subject of controversy, and that is far beyond the subject matter of this study. While some scholars argue that international trade law, in general, has its foundation in and is directed toward the implementation of human rights,⁵³⁷ others will distinguish between both bodies of law.⁵³⁸ The former argument is based on a general approach that assumes free trade serves to enhance social welfare and rights. The latter argument is based on the fact that WTO agreements do not primarily and originally have a human rights basis.⁵³⁹

Hence, for the purposes of the present study, as mentioned before, the principal objective of the TRIPS Agreement, apart from enhancing innovation, is to reinforce the international system of unimpeded trade.⁵⁴⁰ According to one scholar, “the TRIPS Agreement is deeply

⁵³⁵ CESCR, ‘General Comment No. 17’, para. 9.

⁵³⁶ CESCR, ‘General Comment No. 17’, paras. 1 and 3.

⁵³⁷ PETERSMANN, “The WTO Constitution and Human Rights”, 2000, p. 21; see also, PETERSMANN, “Time for a United Nations “Global Compact” for integrating human rights into the law of Worldwide Organisations: Lessons from European Integration”, 2002, pp. 629 and 632.

⁵³⁸ ALSTON, “Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann”, 2002, pp. 825ff. (arguing that the “WTO guarantees of freedom, non-discrimination and property rights are not rights conferred on individuals in the sense of human rights”).

⁵³⁹ BEITER, “Establishing Conformity between TRIPS and Human Rights”, 2016, p. 451.

⁵⁴⁰ CLIFT, “Why IPR issues were brought to GATT: a historical perspective on the origin of TRIPS”, 2010, pp. 3-21 (the author notes that the origin of TRIPS has to be traced back to the will by some developed countries, principally the US, in establishing “a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods”); see also TRIPS Agreement, preamble (the first recital reads: “Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade”).

steeped in notions of free trade, and as such, cannot be considered to follow a human rights approach both in its design and content.”⁵⁴¹ In addition, far from being enshrined in a human rights approach, the TRIPS Agreement may, in some situations, be in conflict with international human rights law, such as for instance the human right to health. Under present international law, the human right to health is not a non-derogable right.⁵⁴² Nevertheless, the UN Sub-Commission on the Promotion and Protection of Human Rights has affirmed “the primacy of human rights obligations under international law over economic policies and agreements [and] called on states to ensure that the implementation of TRIPS should not negatively affect the enjoyment of human rights.”⁵⁴³ A clear example of a potential conflict is given by the tensions between intellectual property protection and the protection of traditional knowledge of indigenous peoples.

However, and despite the recognition of this tension, General Comment No. 17 proposes “the adoption of measures to recognize, register and protect the individual or collective authorship of indigenous peoples under national intellectual property rights regimes”.⁵⁴⁴ In one scholar’s words, “this is unexpected in the context of the Committee’s assertion that the rights recognised under Article 15(1)(c) are to be distinguished from intellectual property rights.”⁵⁴⁵ Indeed, according to the General Comment, “[i]n contrast to human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else.” Most importantly, “whereas the human right to benefit from the protection of the moral and material interests resulting from one’s scientific, literary and artistic productions safeguards the personal link between authors and their creations and between

⁵⁴¹ BEITER, “Establishing Conformity between TRIPS and Human Rights”, 2016, p. 451 (the author argues that there are many ways in which intellectual property rights protected under TRIPS are in conflict with international human rights).

⁵⁴² CULLET, “Patents and medicines: the relationship between TRIPS and the human right to health”, 2003, p. 159.

⁵⁴³ UN Sub-Commission on Human Rights, ‘Intellectual Property and Human Rights’, Resolution 2001/21, 16 August 2001, UN Doc. E/CN.4/SUB.2/RES/2001/21, paras 3 and 5.

⁵⁴⁴ CESCR, ‘General Comment No. 17’, para. 32.

⁵⁴⁵ CULLET, “Human Rights and Intellectual Property Protection in the TRIPS Era”, 2007, p. 423.

peoples, communities, or other groups and their collective cultural heritage [...], intellectual property regimes primarily protect business and corporate interests and investments.”⁵⁴⁶

Hence, in line with the General Comment, Article 15(1) ICESCR should be understood as providing protection to the types of intellectual contribution, namely traditional knowledge, which do not, in general, fulfil the eligibility criteria for protection under existing intellectual property rights.

Additionally, any attempts to link Article 15(1)(c) with the inventorship concept as found in the TRIPS Agreement would involve a series of complex issues, particularly those related to the “public domain.”⁵⁴⁷ The relationship between the concepts of public domain and traditional knowledge will be further analysed in Part II, chapter 3.

⁵⁴⁶ CESCR, ‘General Comment No. 17’, para. 2.

⁵⁴⁷ HELFER and AUSTIN, *Human Rights and Intellectual Property: Mapping the Global Interface*, 2011, p. 454.

Chapter 4 Conclusion

The above analysis of the selected international legal framework leads to the following conclusion, that the current legal framework does not provide for a concrete solution for the protection for traditional knowledge.

The intellectual property approach prioritises its own objectives, i.e. economic development through innovation. Through the lens of human rights, the international instrument that most fully and comprehensively addresses the concerns of indigenous groups in relation to the protection of their traditional knowledge is the UNDRIP.⁵⁴⁸ While it remains a Declaration with no binding force, it constitutes a relevant basis for future developments in the protection of indigenous peoples' traditional knowledge. Hence, some of its provisions may become binding either through becoming customary international law, i.e. through State practice and *opinio juris*, or through the adoption of a subsequent legally binding instrument.⁵⁴⁹ A leading scholar in this field argues that some provisions of the Declaration are already becoming part of the customary international law, mainly the right of indigenous peoples to self-determination.⁵⁵⁰ For example, human rights treaty-based bodies regularly reaffirmed the indigenous peoples' right to self-determination.⁵⁵¹ In addition, it has to be expected that national tribunals, in dealing with disputes arising with regard to indigenous peoples' rights,

⁵⁴⁸ UNDRIP, Article 31 ("Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions [...]. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions. In conjunction with indigenous peoples, States shall take effective measures to recognise and protect the exercise of these rights".)

⁵⁴⁹ BURGER, "The UN Declaration on the Rights of Indigenous Peoples: From Advocacy to Implementation", 2010, p. 55 (noting that the Declaration is increasingly accepted as being of universal application through cases considered by the Inter-American Court of Human Rights, the Inter-American Commission on Human Rights and the international human rights treaty bodies).

⁵⁵⁰ ANAYA, *Indigenous Peoples in International Law*, 1996, pp. 61 and 72.

⁵⁵¹ Human Rights Committee, 'General Comment Adopted by the Human Rights Committee under Article 40, paragraph 4, of the International Covenant on Civil and Political Rights: General Comment No. 23(50), Article 27', adopted on 6 April 1994, UN Doc. CCPR/C/21/Rev.1/Add.5 (HRC, 'General Comment No. 23: Article 27').

will render their decision in light of the Declaration, at least if the state has endorsed the Declaration.⁵⁵²

We have also seen that the approach adopted by the Convention on Biodiversity on the protection of traditional knowledge is mainly one of preservation. Similarly, the Nagoya Protocol is primarily directed to trade through environmentally friendly means. Despite this fact, it distinguishes itself because it incorporates elements of human rights directed to the rights of indigenous peoples with regard to their traditional knowledge and resources.⁵⁵³ Hence, State Parties to the Nagoya Protocol should read and implement their obligations in light of their existing obligations under human rights instruments.⁵⁵⁴

However, while international instruments recognise the legitimacy of claims of indigenous peoples to maintain, control and protect their traditional knowledge, concretely there are no means internationally for indigenous peoples to effectively and legally protect these claims. On the other hand, international instruments equally recognise the legitimacy of claims of inventors and provide them with intellectual property rights to effectively protect their rights. This dichotomy may result in the incorporation of the knowledge developed by indigenous peoples into inventions that are deemed to deserve exclusive rights. This problem will be discussed in the following Part II.

The next Part will break down the analysis of this problem into three parts that, in my view, are fundamental to the comprehension of the present work. The first chapter will ask the question: when does bioprospecting become biopiracy? This will be followed by an analysis of some cases of alleged biopiracy. The second chapter will review both the substantive and formal requirements of patentability by including traditional medicinal knowledge in the analysis in light of the case studies mentioned. Finally, the third chapter will define the public domain, the limbo area in which traditional knowledge is generally accepted to belong in.

⁵⁵² See generally, BARELLI, “The Role of Soft Law in the International Legal System: The Case of the United Nations Declaration on the Rights of Indigenous Peoples”, 2009, pp. 957-983.

⁵⁵³ UNDRIP, Preamble, para. 26.

⁵⁵⁴ SAVARESI, “The International Human Rights Law Implications of the Nagoya Protocol” 2013, p. 54.

PART II IDENTIFYING THE LEGAL PROBLEMS

The CBD Ad Hoc Open Working Group on Article 8(j) and Related Provisions⁵⁵⁵ provided a draft definition for the term “bio-prospecting” at its seventh meeting in 2011. Bio-prospecting was defined as “[t]he scientific research of biological resources for commercial or other purposes. Bio-prospecting may also include research into the traditional knowledge associated with the biological resources.”⁵⁵⁶ Thus, bioprospecting refers both to genetic resources and to the traditional knowledge associated with it. Starting this part with an illustrative example will prove to be helpful for the reader, who will be able to intuitively grasp the issues involved when a bioprospecting activity starts. A typical example of bioprospecting is when a group of scientists, including biologists, anthropologists, and ethnobiologists⁵⁵⁷ explore the biodiversity of tropical forests for commercially valuable genetic resources.⁵⁵⁸ In other words, our scientists are looking for new compounds that may help cure so-far incurable diseases. This operation might prove to be time consuming and very hazardous: it is as hazardous as looking for a needle in a haystack! They are hosted by a traditional community and discuss with its members their daily life, including their knowledge of the traditional medicinal uses of the biodiversity surrounding them. One plant proves to be particularly interesting because of its wide-range of medicinal properties for diseases affecting the community. The group of scientists identifies one of the diseases to be cancer. The scientists fly back to the country where they are based with collected samples of the plant that may prove to be a potential drug candidate. After years of research and development work, the scientists are able to isolate the active principle or the new chemical entity that will eventually lead to a new molecular entity,

⁵⁵⁵ See Part I, chapter 3, 1.1.2.

⁵⁵⁶ CBD WG-8J, ‘Extracts Covering the Evolution of the Issue of Definitions within the *Sui Generis* Agenda Item from the Working Group on Article 8(j) and Related Provisions’, 31 October – 4 November 2011, UNEP/CBD/WG8j/7/INF/1/Add.1, p. 8; see also, CBD WG-8J, ‘A Glossary of Relevant Key Terms and Concepts to be Used within the Context of Article 8(j) and Related Provisions’, 4-7 November 2015, UNEP/CBD/WG8J/9/2/Add.1 (24 September 2015), para. 15, p. 3 (the Secretariat noted that “terms and concepts not in current use in the context of work on Article 8(j) and related provisions of the Convention include: ‘bioprospecting’; ‘biocultural heritage’; ‘innovation’ and ‘research’”).

⁵⁵⁷ Ethnobiology research refers to studying the knowledge of indigenous peoples about the utility, diversity and chemical characteristics of plants found in their environment.

⁵⁵⁸ LAIRD and WYNBERG, “The Commercial Use of Biodiversity: An Update on Current Trends in Demand for Access to Genetic Resources and Benefit-Sharing, and Industry Perspectives on ABS Policy Implementation”, 2006, UNEP/CBD/WG-ABS/4/INF/5, p. 4.

which will be the new anti-cancer drug. In this case, logically the group of persons, or more likely the company backing this research, will want to protect its intellectual property rights on the product.

As stated in the Introduction, many of the concerns related to the protection of traditional knowledge can be identified by answering the following question: “What happens when elements of traditional knowledge are used by third parties beyond the community?”⁵⁵⁹

The utilisation of traditional knowledge covers activities such as publishing articles on the knowledge acquired from the community, using it in any research activities, and doing business with it through a patent, for instance. In other words, traditional knowledge can be either obtained directly from the indigenous community or from secondary sources. In the latter case, the number of “third parties” utilising the knowledge will grow and the question as to their responsibility has to be equally raised. However, in the writer’s opinion, a patented product - that would not have existed without traditional knowledge – generating vast amount of benefits to its rights-holders cannot be strictly compared to an ethnologist who writes an article on a given indigenous community. Having raised this point, this research has chosen to specifically focus upon patents as they are regarded as the main basis for ensuring exclusivity for innovative pharmaceuticals.

Using something that belongs to someone else becomes a problem when (i) authorisation has not been sought; (ii) consent has not been given by the legitimate party; and (iii) the information concerning the use is not clear or complete for the consent to be valid.

In the following chapters, I will discuss the case where pharmaceutical inventions are built upon traditional medicinal knowledge. Chapter One will provide an overview of the debate in relation to “biopiracy” and go through a selected number of actual cases alleged to constitute biopiracy. Chapter Two will address the theoretical aspects of patentable inventions and will demonstrate that traditional medicinal knowledge can be incorporated in a patent claim without disclosing it.

⁵⁵⁹ TAUBMAN and LEISTNER, “Analysis of different areas of indigenous resources”, 2008, p. 60.

Chapter 1 Utilisation of traditional medicinal knowledge beyond its traditional community

1 From Bioprospecting to “Biopiracy” – Free Riding or Bioprospecting without Prior Informed Consent!

Generally speaking, the bioprospecting process can be traced back to colonisation. By the twentieth century, scientific and technological advances in the field of biotechnologies encouraged firms to investigate genetic resources as a valuable starting point for research and development.⁵⁶⁰ This trend was further supported through the adoption of two important international treaties. Firstly, WTO Agreement on Trade-Related Aspects of Intellectual Property Rights adopted in 1994 was a breakthrough in the international protection of intellectual property rights, generally, and patents, particularly. Regarding patents, TRIPS fixed the principle of patentability on inventions in all fields of technology,⁵⁶¹ thus any technology making use of genetic resources and, for the purpose of the present research, the associated traditional knowledge, could now be patented.⁵⁶² Similarly, the importance of the world's genetic resources and the associated traditional knowledge has been fully acknowledged with the adoption the Convention on Biological Diversity in 1993 and its recently adopted Nagoya Protocol in 2010.

When does a bioprospecting activity, becomes an act of biopiracy? One intuitive answer would be when the bioprospecting activity is illegal.⁵⁶³ However, while the term ‘piracy’ in intellectual property law presupposes the infringement of a protected subject matter under this body of law, this is not the case with the concept of biopiracy. While some categories of

⁵⁶⁰ HAYDEN, *When Nature Goes Public: The Making and Unmaking of Bioprospecting in Mexico*, 2003, p. 1 (defines bioprospecting as “the new name for an old practice: it refers to corporate drug development based on medicinal plants, traditional knowledge, and microbes culled from the "biodiversity-rich" regions of the globe--most of which reside in the so-called developing nations. The novelty lies in some distinctive parameters, which we might tentatively call "ethical," that have been placed around these longstanding practices of resource acquisition”)

⁵⁶¹ TRIPS, Article 27.1.

⁵⁶² TRIPS, Article 27.3(b) requires intellectual property protection for micro-organisms, non-biological and microbiological processes and plant varieties.

⁵⁶³ ROBINSON, *Confronting Biopiracy – Challenges, Cases and International Debates*, 2010, p. 23 (stating that “to date, there is no one single international treaty that comprehensively captures all the issues involved in the regulation of bioprospection activities and the prevention of biopiracy”).

knowledge are protectable under the TRIPS Agreement, other knowledge, including indigenous knowledge is not. In addition, the resulting economic consequences are a one-way flow of knowledge resources from biodiverse countries to technologically advanced ones. This dichotomy has given rise to a North-South rhetoric battle, where the rhetoric of “piracy” has been answered with one concerning “biopiracy.”⁵⁶⁴

In this highly politicised context, the concept of biopiracy has been defined as “the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions who seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge. ETC Group (former RAFI) believes that intellectual property is predatory on the rights and knowledge of farming communities and indigenous peoples.”⁵⁶⁵ For activists groups such as ETC Group, all bioprospecting agreements are regarded as biopiracy.⁵⁶⁶

For Carvalho, “the action of unduly extracting traditional knowledge beyond its source community may encompass, amongst others, violations of the privacy right, violation of the right to be informed, and violation of the principles of unfair competition rules. All these actions are commonly referred to as biopiracy, misappropriation⁵⁶⁷ or biosquatting.”⁵⁶⁸ According to Dutfield, misappropriation and theft are inherent to the biopiracy rhetoric,

⁵⁶⁴ AREWA, “Piracy, Biopiracy and Borrowing: Culture, Cultural Heritage and the Globalization of Intellectual Property”, 2006, p. 28.

⁵⁶⁵ The term biopiracy was first used by Pat Mooney of the Canadian Group Rural Advancement Foundation International (RAFI). ETC Group (formerly, RAFI) was the first civil society organization (nationally or internationally) to draw attention to the socioeconomic and scientific issues related to the conservation and use of plant genetic resources, intellectual property and biotechnology. The ETC Group, Mission & Current Focus, at: <http://www.etcgroup.org/mission> [accessed September 2016].

⁵⁶⁶ RAFI, “Captain Hook, the Cattle Rustlers, and the Plant Privateers: Biopiracy of Marine, Plant, and Livestock Continues”, *RAFI COMMUNIQUE*, Biopiracy, May/June 2000, Issue 65, at: http://www.etcgroup.org/files/publication/327/01/com_biopiracy.pdf [accessed September 2016].

⁵⁶⁷ The tort of misappropriation is part of unfair competition law in the common law system. Misappropriation thus entails the wrongful or dishonest use or borrowing of someone’s property, and is often used to found action in cases where no property right as such has been infringed. Misappropriation may refer to wrongful borrowing or to the fraudulent appropriation of funds or property entrusted to someone’s care but actually owned by someone else. See also,

⁵⁶⁸ CARVALHO, “From the Shaman’s Hut to the Patent Office: In search of effective protection for traditional knowledge”, 2003, p. 15.

involving: (i) the misappropriation of traditional knowledge through the patent system; and (ii) the unauthorised collection for commercial purposes of traditional knowledge.⁵⁶⁹

In contrast, some other scholars, amongst them, Jim Chen, assert that “there’s no such thing as biopiracy.”⁵⁷⁰ His line of argumentation is threefold. First, ethno-biological knowledge is a legacy of humanity that belongs in a global commons. Second, “the harsh reality is that there is no economically justifiable reason for protecting ethnobiological knowledge.” Third, “[e]thnobiological knowledge already lies in the public domain.”⁵⁷¹

A report from the Commission on Intellectual Property Rights (CIPR) established by the British Government stated the following relevant to the issue of biopiracy: “the principle of equity dictates that a person should not be able to benefit from an IP right based on genetic resources or associated traditional knowledge acquired in contravention of any legislation governing access to that material.”⁵⁷²

Finally, codes of ethics in relation to biotechnological research also make reference to the term “biopiracy.” For instance, the Queensland Biotechnology Code of Ethics defines the term as “the appropriation of developments or discoveries involving biological resources by another party without consent.”⁵⁷³ What is relevant in this definition is the term “consent.” While “biopiracy” is probably not the most appropriate term, the following definition is a good starting point to understand the problem: the appropriation of developments or discoveries involving biological resources and/or traditional knowledge by another party without consent having been obtained from the owner⁵⁷⁴ or holders.

At present, the term biopiracy extends to a wide range of situations, and implies a multitude of actors.⁵⁷⁵ Hence, several reflections can be made on the provided definitions. First, the

⁵⁶⁹ DUTFIELD, “Protecting the Rights of Indigenous Peoples: Can prior Informed Consent Help?”, 2009, p. 57.

⁵⁷⁰ CHEN, “There’s No Such Thing as Biopiracy ... and It’s a Good Thing Too”, 2006, pp. 28-29.

⁵⁷¹ CHEN, “There’s No Such Thing as Biopiracy ... and It’s a Good Thing Too”, 2006, pp. 22-24 and 28-29.

⁵⁷² CIPR, “Integrating Intellectual Property Rights and Development Policy”, Report, London, 2002, p. 87,

⁵⁷³ Queensland Biotechnology Code of Ethics: Update of the Code of Ethical practice for Biotechnology in Queensland, 2006, p. 8, available at: <https://publications.qld.gov.au/storage/f/2014-02-26T05%3A16%3A20.664Z/qld-biotechnology-code-ethics.pdf> [accessed September 2016]

⁵⁷⁴ We acknowledge that without legal rights they may not be “owners” as such.

⁵⁷⁵ AUBERTIN and MORETTI, “La biopiraterie, entre illégalité et illégitimité”, 2007, p. 91.

biopiracy discourse extends both to genetic resources and traditional knowledge, whether associated to it or not. Second, it refers to the unauthorised extraction of biological resources from the countries of origin⁵⁷⁶ of the resource and its subsequent utilisation and/or incorporation in patent claims. Thirdly, it refers to the extraction of traditional knowledge beyond the traditional community by means of its appropriation through the system of intellectual property rights, be it patent, trademark, copyright, design, or even trade secret, and this appropriation occurs without prior informed consent (PIC)⁵⁷⁷ or free, prior, and informed consent (FPIC)⁵⁷⁸ of the traditional knowledge holders. Fourthly, the disclosure of traditional knowledge, in this case the therapeutic properties of plants, by scientists, such as ethnologists and ethnopharmacologists, is also questionable in the general debate on biopiracy.⁵⁷⁹ This is because documented disclosed knowledge is an important secondary source for the drug industry, the primary source being the traditional knowledge within the community. However, the disclosure of traditional knowledge can also be used as a tool for the protection of traditional knowledge in a defensive way.⁵⁸⁰ Indeed, normally disclosed traditional medicinal knowledge constitutes a bar to the novelty of the claimed invention.

Even though the previous reflections closely interact with each other, it is beyond the scope of the present analysis to address all activities with regard to the use of traditional medicinal knowledge that may be constitutive of biopiracy. The present research will solely focus on the utilisation of traditional medicinal knowledge in an invention for which a patent has been granted without the authorisation of the identified indigenous community.

⁵⁷⁶ CBD, Article 2 states that “the country of origin of genetic resources is the country which possesses those genetic resources in *in-situ* conditions”; see also, Nagoya Protocol, Article 6(1) (“[t]he providing party is either the country of origin of the resources or the party that has acquired the genetic resources in accordance with the CBD. The providing party may also be otherwise determined by a Party”).

⁵⁷⁷ CBD, Article 15.5 and Nagoya Protocol, Articles 6 and 7; see also, Part I, Chapter 3, 1.2.2.

⁵⁷⁸ UNDRIP, Article 11.2 reads: “States shall provide redress through effective mechanisms, which may include restitution, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs”; see also see also, Part I, Chapter 3, 3.1.2.

⁵⁷⁹ See generally, BAUD and GHASARIAN, *Des plantes psychotropes - Initiations, thérapies et quêtes de soi*, 2013 (the contributors to this book ranges from ethnopharmacologists, antropologists, philosophers and psychologists. They analyse the motivations of consumers and users of psychotropic plants as well as their somatic and therapeutic effects).

⁵⁸⁰ The protection approaches will be further discussed in Part III.

1.1 Utilisation of Traditional Medicinal Knowledge without Authorisation or Prior Informed Consent (PIC) – TRIPS Agreement v. CBD

As discussed previously, the roots of the principle of prior informed consent are to be looked for in the human rights framework. The same can be said for the principle of informed consent in medical practice. In the current legal framework, the Convention on Biodiversity (CBD) uses the term ‘prior informed consent’ (PIC), whereas the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) uses the term ‘free prior and informed consent’ (FPIC).

While patents resulting from the use of traditional knowledge associated with genetic resources are allowed under the World Trade Organisation (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), provided they fulfil the patentability criteria, they do not require evidence of prior informed consent from the country providing the resources, be it genetic resources or traditional knowledge. The TRIPS Agreement does not provide any support for the Convention on Biological Diversity (CBD) principle of national sovereignty over these resources.⁵⁸¹ However, it is fair to state that access to and utilisation of traditional knowledge associated with genetic resources without prior informed consent is not legitimate under the CBD and the Nagoya Protocol. Nevertheless, in the absence of national legislation implementing this principle, and particularly in user countries, any interested entity may obtain exclusive rights on products or processes based on traditional knowledge associated with genetic resources of other countries. In the particular case of traditional knowledge, prior informed consent should be primarily obtained from indigenous communities, rather than States. Thus, not only should the user country implement this principle but also the providing country where the indigenous community is located.

The debate on the relationship between the TRIPS Agreement, the CBD, and biopiracy has culminated in a proposal by developing States to link both treaties by proposing a disclosure of origin requirement in patent applications.⁵⁸² The disclosure requirement will receive an in-depth analysis in Part III of the present work.

⁵⁸¹ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 9.

⁵⁸² SIMON, “Institutionalised Exclusion: The Political Economy of Benefit Sharing and Intellectual Property”, 2012, pp. 19-43; OLDHAM and BURTON, “Defusing Disclosure in Patent Applications: A positive

1.2 Utilisation of Traditional Medicinal Knowledge in Patent claims

What are the linkages between claimed inventions and traditional knowledge? A recent WIPO-IGC consultation paper reported that “a significant number of patent applications concern inventions which are in some way related to traditional knowledge.”⁵⁸³ The claimed invention may have only been very remotely influenced by traditional knowledge or, on the contrary, may be directly based on traditional knowledge. Indeed, for some communities, the grant of patents that encompass traditional knowledge within their scope of protection constitutes an offence to their laws and customs.

The following section will discuss some cases of alleged ‘biopiracy,’ where a patent claim has incorporated traditional medicinal knowledge.

2 Selected Case Studies: Utilisation of TMK beyond Traditional Communities

The cases provided below are far from being exhaustive. The reason for their selection is principally due to the fact that they have made their way into consideration by a variety of international fora. In addition, it should also be noted that not all of the following examples concern the traditional knowledge of indigenous peoples. Indeed, traditional knowledge of the properties of turmeric and the neem tree are rather deemed to pertain to the Indian traditional knowledge system. They are, nonetheless relevant for this work, as they help to demonstrate the process by which traditional knowledge can be incorporated or drowned into the meanders of a patent claim.

strategy to strengthen legal certainty in the Nagoya Protocol and support WIPO’s IGC”, 2010; CARR, “Agreements that Divide: TRIPS v. CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications”, 2008, pp. 131-154; CORREA and SARNOFF, *Analysis of options for implementing disclosure of origin requirements in intellectual property applications*, 2006; GIRSBERGER, “Transparency Measures under Patent Law Regarding Genetic Resources and Traditional Knowledge – Disclosure of Source and Evidence of Prior Informed Consent and Benefit-Sharing”, 2004, pp. 451-489; CARVALHO, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution*”, 2000, pp. 371-395.

⁵⁸³ WIPO IGC, ‘Recognition of Traditional Knowledge within the Patent System’, 13-17 October 2008, WIPO/GRTKF/IC/13/7, Annex, pp. 1-2.

2.1 The Turmeric “Bad Patent”

Turmeric is used in almost all Indian, Pakistani, Persian and Afghani meals. This yellowish powder gives a distinct golden brown colour to dishes. Turmeric is obtained from the roots of a plant with the Latin name *Curcuma Longo*, and has culinary, cosmetic and medicinal properties. The active compounds of the rhizomes are known as curcuminoids. Importantly, the utilisation of turmeric powder for its medicinal properties is documented as such in Indian Ayurvedic texts. Its properties are well acknowledged in current traditional therapeutic systems, namely for biliary and hepatic disorder, gastrointestinal diseases, inflammation, rheumatism and diabetic wounds.⁵⁸⁴ This case essentially relates to the medicinal properties of turmeric. Foremost, the uniqueness of this case is that the misappropriation of the traditional knowledge was not committed by an overseas actor, such as a researcher, pharmaceutical or cosmetic company, but by national actors working abroad.

Two Indian scientists, Hari Har Choly and Suma Das, based at the University of Mississippi Medical Centre in Jackson, Mississippi, USA, were granted a US patent in March 1995 for turmeric to be used to heal wounds.⁵⁸⁵ The patent claims protection for a method which augments the healing process for chronic and acute wounds by administering topically and orally a wound healing compound that contains an effective amount of turmeric.⁵⁸⁶ The claims of the inventors were:

*“1. A method of promoting healing of a wound in a patient, which consists essentially of administering a wound-healing agent consisting of an effective amount of turmeric powder to said patient. 2. The method according to claim 1, wherein said turmeric is orally administered to said patient. 3. The method according to claim 1, wherein said turmeric is topically administered to said patient. 4. The method according to claim 1, wherein said turmeric is both orally and topically administered to said patient. 5. The method according to claim 1, wherein said wound is a surgical wound. 6. The method according to claim 1, wherein said wound is a body ulcer”.*⁵⁸⁷

⁵⁸⁴ RAFIEIAN-KOPAEI et al., “Turmeric: A Spice with Multifunctional Medicinal Properties”, 2014, p. 5.

⁵⁸⁵ US Patent No. 5,401,504.

⁵⁸⁶ This claim would not be acceptable under most national patent laws that exclude the patentability of diagnostic, therapeutic and surgical methods for the treatment of humans and animals. US patent law is an exception to this exclusion.

⁵⁸⁷ US Patent No. 5,401,504.

The patent application acknowledged but did not disclose the teaching about the healing properties of turmeric.⁵⁸⁸ It stated simply that “turmeric has long been used in India as a traditional medicine for the treatment of various sprains and inflammatory conditions”.⁵⁸⁹ The patent became controversial at this point. The Indian Council for Scientific and Industrial Research (CSIR) filed a re-examination request with the US Patent and Trademark Office (USPTO) challenging the patent on the grounds of prior art. In other words, CSIR alleged that the invention was actually part of public domain knowledge in India. In US patent law, a re-examination can be filed by anyone at any time during the period of enforceability of a patent in order to verify that the subject matter it claims is patentable. To do so, an interested party has to submit the proof of the prior art that raises a “substantial new question of patentability.”⁵⁹⁰ CSIR argued that turmeric had been used for thousands of years for healing wounds and rashes and therefore its use as a medicine was not a new invention. As the claim had to be backed by written documentation claiming traditional wisdom, CSIR went so far as to present an ancient Sanskrit text as well as a paper published in 1953 in the Journal of the Indian Medical Association. In 1996, the USPTO upheld the objection and cancelled the patent in 1997. Subsequently, the Indian delegation to the WTO has asserted that this patent could have been avoided if there had been a disclosure requirement for source and/or country of origin.⁵⁹¹ However, the US delegation argued that a closer look at the patent application indicates that India was clearly identified as the country of origin.⁵⁹²

The revocation of this patent is widely cited as the first successful attempt to reverse bio-pirating activities and has resulted in the emergence of the concept of “bad patents.” The uniqueness of this case resides in the fact that the patent for the “use of turmeric in wound healing” was revoked because it did not fulfil the patentability criteria, namely novelty. Indeed, the methods claimed in the patent were equivalent to the existing practices in Ayurvedic texts and even contemporary methods in India.

⁵⁸⁸ WTO TRIPS Council, ‘The Relationship between the TRIPS Agreement and the Convention on Biological Diversity’, 8 February 2006, IP/C/W/368/Rev.1, p. 66.

⁵⁸⁹ See U.S. Patent No. 5,401,504.

⁵⁹⁰ US Patent Law, U.S.C. Title 35, § 302 and 303.

⁵⁹¹ Minutes of Meeting, TRIPs Council, WTO Document IP/C/M/50 (May 16, 2006), para.23. The statement of Indian delegation was that the “turmeric case” substantiated the position that an obligation to disclose the source and country of origin would “help in avoiding misappropriation and biopiracy”.

⁵⁹² WTO TRIPS Council, ‘The Relationship between the TRIPS Agreement and the Convention on Biological Diversity’, 8 February 2006, IP/C/W/368/Rev.1, p. 66.

Nevertheless, nowadays, there are nearly hundreds of existing patents, not only in the US but also, amongst others, in Europe and India, that incorporate turmeric. No doubt many of these comply with the patentability criteria set forth in the US Patent Law, for instance. However, drawing upon the conclusions of Marinova and Raven, the number of US patents granted from 1976 to 2005, which incorporate various facets of turmeric properties, amount to 580, and only two of them are owned by Indian inventors.⁵⁹³ A more or less furnished list of patents containing turmeric in their title can be searched for in the main patent search tools, such as the USPTO or WIPO databases. For example, a patent filed in October 2012 claims “a method of treating Alzheimer's disease comprising, administering to a subject in need thereof, an effective amount of a composition containing a curcuminoid mixture with an added essential oil of turmeric [...]”.⁵⁹⁴ Scientific journals and reviews regularly publish new studies and projects on turmeric and its potential medicinal properties.⁵⁹⁵ Furthermore, turmeric-based products in other industries have also widely flourished, namely in the cosmetic industry.

How much should a patent claim differ from the prior art so as to avoid falling into biopiracy, or to be considered as a ‘bad patent’? The prior art in this case was the knowledge pertaining to the wound healing properties of turmeric. As for the use of turmeric in treating Alzheimer’s disease, as far as we know, there is no prior art with respect to the properties of turmeric for treating Alzheimer’s. As will be shown in the following Chapter, there is nothing suspicious under patent law in granting protection to truly novel inventions even if one of the inputs is found in the prior art, namely traditionally known medicinal uses of turmeric. Indeed, within the patent system, not every patent related to turmeric should be considered as constituting a case of biopiracy. The turning point being the comparison of the claims of the patent with the therapeutic properties of turmeric already identified in the prior art. For instance, a patent claiming a “method of masking flavour of curcumin” has no link with the medicinal use of

⁵⁹³ MARINOVA and RAVEN, “Indigenous Knowledge and Intellectual Property: A Sustainability Agenda”, 2006, p. 596.

⁵⁹⁴ U.S. Patent No. 8,859,020.

⁵⁹⁵ RAFIEIAN-KOPAIEI et al., “Turmeric: A Spice with Multifunctional Medicinal Properties”, 2014, pp. 5-8; BELCARO et al., “Efficacy and safety of Meriva, a Curcumin-phosphatidylcholine Complex, during Extended Administration in Osteoarthritis Patients”, 2010, pp. 337-344.

turmeric present in the prior art.⁵⁹⁶ Whilst, turmeric itself (the powder or the pasta), as such, is no longer patentable, derivatives, formulations, delivery systems and synthetic methods can be patented. Does this mean that synthetic analogs (either chemical or biological) of curcumin, the active compound of turmeric, for wound healing could be patented? In this case, the patentability criteria are fulfilled. What about the traditionally known medicinal uses of turmeric for wound healing as prior art? As Dutfield suggest, the question of biopiracy remains open where traditionally known uses of turmeric were an “essential research pointer without which the invention would never have been arrived at.”⁵⁹⁷

Today, countless studies are investigating the miraculous properties of turmeric, drawing on the traditional system in India. Broadly speaking, these studies take place both in India and beyond its territory and in this regard, India is not only seeking to protect its ancestral traditional knowledge from outsiders, but also wants to innovate and to commercially exploit its traditional knowledge. Ultimately, India’s interest in protecting traditional knowledge will not be the same as the interest of traditional communities living in the Amazonian forest.

2.2 The “Morality” of the Neem Patent / Neem patent and prior art

The neem tree (*Azadirachta Indica*) has been mainly used by South-Asian farmers and households for its medicinal and fungicide properties. Roughly 700 herbal preparations based on neem are found in Ayurveda, Unani, and other local health traditions.⁵⁹⁸ In recent decades, it is its use as fungicide that has attracted much of the attention through large-scale research to convert some of the neem’s properties into commercially valuable products. Neem-related patents have thus been granted in the US and in Europe not only to foreign but also to South-Asian inventors. Among all the neem-related patents, only two of them have been opposed due to claims of biopiracy. Furthermore, these two neem patent cases were not related to the medicinal properties of the plant but to its fungicidal properties. The interest resides, for the

⁵⁹⁶ EPO, EP2559347 at: <https://data.epo.org/publication-server/document?PN=EP2559347%20EP%202559347&iDocId=1102429&iPosition=0&iFormat=3> [accessed September 2017].

⁵⁹⁷ DUTFIELD, “A critical analysis of the debate on traditional knowledge, drug discovery and patent-based biopiracy”, 2011, p. 242.

⁵⁹⁸ POSEY and DUTFIELD, “Beyond Intellectual Property – Toward Traditional Resource Rights for Indigenous Peoples and Local Communities”, 1996, p. 80; PORTER Anna Horsbrugh, “Neem: India’s Tree of Life, BBC News, 17 April 2006, available at: http://news.bbc.co.uk/2/hi/south_asia/4916044.stm [accessed September 2016].

purpose of this work, in the fact that it shows the great variability of decisions rendered in regard to biopiracy claims.

In the 1990s, an American Company, W.R. Grace & Co., was granted several patents in both the United States and in Europe. The shared objective of the inventions was “to provide a non-toxic, natural pesticide formulation based on an extract from neem seeds with improved storage stability.”⁵⁹⁹ Indeed, the key feature of the natural formulation was that the preparation lasted for a few days.

The US patent issued on 23 June 1992 was challenged on the basis that the knowledge of the fungicidal properties of the neem tree already existing in traditional rural communities was equivalent to the invention that was the subject matter of the patent claim. Here traditional *uses* constituted prior art. The patent was re-examined by the United States Patent and Trademark Office but it was decided that novelty had not been destroyed because foreign knowledge and usage did not destroy novelty according to § 102 of the United States Patent Act,⁶⁰⁰ except when this foreign knowledge is in the form of printed document.⁶⁰¹ As a result, foreign prior art that is not documented in a publication is not “authentic prior art” that US Courts can examine.⁶⁰²

In Europe, the patent application was filed by the United States Department of Agriculture and W.R. Grace on 12 December 1990 at the European Patent Office. In 1995, a joint opposition⁶⁰³ to the granting of the patent⁶⁰⁴ was filed at the European Patent Office arguing the exploitation of an invention contrary to morality,⁶⁰⁵ lack of novelty⁶⁰⁶ and lack of

⁵⁹⁹ US Patent No. 5,124,349.

⁶⁰⁰ US Patent Law, U.S.C. Title 35, § 102.

⁶⁰¹ Reexamination certificate, US Patent No. B1 5,124,349, issued on 20 October 1998.

⁶⁰² BAGLEY, “Patently unconstitutional: The geographical limitation on prior art in a small world”, 2003, p. 683 (the author questioned the constitutionality of statutory provisions that requires classification of information as relevant or non-relevant based on its geographical origin); KADIDAL, “United States Patent Prior Art Rules and the Neem Controversy: A Case of Subject-matter Imperialism”, 1998, p. 32.

⁶⁰³ The group of opponents represented by Fritz Dolder, professor of intellectual property at the University of Basel, was formed by the Indian activist, Vandana Shiva, the president of the Green grouping in the European Parliament, Magda Aevolet, and the then vice-president of the International Federation of Organic Agriculture Movements (IFOAM), Linda Bullard.

⁶⁰⁴ EP 0436257.

⁶⁰⁵ EPC, Article 53(a).

inventiveness.⁶⁰⁷ Based upon this, the Opposition Division decided to revoke the patent, a decision which was upheld by the Board of Appeal. While in Europe, foreign prior art does not need to be in a written form, the Board of Appeal still relied on a printed document that acknowledged the traditional knowledge on the neem tree, and which had been published by Indian scientists in a scientific periodical in Australia.⁶⁰⁸ According to Dolder, for traditional knowledge that is not acknowledged in a printed document, to constitute prior public use, the opponent has to provide evidence of it.⁶⁰⁹ The EPO will only accept such evidence if it complies with strict evidentiary standards, which it has ruled requires detailed information on what was made available to the public, where, when, how, and by whom.⁶¹⁰

A decade has passed since the decision of the Board of Appeal. Although, it forthrightly recognised “common traditional knowledge” as forming the prior art, it considered that this was not a matter related to morality, but was rather a question of novelty or prior public use.⁶¹¹ Despite the opinion of the Board of Appeal that “no direct connection could be established between the livelihood of a part of the people of India [“using the neem tree for millennia”]⁶¹² and a method for controlling fungi by a special hydrophobic extract of the neem oil, since neither the neem tree or seeds as such nor the neem oil in general is claimed”, there is no doubt that the decision has opened the way for future discussions within the World

⁶⁰⁶ EPC, Article 54.

⁶⁰⁷ EPC, Article 56.

⁶⁰⁸ EPO Technical Board of Appeal, T 0416/01 – *Thermo Trilogy et al., v. Aelvoet et al.*, 8 March 2005, Reasons 4.2 (often referred to as the *Neemfungicide* case).

⁶⁰⁹ SHERIDAN, “EPO Neem Patent Revocation Revives Biopiracy Debate”, 2005, pp. 511-512.

⁶¹⁰ EPO Board of Appeal, T 328/87 – *Thomson-Brandt v. Electrolux*, 4 April 1991 (“When an opposition is based on grounds of prior use, the requirements of Rule 55(c) EPC are only fulfilled if the notice of opposition indicates, within the opposition period, all the facts which make it possible to determine the date of prior use, what has been used, and the circumstances relating to the alleged use. The notice of opposition must also indicate the evidence and arguments presented in support of the grounds of opposition”); see also, DOLDER, “Analysis of the European Patent Law – Traditional knowledge and patenting: the experience of the neemfungicide and the hoodia case”, 2007, p. 587.

⁶¹¹ EPO Opposition Division, 10 May 2000, Grounds of the decision, p. 7, para. 4.2, available at: <https://register.epo.org/application?number=EP90250319&tab=doclist> [accessed September 2016].

⁶¹² EPO Opposition Division, 10 May 2000, Grounds of the decision, p. 7, para. 4.1.

Intellectual Property Organisation and the World Trade Organisation in relation to the patenting of products based on traditional knowledge.⁶¹³

2.1 The *Ayahuasca* Case / Prior Art Printed Publication

Ayahuasca,⁶¹⁴ which means "vine of the soul" in the Quechua language, designates a traditional psychotropic plant that contains *Banisteriopsis caap* (*Caapi*).⁶¹⁵ It is widely used by the indigenous peoples of north-western South America. The area of use has been estimated to extend from Panama in the north to Amazonian Peru and Bolivia in the South and from the coastal areas of Colombia and Ecuador to the Río Negro in Brazil. Although the use of this psychotropic beverage appears to be very old, its use has remained unknown by the outside world until very recent times. In 1852, the botanist Richard Spruce collected specimens for later chemical analysis, which would not be conducted until more than one century later. It was only in 1974 that Loren Miller, owner of the U.S.-based International Plant Medicine Corporation, received samples of a local *ayahuasca* vine from a tribe in Ecuador.

In 1986, Miller obtained a U.S. plant patent for a variation of the *ayahuasca* called "Da Vine" (valid until 2003), "characterized by the rose colour of its flower petals which fade with age to near white, and its medicinal properties."⁶¹⁶ Chapter 15 of the U.S. Patent Act refers to plant patents.⁶¹⁷ A plant patent is granted for an invention or discovery which "asexually reproduces any distinct and new variety of plant, [...] other than a tuber propagated plant or a plant found in an uncultivated state."⁶¹⁸ It precludes others from asexually reproducing or selling or using the patented plant.⁶¹⁹ A plant patent is regarded as limited to one plant, or genome. A mutant of a patented plant would not be considered to be of the same genotype, and would not be covered by the patent to the parent plant, and would, itself, be separately

⁶¹³ SHERIDAN, "EPO Neem Patent Revocation Revives Biopiracy Debate", 2005, p. 511.

⁶¹⁴ Also known as *Yage*.

⁶¹⁵ BOIS-MARIAGE, "Ayahuasca: Une Synthèse Interdisciplinaire", 2002, p. 83 ; see also generally, GEX Maude, "Le divin profane par Da Vine? La contestation du brevet sur l'ayahuasca et les débats autour de la biopiraterie, 2010.

⁶¹⁶ US Plant Patent 5751 P of 17 June 1986, available at: <https://www.google.com/patents/USPP5751> [accessed September 2016]

⁶¹⁷ US Patent Law, U.S.C. Title 35, Chapter 15 – Plant Patents

⁶¹⁸ US Patent Law, U.S.C. Title 3, § 161.

⁶¹⁹ US Patent Law, U.S.C. Title 3, § 163.

patentable, subject to meeting the requirements of patentability. A plant patent expires 20 years from the filing date of the patent application.⁶²⁰ As with *utility* patent applications, when the *plant* patent expires, the subject matter of the patent falls in the public domain.⁶²¹ In order to determine the novelty of the claimed plant, its description will be compared with the closest available prior art. Prior art in this case, constitutes those plants known and available to the skilled artisan at the time of applicant's invention. If the application does not distinguish the claimed plant over such previously known and available plants (either patented or unpatented) the claim will be rejected as failing to distinguish the claimed plant over the known plant.⁶²²

The patent claimed that Da Vine represented a new and distinct variety of *Caapi* that had been discovered in a local garden in the Amazon and it further described the potential medicinal properties of the plant. In 1994, David Downes and Glenn Wiser of the Center for International Environmental Law (CIEL), on behalf of the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) and the Coalition for Amazonian Peoples and their Environment (Amazon Coalition) claimed Miller's new variety was identical to the local domesticated plants.⁶²³ The opponents requested a re-examination of the patent by the U.S. Patent and Trademark office (USPTO). CIEL argued that the plant variety was not distinct and, in addition, that the plant was sacred to Amazon natives and as a result the patent was contrary to public policy and morality.

After examination, the USPTO invalidated the patent because herbarium sheets in Chicago's Field Museum had contained the same plant before Miller's application. The USPTO agreed with the opponents that the claimed plant variety was not distinctive or novel, but did not acknowledge the prior art of the indigenous community who had developed the variety, nor the argument that the plant's sacred and religious values could constitute an exception from

⁶²⁰ General Information about 35 U.S.C. 161 Plant Patents, available at: www.uspto.gov. [accessed September 2016].

⁶²¹ US Patent Law, U.S.C. Title 3, § 163 (“[t]he provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provide”).

⁶²² WISER, “U.S. Patent and Trademark Office Reinstates Ayahuasca Patent – Flawed Decision Declares Open Season on Resources of Indigenous Peoples”, (CIEL), 25 June 2001; see also FECTEAU, “The Ayahuasca Patent Revocation: Raising Questions About Current U.S. Patent Policy”, 2001, pp. 73ff.

⁶²³ WISER, “Legal Elements of the “Ayahuasca” Patent Case”, November 1999, Center for International Environmental Law (CIEL), available at: <http://www.ciel.org/reports/legal-elements-of-the-ayahuasca-patent-case-november-1999-wiser-bw99-10-2/> [accessed September 2016].

patenting. However, in 2001, Miller convinced the USPTO to overturn its earlier decision and the patent was restored to the inventor and the original claims were re-confirmed for the remaining two years of the patent term.⁶²⁴

2.2 Hoodia Case: Challenging a Patent or Entering into an Access and Benefit-Sharing Agreement?⁶²⁵

2.2.1 Towards an Agreement on Benefit-Sharing

Hoodia gordonii is a succulent plant that was originally grown in South Africa and in neighbouring Namibia. The traditional knowledge of the indigenous San peoples⁶²⁶ on the properties of the *Hoodia* plant refers to its role as an appetite and thirst suppressant, a cure for abdominal cramps, haemorrhoids, tuberculosis, indigestion and hypertension, and as an antidiabetic.⁶²⁷

In 1798, the traditional knowledge of the San peoples about the properties of the *Hoodia* plant was first documented in the colonial ethnobotanical records of Francis Masson. Whilst it has not been definitively established, it is highly probable that these records were used by the South African Council for Scientific and Industrial Research (CSIR) as a starting point to further investigate the plants' potential as an appetite suppressant. However, it is not until 1997, after almost 30 years of research and development, that CSIR was able to isolate the

⁶²⁴ WISER, "U.S. Patent and Trademark Office Reinstates Ayahuasca Patent – Flawed Decision Declares Open Season on Resources of Indigenous Peoples", (CIEL), 25 June 2001 (One of the four arguments was the distinct flower petal colour of Da Vine compared to the *Caapi*); for a detailed account of the procedure, see GEX, "Le divin profane par Da Vine? La contestation du brevet sur l'ayahuasca et les débats autour de la biopiraterie", 2010, No. 46.

⁶²⁵ This case study draws substantively from the contributions of Rachel Wynberg, a natural scientist and environmental policy analyst from the University of Cape Town, South Africa, and Roger Chennells, legal representative of the San People. WYNBERG, "Rhetoric, Realism and Benefit-Sharing – Use of Traditional Knowledge of Hoodia Species in the Development of an Appetite Suppressant", 2004, pp. 851-876; CHENNELLS, "Strengthening Partnership between States and Indigenous Peoples: Treaties, Agreements and other Constructive Arrangements: The Hoodia Case", 2012; and CHENNELLS, "Traditional Knowledge and Benefit Sharing after the Nagoya Protocol: Three Cases from South Africa", 2013, pp. 163-185.

⁶²⁶ The San peoples are known to be the oldest human inhabitants in Africa.

⁶²⁷ LEE and BALICK, "Indigenous Use of Hoodia Gordonii and Appetite Suppression", 2007, p. 406.

plant's active substance responsible for suppressing appetite and to patent the use of it in South Africa, which was labelled P57.⁶²⁸

The CSIR subsequently filed an international patent application through the Patent Cooperation Treaty (PCT),⁶²⁹ and filed a European patent application through the European Patent Office.⁶³⁰ P57 was also later licensed to the British pharmaceutical company Phytopharm,⁶³¹ who planned the development of an anti-obesity drug, who then reached a license and royalty agreement with US-based pharmaceutical giant, Pfizer, for further development and commercialisation, for a reported sum of US\$ 21 million.⁶³² According to the agreement, Phytopharm was granted an exclusive worldwide license to manufacture and commercialise all products related to the *Hoodia* plant and to exploit the CSIR intellectual property rights relating to the *Hoodia* species.

Although strict rules of secrecy were observed, the Working Group of Indigenous Minorities in South Africa (WIMSA) uncovered the deal in 2001 and began raising public awareness about it.⁶³³ The case became a public scandal mainly because up until 2001, several agreements for the further development and commercialisation of the *Hoodia* drug had proceeded neither with the prior informed consent (PIC) principle enshrined in the Convention on Biodiversity (CBD), nor with any sort of acknowledgement of the contribution of the San's traditional knowledge to the patented product.

⁶²⁸ South African Patent No. 983170.

⁶²⁹ The CSIR filed an international patent application through the Patent Cooperation Treaty under the publication number WO1998046243 A3, filed on April 15, 1998, covering more than 100 countries, on the basis of its national application. WO9846243, "Pharmaceutical compositions having appetite suppressant activity".

⁶³⁰ EP 1438965, available at: <https://register.epo.org/application?number=EP04002070> [accessed September 2016].

⁶³¹ In September 2013, Phytopharm Plc acquired IXICO Ltd with the change of Phytopharm's name to IXICO plc, available at: www.ixico.com [accessed September 2016].

⁶³² WYNBERG and CHENNELLS, "Green Diamonds of the South: An Overview of the San-*Hoodia* Case", 2009, p. 95.

⁶³³ In 1996, San elders formed the Working Group on Indigenous Minorities in Southern Africa (WIMSA) to gather the San people in Botswana, Namibia and South Africa. The objective was to unite and represent the interests of these communities.

Phytopharm's chief executive, Richard Dixey, defended their position on the grounds that he had been told by CSIR that the 100,000 San purportedly left "had died out."⁶³⁴ The CSIR, in turn, argued that its reluctance to engage with the San was mainly due to a concern that "expectations would be raised with promises that could not be met." CSIR and Phytopharm were also concerned with practical difficulties, namely the identification of the real owners of the traditional knowledge and the possibility that one group could have historically stolen the knowledge from another, etc.⁶³⁵ Eventually, in 2001 a memorandum of understanding was signed between CSIR and the San peoples that recognised the latter as being the custodians of *Hoodia gordonii* and the traditional knowledge regarding its use.

In addition, an agreement was reached in 2003 to share any benefits arising from the commercialisation of the plant (or P57 respectively) with the San.⁶³⁶ The agreement stated that the San peoples would perceive six percent of all royalties received by the CSIR from Phytopharm for products, and eight percent for milestone income when certain targets were reached. The San Hoodia Benefit-sharing Trust has been set up jointly by the CSIR and the South African San Council to share the money among all southern Africa's San. Indeed, San representatives recognised that the knowledge about the plant was held collectively by the San peoples, and acknowledged its indivisibility. The same year, Pfizer announced its withdrawal from the market and cancelled the sublicense agreement with Phytopharm, which in turn, sold its license rights to the multinational company Unilever. In 2008, Unilever pulled out of the *Hoodia gordonii* project after declaring that the final product would not meet the high standards for safety and efficacy of Unilever. In 2010, CSIR and former Phytopharm

⁶³⁴ BARNETT Anthony, "In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to make us thin". The Guardian, 17 June 2001, available at: <http://www.guardian.co.uk/world/2001/jun/17/international/education/news.businessofresearch?INTCMP=SRCH> [accessed September 2016].

⁶³⁵ BARNETT Anthony, "In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to make us thin". The Guardian, 17 June 2001.

⁶³⁶ CSIR Media Release. "the San and the CSIR announce a benefit-sharing agreements for potential anti-obesity drug", 24 March 2003, available at: http://ntww1.csir.co.za/plsql/ptl0002/PTL0002_PGE157_MEDIA_REL?MEDIA_RELEASE_NO=7083643 [accessed September 2016].

cancelled the original licence agreement,⁶³⁷ “placing back the future of the Hoodia back in the hands of the CSIR.”⁶³⁸

Whether or not the financial expectations of the San communities have been met, the legal representative of the San people, Roger Chennells stated, in an interview published by the end of 2010, that the arrangement concluded with CSIR provided the San people with around 73,000 US Dollars in royalties since the 2003 agreement.⁶³⁹

A closer analysis of the agreement reveals major weak points that have been fully listed by the South African scholar Rachel Wynberg.⁶⁴⁰ Three are of major importance. First, although the amount of money received by the San peoples is not insignificant, it is small compared to monies received by CSIR and Phytopharm. Second, whilst the San have received the formal recognition of being the “legal custodians of an ancient body of traditional knowledge on the use of *Hoodia*,”⁶⁴¹ they have no right to claim any ownership or co-ownership of the patents or products derived from those patents.⁶⁴² Indeed, all intellectual property rights resulting from the traditional knowledge of the San on the use of *Hoodia* are exclusively vested with CSIR. Additionally, the Agreement explicitly excludes any further financial claims by the San. Third, the Agreement has created disparities and conflicts between the communities

⁶³⁷ MAKONI Munyaradzi, “San people’s cactus drug dropped by Phytopharm” SciDevNet, 20 december 2010, available at: <http://www.scidev.net/global/indigenous/news/san-people-s-cactus-drug-dropped-by-phytopharm-1.html> [accessed September 2016].

⁶³⁸ CHENNELLS, “Strengthening Partnership between States and Indigenous Peoples: Treaties, Agreements and other Constructive Arrangements: The Hoodia Case”, 2012, p. 4.

⁶³⁹ MAKONI Munyaradzi, “San people’s cactus drug dropped by Phytopharm” SciDevNet, 20 december 2010, available at: <http://www.scidev.net/global/indigenous/news/san-people-s-cactus-drug-dropped-by-phytopharm-1.html> [accessed September 2016]; see also, see MUNYI and JONAS, “Implementing the Nagoya Protocol in Africa: Opportunities and Challenges for African Indigenous Peoples and Local Communities”, 2013, p. 227, FN. 38.

⁶⁴⁰ WYNBERG and CHENNELLS, “Green Diamonds of the South: An Overview of the San-*Hoodia* Case”, 2009, p. 95.

⁶⁴¹ Provision 6 of the Benefit-Sharing Agreement between the CSIR and the South African San Council, March 2003, cited in WYNBERG, “Rhetoric, Realism and Benefit-Sharing – Use of Traditional Knowledge of Hoodia Species in the Development of an Appetite Suppressant”, 2004, pp. 863 ff.

⁶⁴² Provision 4 of the Benefit-Sharing Agreement between the CSIR and the South African San Council, March 2003, cited in WYNBERG, “Rhetoric, Realism and Benefit-Sharing – Use of Traditional Knowledge of Hoodia Species in the Development of an Appetite Suppressant”, 2004, p. 864.

which share the traditional knowledge about *Hoodia*'s properties. The fundamental question has been: who must be considered to be the legitimate custodian and eventual owner of the *Hoodia*-related traditional knowledge? This has forced the San peoples to enter into a process of self-identification. Indeed, the "San" encompasses many communities living in different rural regions of Southern Africa, namely Angola, Namibia and Northern Botswana and the knowledge about *Hoodia*'s properties are shared amongst those communities. Although, the original Agreement did not encompass these other communities, in 2009, an additional benefit sharing agreement between the communities, namely the San and the Nama was reached.⁶⁴³

This case leads to a larger question. Will the access and benefit sharing agreement regime now fully enshrined in the Nagoya Protocol promote and protect rights of indigenous holders?

In my opinion, access and benefit sharing agreements do not constitute an effective tool for the protection of traditional medicinal knowledge of indigenous peoples. The rationale for these agreements is driven by commercial interests. In addition, according to general principles of contract law, only the parties to the agreement are bound by it. They constitute a partnership between indigenous communities and researchers and industry to develop tradable products based on traditional knowledge.

The protection of traditional medicinal knowledge will first and foremost depend on the translation of the full range of the Nagoya Protocol provisions related to traditional knowledge into national legislation and an improvement in the capabilities of the communities to effectively take advantage of the laws. It all comes down to their legal empowerment. The access and benefit sharing approach should be one of a range of measures they can use to achieve their objectives. The fundamental should be looked for in the resources available within the community, such as their proper customary laws and practices.

2.2.2 Was the Patent Inventive?

On 28 October 2013, the Examining Division of the EPO decided that the European patent application should be refused on the grounds of lack of an inventive step in view of the knowledge of the San people on the appetite suppressant properties of the *Hoodia*. However,

⁶⁴³ See, "Report: Hoodia Multi-Stakeholder Meeting, !KHTWA TTU", 22-23 January 2009, available at: https://www.uclan.ac.uk/research/explore/projects/assets/cpe_genbenefit_hoodia_stakeholders.pdf [accessed September 2016]; MUNYI and JONAS, "Implementing the Nagoya Protocol in Africa: Opportunities and Challenges for African Indigenous Peoples and Local Communities", 2013, p. 225.

the subsequent appeal against this refusal changed the story, when the Board of Appeal ruled that the submitted claims involved an inventive step. The Board focused upon two documents relevant to the examination of the prior art (D1 and D8) which mentioned the suppression of hunger after the intake of the plant *Hoodia*. A large number of other publications linking the properties claimed in the invention to the knowledge of the San people were excluded by the Board on the basis that they had been published after the filing date of the patent application.⁶⁴⁴ Of the two retained documents, the Board regarded D1 as being less relevant because of its excessively prudent wording.⁶⁴⁵ After examining D8,⁶⁴⁶ the Board concluded that “a skilled person knowing from document (8) that the consumption of parts of a fibrous, water-storing plant of the genus [...], could not obviously derive from this disclosure that an extract from the plant could be used for the manufacture of an appetite-suppressant, anti-obesity medicament.”⁶⁴⁷ For the Board of Appeal, the patent claim was inventive for two main reasons. First, the appellant had isolated the active substance responsible for *Hoodia*’s particular properties.⁶⁴⁸ Second, the appellant had demonstrated that in order for the raw plant to produce the same effect as the isolated active substance, a patient had to consume a huge amount of the plant. According to the Board, the appellant had provided “an alternative appetite-suppressant having improved activity when compared with prior art compositions [...]”⁶⁴⁹

The fundamental question remaining is the distinction between the way a traditional community would consider the chemical properties of a natural product, and the perspective of a “Western” pharmacologist who identified and extracted a distinct chemical compound from that product, guided by the community’s traditional knowledge. According to the Board

⁶⁴⁴ EPO Technical Board of Appeal, T 0543/04 – Appetite suppressant /*CSIR*, 27 January 2005, Reason 9.

⁶⁴⁵ *ibid*, Reason 10.1. “The edible species [...] have a peculiar pervasively spreading sweet taste which is remarkably persistent and *is said to* quench thirst and hunger for extended periods”.

⁶⁴⁶ *ibid*, Reason 10.1 “... it saved further suffering from the pangs of hunger so efficiently that I could not eat anything for a day after having reached the camp.”

⁶⁴⁷ *ibid*, Reason 16.

⁶⁴⁸ EPO Guidelines, Patent Examination, Part G, chapter II.3 (“if a substance found in nature can prove to produce a technical effect, it may be patentable”).

⁶⁴⁹ EPO Technical Board of Appeal, T 0543/04 – Appetite suppressant /*CSIR*, 27 January 2005, §17.

of Appeal, the link between the disclosed traditional knowledge and the invention as claimed is made through the person skilled in the art more than the traditional knowledge holder.⁶⁵⁰

2.3 The Pelargonium Case: Solely a Question of Patentability ?

In 2007, the German phyto-pharmaceutical company, Dr. Willmar Schwabe GmbH & Co. KG, applied for several patents related to extracts from the *Pelargonium* species (*P. sidoides* and *P. reniforme*)⁶⁵¹ under the European Patent Convention (EPC).⁶⁵² One of these claimed a method for producing an extract from *Pelargonium sidoides* and/or *Pelargonium reniforme*, characterized by subjecting the roots of the plants to certain steps in order to obtain the extract which could be used to treat acute and inflammatory diseases and infections.⁶⁵³ The extraction method used water and alcohol to remove the active ingredients from the *Pelargonium* plants. The description in the patent application also mentioned that *Pelargonium* had been traditionally used in Southern Africa as a medicament for a long period of time.⁶⁵⁴

Several opponents, including the African Center for Biosafety⁶⁵⁵ and *Erklärung von Bern* opposed the patent on the grounds of infringement of *ordre public* and morality (53(a) EPC)

⁶⁵⁰ *Ibid*, §8 and 16.

⁶⁵¹ The Pelargonium is also known under the native name Umckaloabo; MYBURGH André, “Lessons from Alice in Dealing with Biopiracy”, Attorney of the Hight Court of South Africa, Trade Mark Practitioner Fellow of the SA Institute of Intellectual Property Lawyers, 2010 (on file with the author).

⁶⁵² Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000, OJ EPO 2001, Special edition No. 4, p.55 and OJ EPO 2007, Special edition No. 4, synoptic presentation (EPC).

⁶⁵³ EP 1429795 – Method for Producing Extracts of Pelargonium Sidoides and/or Pelargonium Reniforme, granted 13 June 2007, available at: <https://register.epo.org/application?number=EP02777223> [accessed September 2015].

⁶⁵⁴ For a historical and scientific account on the use of Pelargonium, see, BRENDLER and WYK van, “A Historical, Scientific and Commercial Perspective on the Medicinal Use of Pelargonium Sidoides (Geraniaceae)”, 2008, pp. 420-433; see also, WYNBERG and NIEKERK van, “The trade in Pelargonium Sidoides: Rural Livelihood Relief or Bounty for the ‘Bio-buccaneers’?”, 2012, p. 538 (stating that even though South African Legislation has implemented benefit-sharing as provided by the CB, it is rarely the poor people, often custodians of genetic material and traditional knowledge, that directly benefit from benefit-sharing agreements. It is rather communities with high level of organisations that are favoured by industries).

⁶⁵⁵ Acting on behalf of the ‘community Alice’ composed by the Xhosa-speaking communities.

the lack of novelty, the lack of an inventive step and the lack of sufficiency of disclosure.⁶⁵⁶ They submitted that *Pelargonium* roots in sufficient quantities, as well as the traditional knowledge of indigenous communities, were available in South Africa, and that the invention was essentially claiming traditional knowledge. Further, opponents alleged that the invention was contrary to “*ordre public*” and morality under the European Patent Convention (EPC)⁶⁵⁷ because of the failure to comply with the requirements of prior informed consent and benefit-sharing as provided for by the Convention on Biological Diversity (CBD).⁶⁵⁸ In other words, they claimed that the company was obliged to respect, when making and when exploiting the invention, the requirement of “prior informed consent” and “benefit sharing” as stipulated in the CBD. The company had not shown that it had acted in conformity with these requirements.

Concerning the claims based on Article 53(a), the court examined both *ordre public*⁶⁵⁹ and morality.⁶⁶⁰ The decision whether the patented invention falls under Article 53(a) is dependent on a balance of interest between a potential harm to the environment, on one hand, and the benefits that an invention of new medicine supposes for the humanity as a whole, on the other hand.⁶⁶¹ The Court also noted that the question whether the exploitation of the invention would be contrary to “*ordre public*” and morality⁶⁶² according to Article 53(a) of the EPC shall be answered on a case by case analysis.⁶⁶³

⁶⁵⁶ Notice of Opposition by Fritz Dolder, ACB and Berne Declaration 10 March 2008 (on file with the author).

⁶⁵⁷ EPC, Article 53(a).

⁶⁵⁸ CBD, Article 8(j), 15 and 16.

⁶⁵⁹ See EPO Opposition Division – *Pelargonium*, 20 April 2010, Res. 4.1.1 (the original version reads as follows: “Der Begriff der öffentlichen Ordnung schliesst auch den Schutz der Umwelt an”).

⁶⁶⁰ See EPO Opposition Division – *Pelargonium*, 20 April 2010, Res. 4.1.1 (the original version reads as follows: “Der Begriff der guten Sitten knüpft an die Überzeugung an, dass ein bestimmtes Verhalten richtig und vertretbar, ein anderes dagegen falsch ist, wobei sich diese Überzeugung and die Gesamtheit der in einem bestimmten Kulturkreis tief verwurzelten, anerkannten Normen gründet”).

⁶⁶¹ See EPO Opposition Division – *Pelargonium*, 20 April 2010, Res. 4.1.3 (the original version reads as follows: “Die Entscheidung ob Artikel 53(a) EPÜ der Patentierung der vorliegenden Erfindung entgegenstehe, ist abhängig von einer sorgfältigen Abwägung einer möglichen Gefährdung der Umwelt einerseits gegen den Nutzen der Erfindung für die Menschheit anderseits”).

⁶⁶² See Part II, Chapter 2, 2.

⁶⁶³ EPO Opposition Division – *Pelargonium*, 20 April 2010, Res. 4.1.2.

In other words, the court asked whether the “use of any of the subject matter claimed in the patent in-suit is likely to seriously harm the environment or contravenes the generally accepted codes of conduct, at least in the European culture.”⁶⁶⁴ While it acknowledged the importance and relevance of the CBD in European culture, the Court held that the CBD considerations are not linked to patentability requirements.⁶⁶⁵

In a subsequent paragraph, in deciding whether Article 53(a) had been infringed by the patented invention, the Court also proceed to make a balancing test between a potential environmental endangering and the utility of the invention for humanity. The Court concluded that the benefits that the invention of new medicines provided to humanity outperformed a potential risk of harm to the environment.⁶⁶⁶ Indeed, the Court held that the evidence brought by the opponents were not *schlüssig* (conclusive).⁶⁶⁷ The Opposition Division held that obtaining prior informed consent and the sharing of benefits when accessing genetic resources are not part of the patentability requirements and thus their absence is not a ground for revocation under the EPC. Furthermore, the Opposition Division revoked the patent because the method claimed in the patent was not considered to be sufficiently inventive when compared to the prior art, which consisted of a percolation and maceration technique identified by the competitor’s opponents.⁶⁶⁸

⁶⁶⁴ EPO Opposition Division – *Pelargonium*, 20 April 2010, Res. 4.1.3 (the original version in German reads as follows: “Im vorliegenden Fall ist weiter zu entscheiden, ob die Verwertung eines der im Streitpatent beanspruchten Gegenstände die Umwelt voraussichtlich ernsthaft gefährdet oder im Widerspruch zu den allgemein anerkannten Verhaltensnormen zumindest des europäischen Kulturkreises steht.”)

⁶⁶⁵ See EPO, Opposition Division, 20 April 2010, Res. 4.1.3 (original version in German reads as follows: “Angaben zum Schweizerischen oder Deutschen Recht dienen zwar als Orientierung und unterstreichen die Relevanz und Wichtigkeit der CBD im europäischen Kulturkreis, sind aber längst nicht entscheidend.”)

⁶⁶⁶ EPO Opposition Division – *Pelargonium*, 20 April 2010, Res. 4.1.4, second paragraph (original version in German reads as follows: “Damit ist nach der Meinung der Einspruchsabteilung belegt, dass der Nutzen der Erfindung für die Menschheit in der Bereitstellung eines Arzneimittels gesehen werden kann.”).

⁶⁶⁷ EPO Opposition Division – *Pelargonium*, 20 April 2010, Res. 4.1.4, third paragraph.

⁶⁶⁸ EPO Opposition Division – *Pelargonium*, 20 April 2010, Res. 7 ff. (the original version in German reads as follows: “[...] dass keine der beiden beanspruchten Verfahrensvarianten auf einer erfinderischen Tätigkeit beruht”).

Following the decision, the patent holder did not file an appeal, and the decision of the opposition division became final.⁶⁶⁹

3 Concluding Remarks

The cases that have been presented in this Chapter raise fundamental questions that are revealed by the linkage between a claimed invention and traditional knowledge.

Environmental and human rights international instruments have affirmed indigenous peoples' rights to have their say in all issues affecting their cultural identities, ranging from their rights to lands and resources to their cultural and intellectual activities. The very basic foundation of the right to participate in decision-making processes is constituted by the requirement to respect their right to prior informed consent. These case studies have shown that users of indigenous traditional knowledge rarely ask for the consent of indigenous peoples before entering into the laborious undertaking of research and development leading to the production and, finally, the commercialisation of new products on the market. The reasons of this failure are as diverse as the hypotheses on when activities may be constitutive of biopiracy. Chapters Two and Three of this Part II will try to demonstrate the main reasons of this failure; however, I will briefly set them out here. First, the highly technical nature of patents in the realm of pharmaceuticals can easily absorb any other forms of knowledge which are considered to be raw material for "real" innovations. The second main reason is based on the erroneous assumption that this raw material, which is in the public domain, also encompasses the traditional knowledge of indigenous communities. Hence, there is a clear loophole in the patent system with regard to the protection of the knowledge of indigenous peoples.

Third, a larger problem arises from the application of two sets of rights that are evolving separately, i.e. environmental and human rights laws *versus* intellectual property laws. The ongoing controversies with regard to the relationship between the Convention on Biodiversity, the Nagoya Protocol and UNDRIP, on the one side, and the TRIPS Agreement,

⁶⁶⁹ EPO Opposition Division – *Pelargonium*, 20 April 2010, Res. 4.1.6 (original version in German reads as follows: "Die Einspruchsabteilung vertritt die Meinung, dass allein die Nichterfüllung von potenziellen Disclosure Requirements nicht ausreichend ist, um die Voraussetzungen der Anwendung von Art. 53(a) zu erfüllen, im Hinblick auf einen Widerruf des angefochtenen Patents, obgleich sie durchaus dazu führen könnte, dass die aus dem patent stammenden Rechte nicht (voll) ausgeübt werden können je nach diesbezüglicher Rechtslage im jeweiligen Land"); see also, LUZZATTO, "Traditional Knowledge and Patents", pp. 22-23.

on the other side are still the subject of much heated debate. However, a compromise solution might be found in a middle way between these two sets of rights. This will be examined in Part III of this work.

Chapter 2 Incorporating Traditional Medicinal Knowledge into Patentable Inventions

Within the ambit of this research, the relationship between a patented invention and traditional medicinal knowledge can be summarized in the following question: how is traditional medicinal knowledge incorporated into the subject matter of a claimed invention?

The following chapter's intent is to review both the substantive and formal requirements of patentability from the perspective of including traditional medicinal knowledge in the analysis in light of the practical cases studied beforehand. What the following sections will try to demonstrate is how easily a patentable invention can encompass traditional medicinal knowledge developed by others than the patentee. Hence, the purpose is not to enter into broader discussions, such as whether intellectual property rights, generally, and patents in particular, are beneficial or not for human innovation, or whether they are compatible with environmental or development policies.

1 Inventions or Man-Made Living Things *versus* Discoveries

According to Article 27.1 of the TRIPS Agreement, entitled "patentable subject matter," "[...] patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".⁶⁷⁰ In other words, those inventions that fulfil the requirements of Article 27.1 are protectable subject matter. In Europe, Article 52(1) of the European Patent Convention (EPC) has been aligned *verbatim* with Article 27(1) of the TRIPS Agreement after the revised version of the EPC came into effect on December 2007.⁶⁷¹

The new wording of Article 52(1) of the European Patent Convention indicates that patent protection is reserved for innovations in the 'technical' field. This means that the subject

⁶⁷⁰ TRIPS Agreement, Article 27(1).

⁶⁷¹ Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000, OJ EPO 2001, Special edition No. 4, p.55 and OJ EPO 2007, Special edition No. 4, synoptic presentation, p. 48 ("Article 52(1) of EPC has been brought into line with Article 27(1), first sentence, of the TRIPS Agreement with a view to enshrining the word 'technology' in the basic provision of substantive European patent law, clearly defining the scope of the EPC, and making it plain that patent protection is available to technical inventions of all kinds").

matter claimed must involve a ‘technical teaching,’ i.e. an instruction addressed to a skilled person as to how to solve a particular technical problem using particular technical means.

Article 52(2) EPC further clarifies what an invention is, by non-exhaustively listing what shall not be considered as being an invention, with the meaning of paragraph 1.⁶⁷² These non-patentable subject matters are amongst others, “discoveries, scientific theories and mathematical methods.”⁶⁷³ This implies that there is a difference between inventions and other subject matters that do not qualify as such.⁶⁷⁴

An invention is defined to be a technical solution in response to a technical problem as opposed to a discovery.⁶⁷⁵ In Europe, in the consideration of whether the subject-matter of an application is an invention within the meaning of Article 52(1) EPC, the examiner will proceed in two stages. First, he will examine whether the subject matter of the claim falls under the patentability exclusions set forth in Article 52(2) EPC, as listed above. Second, he will examine whether the claimed subject matter has a technical character. In contrast to European patent law, the Patent Act in the United States makes neither reference to technical features underlying the invention nor provides for any patentability exclusions. Section 101 of the US Patent Act defines an invention as an invention or discovery.⁶⁷⁶ However, while

⁶⁷² EPC, Article 52(2); PILA, *The Requirement of an Invention in Patent Law*, 2010, p. 4 (the author notes that most national patent laws have opted not to define the term “invention”. The objective of not defining the term is one of pragmatism. The risk with a definition is that it has great chance to become obsolete and surpassed by the advancement of new techniques. It also excessively limit the judge appreciation, thus preventing the policy-objective of the law that is promoting and boosting the industry).

⁶⁷³ EPC, Article 52(2) (a).

⁶⁷⁴ Article 52(2) of the European Patent Convention expressly stipulates that, inter alia, discoveries shall not be regarded as inventions.

⁶⁷⁵ For instance, the Swiss Patent Act does not define the term “invention”. See ATF 98 Ib 396 c.3, JdT 1973 I 527 (the Swiss case law has provided the following definition, in line with the EPC: “*l’invention n’est ni la force naturelle comme telle, ni le produit de son utilisation. C’est la règle abstraite dont la répétition conduit à un résultat technique détermine, susceptible d’application industrielle. Elle indique comment maîtriser les forces de la nature pour les soumettre à l’homme. N’appartiennent pas à la technique et ne constituent dès lors pas des inventions au sens de la loi des instructions qui prescrivent à l’homme un certain comportement et produisent un résultat détermine, sans intervention directe des forces de la nature.*”

⁶⁷⁶ US Patent Law, U.S.C. Title 35, § 101 (the provision titled “inventions patentable” stipulates the following: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of

discoveries are patentable subject matters, the Supreme Court of the USA has held that only natural products that are the result of human ingenuity can be patentable.⁶⁷⁷

Similarly in Europe, products that occur in nature, also referred to as “naturally occurring subject matter” will not fall within the ambit of protection of a patent because they are not the result of any human intellectual activity in the form of new knowledge of a technical nature. Another distinction commonly accepted in Europe is that an invention implies an applied knowledge where a discovery is a pure knowledge. However, it is important to note that it would not be correct to categorically separate the two concepts that are interrelated because, for instance, the notion of invention encompasses the knowledge acquired through a discovery.⁶⁷⁸

In other words, one should distinguish between materials discovered in nature and material discovered in nature that is made available in a usable form, which involves processing the material so as to involve some technical effects. An invention is a technical solution in response to a technical problem (“technical effect”) as opposed to a discovery.⁶⁷⁹ This definition of the term invention is nowadays generally accepted by all member parties to the European Patent Convention (EPC).

Practically, products of nature include any biological resources or any natural substances occurring naturally, such as wild plants or uncultivated plants, microorganisms⁶⁸⁰ and the substances derived from them. It is not the discovery by itself, be it through bioprospecting or pure hazard, of previously unknown compounds that will render patentability possible. However, the discovery of an unknown compounds, substance or biological resource would

matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title”).

⁶⁷⁷ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), Supreme Court of the United States, 16 June 1980, 100 Supreme Court 2208.

⁶⁷⁸ SPOENDIN, “Erfindung und Entdeckung”, 1988, p. 35 (UNINE A 15.1 g PATE 1988).

⁶⁷⁹ TROLLER, *Précis du droit suisse des biens immatériels*, 2006, p. 150 (“une invention est une règle contenant une information adressée à l’esprit humain pour attirer son attention sur une certaine causalité, entraînant qu’une certaine manière de faire ou l’emploi d’un certain produit aboutit à certains effets”).

⁶⁸⁰ The concept of microorganism is understood broadly by the EPO Board of Appeal. See, EPO Boards of Appeal, T 0356/93 – *Plant Genetic Systems v. Greenpeace*, 21 February 1995, p. 2 (“[t]he term ‘micro-organism’ includes plasmids, viruses and all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory”).

allow further research and development that will result in an invention that could be claimed as distinct from a product of nature.⁶⁸¹

The distinction between the concepts of inventions and discoveries or products of nature has become more challenging with the emergence of biotechnologies⁶⁸². While, neither the TRIPS Agreement nor the CBE have defined the term “invention”,⁶⁸³ it has been clarified through case law and legal literature.⁶⁸⁴ In 1969, the German Federal Supreme Court decision in the case “Rote Taube” defined the term invention as requiring a technical teaching, which in turn was characterised as “a teaching to methodically utilise controllable natural forces to achieve a causal, perceivable result”.⁶⁸⁵ This German case law sets a standard with regard the concept of invention that is still of relevance today. A further important decision has been rendered by the United States Supreme Court as regard to the patentability of living organism. The relevant consideration being that the invention was patentable because it was the product of human intervention.⁶⁸⁶ Thus, the distinction is not between living organism and non-living matters, but between products of nature with or without human intervention. Nevertheless, with the advancement of new techniques in biotechnology, it will become more complex to determine where discoveries end and where inventions begin. This issue will be resolved on a case by case basis though patent office’s practices and judicial decisions.

Along the same lines, Article 3(2) of the European Directive 98/44/EC on the legal protection of biotechnological inventions (Directive 98/44/EC)⁶⁸⁷ clearly authorises the patentability of

⁶⁸¹ BOZICEVIC Karl, “Distinguishing Products of Nature from Products Derived from Nature”, *Journal of the Patent and Trademark Office Society*, 1997, vol. 69, pp. 415-426, p. 421.

⁶⁸² European IPR Helpdesk, “Fact Sheet: Intellectual Property in Biotechnology”, June 2014, p. 1, available at: <https://www.iprhelpdesk.eu/> [accessed September 2016].

⁶⁸³ TVEDT, “One Worldwide Patent System: What’s in it for developing Countries?”, 2010, p. 285 (the author argues that one of the reason that “makes the patent system an extremely dynamic legal system under which the various patent offices have considerable discretion” is the direct consequence of not having defined the term “invention”).

⁶⁸⁴ CORNISH et al., *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 2013, paras. 5-52 ff.

⁶⁸⁵ Decision of the German Federal Court of Justice – *Rote Taube*, BGH 27.3.1069, X ZB 15/67, point 3 of the Reasons.

⁶⁸⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁶⁸⁷ Directive 98/44/EC of the European Parliament and of the Council of the 6 July 1998 on the Legal Protection of Biotechnological Inventions, (1988) OJ L 213, 13-21 (Directive 98/44/EC).

biological material even though it exists in nature with the same characteristics. The novelty criteria is fulfilled because the “biological material has been isolated from its natural environment in a purified form or produced by means of a technical process”. According to Rule 26 of the Implementing Regulations to the EPC 2000, “Biotechnological inventions are inventions which concern a product consisting of or containing biological material or a process by means of which biological is produced, processed or used”.

To illustrate the distinction between a discovery and an invention, the example often used is the discovery of a novel microorganism that is found to have the capability to produce antibiotics. The unknown microorganism by *itself* is not patentable. However, if the same microorganism is given a function, namely antibiotic properties, then it becomes a patentable invention. This example shows how thin the frontier between a discovery and an invention is. In this case, the human intervention consists of giving a function to a discovered natural product. This is what traditional medicinal knowledge is: knowledge about the therapeutic properties of a given plant. However, this knowledge is not patentable because it does not fit into mainstream language deemed to be scientific. In short, it does not fulfil the scientific language criteria. In the field of chemistry, while the discovery of a substance existing in nature is a discovery, the description of the chemical formula of the same substance found in nature becomes an invention.⁶⁸⁸

In the field of pharmaceutical research, great quantities of chemicals have been extracted from products of nature⁶⁸⁹, including plants. This is mainly due to the fact that natural products provide unlimited opportunities for new drug discoveries because of the unmatched availability of chemical diversity. The majority of these extractions have been possible because of the knowledge a given indigenous community had on the therapeutic property of a given plant.⁶⁹⁰ While a plant that is known by indigenous communities to have some therapeutic effect and is used by them will not be patentable, once the active chemical principle in the plant is isolated from its natural environment,⁶⁹¹ the product will become

⁶⁸⁸ EU Directive 98/44, Article 5(2).

⁶⁸⁹ The terms “products of nature”, naturally occurring substance, natural substance are used in a synonymous way.

⁶⁹⁰ See generally, FARNSWORTH and FABRICANT, “The Value of Plants Used in Traditional Medicine for Drug Discovery”, 2001, pp. 69-75.

⁶⁹¹ SASIDHARAN et al., “Extraction, Isolation and Characterization of Bioactive Compounds from Plants’ Extracts”, 2011, p. 1 (“The premier steps to utilize the biologically active compound from plant resources

patentable provided the patentability requirements are met.⁶⁹² Thus, the extent to which products found in nature can be patented is particularly important for traditional medicinal knowledge since, as mentioned earlier, traditional medicinal knowledge mainly relies on substances found in nature.⁶⁹³

In conclusion, the result obtained from the isolation of a plant's active principle becomes an invention as opposed to a discovery, irrespective of whether the invention claims the same subject matter of traditional medicinal knowledge. This does not mean that the invention is patentable. It needs to be demonstrated that the invention is novel and inventive or non-obvious.

2 **“*Ordre Public* and Morality” as an Exception to Patentability**

While Article 27.1 of TRIPS requires that patents be granted for both processes and products in all fields of technology, it permits, under paragraph 2 the exclusion of certain subject matters in national laws. According to Article 27.2, “members may exclude from patentability inventions the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law”.⁶⁹⁴ Similarly, Articles 53(a) of the European Patent Convention⁶⁹⁵ and 6(a) of the EU Directive on Biotechnology provide that “inventions shall

are extraction, pharmacological screening, isolation and characterization of bioactive compound, toxicological evaluation and clinical evaluation. Extraction is the fundamental first step in the analysis of medicinal plants, because it is necessary to extract the desired chemical components from the plant materials for further separation and characterization. The basic operation encompasses steps, such as pre-washing, drying of plant materials, and grinding in order to obtain a homogenous sample.”)

⁶⁹² Directive 98/44/EC, Article 27(a) (“Biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature”); see also EBERMANN, *Patents as Protection of Traditional Medicinal Knowledge? A Law and Economic Analysis*, 2012, p. 101.

⁶⁹³ CRESPI Stephen, “Inventiveness in Biological Chemistry: An International Perspective”, *Journal of the Patent and Trademark Office Society*, 1991, vol. 73(5), pp. 351-370, p. 355.

⁶⁹⁴ TRIPS Agreement, Article 27(2); Directive 98/44/EC, Article 9; similarly, EPC, Article 53(a) states that “European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to *ordre public* or morality; such 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; [...]”.

⁶⁹⁵ EPC, Article 53(a).

be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality”.⁶⁹⁶

Article 6 of the European Union Biotechnology Directive complements Article 53(a) of the EPC by further detailing a non-exclusive list of subject matters that would be contrary to morality and *ordre public*. This list includes processes for cloning humans, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, processes for modifying the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit to mankind or animals.⁶⁹⁷

The link between patentable subject matter and morality is a controversial one today, and there is no reason this situation will change in the future with the rapid growth of new technologies embracing every aspect of our lives. Nowadays, two trends can be distinguished in the discourse related to patents and morality.

According to some, morality and the validity of patents are two separate discussions and should not engage with each other.⁶⁹⁸ It is also generally asserted that patents are property titles in creations of the human mind, and shall stay neutral in this sense. This approach is based on two arguments. First, it is argued that a patent does not provide a positive right to commercially exploit the invention, but is merely a negative right to exclude others from using the invention.⁶⁹⁹ Second, it is asserted that the fact of not granting a patent will not

⁶⁹⁶ Directive 98/44/EC, Article 6(a).

⁶⁹⁷ Directive 98/44/EC, Article 6(a).

⁶⁹⁸ MIN Yan, “Morality: An Equivocal Area in the Patent System”, *European Intellectual Property Review*, 2012, vol. 34(4), pp. 261-265; see also, LAURIE Graeme, “Patenting Stem Cells of Human Origins”, *European Intellectual Property Review*, 2004, vol. 26(2), pp. 65-66.

⁶⁹⁹ EU Directive 98/44/EC, Recital 14; see also, WTO, ‘European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs’, complaint by the United States, Report of the Panel, 15 March 2015, WT/DS174/R, para. 7.210 (The Panel intends to provide an explanation as to question why there is no need for a general exception for public interest within the TRIPS. “These principles reflect the fact that the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public

prevent the applicant or others from working on or exploiting the product or process that is morally reprehensible. In Carvalho's words, "if these ideas are bad, the blame should be put on the ideas themselves and the use made of them, not on patents."⁷⁰⁰

For others, patent offices and courts should take into consideration ethical and moral issues⁷⁰¹ before granting patents to inventions.⁷⁰² This approach considers that property rights, generally, and intellectual property rights, particularly, should be shaped so as to promote the achievement of a just and comprehensive culture that calls all actors and branches of society to move together forward towards an attractive society beyond the idea of "social welfare" prescribed, for instance, by the utilitarian approach. For instance, in its report on the patentability of human stem cells, the European Group on Ethics considers that "there may be also a need to make ethical evaluations in the course of the examination of patent applications involving specific ethical dimensions."⁷⁰³ It is argued that with the advancement of new technologies in the living realm, ethical considerations should be incorporated into the decision-making process for research and technological developments.

policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement").

⁷⁰⁰ CARVALHO, *The Trips Regime of Patents and Test Data*, Wolters Kluwer, 2014, Article 27, pp. 310 ff. (who nevertheless, considers that "some inventions are so repugnant to the social beliefs of a given community that in general they are viewed as not deserving any sort of public appraisal by state agencies [...] – such as cloned human cells or devices expressly conceived to facilitate euthanasia").

⁷⁰¹ The terms "morality" and "ethics" are often use interchangeable as both relate, in broad terms, to customs and behaviours, see BAGLEY, "The New Invention Creation Activity Boundary in Patent Law", 2009, p. 598.

⁷⁰² BONADIO, "Patents and Morality in Europe", 2015, pp. 151 and 152; SAMPSON, "Achieving Ethically Acceptable Biotechnology Patents: A Lesson from the Clinical Trials Directive?", 2003, p. 419; FISHER, "Theories of Intellectual Property", 2001, p. 6.

⁷⁰³ European Group on Ethics in Science and New Technologies to the European Commission, Opinion on the ethical aspects of patenting inventions involving human stem cells, Opinion No.16, Brussels, 7 May 2002, IP/02/675, p. 97; see also DRAHOS, "Biotechnology Patents, Markets and Morality", 1999, p. 441 (The author states: "[I]ike it or not, the creation, operation and interpretation of the patent system is linked to moral standards. Patent law is located within and not outside a public ethic of community values and shared economic and social interests"); and for an overview of the issue concerning morality in the US patent system, see BAGLEY, "The New Invention Creation Activity Boundary in Patent Law", 2009, pp. 577-608.

Morality refers to “the degree of conformity to moral principles”.⁷⁰⁴ The notion of “morality” “is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong ... [This belief] is based on the firm belief founded on the totality of the accepted norms which are deeply rooted in a particular culture”⁷⁰⁵. Furthermore, the concept is not static because moral principles are related to the values prevailing in a given society at a given time.⁷⁰⁶ In turn, “*ordre public*” broadly refers to a notion of security, be it collective or individual. But it goes beyond that.⁷⁰⁷ In general, it corresponds to the fundamental values that a society has embraced at a certain point of time. It derives from French law. Indeed, the original French term is used in TRIPS because it is not an easy notion to translate into English. It suggests concerns about issues menacing the social structures which tie a society together, i.e., issues that threaten the fundamental structure of civil society. For instance, in contract law, freedom of individuals to contract is limited by the concept of *ordre public*, public policy or in the interest of society.⁷⁰⁸ In April 2005, the Appellate Body of the World Trade Organization (WTO) interpreted the concept of “public morals” provided for in Article XIV(a) of the General Agreement on Trade in Services (GATS).⁷⁰⁹ The Panel⁷¹⁰ Report stated that “public morals” denotes “standards of right and wrong conduct maintained by or on behalf of a community or nation”. The Panel further mentioned that the term “public order” involves the preservation of the fundamental interests of a given society, as reflected in public policy and laws.

While Article 27.2 of TRIPS lists certain subject-matters that may be excluded from patentability, a careful reading suggests that the exclusions are not exhaustively limited to

⁷⁰⁴ Concise Oxford Dictionary, 8th edition, 2004.

⁷⁰⁵ EPO Boards of Appeal, T 0356/93 – *Plant Genetic Systems v. Greenpeace*, 21 February 1995, p. 95.

⁷⁰⁶ CARVALHO, *The Trips Regime of Patents and Test Data*, 2014, at Article 27, p. 312.

⁷⁰⁷ EPO Boards of Appeal, T 0356/93 – *Plant Genetic Systems v. Greenpeace*, 21 February 1995, p. 95.

⁷⁰⁸ GERVAIS, *The TRIPS Agreement: Drafting History and Analysis*, 2012, p. 149.

⁷⁰⁹ WTO, ‘US-Measures Affecting the Cross-Border Supply of Gambling and Betting Services’, Panel Report, circulated 10 November 2004, WT/DS285/R, Appellate Body Report, circulated 7 April 2005, WT/DS285/AB/R (in this case, the Appellate Body affirmed that U.S. laws prohibiting the cross-border provision of Internet gambling services, alleged by the United States to be necessary to protect U.S. public morals, were inconsistent with U.S. obligations under GATS).

⁷¹⁰ In the WTO dispute settlement procedure, an independent body is established by the Dispute Settlement body, consisting of three experts, to examine and issue recommendations on a particular dispute in the light of WTO provisions, see WTO glossary terms, at: www.wto.org.

inventions contrary to human, animal or plant life or health and environmental issues.⁷¹¹ However, in accordance with Article 27.2, exclusion from patentability is subject to one important condition.⁷¹² The non-granting of a patent may only be permitted if the commercial exploitation of the invention needs to be prevented to protect higher interests. In other words, invention may not be patentable if its commercial exploitation⁷¹³ is commonly believed to be against the principles of morality or *ordre public*.

For the European Patent Office (EPO), each case involving morality must be considered on its individual merits. Thus, one standard applied by the European Patent Office (EPO) 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.⁷¹⁴ Another method used by the EPO consists of balancing the interests at stake (the utilitarian balancing test) such as used in a case related to a patent on a genetically modified mouse (the so-called “Harvard mouse” or “Onco-mouse”).⁷¹⁵

The EPO has also rendered some rare decisions on the basis of Article 53(a) of the European Patent Convention, and in one particular case, has expounded on the concept of morality. According to the Technical Board of Appeal, “the concept of morality [is] related to the belief that some behaviour [is] right and acceptable whereas other behaviour [is] wrong, this belief being founded on the totality of the accepted norms which [are] deeply rooted in a particular

⁷¹¹ GERVAIS, *L'Accord sur les ADPIC*, 2010, p. 340.

⁷¹² CARVALHO, *The Trips Regime of Patents and Test Data*, 2014, Article 27, p. 317; TAUBMAN et al., *A Handbook on the WTO TRIPS Agreement*, 2012, p. 102.

⁷¹³ GORLIN Jacques, *An Analysis of the Pharmaceutical-Related Provisions of the WTO TRIPS Agreement*, IP Institute, London, 1999, pp. 17-18 (explaining that the term commercial exploitation does not include research).

⁷¹⁴ EPO Guidelines, Patent Examination, Part G, chapter IV, § 4.1.

⁷¹⁵ EPO Technical Board of Appeal, T 315/03 – *Onco-Mouse v. Harvard*, 6 July 2004, p. 97 (The Board confirmed the balancing test suggested by the Technical Board of Appeal) ; EPO Technical Board of Appeal, T0019/90 – *Onco-Mouse v. Harvard*, 3 October 1990, OJ 1990, 476 (the Court decided in this case that the advantages for discovering new therapies against human diseases exceeded its disadvantages, namely eventual environmental risks and the animals suffering); however, see the first decision related the *Onco-mouse*, Decision of the Examining Division, 14 July 1989, *Onco-mouse v. Harvard*, Official Journal of the European Patent Office, 1989, p. 451 (the patent was rejected for not meeting the patentability requirements, but not for morality reasons. The Division “concluded that the patent law was not the right legislative tool for resolving the potential problems”).

culture.⁷¹⁶ For the purposes of the EPC, the culture in question [is] the culture inherent in European society and civilisation. Accordingly, inventions the exploitation of which [is] not in conformity with the conventionally accepted standards of conduct pertaining to this culture [are] to be excluded from patentability as being contrary to morality.”⁷¹⁷

The case analysis and literature suggests that instead of invalidating a patent or not granting it, the EPO rather permits the grant of patent whilst requiring some modification to the subject matter of claims. EPO has very recently granted a European Patent to Monsanto Invest B.V. on a melon plant resistant to a specific virus.⁷¹⁸ Two oppositions were filed against the patent, one being based on the lack of novelty and inventive step, filed by Bayer Crop-Science, and the other based on, amongst others, Article 53(a) by a coalition of NGO’s.⁷¹⁹ In January 2016, the EPO revoked the patent for technical reasons, namely that the subject matter claimed in the patent was insufficiently disclosed, as no biological material had been deposited. In its decision, the EPO confirmed that the “EPC explicitly allows for the patenting of plants”, if the invention is not limited to a variety. No barrier to patenting due to moral reasons can be derived from the simple fact that the patented material will be limited in access, which is the very purpose of a patent.⁷²⁰

The issue of the morality of patents calls for two fundamental remarks. First, the EPO has very rarely rendered a decision on the basis of *ordre public* and morality, and it is doubtful that this will change in the future.⁷²¹ Second, and this is probably the reason for the first

⁷¹⁶ See EPO Opposition Division – *Pelargonium*, 20 April 2010, Res. 4.1.3 (where the Board considered that the invention claimed in the patent was not contrary to the generally accepted norms of behaviour accepted by European Culture circle).

⁷¹⁷ EPO Boards of Appeal, T 0356/93 – *Plant Genetic Systems v. Greenpeace*, 21 February 1995, Reasons paras. 5 and 6 (The EPO Technical Board of Appeal delineated on the meaning and application of the morality provisions).

⁷¹⁸ EP 1962578 – Closterovirus-Resistant Melon Plants, granted 3 September 2008, available at: <https://register.epo.org/application?number=EP06835672> [accessed September 2016].

⁷¹⁹ All documents regarding the proceeding, including the opposition, are available at : <https://register.epo.org/application?number=EP06835672&lng=fr&tab=doclist> [accessed September 2016].

⁷²⁰ EPO Opposition Division – Melon Plants, 24 February 2016, Reason 4.3 of the grounds for the decision of the Opposition Division (the opposition division clearly states that the “Nagoya Protocol [...] mentions patents or foresees a role for the patent offices”).

⁷²¹ See for example, DOLDER, “Analysis of the European Patent Law – Traditional knowledge and patenting: the experience of the neemfungicide and the hoodia case”, 2007, p. 588.

remark, there is no common principle of morality, not even in the European Community in the field of biotechnology matters.⁷²² This argument may be valid in the area of biotechnologies, such as questions related to the use of embryos in research. In these cases, even when some activities are permitted by laws, there is a varying degree of a feeling of “immorality” even in neighbouring countries. In contrast, theft is both illegal and immoral in every single country and culture.

These two remarks result in a question of particular interest in the present study. Does “public order” or morality serve as an argument for opposing a patent that is based on traditional knowledge? For instance, the argument would be that these principles should proscribe the granting of patents or revoke a patent based on traditional knowledge. The answer to this question is not straightforward.

For example would it be possible to argue that when the subject matter of a claim is based on traditional medicinal knowledge, this shall be deemed to be contrary to morality or *ordre public*? The following two hypotheses are given:

- A. The claimed invention is equal to the medicinal properties for which the plant is used in traditional knowledge. For instance, the neem tree case or the isolation of an active principle but with same properties or use.
- B. Traditional medicinal knowledge is used as the entry point to the plant for which other properties are discovered by researchers. In other words, the invention is based on traditional medicinal knowledge. The invention presents an inventive step compared to the specific traditional medicinal knowledge.

Hypothesis A may be viewed as going against the principle of morality. The claim of an invention that is directly based on traditional knowledge is a copy of traditional medicinal knowledge. Patents are designed to reward truly innovative activities. Thus, even though these kinds of inventions should normally be defeated because they do not fulfil the patentability criteria, they would no less be seen as immoral. Because law and morality are very much connected, many illegal activities are seen as a subset of immoral behaviour.⁷²³ The activity of “inventing around traditional medicinal knowledge” could be seen as free-riding or theft in

⁷²² See TORREMANS, “The Construction of the Directive’s Moral Exclusions under the EPC”, 2009, p. 161.

⁷²³ BAGLEY, “The New Invention Creation Activity Boundary in Patent Law”, 2009, p. 591.

the most strict argument.⁷²⁴ In these situations, it can be presumed that the inventors knew about the properties of the plant because it had been previously disclosed (for instance in codified traditional knowledge, such as the Unani or Ayurvedic traditional knowledge) or had been obtained in breach of confidence when traditional medicinal knowledge was held in the community. In both cases, this creative activity is against morality according to fundamental values of our society on which the same intellectual property system is based. However, the recent decision of the EPO opposition division does not go in that direction. The opposition division concluded that “the patenting of plants, even if the traits were isolated from publicly available sources remains compatible with morality and *ordre public*”.⁷²⁵

Hypothesis B, where the invention is inventive beyond the specific traditional medicinal knowledge, the question that should be asked is whether the invention would have taken place without the traditional medicinal knowledge. If the answer is no, there may be place for moral considerations, as in that case, it can be argued that the invention is directly based on traditional medicinal knowledge. In that case, an ethical behaviour would consist in not only acknowledging the source of the patented invention but also in asking for authorisation of use.⁷²⁶ The same behaviour is suggested in the same patent system in relation to dependent patents.

In both hypotheses, traditional medicinal knowledge has been used without asking the permission (prior informed consent) of the holders of the knowledge, i.e. a case of wilful omission. We suppose that, normally, when prior informed consent has been obtained, a benefit-sharing agreement will also be settled, or at least a promise of contracting with a view towards benefit-sharing. Hence, where the patent applicant does not comply with prior informed consent and benefit-sharing principles, as enshrined in the CBD and the Nagoya

⁷²⁴ See however, CARVALHO, “Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution”, 2000, p. 379 (the author argues that “the situation that arises from an invention derived from the use of genetic resources that have been illegally extracted from their *in situ* environment is similar to the situation of an invention that has been developed with the assistance of a stolen microscope. This situation would infringe the common law but not the patent law).

⁷²⁵ EPO Opposition Division – Melon Plants, 24 February 2016, point 4.3 of the grounds for decision.

⁷²⁶ See generally, CARVALHO, “Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution”, 2000, pp. 371-395.

Protocol, the answer could also be yes. In other words, the performing of the invention, involving the utilisation or extraction of traditional medicinal knowledge without prior informed consent could be regarded as contravening morality.⁷²⁷ Hence, it can be argued that the prior informed consent provisions of the CBD and the Nagoya Protocol are also the result of moral considerations.

Consequently, the question of morality may be raised both within the patent system and outside the patent system. These two hypotheses could be included in the broader definition given to biopiracy or misappropriation. With the entry into force of the Nagoya Protocol, member states are obliged to implement the provisions of the Protocol into their national legislation.⁷²⁸ Here, beyond the question of morality, there is the issue of patents that are based on illegal activities. The question has also given rise to controversies among authors.⁷²⁹ Thus, in the case of patents using traditional knowledge, if the activity is immoral is it also illegal or vice-versa? The counter-arguments are mainly twofold. Firstly, as argued by the EPO Division with regard to the patented melon, as there is no relationship between requirements in the Nagoya Protocol and those in the TRIPS Agreement, the patent is neither illegal nor immoral. Secondly, the patenting is not illegal because traditional knowledge is in the public domain. Indeed, indigenous peoples or the holders of this traditional knowledge have no property titles that may legitimate their ownership rights. The contentious relationship between public domain and traditional knowledge will be further analysed in Chapter 3.

⁷²⁷ BAGLEY, “The New Invention Creation Activity Boundary in Patent Law”, 2009, p. 582 (the author noted that “although the questions of the illegality or morality of the *use* of an invention have often come into play throughout history and up to the present time, there appears to be little precedent for considering the acts of *invention creation* in the determination of either patentability or patent enforceability”).

⁷²⁸ See for instance, the New Zealand Patent Act, enacted 13 September 2013, entered into force September 2014, S. 15(3) (NZ Patents Act 2013) (the Patent Act establishes a Maori Advisory Committee to advise the patent office on whether a claimed invention derives from Maori traditional knowledge and, if so, if the commercial exploitation of said invention is likely to be contrary to Maori values); see also Part III, Chapter Three, 3.3.2.

⁷²⁹ For an in-depth discussion of the potential impact of illegal, immoral, or unethical activity in creating inventions on later-obtained patent rights, see BAGLEY, “The New Invention Creation Activity Boundary in Patent Law”, 2009, p. 577-608.

The difficulty in grasping the link between legality and morality, patents and morality, and traditional knowledge and morality is well described in the statement of a scholar in the field of intellectual property, “Law and morality are connected. There is no disagreement about this claim. [...] the problems arrive when one tries to explain the nature of the connection.”⁷³⁰ Similarly, Hart notes that “between law and morality there is a connection which is in some sense ‘necessary’, and that it is this which deserves to be taken as central, in any attempt to analyse or elucidate the notion of law”.⁷³¹

This difficulty does not mean that patent law considerations should be isolated from or neglect other considerations related to public health, environmental and human rights concerns. Rightly because the patent system increases the incentive to invest in certain areas, so should not evolve in isolation but be guided by these higher concerns.

3 Substantive Requirements for Patentability and Traditional Medicinal Knowledge

This section will analyse the three criteria that have to be fulfilled for an invention to be granted a patent when this invention is based on traditional medicinal knowledge. A special focus will be given to inventions relevant for the drug development industry, including chemical inventions and biotechnological inventions.

The substantive conditions of patentability are articulated in Article 27 of the TRIPS Agreement, which states that a patent is granted for inventions that are either a product or a process, in all fields of technology, provided that: (i) they are new; (ii) involve an inventive step (non-obvious); and (iii) are capable of industrial application (useful).⁷³² The same requirements are set out in the European Patent Convention, in Article 52(1).⁷³³ As far as biotechnological inventions are concerned, the EU Directive 98/44/EC states that “inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing

⁷³⁰ DRAHOS, “Biotechnology Patents, markets and morality”, 1999, p. 441.

⁷³¹ HART, *The Concept of Law*, 1997, p. 155.

⁷³² TRIPS Agreement, Art. 27(1).

⁷³³ Swiss Patent Act, Article 1.

biological material or a process by means of which biological material is produced, processed or used”.⁷³⁴

3.1 Novelty – prior art

Generally speaking, because intellectual property is the information embodied in an invention, in contrast to physical property, this information can be easily and simultaneously used in different markets. Contemporary justifications of intellectual property rights are based on the so-called utilitarian paradigm, which holds that patents boost innovation because of the obligation for the patentee to proceed to the public disclosure of information about the invention.⁷³⁵ The ideal goal of any patent system is thus to strike a balance between the interests of the rights-holders to be granted an exclusive right over their invention and the interests of the society at large is to benefit from the advancement of novel technologies. The interest of the patentee is to recover the investment made in the development of their invention and the interest of the society at large to benefit from the dissemination of the technological information the patentee has disclosed. In other words, the public disclosure stimulates technological progress, which in turn promotes the economic growth.

While “new” is not defined in the TRIPS Agreement, it is understood in many jurisdictions to mean that “the claimed inventions show a new characteristic which has not already been disclosed to the public before the relevant date in the body of the existing knowledge in its technical field (called “prior art” or “state of the art”)”.⁷³⁶ For a claimed invention to be deemed novel, it is enough if it encompasses at least one essential technical features distinguishing it from the prior art.⁷³⁷ This condition is in conformity with the already mentioned fundamental principle of patent law that justifies the monopoly position held by the rights-holders in exchange for disclosure. Indeed, if a patent is granted for something that is not new, the rights-holders would be receiving compensation for no development on their side that is deemed to benefit the society.

⁷³⁴ EU Directive 98/44, Article 3(1).

⁷³⁵ See Part I, Chapter 3, 2.1.2 on the “Justification for Patent Protection”; see also generally, MAY, *The Global Political Economy of Intellectual Property Rights: The New Enclosures*, 2010.

⁷³⁶ TAUBMAN et al., *A Handbook on the WTO TRIPS Agreement*, 2012.p. 98.

⁷³⁷ EPO Enlarged Board of Appeal, G 2/88 – *Mobil Oil v. Chevron Research*, 11 December 1989, Reason 7, p. 19.

Because the concept of novelty, as is the case for the other criteria of patentability, is not delimited in the TRIPS Agreement, it is approached differently in different jurisdictions. For instance, the European Patent Convention and the national patent laws of EPC member states apply the “absolute novelty” principle as opposed to the “relative novelty” or “mixed novelty” principle prescribed in the US patent Act before the enactment of the latest amendments to the Patent Act (the Leahy-Smith America Invents Act).⁷³⁸ The following paragraphs will elaborate on the absolute novelty criteria and only briefly discuss the relative novelty criteria as, with the recent amendment of the US Patent Law, the general trend seems to be the adoption of the absolute novelty criteria. They will also describe the concept of “availability” as it becomes particularly important with regard to the issue of traditional medicinal knowledge.

Article 54(1) EPC states that “an invention shall be considered to be new if it does not form part of the state of the art”.⁷³⁹ It further states that “the state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application”.⁷⁴⁰ In other words, prior use of an invention anywhere in the world, by any means will invalidate the European patent application or any national patent application in conformity with the EPC. In addition, as opposed to the assessment of inventiveness, in considering novelty it is not possible to combine separate items of prior art together.⁷⁴¹

In contrast, in the case of relative novelty, the state of the art is delimited by the geographical delimitation of the country. In other words, it is only local knowledge that will destroy the novelty.

⁷³⁸ Leahy-Smith America Invents Act, § 3(o), Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended at 35 U.S.C. § 102) (Leahy-Smith America Invents Act or AIA).

⁷³⁹ EPC, Art. 54(1).

⁷⁴⁰ EPC, Article 54(2).

⁷⁴¹ EPO Technical Board of Appeal, T 305/87 – GREHAL v. Diener, 1 September 1989, Reason 5.3, p. 10 (“[Q]uand le contenu d'un document antérieur unique [...] est considéré isolément pour attaquer la nouveauté d'une revendication, ledit contenu ne doit pas être assimilé à un réservoir dans lequel il serait permis de puiser des caractéristiques appartenant à des modes de réalisation distincts pour créer artificiellement un mode de réalisation particulier qui détruirait la nouveauté, à moins que le document lui-même ne suggère une telle combinaison. [...] il ne suffit pas de se limiter globalement au contenu d'un unique document, encore faut-il considérer isolément chaque entité décrite dans ce document”).

Prior to the 2013 amendments, US law applied the mixed-novelty test according to which the application for a later patent will be rendered invalid if there is a *written* publication anywhere in the world.⁷⁴² In addition, mere prior use or oral publication had to take place within the country for the later invention to be held invalid. This geographical delimitation was statutorily codified in 35 US Code § 102. In other words, only foreign written forms of prior art, including publications and patents were deemed to destroy novelty in the US. The 2011 patent reform bill, known as the Leahy-Smith America Invents Act, has introduced some modifications to the patent law, amongst them, the scope and definition of prior art has been broadened. The new bill substitutes the above-mentioned Section 102 with a provision that expands the scope of the prior art.⁷⁴³ Accordingly, a claimed invention is not deemed to be novel if “patented”, “described in a printed publication”, “in public use” or “on sale”. It further adds a broad but undefined category of prior art that refers to inventions being “otherwise available to the public”. The changes concerning the newly defined prior art entered into force in March 2013. All the applications that have been filed before the entering into force of the new provision will be subjected to the late definition of the prior art.⁷⁴⁴

The absolute novelty principle strengthens the objectiveness of the assessment of novelty. Indeed under it, the state of the art is objectively determined independent of territorial, temporal and means of transmission considerations. Similarly, it is irrelevant to ask whether the inventor was aware of a pertinent prior art at the time of the invention. This is particularly relevant with regard to traditional medicinal knowledge when it is considered as an anticipatory prior art. As traditional medicinal knowledge, as described in this work, is rarely in a written form, countries that align the standards of novelty with the absolute novelty principle contribute to some extent to the reduction of its misappropriation.

⁷⁴² Before the amendments to the US Patent Act, foreign disclosure would only be accepted as a prior art in the US if occurred in a written form. Thus, the relative novelty approach has been eliminated as from 16 March 2013; For an extensive analysis of the prior art in the United States, see BAGLEY, “Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World”, 2003, p. 683 (questioning the constitutionality of statutory provisions that requires classification of information as relevant or non-relevant based on its geographical origin).

⁷⁴³ The Leahy-Smith America Invents Act amends 35 U.S.C. § 102 under new §§ 102(a) and 102(b). Section 102(a)(1) now states that “a person shall receive a patent unless . . . the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention”).

⁷⁴⁴ JANICKE, “A Commentary on the New Patent Law of the United States”, 2011, pages 887-894.

As far as the concept of “availability” is concerned, Article 54(2) EPC states that information available to the public corresponds to any information irrespective of the means of transmission, be it written or oral transmission. “Available to the public” means that at least one member of the public has had access to the information before the filing date of the application, and this person was not bound to secrecy or confidentiality.⁷⁴⁵ The question whether or not a member of the public has actually accessed the information is irrelevant. There is even no need to show that this member of the public has actually accessed the information.⁷⁴⁶

Traditional medicinal knowledge of indigenous communities is rarely in a published form as opposed to Chinese, Indian and Unani traditional medicine that are also traditional but formal in the sense that they are richly documented. Thus, even though oral traditional knowledge can be an invalidating prior art for the claimed invention, it seems unlikely that it be taken into account by patent examiners and judicial authorities. This is mainly because these fora will not assume that some traditional knowledge is involved, or the invention claims the exact same subject matter as the traditional knowledge but expressed in patent jargon.⁷⁴⁷ Whether oral testimony provided by a representative of the traditional community would suffice to anticipate the claimed invention, the question remains open.

⁷⁴⁵ EPO Technical Board of Appeal, T 1081/01 - *New Japan Chemical*, 27 September 2004, point 5 of the Reasons, affirmed by EPO Technical Board of Appeal, T 1309/07 – *Mahle International*, 23 June 2009, point 3.2.1 of the Reasons.

⁷⁴⁶ EPO Technical Board of Appeal, T381/87 – *Research Association*, 10 November 1998, pp. 10-11 (a document available in a library before the filing date of the application is enough to destroy the novelty criteria even if it has been proved that the document has not been subject to no consultation. It is not necessary as a matter of law that any members of the public would have been aware that the document was available upon request on that day, whether by means of an index in the Library or otherwise. It is sufficient if the document was in fact available to the public on that day, whether or not any member of the public actually knew it was available, and whether or not any member of the public actually asked to see it ; see also EPO Technical Board of Appeal, T 84/83 – *Hohe v. Hagus*, 29 September 1983, point 2.4.2 of the Reasons; see also *a contrario* two other decisions: EPO Technical Board of Appeal, T 314/99 – *ExxonMobil v. Fina Research* (“*Diplomarbeit*”), 21 June 2001 and EPO Technical Board of Appeal, T 186/01 – *DeLaval International v. MAASLAND N.V.*, 25 October 2002 (the Board did not accept that a mere theoretical possibility of having access to a means of disclosure rendered it available to the public).

⁷⁴⁷ DUTFIELD, “A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-Based Biopiracy”, 2011, pp. 243-244 (the existence of traditional medicinal knowledge is not discovered in a prior art search).

To be considered as anticipatory prior art, traditional medicinal knowledge should be disclosed whether by the traditional community or by third parties, such as for instance in scientific journals. In the Neem tree case, the Board of Appeal, instead of relying on oral testimonies, rather relied on an article in a scientific periodical recording the traditional knowledge use of the neem tree in India.⁷⁴⁸ Where traditional medicinal knowledge is alleged as a prior public use without written record, the EPO applies strict standards of evidence. In Europe, to obtain the revocation of a patent on the basis of prior use, the review Boards apply two main standards, one being “the balance of probabilities”,⁷⁴⁹ and the other being “beyond reasonable doubt”.⁷⁵⁰ The Board will apply the balance of probabilities standard when both the patent rights-holders and the opponent have access to the material of which public use is alleged. Thus, it must decide what is “more likely than not” to have happened. By contrast, it will apply the second and stricter⁷⁵¹ standard in cases where all evidence of an alleged public prior use lies within the power and knowledge of the opponent, while the patentee has barely any or no access to it at all, and in this case it is incumbent upon the opponent to prove the alleged prior use.⁷⁵² If transposed to the issue of TMK, there are obvious concrete problems. Traditional medicinal knowledge is rarely available in a manner that makes it accessible to a prior art search. As the neem case has shown, even when evidence of prior traditional medicinal knowledge exists, the EPO applies a high standard for proof, namely precise information as to the content and circumstances of the prior disclosure to the public.

⁷⁴⁸ See EPO Technical Board of Appeal, T 0416/01 - *Thermo Trilogy v. Aelvoet*, 8 March 1995, Reasons 4.2.

⁷⁴⁹ see EPO Technical Board of Appeal, T 743/89 – *CIBA-GEIGY v. BORG-WARNER CHEMICALS*, 27 January 1992, p. 6; see also, EPO Technical Board of Appeal, T 804/05 – *DAL v. CREVAN*, 16 October 2007.

⁷⁵⁰ EPO Technical Board of Appeal, T 1140/09, – *Hitachi-Omron v. Gieseck & Devrient*, 18 January 2012; see also EPO Technical Board of Appeal, T 0270/90 – *Asachi v. General Electric*, 21 March 1991, Reasons 2.1 (“As far as each of the parties to the proceedings is concerned, they carry the separate burdens of proof of any fact they allege. The weight of that burden is the balance of probability as distinct from “beyond all reasonable doubt” or “absolute conviction”. In the course of an appeal, therefore, each party must seek to prove facts alleged by it to this degree of proof and, as was said above, it is the function of the Board to decide, applying the same standard, which set of facts is more likely than the other to be true.”)

⁷⁵¹ When applying the standard, the Board’s opinion must amount to a stricter criterion close to the absolute conviction.

⁷⁵² EPO Technical Board of Appeal, T 472/92 – *SEKISUI v. Owens*, 20 November 1996, Reasons 3.1.

The above analysis has demonstrated how the concept of novelty is malleable.⁷⁵³ The requirement of novelty transposed to the problem of protection or misappropriation of traditional knowledge calls for the following remarks. A first remark is that traditional knowledge can be used as a novelty destroying prior art. However, because most national patent offices do not examine novelty at the time the patent has been filed,⁷⁵⁴ any interested party wishing to oppose the patent has to engage in a re-examination procedure only after the patent has been granted.⁷⁵⁵ A solution has been proposed to enhance the efficiency of prior art search with regard to traditional knowledge. It consists of establishing traditional knowledge databases. Part III of this work will discuss the issue of traditional knowledge databases. Secondly, does an invention that claims the exact same therapeutic effect as the traditional medicinal knowledge still pass the test of novelty? The answer is yes. In the neem tree case, the invention was deemed novel because the solvent used for the extraction of the neem oil was not the same as the one used in the document the Board considered as prior art,⁷⁵⁶ even though both the invention and the prior art were directed to the fungicide effect of the neem oil. Here the patent claims the process for obtaining the product. Thus, it seems that traditional medicinal knowledge can only in very rare cases constitute a novelty-destroying prior art in practice. What are other ways to obtain a patent based directly on traditional medicinal knowledge? First, the interested inventor can purify the naturally occurring substance found within the plant and claim a patent on it, as a composition of matter or product. The novelty being that the indigenous groups that have the knowledge on the therapeutic properties of a given plant cannot identify the chemical structure of the active substance. Second, he can claim a new use (the first use being the traditional knowledge on the therapeutic use of the plant) and patent it.⁷⁵⁷

⁷⁵³ See generally, CORREA, *A Guide to Pharmaceutical Patents*, 2012.

⁷⁵⁴ Swiss Patent Act, Article 59(4) (the Article states that “[t]he Institute shall not examine whether the invention is new or whether it is obvious having regard to the state of the art”).

⁷⁵⁵ SMOLCZYNSKI, “Willful Patent Filing: A Criminal Procedure Protecting Traditional Knowledge”, p. 1184.

⁷⁵⁶ EPO Technical Board of Appeal, T 0416/01 – *Thermo Trilogy v. Aelvoet*, 8 March 2005, Reasons 4.3.

⁷⁵⁷ HUFT, “Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights”, 1995, p. 1724; see also CONFORTO, “Traditional and Modern-Day Biopiracy: Redefining the Biopiracy Debate”, 2004, p. 366; CORREA, *A Commentary on the TRIPS Agreement*, 2012, p. 277.

3.2 New Medical Uses⁷⁵⁸ of Known Substances

The distinction between an invention and a substance occurring in nature is also relevant in the patentability of first and second therapeutic uses. For instance, does a mere modification or new use of a substance occurring in nature, make it a patentable subject matter? What does modification mean?

As a first step, the following paragraphs will describe the concepts of first and second therapeutic uses, and distinguish them from the concept of therapeutic and diagnostic methods. As a second step, the link between traditional medicinal knowledge and new medical uses will be described.

Article 27.1 of the TRIPS Agreement does not address the issue of first and second indications. It only obliges Members to grant patents for products and process. Members are thus free to decide whether or not to grant patents to new uses of existing products or processes. At the national level, there is a great disparity between countries as to the patentability of first and second uses.

The question of first and second medical uses⁷⁵⁹ of known substances occurs in the pharmaceutical sector, when, for instance, a new therapeutic use has been discovered for an already known molecule (possibly already in the public domain). They allow the extension of the market exclusivity of a medicament. The strategy is called “life cycle management”, or expressed in depreciatory terms, “evergreening”.⁷⁶⁰

⁷⁵⁸ Second use, second indication shall be deemed synonymous.

⁷⁵⁹ Uses *per se* are patentable if they meet the patentability requirements. Uses are processes if they refer to a series of steps that conduct in a practical result.

⁷⁶⁰ TUOMINEN Nicoleta, “Patenting Strategies of the EU Pharmaceutical Industry – Crossroad between Patent Law and Competition Policy”, Research Papers in Law, College of Europe, 2011, No.1, p. 13 (“Evergreening refers to different ways wherein patent owners take undue advantage of the law and associated regulatory process to extend their IP monopoly particularly over highly lucrative „blockbuster drugs“ by filing disguised/ artful patents on an already patent-protected invention shortly after expiry of the „parent“ patent. These artful patents tend to protect delivery profiles, packaging, derivatives, and isomeric forms, mechanism of action, dosing regimen, and dosing rage, and dosing route, different methods of treatment, combinations, screening methods, biological targets and field of use for the same old molecule”); see also, BANSAL Inderjit Singh, SAHU Deeptymaya, et al., “Evergreening – A Controversial Issue in the Pharma Milieu”, *Journal of International Property Rights*, 2009, vol. 14, p. 299 (“‘Evergreening’ refers to

Let us go back to the principle of patentable inventions that are products or processes. While patents on products cover the product, patents on processes cover the process or methods to perform a product. Patents on products cover all the possible uses of that product, including those that are not yet known at the time the patent was filed. It can be assumed that the rights-holder benefits from an absolute protection. The product is formally claimed as such. For instance, a substance (active principle) can be found to be novel, and it may be patented as such. Let us imagine now that an inventor finds, for the first time, a medicinal use for that same substance. As he will not be able anymore to obtain a product patent, he may attempt to patent the new use of the product as a pharmaceutical. This however is equivalent to a method of treatment that is specifically excluded from patentability by the European Patent Convention.⁷⁶¹

Nevertheless, the European Patent Convention provides that a known substance may be patentable for use in a method of treatment of a human or animal body by surgery or therapy, or in a diagnostic method, provided that its use for any such method is not within the state of the art.⁷⁶² That is the use of the substance has never been associated with medical effects. Thus, the inventor of the first therapeutic use of a known product is able to make a claim on a product but limited to its therapeutic applications, i.e. purpose-limited protection.⁷⁶³ The formulation would be “Product X for use as a medicament.” The condition being that the previous patent on product X has no relation to therapeutic use, for instance X is known as a herbicide. The novelty stems from the fact that its use in medicine was unknown. In this case,

different ways wherein patent owners take undue advantage of the law and associated regulatory process to extend their IP monopoly particularly over highly lucrative „blockbuster drugs“ by filing disguised/ artful patents on an already patent-protected invention shortly after expiry of the „parent“ patent. These artful patents tend to protect delivery profiles, packaging, derivatives, and isomeric forms, mechanism of action, dosing regimen, and dosing rage, and dosing route, different methods of treatment, combinations, screening methods, biological targets and field of use for the same old molecule”).

⁷⁶¹ EPC, Article 53(c); see specifically EPO Enlarged Board of Appeal, G 05/83– *EISAI*, 5 December 1984, para. 13 (“[...] a claim directed to the “use of a substance or composition for the treatment of the human or animal body by therapy” is in no way different in essential content from a claim directed to “a method of treatment of the human or animal body by therapy with the substance or composition”. The difference between the two claims is one of form only and the second form of claim is plainly in conflict with Article 52(4) EPC. Since this is so, no patent can be granted including any such claims”).

⁷⁶² EPC, Article 54(4).

⁷⁶³ EPO Enlarged Board of Appeal, G 02/08 – *Abbott Respiratory*, 19 February 2010.

the owner of the first therapeutic use will have extended rights on all further therapeutic uses of product X even though the claim will describe only one of those uses.⁷⁶⁴ Thus, products encompassed by patents on first therapeutic use are typically chemical substances that have been discovered and synthesized in the previous art, but for which the therapeutic utilisation was unknown. This situation has to be distinguished from the scenario where a new therapeutic use results from the modification of a known drug composition, in which case, a product patent will be granted to the inventor. The invention may consist of, for instance, a modification in the chemical structure of the compound.

Finally, where product X is already patented, the patent on the first medical use will be dependent on the product patent. In that case, the owner of the patent on the first medical use will have to obtain a licence from the owner of the product patent in order to use their invention. In case of refusal, the holder of the patent on the first medical use may request a compulsory licensing if the invention represents an important technical advancement with a considerable economic interest compared to the product patent. Nevertheless, compulsory licenses are rarely used, and this is due to two main reasons. First, inventors will generally enter in contractual agreements. Second, the rights-holders of the product patent and the first medical use patent are very often the same person or entity.

As far as the second pharmaceutical use is concerned, a claim in the form of “Use of product X for the treatment of illness A” would also be equivalent to a method of medical treatment that is specifically excluded from patentability by the European Patent Convention in Article 53(c).⁷⁶⁵ Before its amendment in 2000, the EPC was silent on the issue of second medical

⁷⁶⁴ GRUBB and THOMSEN, *Patents for Chemicals, Pharmaceuticals, and Biotechnology – Fundamentals of Global Law*, 2010, p. 258.

⁷⁶⁵ EPO Enlarged Board of Appeal, G 05/83– *EISAI*, 5 December 1984, para. 12 (“Whilst, therefore, there can be no objection to “use claims” in general, the obvious objection to a patent “with claims directed to the use” being granted for “the use of a substance or composition for the treatment of the human or animal body by therapy” is that it seems to be in direct conflict with the provisions of Article 52(4) EPC (1973), in accordance with which “methods for treatment of the human or animal body by therapy ... shall not be regarded as inventions which are susceptible of industrial application” within the meaning of Article 52(1) EPC.”); and para. 13 (“[...] a claim directed to the “use of a substance or composition for the treatment of the human or animal body by therapy” is in no way different in essential content from a claim directed to “a method of treatment of the human or animal body by therapy with the substance or composition”. The difference between the two claims is one of form only and the second form of claim is plainly in conflict with Article 52(4) EPC. Since this is so, no patent can be granted including any such claims”).

use. In order to overcome the exclusion of Article 53(c), a Swiss made legal fiction had been established⁷⁶⁶ in the form of ‘use of compound X for the *preparation* of an agent for the treatment of disease Y’, the so-called ‘Swiss-Type’ claim.⁷⁶⁷

The relevant decision as to first and second medical indications can be traced back to 1984, when the Enlarged Board of Appeal, in its decision G 5/83, expressly allowed Swiss-Type claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application. It also established in that decision the patentability of second and further therapeutic uses of a known medicament in the broadest sense of the term. The Board considered that the reasons for admitting the first therapeutic indication are valid for further therapeutic indications.⁷⁶⁸ With the revision of the European Patent Convention in 2000, the situation has been simplified and clarified. The purpose-limited protection that was previously allowed only for first therapeutic uses has been extended to second therapeutic uses. In other words, it is acceptable to have a claim in the form “Substance X for use in the treatment of disease A, provided that such a claim fulfils the patentability criteria, namely it involves an inventive step over any prior art disclosing the use of substance X as a medicament. Thus, what is covered by the patent is the “specific use” of

⁷⁶⁶ Swiss Federal Intellectual Property Office, ‘Legal Advice on the Patentability of the Second Medical Use’, 30 May 1984, EPO, OJ 1984, p. 581 (“A claim for the “use of compound X to treat ... (indication) ...” is inadmissible under Swiss Law. Limited claims directed to the “use of a compound ... to produce agents against ...” are admissible even where they relate to a second (or subsequent) medical use of a known medicament. Details concerning the formulation of a medicament (e.g. labelling, packaging or dosage) may be included in a patent application’s description”).

⁷⁶⁷ Since January 2011, the Swiss-Type Claim has been abolished by the Board of Appeal of the European Patent Office. Nevertheless, because of the relative long life of patents, both claim formats will continue to coexist for some time in the future, giving rise to questions of scope. See, EPO Enlarged Board of Appeal, G 02/08 – *Abbott Respiratory*, 19 February 2010 (“where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83”).

⁷⁶⁸ EPO Enlarged Board of Appeal, G 05/83– *EISAI*, 5 December 1984, para. 19 (“As indicated in the Enlarged Board of Appeal’s communication dated 31 July 1984, having regard to the statement of practice of the Swiss Federal Intellectual Property Office, the Enlarged Board has also given careful consideration to the possibility of protecting second (and subsequent) medical indications by means of a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified (new) therapeutic application. Such claims do not conflict with Article 52(4) EPC or Article 57 EPC but there may be a problem concerning the novelty of the invention.”).

the substance, that is, the new therapeutic indication as disclosed by the inventor. As opposed to the patent on the first medical indication, the patent on the new medical indication (second) is limited to a specific therapeutic indication and does not extend to all therapeutic uses.⁷⁶⁹ The “specific use” has been interpreted broadly in the case law of the Boards of Appeal in allowing claims not only directed to the treatment of another disease (disease B), but also with respect to claims drawing their novelty from a method of administration, new dosage regimes or a new class of patients.⁷⁷⁰

The link between new uses of known substances with traditional medicinal knowledge is straightforward:

A discovery in modern science obtained from traditional knowledge of the therapeutic properties of a plant will present the following possibilities. First, the active principle (substance) once purified and isolated may be granted a product patent. Second, the medicinal properties of the plant will be treated as analogous to a first medical use of a known substance. According to the purpose-limited claim, the scope of patent protection will be limited to a particular use of the product, that is, its medical use. Such a claim should cover all therapeutic uses of the substance or compound and not only uses for the specific indication that was disclosed. Third, the substance or compound, known to have one or more pharmaceutical uses, is discovered to have a new therapeutic utility unrelated to any earlier use.

⁷⁶⁹ EPO Enlarged Board of Appeal, G 02/08 – *Abbott Respiratory*, 19 February 2010.

⁷⁷⁰ EPO Technical Board of Appeal, T 1020/03 – *GENENTECH*, 29 October 2004, Reasons 5 and 7 (the Board argued that “a claim directed to the use of a composition for the preparation of a pharmaceutical product is equally clearly directed to an invention which is susceptible of industrial application, within the meaning of Article 57 EPC, and thus, by reason of its subject matter, outside the scope of Article 52(4) EPC first sentence. The Board came to the conclusion that the “‘specified use’ the Enlarged Board of Appeal, in decision G 05/83, required for allowing a second medical use was to be understood “merely by way of contrast to the unspecified therapy allowable in a claim for a first medical use, and not as imposing any special conditions that a further medical use had to fulfil”).

This shows how a piece of traditional medicinal knowledge might prove to be worthy to the drug discovery process and to questions of patentability. Some authors have argued traditional knowledge could be awarded limited protection comparable to second medicinal uses.⁷⁷¹

3.3 Inventive Step

For a novel invention to be eligible for patent protection, it must further fulfil the inventive step requirement as set forth in Article 27 of the TRIPS Agreement, which does not further develop this concept. A footnote to this article stipulates that member countries are allowed to interpret “inventive step” as being synonymous with “non-obvious”.⁷⁷² The question to be asked when assessing the novelty of an invention is whether “the same invention has already been made public”. In contrast, where the assessment is on obviousness, the question is whether “the step over what is already known is considerable enough to be called inventive”.⁷⁷³

There are no harmonised rules on inventive step. The purpose is to permit a certain flexibility depending on the innovation policy of member states and the stage of their economic development. Indeed, the kind of innovation policy a country may want to establish will very much depend on the inventive step criterion. The question is whether the innovation policy wants to encourage inventors or follow-on inventors.⁷⁷⁴

The inventive step condition is commonly considered to be the most important standard in patent law as it performs the function of preserving the main purpose of the patent system that is rewarding truly innovative inventions causing real technological advances. On the other hand, it is also regarded as the most difficult to assess, as it is inherently a subjective assessment of the skilled person in the art. In other words, when assessing inventiveness, the

⁷⁷¹ RAGAVAN Srividhya, *Patent and Trade Disparities in Developing Countries*, Oxford University Press, Oxford, 2012, p. 365.

⁷⁷² EPO Technical Board of Appeal, T 513/90 – *JAPAN STYRENE*, 19 December 1991, OJ 1994, 154, p. 160 (“Obviousness can be explained as an indirect potential availability of the totality of features of a subject-matter through a mental recognition of the consequences of disclosures in the art or, and this should also be relevant, through normal practice in the art including the use of what is available for the purpose”).

⁷⁷³ CORNISH et al., *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 2013, p. 188.

⁷⁷⁴ CORREA, *A Guide to Pharmaceutical Patents*, 2012, p. 44.

patent examiner or the court has to look through the eyes of the skilled person seeking to solve the technical problem in the art at the date of the filing of the patent.⁷⁷⁵

This condition requires that an invention will not be granted a patent if it would have been obvious to a person having ordinary skill in the relevant art at the date of the filing of the patent, or if the invention constitutes the next logical step from a prior art. Two main approaches are taken to settle what constitutes an inventive step. The problem-solution approach is used in countries adhering to the European patent system and the “non-obviousness” approach is used in the US patent system. The following paragraphs will briefly described these two approaches in order to analyse their implications for the issue of traditional medicinal knowledge.

3.3.1 Problem-Solution Approach

The point of departure to assess the inventiveness of an invention is article 56 of the EPC, which states that “an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art”. In turn, the “state of the art” is defined under Article 54(2) EPC, according to which it is everything that is made available to the public anywhere in any language and by any means, such as oral or written description, use or any other way, and before the filing date of the application. According to the EPO Guidelines, “the term ‘obvious’ means that which follows plainly or logically from the state of the art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art”.⁷⁷⁶

The method applied by the problem-solution approach encompasses three steps in order to determine the inventiveness of the claimed invention: (i) determining the closest prior art, and the difference between the claimed invention and the prior art; (ii) starting from this prior art, determine the objective technical problem to be solved; and (iii) assessing the obviousness of the claimed solution to a person skilled in the art. In other words, one has to “subtract” the closest prior art from the claim and see if there is a difference left. If yes, does this difference bring any technical effect? If the answer is again yes, is this technical effect obvious to the

⁷⁷⁵ CORNISH et al., *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, pp. 204ff; see also GRUBB and THOMSEN, *Patents for Chemicals, Pharmaceuticals, and Biotechnology*, 2010, p. 67.

⁷⁷⁶ EPO Guidelines, Patent Examination, Part G, Chapter VII, Section 4.

person skill in the art? So at the end, the patent examiner or the Court are faced with a subjective assessment with regard to the person skill in the art.⁷⁷⁷

When assessing the inventive step, the closest prior art is objectively identified, which might be different from the prior art at the disposal of the inventor or disclosed by him in the patent application.⁷⁷⁸ The closest prior art equates to the starting point from which *it is assumed* (the skilled person in the art *would* depart) the inventor has departed to end up with their invention.⁷⁷⁹ The closest prior art is normally a prior art document or prior use disclosing subject-matter having the same purpose or aiming at the same objective as the claimed invention.⁷⁸⁰ If not, the closest prior art would not lead the skilled person in the art in an obvious way to the claimed invention.

As is the case for novelty, the closest prior art must be publicly available in order to be considered as state of the art in the assessment of patentability of a claimed invention. In a recent case, the Board of Appeal (BoA) concluded that disclosure in an application, which has not been made available to public because of its confidential nature, cannot be used as a starting point for assessing the inventive step, because the disclosed information is not comprised in the state of the art.⁷⁸¹ In three other cases, the BoA has also considered whether old prior art can be considered as the closest prior art or the relevant starting point. Even though according to article 54(2) EPC, “the state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application”, the BoA concluded, that a 65 year old piece of prior art is not a realistic starting point.⁷⁸² However, in

⁷⁷⁷ EPO Guidelines, Patent Examination, Part G, Chapter VII, Section 5.

⁷⁷⁸ EPO Technical Board of Appeal, T 1212/01 – *Pfizer Limited v. Virus Inc.*, 3 February 2005, para 4.4, p. 29.

⁷⁷⁹ As opposed to the assessment regarding the novelty of the invention, where one look for the same invention in one piece already present in the prior art, for the assessment of the inventiveness, the state of the art is looked for in its entirety, that is also for partial solutions.

⁷⁸⁰ This technique is comparable to the above-mentioned US ‘analogous prior art’.

⁷⁸¹ EPO Technical Board of Appeal, T 0211/06 - NGK INULATORS, 25 April 2007, Reasons 3.3, pp. 9-10.

⁷⁸² EPO Technical Board of Appeal, T 479/00 – *Vignali v. TRUKEM*, 15 February 2002, Reasons 3.2, p. 6 (“The issue of inventive step should be considered from the point of view of the skilled person at the priority date of the patent. It is unrealistic to assume that, without hindsight, somebody of average skill in the art of colouring ceramic articles in 1994 would have had the intention to improve a technique which had not received any attention during the last 65 years”); see also, EPO Technical Board of Appeal, T 69/94 – *BEECHAM GROUP v. HOECHT*, 18 June 1996, Reason 5.1, p. 12 (“the Board cannot accept the

two other cases, the BoA stipulated that old prior art can be a starting point, as everything published before the relevant date forms the prior art.⁷⁸³

Once the closest prior art has been established, the extent to which the invention's technical features can be distinguished from the prior art will be determined. The distinction will be based either in terms of structure or function. In the specific field of chemical inventions, and particularly in the pharmaceutical sector, the closest prior art is determined by means of searching not only for the substance that is most structurally similar to the claimed invention, but also the one which presents a sufficiently similar function in the same field.⁷⁸⁴ Generally, the assumption is that "chemical compounds of similar structure normally have similar properties, including biological activity".⁷⁸⁵ It is interesting to note that in most litigated cases involving the assessment of inventiveness in the chemical context, the patentee alleges dramatic changes in activity resulting from small structural modifications over prior art. It is the unpredictable nature of biological reactions that makes the assessment of inventiveness a challenging task. Indeed, even when a high degree of similarity exists between two molecules, the therapeutic effects or their functions may vary considerably.⁷⁸⁶ In other words, a molecule that appeared structurally obvious in light of the prior art is in fact a non-obvious invention if the molecule shows surprising properties.⁷⁸⁷ It seems that for the Board of Appeal, prior

Respondents argumentation that a person skilled in the art would disregard document (6) only because of its publication date about 20 years before the filing date of the application documents forming the basis of the patent in suit.").

⁷⁸³ EPO Technical Board of Appeal, T 1408/04 – *THE PROCTER & GAMBLE v. Kimberly-Clark*, 17 November 2006, Reason 2, p. 19; see also, EPO Technical Board of Appeal, T 113/00 – *Thomas Magnete v. Robert Bosch*, 17 September 2002.

⁷⁸⁴ GRUBB and THOMSEN, *Patents for Chemicals, Pharmaceuticals, and Biotechnology*, 2010, p. 230.

⁷⁸⁵ EPO Technical Board of Appeal, T0964/92 – *EISAI*, 23 August 1994, Res. 2.6, p. 7.

⁷⁸⁶ EPO Technical Board of Appeal, T 0939/92 – *Triazoles herbicides v. AgrEvo UK*, 12 September 1995, Res. 2.6.2 (the Board "accepted as undisputed common general knowledge that even small structural modifications may cause major differences in biological activity. Nevertheless, it is also well accepted that the properties of chemical compounds do indeed largely depend on their chemical structure, and that a skilled person would therefore normally expect that the properties of two compounds would become the more similar the more similar their chemical structures became").

⁷⁸⁷ EISENBERG, "Pharma's Nonobviousness problem", 2008, p. 378 (the author provides an extensive analysis of the obviousness assessment in the pharma industry).

documents outlining the same therapeutic effect can constitute the closest prior art more than a prior art outlining similarity in structure.⁷⁸⁸

The second step in the problem-solution approach is the determination of the objective technical problem to be solved by assessing the technical progress made in the subject-matter of the application against the objectively defined closest prior art. In other words, the technical problem is reconstructed by the examiner as an objective problem facing a person of ordinary skill in the art, based on the particular technical effects achieved by the claimed invention vis-à-vis the closest prior art. Hence, the technical problem as analysed by the examiner or the judge may be different from that defined by the patent applicant.⁷⁸⁹ Thus, in conformity with the Board's practice, the problem-solution approach is essentially based on actual knowledge of technical problems and on the means to solve them technically and, at the priority date,⁷⁹⁰ that the skilled person *would (and not could)* be expected to objectively possess that knowledge, i.e. without being aware of the patent application and the invention that it concerned.⁷⁹¹ The 'could-would test' has been developed to ensure that the evaluation of the inventive step be as far as possible objective in order to avoid *ex post facto* analysis.⁷⁹² This approach is similar to the teaching, suggestion, or motivation test adopted in the US. When a given solution is obvious to try with a reasonable expectation of success, the claimed invention will be considered non-inventive.

⁷⁸⁸ EPO Technical Board of Appeal, T 116/90 – *Beecham v. Hoechst*, 18 December 1991, (the Board argued that substance A with a therapeutic effect X was not relevant for the inventiveness assessment of the same substance A with a therapeutic effect Y).

⁷⁸⁹ CORREA, *A Guide to Pharmaceutical Patents*, 2012, p. 66.

⁷⁹⁰ Paris Convention, Article 4 (the provision provides that once an application has been filed in one country party to the Convention, the patentee is entitled to claim priority for a period of twelve months and the filing date of that first application is considered the "priority date").

⁷⁹¹ EPO Technical Board of Appeal, T 967/97 – *OVD Kinegram*, 25 October 2001, Reason 3.2 ("*Der Aufgabelösungs-Ansatz beruht im wesentlichen auf tatsächlichen Feststellungen über technische Aufgaben und Wege zu deren technischer Lösung, die dem Kenntnisstand und Können des Fachmanns objektiv, d. h. ohne Kenntnis der Patentanmeldung und der Erfindung, die sie zum Gegenstand hat, zum Prioritätszeitpunkt zuzurechnen waren*").

⁷⁹² EPO Technical Board of Appeal, T 631/00 – *SANYO v. STARCK*, 5 May 2004, Reason 3.1.1; see also EPO Guidelines, Patent Examination, Part G, Chapter VII, Section 8 ("It should be remembered that an invention which at first sight appears obvious might in fact involve an inventive step. [...] The examiner should be wary of *ex post facto* analysis of this kind").

The third step in the problem-solution approach is the determination by a person skilled in the art, which is a fundamental concept for assessing the inventiveness of the claimed invention. According to the EPO Guidelines, a person skilled in the *pertinent art* “should be presumed to be a skilled practitioner in the relevant field of technology, who is possessed of average knowledge in the art at the relevant date. [...] He should also be presumed to have had access to everything in the “state of the art”, in particular the documents cited in the search report, and to have had at his disposal the normal means and capacity for routine work and experimentation.”⁷⁹³

The question to be asked in the problem and solution approach is whether a person skilled in the art *would*, on the priority date, have found a technical solution to the problem formulated within the patent claim? The solution that is reached by the person skilled in the art must come within the patent claim. Indeed, there may be various solutions to the same problem. Accordingly, if the patent claim is formulated narrowly it would be more difficult for the person skilled in the art to arrive at the solution. Broadly speaking, the assessment of problem and solution approach is based on the difficulties that the skilled person would have in finding the solution.

It is important to note that the selection of the person skilled in the art will depend on the particular technological field. Thus, persons with different skills will be used in the chemical context, and in the mechanical context. Nevertheless, the scope of knowledge of the person skilled in the art may extend beyond their field of expertise on the condition that similar technical problems are given in all fields of expertise of the man skilled in the art.⁷⁹⁴ In the pharmaceutical field however, the Board had considered that the person skilled in the art with regard to anti-allergic substances was not assumed to possess the required knowledge in appetite-suppressing pharmaceuticals.⁷⁹⁵

⁷⁹³ EPO Guidelines, Patent Examination, Part G – Chapter VII, Section 3.

⁷⁹⁴ EPO Technical Board of Appeal, T 69/94 – *BEECHAM GROUP v. HOECHT*, 18 June 1996.

⁷⁹⁵ EPO Technical Board of Appeal, T 0020/83 – *Benzothioapyran derivatives*, 17 March 1983, OJ 1983, 419, p. 422 (“[i]l s’agissait manifestement de montrer que l’action anorexique des phénéthylamines ne dépend pas de la présence ou de l’absence du reste cyano. Cette connaissance, acquise dans un domaine spécialisé, étroitement limité en raison de la structure et du type d’action des composés concernés, n’aurait pas amené l’homme du métier à franchir le pas le séparant du domaine très éloigné des 4-oxo-benzothioapyranes antiallergiques”).

Eventually, once the particular technological field is determined, the next step will consist of determining the level of skills in the determined field. It is accepted that the more advanced the technology, the higher the required level of education of the person skilled in the art.⁷⁹⁶ While in some cases, the Board has considered the person skilled in the art to be a team of researchers composed of highly educated members, in others, the Board has decided that a professor at a medical faculty was too highly qualified.⁷⁹⁷

The key question for this work is whether traditional knowledge of the therapeutic properties of a plant can be considered to be the departing prior art, that is the prior art that is assumed the inventor has departed from to end up with the invention? If the answer is yes, one has to subtract TMK from the claim and see if there is a difference left. Again, if the answer is yes, is the difference inventive to the person skilled in the art?

The *Hoodia* and the *Neem* cases illustrate the inventiveness assessment of the EPO with regard to products based on traditional medicinal knowledge. In the *Neem* case, the Board of Appeal confirmed the revocation of the patent for lack of inventive step in view of a document published in 1981. Because of the existence of the published document, the Court considered that the prior use was sufficiently proven. In the light of the identified closest prior art, the technical problem was “defined as putting into practice a method of controlling fungi on plants by using an extracted neem oil”.⁷⁹⁸ The solution was in “contacting the fungi with a neem oil formulation containing 0.1 to 10% of a hydrophobic extracted neem oil which is substantially free of azadirachtin, 0.005 to 5.0% of emulsifying surfactant”. The last step consisted of determining whether the proposed solution would have been obvious to a skilled person in the light of the previous art. The Court considered that it would be obvious for the skilled person faced with this problem, that the contact of the fungi with the formulations containing neem oil in some concentration would produce the desired effect. While the published document did not specify which solvent had to be used for extraction, the court held that a person skilled in the art would use their general knowledge of how to isolate natural products from plants. This process commonly takes place by means of solvent extraction and solvent elution that are well known practices in all laboratories working with natural

⁷⁹⁶ DOMEIJ, *Pharmaceuticals Patents in Europe*, 2000, p. 52.

⁷⁹⁷ EPO Technical Board of Appeal, T 383/88 - *Biomeasure*, 1 December 1992, Reason 2.2.4.

⁷⁹⁸ EPO Technical Board of Appeal, T 0416/01 – *Thermo Trilogy et al., v. Aelvoet et al.*, 8 March 2005, Reasons 4.4., p. 17-18.

products.⁷⁹⁹ In this case, the appellant (patentee) failed “to allege that any effect is derived from the use of the surfactant in this specific range other than its usual function as additive for providing formulations suitable for use as pesticides in general”.

As opposed to the *Neem* case⁸⁰⁰, the Board in *Hoodia* case⁸⁰¹, explored more extensively the linkage between traditional knowledge and the claimed invention. Notwithstanding this, it held that the person skilled in the art is most likely to be able to make the link between the disclosed traditional knowledge and the claim more than the traditional knowledge holder.⁸⁰² In this case, the Board followed the ‘problem-solution approach’. For identifying the closest prior art, the Board considered that “the most appropriate starting point for the objective assessment of an inventive step [...] is in the present case considered to be a document aiming at the same purpose as the present application, i.e. appetite-suppression for the treatment of obesity and reduction of calorific intake”.⁸⁰³ For the Board, there was no convincing evidence reflecting the reality of the *Hoodia*’s use by the San people as an appetite suppressant, because the large numbers of publications with regard to this alleged traditional knowledge were published on the internet after the filing date of the patent application. The Board did take into account other publications that refer to other uses of the plant, namely document (8) describing the use of the *Hoodia*’s stems as a substitute for food and water.⁸⁰⁴ The Board was convinced by the argument of the patentee that the stems of *Hoodia* plants consist mostly of fibrous material. These succulent plants generally fill the stomach of the consumer and lead to the feeling of satiety for an extended period. This is not an indication that you could use an

⁷⁹⁹ EPO Technical Board of Appeal, T 0416/01 – *Thermo Trilogy et al., v. Aelvoet et al.*, 8 March 2005, Reasons 4.4., p. 19.

⁸⁰⁰ EPO Technical Board of Appeal, T 0416/01 – *Thermo Trilogy et al., v. Aelvoet et al.*, 8 March 2005

⁸⁰¹ EPO Technical Board of Appeal, T 0543/04 – *Appetite suppressant /CSIR*, 27 January 2005.

⁸⁰² EPO Technical Board of Appeal, T 0543/04 – *Appetite suppressant /CSIR*, 27 January 2005, Reason 8, p. 8.

⁸⁰³ EPO Technical Board of Appeal, T 0543/04 – *Appetite suppressant /CSIR*, 27 January 2005, Reason 5, p. 6 (“In the light of the criteria elaborated by the Boards of Appeal for identifying the closest prior art, the most appropriate starting point for the objective assessment of an inventive step following the problem and solution approach is in the present case considered to be a document aiming at the same purpose as the present application”).

⁸⁰⁴ EPO Technical Board of Appeal, T 0543/04 – *Appetite suppressant /CSIR*, 27 January 2005, Reason 10.3 (The document reports on page 1002 an effect as described by a person having eaten the plant upon advice of a native guide and who is quoted with the words: "... it saved further suffering from the pangs of hunger so efficiently that I could not eat anything for a day after having reached the camp.")

extract from the plants in the manufacture of an appetite-suppressant anti-obesity medicament, foodstuff or beverage. From the perspective of a skilled person, “knowing from document (8) that consumption of parts of a fibrous, water-storing plant of [*Hoodia*] very efficiently “removed the pangs of hunger”, could not obviously derive from this disclosure that an extract from the plant could be used for the manufacture of an appetite-suppressant, anti-obesity medicament”.⁸⁰⁵ In conclusion, the Board held that the claimed invention was inventive because the appellant had provided “an alternative appetite-suppressant having improved activity when compared with prior art compositions”. Thus, even though the publication related to the use of *Hoodia* as an appetite suppressant by the San people was published before the filing date, it seems very likely that the Board would have equally not considered them as a convincing evidence for the assessment of obviousness.

The isolation of an active substance having improved activity is sufficient for it to be considered inventive, irrespective of the knowledge of a traditional community, because the latter cannot describe the therapeutic properties of a plant in a ‘Western’, ‘scientific’ pharmacological language.

3.3.2 Non-Obviousness Approach

In the US patent system, obviousness is the standard by which inventive step is judged. Prior to the enactment of 35 U.S.C. §103 (a) in 1952, the inventiveness requirement was a judicially developed doctrine.⁸⁰⁶ Not only the grant examination, but also the judicial review of the inventiveness requirement was very severe and rigorous at that time, resulting in the requirement that the invention should be the product of a “flash of genius”.⁸⁰⁷ After this statutory enactment, the US Supreme Court articulated four requirements relevant to the determination of non-obviousness in the leading precedent *Graham v. John Deere Co.*⁸⁰⁸

⁸⁰⁵ EPO Technical Board of Appeal, T 0543/04 – *Appetite suppressant /CSIR*, 27 January 2005, Reason 16.

⁸⁰⁶ United States Supreme Court (U.S. S.Ct.), *Hotchkiss v. Greenwood*, 52 U.S. 248, 11 How. 248, 13 L.Ed. 683, 1850 (this case involved doorknobs. The patent claimed substituting porcelain for wood and metal. The court held that “there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention” and thus invalidated the claim).

⁸⁰⁷ U.S. S.Ct, *Cuno Engineering v. Automatic Devices*, 314 U.S. 84, 62 S.Ct. 37, 86 L.Ed. 58, 1941.

⁸⁰⁸ U.S. S.Ct, *William Graham v. John Deere Company Kansas City et al.*, 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed. 2d 545, 1966.

In the US, 35 U.S.C. §103 (a), affirms that “a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the *subject matter as a whole* would have been obvious *at the time the invention was made* to a person having ordinary skill in the art to which said subject matter pertains.”⁸⁰⁹

The interpretation of US, 35 U.S.C. §103 (a) on obviousness has been called the “non-obvious approach”. In contrast to the problem-solution approach, the US examiner directly focuses on the claim and decides whether one skilled person in the art would have found the claimed subject-matter as a whole obvious considering the prior art. In this process, four factors have to be assessed, namely: (i) the scope and the content of the prior art; (ii) the difference between the claimed invention and the prior art; (iii) the level of knowledge and skill of a person of ordinary skill in the art, who will be able or not to bridge the gap between the prior art and the claimed invention; and (iv) finally, the court will take into account secondary considerations, including the commercial success or failure of others to solve the particular problem addressed by the invention in question.⁸¹⁰

An obviousness assessment begins with the determination of the scope and content of prior art. The question here is whether the scope of the prior art in the novelty assessment equates to the one in relation to non-obviousness. Both in the United States and in Europe, the scope of the prior art is reduced to the “analogous prior art”, that is in the same field as the claimed invention or is relevant to the particular problem that the applicant solved, thus considerably narrowing down the scope of prior art. It could be argued that prior art in the pharmaceutical

⁸⁰⁹ US Patent Law, U.S.C. Title 35, § 103(a) (pre-AIA). The enactment of the latest amendments to the Patent Act through the Leahy-Smith America Invents Act has amended this provision, which now reads: “a patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before *the effective filing date of the claimed invention* to a person having ordinary skill in the art to which the claimed invention pertains”; See, US Patent Law, AIA U.S.C. Title 35, § 103(a) (the amended provision presents two differences compared to the old version. Firstly, the principle “first to file” has replaced the principle “first to invent”. Secondly, the scope of the prior art has widened as mentioned previously with regard to the novelty requirement. The amended 35 U.S.C. §102 and §103 will only be applicable to claims with effective filing dates on or after March 16, 2013. At the time of writing, there is no judicial interpretation of the amended provisions.

⁸¹⁰ U.S. S.Ct, *William Graham v. John Deere Company Kansas City et al.*, 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed. 2d 545, 1966, para. 17.

field is still analogous to prior art in the cosmetic field, for instance. The test used to determine if a piece of prior art is analogous to a piece of prior art in another field is if it is reasonably pertinent to the particular problem with which the inventor was concerned.⁸¹¹

In 2007, the US Supreme Court in *KSR International v. Teflex Inc.*⁸¹² held that an invention, which combined previously known elements, was obvious. In other words, the court held that the combination of known elements yielded predictable results.⁸¹³ This case concerned a mechanical patent, and the claimed invention was a combination of two prior art elements: a position-adjustable accelerator pedal and an electronic position sensor attached to the pedal assembly.

Prior to the *KSR* case, US Courts had followed a rigid “teaching, suggestion and motivation” (TSM) test, formalised by the Federal Circuit in 1982 as the standard for obviousness.⁸¹⁴ According to this test, a patent is obvious if “some motivation or suggestion to combine the prior art teachings” is to be found in the prior art. In other words, the examiner (or the party challenging the patent) had to identify a specific teaching, suggestion or motivation that would lead them to conclude that an ordinary person skilled in the art would combine the prior references, and which, once combined, would result in a reasonable expectation of success that the invention could be made. The objective of this approach was to prevent a retrospective view (hindsight bias) on the invention, as often solutions appear to be obvious once they have been found.⁸¹⁵

In *KSR v. Teleflex*, the Supreme Court ruled that TSM has neither a basis in §103(a), nor does it properly address newly emerging and rapidly developing technologies where “suggestions

⁸¹¹ USPTO Manual of Patent Examination Procedure, section 211.01(a): Analogues and Non-analogues. <http://www.uspto.gov/web/offices/pac/mpep/s2107.html> [accessed September 2016].

⁸¹² U.S. S.Ct, *KSR International v. TELEFLEX et al.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 2007.

⁸¹³ U.S. S.Ct, *KSR International v. TELEFLEX et al.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 2007, p. 5 (“Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, for patents combining previously known elements, deprive prior inventions of their value or utility.”)

⁸¹⁴ See, for example, United States Court of Appeals, Federal Circuit, *In re Lee*, 277 F.3d 1338, 2002 (“[w]hen patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness”).

⁸¹⁵ See also the problem and solution approach adopted in Europe, Chapter Two, 3.3.1.

and teachings” in the prior art are difficult to identify.⁸¹⁶ In *KSR*, the district court had invalidated the claim as obvious, but the Federal Circuit reversed on the ground that there was no specific reference ‘teaching or suggesting’ the claimed combination, and therefore, the claim was nonobvious because it passed the TSM test.⁸¹⁷ The Supreme Court reversed, criticising the Federal Circuit’s application of the TSM test as too rigid and formalistic.⁸¹⁸ Nevertheless, the *KSR* case did not set aside the TSM test, but only its status as an exclusive test for obviousness.⁸¹⁹

With *KSR*, the US Supreme Court did not only invalidate the exclusivity of the TSM test but reaffirmed the “obvious-to-try” test in its precedent in the *Graham* case.⁸²⁰ A claimed invention is proved to be obvious if the departure from the prior art undertaken by the inventor would have been *obvious to try*. The Supreme Court found that the Federal Circuit Court should have applied the obvious-to-try test, and, therefore, erred in concluding that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and

⁸¹⁶ U.S. S.Ct, *KSR International v. TELEFLEX et al.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 2007, pp. 3 and 6.

⁸¹⁷ U.S. S.Ct, *KSR International v. TELEFLEX et al.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 2007, p. 3.

⁸¹⁸ U.S. S.Ct, *KSR International v. TELEFLEX et al.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 2007, p. 6 (“[T]he application of rigid rules without regard to common sense is “neither necessary under our case law nor consistent with it”).

⁸¹⁹ United States Court of Appeals, Federal Circuit, *Kinetic Concepts v. Smith & Nephew*, 688 F.3d 1342, 1368, 2012 (“[w]hile the Supreme Court made clear that a mechanical application of the TSM test, requiring an explicit teaching the prior art, is inappropriate, we must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention”).

⁸²⁰ U.S. S.Ct, *KSR International v. TELEFLEX et al.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 2007, p. 3; see also, U.S. S.Ct, *William Graham v. John Deere Company Kansas City et al.*, 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed. 2d 545, 1966.

common sense”.⁸²¹ In other words, the question is whether the input of the patent holder was obvious to try for a person skilled in the art, in the sense that it constitutes merely the next logical step from the prior art. With the *KSR* case, the obviousness criteria has been considerably lifted to a higher threshold.

It remains to be seen if the application by the courts of the obvious-to-try test will depend on the technological field of the patent, i.e. whether the claimed invention is within the predictable or unpredictable arts. Predictable arts are constituted by mechanical and electrical fields, where the technical results of the invention may be easily predicted. It is suggested/proposed that the predictability of chemical reactions and biological responses is far from being straightforward.⁸²²

After the decision in *KSR*, the United States Patent and Trademark Office (USPTO) issued revised examination guidelines. The guidelines state: “*The focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documented prior art, general knowledge in the art, or common sense*”.⁸²³

The decision rendered by the Supreme Court in *KSR* raised concerns in the pharmaceutical sector which argued that the TSM test provided a more objective standard for patentability and ensured that a patent holder could enforce its patent against free-riders.⁸²⁴ This is principally due to the fact that many patents granted on pharmaceutical products cover variations on old successful drugs, such as, for instance, new formulations, namely time release capsules, or new combinations of previous drugs. The implication of the *KSR* case is

⁸²¹ U.S. S.Ct, *KSR International v. TELEFLEX et al.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 2007, pp. 4 (“[the] combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results”).

⁸²² DOMEIJ, *Pharmaceuticals Patents in Europe*, 2000, p. 50.

⁸²³ US Examination Guidelines for Determining Obviousness under 35 U.S.C 103 [R-07.2015], available at: <http://www.uspto.gov/web/offices/pac/mpep/s2141.html> [accessed September 2016].

⁸²⁴ See Brief of *Amicus Curiae* for Pharmaceutical Research and Manufacturers of America in Support of Respondents, *KSR International v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), No. 04-1350.

that the position of generic drug companies can be reinforced by showing that the claimed inventions would have been obvious at the time they were made.

The following paragraphs will, as a first step, assess the impact of the *KSR* case in the assessment of obviousness in the chemical context, and then transpose this to the issue of traditional medicinal knowledge.

In the chemical context, where a patent claims a novel chemical compound, the assessment of obviousness is based on the difference between the claimed invention and the prior art, which normally turns on their structural similarities and differences. This is because pharmaceutical patents are normally described by their structural characteristics, namely their molecular composition or formula. However, another means of describing a product is by its function. Thus, a patent will claim a product that solves problem X, namely curing the disease X. This way of claiming ensures the patent holder exclusive rights over all compositions⁸²⁵ that cure disease X, even though they do not have the same structural characteristics and the patent claimant has not considered such a composition.⁸²⁶ A patent may also encompass both claims. The assessment of obviousness in the chemical context has resulted in divergent rulings in the Federal Circuit Court after the *KSR* decision.

For example, in the *Pfizer v. Apotex* case, the court applied both the TSM and the obvious-to-try test.⁸²⁷ In this case, the new and unexpected properties advanced by the Pfizer, namely

⁸²⁵ U.S. S.Ct, *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S.Ct. 2204, 65 L.Ed. 2d 144, 1980. at 308, (the US S.Ct has defined "composition of matter" to mean "all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids).

⁸²⁶ BAGLEY, *International Patent and Law Policy*, 2013, p. 607 (These types of claim are admitted in the US as opposed to the countries adhering to the EPO, where patents on methods of medical treatment are not permitted).

⁸²⁷ United States Court of Appeals, Federal Circuit, *Pfizer v. Apotex*, 480 F.3d 1348, 2007, reconsideration denied in United States Court of Appeals, Federal Circuit, *Pfizer v. Apotex*, 488 F.3d 1377, 2007 (The Court stated that "where all claim limitations are found in a number of prior art references, the burden falls on the challenger of the patent to show [...] that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so. [...] we have consistently held that 'obvious to try' is not to be equated with obviousness"); for an in-depth analysis of this case, see HAYES, "Three Years Post-KSR: A Practitioner's Guide to "Winning" Arguments on Obviousness and a Look at What May Lay Ahead", 2010, p. 249.

‘good solubility’, ‘stability’ and ‘good processability (non-stickiness)’ were not considered to be sufficiently unexpected, even if superior to the prior art, to be considered non-obvious.⁸²⁸

One of the parameters that made the court decide for obviousness, is that the ‘amlodipine besylate’ compared to its prior art chemical compound ‘amlodipine’ has the same therapeutic effect, that is treating high blood pressure.

A next case addressed by the Federal Circuit Court was *Takeda Chemical Industries Ltd v Alphapharm Pty., Ltd.*⁸²⁹ Even though, the decision was issued three months after Pfizer, the Federal Circuit Court of Appeals applied the TSM test. While *Alphapharm* alleged obviousness of the claimed patent adopting the obvious-to-try test, the court, in its reasoning, relied on the TSM approach. It affirmed that, “in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new chemical compound.”⁸³⁰ The Court agreed with the district court that *Alphapharm* had failed to identify a reason to modify the structural formula of the prior art compound. The court held that a person of ordinary skill would not have selected the compound identified by *Alphapharm* to be the closest prior art, because another prior art reference taught away from modifying the compound identified by *Alphapharm*. The court held that even so, such a choice would not have been made with a reasonable expectation of success.

In a subsequent case⁸³¹, the Federal Circuit Court studied how the assessment of chemical obviousness operated under the Supreme Court’s *KSR* approach. “First, *KSR* assumes a starting reference point or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions. Second, *KSR* presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound. [...] Third, the Supreme Court’s analysis in *KSR* presumes that the record before

⁸²⁸ United States Court of Appeals, Federal Circuit, *Pfizer v. Apotex*, 480 F.3d 1348, 2007, at 1355 (quoting Pfizer statement).

⁸²⁹ United States Court of Appeals, Federal Circuit, *Takeda Chemical Industries v. Alphapharm*, 492 F.3d 1350, 2007.

⁸³⁰ United States Court of Appeals, Federal Circuit, *Takeda Chemical Industries v. Alphapharm*, 492 F.3d 1350, 2007, at 1357.

⁸³¹ United States Court of Appeals, Federal Circuit, *Eisai Co v. Dr. Reddy’s Labs*, 533 F.3d 1353, 2008, at 1356.

the time of invention would supply some reasons for narrowing the prior art universe to a "finite number of identified, predictable solutions."⁸³² The Court concluded that "to the extent an art is unpredictable, as the chemical arts often are, *KSR*'s focus on these identified, predictable solutions may present a difficult hurdle because potential solutions are less likely to be genuinely predictable."⁸³³

In summary, it seems that after the decision rendered in *KSR*, the obviousness assessment in the pharmaceutical field, with the exception of the *Pfizer v. Apotex* case, still begins with a lead compound, i.e. the TSM approach.⁸³⁴

This suggests the following comments with regard to an invention based on traditional medicinal knowledge.

First, it is questionable whether a person of ordinary skill would have known the traditional medicinal knowledge upon which an invention was based given that the pertinent art would be in the pharmaceutical sector. This has to do with traditional medicinal knowledge rarely being available in written form.⁸³⁵ Second, even where traditional medicinal knowledge is available, the doctrine of analogous art might pose a problem. In a case decided in 2011, the Federal Circuit reaffirmed the traditional analogous art approach to determine the scope of prior art. Accordingly, "[a] reference qualifies as prior art for an obviousness determination [...] only when it is analogous to the claimed invention".⁸³⁶ Whether or not a reference to prior art is analogous is determined by means of a two-step test: (i) whether the art is from the same field of endeavour regardless of the problem solved - for traditional medicinal

⁸³² United States Court of Appeals, Federal Circuit, *Eisai Co v. Dr. Reddy's Labs*, 533 F.3d 1353, 2008, at 1359.

⁸³³ United States Court of Appeals, Federal Circuit, *Eisai Co v. Dr. Reddy's Labs*, 533 F.3d 1353, 2008, at 1359.

⁸³⁴ For a more recent case, see United States Court of Appeals, Federal Circuit, *Insite Vision v. Sandoz*, 783 F.3d 853, 2015; see also, MUELLER, "Chemicals, Combinations, and "Common Sense": How the Supreme Court's *KSR* Decision Is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases", 2007, last revised February 2008.

⁸³⁵ CORREA, *A Guide to Pharmaceutical Patents*, 2012, p. 49 (according to the author, the scope of the prior art can vary depending on what the person skilled in the art would consider to be in the prior art).

⁸³⁶ United States Court of Appeals, Federal Circuit, *Re Klein*, 647 F.3d 1343, 2011, at 1352 (The Federal Circuit concluded that the cited references were not encompassed by the scope of analogous art because they did not address the same problem as the patent application).

knowledge this would not be the case; and (ii) if not, whether the references in prior art were reasonably pertinent to the problem addressed by the claimed invention.⁸³⁷ Traditional medicinal knowledge would fulfil this latter test as it solves the same problem, if the therapeutic effect is the same as the one claimed in the invention. Third, in the chemical context, where a patent claims a chemical compound, the assessment of obviousness is based on the difference between the claimed invention and the prior art, which as already mentioned, normally turns on their structural similarities or differences. As traditional medicinal knowledge is not described in a chemical language, the comparison is not feasible.

Accordingly, it seems that the obvious-to-try approach would be more advantageous for the party challenging a patent based on traditional medicinal knowledge. During an opposition to a patent, an expert in indigenous knowledge has to show that the input of the patent holder was obvious to try (the next logical step) for a person skilled in the art departing from traditional knowledge as prior art. Under this approach, the traditional knowledge of the therapeutic properties of plant can constitute prior art and the difference between the claimed invention and the prior art would equate to zero. However, it has still to be determined whether the process of isolating an active substance from a plant is considered mere routine or conventional science. This is a question that remains to be answered by the courts on a case by case basis where the closest prior art is assumed to be traditional medicinal knowledge.⁸³⁸

In turn, under the TSM approach, the opponent (expert in indigenous knowledge) must identify some reason that would have led a chemist to isolate a compound to achieve the claimed invention. In other words, the question is whether a person of ordinary skill in the art would have been motivated to combine the teachings of the prior art references to achieve he claimed invention, and would have had reasonable expectation of success in doing so. This reason could be found in indigenous peoples' traditional knowledge. However, the first step in the obviousness assessment is the identification of the closest analog compound (lead compound) that would be the most promising to modify. It is only after this identification that it has to be determined whether prior art would have provided a reason or motivation to modify the lead compound in a manner that shows the obviousness of the claimed chemical composition. Thus, even though traditional knowledge would have motivated the person

⁸³⁷ United States Court of Appeals, Federal Circuit, *Re Klein*, 647 F.3d 1343, 2011, at 1352.

⁸³⁸ See for example, *Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co. Ltd.*, [1996] RPC 76, at 88 (per Lord Hoffmann).

skilled in the art to reach the claimed invention, the patent can still be held as non-obvious because traditional medicinal knowledge as prior art would not disclose a departing lead compound.

In sum, whatever approaches is adopted in assessing the obviousness of a patent that derives from traditional medicinal knowledge, the unpredictability of chemical substances and biotechnological processes usually provide grounds for inventiveness. For instance, when there is a presumption of obviousness when assessing compounds' structural similarity to prior art, this presumption can be overcome by evidence that the claimed compound exhibits new and unexpected properties. Thus, if the invention, that is a drug, can claim new and unexpected/unpredictable properties, the invention is deemed to be non-obvious.

At the time of writing, no cases have been decided whether a chemical or biotechnological improvement of a plant resource discovered *with the help of an indigenous group* is obvious or not.

3.4 Industrial Application

A further condition for an invention to be patentable is that it must be capable of industrial application.⁸³⁹ The TRIPS Agreement does not provide any definition of this term except that it says in footnote 5 that “capable of industrial application” may be deemed by Members to be synonymous with the term “useful”. The rationale of this criterion is that patents are generally reserved for technological inventions that achieve a practical purpose, and not for purely intellectual creations or abstract ideas that cannot be put into any practical use. In other words, this concept pursues the objective of delimiting the categories of subject matter that fall within the scope of patent protection.⁸⁴⁰ Indeed, scientific and mathematical theories or aesthetic creations generally fall outside the scope of the patent system because they do not have practical application. The same is true for methods of medically treating humans and animals.⁸⁴¹ This can be partly explained by the need to keep scientific theories in the public domain. While this rationale is generally reflected in most national laws, the interpretation of

⁸³⁹ TRIPS Agreement, Art. 27.1 (according to this article, “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”).

⁸⁴⁰ CORNISH, LLEWELYN & ALPIN, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 2013, pp. 221 ff.

⁸⁴¹ This for instance not the case in the US, where those methods are patentable.

industrial applicability not only varies from one country to another but has also undergone considerable changes over the years.

In Europe, under Article 57 of the European Patent Convention, “[a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.”⁸⁴² The concept of industry is generally understood in its broad sense as including any physical activity of “technical character.”⁸⁴³ Thus, this means that an activity must belong to the practical or useful arts as distinct from the aesthetic arts. Furthermore, Rule 42(1)(f) of the EPC states that the patent description shall “indicate[s] explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable.”⁸⁴⁴ In the pharmaceutical field, if the way in which the invention is capable of exploitation in industry (use) is not indicated in the description, not only will the invention lack industrial applicability, but this may also constitute grounds for finding a lack of inventive step.

In a case decided under the EPC, the Board of Appeal questioned whether a chemical compound without any known useful property “could be regarded as being a technical invention at all”.⁸⁴⁵ Nevertheless, the patent application was rather refused for a lack of inventiveness. Industrial applicability or utility cannot be assessed in isolation from the other requirements of patentability, particularly in the field of pharmaceutical inventions. Before the emerging of biotechnological inventions, this criterion was not considered essential in contrast to the other requirements, since very few inventions failed to meet industrial applicability.⁸⁴⁶ However, this requirement has gained particular relevance in the determination of the patentability of inventions in the field of biotechnologies. The Biotechnology Directive (98/44/EC) states that DNA sequences on their own, without an indication of their function, do not contain any technical information and are therefore not

⁸⁴² EPC, Art. 57.

⁸⁴³ EPC Implementing Regulations, Rule 42(1)(a) and (c) and Rule 43(1) expressly states that the invention must be of « technical character » to the extent that it must related to a technical field, must be concerned with a technical problem, and must have technical features in terms of which the matter for which protection is sought can be defined in the claim; see also, Patent Cooperation Treaty (PCT), Article 33(4).

⁸⁴⁴ Patent Examination, Rule 42(1)(f).

⁸⁴⁵ EPO Technical Board of Appeal, T 0939/92 - *Triazoles herbicides v. AgrEvo UK*, 12 September 1995, Res. 2.5.1.

⁸⁴⁶ EPO Guidelines, Patent Examination, Part G – Chapter III, Section 1.

patentable inventions. In addition, Article 5(3) of the Directive states that “the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application”. The goal is to avoid blocking any further research by delimiting the boundaries of a claim that would otherwise cover vast areas without any practical utility.

The implications of this third criterion of patentability with regard to traditional medicinal knowledge necessitates the following comments. First, the motivation of inventor when inventing is distinct from that of indigenous communities. As mentioned previously, the underlying theory of the patent system, as embodied in the TRIPS Agreement, is that the inventor invents ultimately for the purpose of selling his/her invention and to obtain monetary benefits. This goal is not one necessarily pursued by indigenous communities.⁸⁴⁷ Second, traditional medicinal knowledge may constitute an essential feedstock in the development of pharmaceutical patents.

4 Formal Requirements for Patentability and Traditional Medicinal Knowledge

For an inventor to obtain a patent on their invention, an inventor must prepare and file an application describing and claiming the invention, i.e. the specification. The description will disclose the invention clearly and sufficiently enough to ‘enable’ the person skilled in the art to perform the invention. In other words, while the disclosure requirement enacts the underlying rationales of the patent system, that is, monopoly rights are conferred in exchange for publicity of the invention, the claims will define the precise scope of the rights of the patentee to exclude others.

The following paragraphs will give an overview of the specification requirements under the patent system in order to assess their implications for traditional medicinal knowledge.

4.1 Patent Claim / Traditional Medicinal Knowledge within a Patent claim

The most important part of a patent application is constituted by the claims. Indeed, the claims will define the precise scope of the rights conferred by the patent.⁸⁴⁸ The subject matter

⁸⁴⁷ ROHT-ARRIAZA, “Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities”, 1996, p. 939; see generally, GIBSON, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, 2005.

⁸⁴⁸ CORNISH, LLEWELYN & ALPIN, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 2013, pp. 178 ff.

defined by the claims constitutes the exclusive preserve of the inventor. In other words, “what the right holder may ultimately exclude others from practicing is the subject matter defined by the claims”.⁸⁴⁹ Claims are also of essential significance, both in determining what constitutes an infringement and in assessing the validity of the patent itself. The assessment of infringement by imitation will consist of reading the claims and seeing whether the claims describe the imitation. Claims are written in a highly technical language that is almost incomprehensible to the uninitiated. Likewise, the drafting of claims needs a good deal of expertise and practice. It is accepted that drafting a claim is more of an art than a science.⁸⁵⁰ Generally, the specification contains more than one claim and claims may be independent or dependent or a mixed of both.

Patent claims generally fall into two broad categories based on the fundamental distinction between product and process claims. While the first category involves claims to things, the second comprises procedures or means to obtain something. Product claims will confer protection over all uses regardless of the process. For instance, in the chemical sector, product claims will cover claims to chemical substances *per se* or mixtures such as pharmaceutical compositions. On the other hand, process claims will include processes of synthesis, isolation, purification, and extraction of chemical substances or methods of medical treatment and diagnosis (patentable in the US system) or claims on new medical uses (in Europe).⁸⁵¹ There is also an in-between category called the product-by-process claim. The product is defined by means of the process of production and is generally used when there is no other satisfactory way of defining the product by means of its composition or structure.⁸⁵² It is the common way of defining naturally occurring chemical compounds or biotechnological inventions that are defined by the means of their production. Often a patent encompasses two or more of these types of claims, and thus, each claim has to be analysed on its own merit to determine its scope.⁸⁵³

Generally, claims tend to follow an established standard all over the world. This is due to the use of the Paris Convention for the Protection of Industrial Property (Paris Convention), the

⁸⁴⁹ BAGLEY, *International Patent and Law Policy*, 2013, p. 603.

⁸⁵⁰ BAGLEY, *International Patent and Law Policy*, 2013, p. 608.

⁸⁵¹ GRUBB and THOMSEN, *Patents for Chemicals, Pharmaceuticals, and Biotechnology*, 2010, p. 373.

⁸⁵² EPO Technical Board of Appeal, T 0150/82 – *IFF*, 7 February 1984, Reason 8.

⁸⁵³ DOMEIJ, *Pharmaceuticals Patents in Europe*, 2000, p. 68.

Patent Cooperation Treaty system (PCT) and the European Patent Convention (EPC) that permit the filing of applications covering the same claimed invention in multiple countries. However, and departing from the three broad categories mentioned above, a wide variety of special claim formats exist, namely Jepson,⁸⁵⁴ Markush,⁸⁵⁵ functional,⁸⁵⁶ omnibus (central), peripheral and Swiss-type claims. While some of them are specific to a given jurisdiction, others are used globally. In addition, claims also determine the type of invention and its general characteristics, namely mechanical, chemical, pharmaceutical, biotechnological inventions,⁸⁵⁷ or software-related inventions. In turn, each sector of industry will claim different types of invention. For instance, the types of pharmaceutical claims may include an active pharmaceutical ingredient,⁸⁵⁸ processes for making an active pharmaceutical ingredient, pharmaceutical composition of the active pharmaceutical ingredient, methods of treating patients with the pharmaceutical compositions, and methods for drug discovery.

The drafting of claims in the United States and in the United Kingdom is based on peripheral claiming system, as opposed to central claiming system adopted principally by Germany and by some European countries. The rationale of peripheral claiming is to define the boundaries of protection of the claimed subject matter by giving third parties notice of the proprietary scope of the patent so as to avoid infringement. Under central claiming, also called an ‘omnibus claim’, direct reference is made to the specification and/or drawings to define the

⁸⁵⁴ GRUBB and THOMSEN, *Patents for Chemicals, Pharmaceuticals, and Biotechnology*, 2010, pp. 380ff (Jepson Claims are used in Switzerland, Germany, Scandinavian countries and less in the US. In these types of claims, the preamble is a sentence that is admitted to be prior art. Thus, these claims are drafted in such a way as to distinguish what is old from what is new. In other words, they are useful in claiming inventions that are clearly an improvement over a well-known product or process).

⁸⁵⁵ The structural formula, as opposed to functional, is the most common way of defining a chemical compound and this is often called the Markush claim.

⁸⁵⁶ These types of claims allow elements of the claimed subject matter to be described by their function as opposed to their structure.

⁸⁵⁷ Directive 98/44/EC, Article 13; Swiss Patent Act, Article 50a (where a patent claim a biological material, most patent laws provide for a deposit of the biological material).

⁸⁵⁸ DOMEIJ, *Pharmaceuticals Patents in Europe*, 2000, p. 49 (practically speaking a pharmaceutical patent can be defined in two ways, even though the two ways are normally present in a patent claim. On the one hand, it can be defined **structurally** if the claimed invention covers a chemical formula, and on the other hand, it can be defined **functionally** if the claimed invention establishes the biological effects of the pharmaceutical. In the latter form, the patent will cover all products and processes that achieved the function mentioned in the claim).

invention.⁸⁵⁹ This type of claim limits the scope of the claim to only what the applicant has actually disclosed. In other words, the patent will claim what is central about the invention. It seems that peripheral claiming provides a clearer warning to other inventors compared to omnibus claiming. However, scholars are becoming more sceptical about peripheral claiming because, according to them, the scope of legal rights is no longer defined with reference to the invention but rather with reference “to semantic debates over the meaning of words chosen by lawyers [...]”.⁸⁶⁰

Another type of claim is of particular interest in the field of pharmaceuticals, namely the “Swiss-type claim”. As discussed previously,⁸⁶¹ the Swiss type claim permits protection of an invention that would otherwise not be patentable under the European Patent Convention, because it prohibits the patentability of methods of treatment.⁸⁶² The Swiss-type claim evades that prohibition by claiming the manufacture of the medicament for the treatment of a given illness instead of claiming the method of treatment itself.

Finally, the example of the pickled onions gives a good insight into the highly technical nature of patent claims drafting. This example is provided by Grubb and reads as follows: “For example, for an invention that a particular type of pharmaceutical compound could be stabilized in tablet form by the addition of an organic acid, the claim that was drafted read ‘A physiologically acceptable substance stabilized in an acidic medium’, which sounds like a good pioneer claim, except that it literally covers a jar of pickled onions’”.⁸⁶³

The above description demonstrates how the choice of claim formats and their drafting can constitute influential tools for patentees to control and increase their exclusive rights on some subject matters that they would otherwise be excluded from. In the case of a patent claiming a

⁸⁵⁹ The drafting of the claim is in the form: product or process as described with reference to any one of the examples or to any one of the drawings.

⁸⁶⁰ See generally, BURK and LEMLEY, “Fence Posts or Sign Posts? Rethinking Patent Claim Construction”, 2009 pp. 1746-1747 (“Whereas peripheral claiming purports to mark the outermost boundary of the patentee’s claim, central claiming describes the core or gist of the patentee’s contribution to the technology [...]”); See also generally, DRAHOS, *Patent Offices and their Clients*.

⁸⁶¹ Part II, Chapter Two, 2.2 : “New medical uses”.

⁸⁶² EPC, Article 53(3).

⁸⁶³ GRUBB and THOMSEN, *Patents for Chemicals, Pharmaceuticals, and Biotechnology*, 2010, p. 384.

traditional medicinal knowledge without disclosing it, the link to the holder of the knowledge, which forms a substantive part of the invention, is often lost.

4.2 The Disclosure Requirement

Disclosure has mainly two broad objectives. First, it fulfils the function of monitoring whether the invention (defined by the claims) corresponds to the knowledge disclosed by the applicant. In other words, it permits an assessment of whether the claim that defines the rights attached to the patent has the right scope. Second, it ensures that, at the time of filing the application, there was the necessary information in the public domain to enable the person skilled in the art to perform the invention.⁸⁶⁴

According to Article 83 of the European Patent Convention, the patent application should disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. This aspect is also known as the “enablement” requirement that is designed to furnish the public domain, particularly to the benefit of follow-on inventors.

This requirement is mandatory in all patent laws. Article 29(1) of TRIPS makes it a formal condition of patentability.⁸⁶⁵ The failure to disclose the invention in a sufficient or enabling way results in the rejection of the application (*prima facie*) or the invalidation of the patent (post grant).

The disclosure requirement will be met by different means depending on the nature of the invention. For inventions not related to biological materials, such as chemical or mechanical inventions, words and drawings are enough to enable a person skilled in the art to practice the invention. It is accepted that the disclosure of biological material through their description is difficult if not impossible to achieve. In such cases, an applicant can meet the requirement by

⁸⁶⁴ Cornish et al., *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, para. 5.82ff, p. 241ff.

⁸⁶⁵ CBD COP 7, ‘WIPO technical study on patents disclosure requirement related to genetic resources and traditional knowledge’, Submission by WIPO, 15 December 2003, UNEP/CBD/COP/7INF/17, Annex, p. 12 (the study states that disclosure requirement described as a formal requirement of patentability encompasses information that may either refer to the formality or substantive aspects of the disclosure requirement. While formality aspects refer to information such as the name of the inventor and its address, the substantive aspects refer to “the actual nature of the invention as such, and whether it meets the standards set of patentability”).

depositing a sample of the inventive biological material with an international depository authority under the auspices of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (administered by WIPO). Regional and national laws have also recognised such difficulty implicitly⁸⁶⁶ or explicitly.⁸⁶⁷

Ultimately, the question about how to meet the disclosure requirements sufficiently, has given rise to controversies and litigations. In general, the inventor need not give a complete and detailed account of the technology involved in carrying out the invention, but only the amount of information necessary for that purpose.⁸⁶⁸ According to the general principle established by the EPO, “a detailed description of at least one way of carrying out the invention must be given”.⁸⁶⁹ The disclosure requirement under US patent law is based on the principle of “the best mode”⁸⁷⁰. Accordingly, a disclosure is sufficient only if it contains the best way known by the inventor to perform the invention. Thus, it obliges the applicant to disclose any techniques he may have developed where these constitute the best way to carry out the invention. The rationale is to “restrain inventors from applying for patents while at the same time concealing from the public the preferred embodiments of their inventions which they have in fact conceived.”⁸⁷¹ In brief, the rationale of the enablement⁸⁷² is to permit the Courts

⁸⁶⁶ US Patent Law, U.S.C. Title 35, § 161 (the disposition provides that the disclosure of plants for the purpose of plant patent procedures is made enough through a description “as complete as is reasonably possible”).

⁸⁶⁷ Directive 98/44/EC, Article 13; see also Swiss Patent Act, Article 50a (where a patent claim a biological material, most patent laws provide for a deposit of the biological material).

⁸⁶⁸ EPO Technical Board of Appeal, T 0206/83 - *Herbicides/ICI*, 26 March 1986, Reason 3; a French adage resumes well the enablement: “*À un bon entendeur, un demi mot suffit*”.

⁸⁶⁹ EPO Guidelines, Patent Examination, Part F – Chapter III, Section 1; see also EPO Technical Board of Appeal, T 0593/09 – *TOKO KOHAN v. TATA STEEL*, 20 December 2012, Reason 4.1.4 (The Board held that “[w]hat is decisive for establishing insufficiency within the meaning of Art. 83 EPC is whether the parameter, [...], is so ill-defined that the skilled person is not able, on the basis of the disclosure as a whole and using his common general knowledge, to identify (without undue burden) the technical measures (e.g. selection of suitable compounds) necessary to solve the problem underlying the patent at issue”).

⁸⁷⁰ See also, TRIPS Agreement, Article 29(1) (“[...] may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date [...]).

⁸⁷¹ USPTO Manual of Patent Examining Procedure, Chapter 2100, Section 2161, available at: <http://www.uspto.gov/web/offices/pac/mpep/s2161.html> [accessed September 2016].

⁸⁷² CBD COP 7, ‘WIPO Technical Study on Patents Disclosure Requirement Related to Genetic Resources and Traditional Knowledge’, Submission by WIPO, 15 December 2003, UNEP/CBD/COP/7/INF/17, Annex, p. 15 (“[a]n invention is considered enabled if the specification teaches one skilled in the art how to

to invalidate patent claims that are too broad and require undue experimentation for their reproduction by a person skilled in the art. In other words, the broader the claims are, the more precise the disclosure of technical information and alternative embodiments should be.

The requirement to disclose the inventor is of direct relevance in relation to the debate about the utilisation of traditional knowledge in patent claims, without the prior authorisation of its provider.⁸⁷³ Indeed, as shown, there is no requirement under the international standards that apply to the patent system, to disclose the origin and the prior informed consent of holders of traditional medicinal knowledge. Notwithstanding this, the following questions arise: What happens when the relationship between TMK and the claimed invention is so close or where the claimed invention is directly based on TMK? This question suggests two hypotheses.

First, under the general rules of the patent system, where: a patent is based on traditional medicinal knowledge of a community (or generally any other person); this knowledge provides *per se* (in itself or a substantive part) the inventive basis of the claimed invention; and the community is not identified as the holder (or inventor⁸⁷⁴), this could give rise to significant legal implications. The community (holder of TMK) could claim to be entitled to a full or partial share of ownership of the patent or oppose the patent alleging that the patent was obtained by fraud or by misrepresentation, for instance. This would not be an easy task for the community as they have to be aware, at first, of the existence of such a patent or patents, partly or fully claiming their knowledge, without disclosing it. Second, where the knowledge has been disclosed to the public before the patent's priority date, the patent can be challenged on the basis of lack of novelty. In this case, traditional medicinal knowledge is deemed to be in the public domain and should be viewed as anticipatory prior art for assessing the novelty of the claimed invention.

The solution that has been proposed, essentially by a number of biodiverse-rich developing countries, is to amend international patent law in order to require the disclosure of the origin of genetic resources and prior informed consent for the use of traditional knowledge in patent applications (designated as GRs/TMK disclosure requirement). The rationale of this new

make and how to use the invention without undue experimentation. Undue experimentation is determined on several factors, such as the nature of the invention, the breadth of the claims, the state of the art, the level of skill in the art, the predictability of the art", etc.)

⁸⁷³ The disclosure of origin of traditional knowledge will be expressly dealt with in Part III, Chapter 3, 2.3.

⁸⁷⁴ See for example, Paris Convention, Article 4ter.

requirement is to help biodiverse-rich countries to monitor compliance with national rules or contractual obligations of benefit-sharing in the light of the obligations contained both in the Convention on Biological Diversity (CBD)⁸⁷⁵ and the Nagoya Protocol (NP).⁸⁷⁶ This requirement will be analysed in Chapter II of Part III.

5 Conclusion

As we have seen, patents are drafted in a highly complex and technical language. While it is not an easy task to challenge a patent even for a professional in the field, it is questionable how indigenous communities might be able to do so.

The scenarios which demonstrate the linkages between patents and traditional medicinal knowledge can be summarised as follows:

- A. the patent claims traditional knowledge as such, i.e. as it was accessed, acquired; or
- B. the patent derives from traditional knowledge or is somehow linked to it: either
 - (i) the patent claims an invention that has resulted from a modification and/or enhancement of the traditional knowledge (direct link); or
 - (ii) the patent claims an invention based on traditional knowledge, where traditional knowledge serves as a research tool for achieving the invention that may or may not itself have the same utility as the traditional knowledge (indirect link).

In the above mentioned situations, the invention referred to in hypothesis A is probably the only one that might be challenged under the patentability criteria, particularly the novelty requirement.⁸⁷⁷ Indeed, a patent claiming traditional knowledge *per se*, should normally be challengeable because the traditional knowledge constitutes prior art against the patented invention. These cases are commonly referred to as “bad patents.”⁸⁷⁸ Defensive protections, such as the establishment of databases compiling traditional knowledge are the suggested

⁸⁷⁵ CBD, Article 8(j).

⁸⁷⁶ Nagoya Protocol, Article 7.

⁸⁷⁷ TRIPS, Article 27(1); European Patent Convention (EPO), Article 54(2) ; Swiss Patent Act, Article 7.

⁸⁷⁸ WIPO ICG, ‘Draft Report, 4-6 February 2013, WIPO/GRTFKF/23/8/PROV. 2, p. 20 (in WIPO ICG 23rd session, the Delegation of the US commented that the wording “erroneous patent” concerns the not fulfilment of the patent granting conditions. The Delegation further argued that if the IP system contribution to the protection of TK was used to enforce PIC and MAT, it could not support the objective.

solution to avoid this kind of situations.⁸⁷⁹ However, as mentioned in the above analysis, whether traditional knowledge is considered as prior art will depend on the jurisdiction where the patent is being challenged.

In hypothesis B (i), where a patent derives from traditional medicinal knowledge, the patent will normally be valid. For instance, in European countries, whoever creates paths for a follow-up inventive contribution should benefit or gain some of the value of the later development. However, follow-up inventors have the obligation to obtain the consent of the holders of the prior patent and compensate them for using their invention, i.e. dependent patents. It is further argued that there is an economic advantage for a later invention to become dependent on an earlier invention, if the later invention could not have been done without knowledge of the earlier one.⁸⁸⁰ Nevertheless, independent patents suppose two patents, where there is reciprocity of rights and obligations between them. In case of an innovation encompassing traditional knowledge, the latter is not patented and is supposedly hierarchically inferior to the patented knowledge.

Another example of patent deriving from traditional medicinal knowledge would be when traditional knowledge, as found in the community, is translated into the language of hard science.⁸⁸¹ Dufield asks whether “any written documentation of traditional medicinal knowledge that is not a direct transcript of what the healer dictated to the author is a translation whether or not in the language of chemistry”.⁸⁸² This indirectly means that the subject-matter claimed by the invention is at least not obvious if not novel as well. In addition, this assumption supposes bad faith from the inventor.

⁸⁷⁹ WIPO IGC, ‘Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources’, Canada, Japan, Republic of Korea and the United States of America, 4-8 February 2013, WIPO/GRTKF, IC/23/7.

⁸⁸⁰ See, GREEN Jerry and SCOTCHMER Suzanne, “On the Division of Profit in Sequential Innovation”, *The Rand Journal of Economics*, 1995, vol. 26(1), pp. 20-33, p. 31 (the authors studied the division of profit between sequential innovators. They concluded that *ex ante* agreements have the potential to increase the expected profits of both parties without inhibiting later research even though the second innovator has more bargaining power).

⁸⁸¹ DOLDER, “Analysis of the European Patent Law – Traditional knowledge and patenting: the experience of the neemfungicide and the hoodia case”, 2007, p. 584; see also, DUTFIELD, “A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-Based Biopiracy”, 2011, p. 242.

⁸⁸² DUTFIELD, “A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-Based Biopiracy”, 2011, p. 242.

In hypothesis (B) (ii), even though, the patent is valid *per se*, the legality of the process by which the raw material, that is the genetic resources, and the traditional knowledge have been acquired, puts it at risk. Very recently, the International Regime on Access and Benefit-Sharing, i.e. the Nagoya Protocol has entered into force. Hence, member states are obliged to implement its provisions in their national laws and regulations. As discussed above, the Nagoya Protocol imposes on member states an obligation to regulate access to genetic resources and traditional knowledge through a system of prior informed consent. It further calls on States to establish mutual agreed terms for benefits arising from the utilisation of the genetic resources and traditional knowledge.⁸⁸³

The hypotheses discussed above demonstrate the following key question: what should be the nature of the linkage between the claimed invention and traditional knowledge for requiring some sort of responsibility for use? That is, should the linkage only be a direct one?⁸⁸⁴ Should the answer be the same both in the realm of the patent system and under the access and benefit sharing rules? This fundamental question will be analysed in Part III of this research as it is inherently linked to the discussion on disclosure of origin requirements in the patent system.⁸⁸⁵

The next chapter will concentrate on the concept of public domain as it is of high importance with regard to the protection of traditional medicinal knowledge of indigenous communities.

⁸⁸³ Nagoya Protocol, Article 7; See also Part I, Chapter 3, 1.2.2.

⁸⁸⁴ WIPO ICG, 'Initial Draft Report', the Secretariat, 21 March 2016, WIPO/GRTKF/IC/29/8 Prov., para. 232, p. 58 ("[t]he Delegation of Switzerland responded that the notion of "directly based on" was supposed to describe the relation between the invention, and the GRs or the TK. An invention which was "directly based on" would mean an invention that would not exist without the GR or the TK").

⁸⁸⁵ ADDOR, "Switzerland's Proposals for Disclosure of the Source of Genetic Resources and Traditional Knowledge in Patent Applications", 2005, p. 38.

Chapter 3 One Public Domain *versus* Different Knowledge Systems

It is worth starting this Chapter by quoting Rosemary Coombe, who is both a lawyer and an anthropologist:

“I am uncomfortable with any vision of democracy which poses complete freedom of speech and full access to all cultural forms as the only response to corporate possession of culture, broadly defined. Absolute rights of private property and absolute rights of access to the public domain entertain only extreme points of a Eurocentric spectrum of possibility that needs to be challenged by the cultural mores of others. Peoples have other relationships to cultural forms – trust, secrecy, guardianship, stewardship, initiation, sacralisation – and obligations to relatives, ancestors, spirits and future generations which make models of access and ownership appear extremely impoverished”.⁸⁸⁶

1 Public Domain: An Overview

Any discussion with regard to public domain will differ considerably depending on the purpose of the discourse. In the present section, this discussion will take place solely in the realm of intellectual property rights, generally, and of patents, specifically. The discussion will then be extended to the specific issue of traditional medicinal knowledge.

In the realm of intellectual property rights, it is often assumed that public domain is a kind of space that has emerged from the very existence of intellectual property rights.⁸⁸⁷ In civil law traditions, the concept of public domain derives from the concepts of ‘public property’ or ‘common property’. It is also interesting to note that the concept of public domain first appeared in some nations in relation to publicly owned lands.⁸⁸⁸ In the nineteenth-century,

⁸⁸⁶ COOMBE, “Comments on the Article written by BROWN Michael, “Can culture be copyright?” 1998, p. 208.

⁸⁸⁷ CAENEGEM, “The Public Domain: Scientia Nullius?”, 2002, p. 324 (public domain has generally been defined as being the pool of information not subject to intellectual property rights); FROW John, “Public Domain and Collective Rights in Culture”, 1998, p. 39 (“[p]ublic domain is seen as the space that remains after intellectual property rights have been exhausted”).

⁸⁸⁸ BOYLE, “the Second Enclosure Movement and the Construction of the Public Domain”, 2003, p. 58; see also, COHEN, “Copyright, Commodification, and Culture: Locating the Public Domain”, 2006, p. 128 (In the US, the public lands model of the public domain was designate to facilitate the transfer of public lands to productive use by private parties. Individuals could not claim any rights on these lands without the

while the concept of public domain was used in American Courts to designate subject matter for which patent protection had expired, terms such as ‘public property’,⁸⁸⁹ ‘common property’,⁸⁹⁰ and ‘*publici juris*’⁸⁹¹ were used to refer to non-patentable subject matter such as ideas, facts or pre-existing knowledge.⁸⁹² Progressively, this older terminology fell into obsolescence in intellectual property law and what remains today is the concept of public domain. If one asks if the public domain is the same as the commons, the answer will depend on the context in which the terms are used.⁸⁹³

In contemporary intellectual property law, the emergence of the debate in relation to the public domain started with David Lange and Jessica Litman. Rather than defining public domain as the reverse side of intellectual property, Lange characterised it as a matter of public right.⁸⁹⁴ Litman, in turn, sought to define public domain by determining its essential elements. According to her theory, the concept of public domain legitimates the author’s claim of originality.⁸⁹⁵ The relationship between intellectual property rights and public domain are, in some way, inversely proportional. The more criticism intellectual property rights receive, the more praise public domain wins, and *vice versa*. Indeed, public domain was first seen “as the

sovereign consent. COHEN argues that the public lands model establishes a template for the jurisprudential concept of public domain in intellectual property law).

⁸⁸⁹ See for instance, case law cited by COHEN, “Copyright, Commodification, and Culture: Locating the Public Domain”, 2006, p. 129 (The concept of public property was applied to publicly owned land, buildings, durable goods, and to matters such as publicly known information).

⁸⁹⁰ Common property referred to property owned by two or more persons, but also natural resources in which the public acquired vested rights.

⁸⁹¹ This term referred to un-owned or abandoned property. A concept that was akin to *res nullius*.

⁸⁹² LEE, “The Public’s Domain: the Evolution of Legal Restraints on the Government’s Power to Control Public Access through Secrecy or Intellectual Property”, 2003, p. 102.

⁸⁹³ For instance, LITMAN, “The Public Domain”, 1990 (the author uses the terms ‘public domain’ and ‘commons’ interchangeably to signify that certain information resources can be used without intellectual property rights or other restrictions and hence are common resources to all for all purposes); see also CHANDER and SUNDER, “The Romance of the Public Domain”, 2004, p. 1332 (the authors also use the term interchangeably).

⁸⁹⁴ LANGE, “Recognising the Public Domain”, 1981, p. 147; see also LANGE, “Reimagining the Public Domain”, *Law and Contemporary Problems*, 2003, pp. 473-474 (the authors states that “intellectual property can go on being intellectual property, reformed or otherwise. Meanwhile, the public domain certainly can and should be envisioned as a thing apart”).

⁸⁹⁵ LITMAN, “The Public Domain”, 1990, p. 975.

space that remains after intellectual property rights have been exhausted”,⁸⁹⁶ a sort of residual amount of material with no more utility. With time, this perception has changed and public domain is rather seen as a valuable space that fosters productivity.⁸⁹⁷ In other words, the understanding of the public domain as the opposite of property is a misconception. On the contrary, the public domain is the *sine qua non* to the private property system “because it offers a sphere of free works upon which capitalists can draw without either seeking consent or drawing liability”.⁸⁹⁸ Many scholars recall a fundamental principle, that is: “free use is the rule, and intellectual property protection is the exception”.⁸⁹⁹

The number of academic studies on the public domain has vastly increased, ranging from writings of David Lange,⁹⁰⁰ Jessica Litman,⁹⁰¹ James Boyle,⁹⁰² to those of Anupman Chander and Madhavi Sunder, and so have the definitions of the public domain. For instance, Pamela Samuelson has compiled thirteen different definitions provided by academic writers, not all of which are necessarily related to intellectual property rights.⁹⁰³ Broadly, three trends can be distinguished in reference to public domain discussion.

A first group of legal scholars considers that the rapid and growing expansion of intellectual property rights might gradually eat up the public domain.⁹⁰⁴ Advocates for a wide and strong

⁸⁹⁶ FROW John, “Public Domain and Collective Rights in Culture”, 1998, p. 51.

⁸⁹⁷ LITMAN Jessica, “The Public Domain”, 1990, p. 966.

⁸⁹⁸ CHANDER and SUNDER, “The Romance of the Public Domain”, 2004, p. 1343.

⁸⁹⁹ KÖKLÜ and NÉRISSON, “How Public is the Public Domain?”, 2016, p. 573.

⁹⁰⁰ LANGE, “Reimagining the Public Domain”, 2003, p. 466 (“[t]he public domain I had in mind would become a place of sanctuary for individual creative expression, a sanctuary conferring affirmative protection against the forces of private appropriation that threatened such expression”).

⁹⁰¹ LITMAN, “The Public Domain”, 1990, p. 966 (the authors puts at doubt the romantic notion of authorship on which the copyright law is based, according to which authors create something from nothing, that works owe their origin to the authors who produce them); see also generally, BENSAMOUN et al., *L’Oeuvre de l’esprit en question(s) – Un exercice de qualification*, 2015.

⁹⁰² BOYLE, “The Second Enclosure Movement and the Construction of the Public Domain”, 2003, pp. 33-74.

⁹⁰³ SAMUELSON, “Enriching Discourse on Public Domains”, 2006, pp. 783-834.

⁹⁰⁴ See for instance, BOYLE, “The Second Enclosure Movement and The Construction of The Public Domain”, p. 44 (fears a second enclosure movement in which stronger intellectual property rights will choke off, rather than promote, innovation and other socially valuable uses of information); HELLER Michael, “The Tragedy of the Anticommons: A Concise Introduction and Lexicon”, 2013, 76(1), p. 21; see also BROWN Michael, “Can culture be copyright?”, 1998, p. 196.

public domain advance the “tragedy of anti-commons”⁹⁰⁵ thesis according to which when too many people own pieces of one thing, nobody can in practice use it.⁹⁰⁶ Indeed, the information in the public domain constitutes their main working tool. Information and data in the public domain are essential inputs to future knowledge assets. This movement has arisen as a counter response to the natural and personal rights⁹⁰⁷ legitimating narratives of intellectual property rights. The latter are also critically referred to as the “romantic author” group.⁹⁰⁸

The second group is constituted by advocates of broad and strong intellectual property rights. According to them, the public domain, far from being eaten up by intellectual property rights, is rather enlarged and enriched because intellectual property rights foster creativity and innovation that eventually fall into the public domain as added knowledge. They do not see any conflict between intellectual property rights and the public domain. In the specific case of patents, the main argument is that it is the existence of patents that makes the invention available - through disclosure, at first, and falling into the public domain, eventually - amongst competitive firms, which would otherwise keep it undisclosed and unavailable through secrecy, for instance.⁹⁰⁹ According to Heller, this assumption is becoming obsolete

⁹⁰⁵ As opposed to the tragedy of commons thesis coined by HARDIN, “The Tragedy of Commons”, 1968, 1244 (“Ruin is the destination toward which all men rush, each pursuing his own best interest in a society that believes in the freedom of the commons. Freedom in a commons brings ruin to all”).

⁹⁰⁶ See the extensive work conducted through the Centre for the Study of the Public Domain at Duke Law School directed by James Boyle, available at: <http://www.law.duke.edu/cspd> [accessed September 2016].

⁹⁰⁷ HAUNSS, *Conflicts in the Knowledge Society – The Contentious Politics of Intellectual Property*, 2013, p.33.

⁹⁰⁸ BOYLE, “The Second Enclosure Movement and the Construction of the Public Domain”, 2003, p. 54; BOYLE, *The Public Domain – Enclosing the Commons of the Mind*, 2008(who criticises the romantic notion of the author and inventor based on the natural and personal rights-based draw on Locke’s and Hegel’s property theories, taking into account that contemporary rightholders of intellectual property rights are rarely individual authors and inventors but rather corporations.); see also, BOYLE, *Shamans, software, and Spleens – Law and the Construction of the Information Society*, 1996 (in this study, Boyle essentially express its critical opinion about the morality of legally recognizing some members of society as authors and not others); see also MAY, *The Global Political Economy of Intellectual Property Rights: The New Enclosure*, 2010(the author argues that creation and innovation are processes that heavily build on existing knowledge and cultural material).

⁹⁰⁹ See for instance, LANDES and POSNER, *The Economic Structure of Intellectual Property Law*, 2003, pp. 294 ff.; ABRAMOWICZ and DUFFY, “The Inducement Standard of Patentability”, 2011, p. 1595.

nowadays, particularly in the field of patents. Thirty years ago at the advent of biotechnological innovation, one got a patent for an innovative product. At the present time however, ownership rights are so fragmented and overlapping, that some argue that there is an underuse, in opposition to an overuse, of resources.⁹¹⁰ According to the same author and numerous other scholars, a wide range of potential life-saving drugs, such as the Alzheimer's drug, are lost somewhere in the anti-commons property rights.⁹¹¹ The origin of the Convention on Biological Diversity was partly due to the threat of overuse of genetic resources placed in the commons. Thus privatisation through the national sovereignty rights of States has been seen as the solution to this problem. Whether this solution is a good one, only time will tell us.

The third group, composed of indigenous groups and proponents of traditional knowledge protection, fits in neither camp, because both acknowledge traditional knowledge as pertaining to the public domain. Hence, the claims of indigenous peoples to their traditional knowledge have broken the traditional dichotomist view of intellectual property rights *versus* public domain.⁹¹² Advocates of traditional knowledge protection raise concerns in relation to knowledge that is created and evolving in social groups that possess different normative construction regarding claims over knowledge.⁹¹³ They suggest that the concerns relating to the protection of traditional knowledge are as important as the concerns about a rich and robust public domain. They further contend that a large public domain as supported by the intellectual property system is responsible for the misappropriation and misuse of traditional knowledge.

⁹¹⁰ See HELLER, "The Tragedy of the Anti-commons: A Concise Introduction and Lexicon", 2013, p. 21.

⁹¹¹ HELLER and EISENBERG, "Can patents Deter Innovation? The Anti-commons in Biomedical Research", 1998, pp. 698-710; LEMLEY and BURK, "The Patent Crisis and How The Courts Can Solve It", 2009, p. 89; for a contrasted view, see NELSEN Robert and BISHOP Hans, "New Patent Law Would Trash Disease Cures", in FORBES, 24 March 2015 (Cofounder of ARCH Venture and Juno Therapeutics, respectively, stress that "fix"[ing] the US legal system on patent will weaken patent laws [and] will decimate long-term investment in cures for diseases such as Alzheimer's, Parkinson's, and Huntington's, as well as funding for new therapies to treat autism and breast, colon, lymphoma and prostate cancers"), available at www.forbes.com [accessed September 2016).

⁹¹² SUNDER, "The Invention of Traditional Knowledge", 2007, p. 101.

⁹¹³ GIBSON Johanna, "Audiences in Traditions: Traditional Knowledge and the Public Domain", 2007, pp. 174-188; see also generally KIENE, *The Legal Protection of Traditional Knowledge in the Pharmaceutical Field – An Intercultural Problem on the International Agenda*, 2011.

While the number of academic writings on public domain is vast, the concept of public domain remains not legally defined. In the realm of intellectual property rights, the TRIPS Agreement makes a reference to the concept of public domain in Article 70, paragraph 3, entitled “Protection of Existing Subject Matter”. This provision reads as follows: “There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain”. According to numerous commentaries on the TRIPS Agreement, it seems that the application of paragraph 3 refers to subject matter that has once been protected but has entered into the public domain before “the date of application of this Agreement (for instance for failure to pay the patent fees).⁹¹⁴

Generally speaking, the extent of the public domain informs about the legal status of categories of information and what kinds of uses are permitted with this information. In the field of intellectual property law, the public domain encompasses intangible goods that are not subject to exclusive intellectual property rights and which are freely available to be used or exploited by any interested person. Under patent law, and depending on the applicable national laws, public domain is delimited by various considerations. It encompasses material that is not, or is no longer, protected by patent laws, either because it has never been protected or because the term of protection has expired. In other words, while some inventions do not fulfil the patentability criteria,⁹¹⁵ others, which would otherwise be within the scope of patent protection, are excluded under national laws, for instance, for considerations based on morality and public order.⁹¹⁶ Thus, entry into the space of public domain is far from being uniform, and will depend on each patent law. For instance, country A might be more severe than country B in granting patents, and in this regard, the same subject matter will be in the public domain in one country and not in another country.

Having outlined the main characteristics of the concept of public domain and some of the ongoing debates amongst scholars, the following paragraphs will try to clarify the “local”

⁹¹⁴ CARVALHO, *The Trips Regime of Patents and Test Data*, 2014, Commentary on Article 70; see also, CORREA, *A Commentary on the TRIPS Agreement*, 2012, Commentary on Article 70, p. 510 (él

⁹¹⁵ The patentability conditions will significantly vary from one country to another depending on the level of standard of protection applied in each national law.

⁹¹⁶ See Part II, chapter 2 that fully discusses the patentability criteria.

position of traditional knowledge with regard to the pool of public domain knowledge and the pool of knowledge subject to exclusive rights.

2 **Public Domain and Intellectual Property Rights: What about Traditional Medicinal Knowledge?**

When looked through the prism of the legal doctrines underlying the intellectual property system, traditional knowledge is in the public domain as any other knowledge that is no longer protected by IP or that is excluded from the protection of IP (e.g. mathematics theories, or public order reasons). As commented by Gibson, “the application of the label of public domain to traditional knowledge assists in the organisation of all knowledge without reference to indigenous or local tradition”.⁹¹⁷ Traditional knowledge of indigenous communities has undergone a continuous process of assimilation into a globalised public pool of knowledge, whose borders are designated by intellectual property rights without consideration of the historical context and the present situation of indigenous peoples. Scholars often use an explicit analogy between the United States settlement of lands and appropriation of traditional knowledge of indigenous peoples and local communities. Indeed, these lands were considered to be *res nullius* ignoring the prior claims of Native Americans.⁹¹⁸ Today, the problem of appropriation that some indigenous and local communities face stems from the fact that their traditional knowledge is considered to be in the public domain.⁹¹⁹

According to Anthony Taubman “a hard utilitarian approach would presumably argue for the benefit of as much TK as possible to reside in the public domain”.⁹²⁰ Despite the fact that the

⁹¹⁷ GIBSON, “Audiences in Traditions: Traditional Knowledge and the Public Domain”, 2007, p. 177; see also CHANDER and SUNDER, “The Romance of the Public Domain”, 2004, p. 1332 (the authors stress on the erroneous “belief that because a resource is open to all by force of law, it will indeed be equally exploited by all”).

⁹¹⁸ COHEN, “Copyright, Commodification, and Culture: Locating the Public Domain”, 2006, (the author considers that public domain is metaphorically burdened by the original American usage that valorise private appropriation of the public domain of unsettled lands), p. 152.

⁹¹⁹ CAENEGBEM, “The Public Domain: Scientia Nullius?”, 2002, p. 329 (The concept of public domain justifies the denial of rights and rules relating to knowledge that has legitimacy within the confines of indigenous communities).

⁹²⁰ TAUBMAN, “Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge”, 2005, p. 548.

term public domain is “elastic and inexact”,⁹²¹ public domain will continue to be defined in relation to patents. In other words, intellectual property rights, generally, and patents, specifically, delimit the line where knowledge is free for use or not. As already discussed before, intellectual property rights, namely patents, trademarks and design are essentially driven by economic purposes. Because of their interdependency with the public domain, the latter is also a construction driven by commercial interests, consisting of those goods not anymore under exclusive or monopoly rights. In contrast, traditional knowledge, as described, is not fundamentally and solely about commercially driven goods.⁹²² It is rather an essential component of the cohesion and cultural integrity of the community. There are customary norms and rules governing the creation, preservation, transmission and access to traditional knowledge amongst the members of the community.⁹²³ Hence, with the exportation of traditional knowledge beyond the community, the issue of consent becomes fundamental. The next section will elaborate more extensively on the issue of the consent of indigenous peoples and the availability of their knowledge.

For some authors, public domain, as defined by intellectual property law, is a construct that cannot be transposed to traditional knowledge. Others suggest that the peril to the interest of indigenous peoples does not lie in the excessive appropriation by means of intellectual property rules, at least where the fundamental requirements of those rules are respected and patentability is properly confined to new and inventive circumstances. The real problem lies in the rule that all knowledge that is not deemed to be appropriated through intellectual property rules is in the public domain, available for unconditional use by all.⁹²⁴

If traditional knowledge of indigenous communities is considered as any other knowledge, then this traditional knowledge is definitely in the public domain. This assumption often

⁹²¹ LANGE, “Reimagining the Public Domain”, 2003, p. 463.

⁹²² FRANKEL, “Using Intellectual Property Rules to Support the Self-Determination Goals of Indigenous Peoples”, 2015, p. 639.

⁹²³ FROW, “Public Domain and Collective Rights in Culture”, 1998, pp. 39-52 (“Indigenous cultural systems are not built upon a principle of open access but are highly regulated and restricted: they are built upon secrecy as much as openness”).

⁹²⁴ CAENEGEM, “The Public Domain: Scientia Nullius?”, 2002, p. 330 (arguing that the public domain should be treated with circumspection. He proposed an approach to intellectual property law based on an elaborated taxonomy of knowledge, rather than on “crude and *ex-post facto* divisions such as that between proprietary and public domain knowledge).

stems from a general misapprehension that traditional knowledge is equivalent to the so-called grandmothers' recipes or knowledge widely practiced in Europe at a household level. What exactly is the difference between old wives tales and traditional knowledge? Chapter One of the first Part of this work has tried to bring some clarity to this question.

The differences between both sets of knowledge are mainly threefold. First and foremost, while in our technologically advanced societies, we have *consented* to place our traditional knowledge in the public domain, this is not the case with indigenous communities. This distinction is, in my opinion, fundamental and constitutes the main justification for indigenous peoples' claim to protect their knowledge from use by third parties, whether commercial or not, without their consent. Fundamentally, this claim has to be placed in the broader context of the indigenous peoples' right to self-determination.

Second, most indigenous communities, although living in a globalised world, have kept a distinctive way of living. Generally speaking, their lives are still governed by some paradigms that we have abandoned. In particular, they abide by their customary norms and rules which govern every aspect of their daily life, including the management of their traditional knowledge.

Third, the difference also stems from historical context and contemporary considerations. In comparison with indigenous peoples who suffered colonisation in the past, and marginalisation in the present, the knowledge of national minority groups, such as Bavarians, Basques, Catalans or Azeris for instance, might be less vital for their survival, or they do not feel the same level of threat in practicing their way of life. This is probably why they did not feel the same need for protection that many indigenous groups claimed.⁹²⁵ However, it should be noted that a discussion on minorities goes far beyond the subject matter of this work.⁹²⁶

Hence, the main characteristic of the traditional knowledge of indigenous peoples is that it evolves within the confines of a traditional community and it is inherently linked to the identity of that community. In that sense, it would be wrong to state that traditional

⁹²⁵ LEWINSKY, "Comments on Susy Frankel: 'Ka Mate Ka Mate' and the protection of traditional knowledge – an international perspective", 2014, p. 215.

⁹²⁶ For an in-depth analysis on the issue of minorities in international law, see MEIJKNECHT, *Towards International Personality: The Position of Minorities and Indigenous Peoples in International Law*, 2001.

knowledge forms part of a pool of information, unrestricted and free to be used by anyone.⁹²⁷ In that regard, many indigenous peoples do not recognise the concept of public domain.⁹²⁸

For instance, an indigenous group stated: “There is no public domain in traditional knowledge. [...] The idea of “already disclosed” and “non-disclosed” knowledge also is a false distinction. While the Western IP system often makes a distinction between knowledge for which there has been an attempt to keep it secret, and disclosed knowledge which has fallen or placed into the so called “public domain,” this distinction is not typically made in indigenous communities. Certainly, some knowledge is held in secret. Other knowledge is shared openly. Open sharing, however, does not automatically confer a right to use the knowledge. [...] When knowledge is shared, it is shared among those who are trusted to know their roles and responsibilities in using the knowledge.”⁹²⁹ Similarly, one member of the indigenous Saami Council summarized how indigenous peoples commonly see the concept of public domain: “Indigenous peoples had rarely placed anything in the so-called “public domain,” a term without meaning to them. The Committee should acknowledge that the

⁹²⁷ Presentation made by Professor Ruth OKEDIJI during the WIPO seminar on Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: Regional, National and Local Experiences, WIPO, Geneva, 30 March-1 April (“Saying that something that is in the public domain does not mean it is free to appropriate”); for a contrasted view, see HAHN, *Traditionelles Wissen indigener und lokaler Gemeinschaften zwischen geistigen Eigentumsrechten und der “Public Domain”*, 2004, p. 376 (the author argues that traditional knowledge are not eligible for intellectual property rights. She further argues that “the demarcation defined through the system of intellectual property rights between intellectual property rights and freely accessible public domain knowledge is valid for traditional knowledge as well as for all other forms of knowledge in an equal manner and should, in principle, not be altered”).

⁹²⁸ LONG, “Traditional Knowledge and the Fight for the Public Domain”, 2006, p. 320 (The author quotes some of the questions indigenous peoples ask when they are asked about public domain: “How come ‘public domain’ is my stuff? Yours is copyrightable and mine is in the public domain. How did that happen?” The answer, of course, is that we have developed a nice approach to protection. New works get protected. Their works have been around too long. Therefore, we all get to use them”).

⁹²⁹ WIPO ICG, ‘Statement by the Tulalip Tribes of Washington on Folklore, Indigenous Knowledge, and the Public Domain’, 9 July 2003, fifth session, available at: <http://www.wipo.int/export/sites/www/tk/en/igc/ngo/tulaliptribes.pdf> [accessed September 2016].

public domain is a construct of the IP system and does not take into account domains established by customary indigenous laws”.⁹³⁰

Another distinction highlighted previously, and which is important with regard to the discussion related to public domain, is as follows. Traditional medicinal knowledge falls into two main categories: (i) codified knowledge not necessarily linked to indigenous peoples; and (ii) non-codified knowledge forming part of the oral traditions of indigenous communities. Traditional medicinal knowledge evolving in an indigenous community context, which is rarely in written form, has to be distinguished from traditional medicinal knowledge that is in written form such as Ayurveda, Unani and traditional Chinese medicine. Codified traditional medicinal knowledge, such as Ayurvedic medicine, is perceived by more and more States to form part of their national cultural heritage.⁹³¹ Hence, does this mean that instead of falling into the public domain, the knowledge becomes part of the national cultural heritage of the State, such as Traditional Chinese Medicine, for instance? In contrast, orally transmitted traditional medicinal knowledge is perceived as only part of the cultural identity of indigenous communities, whose interests are often at odds with the State within which they live.

This distinction is important because the rationale for protection, and the means used to achieve it, will vary whether traditional medicinal knowledge is codified or not. With regard to inventions that are based on traditional medicinal knowledge, this distinction then becomes crucial. The probability of appropriation of traditional knowledge through patents (i.e. through the grant of bad patents) is significantly reduced when traditional medicinal knowledge is codified. The reason for this is that a Court, when assessing the novelty and inventiveness of an invention, will be more convinced by the evidence of a written prior art than a prior art use by indigenous communities.⁹³² However, and as has been shown earlier,⁹³³

⁹³⁰ WIPO IGC, ‘Report of the Fifth ICG Session, July 2003, WIPO/GRTKF/IC/5/15, para. 53, p. 25 (the representative of the Saami Council commented noted that “[i]ndigenous peoples had rarely placed anything in the so-called “public domain”, a term without meaning to them”).

⁹³¹ For instance, India proclaims sovereignty right over this ancestral system of medicine. India has implemented the traditional knowledge digital library (TKDL) especially encompassing traditional medicinal knowledge in 2001. International patent offices have access to the TKDL for patent search and examination. See in contrast, the South African Intellectual Property Laws Amendment Act 2013, p. 12, 37 and 56 (recognising traditional knowledge as the heritage of the community identified as the holder of the knowledge).

⁹³² See Part II, Chapter 2, 3.1 with regard to the assessment of novelty.

the fact that the knowledge is codified will not prevent the patenting of inventions based on traditional knowledge, if considered novel and inventive. Under this latter hypothesis, there is however a problem of use of traditional knowledge without the consent of the holders of such knowledge, whether States or indigenous and local communities.

Hence, in the realm of patents, public domain plays an important role as a watchdog of “bad patents” or erroneous patents; even though it is rather the prior art that better performs this. The draft Substantive Patent Law Treaty (SPL) defines prior art as “all information which has been made available to the public anywhere in the world in any form before the priority date of the claimed invention.”⁹³⁴

At this point, some clarifications have to be made as to other concepts such as “prior art”⁹³⁵ or “state of the art”⁹³⁶ and knowledge that is ‘publicly available’. These clarifications are fundamental to understanding the link between public domain and traditional knowledge.

First, once a patent is published, the subject matter of the claim becomes part of the prior art. However, this does not mean that the subject matter of claim enters the public domain. Indeed, the rights-holder will have exclusive rights over the claimed subject matter until the patent expires, normally after 20 years of protection. It is only then that the subject matter of the claim falls into the public domain, and is freely available to be used by anyone. Consequently, traditional medicinal knowledge might be considered prior art to an invention. However, this does not mean that traditional medicinal knowledge is in the public domain.

⁹³³ See generally, Part II, Chapter 2.

⁹³⁴ The draft Substantive Patent Law Treaty (SPLT) was discussed within WIPO SCP. See a description of the progress of SPLT negotiations at www.wipo.int/patent-law/en/harmonization.htm. The negotiations were put on hold in 2006 due on the lack of consensus. See, TVEDT, “One Worldwide Patent System: What’s in it for developing Countries?”, 2010, p. 284 (the author discusses a range of negative effects for developing countries if a “world patent system” is established); see also generally, TVEDT Morten, “How Will a Substantive Patent Law Treaty Affect the Public Domain for Genetic Resources and Biological Material?”, 2005, pp. 311-344.

⁹³⁵ “Prior art” is considered as the information that has been published in a written form or has otherwise been made available to the public, for instance, through public use, in any country before the date of filing of a patent. See Part II, Chapter 2, 3.1 and 3.2.

⁹³⁶ See for example, Swiss Patent Act, Article 7 : “*L’état de la technique est constitué par tout ce qui a été rendu accessible au public avant la date de dépôt ou de priorité par une description écrite ou orale, un usage ou tout autre moyen.*”

Second, the distinction between the concepts of ‘public availability’ or ‘public accessibility’ and ‘public domain’ is equally important with regard to traditional knowledge. The concept of public availability completes the notion of prior art, which refers to all knowledge that has been made available to the public prior to the priority date of a patent application. In other words, prior art must be publicly available in order to be considered as state of the art in a patentability assessment of a claimed invention. As defined earlier in this work, in the realm of the patent system, “available to the public” means that at least one member of the public had access to the information before the filing date of the application and in an unrestricted way, i.e. this person was not bound to secrecy or confidentiality.⁹³⁷ In the *NGK INULATORS* case mentioned earlier, the Board of Appeal of the European Patent Office concluded that the disclosure in an application, which has not been made available to public because of its confidential nature, cannot be used as a starting point for assessing the inventive step because the said disclosed information is not comprised in the state of the art.⁹³⁸

Consequently, if traditional knowledge is to be considered prior art in the assessment of patentability, this means that it should be publicly available under the intellectual property system paradigm, and in an unrestricted way. But importantly, this does not mean that traditional knowledge is freely available to be used by anyone in a patented invention, and without asking for authorisation.

This section has reached the following conclusions. When traditional knowledge constitutes prior art in the assessment of patentability, this knowledge will be publicly available. Although, this assumption does not equate to an assertion that traditional knowledge is in the public domain and freely available, it does entail other consequences. The following examples will help to better explain these subtleties.

- A. The invention is a pure copy of traditional medicinal knowledge.
- B. The invention is based on traditional medicinal knowledge, whether directly or indirectly.

For the assessment of patentability in case A, a court may reach different conclusions:

⁹³⁷ EPO Technical Board of Appeal, T 0245/88, *Union Carbide v. Linde*, 12 March 1991, Res. 3.2 (“the area inside the fence of a shipyard or a factory is certainly a non-public property”).

⁹³⁸ EPO Technical Board of Appeal, T 0211/06 - *NGK INULATORS*, 25 April 2007, Reasons 3.3, pp. 9-10.

First, it may uphold traditional knowledge as prior art because it is publicly available. The patent will then be invalid with regard to the novelty and inventiveness requirements. If traditional knowledge is considered to be part of the prior art, the patent will not be granted or will be invalidated, and the subject matter, i.e. the claimed traditional knowledge, will fall into the public domain. Consequently, the traditional knowledge can be freely used in a follow-up invention. This brings us directly to case B. Again, the court will assess the validity of the patent as regard to its novelty and inventiveness. As far as traditional knowledge is concerned, it is in the public domain, and can be used as many times as necessary in the future.

Second, the court can also conclude that traditional knowledge does not form part of the prior art, because it is not publicly available. Indeed, the general public is restricted from accessing traditional knowledge.⁹³⁹ Here the validity of the patent will not be based on a novelty and inventiveness assessment in comparison to the prior art, but on different grounds, such as morality or *ordre public* or access and benefit-sharing legislation. We have seen previously that the banning of patents based on traditional knowledge on morality grounds varies enormously from one region to another. This variability results in a diminishing of the principle of legal certainty.

The following section will elaborate further on the relationship between publicly available traditional medicinal knowledge and access and benefit-sharing obligations.

3 Publicly Available Traditional Medicinal Knowledge and Prior Informed Consent

The previous paragraphs have tried to give a definition of public domain through the prism of intellectual property rights. From both an intellectual property and public domain standpoint, the main objection to the protection of traditional knowledge is that creativity and innovation will depend on the ability to use the knowledge and works of others (placed in the public domain), which is publicly known and available.⁹⁴⁰

⁹³⁹ HAHN, *Traditionelles Wissen indigener und lokaler Gemeinschaften zwischen geistigen Eigentumsrechten und der "Public Domain"*, 2004, p. 165 ("besteht das Wissen innerhalb der gesamten Gemeinschaft, dann muss dies allein nicht bereits neuheitsschädlich sein, wenn die Gemeinschaft nicht mit der Öffentlichkeit gleichzusetzen ist").

⁹⁴⁰ FRANKEL, "Traditional Knowledge and Innovation as a Global Concern", 2015, p. 224.

The question is: Why should the use of traditional knowledge be justified only with respect to an IP delimitation of public domain? In other words, in the context of an intellectual property system, knowledge can be used if it is not, or is no longer protected by intellectual property rights. As mentioned before, free use is the general rule, while IP protection is the exception. However, according to UNDRIP and to the Nagoya Protocol,⁹⁴¹ public domain does not constitute an exception to the requirement to obtain prior informed consent from indigenous communities when accessing and using their knowledge.⁹⁴² Hence, the concept of public domain that applies to the conventional intellectual property system shall not restrict the requirement to obtain the prior informed consent of indigenous communities when accessing and using their knowledge.⁹⁴³ There are no justifications in distinguishing between traditional knowledge, whose use is subject to the requirement to obtain PIC, and traditional knowledge that is not subject to this requirement, or traditional knowledge to which only subject to access and benefit-sharing obligations.

Indeed, the Group of Technical and Legal Experts on Traditional Knowledge noted that “there is a critical distinction between traditional knowledge being in the public domain *versus* being publicly available.”⁹⁴⁴ The term public domain, indicating available for free, has been taken out of context and applied to traditional knowledge that might be publicly available. They further argue that “it cannot be assumed that traditional knowledge that has been removed from its distinctive cultural context [and] made available publicly does not belong to somebody”.⁹⁴⁵ They conclude that “within the concept of public availability, PIC from a traditional knowledge holder that is identifiable, could still be required, as well as provisions of benefit-sharing [...] including when a change in use is discernible from any earlier prior informed consent provided”.⁹⁴⁶

⁹⁴¹ The Nagoya Protocol makes direct references to UNDRIP and the right of indigenous peoples in its preambular paragraphs. See Part I, Chapter 3, 1.2.

⁹⁴² Nagoya Protocol, Article 5.5 (obligation to share the benefits every time traditional knowledge is used) and Article 7 (requirement to obtain PIC from indigenous communities).

⁹⁴³ NIJAR, “An Asian Developing Country’s View on Implementation Challenges”, 2013, p. 259.

⁹⁴⁴ CBD WG-ABS, ‘Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing’, 9-15 November 2009, UNEP/CBD/WG-ABS/8/2, para. 122, p. 21.

⁹⁴⁵ *Ibid.*

⁹⁴⁶ *Ibid.*

However, obtaining prior informed consent presupposes the identification of the indigenous community or communities as holders of the knowledge. Indeed, in some cases, traditional knowledge has become so widely accessible that its holders are not anymore identifiable. Maybe, this is the point where grandmothers' recipes and widely accessible traditional knowledge meet. In this case, any attempt to protect traditional knowledge reaches its limits. But the terms "widely accessible" could also cover situations where traditional knowledge is shared by various indigenous communities spread in various states. In that case, traditional knowledge shall still be eligible for protection.⁹⁴⁷

One example might be the "westernisation" of that community, namely when the community loses its indigenous identity, i.e. when the holders of traditional knowledge are not identifiable anymore.⁹⁴⁸ However, this assertion presupposes the following questions that remain to be dealt with: What should be the required steps to identify the holders? Who should take them? Part III will try to answer these questions.

⁹⁴⁷ See Part III, chapter 2, Section 1, "subject matter of protection".

⁹⁴⁸ Nagoya Protocol, Article 10 (the provision envisages the cases where it is not possible to grant PIC); see for example, TAUBMAN and LEISTNER, "Analysis of different areas of indigenous resources", 2008, pp. 79 and 80.

Chapter 4 Conclusion

This Part of the work had the intention of demonstrating how easily traditional medicinal knowledge can be integrated into a patented invention through selected illustrative case studies and a theoretical legal analysis. The direct or indirect use of traditional knowledge in a biotechnological invention raises questions about the patentability of the invention, namely for lack of novelty and/or inventiveness. However, the lack of description of the cultural knowledge increases the chance that its use goes unnoticed in the patent examination procedure. The fact that this knowledge is not widely inserted in and disseminated through the dominant scientific and technological discourses also causes patent offices and the Courts to grant patents based on traditional medicinal knowledge.⁹⁴⁹

In addition, the legitimacy of the appropriation is not questioned because traditional knowledge is deemed to be part of the public domain. Generally speaking, public domain is a device that permits the full functioning of the patent system by leaving the raw material available for inventors to use⁹⁵⁰ in order to create something new or original. “The public domain is the means and the end to promote the progress of science”,⁹⁵¹ and the society in general.⁹⁵² At the time of writing, the debate about public domain continues to be heated. The main reason for this may stem from the divergent theoretical justifications of property rights in information and the lack of strong empirical evidence to support these divergent theoretical claims. In other words, the answer to the basic question “do intellectual property rights foster

⁹⁴⁹ KOOPMAN, “Amidst Peril and Progress”, 2006, pp. 129-154 (“Here, one is confronted with different ways of looking at what substantially is the same [...] A notorious example is the European Patent (no. EP 436 257 B1) that was granted for a ‘...novel insecticide and ... fungicide derived from a neem seed’. This patent encompassed cultural knowledge, which had been applied for hundreds of years in India, and that – for purpose of acquiring the patent- was ‘technicised’ by the patent applicant”); see also GREENFIELD, ‘Recombinant DNA Technology: A Science Struggling with the Patent Law’, 1992, p. 1067 (stating that “[T]he modern trend is to allow patents for ‘products of nature’ so long as the inventor has changed the product to conform to the utility, novelty, and nonobviousness requirements of the patent statute”).

⁹⁵⁰ LITMAN, “The Public Domain”, 1990, p. 968.

⁹⁵¹ In the US Constitution formulation.

⁹⁵² GUIBAULT and HUGENHOLTZ, *The Future of the Public Domain: Identifying the Commons in Information Law*, 2006, p. 4 (“Under an ideal system of intellectual property law, rights and freedoms constitute a delicate balance between exclusivity and public domain, in which intellectual property’s incentives, principles of natural justice, the public interest and fundamental freedoms are all reflected”).

creativity?” is controversial and experts’ opinions diverge considerably.⁹⁵³ This debate goes far beyond the subject matter of the present analysis. The present work refers to another layer of interested rights-holders, who are indigenous peoples. It would be wrong to state that extracting traditional knowledge from the public domain, will reduce the pool of knowledge available. Indigenous peoples have not consented to nourish the public domain with their traditional knowledge, and it is questionable whether their traditional knowledge is in any event part of the public domain. Indeed, under the customary laws of indigenous groups, any use outside the community could be constitutive of a violation.⁹⁵⁴ Chapter Three of this Part has demonstrated that even though indigenous communities cannot claim ownership rights, such as patents, they still can assert some control over their publicly available traditional knowledge by requiring that the access and use of their traditional knowledge be subject to their prior informed consent.⁹⁵⁵ In other words, traditional medicinal knowledge that is publicly available is not in the public domain. In contrast, traditional medicinal knowledge that has lost its bonds with indigenous communities or that is not anymore claimed by indigenous communities may be assumed to be in the public domain. This has to be decided on a case by case basis.

This Part has also indirectly acknowledged the incompatibility of patents, specifically, and other forms of intellectual property, generally, as means for the protection of traditional knowledge of indigenous peoples. In the words of Dutfield, an eminent expert in the field of intellectual property rights and the rights to genetic resources and TK, patents principally fragment incremental collective innovative processes into “pieces” that are normally attributed to individuals or a team. By doing so, all other contributors are excluded.⁹⁵⁶ This finding has led to the search for other means of protection compatible with the characteristics of traditional knowledge, namely through a *sui generis* system. However, it would be wrong to conclude that the *sui generis* system should be completely alien from intellectual property

⁹⁵³ SIMON, “Intellectual Property and Traditional Knowledge: A Psychological Approach to Conflicting Claims of Creativity in International Law”, 2005, pp. 1613-1684.

⁹⁵⁴ See for instance, CBD WG-8j, ‘Report of the Expert Group on the Repatriation of Traditional Knowledge Relevant to the Conservation and Sustainable Use of Biological Diversity’, Montreal, 4-7 November 2015, UNEP/CBD/WG8J/9/INF/4, para. 30 (“Misuse of traditional knowledge outside the community could lead to specific cultural harm that might not generally be recognised in national laws and dominant cultures”).

⁹⁵⁵ We have seen in Chapter 3 of Part I, that international agreements provide the basis for their claims.

⁹⁵⁶ DUTFIELD, ‘Harnessing Traditional Knowledge and Genetic Resources for Local Development and Trade’, International Seminar on Intellectual Property and Development, WIPO, 2005, p. 19.

system, because, as already mentioned, this would annihilate the new system of protection, and render it ineffective. Another outcome may be that, in some jurisdictions, a *sui generis* system might overrule any prior conflicting laws.⁹⁵⁷ In other words, conflicts arising out of the interface between the *sui generis* system and the intellectual property system shall be resolved through a mechanism that will satisfy both users and providers of traditional medicinal knowledge.

⁹⁵⁷ FRANKEL, “‘Ka Mate Ka Mate’ and the protection of traditional knowledge”, 2014, p. 211.

PART III DEFINING A LEGAL REGIME OF PROTECTION

The first chapter will start with an assessment of the way in which the World Intellectual Property Organisation's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC) deals with traditional knowledge compared to the mandate of the Convention on Biodiversity's *Ad Hoc* Open-ended Working Group on Art. 8(j) and Related Provisions of the Convention (WG-8J) and whether or not an international binding treaty is foreseeable in the future. It will then discuss the policy objectives that motivate the protection of traditional knowledge before assessing how the principal beneficiaries – indigenous peoples – are participating in the negotiation process.

The second chapter will then turn to look at the WIPO-IGC's most recent Draft Articles and further examine selected provisions. The remaining part of the second chapter will emphasize the importance of recognising customary laws of indigenous peoples in any attempt to protect their traditional knowledge. This recognition goes hand with hand with respect for the principle of prior informed consent.

The third chapter will, first, analyse the proposal to register traditional knowledge to better protect it. Secondly, it will focus on the requirement to disclose traditional knowledge in a patent application. Specifically, it will examine discussions held at the World Trade Organisation (WTO) with regard to the protection of traditional knowledge, and particularly the proposal to render the objectives of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) compatible with the objectives of the CBD and the Nagoya Protocol through the disclosure of origin of traditional knowledge.

The remaining part will analyse the approaches adopted by Switzerland, Peru and the New-Zealand in their national laws.⁹⁵⁸ The present author has chosen these countries for the following reasons. In the first place, Switzerland has been chosen because not only has it been one of the first user countries to amend its legislation to render it in conformity with the ratified Nagoya Protocol, but also its legislation constitutes a fair balance between the interests of users and those of the providers of traditional knowledge associated with genetic resources. Peru has been selected as a provider country, as home to a large number of

⁹⁵⁸ An in-depth and comparative analysis of the various national and regional laws on the legal protection of traditional knowledge will be beyond the scope of the present subject matter.

indigenous communities, and because the Peruvian *sui generis* law for protection of “collective knowledge” constitutes, at present, one of the most advanced national laws in terms of the rights of indigenous peoples over their knowledge.⁹⁵⁹ Finally, our analysis looks at the solution in place in New Zealand because it constitutes both a user and a providing country, home to Māori.

Chapter 1 Towards an International *sui generis* System of Protection

As analysed in Part One, there are numerous instruments and multilateral bodies where traditional knowledge has become the subject of debates. Each of them has its own policy objectives and does not necessarily deal with the legal aspects of protecting traditional knowledge. As far as the subject matter of this work is concerned, the relevant fora where processes regarding multilateral treaty-negotiations are taking place are WIPO and WTO. However, the work of other multilateral bodies such as the “Ad Hoc Open-Ended Intersessional Working Group on Article 8(j) and Related Provisions” (WG-8J) and the United Nations Permanent Forum on Indigenous Issues (UNPFII) are also relevant for the debates and negotiations at WIPO and WTO. Indeed, they bring into the discussion fundamental matters essential for the protection indigenous peoples and local communities’ traditional knowledge as the first beneficiaries of the protection. These include their role in the conservation of biodiversity, their rights to: land; collective ownership; to be actively involved in decision making process directly involving their way of living; to be consulted and informed before using their knowledge; and last but not least, their right to see their customary laws reflected into national laws.

This chapter will start with an assessment of the way in which the IGC is dealing with traditional knowledge as compared to the CBD WG-8J and whether or not an international binding treaty is foreseeable in the future. It will then discuss the policy objectives that motivate the protection of traditional knowledge before assessing how the principal beneficiaries – indigenous peoples – are participating in the negotiation process.

⁹⁵⁹ WIPO, ‘Seminar on Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: Regional, National and Local Experiences’, Geneva, 30 March to 1st April 2015, WIPO/IPTK/GE/15/INF/1 PROV.2.

1 **WIPO-IGC and the CBD Working Group on Article 8(j)**

At the time of writing, while the responsibility for protecting traditional knowledge - specifically related to biodiversity - lies primarily with the Convention on Biological Diversity (CBD), in conformity with its Article 8(j),⁹⁶⁰ the overall discussion concerning the protection of traditional knowledge is mainly evolving within the World Intellectual Property Organisation (WIPO).⁹⁶¹

As mentioned earlier, the WIPO-IGC is, in accordance with its mandate, undertaking text-based negotiations with the objective of reaching agreement on three international legal instruments, which will ensure the effective protection of three subject matters, namely: traditional knowledge; genetic resources (whether or not associated with traditional knowledge) and traditional cultural expressions. While the instrument concerning the protection of genetic resources also partly deals with traditional knowledge associated with genetic resources, this work will solely focus on the instrument related to the protection of traditional knowledge. Notwithstanding, the analysis of the WIPO IGC Draft Articles will make some comparisons between both texts to highlight some contradictions.

As articulated in Part I, in 1998 the fourth Conference of the Parties (COP-4) of the Convention on Biodiversity, established the Working Group on Article 8(j) (WG-8J), and its work continues as of today, to consider the development of elements of a *sui generis* system for the protection of traditional knowledge associated with biodiversity.⁹⁶² The collaboration between WIPO-IGC and CBD bodies crystallised at COP-4 when the latter recognised that “intellectual property rights may have implications for the implementation of the Convention and achievement of its objectives under Article 8(j)”. It further stated that the CBD and

⁹⁶⁰ CBD, Article 8(j) (the provision states that “[e]ach Contracting Party Shall, as far as possible and as appropriate: subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices”).

⁹⁶¹ The Council for TRIPS is also involved in the issue relating to the protection of traditional knowledge following instructions by the Doha Declaration. See Part I, Chapter 3, 2.2.

⁹⁶² CBD COP, ‘Report of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity’, 4-15 May 1998, UNEP/CBD/COP/4/27, Annex, Decision 9, pp. 111 ff.

intellectual property agreements should be made mutually supportive, and that further cooperation and consultation with WIPO was particularly desirable.⁹⁶³

Thus, because of this close cooperation, there is significant overlap with regard to the issues and the proposals on the protection of traditional knowledge being developed by the WG-8J and the IGC. First, proposals by either side rely on the need to tackle misappropriation as the primary objective for the protection of traditional knowledge. Second, both recognise the rights of indigenous and local communities to prior informed consent and benefit-sharing arising from the use of their traditional knowledge. Third, they both acknowledge the fundamental role of customary laws and practices and the requirement of prior informed consent in the development of measures aiming to protect traditional knowledge.⁹⁶⁴

However, the mandate of the WG-8J is different from that of the WIPO-IGC. While the former is clearly delimited by the objectives of the CBD, i.e. the conservation and sustainable use of biodiversity, which only applies to traditional knowledge associated with genetic resources,⁹⁶⁵ the latter covers the content or substance of knowledge resulting from intellectual activity in the traditional context independent of any field and is clearly focused on intellectual property rights. Further, as opposed to the WG-8J, which essentially performs an advisory function for the implementation of Article 8(j) of the CBD and the newly adopted Nagoya Protocol⁹⁶⁶ in national and regional laws, the new mandate of the IGC consists in negotiating a final international instrument for the protection of traditional knowledge.⁹⁶⁷ In

⁹⁶³ CBD COP, 'Report of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity', 4-15 May 1998, UNEP/CBD/COP/4/27, Annex, Decision 9, pp. 111 ff.

⁹⁶⁴ CBD WG-8J, 'Possible Elements of *Sui Generis* Systems for the Protection of Traditional Knowledge, Innovations and Practices of Indigenous and Local Communities', 7-11 October 2013, UNEP/CBD/WG8J/8/6/Add.1, p. 3. ; See also, WIPO, 'Customary Law, Traditional Knowledge and Intellectual Property: An Outline of the Issues, 2013.

⁹⁶⁵ CBD WG-8J, 'Possible Elements of *Sui Generis* Systems for the Protection of Traditional Knowledge, Innovations and Practices of Indigenous and Local Communities', 7-11 October 2013, UNEP/CBD/WG8J/8/6/Add.1, p. 2.

⁹⁶⁶ While the recently adopted Nagoya Protocol clearly concretise many aspirations of indigenous and local communities with regard to their traditional knowledge, it nevertheless places the responsibility upon States to recognise and provide their rights with regard to their knowledge by enacting national laws in that sense.

⁹⁶⁷ WIPO GA, 'Draft Report', adopted by the 47th session of the GA, 2 November 2015, WO/GA/47/19 PROV, para. 288, p. 56; see also, WIPO agenda for 2016-2017 at: www.wipo.int/tk/en/igc/ [accessed September 2016]; see also, Juscancz countries, including the EU, which regard the WIPO-IGC, as the

the event that the WIPO negotiations successfully lead to a binding instrument, the resulting treaty shall be mutually supportive of the Nagoya Protocol pursuant to its Article 4(3).⁹⁶⁸

The IGC's debates and discussions are characterized by the interplay of politics. The divergent opinions regarding key issues related to the protection of traditional knowledge appear at different levels within the IGC as well as in other multilateral fora. At one level, there is often a lack of consensus between developing and developed countries. At another level, the divergences result from the conflicting relationship between some Member States and indigenous peoples living within their jurisdiction.⁹⁶⁹ Broadly speaking, there are principally four categories of stakeholders in the debate concerning the protection of traditional knowledge: indigenous peoples; member states; the industry; and non-governmental organisations. In the multilateral fora where these debates are taking place, indigenous stakeholders are represented by individuals from indigenous communities or national and international non-governmental organisations. States include countries that are members of the multilateral forum or signatories of international instruments dealing with the issue of traditional knowledge. In turn, industry stakeholders represent industries which have either direct or indirect commercial interests in traditional knowledge debates.

A highly controversial issue between the stakeholders concerns the choice of the forum that should address the protection of traditional knowledge. As already mentioned, each forum has its own policy objectives.⁹⁷⁰ Generally speaking, developed countries, including the United States and the European Communities and their Member States favour WIPO as the

primary international forum and decision-making body for any debate on the intellectual property law aspects of the protection of traditional knowledge, see CBD WG-8J, 'Development of Elements of *Sui Generis* System for the Protection, Preservation and Promotion of Traditional Knowledge, Innovations and Practices Relating to Biological Diversity', 7-11 October 2013, UNEP/CBD/WG8J/8/6, pp. 4 and 5.

⁹⁶⁸ Nagoya Protocol, Article 4(3) reads as follow: "This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol".

⁹⁶⁹ NEW William, "New Texts in Play in WIPO Traditional Knowledge, Genetic Resources Talks", Intellectual Property Watch, 12 May 2011, available at: <http://www.ip-watch.org/2011/05/12/new-texts-in-play-in-wipo-traditional-knowledge-genetic-resources-talks/>, [accessed September 2016].

⁹⁷⁰ BOYLE, *Shamans, software, and Spleens – Law and the Construction of the Information Society*, 1996, p. 12.

appropriate forum. Their argument is that WIPO has already been working on this issue for more than a decade and has thus acquired an in-depth expertise on these matters. Further, a change of forum would unnecessary duplicate the work already performed.⁹⁷¹ Other, mostly developing countries, but also some developed ones, support a coordination of efforts between all the fora involved in discussing the protection of traditional knowledge. In other words, they consider that discussions should proceed in parallel in WIPO, WTO and CBD forums to ensure a systematic and mutually supportive solution.⁹⁷² They stress that a final international instrument agreed within WIPO-IGC would be meaningless if it is not supported by the main legal basis of the global intellectual property rights systems that is the TRIPS Agreement. Any change to the TRIPS Agreement has to be necessarily discussed at the WTO.⁹⁷³ It is equally important to note that, at this stage of discussions, the WTO would not constitute the appropriate forum to take the lead in an issue that directly affects the situation of traditional knowledge holders. Indeed, in contrast to other forums, indigenous stakeholders cannot participate in the WTO meetings.

At the time of writing, the WIPO-IGC continues to take the lead in the multilateral debates on the protection of traditional knowledge. In the WTO, no substantial results have been reached, and discussions in the latter forum are at a standstill.

2 An International Binding Treaty

Aside from debates over the choice of forum, the most controversial issue between Member States concerns the nature of an international regime, i.e. whether it should be legally binding or not. In general, whereas developing countries, including the group of Like-Minded Megadiverse Countries (LMMC)⁹⁷⁴ support a legally binding instrument, developed countries,

⁹⁷¹ WTO TRIPS Council, 'The Relationship between the TRIPS Agreement and the Convention on Biological Diversity', 8 February 2006, IP/C/W/368/Rev.1, p. 8.

⁹⁷² WTO TRIPS Council, 'The Protection of Traditional Knowledge and Folklore – Summary of Issues Raised and Points Made', 9 March 2006, IP/C/W/370/Rev.1, p. 7.

⁹⁷³ See also KIENE, *The Legal Protection of Traditional Knowledge in the Pharmaceutical Field – An Intercultural Problem on the International Agenda*, 2011, p. 197.

⁹⁷⁴ The Like-Minded Megadiverse Countries (LMMC) is a group of countries that harbour the majority of the Earth's species and are therefore considered extremely biodiverse. They are rich in biological diversity (60-70% of the world's biodiversity) and associated traditional knowledge. More information on the LMMC is available at: <https://lmmcgroup.wordpress.com/2014/03/24/welcome-to-the-group-of-like-minded-megadiverse-countries/> [accessed September 2016].

including JUSCANZ⁹⁷⁵ are opposed to such a binding treaty. Some countries, namely the United States, do not endorse an instrument even in the form of a declaration, because even if non-binding, the final instrument might create expectations of compliance that could gain some form of authority with time.

Thus, whilst in 2003, developed countries and representatives of indigenous peoples considered that it was premature to move forward to negotiations on an international instrument “without the development of an informed understanding of what that regime might entail”,⁹⁷⁶ developing countries, generally, and the Asian and African Group, particularly, proposed a deadline for discussions at the end of which an international instrument should be negotiated.⁹⁷⁷

In 2009, the renewed mandate of the WIPO-IGC indicated that the Committee would undertake “text-based negotiations with the objective of reaching an agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of genetic resources, traditional knowledge, and traditional cultural expressions.”⁹⁷⁸ While this mandate has been considered to be the strongest mandate of the WIPO-IGC, it failed to mention the legal nature of the international instrument. Nor does the decision make any express mention of the holders of traditional knowledge, but merely refers to “the participation of experts from developing countries and least developed countries”.⁹⁷⁹

⁹⁷⁵ The JUSCANZ group includes Australia, Canada, Iceland, Japan, New Zealand and the US and subsequently expanded to include Switzerland and Norway. It is a caucus of like-minded countries on certain environment-related issues such as climate change. This is an alliance of Japan, the US, Canada, Australia, New Zealand, Norway, Israel and others. It essentially includes most major non-European Union members of the WEOG, plus Japan. It ensures the European Union is not able to dominate WEOG discussions and proposals. WEOG is in turn constituted by mostly Western European and other Groups. More information on United Nations Regional Groups of Member States is available at: <http://www.un.org/depts/DGACM/RegionalGroups.shtml> [accessed September 2016].

⁹⁷⁶ WIPO IGC, ‘Report’, 7-15 July 2003, WIPO/GRTKF/IC/5/15, para. 172, p. 64.

⁹⁷⁷ WIPO IGC, ‘Report’, 7-15 July 2003, WIPO/GRTKF/IC/5/15, para. 129, 134, p. 54, 56 (the Delegation of India stressed that “norm-setting efforts should be at the core of the future work of the Committee”).

⁹⁷⁸ WIPO GA, ‘Report’, adopted by the 38th GA, Geneva, 1st October 2009, WO/GA/38/20, para. 217, pp. 60-61.

⁹⁷⁹ WIPO GA, ‘Report’, adopted by the 38th GA, 1st October 2009, WO/GA/38/20, para. 217, p. 61.

In 2011, the WIPO General Assembly again mandated the IGC to come up with a solution to the problem of theft of traditional knowledge, folklore and genetic resources, which is particularly problematic in developing countries.⁹⁸⁰ However, in September 2014, the WIPO IGC process suffered a major setback when its work faced strong opposition by the United States, which is not a party to the Nagoya Protocol, to establishment of a diplomatic conference on any of its three draft instruments.⁹⁸¹

While the 2014 WIPO General Assembly did not make a decision on the work programme of the IGC, it did renew the IGC mandate for the next biennium 2016-2017. The Committee's mandate, as renewed, stipulates that "the Committee will, during the next budgetary biennium 2016/2017, continue to expedite its work, with a focus on narrowing existing gaps, with open and full engagement, including text-based negotiations, with the objective of reaching an agreement on an international legal instrument(s), without prejudging the nature of outcome(s)⁹⁸², relating to intellectual property which will ensure the balanced and effective protection of genetic resources (GRs), traditional knowledge (TK) and traditional cultural expressions (TCEs)."⁹⁸³

The mandate further states that the Committee's priority will be to reach a common understanding on essential issues, such as the definition of misappropriation, beneficiaries, subject matter, the scope of protection at the international level, and the linkages with public domain.

The most recent discussions within the Committee show that while all Member States agree on the need for an instrument, the positions of developing countries and developed countries has not changed with regard to the legal nature of the final instrument. While developing countries stand firm on the need for a legally binding international treaty, developed countries

⁹⁸⁰ WIPO GA, 'Report, adopted by the 41st GA, 9 October 2012, WO/GA/41/15, p. 1.

⁹⁸¹ WIPO GA, 'Report', adopted by the 46th session of the GA, 15 January 2015, WO/GA/46/12, para. 173, p. 46.

⁹⁸² Concerning the possible form or status of any outcome, see WIPO IGC, 'Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources: The International Dimension', 15-19 March 2004, WIPO/GRTKF/IC/6/6, p. 14.

⁹⁸³ WIPO GA, 'Report', adopted by the 47th session of the GA, 14 October 2015, WO/GA/47/19, para. 288, p. 56.

are clearly reluctant.⁹⁸⁴ In a recent statement, the Delegation of the European Union clearly stated that “the IGC would not succeed in balancing both a better recognition of TK and safeguarding existing freedoms and the public domain, if it continued working in the context of binding instrument”.⁹⁸⁵

As far as indigenous stakeholders are concerned, they are not opposed to an international treaty as long as “the primary objective of the international legal instrument is to protect indigenous peoples’ rights and interests as owners / holders of traditional knowledge” and that “the instrument recognises the principle of free, prior and informed consent of indigenous peoples”.⁹⁸⁶

At the eighteenth session of the WIPO IGC, in 2011, indigenous peoples submitted a joint statement reaffirming their position with regard to the proposed WIPO international legal instrument. Additionally, they stated: “Our continued presence in IGC-18 in no way can be taken to say that Indigenous Peoples have collaborated in the drafting of these documents in this session. Nor can our observation of this process be inferred as giving any consent to the results of any process in which Indigenous Peoples have not been actively involved”.⁹⁸⁷

According to one author, the discussion with regard to the nature of a potential instrument is characterised by a battle between “stalling delegations” and “speeding up delegations”, respectively developed and developing countries.⁹⁸⁸ For the former, the strategy is to argue

⁹⁸⁴ See also, OGUAMANAM, *Intellectual Property in Global Governance. A Development Question*, 2013, p. 180 (the author considers that the new mandate reflects “a forced shift from developed countries’ censorship of a norm-setting approach” to the acceptance of the need to reach an agreement on a binding treaty on traditional knowledge).

⁹⁸⁵ WIPO IGC, ‘Report’, 24 March to 4 April 2014, WIPO/GRTKF/IC/27/10, para. 53, p. 18.

⁹⁸⁶ WIPO IGC, ‘Report’, adopted by the IGC, Geneva, 9 - 13 May 2011, WIPO/GRTKF/IC/18/11, para. 380, p. 58.

⁹⁸⁷ Text submitted by the representative of the Indigenous peoples during the WIPO IGC, 9 – 13 2011. Later referenced in WIPO IGC, ‘Report’, adopted by the IGC, Geneva, 9 - 13 May 2011, WIPO/GRTKF/IC/18/11, para. 380, p. 58 (“[our] continued participation must not be construed as endorsing the drafting proposals or any outcomes for that matter”).

⁹⁸⁸ For an in-depth discussion of the political interplays and communicative strategies within the WIPO IGC, see, GROTH, “Negotiating Tradition. The Pragmatics of International Deliberations on Cultural Property”, 2012, p. 44 (the author acknowledges that “the distinction is only an abstraction of a more complex constellation of actors and motivations to characterise far more complex and multi-layered processes”).

that “available documentation and information is not sufficient to make decisions about substantive questions”.⁹⁸⁹ Member States, including the United States, repeatedly call for “an extended discussion of already discussed questions in order to prevent the negotiations from proceeding”.⁹⁹⁰ By sticking to procedural issues, they circumvent substantive question. These strategies are repeatedly questioned by “speeding up delegations”. For instance, the delegation of Egypt compared the discussions at the WIPO IGC to a “talk shop where positions are consistently restated without any evolution”.⁹⁹¹

It is unforeseeable whether Member States will arrive at an agreement on the legal nature of the potential instrument until the General Assembly meets again in 2017 and whether the mandate of the Committee will be renewed for a next biennium. What is undeniable, however, is the extensive work that the Committee has carried from its creation until now, particularly by identifying a myriad of issues in need of determination, including the policy objectives, the subject matter of protection, the beneficiaries of protection, the scope of protection and its duration, sanctions, transboundary cooperation and the relationship with other international agreements. This list of issues has since then taken shape in the form of the Draft Articles on the protection of traditional knowledge. Similarly, the work of the committee has been a source of inspiration for efforts at the national and regional level. A number of WIPO Member States have enacted or are in the process of developing law on the protection of traditional knowledge by applying and adapting the draft WIPO provisions to their national circumstances. These countries include, amongst others, Peru, Costa Rica, Panama, and the Philippines.⁹⁹²

⁹⁸⁹ GROTH, “Negotiating Tradition. The Pragmatics of International Deliberations on Cultural Property”, 2012, p. 126.

⁹⁹⁰ GROTH, “Negotiating Tradition. The Pragmatics of International Deliberations on Cultural Property”, 2012, p. 54; see for example, the comment made in a later session referred to in WIPO IGC, ‘Report’, 30 May – 3 June 2016, WIPO/GRTKF/IC/30/10, para. 59, p. 27 (“[t]he Delegation of the United States of America pointed out that, since document WIPO/GRTKF/IC/30/5 contained an indicative list of outstanding and pending issues to be solved, it was its understanding that it would be allowed to raise and discuss additional issues that were not contained in that list”).

⁹⁹¹ WIPO IGC, ‘Report’, 3 July 2009, WIPO/GRTKF/IC/14/12, para. 22, p. 8; see also, WIPO IGC, ‘Report’, 30 May – 3 June 2016, WIPO/GRTKF/IC/30/10, para. 65 (“the African Group was concerned that [the additional issues that the US would raise] might not help to narrow gaps envisaged”).

⁹⁹² See Indigenous Peoples Rights Act of 1997 referred to in WIPO IGC, ‘Comparative Summary of Existing National Sui Generis Measures and Laws for the Protection of Traditional Knowledge’, 7 – 15 July 2003,

Equally, at the regional level, in 2010, the African Regional Intellectual Property Organisation (ARIPO)⁹⁹³ adopted the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore.⁹⁹⁴ This protocol is a *sui generis* system of protection of traditional knowledge. Traditional owners are recognised as having the exclusive right to authorise use and exploitation of their traditional knowledge.⁹⁹⁵ The Swakopmund Protocol's provisions are very similar to the draft articles prepared by the WIPO IGC. The Protocol establishes minimum standard in broad terms for States to further implement. Thus, while the Protocol recognises communities' rights of ownership, the control of third party use of traditional knowledge lies with the national authorities.⁹⁹⁶ Indeed, the recognition of rights in the Protocol conflicts with the law of the majority of African countries, where the State is recognised as the only owner of traditional knowledge, and as such also controls the use of traditional knowledge by third parties.

Eventually, if Member States agree to conclude an international binding agreement on the protection of TK, some tricky legal questions may need to be resolved first. Amongst those is the major question of the recognition of foreign rights-holders within a national jurisdiction. At the regional and international level, the principle of "most-favoured nation"⁹⁹⁷ and of national treatment⁹⁹⁸ should be considered. This is more so because amongst the existing national *sui generis* law regarding the protection of traditional knowledge, traditional knowledge is only protected domestically. This solution is far from being satisfactory as

WIPO/GRTKF/IC/5/INF/4, Annex, p. 5; see also, MAHOP, *Intellectual Property, Community Rights and Human Rights – The biological and genetic resources of developing countries*, 2010, p. 48.

⁹⁹³ English-speaking African States excluding South Africa, have formed their own regional African IP Systems.

⁹⁹⁴ Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the African Regional Intellectual Property Organisation (ARIPO), adopted by the Diplomatic Conference of ARIPO at Swakopmund (Namibia), 9 August 2010 (Swakopmund Protocol).

⁹⁹⁵ Swakopmund Protocol, Section 7.1.

⁹⁹⁶ NWAUCHE, "The Swakopmund Protocol and Community Ownership and Control of Expressions of Folklore in Africa", 2014, p.191

⁹⁹⁷ See, for example, TRIPS, Article 4 (the Article states that: "with regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members").

⁹⁹⁸ See also, TRIPS, Article 3 (the Article states that "each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property").

awareness of the international dimension has arisen principally because of the expectation that traditional knowledge originating in one country should be protected against misappropriation in other jurisdictions.

3 **Protection according to Policy Objectives**

Before analysing the substantive provisions of the WIPO-IGC Draft Articles, the following will provide an overview of the different objectives of protection generally, and the specific objectives endorsed by the WIPO-IGC.

Generally speaking, different objectives lie behind the motivations for the protection traditional knowledge. This section does not intend to list all of them, but only those that are of interest for the purpose of this work. First, if we consider that the subject matter of protection is traditional medicinal knowledge without any reference to the rights of communities generating, holding and perpetuating this knowledge, the rationale of protection will be the prevention of the disappearance of traditions, that is, the conservation of traditions. The objective may also be the preservation of biological diversity, an objective that may be reached through the preservation of traditional knowledge. Thus, the protection of traditional medicinal knowledge would ensure the preservation of mankind's cultural heritage or biodiversity subject to perish. Thus, the beneficiaries of protection will be humankind in general. This kind of traditional medicinal knowledge does not normally encompass codified systems of traditional medicinal knowledge, such as Ayurvedic, Unani or codified traditional Chinese medicine, which are not at risk of perishing due to their codification. Second, the protection of traditional medicinal knowledge, in the sense of its preservation, is also directed to promoting health care in poor regions of the world where the inaccessibility of essential drugs is a reality.⁹⁹⁹ Third, economic and social development through innovation based upon previous knowledge, knowledge often deemed to be in the public domain, including traditional medicinal knowledge is another policy objective. Under that hypothesis, the interested actors might be academic research institutions, individual researchers, bio-prospectors, industries, States and potentially, but rarely, indigenous communities. Building

⁹⁹⁹ WHO, 'Report of the Commission on Intellectual Property Rights, Innovation and Public Health: Public Health, Innovation and Intellectual Property Rights', 2006, p. 164 (the concerns expressed by the World Health Organisation concern the risk "that introducing a form of intellectual property protection for traditional knowledge may actually have the effect of restricting access by others, thereby inhibiting downstream innovation").

on this hypothesis, the fourth policy objective concerns the protection of traditional medicinal knowledge in a legal sense, that is, “protection against the kinds of illicit uses and misappropriation that intellectual property rules usually address”.¹⁰⁰⁰ Protection in that sense involves a continuing control over the traditional medicinal knowledge, such as a right to exclude or other means of continuing entitlement linked to the knowledge.¹⁰⁰¹ To date, this policy objective is the task that the WIPO IGC has focused upon since 2000. Indeed, this is expressly stated in the policy objectives of the latest Draft Articles.¹⁰⁰²

Although there is no doubt that the work of the WIPO IGC on the protection of traditional knowledge is essentially driven by intellectual property rights considerations,¹⁰⁰³ which corresponds to its mandate, which corresponds to the objectives of the Convention Establishing the World Intellectual Property Organisation,¹⁰⁰⁴ the WIPO IGC envisions reaching an understanding amongst States on issues beyond the conventional intellectual property system.¹⁰⁰⁵

¹⁰⁰⁰ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Objectives and Principles’, 30 November – 8 December 2006, WIPO/GRTKF/IC/10/5, para. 17, p. 5.

¹⁰⁰¹ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Gap Analysis: Revision’, 11 October 2008, WIPO/GRTKF/IC/13/5(b) Rev., para. 11, p. 6.

¹⁰⁰² WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7-9 July 2014, WIPO/GRTKF/IC/28/5, Annex, p. 4 (the first policy objective of the Draft Articles is to “prevent the [misappropriation/misuse/unauthorised use/unfair and inequitable uses] of their traditional knowledge”).

¹⁰⁰³ See WIPO GA, ‘Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore’, Document prepared by the Secretariat, 25 September – 3 October 2000, WO/GA/26/6, para. 14, p. 4 (the General Assembly decided that “[t]he Intergovernmental Committee would constitute a forum in which discussions could proceed among Member States on the three primary themes which they identified during the consultations: intellectual property issues that arise in the context of (i) access to genetic resources and benefit sharing; (ii) protection of traditional knowledge, whether or not associated with those resources; and (iii) the protection of expressions of folklore”).

¹⁰⁰⁴ Convention Establishing the World Intellectual Property Organisation, Stockholm, 14 July 1967, WO029, as amended in 1979, 828 UNTS 3 (WIPO-Convention). The main objectives of the WIPO-Convention are: (i) to promote the protection of intellectual property throughout the world; (ii) to encourage the conclusion of international agreements aiming to promote the protection of intellectual property; and (iii) the administration of international intellectual property rights treaties and agreements.

¹⁰⁰⁵ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Objectives and Principles’, 30 November – 8 December 2006, WIPO/GRTKF/IC/10/5, para. 17, p. 6; see also OGUAMANAM, *Intellectual Property in*

WIPO has itself repeatedly acknowledged the “dual task”¹⁰⁰⁶ with which it is confronted, and notes that while the protection of traditional knowledge forms an integral part of policies concerning the promotion and protection of innovation, the protection of traditional knowledge touches upon other important policy areas. These encompass the safeguarding and preservation of diverse knowledge systems and the intellectual and cultural heritage of communities; respect for the rights, interests and claims of indigenous peoples; conservation of the components of biodiversity and associated TK, and mechanisms for prior informed consent and equitable benefit-sharing; access to knowledge and the scope of the “public domain”; addressing the challenges of multiculturalism; and, the promotion of cultural diversity and the distinctive character, values and beliefs of diverse knowledge systems.¹⁰⁰⁷

The “policy objectives” of the latest Draft Articles also reflects this “dual task”. They state that the instrument should aim:

- (a) to provide Indigenous Peoples with the legal means to: (i) prevent the misappropriation of their traditional knowledge; (ii) control ways in which their TK is used beyond the traditional and customary context;¹⁰⁰⁸ (iii) promote equitable benefit-sharing arising from use with prior informed consent; (iv) encourage and protect tradition-based creation and innovation.

Global Governance. A Development Question, 2013, p. 178 (the author argues that “the Committee represents the tension between a holistic and bifurcated or fragmented approach to TK”).

¹⁰⁰⁶ KIENE, *The Legal Protection of Traditional Knowledge in the Pharmaceutical Field – An Intercultural Problem on the International Agenda*, 2011 (the author affirms that the role of the WIPO with regard to the protection of TK is characterised by its “dual task” of promoting the global intellectual property system and assessing the potential changes to this system in order to adequately protect TK).

¹⁰⁰⁷ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Objectives and Principles’, 30 November – 8 December 2006, WIPO/GRTKF/IC/10/5, para. 15, p. 5.

¹⁰⁰⁸ WIPO IGC, ‘The Protection of traditional Knowledge: Revised Objectives and Principles’, 9-13 May 2011, WIPO/GRTKF/IC/18/5, FN 44, p. 17 (The Delegation of South Africa opposed the suggestion of the United States to delete the wording ‘beyond its traditional context’ “because that was why the misappropriation and misuse beyond the control of communities happened and that was why they needed protection. The use and misappropriation within the traditional communities was regulated by customary law within those communities. To delete ‘beyond its traditional context’ meant that protection which was beyond its boundaries was actually being eliminated in that context”).

(b) To prevent the grant of erroneous patents rights over traditional knowledge.¹⁰⁰⁹

These policy objectives have to be translated into concrete rights for the originators of traditional knowledge in accordance with Article 31 of the UN Declaration on the Rights of Indigenous Peoples. In other words, the design of a *sui generis* system for the protection of traditional knowledge must be tailored in such a way as to fit the *distinctive* character of traditional knowledge. By doing this, it has to pay due respect to the indigenous peoples' own approach to defining and protecting traditional knowledge.

4 The Voice of Indigenous Peoples in the International Debate

WIPO Member States are the principal actors in the WIPO Intergovernmental Committee. While it was established that the WIPO-IGC would be open to all Member States, the “relevant intergovernmental organizations and accredited international and regional non-governmental organizations [were] invited to participate in an observer capacity”.¹⁰¹⁰ Decisions concerning accreditations are made by Member States at the beginning of each IGC session.¹⁰¹¹ The NGOs accredited to participate in IGC meetings encompass organisations holding interests in intellectual property rights¹⁰¹² and organisations representing indigenous peoples.¹⁰¹³

The participation of indigenous peoples has been enhanced through the establishment, in 2005, of the WIPO Voluntary Fund for Accredited Indigenous and Local Communities (“Voluntary Fund”), which recognised that their ability to participate would depend on proper

¹⁰⁰⁹ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7-9 July 2014, WIPO/GRTKF/IC/28/5, Annex, p. 4.

¹⁰¹⁰ WIPO GA, ‘Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore’, 25 September – 3 October 2000, WO/GA/26/6, para. 16, p. 4.

¹⁰¹¹ The updated list of accredited NGOs is published on the WIPO IGC’s website, at: <http://www.wipo.int/tk/en/igc/participation.html> [accessed September 2016].

¹⁰¹² International Association for the Protection of Intellectual Property (AIPPI), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), International Chamber of Commerce (ICC), etc.

¹⁰¹³ Foundation for Aboriginal and Islander Research Action (FAIRA); *Instituto de Indígena Brasileiro de Propriedade Intelectual* (InBraPi); Assembly of First Nations; Indigenous Peoples’ Council on Biocolonialism (IPCB); Saami Council; Traditions for Tomorrow; Indigenous Peoples’ Biodiversity Network; Tulalip Tribes of Washington Governmental Affairs Department, etc.

financial support.¹⁰¹⁴ While the Voluntary Fund is able to receive contributions from governments, NGOs, and public or private entities on a voluntary basis, the twenty-eighth session of the IGC was unable to fund any indigenous participants due to a lack of resources. The absence of indigenous representatives at the IGC's session, might seriously undermine the credibility of any future outcome directly concerning indigenous communities. The proposal of some Member States to resort to the regular WIPO budget to finance their participation was heavily opposed by the United States, Germany and Sweden.¹⁰¹⁵

As far as their involvement in the drafting process goes, WIPO has adopted measures to strengthen the participation of indigenous representatives, such as for instance, the creation of a webpage, where indigenous and local communities can submit their "experience" on the protection of their knowledge.¹⁰¹⁶ However, the fact remains that indigenous and local communities are not permitted to participate actively in negotiations. In other words, their submissions during the drafting of the Articles are only taken into consideration if they are backed up by at least one Member State. "Compared to the COP of the CBD, the WIPO-IGC is still not as open to non-governmental stakeholders and so to representatives of traditional knowledge holders as the COP, where their participation is much easier."¹⁰¹⁷ The reason is probably due to the fact that the CBD COP is unlikely to negotiate legally binding international norms on the protection of traditional knowledge in the context of intellectual property rights.¹⁰¹⁸

Notwithstanding the efforts made in WIPO IGC and in the CBD forums, the participation of indigenous stakeholders has no real impact on any final decision concerning their knowledge

¹⁰¹⁴ WIPO GA, 'Participation of Indigenous and Local Communities: Establishment of a Voluntary Fund', 5 October 2005, WO/GA/32/6, Annex, p. 1.

¹⁰¹⁵ WIPO Program and Budget Committee (PBC), 'Participation of Representatives of Accredited Indigenous and Local Communities in the Work of the IGC: Proposal for Subsidiary Funding from the Regular Budget of WIPO', Proposal by the Delegations of Australia, Finland, Holy See, New Zealand and Switzerland, 1-5 September 2014, WO/PBC/22/24.

¹⁰¹⁶ WIPO, 'Indigenous and Local Community Experiences', available at: <http://www.wipo.int/tk/en/igc/panels.html> [accessed September 2016].

¹⁰¹⁷ In contrast to the CBD and WIPO forums where indigenous stakeholders may attend as observers, in the WTO, indigenous stakeholders are not allowed to participate not even as observers.

¹⁰¹⁸ See DUTFIELD, *Protecting Traditional Knowledge and Folklore. A Review of Progress in Diplomacy and Policy Formulation*, 2003, p. 47.

and their rights.¹⁰¹⁹ This is due to the simple fact that these forums are member driven, and indigenous participants, in their capacity as observers, do not have the right to vote.¹⁰²⁰

According to one author, “if Indigenous peoples were to decide to retire as a block from the IGC process, it is hard to see how states could legitimately adopt any regime over Indigenous peoples’ traditional knowledge”.¹⁰²¹ This may not be the worst scenario. A less desirable scenario would be to adopt an instrument, which, in practice, is likely to offer weak protection to traditional knowledge.

¹⁰¹⁹ GORDON, “Appropriation without Representation? The Limited Role of Indigenous Groups in WIPO’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, And Folklore”, 2014, p. 629-639.

¹⁰²⁰ For an overview of the power relations in WIPO, CBD and WTO forums, see MAINA, “Power Relations in the Traditional Knowledge Debate: A Critical Analysis of Forums”, 2011, pp. 143-178.

¹⁰²¹ TOBIN, *Indigenous Peoples, Customary Law and Human Rights*, 2014, pp. 169 and 170.

Chapter 2 “Draft Articles” of the WIPO IGC for the Protection of Traditional Knowledge

From its establishment in 2000 until today, the WIPO IGC has provided an essential arena of discussions and studies on the issue of the protection of traditional knowledge. Since the start of text-based negotiations in the seventh session of the IGC,¹⁰²² Member States’ drafting proposals (Draft Articles or Draft Provisions) have been continuously inserted in the working documents.¹⁰²³ After each session an updated version is produced by the Secretariat. The following will analyze the latest draft proposal elaborated at the twenty-eighth session of the WIPO IGC in July 2014, and selected provisions shall be analysed in detail.¹⁰²⁴

The WIPO IGC has been struggling for more than a decade with formulating the core provisions of a future instrument, namely the subject matter of protection, the eligible beneficiaries and the scope of protection.

1 Subject Matter of Protection

The determination of the subject matter of protection will identify what will be protected under a given legislation. The subject matter being traditional knowledge, the task boils down to defining the traditional knowledge that is sought to be protected. The options are mainly twofold.

First, traditional knowledge may be defined very broadly, so as to capture the overall diversity of knowledge systems within a single definition, in order to be in conformity with the holistic worldview of indigenous communities. However, this approach might annihilate the core objective of a legal text and legal certainty. A broad definition of traditional knowledge encompassing all its characteristics will not sufficiently describe the subject matter to be considered for legal protection. For reasons of legislative pragmatism, there should be a distinction between a descriptive characterisation of traditional knowledge and the formulation of a definition of protected subject matter as such.¹⁰²⁵ Legislative drafters should

¹⁰²² WIPO IGC, ‘Protection of Traditional Knowledge: Overview of Policy Objectives and Core Principles’, 20 August 2004, WIPO/GRTKF/IC/7/5.

¹⁰²³ Every single drafting proposal is referenced by a footnote indicating the delegation that made the proposal.

¹⁰²⁴ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7-9 July 2014, WIPO/GRTKF/IC/28/5.

¹⁰²⁵ TAUBMAN and LEISTNER, “Analysis of Different Areas of Indigenous Resources”, 2008, p. 72.

possess an understanding of the characteristics and holistic qualities of traditional knowledge systems but it might be counterproductive to include all these characteristics in a formal definition. Ultimately, these considerations could be encapsulated in the preamble of a future legal instrument on the protection of traditional knowledge.¹⁰²⁶

A second approach might be limiting the scope of protection to certain categories of traditional knowledge, for example as provided for by the WIPO IGC. As previously mentioned, WIPO has subdivided traditional knowledge into two categories: traditional cultural expressions, and traditional knowledge *stricto sensu*. The term traditional knowledge *stricto sensu* refers to “the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes know-how, skills, innovations, practices and traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any technical field, and may include medicinal, agricultural, environmental knowledge and knowledge associated with genetic resources”.¹⁰²⁷

Most importantly, a definition will be dependent on the policy objectives of a legal instrument. For instance, particular policy objectives may be directed to protection of traditional medicinal knowledge,¹⁰²⁸ or, as in the case of the CBD, to traditional knowledge that is relevant for the conservation of biological diversity. Ultimately, policy makers may decide to opt for the protection of traditional knowledge held by indigenous peoples that live outside the cultural mainstream of a State.

It is undeniable that the concept of TK is very broad. As mentioned before, the Convention on Biological Diversity and the Nagoya Protocol are the sole binding international treaties that expressly acknowledge the “relevant” role of traditional knowledge, innovations and practices in biodiversity conservation and sustainable development as well as the need to guarantee

¹⁰²⁶ TAUBMAN and LEISTNER, “Analysis of Different Areas of Indigenous Resources”, 2008, pp. 68ff.

¹⁰²⁷ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Gap Analysis: Revision’, 13 - 17 October 2008, WIPO/GRTKF/IC/13/5(b) Rev., Annex I, p. 4.

¹⁰²⁸ Thailand’s Act on Protection and Promotion of Traditional Thai Medicinal Intelligence, B.E. 254 referred to in WIPO IGC, ‘Comparative Summary of Existing National Sui Generis Measures and Laws for the Protection of Traditional Knowledge’, 7 – 15 July 2003, WIPO/GRTKF/IC/5/INF/4.

their protection, whether by means of intellectual property rights or otherwise.¹⁰²⁹ Nevertheless, due to the vagueness of Article 8(j) of the CBD, no specific legal requirements can be ascertained. Indeed, this article only encompasses a concept and not an exercisable right in itself. Traditional knowledge can imply innovations and practices that may be relevant for commercial purposes and imply different forms of protection, whether they are intellectual property rights or not. And the protection sought might be dependent on the category of knowledge. In other words, the question remains open whether traditional medicinal knowledge may require a different set of protection measures to the traditional knowledge of farming communities or the traditional knowledge related to biodiversity preservation and management systems.¹⁰³⁰ For one scholar, “if the policy objective is to not allow commercial exploitation (e.g. traditional medicinal preparation) but rather to prevent the use of and potential damage to an ecosystem, then perhaps recourse to the intellectual property system is an altogether improper response and environmental rules should govern instead”.¹⁰³¹

However, if we consider the protection of traditional knowledge in the context of human rights principles, namely human dignity and the self-determination of indigenous peoples, then we should also rely on international human rights obligations. The policy objective would then be the empowerment of indigenous peoples under a new legal framework, i.e. a *sui generis* system. Indeed, it is now commonly agreed that the main beneficiaries of any policy initiative with regard to the protection of traditional knowledge are traditional knowledge holders.¹⁰³² It should be noted that any *sui generis* system rather than being autonomous from intellectual property system should be supported by it.¹⁰³³

¹⁰²⁹ CBD, Art. 8 (j) requires the state parties to “respect, preserve and maintain knowledge, innovations, and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity to promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices.

¹⁰³⁰ SAMPATH, “Defining an intellectual property right on traditional medicinal knowledge: a process-oriented perspective”, 2004, p. 715.

¹⁰³¹ GERVAIS Daniel, “Traditional Knowledge & Intellectual Property: A TRIPS-Compatible Approach”, 2005, p. 153.

¹⁰³² See TAUBMAN, “Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge”, 2005, p. 562; see also DUTFIELD, “Legal and Economic Aspects of Traditional Knowledge”, 2005, pp. 495-520, p. 497; MAHOP, *Intellectual Property, Community Rights and Human Rights – The Biological and Genetic Resources of Developing Countries*, 2010, p. 35; see also

Once the subject matter is delimited, that is, for instance, traditional knowledge associated with biodiversity or not, traditional medicinal knowledge or traditional knowledge *stricto sensu*, there is still a need to delimit the subject matter of protection by determining the eligibility *criteria* for protection.

Generally speaking, international instruments typically only set some minimum standards with regard to a subject matter that is sought to be protected. They thus defer to national law for determining a more precise scope for the protection of the subject matter. At the international level, the options are twofold: the introduction of a set of criteria for eligible subject matter or no definition at all. In the IP context, for instance, the Paris Convention and the TRIPS Agreement do not define the term “invention”. No definition at all or a single exhaustive definition would not be an appropriate choice considering both the very diverse and the dynamic nature of traditional knowledge and the differences in national *sui generis* laws. These national laws, although diverse, share common characteristics with regard to the eligible criteria for the subject matter to be protected.

Fundamentally the question to be asked is: what is the essence of traditional knowledge, what makes it traditional? This question has previously been answered in the first Part of this work. It is worth restating it at this point. What distinguishes or characterises traditional knowledge is the way that it has been created, preserved and transmitted through generations within the context of a traditional community. This question may help to define the eligibility criteria, i.e. the features of indigenous peoples’ traditional knowledge which are commonly shared.

The following paragraphs will focus on the latest version of Article One of the Draft Provisions, titled “Subject Matter of Protection”, which reads as follows:¹⁰³⁴

“The subject matter of [protection]/[this instrument] is traditional knowledge:

GIBSON, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, 2005.

¹⁰³³ KOOPMAN, “Bumps and Bends in the Road to Intellectual Property for Traditional Knowledge: On Knowledge Models, Legal Orders and the Anti-commons in Biotechnology”, 2005, p. 269.

¹⁰³⁴ At this point, it is important to note that the text is heavily bracketed. This is not specific to the WIPO IGC negotiation text but it is a common features shared by all negotiating documents. The brackets indicate the proposition made by the negotiators but not yet agreed upon. For a detail insight of negotiators statements and proposals, see for instance, WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, 9-13 May 2011, WIPO/GRTKF/IC/18/5, Annex, p. 21.

- (a) That is created, and [maintained] in a collective context, by indigenous [peoples] and local communities [or nations] [, whether it is widely spread or not];
- (b) that is [directly] [linked]/[distinctively associated] with the cultural [and]/[or] social identity and cultural heritage of indigenous [peoples] and local communities [or nations];
- (c) that is transmitted from generation to generation, whether consecutively or not;
- (d) which may subsist in codified, oral or other forms; and [or]
- (e) which may be dynamic and evolving.”¹⁰³⁵

What this provision intends is to determine what qualities traditional knowledge should have, at least, to be eligible for protection under the Draft Articles. Importantly, this provision makes a conceptual link between traditional knowledge and the beneficiaries of the protection, who are specified in Article 2 entitled “Beneficiaries of Protection”. Indeed, the reason underlying the conceptual link is rooted in the question whether the entitlement to protection is based on the subject matter of protection - traditional knowledge - or on the beneficiaries of protection who are the rights-holders, i.e. the eligible indigenous and/or local communities.¹⁰³⁶ This linkage is cemented by various criteria for the eligibility of protection, namely the development, the preservation and transmission of knowledge in a traditional context; the intergenerational character; the link between traditional knowledge and indigenous and local communities. Furthermore, the traditional knowledge has to be “distinctively associated” with the “cultural identity and cultural heritage of indigenous peoples”.

While the provision settles the minimal criteria that traditional knowledge should have to be eligible for protection, it does not define many of the terms used. Thus, the terms “traditional context”, “distinctively associated”, and “widely spread” are not precisely defined. This is certainly so as to provide a certain degree of flexibility to states. However, the principle of flexibility should not run counter the principle of legal effectiveness. For instance, it is not

¹⁰³⁵ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, the Secretariat, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5, Article 1, p. 7.

¹⁰³⁶ WIPO IGC, ‘Practical Means of Giving Effect to the International Dimension of the Committee’s Work’, the Secretariat, 6 – 10 June 2005, WIPO/GRTKF/IC/8/6, para. 44, p. 18 (a fundamental question is whether entitlement to protection is based on the subject matter of protection (traditional knowledge), on the beneficiaries of protection).

clear whether the wording “widely spread” means “publicly available” as defined in the Draft Articles, which define it as “publicly available means the subject matter that *has lost its distinctive association* with any indigenous community and that as such has become generic or stock knowledge, notwithstanding that its historic origin may be known to the public”.¹⁰³⁷ In other words, once knowledge is publicly available, it is not anymore distinctively associated with the cultural identity and cultural heritage of indigenous people.¹⁰³⁸ *A contrario*, would this mean that only when traditional knowledge conserves its distinctive character and is kept secret within the community, is it thus eligible for protection? In addition, there is clearly a negative burden of proof that has to be borne by indigenous peoples, in the sense that, for instance, they have to demonstrate that traditional knowledge was kept secret until it was made available (disclosed) in a non-consensual manner. As mentioned above,¹⁰³⁹ traditional knowledge that is publicly available does not equate to its free availability. The prior informed consent of its holders shall still be obtained and the benefits resulting from its use shall be shared. In other words, the knowledge is not in the public domain, and is still eligible for protection. As for widely accessible/spread knowledge, when shared amongst different indigenous communities, Article 10 of the Nagoya Protocol proposes to consider a multilateral benefit-sharing fund.¹⁰⁴⁰

In the present author’s opinion, the criteria determining this distinctiveness should not be the degree of availability of the knowledge, but the continuing existence of the inherent link between traditional knowledge and the cultural identity and heritage of its holders, i.e. indigenous peoples. An inherent link is one where traditional knowledge should continue to be used by the traditional community.¹⁰⁴¹ As mentioned earlier in this work, this bond is broken when there is a loss of traditional practices. Thus, even though traditional knowledge

¹⁰³⁷ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5, Article 1, p. 5.

¹⁰³⁸ WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, 9 – 13 May 2011, WIPO/GRTKF/IC/18/5, Annex, p. 19, FN 58. (The US delegation made the following comment: “the association of the knowledge to the community should have a distinctive character, meaning that traditional knowledge is characteristically associated with the community and not the public as a whole”).

¹⁰³⁹ See Part II, Chapter 3, 3 on “Publicly Available Traditional Medicinal Knowledge”.

¹⁰⁴⁰ Nagoya Protocol, Article 10; see also, RUIZ, *Protecting Shared and Widely Distributed Traditional Knowledge: Issues, Challenges and Options*, 2013, p. 18.

¹⁰⁴¹ A parallel can be drawn with the test of continuity on indigenous peoples’ claims to their ancestral lands.

might be widely known or accessible, if the link with the traditional community is preserved the subject matter shall be eligible for protection under the Draft Articles.

In the context of traditional knowledge, if the traditional knowledge has been accessed by a third party through any means, this does not mean that it can be used unless prior informed consent has been obtained through, for instance, a licence agreement for the use of the said knowledge.

Eventually, under the current version, Article 1 and 3 of the Draft Articles concerning the subject matter and the scope of protection of traditional knowledge seem to contradict each other. While Article 1 would suggest that traditional knowledge that is not distinctively associated, i.e. publicly available, is not eligible for protection, Article 3.2 extends the scope of protection equally to traditional knowledge that is publicly available. Article 3 will be analysed later in this chapter under the scope of protection.

2 Beneficiaries

As it has been stated throughout this research work, the principal beneficiaries of any protection regarding traditional knowledge shall be the communities who have created, developed and preserved their traditional knowledge in a traditional context, according to the rules and practices governing the access and use of the knowledge. These communities may generally be formed by indigenous peoples and/or local communities. This thesis has focused on indigenous peoples, as defined in the first Part of this research, and will continue to proceed as such. However, the author considers that the WIPO-IGC Draft Articles should include both indigenous peoples and local communities as beneficiaries of rights in order to be as responsive and inclusive to the different situations existing at the national level. This is because, as discussed earlier, some countries, including African States for instance, view their whole populations as being indigenous. Others, including India,¹⁰⁴² Egypt and China,¹⁰⁴³ deny the existence of indigenous peoples within their borders, and see themselves as holders of

¹⁰⁴² WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, 9 – 13 May 2011, WIPO/GRTKF/IC/18/5, Annex, p. 33.

¹⁰⁴³ WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, 9 – 13 May 2011, WIPO/GRTKF/IC/18/5, Annex, p. 33 (“the Delegation of China believed that, in establishing beneficiaries of protection, the existence of ethnic groups as bearers of TK should also be taken into consideration”).

traditional knowledge. Furthermore, while some States limit the protection to traditional knowledge of indigenous peoples,¹⁰⁴⁴ others extend protection to indigenous and local communities.¹⁰⁴⁵ This will depend on the historical context of each state. Other countries have included states as beneficiaries of protection. However, this has the risk of facilitating the dispossession of the communities who create and are dependent on their traditional knowledge. As stressed by Tobin, the recognition of states as beneficiaries may also increase the reluctance of user countries to deny the role of customary laws in the governance of traditional knowledge.¹⁰⁴⁶

Similarly, it has been suggested that individuals be included in the list of rights-holders. While in the 2011 version of the Draft Articles, individuals were mentioned as beneficiaries of protection,¹⁰⁴⁷ this is not the case in the latest Draft.¹⁰⁴⁸ As already recommended the power to determine the identity of groups or individuals should not be vested in states, but in the indigenous groups through their representative bodies based on their customary laws and practices.

Article 2 of the latest WIPO IGC Draft Articles is divided into three paragraphs. The first paragraph determines the beneficiaries of protection. The second paragraph envisions the establishment of a national authority in situations where the protected subject matter is not claimed by an indigenous or local community. The third paragraph recommends that the identity of the established authority should be communicated to WIPO.

The first paragraph is currently drafted as two alternative proposals. While the first proposal suggests that the beneficiaries of protection are indigenous peoples and local communities and/or nations who create, maintain, use and/or develop traditional knowledge, the second proposal, divides the beneficiaries into two layers: first, indigenous peoples and local communities; and second, Member States. The advantage of the second proposal is that it

¹⁰⁴⁴ Peruvian Law 27811 refers to “collective knowledge of indigenous peoples”.

¹⁰⁴⁵ Portuguese Decree-Law No. 118/2002, 20 April 2002, Article 3 refers to “local populations” as the owners of traditional knowledge.

¹⁰⁴⁶ TOBIN, *Indigenous Peoples, Customary Law and Human Rights*, 2014, p. 169.

¹⁰⁴⁷ WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, 9 – 13 May 2011, WIPO/GRTKF/IC/18/5, Annex, p. 31.

¹⁰⁴⁸ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5, Annex, p. 8.

does not put indigenous and local communities on the same footing as nation States. However, it is still problematic. Indeed, the provision states that “it is only when Member States do not recognise indigenous peoples or local communities, in their constitution, that they can act as beneficiaries”.¹⁰⁴⁹ Practically speaking, this would mean that only those indigenous peoples that are recognised in the constitution of a Member States may be considered as beneficiaries under the Draft Articles.¹⁰⁵⁰

The second paragraph concerns situations where traditional knowledge is not claimed by specific indigenous peoples or local communities despite reasonable efforts to identify them. In this case, Member States shall designate a national authority as the custodian of the benefit arising from the use of TK or the custodian of protection under the instrument. This second paragraph¹⁰⁵¹ calls for the following remarks.

First, as far as the drafting of the article is concerned, some wording remains vague, namely “specific” indigenous peoples and “despite reasonable efforts to identify them”. It is not clear whether the word “specific” presupposes that to be considered indigenous the claiming group has first to fulfil some criteria of eligibility. Similarly, it is not clear who has to make “reasonable efforts to identify” the indigenous community. Is it an obligation of the States or indigenous communities themselves? The remaining part of this paragraph provides that after

¹⁰⁴⁹ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5, Annex, p. 8.

¹⁰⁵⁰ While it is not rare that Member States do not recognise indigenous peoples in their constitution or national laws, they cannot easily deny certain recognition of local communities within their borders, such as communities of traditional farmers; See the concept of local community in Part I, Chapter 1, 1.3; see also, GIRSBERGER, *Biodiversity and the Concept of Farmers’ Rights in International Law – Factual Background and Legal Analysis*, 1999.

¹⁰⁵¹ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5, Annex, p. 8 (paragraph 2.2 reads: “[Where the [subject matter]/[traditional knowledge] [is not claimed by specific indigenous [peoples] or local communities despite reasonable efforts to identify them,] [Member States]/[Contracting Parties] may designate a national authority as custodian of the [benefits]/[beneficiaries] [of protection under this instrument] where the [subject matter]/[traditional knowledge] [traditional knowledge meeting the eligibility criteria in Article 1] as defined in Article 1: (a) is held by a community [whose] in a territory [is] that is entirely and exclusively coterminous with the territory of that [Member State]/[Contracting Party]; (b) [is not confined to a specific indigenous [people] or local community; (c) is not attributable to a specific indigenous [people] or local community; or (d) [is not claimed by a specific indigenous [people] or local community.]]”).

failing to identify the indigenous community, Member States *may* designate a national authority as custodian of the benefits/beneficiaries where the subject matter meets the eligibility criteria set in Article 1. This requirement is not mandatory as the use of the word “may” suggests. The role of this national authority would be to safeguard the interests of the unidentified beneficiaries. This national authority, if established, will certainly lack legitimacy amongst indigenous communities.

A practical solution could be the establishment of a Council, gathering indigenous experts recognised and legitimized by the members of each indigenous community at the national level. The principal advantage is that such a central body could be empowered to manage the claims coming from diverse indigenous communities, and could abide by customary rules governing the access and use of traditional knowledge.¹⁰⁵² Thereby, the question regarding which authority may be legitimate to identify the indigenous communities would be resolved. The objectives of the Council, or the modalities regarding its eligibility or the recognition of its decisions by the administrative and judicial authorities of a given State will be provided by domestic laws, but also ideally governed by regional laws, having due regard to the involvement of indigenous communities in all decision-making.¹⁰⁵³

In situations where the Council and its members cannot reach an agreement as to the identity of an indigenous community as the sole beneficiary of protection, the Council can act as the custodian of any benefits arising from the access and use of traditional knowledge with the support of the competent authority of the State. Benefits may be deposited into a Fund that the Council will keep in trust.

A situation where traditional knowledge is not claimed by any indigenous community, suggests two comments. First, it can be argued that if no beneficiaries are identified this is mainly due to the fact that the required linkage between the indigenous communities and the

¹⁰⁵² Pacific Islands Forum Secretariat, ‘Guidelines for Developing Legislation for the Protection of Traditional Biological Knowledge, Innovations and Practices Based on the Traditional Biological Knowledge, Innovations and Practices Model Law’, Fiji 2010, p. 34 (“policy-makers may wish to consider whether a state body should be tasked with determining the identity of the owner of whether this would be more appropriately addressed through other means such as customary laws and practices”).

¹⁰⁵³ This has been done, for instance, in New Zealand, where the patent law requires that the established Maori Advisory Committee shall provide the Patent Office with advice on conflicts with Maori culture. See NZ Patent Act, S. 225-228 on “Māori Advisory Committee”.

traditional knowledge is lost. In other words, the traditional knowledge is no longer used and transmitted amongst the indigenous communities. In this case, one logical solution would be to consider the traditional knowledge as forming part of the broader national heritage of the State. In this case, the rights-holders would become the State, who can put any potential benefit deriving from the use of traditional knowledge towards social welfare or cultural programmes. It is this particular hypothesis that is provided for in Article 2 of the Draft Articles. This approach is however problematic, because it empowers the State to fix all the parameters with regard to the question of whether traditional knowledge has been claimed or not by indigenous peoples.

Second, the provision suggests that indigenous peoples have to claim their rights to a given piece of traditional knowledge. While this provision puts the burden on indigenous peoples to make claims when their knowledge is accessed or used, this is in accordance with their desire to define for themselves what constitutes their own intellectual and cultural property.¹⁰⁵⁴ However, indigenous peoples will also have to make a claim as beneficiaries of traditional knowledge when their knowledge has been accessed and/or used¹⁰⁵⁵ without their consent, such as patents based on traditional knowledge. The main problem here is that indigenous communities are rarely aware that their traditional knowledge has been used.

Here again a central indigenous peoples’ authority, such as a Council of indigenous experts could be more effective in making claims on behalf of different existing communities. However, even with the establishment of a central authority composed of indigenous peoples, it would not be an easy task to monitor any access or use of traditional knowledge by third

¹⁰⁵⁴ WIPO IGC, ‘Traditional Knowledge – Operational Terms and Definitions’, 13 - 21 June 2002, WIPO/GRTKF/IC/3/9, p. 13, para. 33.

¹⁰⁵⁵ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5, Annex, p. 6 (the term “use” or “utilisation” means: (a) where the traditional knowledge is included in a product [or] where a product has been developed or obtained on the basis of traditional knowledge, the (i) the manufacturing, importing, offering for sale, selling, stocking or using the product beyond the traditional context; or (ii) being in possession of the product for the purposes of offering it for sale, selling it or using it beyond the traditional context. (b) where the traditional knowledge is included in a process [or] where a process has been developed or obtained on the basis of traditional knowledge: (i) making use of the process beyond the traditional context; or (ii) carrying out the acts referred to under sub-clause (a) with respect to a product that is a direct result of the use of the process; (c) the use of traditional knowledge in non-commercial research and development; or (d) the use of traditional knowledge in commercial research and development”).

parties. In the case of patents, some solutions are currently under discussion, which include the disclosure of origin of traditional knowledge, disclosure of prior informed consent, certificates of compliance for monitoring any use of traditional knowledge in the patent system and the creation of digital databases compiling traditional knowledge. These proposals will be further analysed in Chapter Three of this Part. The analysis will also include some illustrative examples taking place at the national level.

At this point, it has to be noted that Article 5 of the Draft Articles, titled “Administration of Rights”¹⁰⁵⁶ suggests that a “competent authority” may be appointed to administer the rights and interests of indigenous communities in conformity with their customary protocols. It is not clear whether the “national authority” provided for in Article 2 is the same as the “competent authority” provided for in Article 5. The reading of both articles suggests that this is not the case. It seems that while indigenous peoples do have a certain degree of participation and involvement within the authority set forth in Article 5, they have no rights within the authority set forth in Article 2. Furthermore, while the latter appears to be an *ad hoc* authority, this is not the case for the competent authority provided for in Article 5 of the Draft Articles. Instead of establishing two distinct authorities, Article 2 may simply refer to the competent authority set forth in Article 5, which will perform the same activities as those proposed for a council of indigenous experts.

This proposal would be in conformity with Articles 18 and 19 of the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). Article 18 establishes that “indigenous peoples have the right to participate in decision-making in matters which would affect their rights, through representatives chosen by themselves in accordance with their own indigenous decision-making institutions”.¹⁰⁵⁷ While the modalities of indigenous peoples’ participation are not stated, two conditions have to be fulfilled: procedural and substantive. The first presupposes that there are mechanisms and institutions permitting their collective participation, and that indigenous peoples are aware of their existence. The second requires

¹⁰⁵⁶ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5, Annex, p. 15 (the provision reads: “[Member States]/[Contracting Parties] [may]/[shall] [establish]/[appoint] a competent authority or authorities, [with the free, prior and informed consent of] [in consultation with] [traditional knowledge [holders]/[owners]], in accordance with their national law [and without prejudice to the right of traditional knowledge [holders]/[owners] to administer their rights/interests according to their customary protocols, understandings, laws and practices]”).

¹⁰⁵⁷ UNDRIP, Article 18.

that indigenous peoples have an effective political participation with the capacity to influence the results of decision-making processes.¹⁰⁵⁸ Equally important is Article 19, which requires States to “consult and cooperate in good faith with the indigenous peoples concerned through their own representative institutions in order to obtain their free, prior and informed consent before adopting and implementing legislative or administrative measures that may affect them”.¹⁰⁵⁹

A further comment is that the last version of the Draft Articles has continued to use the term “indigenous peoples”. This breaks with the terminology adopted in the Convention on Biological Diversity and the Nagoya Protocol, which refer to ‘indigenous and local communities’. This is an important distinction for indigenous peoples as it highlights their rights as peoples to self-determination. This terminology also further acknowledges their claim not to be assimilated into other minority groups under international human rights law.¹⁰⁶⁰

Finally, the WIPO-IGC is also separately working on an international draft proposal for the protection of genetic resources. This instrument also covers traditional knowledge to the extent that it is associated with genetic resources. Its objective is to prevent misappropriation through the patenting of properties of these resources and of related traditional knowledge by third parties.¹⁰⁶¹ In contrast to the Draft Articles related to the protection of traditional knowledge, the draft text on the protection of genetic resources and traditional knowledge associated with genetic resources does not recognise indigenous peoples as beneficiaries.¹⁰⁶² Such a task is left to the national legal system of the country of origin. Whatever approach is selected, it is crucial that both instruments follow the same one.

¹⁰⁵⁸ ILA, ‘Rights of Indigenous Peoples’, Interim Report, The Hague Conference, 2010, p. 14.

¹⁰⁵⁹ UNDRIP, Article 19.

¹⁰⁶⁰ TOBIN, *Indigenous Peoples, Customary Law and Human Rights*, 2014, p. 163.

¹⁰⁶¹ WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/4, Annex, p. 6; see also the latest version, WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, 30 May – 3 June 2016, WIPO/GRTKF/IC/30/4, Annex, p. 6.

¹⁰⁶² WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/4, Annex, p. 7; see also the latest version, WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, 30 May – 3 June 2016, WIPO/GRTKF/IC/30/4, Annex, p. 7.

3 **Scope of Protection: From a Defensive to a Differential Approach - Reconsidering the Boundaries of Public Domain?**

Another controversial issue that is no less fundamental is whether the rights conferred should be within the ambit of intellectual property rights. While some states reiterate the view that existing intellectual property rights are sufficient for the protection of traditional knowledge,¹⁰⁶³ others argue for a *sui generis* form of protection that does not consist in the creation of a new subject matter of intellectual property rights but that is consistent with UNDRIP.¹⁰⁶⁴ This is very symptomatic of the “dual task”, with which WIPO is confronted. On the one side, the term protection is understood in an intellectual property context. On the other side, the WIPO-IGC also endorses non intellectual property elements for the protection of traditional knowledge.¹⁰⁶⁵

From its creation up until the end of 2009, the approach taken by the WIPO-IGC has been principally centered on a defensive protection approach. A defensive protection ensures that third parties are not granted illegitimate intellectual property rights over traditional knowledge. This approach, in the earlier phase of the negotiations, was considered as providing an adequate solution to the biopiracy cases concerning *turmeric*, *neem* or the *ayahuasca*. In this context, the term protection refers to the necessity of impeding misappropriation and the granting of intellectual property rights over traditional knowledge whenever this constitutes an unfair act in the sense of Article 10*bis* of the Paris Convention.¹⁰⁶⁶

In its seventh session, in 2004, the WIPO IGC acknowledged that the suppression of misappropriation should be seen not only as an end in itself, but also as a justification and/or

¹⁰⁶³ See, for example, COTTIER and PANIZZON, “Legal perspectives on traditional knowledge: The Case for Intellectual Property Protection”, 2005, pp. 565-594.

¹⁰⁶⁴ TOBIN, *Indigenous Peoples, Customary Law and Human Rights*, 2014; KIENE, *The Legal Protection of Traditional Knowledge in the Pharmaceutical Field*, 2011; GIBSON, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, 2005.

¹⁰⁶⁵ KIENE, *The Legal Protection of Traditional Knowledge in the Pharmaceutical Field*, 2011, p. 213.

¹⁰⁶⁶ WIPO IGC, ‘Protection of Traditional Knowledge: Overview of Policy Objectives and Core Principles’, 1-5 November 2004, WIPO/GRTKF/IC/7/5, Annex II, pp. 15-16.

organizing rationale for the protection of traditional knowledge.¹⁰⁶⁷ Despite this acknowledgement, in the subsequent sessions of the IGC, namely at its sixteenth session, the focus was still mainly on the misappropriation approach included in the first Article of the substantive provisions entitled “Protection against Misappropriation”.¹⁰⁶⁸ The provision represses unfair acts without creating distinct private property titles over the knowledge that is protected against those illegitimate acts.¹⁰⁶⁹ This approach has essentially linked the misappropriation regime to the unfair competition branch of law, as had been proposed earlier by the Delegation of Norway at the third session of the IGC.¹⁰⁷⁰

Article 1, as elaborated in the sixteenth session draft provisions is as follows.¹⁰⁷¹ First, it defines misappropriation as an unfair act which should be repressed without creating exclusive rights over the subject matter of protection, i.e. traditional knowledge. Second, it provides a general description of misappropriation in a non-exhaustive manner by stating that “any acquisition, appropriation, revelation or utilization of traditional knowledge *by unfair or illicit means* constitutes an act of misappropriation or misuse”.¹⁰⁷² Third, it enumerates an

¹⁰⁶⁷ WIPO IGC, ‘Protection of Traditional Knowledge: Overview of Policy Objectives and Core Principles’, 5 November 2004, WIPO/GRTKF/IC/7/5, Annex II, p. 15 (referring to the suppression of misappropriation as the “main organizing principle”).

¹⁰⁶⁸ WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, 22 March 2010, WIPO/GRTKF/IC/16/5, Annex, p. 13.

¹⁰⁶⁹ WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, 3-7 May 2010, WIPO/GRTKF/IC/16/5, Annex, p. 13.

¹⁰⁷⁰ WIPO IGC, ‘Report’, 13-21 June 2007, WIPO/GRTKF/IC/3/17, para 227 (The Delegation of Norway referred to Article 10*bis* of the Paris Convention which contains measures against unfair competition. This article stipulates that the countries of the Paris Union were bound to assure to nationals of such countries effective protection against unfair competition. According to the article, any act of competition contrary to honest practices in industrial or commercial matters constituted an act of unfair competition).

¹⁰⁷¹ WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, 3-7 May 2010, WIPO/GRTKF/IC/16/5, Annex, p. 13.

¹⁰⁷² The term “misuse” has been included at the sixtieth session of the WIPO-IGC: The Delegation of Australia noted that misuse was a term that was used in the CBD context within the draft negotiating text for an international regime on access and benefit sharing of GR and associated TK. It was used to refer to acts that were contrary to mutually agreed terms, while misappropriation referred specifically to acquisition without prior informed consent. It called for further discussion as to the meaning of these terms in the context of this Committee and in relation to IP rather than access to TK associated with GR. The Delegation of Zambia noted that what amounted to “misuse” may require elaboration. See WIPO IGC, ‘The Protection of

extensive list of specific acts which should be considered as acts of misappropriation.¹⁰⁷³ Finally, the provision makes a direct link to the other acts of unfair competition listed in Article 10*bis* of the Paris Convention. This provision, per se, does not create any rights for the holders of traditional knowledge. Importantly, it leaves Member States free to determine which acts are constitutive of misappropriation under their national laws and to proscribe the means to prevent them. This approach, also called the “means-based approach”, has diverse shortcomings.

First, the definition of misappropriation suggests that the misappropriation of traditional knowledge should be defined as violations of national law. In other words, if national laws fail to protect traditional knowledge, no misappropriation occurs by definition.

Second, the utilisation of traditional knowledge, which under the conventional intellectual property rights regime is considered as being part of the public domain, would not constitute an act of misappropriation pursuant to this provision, because this utilisation does not entail any *unfair or illicit means*. In other words, the threshold of what is licit or illicit is provided for by principles of intellectual property rights. Accordingly, only traditional knowledge that is not deemed to be in the public domain, that is traditional knowledge kept secret, could benefit from this provision.

Third, while the misappropriation regime provides a rationale for protecting traditional knowledge, it does not define clear criteria that will precisely delimit the content of a legal regime of protection.¹⁰⁷⁴

The structure of the Draft Articles, as set out in the last WIPO IGC meeting, at its twenty-eighth session, shows significant changes from the draft articles up until 2009, which were

Traditional Knowledge: Revised Objectives and Principles’, 22 March 2010, WIPO/GRTKF/IC/16/5, Annex, p. 22.

¹⁰⁷³ The list includes: (i) the illicit acquisition of TK, including by theft, bribery, deception, breach of contract, etc; (ii) breach of the principle of prior informed consent for access to TK, when required under national or regional measures; (iii) breach of defensive protection measures of TK; (iv) commercial or industrial uses which misappropriate the value of TK where it is reasonable to expect the holders of TK to share the benefits from this use; and (v) wilful morally offensive uses of TK which is of particular moral or spiritual value to the TK holder.

¹⁰⁷⁴ See also, KIENE, *The Legal Protection of Traditional Knowledge in the Pharmaceutical Field – An Intercultural Problem on the International Agenda*, 2011, p. 253.

uniquely focusing on a misappropriation regime. In particular, Article 3 referring to the scope of protection has been substantially changed. As an alternative option to the misappropriation approach (means-based approach), the article introduced exclusive rights (rights-based approach).¹⁰⁷⁵

Fundamentally, Article 3 of the latest Draft Articles now reflects a “tiered approach”, which consists of a system of differentiated protection set out in three levels.¹⁰⁷⁶ Under this approach, the protection of traditional knowledge will vary according to two main criteria: first, the degree of diffusion of traditional knowledge; and second, the extent to which it can be established that the indigenous community has a close cultural link or exclusivity with the traditional knowledge. In other words, it has to be established whether the traditional knowledge is: (i) “sacred, secret, or closely held within indigenous peoples or local communities”; (ii) “publicly available but not widely known, sacred, nor secret”; and (iii) “publicly available and widely known”.

At the highest level, Member States will have to ensure that *beneficiaries* of traditional knowledge have the exclusive and collective right to: (i) maintain, control, and discourage the unauthorised disclosure and use of their knowledge; (ii) authorise or deny access to, and use of, their traditional knowledge based on prior informed consent; and (iii) to be informed of access to their knowledge through a disclosure mechanism in intellectual property applications, which will require evidence of compliance with prior informed consent. As far as users are concerned, Member States will ensure that they attribute traditional knowledge to the beneficiaries and provide beneficiaries with a fair and equitable share of benefits based on mutually agreed terms. In addition, users will have to use the knowledge in a manner compatible with the cultural norms and practices of indigenous peoples and their inalienable, indivisible and imprescriptible moral rights.¹⁰⁷⁷

¹⁰⁷⁵ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5, Annex, p. 9

¹⁰⁷⁶ This approach is based upon a proposal made by the Ambassador of Jamaica, Wayne McCook, appointed Chair of the IGC 27 in an informal document, available at: http://www.wipo.int/export/sites/www/tk/en/igc/pdf/igc_28_issues.pdf [last visited on 1 December 2015].

¹⁰⁷⁷ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5, Annex, pp. 9-10.

At the middle level, where traditional knowledge is publicly available but not widely known, States are responsible for encouraging users to attribute and acknowledge the beneficiaries as the source of the knowledge, provide beneficiaries with a fair and equitable share of benefits, and use the knowledge in a manner compatible with the cultural norms, practices and moral rights of the beneficiaries. The provision also entails the right for beneficiaries to be informed of access to their knowledge through a disclosure mechanism in intellectual property applications.

At the lower level, where the knowledge is publicly available and widely known, Member States are required to ensure that users attribute the said knowledge to the beneficiaries, and use the knowledge in a manner compatible with the cultural norms, practices and moral rights of the latter. Some WIPO Member States, including the US delegation,¹⁰⁷⁸ have argued that no protection shall extend to traditional knowledge that is widely known or used outside the community of the beneficiaries, is in the public domain, and/or protected by an intellectual property right.

This Article surely has enhanced the protection of traditional knowledge by providing some degree of control to its holders. It has thus gone beyond a pure misappropriation regime.

Under this proposal, only when TK is secret or sacred, beneficiaries have the right, in accordance with national laws to: (i) maintain, control and develop their traditional knowledge; (ii) authorise or deny access to and use of their traditional knowledge in accordance with prior informed consent; and (iii) monitor any access and use of their traditional knowledge by means of a disclosure mechanism in intellectual property applications that may require evidence of compliance with the principle of prior informed consent as well as agreements on benefit-sharing. While this *sui generis* form of protection of TK pivots on the obligation to obtain prior informed consent in relation to access and use of TK, it does only so with regard to secret or sacred traditional knowledge. This is a major defect from the traditional knowledge holder's point of view.

In addition, it has left aside one fundamental aspect, which is the respect and recognition of customary laws of indigenous peoples. This is probably the major defect of the latest Draft

¹⁰⁷⁸ WIPO GA, 'Matters concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) : Proposal of the United States of America to the WPO GA', by the Secretariat, 4 September 2015, WO/GA/47/17.

proposal. Between 2006 and 2008, WIPO acknowledged the important role of indigenous peoples’ customary laws in protecting traditional knowledge by preparing various studies on customary laws and intellectual property.¹⁰⁷⁹ These studies were only officially released in 2013.¹⁰⁸⁰ Similarly, at the nineteenth session of the WIPO IGC, in 2011, the Draft Provisions¹⁰⁸¹ contained various references to customary laws and their role in defining traditional knowledge, guiding the sharing of benefits, delineating the custodianship responsibility or collective ownership of TK holders *vis a vis* their knowledge.¹⁰⁸² All these references to customary laws are do not exist in the latest draft negotiating texts. The only reference to customary law in the latest WIPO IGC proposal is with regard to the development of traditional knowledge databases.¹⁰⁸³

Finally, it can be noted that the approach adopted in the latest version of the WIPO IGC Draft Articles is strongly influenced by the solution proposed by the legislation adopted in Peru.¹⁰⁸⁴

4 Fundamental Role of Customary Laws in a *Sui Generis* System of Protection of Traditional Knowledge

As we have seen in Part I, various international instruments, some formally binding or otherwise, have recognised the importance of indigenous communities’ customary laws for the protection of indigenous peoples’ rights over their traditional knowledge. Regional and national laws are also flourishing in this regard. In parallel, indigenous peoples are taking unilateral actions to protect their interests. One of these initiatives concerns the enactment of

¹⁰⁷⁹ See WIPO website on “Customary Law and Intellectual Property”, available at: http://www.wipo.int/tk/en/indigenous/customary_law/.

¹⁰⁸⁰ WIPO, ‘Customary Law, Traditional Knowledge and Intellectual Property: An Outline of the Issues’, 2013.

¹⁰⁸¹ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 18-22 July 2011, WIPO/GRTKF/IC/19/5.

¹⁰⁸² WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 18-22 July 2011, WIPO/GRTKF/IC/19/5 (Article 1 reads: “Protection extends to traditional knowledge that is identified with the cultural identity of indigenous and local communities [...] Such a relationship may be established by customary laws and protocols”).

¹⁰⁸³ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5 (Article 3*bis* reads: Member States should subject to and consistent with national and customary law facilitate / encourage the development of national traditional knowledge databases for the defensive protection of traditional knowledge [...]).

¹⁰⁸⁴ The Peruvian approach will be discussed in the following Chapter 3, 3.2.

so-called “community protocols”, also referred to as “biocultural protocols”.¹⁰⁸⁵ These community protocols are the expression, or the translation, of customary laws directed at the users of traditional knowledge by third parties beyond indigenous communities. They constitute useful guidelines addressed to the potential users of traditional knowledge as well as the national authorities.

Customary laws and practices are not specific to the indigenous way of life. Legal systems worldwide, including civil law and common law traditions, partly have their origin in customary laws and practices.¹⁰⁸⁶ While in our modern legal systems, customary laws do not play the same important role as before,¹⁰⁸⁷ they continue to be regarded as a source of law both at international¹⁰⁸⁸ and national¹⁰⁸⁹ levels. In addition, some legal systems, in countries encompassing indigenous communities,¹⁰⁹⁰ incorporate customary laws into the national legal order. As already mentioned, this is the case in most Latin American countries, and generally other former colonies, accept a certain degree of legal pluralism within their legal system.

While an endeavour to define and characterise customary law is beyond the reach of this research, the following paragraphs will provide some useful insights into the term and its inherent relationship with indigenous peoples’ way of life. Two preliminary comments will be made at this point before providing a definition of customary law.

¹⁰⁸⁵ TOBIN, *Indigenous Peoples, Customary Law and Human Rights*, 2014, p. 176; see NIJAR, “Traditional Knowledge Systems, International Law and National Challenges”, 2013, p. 1220.

¹⁰⁸⁶ For an analysis of the role of customary law in international and national laws, see BEDERMAN, *Custom as a Source of Law*, 2010.

¹⁰⁸⁷ HART, *The Concept of Law*, 1997, pp. 44 ff (the author notes that “[c]ustom is not in the modern world a very important ‘source’ of law”. It is usually a subordinate one, in the sense that the legislature may by statute deprive a customary rule of legal status”).

¹⁰⁸⁸ Statute of the International Court of Justice (ICJ Statute), Article 38 states that the Court shall examine “international custom, as evidence of a general practice accepted as law”; see also, International Law Association (ILA), Committee on Formation of Customary International Law, London Conference 2000, p. 8 (the ILA provides a definition of customary international law as a “rule that is created and sustained by the constant and uniform practice of States in circumstances that give rise to the legitimate expectation of similar conduct in the future”).

¹⁰⁸⁹ For example, the Swiss Civil Code, Article 1, paragraph 2 states that “in the absence of a provision, the court shall decide in accordance with customary law [...]”.

¹⁰⁹⁰ Minorities, including religious minorities, also abide by their customary laws and practices. These categories will not be treated as the subject matter is beyond the scope of the present work.

First, it is important to distinguish between customs and laws. While it seems evident that not all customs form part of law, the answer to the question whether custom is law is less straightforward. For Hart, “custom is law only if it is one of a class of customs which is ‘recognised’ as law by a particular legal system”, i.e. formal recognition.¹⁰⁹¹ The author further argues that the legal recognition of custom as law occurs through a sovereign act, including an act of legislature, the application of customs by courts, as well as centrally organised sanctions.¹⁰⁹² Hart also clearly refuses to apply the concept of custom to “primitive communities”, because it would “imply that the customary rules are very old.”¹⁰⁹³ Accordingly, Hart opts for using the terms “primary rules of obligations” rather than customary laws. He stresses that the rules of these primitive communities are characterised by uncertainty, inefficiency and the fact of being stasis because they lack the “system of secondary rules”, which include the whole process of law-making operations of the legislator. Hart’s position on primitive communities cannot be supported as it supposes that indigenous legal systems are unelaborated and inefficient as they cannot be enforced.

By contrast Bederman supports the thesis that “customary norms live as an authentic source of legal obligation”,¹⁰⁹⁴ and do not necessarily need a formal recognition through statutory enablement or through judicial implementation. Customs may both be enforced formally or informally, that is through unofficial community-based mechanisms. However, he also admits that customary regimes operate with definite constraints. He follows the traditional view that two main characteristics are necessary for creating a customary binding norm: the objective usage and the subjective value given to the custom by a given community. He notes that it would be futile to look for a single answer to what makes a custom a binding norm. The “extra ingredient for a customary norm to be considered binding will depend on the kind of norm at issue”.¹⁰⁹⁵ For instance, while for commerce and trade, the economic efficiency of the trade usage matters, for property law and local customs, the compulsory character of the norm is what counts predominantly. He highlights the main virtue of custom: it is made by “community participants and not by some sovereign overlord”.¹⁰⁹⁶ He concludes that custom

¹⁰⁹¹ HART, *The Concept of Law*, 1997, pp. 44 ff.

¹⁰⁹² HART, *The Concept of Law*, 1997, pp. 48 and 157.

¹⁰⁹³ HART, *The Concept of Law*, 1997, p. 91.

¹⁰⁹⁴ BEDERMAN, *Custom as a Source of Law*, 2010, p. 176.

¹⁰⁹⁵ BEDERMAN, *Custom as a Source of Law*, 2010, p. 176.

¹⁰⁹⁶ BEDERMAN, *Custom as a Source of Law*, 2010, p. 176.

is the purest expression of democracy because it is the “people” that make their own “laws” without recourse to “formal” institutions or impediments, i.e. a bottom-up approach. While he admits that this assumption goes too far because custom is typically made by small and insular communities, one cannot help think that this assumption somehow resonates with direct and semi-direct democracies.

Second, it is important to discard the stereotypes with which customary laws are commonly associated.¹⁰⁹⁷ Indeed, customary laws are frequently associated with inhuman punishments or discriminatory practices towards women, mostly in family law.¹⁰⁹⁸ While, this might certainly be the case, discriminatory norms equally exist in the family of common and civil legal systems, and those practices are only one negative aspect of customary laws. Customary laws also encompass many positive aspects that are not damaging to human rights, and, which rather promote the rule of law.¹⁰⁹⁹

Black’s Law Dictionary defines “customary law” as “customs that are accepted as legal requirements or obligatory rules of conduct; practices and beliefs that are so vital and intrinsic a part of a social and economic system that they are treated as if they were laws”.¹¹⁰⁰ Alternatively, the International Council on Human Rights Policy refers to non-state legal orders that “are norms or institutions – often viewed as having the force of law by those subject to them – that claim to draw their moral authority from contemporary or traditional culture or customs or religious beliefs and practices rather than from the political authority of the state”.¹¹⁰¹ Non-state legal orders are often constituted, for instance, by minority and indigenous systems of laws. It must also be stated that, in practice, state laws and non-state

¹⁰⁹⁷ PERRY, “Balancing Rights or Building Rights? Reconciling the Right to Use Customary Systems of Law with Competing Human Rights in Pursuit of Indigenous Sovereignty”, 2011, p. 75; see also, TOBIN, *Indigenous Peoples, Customary Law and Human Rights – Why Living Law Matters*, 2014, p. 9.

¹⁰⁹⁸ International Council on Human Rights Policy (ICHRP), ‘When legal worlds overlap human rights, state and non-state law’, 2009, pp. 66 ff., see also, NDULO Muna, “African customary law, customs, and women’s rights”, 2011, pp. 98 ff. (the author argues that customary laws shall be interpreted in the light of international human rights norms by courts).

¹⁰⁹⁹ International Council on Human Rights Policy (ICHRP), ‘When legal worlds overlap human rights, state and non-state law’, 2009, pp. 56-57.

¹¹⁰⁰ Black’s Law Dictionary, 9th edition, 2009.

¹¹⁰¹ International Council on Human Rights Policy (ICHRP), ‘When legal worlds overlap human rights, state and non-state law’, 2009, p. 43.

laws are often intertwined. For instance, in countries with a colonial past, state and non-state laws influence each other. Even today, customary laws are regularly used by some states.¹¹⁰²

In the field of legal anthropology, customary law is defined as a “customary mode of the production of law”.¹¹⁰³ In other words, instead of resulting from a top-down social construct, customary laws are equally positive acts of law-making by relevant communities, including indigenous communities.¹¹⁰⁴ This bottom-up process of making law suggests a fundamental characteristic of customary law, which is the recognition and acceptance of legal pluralism.¹¹⁰⁵ Thus, if customary laws are solely characterised by their mode of production compared to other systems of law, then they ought to be equal in status to those other legal systems.¹¹⁰⁶ However, this assumption is not widely accepted. Law practitioners rarely consider customary laws as a sophisticated system of law.¹¹⁰⁷ As stated by Hart, “[c]ustom is not in the modern world a very important ‘source’ of law. It is usually a subordinate one [...]”.¹¹⁰⁸

Although customary laws are not exclusively used by indigenous peoples, in the present work, the term customary laws will solely target indigenous peoples’ legal systems. Other terms, such as traditional laws and indigenous laws will be used interchangeably as they are often used in the literature to refer to customary law.¹¹⁰⁹ Because of the correlation that exists

¹¹⁰² MALZBENDER et al., *Traditional water governance and South Africa’s “National Water Act” – Tension or cooperation?*, 2005, p. 18-2 (in South Africa, customary law plays a strong governance role in the management of adequate water supply. The authors further argue that “[l]egal pluralism is a response to inadequate new institutions that are not yet able to replace traditional and customary ways of coping with water scarcity”).

¹¹⁰³ ROULAND, “Custom and the Law”, 2001, p. 14.

¹¹⁰⁴ BEDERMAN, *Custom as a Source of Law*, 2010, preface, p. x.

¹¹⁰⁵ PERRY, “Balancing Rights or Building Rights? Reconciling the Right to Use Customary Systems of Law with Competing Human Rights in Pursuit of Indigenous Sovereignty”, 2011, p. 73.

¹¹⁰⁶ For an in-depth discussion of the question whether custom is law?, see BEDERMAN, *Custom as a Source of Law*, 2011.

¹¹⁰⁷ ROULAND, “Custom and the Law”, 2001, p. 14.

¹¹⁰⁸ HART, *The Concept of Law*, 1997, pp. 44 ff.

¹¹⁰⁹ PERRY, “Balancing Rights or Building Rights? Reconciling the Right to Use Customary Systems of Law with Competing Human Rights in Pursuit of Indigenous Sovereignty”, 2011, p. 75 (“Traditional law generally refers to non-state systems that have existed at least since pre-colonial times and are commonly confined to rural areas”).

between the concepts of ‘customary’ and ‘indigenous’, the difficulty of defining the concept of customary reflects the difficulties associated with defining the term indigenous. Indigenous peoples are often reluctant to use such terms, and prefer to refer to their laws by specifying the name of the indigenous groups or communities, such as *Tikanga Maori*¹¹¹⁰ in New Zealand.

The very nature and diversity of customary laws makes it unfeasible to seek a unanimously accepted definition. For instance, in South Africa, in a case decided in 2003, the Constitutional Court (CC) held that “indigenous law”¹¹¹¹ is not a fixed body of formally classified and easily ascertainable rules. By its very nature it evolves as the people who live by its norms change their patterns of life... In applying indigenous law, it is important to bear in mind that, unlike common law, indigenous law is unwritten. It is a system of law that was known to the community, practiced and passed from generation to generation, [...] that has his own values and norms”.¹¹¹²

For instance, Mayans describe their customary laws as follows “Indigenous law consists of a series of unwritten oral principles that are abided by and socially accepted by a specific community. Although these norms may vary from one community to another, they are all based on the idea of recommending appropriate behaviour rather than on prohibition [...]. Customary indigenous law aims to restore the harmony and balance in a community; it is essentially collective in nature, whereas the Western judicial system is based on individualism. Customary law is based on the principle that the wrongdoer must compensate his or her victim for the harm that has been done so that he or she can be reinserted into the community, whereas the Western system seeks punishment.”¹¹¹³

¹¹¹⁰ According to the Maori dictionary, “Tikanga” means the “correct procedure, custom, habit, lore, method, manner, rule, way, code, meaning, plan, practice, convention, protocol - the customary system of values and practices that have developed over time and are deeply embedded in the social context”, available at: <http://maoridictionary.co.nz/> [accessed August 2016].

¹¹¹¹ Synonymous of customary law of indigenous peoples.

¹¹¹² Constitutional Court of South Africa, *Alexkor Ltd v. The Richtersveld Community & Others*, 12 BCLR 1301 (CC), decided on 14 October 2003, para. 53, p. 27.

¹¹¹³ Mayans’s description of their customary laws cited in REYNOLDS, “Mayan Law Still Lacks Official Recognition”, Latin America Press, Guatemala, 10 June 2006, available at: <http://lapress.org/articles.asp?item=1&art=4849> [accessed September 2016].

In the face of the wide diversity of customary law regimes, a study coordinated by the International Institute for Environment and Development (IIED) has identified many shared values and principles amongst indigenous customary laws. These are, amongst others, respect for Mother Earth,¹¹¹⁴ the principle of reciprocity, and the principle of solidarity, i.e. “helping those in need and serving the common good”.¹¹¹⁵ Generally, it found that customary laws are, in the majority of cases, moulded by the interrelationship between spirituality and natural resources.¹¹¹⁶

An appropriate *sui generis* system of legal protection of indigenous peoples’ traditional knowledge can only be achieved through the recognition and application of laws and customs governing the cultural, social and spiritual aspects of their lives within their communities.¹¹¹⁷ Some of these aspects include its role in defining the rights and obligations of the members of the community, generally, and in particular, the responsibilities and means of maintaining, disseminating and using traditional knowledge, including the procedures to obtain prior informed consent and to share benefits amongst the members of indigenous communities.¹¹¹⁸

Recognition of customary laws by States means that this recognition is somehow reflected in their national legal order. Bederman firmly argues that “customary norms can be successfully integrated into most legal systems”.¹¹¹⁹ The recognition of customary laws by States may take

¹¹¹⁴ CAPAJ, ‘Document Presented for Consideration by the XXII Session of the IGC’, 2012 (Despite the best efforts of the conquistadors, our original peoples always maintained a relationship with PACHAMAMA (the Mother Earth that feeds us) that was based on respect and duty), available at: <http://www.wipo.int/tk/en/igc/ngo/> [accesses September 2016].

¹¹¹⁵ SWIDERSKA, “Banishing the Biopirates: A New Approach to Protecting Traditional Knowledge, IIED, *Gatekeepers Series*, 129, 2006, p. 14.

¹¹¹⁶ DE LA CRUZ, ‘Customary Law in the Protection of Traditional Knowledge – Regional Study in the Andean Countries’, prepared for WIPO, Quito, 2006, p. 32 (Guampía People in Colombia believe that: “the co-existence with biodiversity is a sacred and age-old practice, because in its relationship it seeks to maintain co-existence without destruction, as it contains the sacred and ceremonial sites that must be respected: rocks, rivers, mountains, plants, animals which provide life and spirits which give form to the vision of the world”); see also, SWIDERSKA Krystyna, “Banishing the Biopirates: A New Approach to Protecting Traditional Knowledge, IIED, *Gatekeepers Series* 129, 2006, p. 14.

¹¹¹⁷ See generally, TOBIN, *Indigenous Peoples, Customary Law and Human Rights*, 2014.

¹¹¹⁸ WIPO, ‘Customary Law, Traditional Knowledge and Intellectual Property: An Outline of the Issues’, 2013, p. 9.

¹¹¹⁹ BEDERMAN, *Custom as a Source of Law*, 2010, p. 181.

various forms. The form of incorporation may be categorised as follows: directly applicable law, a source of law, factual background for interpreting laws in equity by the courts, or constitutional recognition. Existing laws show a wide spectrum of possible options ranging from no recognition of customary law to direct and extraterritorial legal effect of customary laws.¹¹²⁰ Furthermore, the recognition may be functional, in the sense that the recognition of customary laws would only be context-related.¹¹²¹ While acknowledging the holistic worldview of indigenous peoples, customary laws of indigenous peoples must be recognised and respected at least with regard to issues that are fundamental for the survival of their community, such as their native lands, their natural resources and their traditional knowledge.¹¹²²

According to Tobin, for indigenous peoples' rights to be respected in conformity with the human rights' obligations of states, it is essential that their own legal regimes and decision-making process be duly recognised and enforced. In other words, only a full recognition of the customary laws of indigenous peoples into the dominant legal traditions will appropriately achieve the purpose of protecting traditional knowledge. Other authors, while considering customary laws to best fit the interests of indigenous peoples, foresee some challenges to their application, such as for instance, the lack of written evidence of customary laws, and the

¹¹²⁰ For a recent review of States' recognition of customary laws, see CUSKELLY, *Customs and Constitutions: State Recognition of Customary Law around the World*, 2011 (the author has analysed 190 constitutions out of which 115 were found to have recognised customary law either directly or indirectly).

¹¹²¹ WIPO, 'Customary Law, Traditional Knowledge and Intellectual Property: An Outline of the Issues, 2013, p. 18; see also, International Council on Human Rights Policy (ICHRP), 'When Legal Worlds Overlap Human Rights, state and non-state law', 2009, p. 139 (the report states that "a functional rather than a categorical approach to the recognition of indigenous peoples' customary law or justice mechanisms is more likely to produce positive human rights outcomes").

¹¹²² The choice of functional recognition is a pragmatic one, because it limits the scope of recognition of customary laws to traditional knowledge protection. Doing otherwise would lead the author to considerations beyond the scope of the present subject matter, such as the conflicts existing between customary systems of law and some fundamental human rights. See generally, PERRY, "Balancing Rights or Building Rights? Reconciling the Right to Use Customary Systems of Law with Competing Human Rights in Pursuit of Indigenous Sovereignty", 2011, pp. 71-114 (he argues that the tension between customary systems of law and basic human rights standards reflects the human rights debate on cultural relativism).

unwillingness of some indigenous communities to disclose their customary laws.¹¹²³ They consider that the difficulties in recognising customary laws within the dominant legal orders are mainly threefold: (i) the comprehension of the content of customary law systems; (ii) the conflicts between national laws and customary laws; (iii) and the sphere of application of customary laws, i.e. non extraterritoriality.¹¹²⁴

One of the most challenging tasks states are faced with is obtaining evidence or proof of the customary law.¹¹²⁵ Similarly, even in cases where oral customary laws have been codified, the question remains as to the accuracy of such codification.¹¹²⁶ It is key here then, that judges when confronted with cases involving customary laws have at least some expertise in the language of the communities abiding by these customary laws. Additionally, in the process of establishing indigenous laws, judges may also be confronted with conflicting views amongst indigenous communities on the applicability of customary law on a given subject matter. These difficulties may be overcome with the support and active participation of indigenous communities themselves. A good start would be to have recourse to the above-mentioned community protocols that can help the courts to better grasp the intricacies of indigenous customary laws. Similarly, the establishment of a national council of indigenous experts might prove to be helpful if not essential in building trust and dialogue, both at the communities’ level but also between indigenous and non-indigenous nationals within the State.¹¹²⁷

¹¹²³ LEWINSKI, *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore*, 2008, p. 518 (considering the difficulties related to the application of customary laws, the author argues that a *sui generis* regime inspired by intellectual property rules and influenced by human rights and customary laws has more chance to be implemented).

¹¹²⁴ LEWINSKI, *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore*, 2008, p. 518.

¹¹²⁵ LEWINSKI, *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore*, 2008, p. 518.

¹¹²⁶ Constitutional Court of South Africa, *Alexkor Ltd v. The Richtersveld Community & Others*, 12 BCLR 1301 (CC), decided on 14 October 2003, para. 53, FN 54.

¹¹²⁷ TOBIN, *Indigenous Peoples, Customary Law and Human Rights*, 2014, p. 31; see also GIBSON, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, 2005, pp. 275 ff. (the author argues that “[t]he willingness of individuals within communities to observe customary laws [...] is a critical factor in achieving international legitimacy of traditional laws and practices”).

Within a national jurisdiction, problems will also arise when courts have to mediate between state and customary laws. Generally speaking, where national laws recognise customary laws, their application is restricted where it would be in conflict, for instance, with the national constitution,¹¹²⁸ national laws,¹¹²⁹ or the fundamental rights of the person.¹¹³⁰ Typically, this is the case when indigenous title to property enters in conflict with non-indigenous title to property. Nevertheless, states have shown an increasing willingness to recognise customary law, not only as a source of law, but also its place in the hierarchy of their national laws.¹¹³¹ From 1970 onwards, the situation of indigenous peoples with regard to their ancestral lands has radically changed, and this is principally due to the constant increase of cases brought into national courts.¹¹³² According to an expert, what is common to the body of jurisprudence is that customary laws have played an important role in guiding judges towards the

¹¹²⁸ Constitutional Court of South Africa, *Alexkor Ltd v. The Richtersveld Community & Others*, 12 BCLR 1301 (CC), decided on 14 October 2003, para. 51 (in this case, the CC held that “the Constitution acknowledges the originality and distinctiveness of indigenous law as an independent source of norms within the legal system. At the same time the Constitution, while giving force to indigenous law, makes it clear that such law is subject to the Constitution and has to be interpreted in the light of its values”).

¹¹²⁹ Constitution of Colombia, 1991, Article 246.

¹¹³⁰ Political Constitution of Peru, 1993, Article 149; see also, UNDRIP, Article 34 that reads: “Indigenous peoples have the right to promote, develop and maintain their institutional structures and their distinctive customs, spirituality [...] in accordance with international human rights standards”.

¹¹³¹ CUSKELLY, *Customs and Constitutions: State Recognition of Customary Law around the World*, 2011.

¹¹³² See for example, High Court of Australia, *Mabo and Others v. Queensland*, No. 2, 175 CLR 1 F.C. 92/104, 107 ALR 1, decided 3 June 1992, para. 43 (The *Mabo v. Queensland* decision overturned the doctrine of *terra nullius* and inserted for the first time the legal doctrine of native title into Australian law. However, the Australian High Court while recognising native title, held that it had no power to take any decision that would “fracture a skeletal principle of our legal system”); see however, High Court of Australia, *Western Australia v. Ward & Others*, 213 CLR 1; 76 ALJR 1098; 191 ALR 1, decided 8 August 2002, p. 185 (this decision has significantly eroded the strength of the doctrine of native title. In this case, the Court imposed a strict requirement for a physical connection to land. The High Court further concluded that the protection of cultural knowledge is not a right protected by the Native Title Act). In Canada: *R v. Van Der Peet*, 2 SCR 507, decided 21 August 1996, para. 46 (“in order to be an aboriginal right an activity must be an element of practice, custom or tradition integral to the distinctive culture of the aboriginal group claiming the right”). In South Africa: Constitutional Court of South Africa, *Alexkor Ltd v. The Richtersveld Community & Others*, 12 BCLR 1301 (CC), decided on 14 October 2003, para. 51 (the Constitutional Court held that “while in the past indigenous law was seen through the common law lens, it must now be seen as an integral part of our law”).

identification of native titles, although with varying results in the end.¹¹³³ Indeed, while recognising native titles, courts are not only reluctant to place them on an equal footing with property rights pre-existing under the State’s law, but also place a higher burden of proof on indigenous communities by establishing a very restrictive test for the identification of indigenous rights to lands, such as a continuity test or physical connection.¹¹³⁴

Another example that falls under the subject matter of the present work is where indigenous peoples’ traditional knowledge rights are in conflict with patent rights. As analysed in Part II, patent offices and courts are reluctant to deny patents where the claimed invention derives from an unapproved use of traditional knowledge. In contrast to the issue of indigenous rights to land, where conflicts arise in the jurisdiction of the state where indigenous peoples live, with respect to indigenous rights to their traditional knowledge, conflicts arise in a foreign jurisdiction where the patent is registered. While some national jurisdictions recognise customary laws in one way or other customary laws should also be recognised in foreign jurisdictions, namely in those countries where traditional knowledge is used.¹¹³⁵

What then are the options to oblige third parties, in foreign jurisdictions, to recognise customary laws applying to the access and use of traditional knowledge in the country of origin? The most effective solution is through international binding agreements. Article 12 of the Nagoya Protocol provides the legal framework for recognising customary laws by obliging Parties to take into account the customary laws of indigenous peoples. It is the first binding international treaty to recognise the extraterritorial character of indigenous peoples’ customary laws.¹¹³⁶ Despite the implementation of regional¹¹³⁷ and national laws¹¹³⁸ relating

¹¹³³ McHUGH, *Aboriginal Title: The Modern Jurisprudence of Tribal Land Rights*, 2011, pp. 120ff.

¹¹³⁴ GIBSON, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, 2005, pp. 240 ff. (the author argues that the “connection requirement is not obvious” where colonisation almost inevitably breaks this connection).

¹¹³⁵ TOBIN, “Traditional Knowledge Sovereignty: The Fundamental Role of Customary Law in the Protection of Traditional Knowledge”, 2015, pp. 565-592, p. 590 (for the author, the revival of indigenous laws will “be of little utility for the protection of rights over TK unless met by a willingness of national and regional authorities and judicial and administrative bodies in countries into which indigenous peoples’ resources and TK are imported to recognise its role in the regulation and adjudication of access and benefit-sharing agreements and the resolution of disputes arising from the misappropriation of genetic resources or traditional knowledge”).

¹¹³⁶ TOBIN Brendan, *Indigenous Peoples, Customary Law and Human Rights*, 2014, p. 160.

to the protection of traditional knowledge, the failure of these laws to adequately protect traditional knowledge stems from the fact that they suffer from a lack of effective compliance mechanisms, which not only fail to recognise native customary laws but also customary laws of indigenous peoples from foreign jurisdictions. At present, the “best opportunity for securing the development and implementation of compliance mechanisms now lies with the WIPO IGC”¹¹³⁹ Draft Articles. Indeed, if a binding international instrument on the protection of traditional knowledge is eventually adopted, this will oblige parties to respect and recognise customary laws of indigenous peoples for the protection of traditional knowledge whether related to genetic resources or not.

¹¹³⁷ EU Regulation 511/2014 (the EU Regulation for the implementation of the Nagoya Protocol while requiring users to demonstrate due diligence in ensuring prior informed consent exists for the use of genetic resources, makes no reference to customary laws and offers a limited protection for traditional knowledge); see also Part I, Chapter 3, 1.2.3.

¹¹³⁸ Peruvian Law 27811, in Article 46, only provides a limited role to the customary laws of indigenous peoples by recognising their rights to resort to their “traditional forms of dispute settlement” for resolving internal disputes with regard to issues such as benefit-sharing. However, there is no place for the recognition of customary laws with regard to access to traditional knowledge and the compliance of benefit-sharing agreements. Neither is there any obligation for the judicial system to take customary laws into account in the resolution of disputes with third parties.

¹¹³⁹ TOBIN, “Traditional Knowledge Sovereignty: The Fundamental Role of Customary Law in the Protection of Traditional Knowledge”, 2015, pp. 565-592, p. 567.

Chapter 3 Toward Concrete Means of Protection of Traditional Knowledge

As mentioned before, the system of intellectual property protection is currently founded on a balance between the rights of the inventor and the benefits to the society at large. As far as the issue of traditional knowledge is concerned, the debate is centred, on the one hand, on the commercialisation of traditional knowledge, and on the other hand, on the protection of traditional knowledge against its misappropriation.

There is a continuing controversy over the impact of intellectual property systems on traditional knowledge. Many indigenous peoples' representatives, as well as other scholars argue that existing IP systems not only have a negative impact on traditional knowledge but they are inadequate to protect indigenous intellectual contributions.¹¹⁴⁰ Some argue that the two systems are completely at odds. While intellectual property rights are oriented around the concept of private ownership, individual invention and commercial exploitation, indigenous cultures are directed to collective creation of knowledge and exchange within the community with a strong link to cultural identity. On the other side, there are those who consider that the conventional intellectual property system would be appropriate for the protection of TK.¹¹⁴¹ They argue that protection could encompass two approaches: positive and defensive protection. While the positive approach envisages the protection of traditional knowledge by means of patents, the defensive approach envisages that the principles that form the basis of patents constitute a bar to the very patenting of traditional knowledge. Both these extremes are inadequate, since, as mentioned earlier, intellectual property rights and a new system for the protection of traditional knowledge have to coexist together and be mutually supportive,

¹¹⁴⁰ Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples, Whakatana, 12-18 June 1993, Aotearoa, New Zealand (150 indigenous representatives from several countries in the Pacific and the Americas participated in this Conference. In its Preamble, the Declaration recognises that "Indigenous Peoples are capable of managing their traditional knowledge themselves, but are willing to offer it to all humanity provided their fundamental rights to define and control this knowledge are protected by the international community"); see also GIBSON, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, 2005, p. 7 (the author considers that "the fundamental question to be asked is whether the protection against misappropriation of traditional knowledge can be realistically achieved through a system that facilitates and ultimately legitimates that very misappropriation of the traditional knowledges?"); for an opposite view, see CARVALHO, *The Trips Regime of Patents and Test Data*, 2014, p. 344 (the author argues that the "TRIPS Agreement facilitates the private appropriation of inventions [but not] the misappropriation of knowledge").

¹¹⁴¹ DOWNES, "How intellectual property could be a tool to protect traditional knowledge", 2000, p. 258.

otherwise, the risk is that one will supersede the other depending upon in which jurisdiction one stand.¹¹⁴²

A workable *sui generis* system for the protection of traditional knowledge will need to be backed up by the intellectual property system, and with regard to the present analysis, specifically by patents. Two proposals are actually currently on the table: (a) digital capture of traditional knowledge; and (b) disclosure of origin of traditional knowledge in the patent application.

1 **Databases as a Defensive Protection of Traditional Knowledge**

At the time of writing, the holders of traditional medicinal knowledge can principally rely on one solution, which consists of challenging patents by claiming lack of novelty and/or inventiveness. Traditional medicinal knowledge of indigenous communities is rarely included in prior art searches by patent examiners at a pre-grant stage. Thus, it is only at a post-grant stage - judicial review - that indigenous communities can oppose patents through their representatives. This path often proves to be lengthy and costly. In addition, as the case analysis has shown, evidence of oral traditional knowledge as prior use is rarely taken into account by courts in the assessment of novelty. A document with a date of first public availability is considered to possess a higher degree of proof. Moreover, and still relying on the cases studied, it is doubtful whether the proof of lack of novelty and inventiveness will be held to be sufficient enough by the courts to nullify the grant of a patent.

The registration of traditional knowledge pursues various objectives. First, it constitutes a defensive tool against its misappropriation. The collection and digitisation of traditional knowledge was first proposed by Switzerland¹¹⁴³ in order to prevent its appropriation through “bad patents”, i.e. patents that are not novel or inventive. Second, the compilation of traditional knowledge into databases may also constitute a condition for the legal protection of traditional knowledge. In other words, the registration is a formality that has to be fulfilled for

¹¹⁴² See generally FRANKEL, “Using intellectual property rules to support the self-determination goals of indigenous peoples”, 2015, pp. 627-640.

¹¹⁴³ See WTO TRIPS Council, ‘Review of Article 27.3(b): The View of Switzerland’, Communication from Switzerland, 15 June 2001, IP/C/W/284, para. 16 (Switzerland proposed the establishment of a database at the international level by electronically linking regional, national and local databases, which should be administered by WIPO).

traditional knowledge to be protected. Third, registries can also perform a preservation and a development role.¹¹⁴⁴

After the *turmeric* and the *neem* cases, countries such as India have implemented traditional knowledge digital libraries, namely the Traditional Knowledge Digital Library (TKDL).¹¹⁴⁵ As already mentioned, India possesses a rich heritage in traditional knowledge, particularly in traditional medicinal knowledge, which principally derives from a multitude of medicinal traditions, including Ayurveda, Siddha and Unani. Indian traditional medicinal knowledge is constituted both by oral and written traditions. However, most of Indian traditional medicinal knowledge is codified, and is written down in often inaccessible classical literature in diverse languages such as Hindi, Sanskrit, Persian, Urdu, Arabic and others. Despite the often inaccessibility of Indian traditional medicinal knowledge, its ancestral codification provides it with a public domain status.¹¹⁴⁶

By collecting and cataloguing all traditional knowledge in a database, India's purpose is to render its content accessible for patent examiners when assessing the state of the art. For instance, in 2009, India signed an agreement with the European Patent Office (EPO) in order to prevent traditional knowledge from being patented.¹¹⁴⁷ Today, key patent offices around

¹¹⁴⁴ See, for example, the World Bank Database on Traditional Knowledge that compiles practical and instrumental traditional knowledge useful for appropriate innovative solutions. Available at: http://www.tkwb.org/w/index.php/Main_Page [accessed September 2016].

¹¹⁴⁵ The Traditional Knowledge Digital Library (TKDL) is a collaborative initiative between the National Institute of Science Communication and Information Resources, the Department of Indian System of Medicine and Homeopathy, and the Ministry of Health and Family Welfare.

¹¹⁴⁶ For a review of the background and the mechanisms of the Traditional Knowledge Digital Library, see GUPTA, "India's TKDL: Definition and Classification of Intangible Cultural Heritage and Traditional Knowledge in the Context of Inventory", 2009, pp. 101-111; see also, OGUAMANAM, "Patents and Traditional Medicine: Digital Capture, Creative Legal Interventions, and the Dialectics of Knowledge Transformation", 2008, p. 499.

¹¹⁴⁷ See EPO, "EPO gains access to the Indian Traditional Knowledge Digital Library", Press Releases, 2009, available at: <https://www.epo.org/news-issues/press/releases/archive/2009/20090211.html> [accessed September 2016].

the world have now signed access agreements with the TKDL that enable patent examiners to investigate the library for prior art.¹¹⁴⁸

While the TKDL constitutes a defensive protection for Indian traditional medicinal knowledge, it has also renewed interest in Indian medical heritage by external stakeholders. In that regard, the digital library also has the potential to attract research and partnership with foreign investors for the development of novel drugs.¹¹⁴⁹ Additionally, the TKDL has been fashioned after the model of the International Patent Classification (IPC), which is called the Traditional Knowledge Resource Classification (TKRC). The consequence is that traditional knowledge formulations codified in age-old texts have been decoded or translated into modern Western terminology.¹¹⁵⁰ It should be noted here, as previously mentioned, traditional knowledge that is currently being included in the TKDL is mostly based upon Ayurvedic texts that are widely published volumes freely available in Indian universities and libraries. In addition, Ayurvedic knowledge is not linked to a particular indigenous community living in India in contrast to indigenous knowledge that is rarely codified. The Indian solution is, thus, based both on a defensive approach and a development approach.

In contrast to India, in Peru, Law No. 27811 for the protection of traditional knowledge¹¹⁵¹ establishes a system of registration with varying degrees of confidentiality. As with most databases, the Peruvian registers do not grant rights over the collective knowledge per se.¹¹⁵² The two main goals are to permit indigenous communities to control the dissemination and recording of their collective knowledge and to permit the blocking by the Peruvian National Institute for the Defence of Free Competition and the Protection of Intellectual Property (INDECOPI) of patent applications that do not disclose the use of traditional

¹¹⁴⁸ Following the model of the Indian initiative, China, Thailand, Japan and Taiwan have also created databases of their traditional medicinal systems. Importantly, patent officers globally recognise these databases as fundamental sites for prior art search.

¹¹⁴⁹ GUPTA, “India’s TKDL: Definition and Classification of Intangible Cultural Heritage and Traditional knowledge in the Context of Inventory”, 2009, p. 102.

¹¹⁵⁰ OGUAMANAM, “Patents and Traditional Medicine: Digital Capture, Creative Legal Interventions, and the Dialectics of Knowledge Transformation”, 2008, p. 502.

¹¹⁵¹ *Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos, Ley 27811* (Protection of Indigenous Peoples’ Collective Knowledge Associated with Biological Resources, Peruvian Law 27811), 24 July 2002.

¹¹⁵² Peruvian Law 27811, Article 16.

knowledge with the prior informed consent of its holders.¹¹⁵³ In that sense, the Peruvian solution does not only perform a defensive approach aimed at preventing “bad patents” but also allows for a positive protection in favour of indigenous communities.

Depending on the degree of confidentiality of the traditional knowledge, the Peruvian law provides for three layers of registers. These are: the national public register, the national confidential register and local registers.¹¹⁵⁴ Both the national public register and the national confidential register are under the responsibility INDECOPI. The national public register incorporates TK that is in the public domain, which will be used by patent offices worldwide to assess the novelty and inventiveness of patent applications. The onus is on INDECOPI to ensure that the information compiled in the national public register is brought to the attention of patent offices.

In contrast, the national confidential register may not be consulted by third parties and the responsibility of INDECOPI is to keep its content confidential.¹¹⁵⁵ This register was proposed by indigenous groups during the consultation process of the law. Its exact role is still not clear. For instance, it is not clear whether only TK, which is not in the public domain, is incorporated within the national confidential register or also TK that is in the public domain. In the first case, the information may not be considered as source of prior art. In the second case, the information is considered as a source of prior art, but it is only accessible to patent offices. This second hypothesis would mean that even when TK is in the public domain, it is not freely available, and its access and use will depend on the prior informed consent of its holders. This hypothesis seems more uncertain under the Peruvian law, which states in Article 42 that: “Indigenous Peoples possessing collective knowledge shall be protected against the disclosure, acquisition or use of that collective knowledge without their consent and in an improper manner *provided that the collective knowledge is not in the public domain.*”¹¹⁵⁶

The local registers are administered by the communities themselves according to their customary laws and practices.¹¹⁵⁷ Generally, these local registers are more oriented toward a preservation role rather than a protection role. However, it is not clear to what extent they

¹¹⁵³ Peruvian Law 27811, Article 16.

¹¹⁵⁴ Peruvian Law 27811, Article 15.

¹¹⁵⁵ Peruvian Law 27811, Article 18.

¹¹⁵⁶ Peruvian Law 27811, Article 42.

¹¹⁵⁷ Peruvian Law 27811, Article 24.

play an active role in securing legal protection for traditional knowledge. This will depend on how national law incorporates local registers into national efforts to protect traditional knowledge. Finally, according to Article 19, each indigenous peoples' representative bodies may apply to INDECOPI to register its collective knowledge within both national registers.¹¹⁵⁸

Generally, the question whether the information contained in local registers would be recognised as a source of evidence of traditional knowledge rights remains equally open.¹¹⁵⁹ Indeed, as mentioned, registries may also constitute a compulsory step in the protection of traditional knowledge. National laws have opted for varying approaches with regard to the formalities of protection. Peruvian Law No. 27811, while establishing registries of traditional knowledge, does not link the protection of collective knowledge to them.¹¹⁶⁰ In contrast, the Portuguese Decree-Law on Autochthonous plant material requires registration as a condition for protection.¹¹⁶¹ Registration as a precondition for the recognition of rights has nevertheless been the subject of strong concerns. The main reason invoked is that the recording of traditional knowledge potentially facilitates its dissemination and its misappropriation. The registration of traditional knowledge will also run counter the customary rules concerning its transmission.¹¹⁶² Accordingly, provided that customary norms of indigenous communities are respected, registration or recording may assist in creating a climate of transparency and certainty, and thus may serve the interests of traditional knowledge holders in some

¹¹⁵⁸ Peruvian Law 27811, Article 19.

¹¹⁵⁹ As indigenous communities do not generally recognise the concept of public domain, traditional knowledge contained in local registers may be in the public domain or not.

¹¹⁶⁰ Peruvian Law 27811, Articles 1 and 16.

¹¹⁶¹ *Decreto-Lei n.º 118/2002 de 20 de Abril sobre Material vegetal autóctone* [hereafter, Portuguese Law 118/2002], Article 3 ([Traditional] knowledge shall be protected against reproduction or commercial or industrial use or both as long as [...]: (a) the traditional knowledge shall be identified, described and registered in the Register of Plant Genetic Resources [...]).

¹¹⁶² CBD WG-8J, 'Report of the expert group on the repatriation of traditional knowledge relevant to the conservation and sustainable use of biological diversity', 4-7 November 2015, UNEP/CBD/WG8J/9/INF/4, p. 3 ("databases and registers were only one approach in the effective protection and promotion of traditional knowledge, and their establishment should be voluntary, not a requirement for protection, and established with the prior informed consent of indigenous peoples and local communities"); see also, WIPO IGC, 'Protection of Traditional Knowledge: Overview of Policy Objectives and Core Principles', 1-5 November 2004, WIPO/GRTKF/IC/7/5, pp. 40-41 ("the general safeguard against misappropriation would not be conditional on registration of TK in databases, registries or any other formalities").

circumstances, such as the promotion and the preservation of TK and preventing its misappropriation.¹¹⁶³

Indeed, databases present a principal advantage for national authorities in their efforts to challenge the novelty and inventiveness of an invention. Despite this advantage, the compilation of traditional knowledge in databases has some limitations that should be mentioned.

First, while the compilation of traditional medicinal knowledge in databases such as the TKDL has developed a bridge between traditional medicinal knowledge and Western allopathic knowledge,¹¹⁶⁴ it is far from having created a situation of parity between both systems.¹¹⁶⁵ Indeed, traditional knowledge has to go through a process of de-codification and translation in order to become compatible with the language and standards of the patent system.¹¹⁶⁶ In other words, traditional knowledge is first tested and validated in conformity with scientific criteria.¹¹⁶⁷ The question that can then be raised is whether there remains anything traditional about this “purified” knowledge?¹¹⁶⁸

Second, as far as the TKDL is concerned, the effective participation of holders of traditional knowledge is not clearly defined as the TKDL is a state-sponsored project. The question to be asked is whether the holders of traditional knowledge are entitled to oppose the use of their knowledge? The answer is clearly no because the registration of traditional knowledge is solely a defensive approach with no positive rights granted to traditional knowledge holders to

¹¹⁶³ WIPO IGC, ‘Protection of Traditional Knowledge: Overview of Policy Objectives and Core Principles’, 1-5 November 2004, WIPO/GRTKF/IC/7/5, p. 41.

¹¹⁶⁴ OGUAMANAM, “Patents and Traditional Medicine: Digital Capture, Creative Legal Interventions, and the Dialectics of Knowledge Transformation”, 2008, p. 503.

¹¹⁶⁵ For a discussion between two systems of knowledge, see Part. I, Chap.1, section 2.2; see also AGRAWAL, “Indigenous Knowledge and the Politics of Classification”, 2002, p. 290 (the author criticises the “scientisation” of traditional knowledge with the aim of including it in a database).

¹¹⁶⁶ For an analysis of the scope of the work on TKDL, see WIPO IPC Union, ‘Development of Classification Tools for Traditional Knowledge’, by the International Bureau, 18 February 2002, IPC/CE/31/6, p. 13.

¹¹⁶⁷ AGRAWAL, “Indigenous Knowledge and the Politics of Classification”, 2002, p. 290.

¹¹⁶⁸ AGRAWAL, “Indigenous Knowledge and the Politics of Classification”, 2002, p. 292 (the author states that “in the very moment that indigenous knowledge is proved useful to development through the application of science, it is, ironically, stripped of the specific characteristics that could even potentially mark it as indigenous”).

take any active decision on their knowledge. This, however, does not seem to be the case in Peru, where the registers not only perform a defensive role but also a positive one, except where traditional knowledge is in the public domain.

An intellectual property expert has made a proposal to provide special rights for traditional knowledge holders to actively manage their own traditional knowledge databases.¹¹⁶⁹ This solution was built on the intellectual property protection of databases.¹¹⁷⁰ However, these types of rights do not confer legal rights over the information and data contained in databases, that is traditional knowledge, but only the way in which they are compiled and organised.

At this point, it should also be noted that an important number of existing databases on traditional knowledge, which were established before the entry into force of the CBD, have collected TK without the prior informed consent of indigenous peoples. An example is Natural Product Alert at the University of Illinois, also known as NAPRALERT, which is a database of natural products, including ethno-medicinal information that has been obtained from over 200,000 scientific papers and reviews since 1975.¹¹⁷¹ The uniqueness of this database is that it is freely available for research purposes. While it offers a valuable source of information, it places traditional knowledge in the public domain without the prior informed consent of its holders, which then becomes freely available.

Third, traditional knowledge registered for the purpose of its recognition as prior art in patent applications, is at the risk of becoming part of the public domain if the information is made available to the public. Similarly, while some traditional knowledge is already publicly available in theory, it is in practice, difficult to access. Thus, the documentation of this material may render it much more readily available.¹¹⁷² This also means that this pool of registered traditional knowledge will become an important source of inspiration for future

¹¹⁶⁹ See, CARVALHO, “From the Shaman’s Hut to the Patent Office: How Long and Winding is the Road?”, 1991, pp. 3-17.

¹¹⁷⁰ See Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the Legal Protection of Databases, OJ L 77, 20-28 (Directive 96/9/EC).

¹¹⁷¹ See NAPRALERT website at: <https://www.napralert.org/about/>, [accessed September 2016].

¹¹⁷² WIPO IGC, ‘Practical Mechanisms for the Defensive Protection of Traditional Knowledge and Genetic Resources within the Patent System’, the Secretariat, 14 May 2003, WIPO/GRTKF/IC/5/6, p. 10.

inventions. In that case, interested third parties will have no obligation to seek prior informed consent for its use.¹¹⁷³

The compilation of traditional knowledge in databases was perceived to be a major issue in relation to the protection of traditional knowledge during the first years of the WIPO IGC process.¹¹⁷⁴ At present, while some countries, including the United States, Canada, Japan and the Republic of Korea clearly favour the use of databases as the sole feasible defensive protection of traditional knowledge,¹¹⁷⁵ the trend increasingly favours a solution based on the disclosure of the origin of traditional knowledge in the patent system, without entirely discarding the defensive role of databases.¹¹⁷⁶

2 Disclosing the Use / Origin of TK and PIC in Patent Descriptions or Claims

The second main development endeavouring to bridge the gap between the protection of traditional knowledge and the patent system is the requirement to disclose traditional knowledge within the patent application.

¹¹⁷³ CBD WG-8J, 'Report of the expert group on the repatriation of traditional knowledge relevant to the conservation and sustainable use of biological diversity', 4-7 November 2015, UNEP/CBD/WG8J/9/INF/4, p. 3 (the expert group reaffirmed the requirement of prior informed consent in the establishment of databases that had already been emphasised by the Conference of the Parties in its decision VII/161173).

¹¹⁷⁴ See WIPO IGC, 'Practical Mechanisms for the Defensive Protection of Traditional Knowledge and Genetic Resources within the Patent System', the Secretariat, 7-15 July 2003, WIPO/GRTKF/IC/5/6; WIPO IGC also developed the Inventory of Traditional Knowledge-related Periodicals and the Inventory of Traditional Knowledge-related Databases, and the Online portal of Traditional Knowledge Databases, available respectively at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=2142 and http://www.wipo.int/tk/en/resources/db_registry.html [accessed April 2016]; see also WIPO PCT UNION, 'PCT Minimum Documentation: Traditional Knowledge', International Bureau, 26 January 2005, PCT/MIA/11/5.

¹¹⁷⁵ WIPO IGC, 'Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources', 22-26 April 2013, WIPO/GRTKF/IC/24/7; see also, WIPO IGC, 'Proposal for the Terms of References for the Study by the WIPO Secretariat on Measures Related to the Avoidance of the Erroneous Grant of Patents and Compliance with Existing Access and Benefit-Sharing Systems', submitted by the Delegations of Canada, Japan, Norway, the Republic of Korea, the Russian Federation and the United States of America, 7-9 July 2014, WIPO/GRTKF/IC/28/9.

¹¹⁷⁶ WIPO ICG, 'Initial Draft Report', the Secretariat, 21 March 2016, WIPO/GRTKF/IC/29/8 Prov. p. 7.

2.1 The Background – From the Ministerial Declaration at Doha to the Disclosure Requirement Debate

As discussed previously, in the patent system, the disclosure requirement is the counterpart of the time-limited-monopoly accorded to the rights-holder. Patent laws impose an obligation on applicants, as stipulated in Article 5 of the Patent Cooperation Treaty (PCT), “to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art”.¹¹⁷⁷

After the adoption in 2002 of the Bonn Guidelines, the CBD’s Conference of the Parties (COP) encouraged Member States to require the disclosure of the country of origin of genetic resources and of associated traditional knowledge in patent applications. Since the adoption of the Bonn Guidelines, diverse proposals on disclosure of origin have emerged. In short, countries rich in genetic resources and traditional knowledge have required that patents for inventions based on genetic resources or traditional knowledge should only be granted if those resources had been obtained in conformity with the requirements of the Convention on Biological Diversity, the Nagoya Protocol and national access and benefit-sharing and traditional knowledge protection laws. The way to monitor whether these requirements were met would be the disclosure of origin of these resources in patent applications, the proof of prior informed consent, and an agreement on benefit-sharing.

In other words, the discussions on the introduction of a disclosure requirement (DR) go back to two main issues: (i) the need to protect traditional knowledge against its misappropriation by the mainstream system of intellectual property rights; and (ii) the need to clarify the relationship between the Convention on Biodiversity and the TRIPS Agreement.

The Ministerial Declaration at Doha (Doha Declaration) formally introduced the issue of the protection of traditional knowledge onto the official World Trade Organisation (WTO) agenda with the objective of revising Article 27.3(b) of the TRIPS Agreement. Furthermore, in paragraph 19, the Doha Declaration explicitly links the relationship between the TRIPS Agreement and the CBD with the protection of traditional knowledge. Pursuant to this, WTO

¹¹⁷⁷ PCT, Article 5.

members instructed the TRIPS Council to consider the protection of traditional knowledge.¹¹⁷⁸

As far as the relationship between the TRIPS agreement and the CBD is concerned, the question is whether there is a conflict between these two international binding treaties.¹¹⁷⁹ The potential conflict stems from three main points, which are, state sovereignty, prior informed consent, and benefit-sharing. First, while the central principle of the CBD is State sovereignty over their genetic resources, the TRIPS Agreement makes mandatory the patentability of all inventions in all fields of technology, including inventions deriving from or implicating genetic resources. According to the CBD, the appropriation of resources, under the jurisdiction of nation states, by private parties can take place once the prior informed consent of the providing State has been obtained. Again, the TRIPS Agreement does not incorporate this requirement. Finally, while the CBD stipulates that user States shall share the benefits arising from the access and/or utilisation of such resources and/or associated traditional knowledge with the providing States, the TRIPS Agreement remains silent on this issue.¹¹⁸⁰

The views expressed by countries can be briefly categorised in two broad groups.¹¹⁸¹ The first group, consisting of, for instance, India,¹¹⁸² Brazil, Ecuador, Peru¹¹⁸³ and the African Group,¹¹⁸⁴ considers that there is a conflict between these two agreements, and, in order to avoid such a conflict, the TRIPS Agreement should be amended. The second group,

¹¹⁷⁸ WTO Ministerial Conference, 'Ministerial Declaration', adopted 14 November 2001, Fourth Ministerial Conference, Doha, 9-14 November 2001, WT/MIN(01)/DEC/1 (Doha Declaration).

¹¹⁷⁹ WTO TRIPS Council, 'The Relationship between the TRIPS Agreement and the Convention on Biological Diversity', 8 February 2006, IP/C/W/368/Rev.1, p. 3; See also GERVAIS, *The TRIPS Agreement – Drafting History and Analysis*, 2012, p. 366.

¹¹⁸⁰ WTO TRIPS Council, 'The Relationship between the TRIPS Agreement and the Convention on Biological Diversity, Note by the Secretariat, 8 February 2006, IP/C/W/368/Rev. 1, para. 18, p. 9; See also MGBEOJI, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge*, 2006, p. 128.

¹¹⁸¹ WTO TRIPS Council, 'The Relationship between the TRIPS Agreement and the Convention on Biological Diversity', 8 February 2006, IP/C/W/368/Rev.1, p. 4.

¹¹⁸² WTO TRIPS Council, 'Protection of Biodiversity and Traditional Knowledge – The Indian Experience', Submission by India, 14 July 2000, WT/CTE/W/156 (IP/C/W/198).

¹¹⁸³ WTO TRIPS Council, 'The Relationship between the TRIPS Agreement and the Convention on Biological Diversity', 8 February 2006, IP/C/W/368/Rev.1, p. 8.

¹¹⁸⁴ WTO TRIPS Council, 'Review of the Provisions of Article 27.3(b) of the TRIPS Agreement' Submission by Kenya on behalf of the African Group, 8 November 1999, IP/C/W/163.

including, the European Group,¹¹⁸⁵ USA,¹¹⁸⁶ Japan,¹¹⁸⁷ Australia and Norway, state that the two international treaties have different subject matters and purposes. Accordingly, in their view, there is no conflict between the TRIPS Agreement and the CBD. The main argument put forward is that “nothing in the provisions of either agreement prevents a State from fulfilling its obligations under both”.¹¹⁸⁸

As far as traditional knowledge is concerned, the argument is that even though the TRIPS Agreement does not contain provisions on the protection of traditional knowledge, Member States are free to adopt such protection in their national laws.¹¹⁸⁹ At the time of writing Member States have kept the same views and there is no agreement as to whether there is a conflict between the two international treaties.

Moreover, with the entry into force of the Nagoya Protocol in 2014, it is arguable that another layer of conflicting norms has emerged. With the negotiations of the Nagoya Protocol, some Member States foresaw that the Protocol would address the issue of the asymmetry between the TRIPS Agreement and the biodiversity regime.¹¹⁹⁰ Indeed, in March 2010, the draft protocol included a disclosure requirement as a mandatory measure to secure compliance with the access and benefit sharing obligations by using intellectual property examination offices as checkpoints.¹¹⁹¹ The provision of an international certificate of compliance to patent

¹¹⁸⁵ WTO TRIPS Council, ‘Review of the Provisions of Article 27.3(b) of the TRIPS Agreement’ Submission by the European Communities and their Member States, 13 June 2001, IP/C/W/254.

¹¹⁸⁶ WTO TRIPS Council, ‘Review of the Provisions of Article 27.3(b) of the TRIPS Agreement’ Submission by the USA, 29 October 1999, IP/C/W/162, p. 4.

¹¹⁸⁷ WTO TRIPS Council, ‘Review of the Provisions of Article 27.3(b) of the TRIPS Agreement’ Communication from Japan, 11 December 2000, IP/C/W/236, p. 6.

¹¹⁸⁸ WTO TRIPS Council, ‘Review of the Provisions of Article 27.3(b) of the TRIPS Agreement’ Submission by the European Communities and their Member States, 13 June 2001, IP/C/W/254.

¹¹⁸⁹ For a detailed review of the arguments and counter-arguments of the groups of States, see WTO TRIPS Council, ‘The Relationship between the TRIPS Agreement and the Convention on Biological Diversity’, Note by the Secretariat, 8 February 2006, IP/C/W/368/Rev.1.

¹¹⁹⁰ WTO TRIPS Council, ‘Minutes of Meeting’, 1st March 2011, IP/C/M/65, para. 59 (Brazil declared that the “Nagoya Protocol had increased the importance of the discussion in the TRIPS Council on how to WTO Members could establish a mutually supportive relationship between the TRIPS Agreement and the CBD”).

¹¹⁹¹ CBD WG ABS, ‘Report of the First Part of the Ninth Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing’, Cali, 22-28 March 2010, Annex I, p. 44 (Article 13 reads: “Parties shall

applicants (the users of genetic resources) was the means to provide proof of fulfilment of the disclosure requirement, including the origin of genetic resources, proof of prior informed consent, and benefit sharing.¹¹⁹²

It has to be stressed that the disclosure requirement in the draft Nagoya Protocol was only meant for genetic resources and not traditional knowledge. Today, specific mentions of a disclosure requirement and a requirement for intellectual property examination offices to act as checkpoints have disappeared from the final version of the Nagoya Protocol. Article 17 of the Protocol, titled “Monitoring the utilisation of Genetic Resources” leaves State Parties to introduce a disclosure requirement on a voluntary basis.¹¹⁹³ While a few experts¹¹⁹⁴ consider that such a disclosure requirement would constitute an unnecessary burdensome measure for intellectual property rights offices and would cause major trade disputes, others¹¹⁹⁵ consider that a disclosure requirement is both essential for providing more transparency to the intellectual property system and for assuring the mutual supportiveness of both treaties.

It would not be wrong to state that the discussions in relation to the protection of traditional knowledge taking place in the review of Article 27.3(b) of the TRIPS agreement and on the relationship between the two international treaties have been substituted by the debate on the implementation of a disclosure requirement in the patent system, through the proposal to amend Article 29 of the TRIPS Agreement. This proposal by the African Group assumes a

take measures, as appropriate, to monitor the utilization of genetic resources [...] Such measure include the identification and establishment of check points and disclosure requirements [...].”.)

¹¹⁹² PAVONI, “The Nagoya Protocol and WTO Law”, 2013, p. 203.

¹¹⁹³ Nagoya Protocol, Article 17.

¹¹⁹⁴ See for instance, SAFRIN, “Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life”, 2004, p. 669 (arguing that “the sovereign enclosure regimes are deterring companies and researchers from bioprospecting in genetically rich countries”).

¹¹⁹⁵ PAVONI, “The Nagoya Protocol and WTO Law”, 2013, p. 204 (according to the author, one of the fundamental consequences of the failure of the Nagoya Protocol to include a mandatory disclosure requirement is that, in case of disputes at the WTO in the area of ABS, the country that is the author of those measures would not be able to find relief in the Nagoya Protocol’s framework); see also, VOGEL et al., “The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing”, 2011; see also, WTO Trade Negotiations Committee, ‘Draft Modalities for TRIPS Related Issues’, submitted by Brazil, the EU, India, and Switzerland, 19 July 2008, TN/C/W/52 (coalition of 110 WTO members).

new formal requirement in the patent system. The African Group suggested the modification of Article 29 of TRIPS by adding a third paragraph to the provision:¹¹⁹⁶

Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin.

As argued by Carvalho, while this proposal has had the merit of renewing the debate in the TRIPS Council, the negotiations have similarly stayed in a deadlock that has existed since 2002.¹¹⁹⁷ The next paragraphs will briefly examine the position of Member States with regard to the disclosure requirement.

2.2 Member States' Positions and Types of Disclosure Requirements

Member States' positions on the disclosure requirement in the patent system can be broadly divided in four groups no matter what fora the debates are taking place in, either the WTO, WIPO or the CBD. The following will briefly summarise the four approaches to the disclosure requirement.

2.2.1 The TRIPS Disclosure Proposal

The first group contains countries rich in biological resources and traditional knowledge. This group is constituted by the African Group, Brazil, Peru and India. Their position is commonly named the "TRIPS Disclosure proposal". The proposal suggests a *mandatory disclosure of origin* requirement in the TRIPS Agreement "for the purpose of establishing a mutually supportive relationship between the TRIPS Agreement and the Convention on Biodiversity".¹¹⁹⁸ This would require the patent applicant to disclose: (i) the source and

¹¹⁹⁶ WTO Trade Negotiations Committee 'Draft Decision to Enhance Mutual Supportiveness Between the TRIPS Agreement and the Convention on Biological Diversity' Communication by Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group, 19 April 2011, p. 2 ; WTO TRIPS Council, 'Taking forward the Review of Article 27.3(b) of the TRIPS Agreement' Joint Communication from the African Group, 26 June 2003, IP/C/W/404, p. 6; see also WTO TRIPS Council, 'Response to Questions Raised on the Draft Amendment to TRIPS – Article 29Bis' Communication by Brazil, 24 July 2006, IP/C/W/475.

¹¹⁹⁷ CARVALHO, *The TRIPS regime of Patents and Test Data*, 2014, p. 372.

¹¹⁹⁸ WTO Trade Negotiations Committee, 'Draft Decision to Enhance Mutual Supportiveness Between the TRIPS Agreement and the Convention on Biological Diversity', Communication by Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group, 19 April

country of origin of the biological resource and of the traditional knowledge used in the invention; (ii) evidence of prior informed consent from the authorities under the relevant national regime; and (iii) evidence of fair and equitable benefit sharing under the relevant national regime. Member States would have to implement the proposed disclosure requirements in their national laws. Thus, the disclosure requirements would be obligatory for applicants at the time of applying for a patent. The burden on the patent applicant would be limited to providing information and evidence that is known to him, or should have been known to him.¹¹⁹⁹

In short, this proposal would amount to a strong disclosure requirement, interdependent with the patent system, in the sense that it would constitute a new condition to the granting of a patent. Indeed, this strong form of disclosure requirement connects patentability, nullity or revocation of patents with disclosure of origin. Consequently, various suggestions have been made to amend the TRIPS agreement, amongst them the aforementioned revision of Article 29.¹²⁰⁰ Thus, introducing these requirements into the TRIPS Agreement would have an impact on the patent not only at the stage of processing, but also at the post-grant stage, where the patent could be revoked, particularly where fraudulent intent is established.¹²⁰¹

With regard to what triggers disclosure, the proposal suggests that any use, including incidental use, of genetic resources and/or associated traditional knowledge should result in an obligation to disclose the origin of these resources. Such uses could include those that form part of the claimed invention; use during the process of developing the invention; use that is a

2011, TN/C/W/59, p. 2; WTO TRIPS Council, 'Taking forward the Review of Article 27.3(b) of the TRIPS Agreement', Joint Communication from the African Group, 26 June 2003, IP/C/W/404, p. 2.

¹¹⁹⁹ WTO TRIPS Council, Minutes of Meeting, Statement of Brazil, 15 September 2005, IP/C/M/48, para. 36.

¹²⁰⁰ WTO TRIPS Council, 'The Relationship between the TRIPS Agreement and the Convention on Biological Diversity', Note by the Secretariat, 8 February 2006, IP/C/W/368/Rev.1, p. 31.

¹²⁰¹ WTO TRIPS Council, 'The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge – Elements of the obligation to disclose evidence of prior informed consent under the relevant national regime', Submission from Brazil et al., 10 December 2004, IP/C/W/438, para. 14, p. 4.

necessary prerequisite for the development of the claimed invention; or uses that form part of the necessary background material for the development of the invention.¹²⁰²

As to the burden of proof in case of non-compliance, it has been proposed that applicants should be required to positively discharge a burden of proof that the genetic resources and/or traditional knowledge have been legally accessed and that the condition of a benefit-sharing agreement has been met through mutually agreed terms (MAT).¹²⁰³

In conclusion, the intent behind requiring the disclosure of origin is to use the intellectual property system as a checkpoint for monitoring users' compliance with national laws on access and benefit-sharing and traditional knowledge. According to one Swiss scholar, this option "is obviously the most protective of the interests of local communities due to its extensive reach".¹²⁰⁴

One of the principal problems with the disclosure of origin requirement is that many genetic resources, and traditional knowledge associated with these resources, are kept in *ex-situ* collections. Indeed, the term "country of origin" is too restrictive and does not acknowledge the wide range of other entities that may be involved in access and benefit-sharing,¹²⁰⁵ such as botanical gardens, the multilateral system of the International Treaty on Plant Genetic Resources and indigenous communities.¹²⁰⁶

¹²⁰² WTO TRIPS Council, 'Elements of the obligation to disclose the source and country of origin of the biological resources and/or traditional knowledge used in an invention', Submission from Brazil et al., 27 September 2004, IP/C/W/429/Rev.1, para. 8, p. 3.

¹²⁰³ WTO TRIPS Council, 'Elements of the obligation to disclose the source and country of origin of the biological resources and/or traditional knowledge used in an invention', Submission from Brazil et al., 27 September 2004, IP/C/W/429/Rev.1, para. 15, p. 5.

¹²⁰⁴ DE WERRA, "Fighting against biopiracy: does the obligation to disclose in patent applications truly help?", 2009, p. 150; see also generally, CORREA and SARNOFF, *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*, 2006.

¹²⁰⁵ GIRSBERGER, *Certificates of Source – Disclosure of Source*, 2004, pp. 141-146.

¹²⁰⁶ CBD, Articles 15.4 and 15.7; Bonn Guidelines, paras. 17, 18, 28, 31, 32 and 48; International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), Articles 10 to 13.

2.2.2 The Mandatory Disclosure Proposal

The second proposal, which has been submitted by the European Union and its Member States, is called “The mandatory disclosure requirement proposal”.¹²⁰⁷ As an initial matter, these States believe that, the disclosure of origin requirement should be discussed and negotiated in international fora other than the WTO, namely in WIPO.¹²⁰⁸ However, the proposal is open to further discussion on the legal form the disclosure requirement should adopt. According to this proposal, each country would be obliged to require patent applicants to disclose information on the country of origin or source of genetic resources, and the traditional knowledge used in the invention, which patent applicants know or have reason to know of. However, this mandatory disclosure requirement should not constitute an additional condition for patentability, but should be a purely formal requirement. This means that if the required information is missing in the patent application, the application is not processed until the information is provided. However, once the patent has been granted, the legal consequences for the non-fulfilment of this requirement should be provided for outside patent law. The legal effects should be implemented in national laws, whether through sanctions in civil law or fines in administrative law.¹²⁰⁹

This disclosure requirement would be triggered when the invention is directly based on the genetic resource or traditional knowledge. This means that the resource or knowledge should form part of the claimed invention or has been necessary for the development resulting in the invention.¹²¹⁰ In opposition to the “TRIPS disclosure proposal”, the burden of proof would rest on the party who contests the disclosure provided by the applicant. The main advantage of this proposal resides in the fact that, while facilitating the implementation of the objectives

¹²⁰⁷ WTO TRIPS Council, ‘The Relationship between the TRIPS Agreement and the Convention on Biological Diversity’, Note by the Secretariat, 8 February 2006, IP/C/W/368/Rev.1, p. 33.

¹²⁰⁸ The recently adopted EU Regulation 511/2014 implementing the Nagoya Protocol makes no reference to the disclosure requirement.

¹²⁰⁹ WTO TRIPS Council, ‘Review of Article 27.3(b) of the TRIPS Agreement, and the relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore’ Submission by the European Communities and their Member States, 17 October 2002, IP/C/W/383, p. 2.

¹²¹⁰ WTO TRIPS Council, ‘The Relationship between the TRIPS Agreement and the Convention on Biological Diversity’, Note by the Secretariat, 8 February 2006, IP/C/W/368/Rev.1, p. 33.

of the Convention on Biological Diversity, it would not affect the balance of rights and obligations provided in the TRIPS Agreement.

2.2.3 The Patent Cooperation Treaty Disclosure Proposal

A third proposal, called the “Patent Cooperation Treaty (PCT) Proposal” or “the optional approach” has been suggested by Switzerland.¹²¹¹ For Switzerland, disclosing the source of genetic resources and traditional knowledge in patent applications would assist patent examiners and judges in the establishment of prior art with regard to inventions that somehow relate to these resources or this knowledge. In other words, the Swiss proposal refers to a transparency approach.

The proposal consists of amending the Regulations under the PCT, by adding Rule 51 bis(1)(g), to explicitly enable national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications. In other words, it is up to each Member State to the PCT to decide whether such a requirement is to be introduced into its national patent legislation.

This proposal has three main practical advantages. First, because it has been argued that the TRIPS Disclosure Proposal would not be compatible with Articles 27.1 and 29 of the TRIPS Agreement,¹²¹² the PCT Disclosure Proposal has been suggested as a pragmatic alternative related to procedural matters rather than the substantive conditions of patentability. Second, while the TRIPS Agreement may be amended, the time necessary to amend the regulations under the PCT will be considerably less than the amendment of the TRIPS Agreement.¹²¹³

¹²¹¹ WIPO, Working Group on Reform of the Patent Cooperation Treaty (PCT), ‘Proposals by Switzerland regarding the declaration of source of genetic resources and traditional knowledge in patent applications’, 5 May 2003, PCT/R/WG/4/13.

¹²¹² CARVALHO, “Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution”, 2000, p. 379 (the author states that “to require that patent applicants identify the source of genetic resources and give evidence of prior informed consent as conditions of patentability conflicts with the TRIPS Agreement. First, the conditions of patentability are limited to novelty, inventiveness, and industrial applicability. Second, the disclosure requirement is limited to the obligations established by Article 29. Third, it is not reasonable under Article 62 to impose formal requirements that place an unreasonable burden on the patent applicant).

¹²¹³ ADDOR and GIRSBERGER, “How to Address the Disclosure Requirement at the International Level”, 2005, pp. 18-19.

Finally, the amendment of the PCT regime will enable Member States to include the disclosure requirement into their national laws in a manner consistent with the Patent Law Treaty (PLT). The Swiss proposal was made after the adoption of the PLT but before its entry into force in 2005.¹²¹⁴

A patent applicant would have to disclose the source if the invention is directly based on genetic resources and traditional knowledge. The term “source” should be understood in its broadest sense possible, including primary sources and secondary sources. Primary sources include the country of origin, the country which possesses genetic resources and / or traditional knowledge in *in-situ* conditions and the country providing these resources and/or traditional knowledge in accordance with the CBD,¹²¹⁵ and indigenous and local communities.¹²¹⁶ Secondary sources include, in particular, *ex situ* collections and scientific literature. The utilisation of the term “source” allows the encompassing of the multitude of entities that may be involved in access and benefit sharing arrangements.¹²¹⁷

In other words, there would be “a cascade of possible primary and secondary sources”.¹²¹⁸ In order to fulfil the requirement, patent applicants must declare the primary source, if they have information about this primary source at hand, whereas a secondary source may only be

¹²¹⁴ For a detailed study on the interface between the PLT and the PCT, see WIPO Standing Committee on the Law of Patents (SCP), ‘Study on the interface between the SPLT, the PLT and the PCT, prepared by the International Bureau, Geneva, 5-9 November 2001, SCP/6/5.

¹²¹⁵ CBD, Articles 15, 16 and 19.

¹²¹⁶ CBD, Article 8(j).

¹²¹⁷ For a detailed study of the Swiss proposal, see WIPO, Working Group on Reform of the Patent Cooperation Treaty (PCT), ‘Proposals by Switzerland regarding the declaration of source of genetic resources and traditional knowledge in patent applications’, 5 May 2003, PCT/R/WG/4/13, Annex, p. 11; WIPO IGC, ‘Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposals by Switzerland’, Document submitted by Switzerland, 3 – 12 July 2007, WIPO/GRTKF/IC/11/10, Annex, p.4; see also ADDOR and GIRSBERGER, “How to Address the Disclosure Requirement at the International Level”, 2005, pp. 18-19.

¹²¹⁸ ADDOR, “Switzerland’s proposals for disclosure of the source of genetic resources and traditional knowledge in patent applications; and views on prior informed consent and benefit sharing in patent applications”, 2005, p. 37.

declared if patent applicants have no information at hand about the primary source.¹²¹⁹ The applicant would have at least two months from the date of the patent office's notification to comply with this requirement, and if not, the sanction would include rejecting the application or deeming it to be withdrawn.¹²²⁰

In regard to traditional knowledge, what would trigger the disclosure requirement is that the inventor must know that the invention is directly based on such knowledge, i.e. the applicant must consciously derive the invention from this knowledge. An additional benefit of this proposal is that a requirement to disclose the source of traditional knowledge would simplify searching the databases on traditional knowledge. Indeed, Switzerland considers that the collection of traditional knowledge in databases is complementary to the disclosure requirement.

While the Swiss proposal was supported by the EU and its Member States,¹²²¹ it was rejected by some other countries, primarily developing countries. For instance, Brazil noted that “[t]he implementation of the disclosure requirements, once agreed and defined under the TRIPS Agreement, could facilitate actions elsewhere. On the other hand, changes made elsewhere without the proposed amendment to the TRIPS Agreement would not be sufficient to address either the mandate Members had or the problems Members wished to address”.¹²²²

2.2.4 From No Need for a Disclosure Requirement towards an Unexpected Coalition

The fourth group is constituted by the US and Japan who argue that there is no need for a disclosure requirement , and that such a requirement will have detrimental effect on

¹²¹⁹ WIPO IGC, ‘Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposals by Switzerland’, Document submitted by Switzerland, 3 – 12 July 2007, WIPO/GRTKF/IC/11/10, Annex, p. 7.

¹²²⁰ ADDOR and GIRSBERGER, “How to Address the Disclosure Requirement at the International Level”, 2005, pp. 18-19; see also, the newly adopted Swiss Patent Act in PART III, Chapter 3, 3.1.1 (under the Swiss Patent Act, the concept of source covers any type of provenance and origin).

¹²²¹ WIPO IGC, ‘Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications’, submitted by the European Community and its Member States, 6-10 June 2005, WIPO/GRTKF/IC/8/11, Annex, p. 1 (the European Community advocates for a binding disclosure requirement that should be applied to all patent applications).

¹²²² See, WTO TRIPS Council, ‘Minutes of Meeting’, 14-15 June 2005, IP/C/M/48, para. 31.

technological progress because it will increase the workload burden¹²²³ of the whole patent system.¹²²⁴ If the purpose of disclosing the source or origin, evidence of prior informed consent and evidence of benefit sharing is to prevent bad patents, Member States should establish a comprehensive database or introduce a mechanism for third parties to be involved easily in the process of patenting, including through post-grant opposition.¹²²⁵ Any disclosure requirement in the patent system should solely pursue the objective of disclosing the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In other words, only the disclosure requirement that is material to patentability is required.

However, in June 2008, before the WTO Ministerial Conference, an unexpected coalition of developed and developing countries submitted a proposal, the commonly called “draft modalities” text on intellectual property matters at the WTO, which addressed, amongst others, the disclosure requirements on patent applications. The text was put forward by a coalition led by India, Brazil, Switzerland, and the EU.¹²²⁶ The coalition advocated that three contentious intellectual property issues be included in the negotiations as part of a “single

¹²²³ For a different view, see OLDHAM and BURTON, “Defusing Disclosure in Patent Applications”, 2010, p. 14 (According to the authors, “the Bayh-Dole Act in the United States provides an example of a fully functioning disclosure requirement that is included in the patent law”. They conclude that “arguments that disclosure requirements inevitably create a heavy burden for applicants and patent offices are not supported by experience in the United States”. The Bayh-Dole Act permits a university, small business, or non-profit institution to elect to pursue ownership of an invention in preference to the government. The applicant is required to disclose the source of federal funding in the text of a patent application); see also the declaration made by the delegation of Switzerland in WIPO IGC. [references]

¹²²⁴ WTO TRIPS Council, ‘Article 27.3(b), The Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore’, Communication by the United States, 10 June 2005, IP/C/W449 (“In our view, new patent disclosure requirements are not an appropriate solution to the concerns raised, and only further convinces us that the most effective way to ensure the objectives of ensuring prior informed consent and equitable benefit sharing is tailored, national laws outside the patent system that directly and effectively regulate the relevant conduct”); see also WTO TRIPS Council ‘Article 27.3(b), The Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore’, Communication by the United States, 26 November 2004, IP/C/W/434.

¹²²⁵ WTO TRIPS Council, Minutes of Meeting, Statement of United States, 15 September 2005, IP/C/M/48, para. 62.

¹²²⁶ Prior to this coalition, Switzerland and the EU, while being in favour of a disclosure requirement, considered that TRIPS was not the appropriate legal instrument that should deal with this issue.

undertaking”.¹²²⁷ According to the “draft modalities”, prior to any official negotiations on issues related to a disclosure requirement, Member States would agree to amend the TRIPS Agreement in order to render a disclosure requirement mandatory in all patent applications. In addition, when disclosing the origin of genetic resources and traditional knowledge, patent applications would also have to produce proof of prior informed consent and benefit sharing.¹²²⁸ The coalition included 110 developing and developed countries, that is, more than two-third of WTO Members. Not unexpectedly, however, the “draft modalities” was met with harsh opposition from a group of countries, including, amongst others, Argentina, Australia, Canada, Chile, Japan, Mexico, New Zealand, South Africa, Taiwan, and the US, who put forward the “joint proposal”. They argued that intellectual property issues should not be discussed jointly with the Doha negotiations on liberalising trade in agriculture and industrial goods. Indeed, the proposal suggests recourse to other alternative and more effective solutions, such as, for instance, “the establishment under WIPO of improved databases on traditional knowledge available to patent examiners and through contractual arrangements under national access and benefit-sharing laws”.¹²²⁹ After the “draft modalities” proposal stalled, discussion returned to the issue from which the disclosure requirement originates, that is, the relationship between the TRIPS Agreement and the CBD.¹²³⁰ Thus, it seems that if any

¹²²⁷ The three conflicting issues were: (i) the disclosure of the source of genetic resources and traditional knowledge in patent applications; (ii) the extension of geographical indications (GIs) to all goods; and (iii) the establishment of a multilateral register for GIs for wines and spirits.

¹²²⁸ WTO Trade Negotiations Committee, ‘Draft Modalities for TRIPS Related Issues’, submitted by Brazil, the EU, India, and Switzerland, 19 July 2008, TN/C/W/52, p. 3 (“Members agree to amend the TRIPS Agreement to include a mandatory requirement for the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge in patent applications. Patent applications will not be processed without completion of the disclosure requirement”).

¹²²⁹ WTO General Council, Trade Negotiations Committee, ‘Issues related to the Extension of the Protection of Geographical Indications [...] and those related to the Relationship between the TRIPS Agreement and the Convention on Biological Diversity’, Report by the Director-General, 9 June 2008, WT/GC/W/591 – TN/C/W/50, para. 7, p. 2.

¹²³⁰ WTO News Item, ‘TRIPS Council Discusses Biodiversity, Health, Reviews China’s Implementation’, 28 October 2008, available at: https://www.wto.org/english/news_e/news08_e/trips_28oct08_e.htm [accessed September 2016].

agreement is to be reached on the disclosure requirement, the issue of the TRIPS/CBD relationship has first to be agreed upon.¹²³¹

At the time of writing, because the deadlock on the disclosure requirement continues at the WTO,¹²³² many countries, including Canada,¹²³³ Australia¹²³⁴ and Japan,¹²³⁵ have been calling for the disclosure requirement to be dealt with in the framework of negotiations held under the WIPO.¹²³⁶ For now, at the international level, the role of a disclosure requirement in the patent system for the specific protection of traditional knowledge is being extensively debated within the WIPO-IGC.¹²³⁷

¹²³¹ For an in depth discussion of the feasibility of disclosure requirement in national laws and the amendment of the TRIPS Agreement, see, CARVALHO, “Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution”, 2000 (The author makes a distinction between invalidating the patent application for failure to disclose the origin, which he considers TRIPS non-compliance and a refusal to enforce it post-grant, which he considers to be TRIPS compliant. The solution he proposes is not to make the requirement a condition of patentability but a condition for its enforceability after it has been granted).

¹²³² PAVONI, “The Nagoya Protocol and WTO Law”, 2010, p. 200.

¹²³³ WTO TRIPS Council, ‘Minutes of Meetings’, 5-6 March 2013, IP/C/M/72, para. 5.42.

¹²³⁴ WTO TRIPS Council, ‘Minutes of Meetings’, 5-6 March 2013, IP/C/M/72, para. 5.41.

¹²³⁵ WTO TRIPS Council, ‘Minutes of Meetings’, 5-6 March 2013, IP/C/M/72, para. 5.39.

¹²³⁶ In contrast, Switzerland’s position could be summarised as “while the TRIPS Agreement and the CBD were mutually supportive, the relationship could be further enhanced through the inclusion of a provision of a mandatory, non-burdensome requirement to declare in patent applications the source of genetic resources and traditional knowledge on which an invention was directly based. Switzerland was convinced that such a provision in the TRIPS Agreement would work in favour of the credibility of the patent system as a whole and the acceptance of the patentability of inventions in the field of biotechnology in particular. Therefore, Switzerland was a Member of the W/52 coalition - a large group of WTO Members which had proposed modalities language for three TRIPS issues negotiated in the Doha Round”. WTO TRIPS Council, ‘Minutes of Meetings’, 5-6 March 2013, IP/C/M/72, para. 5.43, pp. 12-13.

¹²³⁷ The IGC Secretariat produced an in-depth study on patent disclosure requirements and on its prospective role as a defensive protection tool for traditional knowledge. See, WIPO IGC, ‘Initial Report on the Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge’, prepared by the Secretariat, 20 November 2002, WIPO/GRTKF/IC/4/11; see generally, CBD COP 7, ‘WIPO Technical Study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge’, 15 December 2003, UNEP/CBD/COP/7INF/17.

2.3 Disclosure of Traditional Knowledge

The previous sections briefly discussed the background to the debates on the need for a disclosure requirement and its policy objective, that is, to help monitor the utilisation of genetic resources, and realise fair and equitable benefit-sharing as required by the Convention on Biodiversity (CBD) and the Nagoya Protocol, as well as the diverging positions of groups of countries.

With regard to the specific issue of the protection of traditional knowledge, the disclosure of origin requirement has gained a fundamental role in the development of a *sui generis* regime of protection for traditional knowledge within the WIPO IGC.¹²³⁸

This section will analyse the requirements for both the disclosure of origin of traditional knowledge and of the prior informed consent of indigenous peoples as holders of traditional knowledge. It will start with a review of the Nagoya Protocol's provisions on compliance and monitoring as they are directly linked to the disclosure requirement.

2.3.1 Compliance, Monitoring and Disclosure

The discussion on the disclosure of the origin of traditional knowledge in a patent claim is inherently linked with the international monitoring system established under the Nagoya Protocol.¹²³⁹ Even though, the final adopted text of the Nagoya Protocol does not make any explicit reference to the link between genetic resources, associated traditional knowledge and the intellectual property system, this tie clearly appears in Articles 16 and 17 of the Nagoya Protocol and in the current discussions and negotiations in international fora relating to the disclosure requirement.

Article 16 of the Nagoya Protocol calls upon “each Party to take appropriate [...] measures to provide that traditional knowledge associated with genetic resources¹²⁴⁰ utilized within their jurisdiction has been accessed in accordance with prior informed consent [...] of indigenous and local communities, and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation [...]”.

¹²³⁸ TOBIN, “Bridging the Nagoya Compliance Gap: the Fundamental Role of Customary Law in Protection of Indigenous Peoples’ Resources and Knowledge Rights”, 2013, p. 151.

¹²³⁹ See Part III, Chapter 3, 2.1.

¹²⁴⁰ Nagoya Protocol, Article 15 solely concerns genetic resources.

Article 17 of the Nagoya Protocol provides for the creation of an international legal framework that permits the monitoring of whether or not users comply with domestic access and benefit sharing (ABS) legislation as provided for in Article 16 of the Protocol. However, Article 17 establishes the framework for an international monitoring system only with regard to the utilisation of genetic resources, with no such reference to the utilisation of traditional knowledge.

Indeed, Article 17 of the Nagoya Protocol only calls upon each State Party to take measures (i) “to monitor and to enhance transparency about the utilization of genetic resources” through the designation of checkpoints,¹²⁴¹ and (ii) to make available domestic permits to the international ABS Clearinghouse¹²⁴² attesting compliance with providers countries’ domestic ABS legislation.¹²⁴³ This internationally recognised certificate of compliance¹²⁴⁴ will provide the evidence that the genetic resource has been accessed in accordance with prior informed consent and that mutually agreed terms have been established.

While this omission seriously undermines the spirit of Article 16, a broad interpretation could extend the scope of Article 17 to traditional knowledge.¹²⁴⁵ This interpretation is supported by the Preamble to the Nagoya Protocol, which emphasises “the interrelationship between genetic resources and traditional knowledge [and] their inseparable nature”.¹²⁴⁶ It has also been argued that “the lack of measures to control or monitor the utilisation of traditional knowledge” in the Protocol stems from the fact that the negotiators wanted to leave the question of a disclosure requirement to be addressed by WIPO IGC negotiators.¹²⁴⁷ However,

¹²⁴¹ Nagoya Protocol, Article 17.1.

¹²⁴² According to Article 14(1) of the Nagoya Protocol, the role of the ABS Clearinghouse is (i) to share the information related to ABS, and (ii) to provide access to information made available by each Party with regard to the implementation of the NP.

¹²⁴³ Nagoya Protocol, Article 17.3.

¹²⁴⁴ For a detailed discussion on certificates of compliance, see TOBIN, BURTON and FERNANDEZ-UGALDE, *Certificates of Clarity or Confusion*, 2008.

¹²⁴⁵ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 269.

¹²⁴⁶ Nagoya Protocol, Preamble 22.

¹²⁴⁷ CANDEIRA LAGO and SILVESTRI, “Challenges in the Implementation of the Nagoya Protocol from the Perspective of a Member State of the European Union: The Case of Spain”, 2013, p. 292.

if so, it is not clear why the same approach was not envisioned for genetic resources, which are also covered by the WIPO IGC negotiations.

Despite the absence of international rules on monitoring the utilisation of traditional knowledge, some countries have chosen to include such rules, including the disclosure requirement obligations. Section Three of this Chapter will analyse some examples of national laws encompassing the disclosure requirement.

The following paragraphs will analyse Article 4*bis* of the WIPO IGC latest Draft Articles on the protection of traditional knowledge, and will briefly make a comparison between Article 4*bis* and Article 2 of the latest Draft Articles on the protection of genetic resources, which is also relevant for traditional knowledge that is associated with genetic resources.

2.3.2 WIPO IGC Draft Articles on Requirements for the Disclosure of Traditional Knowledge

An individual article on disclosure requirements has only been introduced recently, in 2013, at the 24th session of the WIPO IGC.¹²⁴⁸ From the 24th session until the most recent session of the IGC, the wording of the provision has not changed, except that in the latest version of the Draft Articles, negotiators have introduced an alternative to Article 4*bis* that we shall examine later.¹²⁴⁹

In the previous drafts, disclosure requirements were mentioned in one of the options under Article 3 on the scope of protection. The option stated that beneficiaries shall be provided “the exclusive rights to prevent the granting of IP rights involving the use of their traditional knowledge, without the mandatory disclosure of traditional knowledge holders and their country of origin as well as evidence of compliance with prior informed consent and benefit-sharing requirements”.¹²⁵⁰ The main issue with this text is that beneficiaries can only be Member States, because it is difficult to see how holders of traditional knowledge can prevent

¹²⁴⁸ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, the Secretariat, 22-26 April 2013, WIPO/GRTKF/IC/24/4, Article 4 *bis*, p. 17.

¹²⁴⁹ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, the Secretariat, 2 June 2014, WIPO/GRTKF/IC/28/5, Article 4BIS, p. 14.

¹²⁵⁰ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, the Secretariat, 20 May 2011, WIPO/GRTKF/IC/19/5, Article 3, Option 1, p. 5.

the patenting of their traditional knowledge in circumstances precisely when the use and the origin of their knowledge has not been disclosed in the patent application.

Under the current Article 4 *bis*, an invention that relates to or uses traditional knowledge shall include information on the providing country, and the country of origin if the providing country¹²⁵¹ is not the same as the country of origin of the traditional knowledge.¹²⁵² It is interesting to note that this paragraph and the following paragraph are greatly influenced by the wording of section 8(b) of the Norwegian Patent Act, which uses the terms “country of origin”¹²⁵³ and “providing country”.¹²⁵⁴

Under this provision what triggers the disclosure requirement is the “utilisation” of traditional knowledge in contrast to the requirement that the invention must be “directly based on” traditional knowledge. While the term “utilisation” is straightforward and already defined in the Nagoya Protocol, the terms “directly based on” add a degree of uncertainty.

As stated previously, traditional knowledge can be obtained directly from its holders or from other sources. In the former case, the applicant will disclose the country of origin of the traditional knowledge.¹²⁵⁵ In the latter case, the applicant will have to disclose the source of the traditional knowledge. In other words, the patent applicant has obtained traditional knowledge from other sources, including ethno-medical materials or registries and databases, for instance.

In contrast, the other instrument being discussed at the WIPO–IGC, on genetic resources and associated traditional knowledge, uses the terms country of origin and source of genetic

¹²⁵¹ Nagoya Protocol, Article 5 (under this provision, “providing country” means “the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention [on Biological Diversity]”).

¹²⁵² Norwegian Patent Act No. 9 of 15 December 1967 (consolidated version of 2010, which takes into account amendments up to the Law No. 8 of 26 March 2010), Section 8b.

¹²⁵³ Norwegian Patent Act, Section 8b defines country of origin for traditional knowledge, “the country in which the knowledge was developed”.

¹²⁵⁴ Norwegian Patent Act, Section 8b defines provider country as “the country from which the inventor collected or received the knowledge”.

¹²⁵⁵ While under Article 2 of the CBD country of origin means “the country from which the material was collected from its natural environment”, there is no such definition for country of origin for traditional knowledge.

resources and associated traditional knowledge.¹²⁵⁶ As will be discussed later, Switzerland has opted for the disclosure of the source of traditional knowledge, with the understanding that source has to be understood in its broadest sense. In other words, source would encompass the country of origin, indigenous peoples and local communities, and other sources, such as *ex situ* collections.

With regard to the use of the term “origin” in relation to traditional knowledge, the main problem resides in the fact that it may be confused with the concept of “country of origin” as defined under the CBD and the Nagoya Protocol.¹²⁵⁷ Ideally, traditional knowledge, unlike genetic resources, should not fall under the sovereignty of States. Consequently, the disclosure of the origin of traditional knowledge will amount to the identification of the community holding that knowledge or to the originators of the traditional knowledge from whom prior informed consent must be obtained. In cases where traditional knowledge has been shared amongst various communities, Article 11 of the Nagoya Protocol states that when “the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol”. This Article must be read with Article 12 of the Nagoya Protocol and in line with UNDRIP. Consequently, States must ensure the involvement of indigenous communities and take into consideration their customary laws.¹²⁵⁸

As opposed to the disclosure of the origin, the disclosure of the source does not necessarily reveal where the traditional knowledge originally came from, but only where the user has obtained it.¹²⁵⁹ The main criticism addressed by developing countries to the requirement to disclose the source is that it can be interpreted as indicating that the rights from genetic resources and traditional knowledge will stem from the source and not from the country of

¹²⁵⁶ WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, 30 May-2 June 2016, WIPO/GRTKF/IC/30/4, Article 2, p. 7.

¹²⁵⁷ GIRSBERGER, *Certificates of Source – Disclosure of Source*, in *Proceedings of the International*, 2004, p. 143.

¹²⁵⁸ See Part III, Chapter 2, 4 on the fundamental role of customary laws.

¹²⁵⁹ DROSS and WOLF, *New Elements of the International Regime on Access and Benefit-Sharing of Genetic Resources – The Role of Certificates of Origin*, 2005, p. 75.

origin.¹²⁶⁰ However, while this criticism might be valid for genetic resources, this is not the case for traditional knowledge that should not be under the sovereignty of States. Indeed, national legislation of countries of origin may not always reflect the rights of knowledge holders, as relations between governments and indigenous peoples are tense in many countries. Additionally, in contrast to the disclosure of origin requirement, that also includes prior informed consent and mutually agreed terms from the country of origin, this is not the case for the disclosure of the source. Indeed, the disclosure of the source pursues two main objectives: transparency in ABS proceedings and assisting the determination of prior art by patent examiners.¹²⁶¹

In the present author's view, the applicant shall disclose the origin of traditional knowledge, that is, the community holding the traditional knowledge. If the information is not known, then the applicant must disclose the source from which they obtained the information. Finally, it is important to state that disclosing the source of traditional knowledge does not amount to a requirement to disclose the content of that knowledge. As stated by the Tulalip Tribes during the twenty-ninth WIPO IGC session, the publication of traditional knowledge itself could make that traditional knowledge move outside the circle of protection.¹²⁶²

In addition with respect to the origin of traditional knowledge, Article 4 *bis* states that “the applicant shall state whether PIC to access and use [of traditional knowledge] has been obtained”. In turn, Article 2 of the Draft Articles on genetic resources states that the applicant “shall [Provide relevant information, as required by the national law of the [IP] [patent] office, regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where appropriate]”.

While under Article 4*bis*, it is not clear whether there is an obligation for the applicant to provide evidence of PIC and from whom it has been obtained, Article 2 of the Draft Articles on genetic resources makes the obligation contingent upon the provider country's national law requiring evidence of PIC from indigenous communities. In this latter case, the user country¹²⁶³ will have to give legal effect to the PIC requirement of another country. Here, the

¹²⁶⁰ TOBIN, BURTON and FERNANDEZ-UGALDE, *Certificates of Clarity or Confusion*, 2008, p. 16.

¹²⁶¹ GIRSBERGER, *Certificates of Source – Disclosure of Source*, 2004, p. 144.

¹²⁶² WIPO IGC, 'Report', 15-19 February 2016, WIPO/GRTKF/IC/29/8, para. 208, p. 53.

¹²⁶³ For instance, the country where a patent is applied for.

obligation to protect the rights of indigenous peoples rests both upon the country of origin of the indigenous community and on user countries in general.

Generally speaking, the obligation to disclose the prior informed consent of holders of traditional knowledge provides a basis for the adequate protection of traditional knowledge both defensively and as a positive tool for protection. The free, prior and informed consent principle in the context of the patent system amounts to a defensive protection, where any utilisation of traditional knowledge, and in particular claimed inventions derived from, or (directly) based on traditional knowledge without the prior consent of the indigenous community, can be challenged. In this sense, the patent system will be an effective tool to prevent the problem of misappropriation, and will help to implement obligations under both environmental and human rights law treaties. Free, prior and informed consent also provides for positive forms of protection, where, for instance, an indigenous community would have the right to authorize any use of its knowledge by a third party, including any commercial exploitation. “In fact, the disclosure of prior informed consent in patent applications (or biodiversity laws) seeks to create an obligation to provide information in relation to circumstances in which traditional knowledge has been obtained. In other words, it seeks to assess the legitimacy of actions taken prior to the process of the invention itself.”¹²⁶⁴ Carvalho has suggested that the doctrine of clean-hands could apply in the event of a failure to comply with the requirement to obtain the prior informed consent. This situation would render the patent unenforceable until the patentee rectifies their conduct.¹²⁶⁵

The main problem with making the disclosure requirement of PIC from the holders of traditional knowledge, contingent upon the enactment of national laws, is that the consequences for non-compliance will potentially be as diverse as the national laws on which they are based.¹²⁶⁶ However, the level of divergence of the solutions will mainly depend on the sanctions each country provides in case of non-compliance, i.e. sanctions within or outside the patent law.

¹²⁶⁴ CBD WG-ABS, ‘Technical study on disclosure requirements related to genetic resources and traditional knowledge’, submitted by WIPO, 2003, UNEP/CBD/WG-ABS/2/INF/4, para. 124, p. 46.

¹²⁶⁵ See generally, CARVALHO, “Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution”, 2000, pp. 371-395; CARVALHO, , *The Trips Regime of Patents and Test Data*, 2014, p. 344.

¹²⁶⁶ CHIAROLLA, “The Role of Private International Law under the Nagoya Protocol”, 2013, pp. 423-449.

Most importantly, in the context of traditional knowledge, countries of origin either do not protect traditional knowledge in their legislation or if they do so, their laws are paternalistic and do not empower indigenous communities to take an active part in protecting their knowledge. On the other hand, most developed countries do not include a disclosure requirement for traditional knowledge, with few exceptions, including Switzerland and Norway. In addition, in none of the developed countries' legislation is the validity of patents affected by non-compliance with disclosure requirements.

Article 4*bis* introduces an interesting distinction between “access” and “use”. Indeed, this distinction recalls controversial interpretations that are currently taking place with regard to the question of whether evidence of prior informed consent is required only at the time of access¹²⁶⁷ or also for each subsequent utilisation of a genetic resource.¹²⁶⁸ However, a careful reading of Articles 5.5¹²⁶⁹ and 7¹²⁷⁰ of the Nagoya Protocol, that solely concern traditional knowledge, leads us to the conclusion that both access and subsequent utilisation of traditional knowledge requires the prior informed consent of the holders of traditional knowledge. This interpretation is not only in line with the Nagoya Protocol but also with the United Nations Declaration on the Rights of Indigenous Peoples.

The second paragraph of the provision envisages a situation where the information is not known to the applicant. In this case the applicant will provide the immediate source from which the applicant collected the traditional knowledge, and, if the source is unknown to the

¹²⁶⁷ Nagoya Protocol, Article 6.

¹²⁶⁸ Nagoya Protocol, Article 5.1 and 5.2; see also, GODT, “The Multi-Level Implementation of the Nagoya Protocol in the European Union”, 2015, p. 311 (The author suggests that the NP “creates a double distinction – access/benefit-sharing and commercial/non-commercial– and it submits ABS to different rules”).

¹²⁶⁹ Nagoya Protocol, Article 5.5 reads as follows: “Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the *utilization* of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms”.

¹²⁷⁰ Nagoya Protocol, Article 7 reads: “In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is *accessed* with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established”.

patent applicant or inventor, he or she should have the possibility to make a declaration to that effect.

The third and fourth paragraphs of Article 4*bis* concern the sanctions for non-compliance. A distinction is made between pre-grant and post-grant sanctions. The wording is largely inspired by the solution adopted in the Swiss Patent Act. It should be further noted that the other Draft Articles under negotiation in the WIPO IGC, which relate to genetic resources and associated traditional knowledge, provide a separate Article 5 titled “sanctions and remedies”. This Article also distinguishes between pre-grant and post-grant sanctions and the provision clearly defers the establishment of sanctions to national legislation. The sanctions range from preventing the further processing of a patent and refusing the grant of a patent, to publication of judicial rulings regarding the failure to disclose, and other measures including the revocation of patents.¹²⁷¹

Thus, if the patent application does not contain the required information, the patent application shall be stopped until rectification. If the applicant does not submit the information within the provided time limit, the intellectual property office may reject the application. In contrast, any later discovery of a failure to comply with the previous paragraphs will not require the patent to be revoked. Each party may provide for other sanctions outside of the patent system, including criminal sanctions.¹²⁷²

The most controversial debates on the disclosure requirement concern the nature of the obligation: voluntary disclosure *versus* a mandatory disclosure requirement. The difference resides principally in the legal effects that they engender in the case of non-compliance. Accordingly, what would be the legal sanctions? While a voluntary disclosure requirement would engender no sanctions, this would not be the case where the disclosure requirement is mandatory. In the circumstances where the disclosure is mandatory, should the sanctions be enshrined in the patent system or outside the patent system? Where the legal principle

¹²⁷¹ WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, 30 May-3 June 2016, WIPO/GRTKF/IC/30/4, Article 5, p. 8

¹²⁷² With regard to the Draft Articles on genetic resources, see WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, 30 May-3 June 2016, WIPO/GRTKF/IC/30/4, Article 5.2, p. 8 (the sanctions for non-compliance are included in a separate Article 5. Article 5.2 provides that “[failure to fulfil the disclosure requirement, [in the absence of fraud], shall/should not affect the validity or enforceability of granted [IP] [patent] rights.]”

underlying the disclosure requirement lies within the patent system, the disclosure requirement is conceived as a condition to patent but the consequences of a failure to disclose could be implemented in two distinct ways. First, whether the applicant has fulfilled the disclosure requirement or not, is not verified at the stage of granting a patent. This option is known as the ‘unclean hands doctrine’. However this failure to disclose could be rectified through modifications to the patents, for instance its scope, at a post-grant stage. Second, the disclosure requirement could be implemented as constituting a condition for patentability, and the failure to do so would mean that a patent is not issued. In this case, the grant of the patent is made conditional on the fulfilment of the disclosure requirement. In other words, failing to provide the disclosure of the origin would amount to non-grant of the patent or to the revocation of the patent in cases where the patentability conditions are not examined during the application process.¹²⁷³ This solution runs the risk of exceeding the requirements under the TRIPS Agreement.¹²⁷⁴

An alternative to those outlined in previous paragraphs foresees the revocation of patents “when the applicant has failed to comply with the obligations of mandatory requirements as provided for in this article or provided false or fraudulent information”.¹²⁷⁵ This proposal has received positive support from representatives of indigenous groups in WIPO IGC. For instance, the Tulalip Tribes have stated that “with a well-functioning disclosure mechanism, revocation would be extremely rare, because the application would have to indicate where the GRs came from and whether the TK had been validly acquired. However, a system where revocation was not possible was the equivalent of a license to steal”.¹²⁷⁶

The latest version of the Draft Articles encompasses a new alternative to the previous whole of Article 4*bis*, which reads as follows: “patent disclosure requirements shall not include a mandatory disclosure requirement relating to traditional knowledge unless such disclosure is

¹²⁷³ See for instance the Swiss Patent Law, Article 59(4).

¹²⁷⁴ For an in-depth discussion on the legal effect of a mandatory disclosure requirement on the validity of patents, see CARVALHO, “Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution”, 2000, pp. 371-395.

¹²⁷⁵ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, the Secretariat, 7-9 July 2014, WIPO/GRTKF/IC/28/5, Article 4*bis*, p. 14.

¹²⁷⁶ See statement of Tulalip Tribes in WIPO IGC, ‘Initial Draft Report’, the Secretariat, 15-19 February 2016, WIPO/GRTKF/IC/29/8 Prov., p. 69, para. 292.

material to the patentability criteria of novelty, inventive step or enablement”¹²⁷⁷ This alternative is supported by a coalition of Member States, including the United States, Canada and Japan. In other words, for the proponents of this proposal, the role of the patent system is not to support other legal structures. There should be no other basis for having a disclosure requirement other than disclosure on prior art that is material to patentability.¹²⁷⁸

The divergence of opinion is clearly reflected in Article 4*bis* on disclosure requirements. As already mentioned, absent a consensus at the international level, numerous Member States have now enacted disclosure requirements with varying legal effects in their national laws. The following section will examine legislation in Switzerland, Peru and New Zealand.

2.3.3 Concluding Remarks on the Disclosure of Traditional Knowledge

The disclosure of the origin of traditional knowledge in patent applications fundamentally pursues two objectives. First and foremost, it will assist indigenous peoples in monitoring the access to, and the use of, their traditional knowledge. Second, the disclosure requirement will constitute a basis for entering into an access and benefit-sharing agreement either directly with the holders of traditional knowledge or indirectly with the relevant national authority who shall act for the beneficiaries.

At present, disclosure requirements are included in national legislation, in various countries whose content varies considerably. While some of them are voluntary others are mandatory; some only apply to genetic resources, whereas others exclude traditional knowledge. In addition, because patents are territorial by nature, the disclosure requirement applies only with regard to patents in the country which they are granted. In other words, the disclosure requirement in Peru will have no bearing on patents issued in Germany or Canada.¹²⁷⁹

¹²⁷⁷ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, the Secretariat, 7-9 July 2014, WIPO/GRTKF/IC/28/5, Article 4*bis*, p. 14.

¹²⁷⁸ WIPO IGC, ‘Proposal for the Terms of References for the Study by the WIPO Secretariat on Measures Related to the Avoidance of the Erroneous Grant of Patents and Compliance with Existing Access and Benefit-Sharing Systems’, submitted by the delegations of Canada, Japan, Norway, the Republic of Korea, the Russian Federation and the United States of America, 7-9 July 2014, WIPO/GRTKF/IC/28/9.

¹²⁷⁹ See for instance the declaration of the delegation of South Africa in WIPO IGC, ‘Initial Draft Report’, The Secretariat, 15-19 February 2016, WIPO/GRTKF/IC/29/8 Prov., p. 11 (the representative of South Africa declared that it had established a mandatory disclosure obligation in the Patent Act of 1975; however, the

It can further be noted that there is a clear divide between industrialised and megadiverse countries with regard to the goals pursued by the disclosure requirement. On the one hand, in most European countries, the disclosure requirement engenders no legal effects with regard to the validity of patents. Furthermore, these countries do not require applicants to demonstrate evidence of prior informed consent as a precondition of granting a patent. Additionally, few of them have extended the disclosure requirement to traditional knowledge. On the other hand, in megadiverse countries, the requirement of evidence of prior informed consent becomes a condition for processing patent applications and non-compliance may result in their revocation.¹²⁸⁰

This divide is clearly counter-productive. Rather, there is a need for collaboration between provider and user countries. Disclosing the origin or the source of traditional knowledge and sharing the benefits must be obligations of user countries, whereas enacting law and regulations on how to access these resources must be the obligation of countries of origin and/or providing countries. While this collaboration is fundamental, it will not avoid the great diversity, already present, in both user and provider countries' laws.¹²⁸¹

For instance, as to the question of what triggers a disclosure requirement in the patent application, the answer is as diverse as existing laws on the issue. For the time being, this task is being left to national laws, and the risk is that it may engender a huge variety of diverging disclosure requirements when the invention is somehow related to traditional knowledge. This divergence is no less important than what kind of information has to be disclosed in relation to traditional knowledge, and traditional knowledge associated to genetic resources, i.e. the disclosure of origin of traditional knowledge and/or evidence of prior informed consent and mutual agreement. Last but not least, and probably the most controversial issue is related to the sanctions in cases of non-compliance with the disclosure requirement.

These problems justify an international solution. Additionally, including for the sake of harmonization and coherence, an international obligation requiring disclosure should settle

provision at national level was largely ineffective owing to the absence of an internationally binding obligation”).

¹²⁸⁰ TOBIN, JOHNSTON and BARBER, *Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity*, 2015, p. 33.

¹²⁸¹ KAMAU, “The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and What are the Implications for Provider and User Countries and the Scientific Community”, 2010, p. 256.

some minimum standards to assure a worldwide implementation.¹²⁸² Even if the disclosure requirement is dealt with internationally, patent offices and courts will still be required to decide whether the access or use of traditional knowledge in another country was legitimate and forms a legitimate basis for a patent application or a granted patent in their jurisdiction. In other words, an international solution will also have to ensure that Member States will have to give domestic legal effect to foreign jurisdiction's laws and court decisions. Particularly, they will have to determine which jurisdictions laws should be applied, for instance, in the assessment of the legitimacy of access and use of traditional knowledge.¹²⁸³ Fundamentally, they shall equally take into consideration the customary laws of the holders of traditional knowledge.

3 Selected National Approaches

At the national level, while several countries have introduced disclosure requirements into patent laws,¹²⁸⁴ others have no disclosure requirements in their laws, including the United States, Japan, Australia, and Canada. Even though a majority of countries have implemented a disclosure requirement, these laws are extremely diverse with regard to their approach, such as with respect to their binding nature, their scope and the sanctions for lack of fulfilment. Some national laws integrate the disclosure requirement into patent laws.¹²⁸⁵ Other countries have enacted specific legislation on biodiversity and the protection of traditional knowledge that refer to patents.¹²⁸⁶

¹²⁸² See generally, CORREA and SARNOFF, "Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications", 2006.

¹²⁸³ See generally, CHIAROLLA, "The Role of Private International Law under the Nagoya Protocol", 2013, pp. 423-449.

¹²⁸⁴ See the Andean Decision 486 on a Common Intellectual Property Regime, 2000 and the Andean Decision 391 on a Common Regime on Access to Genetic Resources, 1996.

¹²⁸⁵ Swiss Patent Act, Article 49a.

¹²⁸⁶ WTO TRIPS Council, 'Combating Biopiracy – the Peruvian Experience', 19 September 2007, IP/C/W/493; see also, WTO TRIPS Council, 'Biodiversity, Traditional Knowledge and Intellectual Property: Peru's Position in Relation to Disclosure of Origin and Legal Provenance', 8 June 2005, IP/C/W/447.

3.1 The Transparent and Pragmatic Approach of Switzerland

Switzerland has been very active in the numerous debates on disclosure requirements both at the international¹²⁸⁷ and national levels.¹²⁸⁸ The Swiss proposal at the international level has already been discussed earlier.¹²⁸⁹ The following will focus on the newly revised Patent Act, which entered into force in July 2008, and the implementation of the Nagoya Protocol in the Federal Act on the Protection of Nature and Cultural Heritage.¹²⁹⁰

3.1.1 The Swiss Patent Act

Article 49a of the Swiss Patent Act states that the patent application shall include information concerning the source of the genetic resource and the traditional knowledge associated with it as long as the applicant has had access to these resources, and the invention is directly based on traditional knowledge or genetic resources. At this point, some comments shall be made with particular attention to traditional knowledge.

First, Article 49a covers traditional knowledge only if it is associated with genetic resources.¹²⁹¹ Second, where the applicant has had no access to traditional knowledge, Article 49a will not apply. This would be the case, for instance, when the applicant discovers a therapeutic property of a given plant without knowing that this knowledge is held by an indigenous community.¹²⁹² However, if the plant has been newly discovered or is very specific to a certain region, it might be very difficult or only by chance that an applicant could have been able to identify its therapeutic property without having had recourse to a lead or

¹²⁸⁷ WIPO IGC, 'Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposals by Switzerland', Document submitted by Switzerland, 3 – 12 July 2007, WIPO/GRTKF/IC/11/10.

¹²⁸⁸ Swiss Patent Act, Article 49a.

¹²⁸⁹ Part III, Chapter 3, 2.2.3.

¹²⁹⁰ Swiss Federal Act on the Protection of Nature and Cultural Heritage, 1 July 1966, Systematically Recorded under No 451 (Swiss Act on the Protection of Nature and Cultural Heritage, NCHA).

¹²⁹¹ HEINRICH, *PatG/EPÜ - Schweizerisches Patentgesetz/Europäisches Patentübereinkommen: Kommentar in synoptischer Darstellung*, 2010, Article 49a, para. 6.

¹²⁹² KRAUS and GHASSEMI, *Commentaire des articles 9 et 9a, 32, 35a et 35b, 36 à 40e et 49a de la Loi sur les brevets d'invention in de WERRA and GILLIERON (eds.), Commentaire romand de propriété intellectuelle (PI) - Loi sur le droit d'auteur, Loi sur la protection des marques, Loi sur les designs, Loi sur les brevets*, 2013, Article 49a LBI, para. 12.

hint from primary sources (indigenous community) or secondary sources referring to an indigenous community's knowledge.

Third, the invention must be directly based on traditional knowledge, that is, without the knowledge, there would be no invention.¹²⁹³ In other words, there must be a close relation between the genetic resources and the traditional knowledge.¹²⁹⁴ However, it should be noted that if the relationship is too close, the patent may simply be invalid due to a lack of novelty or obviousness. In all the cases analysed previously, the invention was directly based on traditional knowledge.

The requirement that the invention must be directly based on traditional knowledge may be interpreted in two ways. On one hand, it may require that the patented drug has the same therapeutic property as the therapeutic properties of a specific plant used in traditional medicine. In other words, the product patent must cover the active substance responsible for the therapeutic properties described by the traditional knowledge holders or healer. On the other hand, it may allow for a broader interpretation to cover cases where the patented drug does not have the same property as a specific plant used in traditional medicine, i.e. where the product patent covers a different active substance isolated from the plant with other therapeutic properties than the one described by traditional knowledge holders. In this case, it can also be argued that there would be no invention without the traditional knowledge as a lead. In addition it should be noted that, in the first case, the patent will normally be deemed to be invalid.¹²⁹⁵ Whether an invention is directly based on traditional knowledge or not has to be assessed and decided on a case-by-case basis.

Finally, in contrast to other national laws, Switzerland has opted for the use of the term “source” for the following reasons. The main reason is that it has the advantage of being flexible and avoiding confusion with country of origin / geographic origin, in the sense that it provides an opportunity to include concepts such as country of origin, provider country and other possible sources. In that sense, the notion of source encompasses both primary and secondary sources. Patent applicants will have to declare the primary source, if they have the

¹²⁹³ See explanation given by the Delegation of Switzerland in WIPO IGC, ‘Initial Draft Report’, the Secretariat, 21 March 2016, WIPO/GRTKF/IC/29/8 Prov., p. 58, para. 232.

¹²⁹⁴ HEINRICH, *PatG/EPÜ - Schweizerisches Patentgesetz/Europäisches Patentübereinkommen: Kommentar in synoptischer Darstellung*, 2010, Article 49a, para18.

¹²⁹⁵ This is not always the case, see discussion in Part II, Chapter 2 of the present work.

necessary information at hand. If the applicants have no immediate information, only then may they declare the secondary source.¹²⁹⁶

Another reason is that it has the advantage of avoiding the placement of a too heavy burden on the applicant, who otherwise will have to undertake disproportionate or “unjustifiable” efforts to find the primary source. Thus, the applicant is only required to provide the information at hand.¹²⁹⁷ This reasoning might be true for genetic resources that have been transmitted over and over to different users, and which have certainly been transformed over time.¹²⁹⁸ However, this might not be so for traditional knowledge. First, the connection between traditional knowledge and the indigenous community, which is its source, is still strong, because traditional knowledge continues to be used in these communities and it is not synonymous with a forgotten or old knowledge. Second, because in this case, it might be easier for the patent applicant to trace back the information at hand to the original source. This was indeed the case for the turmeric patents, but also for the *Ayahuasca* and the *Hoodia* case, for instance.

Where the source is not known, the applicant must declare this in writing. In case the application does not include the required information, the applicant has 3 months to remedy it by providing the information concerning the source.¹²⁹⁹ Subsequent to this deadline, the office can reject the patent application if the necessary information is not provided.¹³⁰⁰ While the invalidation of a granted patent is not provided for,¹³⁰¹ intentionally providing false information will result in the imposition of a fine for a maximum amount of 100,000 Swiss francs, and the publication of the judgement.¹³⁰² At this point, it should be noted that the

¹²⁹⁶ WIPO IGC, ‘Policies, measures and experiences regarding intellectual property and genetic resources: Submission by Switzerland’, 3-7 May 2010, WIPO/GRTKF/IC/16/INF/14, p. 3.

¹²⁹⁷ Dispatch of the Federal Council concerning the Amendment to the Patent Act, 23 November 2005, FF 2006 1, p. 76; see also WIPO IGC, ‘Policies, measures and experiences regarding intellectual property and genetic resources: Submission by Switzerland’, 3-7 May 2010, WIPO/GRTKF/IC/16/INF/14, p. 3.

¹²⁹⁸ Dispatch of the Federal Council concerning the Amendment to the Patent Act, 23 November 2005, FF 2006 1, p. 76.

¹²⁹⁹ Swiss Patent Act, Article 138(b).

¹³⁰⁰ Swiss Patent Act, Article 59a; see also, FEHLBAUM, *Commentaire romand de propriété intellectuelle – Loi sur le droit d’auteur, Loi sur la protection des marques, Loi sur les designs, Loi sur les brevets* : commentaire de l’article 59a LBI, para. 7.

¹³⁰¹ Swiss Patent Act, Article 26(d).

¹³⁰² Swiss Patent Act, Article 81a.

provision is of limited reach as it only applies to Swiss national patents, whereas the majority of patents in Switzerland are patents granted under the European Patent Convention.

3.1.2 The Swiss Federal Act on the Protection of Nature and Cultural Heritage

In addition to the amendment in its patent legislation, Switzerland has also implemented the Nagoya Protocol by amending the Swiss Federal Act on the Protection of Nature and Cultural Heritage (NCHA). On 12 October 2014, a new Chapter 3c of the NCHA was introduced. The new provision includes a due diligence requirement¹³⁰³ under Article 23n of the NCHA. Users of genetic resources and associated traditional knowledge,¹³⁰⁴ and those directly benefiting from such utilisation, are required to conduct due diligence appropriate to the circumstances to ensure that access to these resources was lawful¹³⁰⁵ and that mutually agreed terms have been negotiated. Article 23n paragraph 4 of the NCHA states that access is deemed to be lawful if it has been in accordance with the providing country's laws on access and benefit-sharing. The obligation to do due diligence seems to be required for each initial actor along the biodiversity-based value chain who directly benefits from the use of traditional knowledge.¹³⁰⁶ In short, the Swiss legislation links domestic legal consequences to the violation of foreign legislation. In other words, it recognises the extraterritorial effect of foreign laws.¹³⁰⁷

Article 23o appoints the Federal Department of the Environment, Transport, Energy and Communications (Federal Office for the Environment – FOEN) as the National Focal Point,

¹³⁰³ Originally, due diligence refers to the legal process of disclosing and collecting information in business transactions with the objective of minimizing risks. The term has evolved to also apply to environmental settings with the objective of securing that the sourcing of natural resources is in compliance with applicable law. See, for instance, OLIVA, “Private Standards and the Implementation of the Nagoya Protocol: Defining and Putting in Practice Due Diligence in the EU Regulation on ABS”, 2015, p. 295.

¹³⁰⁴ NCHA, Article 23p clarifies that the due diligence requirement also applies to associated traditional knowledge.

¹³⁰⁵ NCHA, Article 23n (4) states that access is deemed to be lawful if it has been in accordance with the providing country's laws on access and benefit-sharing.

¹³⁰⁶ Dispatch of the Federal Council concerning the ratification of the Nagoya Protocol, 10 April 2013, FF 2013 2659, p. 2685.

¹³⁰⁷ GODT, “The Multi-Level Implementation of the Nagoya Protocol in the European Union”, 2015, p. 311; see also DALY, “Legislation on biopiracy in Europe: too little, too late?”, 2015, p. 378 (the author affirms that the Swiss Law goes further than the newly adopted European Regulation implementing the Nagoya Protocol).

to which compliance with the due diligence requirement has to be notified before marketing will be authorised or before its commercialisation.¹³⁰⁸ Clearly, the mandatory notification does not apply to inventions based directly on genetic resources and associated traditional knowledge, subject to patent applications.¹³⁰⁹ This is because the previously mentioned Article 49a of the Swiss Patent Act already encompasses an obligation to disclose the source. However, the granting of a license is still subject to the obligation to inform the FOEN.¹³¹⁰

With regard to the issue of associated traditional knowledge, Article 23p specifically stipulates that, the requirements under Articles 23n and 23o, also apply to associated traditional knowledge as long as the associated traditional knowledge is not freely available to the public. The article reads as follows: “Articles 23n and 23o also apply to traditional knowledge associated with genetic resources pertaining to indigenous and local communities, as far as this traditional knowledge is not freely accessible to the public.”¹³¹¹

It remains to be clarified what is associated traditional knowledge that is or is not freely available to public. The explanatory guide to the Swiss Ordinance to the NCHA refers to the negotiations under way at WIPO IGC to resolve the issue of publicly available traditional knowledge.¹³¹² Interestingly, the provision neither makes reference to the concept of public domain nor to the concept of available to the public, but rather to *freely* available to the public. As suggested earlier in this study, a given knowledge may be available to public but this does not mean that it is necessarily free to use.¹³¹³ Hence, it might be argued that the requirements under Articles 23n and 23o will also apply to associated traditional knowledge that might be already publicly available but not freely available.

¹³⁰⁸ NCHA, Article 23o (1).

¹³⁰⁹ Dispatch of the Federal Council concerning the ratification of the Nagoya Protocol, 10 April 2013, FF 2013 2659, p. 2689.

¹³¹⁰ Dispatch of the Federal Council concerning the ratification of the Nagoya Protocol, 10 April 2013, FF 2013 2659, p. 2689 (commercialisation encompasses any legal activities generating monetary benefits stemming from the utilisation of genetic resources or traditional knowledge, including license agreements).

¹³¹¹ NCHA, Article 23p (“[l]es art. 23n et 23o s'appliquent également aux connaissances traditionnelles associées aux ressources génétiques détenues par des communautés autochtones et locales, pour autant que ces connaissances traditionnelles ne soient pas déjà librement accessibles au public”).

¹³¹² Swiss Federal Council, FOEN, ‘Ordinance on the Nagoya Protocol – Explanatory Report’, 11 December 2015, p. 18 (the explanatory report to the Swiss Ordinance refers to the negotiations under way at the WIPO IGC that should clarify this concepts in the near future).

¹³¹³ Part II, Chapter 3, 3.

In addition to the NCHA, the Swiss Federal Council has also recently adopted the Ordinance on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (NagO), whose objective is to clarify the provisions of the NCHA.¹³¹⁴ In particular, it further determines the requirements relating to due diligence¹³¹⁵ and notification.¹³¹⁶ Article 3 lists a series of pieces of information that the user has to record and transmit to the subsequent users, namely an international certificate of compliance delivered in conformity with the Nagoya Protocol.¹³¹⁷

The Swiss legislation goes further than the Nagoya Protocol with regard to the “user compliance measures”¹³¹⁸ in the sense that an internationally recognised certificate of compliance¹³¹⁹ would also apply to associated traditional knowledge.¹³²⁰ In other words, the certificate of compliance would have to supply evidence that associated traditional knowledge has been accessed and used in conformity with the provider countries’ domestic legislation. For instance, if Peru is the country of origin of the traditional knowledge, the user of associated traditional knowledge, in Switzerland, would have to abide by the Peruvian legislation, which in this case requires the prior informed consent of the holders of “collective knowledge”.¹³²¹

The Swiss due diligence requirement applies both to the users of genetic resources and associated traditional knowledge and to those who directly benefit from the use of those resources. These are, for instance, the researchers and the pharmaceutical or cosmetic

¹³¹⁴ *Ordonnance sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (ONag)*, 11 December 2015, Systematically Recorded under No 451.61, Ordinance on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Ordinance, NagO).

¹³¹⁵ NagO, Article 3.

¹³¹⁶ NagO, Article 4.

¹³¹⁷ Nagoya Protocol, Article 17(2)–(4).

¹³¹⁸ Nagoya Protocol, Articles 15 and 16.

¹³¹⁹ NagO, Article 2 defines the internationally recognised certificate of compliance as follows: a permit delivered by the competent authority at the time of access and recorded within the International Clearing House in conformity with the Nagoya Protocol (translation done by the author).

¹³²⁰ NCHA, Article 23p clarifies that the due diligence requirement also applies to associated traditional knowledge.

¹³²¹ Peruvian Law 27811 in relation to the protection of collective knowledge.

industries, respectively.¹³²² In addition, this requirement only applies when the resources are used in the sense of Article 2 of the Nagoya Protocol,¹³²³ in order to exclude the application of the due diligence requirement to the use of genetic resources as consumption goods.¹³²⁴ With regard to the utilisation of traditional knowledge, there is neither an explicit definition in the Nagoya Protocol nor in the Swiss legislation. However, as traditional knowledge under the Nagoya Protocol serves as lead information for the utilisation of genetic resources, utilisation of traditional knowledge could be defined by analogy as research and development on traditional knowledge.¹³²⁵

In contrast to the Swiss legislation, the also recently adopted European Union Regulation on compliance measures for users from the Nagoya Protocol barely addresses the issue of traditional knowledge.¹³²⁶ Indeed, while Article 2 stipulates that “this Regulation applies to genetic resources over which States exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union”, Article 3 excludes traditional knowledge that is not explicitly described in the mutually agreed terms. To put it differently, “where there is no contract for access to traditional knowledge, [...] European law would therefore provide no protection against biopiracy”.¹³²⁷

As a concluding remark, it should be recalled that Switzerland is a user and a provider country, home to pharmaceutical and cosmetic industries. As such, Switzerland has the merit of being one of the first countries in Europe to have amended its patent law to include the

¹³²² Dispatch of the Federal Council concerning the ratification of the Nagoya Protocol, 10 April 2013, FF 2013 2659, p. 2684.

¹³²³ Nagoya Protocol, Article 2(c) reads: “utilisation of genetic resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology”.

¹³²⁴ Dispatch of the Federal Council concerning the ratification of the Nagoya Protocol, 10 April 2013, FF 2013 2659, p. 2685.

¹³²⁵ MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, p. 74.

¹³²⁶ EU Regulation 511/2014.

¹³²⁷ For a discussion on the provisions of the EU Regulation 511/2014, GODT, “The Multi-Level Implementation of the Nagoya Protocol in the European Union”, 2015, pp. 308-327; see also, TOBIN, “Biopiracy by Law: EU Draft Law Threatens Indigenous Peoples’ Rights over their Traditional Knowledge and Genetic Resources”, 2014, pp. 75-146.

requirement to disclose the source of both genetic resources and associated traditional knowledge. In addition, in the context of market access regulation, it has also modified its Federal Act on the Protection of Nature and Cultural Heritage to require users of genetic resources and associated traditional knowledge to conduct due diligence to ensure that access to these resources was lawful under the national laws of the source countries.¹³²⁸ In other words, compliance with the duty to do due diligence must be notified to the Swiss Federal Department of the Environment before the commercialisation of a product using genetic resources and/or associated traditional knowledge.¹³²⁹

Finally, according to one author, while the Swiss Patent Act only timidly provides a moral right for indigenous communities, the obligation to disclose the source of the traditional knowledge facilitates any subsequent claim for compensation by the rights-holders.¹³³⁰

3.2 The Peruvian *Sui Generis* Law

In contrast to Switzerland, Peru is mainly a provider country, possessing one of the most biodiverse ecosystems in the world. Similarly, it is home to various indigenous communities living within its territory.¹³³¹ Peru has often taken the lead amongst developing countries in international fora in debates concerning the disclosure requirement. At the national level, Peru is one of the rare countries, if not the sole, in having adopted a national *sui generis* law on the

¹³²⁸ The Swiss Academy of Sciences has also provided comprehensive guidance for researchers. See, for instance, BIBER-KLEMM et al., *Access and Benefit-Sharing in Latin America and the Caribbean – A science-policy dialogue for academic research*, 2014, available at: <http://www.naturalsciences.ch> [accessed August 2016]; see also, BURTON, “Implementation of the Nagoya Protocol in JUSCANZ Countries: The Unlikely Lot”, 2013, pp.307-308.

¹³²⁹ NCHA, Article 23o.

¹³³⁰ DESSEMONTET, *La propriété intellectuelle et les contrats de licence*, 2011, p. 219.

¹³³¹ Peru is regarded as a megadiverse country due to its very high level of biological diversity. It is also home to over fifty ethno-linguistic groups located mostly in the Amazonian and Andean region. Similarly Peru has more than 4,000 known medicinal plants. Information available at: <https://www.cbd.int/countries/profile/default.shtml?country=pe> [accessed September 2016].

protection of traditional knowledge.¹³³² Peru adopted its legislation on the protection of traditional knowledge in 2002 (hereafter, Peruvian Law 27811).¹³³³

3.2.1 Disclosure Requirement

Since 1994, Peru has submitted various proposals on the necessity to link the patent system to the protection of traditional knowledge and the regime of access to genetic resources contained in the CBD, WTO and WIPO. Peru's position consists in amending the TRIPS Agreement to include the requirement that, an applicant for a patent on biological materials or traditional knowledge, disclose: (i) the source and country of origin of the resource used in the invention; (ii) evidence of prior informed consent; and (iii) evidence of fair and equitable benefit-sharing.¹³³⁴

Decision 486 on a Common Industrial Property Regime (14 September 2000) of the Andean Community, which establishes the legal industrial property framework (patents, designs, utility models, marks, etc.) applicable in the countries of the Andean region, consolidates the idea of disclosure of origin and legal provenance. Article 3 of this Decision provides that in the case of a violation of a biodiversity law, such a violation could be grounds for restricting intellectual property rights, particularly in cases of biotechnological patents. In short, patent applications based on biological resources will have to prove that the traditional knowledge incorporated in the invention has been legally *accessed* in conformity with regional¹³³⁵ and national legislation of the Andean Community Members, i.e. in the case of Peru, Law 27811.

¹³³² CABRERA MEDAGLIA, "The Implementation of the Nagoya Protocol in Latin America and the Caribbean: Challenges and Opportunities", 2013, pp. 333ff.

¹³³³ *Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos, Ley 27811* (Protection of Indigenous Peoples' Collective Knowledge Associated with Biological Resources, Peruvian Law 27811), 24 July 2002.

¹³³⁴ WTO TRIPS Council, 'Combating Biopiracy – the Peruvian Experience', 19 September 2007, IP/C/W/493; see also, WTO TRIPS Council, 'Biodiversity, Traditional Knowledge and Intellectual Property: Peru's Position in Relation to Disclosure of Origin and Legal Provenance', 8 June 2005, IP/C/W/447.

¹³³⁵ Andean Decision 391 on a Common Regime on Access to Genetic Resources provides that the Andean Community shall develop a regional regime for the protection of traditional knowledge. Although national legislation has been produced, the protection of traditional knowledge in a regional instrument is paralysed because of various limitations, including high transaction costs arising from the complexity of administrative procedures; see CLARK et al., "The Protection of Traditional Knowledge in Peru", 2004, p. 769.

As far as the disclosure of prior informed consent of indigenous peoples is concerned, Decision 486 also stipulates that “the grant of patents relating to inventions developed on the basis of material derived from that heritage or knowledge shall be subject to that material having been acquired in accordance with international, community and national legal provisions.”¹³³⁶ Member countries shall recognize the right and competence of indigenous Afro-American or local communities to decide on matters pertaining to their collective knowledge”.¹³³⁷ The Decision further requires patent applicants utilising traditional knowledge from the Andean Community to show that prior informed consent has been obtained for its use.¹³³⁸ According to Article 26 (i) of Decision 486, a patent application shall contain “a copy of the document accrediting the licensing or the authorization of the use of the collective knowledge of the indigenous Afro-American or local communities of member countries”. Failing to fulfil this requirement, the application is considered abandoned.¹³³⁹ A failure to submit a copy of the access contract can also constitute a ground for invalidating the patent.¹³⁴⁰

Because Decision 486 has no effect on patenting outside the Andean Community, Peru enacted Law 28216 on the Protection of Access to Peruvian Biological Diversity and Collective Knowledge of Indigenous Peoples, called the Anti-Biopiracy Law.¹³⁴¹ Law 28216 has established the National Commission for the Prevention of Biopiracy presided by INDECOPI.¹³⁴² The functions of the Commission mainly include the “establishing and maintaining of a register of biological resources and traditional knowledge of indigenous peoples of Peru, [...] and] identifying and following up patent applications filed or patents granted abroad that relate to [...] traditional knowledge of indigenous peoples of Peru.”¹³⁴³ At the time of writing, the Commission has reported, that so far, it has “succeeded in resolving

¹³³⁶ Peruvian Law 27811, Article 5 states that any use of collective knowledge is conditioned on receipt of the prior informed consent of indigenous peoples.

¹³³⁷ Andean Decision 486 on a Common Intellectual Property Regime, para. 1.

¹³³⁸ Andean Decision 486 on a Common Intellectual Property Regime, para. 26.

¹³³⁹ Andean Decision 486 on a Common Intellectual Property Regime, para. 39.

¹³⁴⁰ Andean Decision 486 on a Common Intellectual Property Regime, para. 75(g).

¹³⁴¹ *Ley de protección al acceso a la Diversidad Biológica Peruana y los conocimientos colectivos de los pueblos indígenas*, Ley 28216 (Protection of Access to Peruvian Biological Diversity and Collective Knowledge of Indigenous Peoples, Peruvian Law 28216), 30 April 2004.

¹³⁴² Peruvian Law 28216, Article 2.

¹³⁴³ Peruvian Law 28216, Article 2.

15 cases related to traditional knowledge of indigenous peoples used to treat and cure various diseases, based on native species”.¹³⁴⁴ The Commission, since its creation, has also been active in identifying and monitoring patent applications filed and granted in foreign jurisdictions which relate to Peruvian biological resources and collective knowledge of indigenous peoples. Concretely, this work is done by searching the databases of WIPO, the European, US and Japanese patent offices, using as search criteria the most well-known common names, the scientific names of biological resources and their synonymous.¹³⁴⁵

Finally, a regional law on the protection of traditional knowledge is still pending in the Andean Community. A harmonised regional law would further enhance the recognition and rights of indigenous peoples.¹³⁴⁶ Thus, the Andean Community decisions and national legislation on the protection of traditional knowledge provide a solid framework for indigenous peoples to protect their traditional knowledge in accordance with their customs and traditions.¹³⁴⁷

3.2.2 Law 27811

The origin of Law 27811 can be traced back to two important decisions adopted by the Andean Community. Peru, Bolivia, Colombia and Ecuador are the four members of the Andean Community, which has the power to legislate by way of decisions. Its decisions are regionally binding legislation, and are directly applicable in each of the four member state’s national legislation countries.¹³⁴⁸ In relation to the protection of traditional knowledge, the Andean Community has enacted Decision 391 and Decision 486. Decision 391 establishes a Common Regime on Access to Genetic Resources.¹³⁴⁹ It requires evidence of prior informed consent, disclosure of origin and benefit sharing for a grant of a patent. As far as the

¹³⁴⁴ INDECOPI, “Peru presents successful results in the defence of its genetic resources and of traditional knowledge of indigenous people”, 25 February 2016, available at: <https://www.indecopi.gob.pe/inicio> [accessed March 2016]. No details on these patents have yet been published.

¹³⁴⁵ For a detailed illustration of problems faced by the Commission see, WIPO IGC, ‘Combating Biopiracy – The Peruvian Experience’, submitted by Peru, Geneva, 3-12 July 2007, Annex, pp. 5 and 10ff.

¹³⁴⁶ See, CLARK et al, “The Protection of Traditional Knowledge in Peru”, 2004, p. 769.

¹³⁴⁷ See also, TOBIN, “Traditional Knowledge sovereignty: the fundamental role of customary law in the protection of traditional knowledge”, 2015, pp. 577-578.

¹³⁴⁸ Treaty Creating the Court of Justice of the Andean Community, 18 ILM 1203, amended by the Cochabamba Protocol, 28 May 1996 (TCCJ), Article 3.

¹³⁴⁹ Andean Decision 391 on a Common Regime on Access to Genetic Resources, 1996.

protection of traditional knowledge is concerned, the decision provides indigenous communities with the right to authorise access to, and use of, traditional knowledge related to genetic resources. It thus established that the Andean Community should develop a common regime for the protection of traditional knowledge. Four years later, the Andean Community further adopted Decision 486, which established a regional intellectual property regime.¹³⁵⁰ As a fundamental principle, the grant of a patent is conditioned upon respecting the legal obligation to disclose the origin of, and demonstrate legal authorisation to use, genetic resources and traditional knowledge in patent applications.¹³⁵¹

First and foremost, Article One of Law 27811 states that “[t]he Peruvian State recognizes the right and power of indigenous peoples and communities to dispose of their collective knowledge as they see fit”.¹³⁵²

The recognition of indigenous peoples’ rights to their traditional knowledge echoes the right to internal self-determination of indigenous peoples, which is also established in Article 149 of the Peruvian Constitution.¹³⁵³ Indeed, this Provision states that the “[a]uthorities of rural and native communities, in conjunction with the peasant patrols (*ronda campesina*), may exercise jurisdictional functions at the territorial level in accordance with common law, provided they do not violate the fundamental rights of individual”.¹³⁵⁴ In contrast to other Latin American states, which also recognise some form of autonomy for indigenous peoples, in Peru, indigenous jurisdiction is not subordinated to state jurisdiction, but must not violate fundamental rights of individuals. The text of the Peruvian Constitution is probably one of the few where legal pluralism is given its widest expression.¹³⁵⁵

¹³⁵⁰ Andean Decision 486 on a Common Intellectual Property Regime, 2000.

¹³⁵¹ CLARK et al., “The Protection of Traditional Knowledge in Peru”, 2004, p. 769.

¹³⁵² Peruvian Law 27811, Article 1.

¹³⁵³ Political Constitution of Peru, 1993, Article 149 (“*Las autoridades de las Comunidades Campesinas y Nativas, con el apoyo de las Rondas Campesinas, pueden ejercer las funciones jurisdiccionales dentro de su ámbito territorial de conformidad con el derecho consuetudinario, siempre que no violen los derechos fundamentales de la persona. La ley establece las formas de coordinación de dicha jurisdicción especial con los Juzgados de Paz y con las demás instancias del Poder Judicial*”).

¹³⁵⁴ English translation of the Political Constitution of Peru, 1993, Article 149, available on the Peruvian Congress website at : <http://www.congreso.gob.pe/eng/?K=362> [accessed September 2016].

¹³⁵⁵ For a brief discussion on legal pluralism, see Part. I, Chap. 3, 1.2.3.

Another specificity of the Law 27811 is that it recognises the holders of traditional knowledge as guardians and custodians and not as owners. Therefore, indigenous peoples' representative organisations are not entitled to transfer traditional knowledge. Any use has to be determined and authorised through the establishment of a license agreement between the indigenous peoples' representative organisations and the third party user. The license has to specify the benefit-sharing modalities and be registered with the INDECOPI.¹³⁵⁶

Finally and as previously mentioned the solution proposed by the Peruvian Law is mostly defensive¹³⁵⁷ and is based on registration of traditional knowledge for its preservation and protection against misappropriation.¹³⁵⁸ The rationale of registration with INDECOPI is mainly threefold. It first permits the preservation and safeguarding of the knowledge. Second, it provides the necessary information in order to prevent the unauthorised appropriation of traditional knowledge by recognising traditional knowledge as prior art in the novelty and the non-obviousness assessment of any patented invention. Third, it permits indigenous communities to monitor the use of their knowledge and the degree of its dissemination beyond the community.

- Subject matter of protection

Article 3 of the Law clearly delimits the subject matter of protection.¹³⁵⁹ The subject matter of protection is constituted by collective traditional knowledge related to biodiversity and its components, and which is not in the public domain.¹³⁶⁰

Importantly, “the Peruvian State recognizes the rights and power of indigenous peoples and communities to dispose of their collective knowledge as they see fit”.¹³⁶¹ Collective knowledge is defined as “the accumulated, transgenerational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of

¹³⁵⁶ Peruvian Law 27811, Article 27.

¹³⁵⁷ A defensive approach means preventing others from using the knowledge without authorisation, for example, through registration of traditional knowledge for example.

¹³⁵⁸ See Part III, Chapter 3, Section 1.

¹³⁵⁹ Peruvian Law 27811, Article 3 (the provision states that “[t]his legislation establishes a special protection regime for the collective knowledge of indigenous peoples that is connected with biological resources”).

¹³⁶⁰ Peruvian Law 27811, Articles 13 and 42 providing for the exclusion of the public domain.

¹³⁶¹ Peruvian Law 27811, Article 1.

biological diversity”.¹³⁶² Typically legal protection extends to knowledge of the therapeutic or cosmetic properties of plants or knowledge of the nutritional values of native crops. Both sets of knowledge may prove to be valuable to modern industries, including the pharmaceutical, food and cosmetic sectors.

The Peruvian Law puts a strong emphasis on the inherent link between indigenous peoples and their collective knowledge. It goes as far as to establish that “the rights of indigenous peoples in their collective knowledge are inalienable and indefeasible”¹³⁶³ because “collective knowledge forms part of the cultural heritage of indigenous peoples”.¹³⁶⁴ According to Black’s Law Dictionary, an “indefeasible” right is one that is “not vulnerable to being defeated, revoked, or lost”.¹³⁶⁵

Despite the indefeasible rights of indigenous peoples over their collective knowledge, Articles 13 and 42 of the Peruvian Law provide one exception to the subject matter of protection, that is, when collective knowledge is in the public domain. The Law sets out two situations when collective knowledge becomes part of the public domain. First, when the knowledge has been made accessible to persons other than indigenous peoples by means of mass media. Second, where uses and properties of a biological resource have become extensively known beyond indigenous peoples’ communities, the collective knowledge equally becomes part of the public domain. This exception alone weakens the overall purpose of Law 27811. The reason is that an extensive part of traditional knowledge has been shared beyond the sphere of traditional communities. While it is possible, due to the sharing ethos of indigenous peoples, that the transmission of knowledge has been consented to, it is less certain whether it was an informed consent. Hence, according to this law, even though indigenous communities still use and practice their traditional knowledge, they lose any control over its use once the knowledge has become publicly available.

However, the Law provides an exception to the situation where traditional knowledge has entered into the public domain. If the collective knowledge has passed into the public domain within the previous twenty years, “a percentage which shall not be less than ten per cent of the value, before tax, of the gross sales resulting from the marketing of the goods developed on

¹³⁶² Peruvian Law 27811, Article 2.

¹³⁶³ Peruvian Law 27811, Article 12.

¹³⁶⁴ Peruvian Law 27811, Article 11.

¹³⁶⁵ Black’s Law Dictionary, 9th ed., 2009.

the basis of that knowledge shall be set aside for the Fund for the Development of Indigenous Peoples”.¹³⁶⁶ In conclusion, the prior informed consent would only be relevant if traditional knowledge is kept secret. Once the knowledge has been disclosed to the public, the law only provides for a monetary means of compensation that is to be paid into a fund.

- Beneficiaries

Under the Peruvian Law 27811, indigenous peoples are those who have held rights that existed prior to the formation of the Peruvian State, maintaining their own culture, territory and self-identity.¹³⁶⁷ Article 14 of the Law provides that “indigenous peoples shall be represented by their representative organizations”. There is no one centralised organisation representing the interests of indigenous communities, but each community may empower an organisation to represent them. Peruvian Law is silent as to the role of customary law in the identification of the subject matter and on the beneficiaries entitled to provide consent prior to access and use.

Thereby, while Law 27811 acknowledges indigenous peoples as the beneficiaries of protection and rights, it does not empower these communities to directly bring a claim through the national judicial system. Indeed, the role of indigenous peoples is limited to notifying the INDECOPI through their representative organisations. The judicial process per se is handled by INDECOPI with no involvement of the concerned indigenous communities.¹³⁶⁸

In conclusion, it is questionable whether Law 27811 fulfils the requirements of the aforementioned Article 18 and 19 of the UNDRIP with regard to the effective participation of indigenous communities in decision-making processes in matters affecting their rights.

- Scope of protection

The scope of rights conferred on the beneficiaries is provided for in Article 42 of the Law. The provision states that the rights of “[i]ndigenous peoples possessing collective knowledge shall be protected against the disclosure, acquisition or use of that collective knowledge without their consent and in an improper manner provided that the collective knowledge is not in the public domain. It shall likewise be protected against unauthorized disclosure where a

¹³⁶⁶ Peruvian Law 27811, Articles 8 and 13.

¹³⁶⁷ Peruvian Law 27811, Article 2.

¹³⁶⁸ Peruvian Law 27811, Articles 47 to 62 with regard to “infringement actions”.

third party has legitimately had access to collective knowledge covered by a safeguard clause”.

Under Peruvian Law 27811, indigenous peoples’ rights are fundamentally based on the principle of prior informed consent.¹³⁶⁹ Thus, indigenous groups have a positive right to control access to, and the use of, their collective traditional knowledge as the legitimate holders. However, the Law expressly provides for an exception: third party users have the right to access and use knowledge without the prior informed consent of indigenous groups when traditional knowledge is part of the public domain.¹³⁷⁰ In this case, holders of traditional knowledge are no longer entitled to oppose the use of their knowledge, however, the law provides for compensation when the traditional knowledge has passed into the public domain within the previous twenty years. Beyond that time frame, no compensation is due. This regime mirrors the principle behind open access regimes,¹³⁷¹ where publicly available knowledge is not automatically free to use.¹³⁷²

Yet, it is questionable whether access to traditional knowledge¹³⁷³ that is in the public domain should deprive the holders of traditional knowledge of their right to benefit-sharing. Indeed, both Article 5(b) of the Peruvian Law¹³⁷⁴ and Article 5.5 of the Nagoya Protocol, link the benefit-sharing obligation to the utilisation of traditional knowledge.¹³⁷⁵

¹³⁶⁹ Peruvian Law 27811, Articles 5(d) and 6.

¹³⁷⁰ According to Article 13 of the Peruvian Law 27811, collective traditional knowledge is in the public domain “when it has been made accessible to persons other than the indigenous peoples by mass communication media such as publication or, when the properties, uses or characteristics of a biological resource are concerned, where it has become extensively known outside the confines of the indigenous peoples and communities”. Hence, under this provision, public domain is determined by where the knowledge is found and not how it got in the public domain.

¹³⁷¹ See generally, TOBIN, “Open Access Seeds and Breeds: the Role of the Commons in Protecting Farmers and Livestock keepers”, 2013, pp. 75-100.

¹³⁷² See Part II, Chapter 3, 2.

¹³⁷³ Peruvian Law 27811, Article 6.

¹³⁷⁴ Peruvian Law 27811, Article 5(b) reads: “To promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge”.

¹³⁷⁵ The question as to whether access or utilisation triggers benefit-sharing is a controversial one. For more discussion on this subject, see MORGERA et al., *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, 2014, pp. 115 and 130; see also NIJAR, “An Asian Developing Country’s View on Implementation Challenges”, 2013, p.

While the Peruvian law provides for compensation for publicly available collective knowledge, in this circumstance the obligation to require prior informed consent is extinguished. With regard to collective knowledge that is not publicly available, the Peruvian law raises a major question concerning the requirement of prior informed consent: who is legitimate to grant prior informed consent? This problem is not inherent to the Peruvian Law but to the fact that traditional knowledge is often shared amongst multiple indigenous communities. Indeed, Article 6 of Law 27811 envisages entitling “the greatest possible number of indigenous peoples” in the decision-making process in relation to the commercial use of their traditional knowledge.¹³⁷⁶ This may potentially lead to conflicts and frictions amongst various indigenous groups with diverging interests. As stated by Peruvian scholars, “[i]ndigenous communities’ interests range from those that are quite progressive and seek to develop a close relationship with the modern world, to those that oppose integration or any type of interaction related to accessing and using their TK”.¹³⁷⁷ This is a typical case where customary rules of indigenous groups should govern their decision-making processes in order to prevent any potential conflicts within indigenous communities. It can be undertaken through a transparent domestic process of consultation between the national authorities and indigenous communities.¹³⁷⁸

In conclusion, the objectives of Law 27811 are mainly threefold. First, it aims to provide a degree of control to indigenous peoples over the utilisation of their knowledge and share the benefits derived from the said utilisation. Second, it seeks to prevent misappropriation

259 (the author argues that publicly available TK must be subject to PIC and Benefit-Sharing because the CBD and the Nagoya Protocol provide for no exceptions with regard to TK that is in the public domain).

¹³⁷⁶ Peruvian Law 2781, Article 6; see also, the newly adopted *Ley de Derecho a la Consulta Previa a los Pueblos Indígenas u Originarios Reconocido en el Convenio 169 de la Organización Internacional del Trabajo (OIT) Ley 29785* (Law on the Right of Consultation of Indigenous Peoples, Peruvian Law 29785), 8 August 2011 (under this law, indigenous communities are entitled to request the opening of a consultation process if the measures in question affect their lands).

¹³⁷⁷ CLARK et al., “The Protection of Traditional Knowledge in Peru: A Comparative Perspective”, 2004, p. 793.

¹³⁷⁸ See IACHR, *Saramaka People v. Suriname*, Interpretation of the Judgement on Preliminary Objections, Merits, Reparations, and Costs, Judgement of 12 August 2008, IACHR 2008, para. 26 (the Court observed “that, pursuant to paragraph 164 of the Judgement, in the event that any internal conflict arises amongst members of the Saramaka People [with regard to benefit-sharing], it must be resolved by the Saramaka community in accordance with their own traditional customs and norms, not by the State or this Court in this particular case”).

through a monitored use of the patent system.¹³⁷⁹ Third, it aims to find a fair balance between various interest groups, namely indigenous peoples, researchers and industry at large.¹³⁸⁰

3.3 New Zealand's Case-by-Case Approach

As advanced by a scholar in this field, any discussion over Māori cultural heritage and its protection against an “inappropriate use” in New Zealand has to take into account the Treaty of Waitangi.¹³⁸¹ The Treaty was signed in 1840 on behalf of the English Crown and the indigenous peoples (500 Māori chiefs) of New Zealand.¹³⁸² The Treaty enshrines the relationship between the Crown and the Māori and is considered to be an integral part of New Zealand's laws with constitutional significance.¹³⁸³ In 1975, the Treaty of Waitangi was given due recognition in New Zealand law through the Treaty of Waitangi Act 1975,¹³⁸⁴ which established the Waitangi Tribunal. The Tribunal is a quasi-judicial body that makes recommendations through reports on Māori claims relating to the practical application of the Treaty's principles by the Crown. While the power of the Tribunal is merely recommendatory, its “[r]eports frequently set the tone for negotiations between *iwi*¹³⁸⁵ and the Crown over the return of assets, and have helped set the parameters for future governmental

¹³⁷⁹ CLARK et al., “The Protection of Traditional Knowledge in Peru: A Comparative Perspective”, 2004, p. 774.

¹³⁸⁰ RUIZ, *Protecting Shared and Widely Distributed Traditional Knowledge: Issues, Challenges and Options*, 2013, pp. 1-32; for an in-depth discussion on the relationship between customary law and Peru's Law 27811, see TOBIN and TAYLOR, “Across the Great Divide: A Case Study of Complementarity and Conflict between Customary Law and TK Protection Legislation in Peru”, 2009.

¹³⁸¹ For a discussion of what Māori culture means in modern-day in New Zealand, see, LAI, *Indigenous Cultural Heritage and Intellectual Property Rights – Learning from the New Zealand Experience?*, 2014, p. 21 (the author concludes that even if it is difficult to determine what may or may not be deemed inappropriate use, “prior consultation” is always advisable”).

¹³⁸² For a concise description of the Treaty's history see ORANGE, *An Illustrated History of the Treaty of Waitangi*, 2004.

¹³⁸³ ZOGRAFOS, “New Perspectives for the Protection of Traditional Cultural Expressions in New Zealand”, 2005, p. 931; see also, ROSANOWSKI, “Protection of Traditional Cultural Expressions within the New Zealand Intellectual Property Framework: A Case Study of the *Ka Mate Haka*”, 2015, pp. 275ff; FRANKEL, “‘Ka Mate Ka Mate’ and the Protection of Traditional Knowledge”, 2014, pp. 193-214.

¹³⁸⁴ Treaty of Waitangi Act 1975, 10 October 1975, New Zealand (Treaty of Waitangi Act), available at: <http://www.legislation.govt.nz/> [accessed September 2016].

¹³⁸⁵ Māori word for tribe.

policy agenda”, including the adoption of the Tribunal’s recommendations by the government.¹³⁸⁶

The Treaty was originally written in both Māori and English versions. This has given rise to some contradictory interpretations and has led the Parliament to refer to the “[p]rinciples of the Treaty in legislation, rather than to the Treaty texts”.¹³⁸⁷ In other words, it is the spirit and the essence of the agreement that has to guide government bodies and judges in their decision-making. According to the courts and the Waitangi Tribunal the principles are not fixed. This flexibility is due to the fact that the principles are constantly evolving as the Treaty is applied to new situations and circumstances. Three main principles have been recognised to constitute the essence of the Treaty, which are: the principle of partnership,¹³⁸⁸ the principle of active protection,¹³⁸⁹ and the principle of redress.¹³⁹⁰

The principle of partnership describes the relationship between the Crown and the Māori. While the Waitangi Tribunal and the national courts concur on the concept of partnership, they diverge slightly on its premise. While for the Tribunal, the principle is based on the equal

¹³⁸⁶ AUSTIN, “Re-Treating Intellectual Property? The Wai 262 Proceeding and the Heuristics of Intellectual Property Law”, 2003, p. 347.

¹³⁸⁷ TE PUNI KOKIRI, *He Tirohanga o Kawa ki te Tiriti o Waitangi: A Guide to the Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal*, 2002, p. 74 available at: <http://www.waitangitribunal.govt.nz/treaty-of-waitangi/principles-of-the-treaty/> [accessed September 2016].

¹³⁸⁸ TE PUNI KOKIRI, *He Tirohanga o Kawa ki te Tiriti o Waitangi: A Guide to the Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal*, 2002, p. 77.

¹³⁸⁹ TE PUNI KOKIRI, *He Tirohanga o Kawa ki te Tiriti o Waitangi: A Guide to the Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal*, 2002, p. 93 (“[t]he principle encompasses the Crown’s obligation to take positive steps to ensure that Māori interests are protected. The Courts have considered the principle primarily in association with the property interests guaranteed to Māori in Article II of the Treaty”).

¹³⁹⁰ TE PUNI KOKIRI, *He Tirohanga o Kawa ki te Tiriti o Waitangi: A Guide to the Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal*, 2002, p. 100 (according to this principle, “the Crown has an obligation to remedy past breaches of the Treaty, arising from its duty to act reasonably and in good faith as a Treaty partner.”).

status of the Treaty partners, the courts have remained silent on the status of the parties to the partnership.¹³⁹¹

Both the courts and the Tribunal emphasise the obligation on the parties to act reasonably, honourably, and in good faith. For the Tribunal, the principle of partnership includes the principles of reciprocity and mutual benefit that refer to the equal status of the Treaty partners. Inherent to the principle of reciprocity is the acknowledgement by the Crown of the Māori's existence and the prior occupation of the land. According to the principle of mutual benefit, it is recognised that both parties have signed the Treaty with a win-win expectation. In other words, "the principle requires that the needs of both cultures must be provided for and compromise may be needed in some cases to achieve this objective".¹³⁹² On the other hand, the New Zealand courts have found that acting in good faith requires that the Crown is obliged to make informed decisions on matters affecting the interests of the Māori. This obligation will in some cases require the Crown to consult with the Māori. However, it seems that this duty to consult is not absolute, and will depend on the importance of the issue in question.¹³⁹³ However, this limitation seems to be contestable as the second principle of the Treaty refers to the duty of active protection. Indeed, the Courts have also recognised that "it is not permissible for the Crown to try to limit the principles of the Treaty to mere consultation, when its obligation included the already mentioned principle of active protection".¹³⁹⁴ Furthermore, it is a matter of debate as to who is competent to decide the importance of an issue in question or what matters that affect the Māori's interests are.

Article 2 of the English text¹³⁹⁵ of the Treaty of Waitangi, which is particularly relevant to intellectual property states that "[h]er Majesty the Queen of England confirms and guarantees to the Chiefs and Tribes of New Zealand and to the respective families and individuals thereof the full exclusive and undisturbed possession of their Lands and Estates Forests Fisheries and

¹³⁹¹ TE PUNI KOKIRI, *He Tirohanga o Kawa ki te Tiriti o Waitangi: A Guide to the Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal*, 2002, p. 77.

¹³⁹² TE PUNI KOKIRI, *He Tirohanga o Kawa ki te Tiriti o Waitangi: A Guide to the Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal*, 2002, p. 82.

¹³⁹³ TE PUNI KOKIRI, *He Tirohanga o Kawa ki te Tiriti o Waitangi: A Guide to the Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal*, 2002, p. 85.

¹³⁹⁴ TE PUNI KOKIRI, *He Tirohanga o Kawa ki te Tiriti o Waitangi: A Guide to the Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal*, 2002, p. 87.

¹³⁹⁵ The Treaty of Waitangi is in both Māori and English versions, which are both official versions.

other properties (*taonga*)¹³⁹⁶ which they may collectively or individually possess so long as it is their wish and desire to retain the same in their possession”.¹³⁹⁷ At this point it is important to make two comments.

First, while the English text of Article 2 of the Treaty refers to notions of Western property, such as ownership, possession and exclusive rights, the Māori version rather uses words, such as *tino rangatiratanga*, referring to concepts such as autonomy and self-determination, and *kaitiakitanga*, meaning Māori guardianship or stewardship over *taonga*.¹³⁹⁸ Second, although, the provision does not explicitly mention intellectual property, the concept of *taonga* also refers to intellectual property according to the holistic worldview generally shared by indigenous peoples.¹³⁹⁹ Accordingly, it can be assumed that the Treaty of Waitangi provides a strong normative justification for the protection of Māori traditional knowledge in New Zealand.¹⁴⁰⁰

3.3.1 The Wai 262 Claim and the Tribunal of Waitangi's Report

Since its establishment, the Tribunal of Waitangi has issued many reports on claims filed by indigenous tribes in New Zealand. One claim is of particular relevance for the issue of the interface between *Mātauranga* Māori (all aspects of indigenous cultural heritage, including traditional knowledge) and intellectual property rights. In 1991, various tribes,¹⁴⁰¹ representing the indigenous peoples of New Zealand filed the Wai 262 Claim, also called the

¹³⁹⁶ According to the Māori dictionary, “*taonga*” means “property, goods, possessions, effects”, available at: <http://maoridictionary.co.nz/> [accessed August 2016].

¹³⁹⁷ Treaty of Waitangi Act, Article 2.

¹³⁹⁸ LAI, *Indigenous Cultural Heritage and Intellectual Property Rights – Learning from the New Zealand Experience?*, 2014, p. 230; see also LAI, “Maori Traditional Knowledge and the Wai 262 Report: A Coherent Way Forward?”, 2012, pp. 8 ff.

¹³⁹⁹ ZOGRAFOS, “New Perspectives for the Protection of Traditional Cultural Expressions in New Zealand”, 2005, p. 930; LAI, *Indigenous Cultural Heritage and Intellectual Property Rights – Learning from the New Zealand Experience?*, 2014, p. 17.

¹⁴⁰⁰ FRANKEL, “‘Ka Mate Ka Mate’ and the Protection of Traditional Knowledge”, 2014, p. 203; see also, LAI, “Maori Traditional Knowledge and New Zealand Patent Law”, 2014, p. 134.

¹⁴⁰¹ The claim was filed by six *iwi* (tribes), namely the Ngāti Kuri, Ngāti Wai, Te Rarawa, Ngāti Porou, Ngāti Kahungunu and Ngāti Koata.

“Māori claim over fauna and flora” or the “Māori intellectual property claim”.¹⁴⁰² However, the claim is not solely confined to those two aspects but encompasses “all those things [...] that make [Māori] culture and heritage” such as oral traditions, arts, spirituality, nature, justice, traditional medicinal knowledge and therapeutic properties of plants.¹⁴⁰³ In essence, the claim is over the principle of self-determination.¹⁴⁰⁴ It particularly addresses the ownership of Māori traditional knowledge, cultural expressions, and indigenous species of fauna and flora, all of them encompassed under the aforementioned Māori word *taonga* and their use within inventions.

The claimants alleged that the Crown had breached its obligations under Article 2 of the Treaty of Waitangi, and its principles, with respect to *taonga* by adopting intellectual property acts and by adhering, amongst others, to international intellectual property law instruments without proper prior informed consultation with Māori. Thus, the claimants requested the Crown to undertake a complete review of all existing laws and policies in order for the Crown to comply with its duty to actively protect Māori *taonga*.¹⁴⁰⁵ Finally, the claim, rather than questioning the appropriateness of categories of intellectual property rights for the protection of traditional knowledge, sought to show that the imposition of the Western notion of intellectual property has been adverse to the interests of Māori communities.

The Tribunal took 20 years to complete its report mainly because the claim was broad and complex.¹⁴⁰⁶ The report was submitted to the government of New Zealand in July 2011. The

¹⁴⁰² For an overview of the 262 Wai claim and proceeding, see AUSTIN, “Re-Treating Intellectual Property? The Wai 262 Proceeding and the Heuristics of Intellectual Property Law”, 2003, pp. 340ff.

¹⁴⁰³ AUSTIN, “Re-Treating Intellectual Property? The Wai 262 Proceeding and the Heuristics of Intellectual Property Law”, 2003, p. 352.

¹⁴⁰⁴ AUSTIN, “Re-Treating Intellectual Property? The Wai 262 Proceeding and the Heuristics of Intellectual Property Law”, 2003, p. 351.

¹⁴⁰⁵ AUSTIN, “Re-Treating Intellectual Property? The Wai 262 Proceeding and the Heuristics of Intellectual Property Law”, 2003, p. 340.

¹⁴⁰⁶ ZOGRAFOS, “New Perspectives for the Protection of Traditional Cultural Expressions in New Zealand”, 2005, p. 935.

report of the Tribunal is built on the principles mentioned earlier of the Treaty of Waitangi, namely the principle of partnership and the duty of active protection.¹⁴⁰⁷

With regard to the specific relationship between intellectual property rights and *taonga* works,¹⁴⁰⁸ the Tribunal noted that any future steps will have to be sought in a balance “between the obligations of *kaitiaki* in respect of *taonga* works and *mātauranga* Māori¹⁴⁰⁹ on the one hand, and the requirements of New Zealand’s IP laws on the other”.¹⁴¹⁰ The Tribunal acknowledged that both systems “can be seen as different ways of thinking about the same issue”.¹⁴¹¹ In other words, while *kaitiaki* focuses on obligations and relationships deriving from kinship, property is based on the rights of owners. Thus, the central question the report tries to answer is whether and how the interests of *kaitiaki* in *taonga* works and *mātauranga* Māori might be protected within or alongside the IP framework.

With regard to patents specifically, claimants expressed their concerns about patented inventions that derive from *mātauranga* Māori without prior consent. They stress that third parties must ask for consent and provide appropriate acknowledgement when using *mātauranga* Māori, whether or not the traditional knowledge is in the public domain.¹⁴¹² The fact that a great amount of traditional knowledge has already entered into the public domain does not undermine the kinship relationship with traditional knowledge and the responsibilities *kaitiaki* have towards it. For Maori, protection of their *mātauranga* means prohibiting its offensive use. In other words, what shall be prevented is the unauthorised use of *taonga* works and *mātauranga* Māori.

For its part, the Crown questioned whether these conflicting interests could co-exist without undermining creativity and economic development by deterring foreign investment in New

¹⁴⁰⁷ Wai 262 Report I, vol. 1, p. 24 (The tribunal notes that “it is vital to remember that the promises made to Māori in exchange for their acceptance of British government are of the utmost importance. They are constitutional promises solemnly made in this country’s pre-eminent constitutional document”).

¹⁴⁰⁸ Wai 262 Report I, p. 44 (*taonga* works refer to all of the technologies and arts associated with traditional Māori life).

¹⁴⁰⁹ Wai 262 Report I, p. 22 (*mātauranga* Māori refers not only to Māori knowledge, but also to the Māori way of knowing).

¹⁴¹⁰ Wai 262 Report I, pp. 29 and 33.

¹⁴¹¹ Wai 262 Report I, vol. 1, pp. 29 and 34.

¹⁴¹² Wai 262 Report I, p. 583

Zealand.¹⁴¹³ The Crown's main argument was that a vast amount of *taonga* works and associated *mātauranga* Māori had already fallen into the public domain to be freely accessed by all. It stressed that it was the responsibility of Māori to keep their *mātauranga* out of the public domain. Additionally, the Crown argued that it was impractical to impose retrospective controls on that material, and that the claimants' pretensions with regard to the "retreat"¹⁴¹⁴ of intellectual property rights in respect of *taonga* works "were unrealistic in the contemporary world".¹⁴¹⁵ However, it accepted that some degree of protection of traditional knowledge was justified. Accordingly, the Crown made reference to its proposal of reforming the patent system by introducing a Māori committee to advise the Commissioner of Patents of the Intellectual Property Office of New Zealand (IPONZ).¹⁴¹⁶ Its role would consist of informing the Commissioner whether the invention derives from Māori traditional knowledge, and whether the granting of a patent would be contrary to Māori values. In view of both parties' arguments, the Tribunal made the following recommendations.

First, the Tribunal considered that Article 2 of the Treaty is relevant to the question of the protection of *taonga* works, including *mātauranga* Māori. While it considered that the Treaty of Waitangi does not provide for exclusive ownership in *mātauranga* Māori or the intangible aspects of *taonga* works, some *mātauranga* Māori are entitled to a certain degree of protection based on the relationship between *kaitiaki* and the *taonga* work. In that sense, the Tribunal made a distinction between *taonga* works and *taonga*-derived works. It concluded that the protection of *taonga*-derived works ought to be more limited compared to *taonga* works.¹⁴¹⁷ This is because *taonga*-derived works have lost their *kaitiaki* relationship. The Tribunal concluded that the greater the effect of those rights on the *kaitiaki* relationship, the greater the right of participation in decision-making processes. In other words, what makes a work a *taonga* work is the relationship between the Māori and the work. Contrary to *taonga*-derived works, the Tribunal recommended more than mere defensive rights for *taonga* works.

¹⁴¹³ Wai 262 Report I, vol. 1, p. 40.

¹⁴¹⁴ See generally, AUSTIN, "Re-Treating Intellectual Property? The Wai 262 Proceeding and the Heuristics of Intellectual Property Law", 2003, p. 359.

¹⁴¹⁵ Wai 262 Report I, vol. 1, p. 40.

¹⁴¹⁶ This proposal is similar to that already in place in the trade marks law in New Zealand.

¹⁴¹⁷ Wai 262 Report I, p. 47 ("*taonga* derived works is a work that derives its inspiration from *mātauranga* Māori or a *taonga* work, but does not relate to or invoke ancestral connections, not contain or reflect traditional narratives or stories, in any direct way").

The presence of a *kaitiaki* relationship justifies the right to consultation and to prior informed consent for the use of *taonga* works. Whereas for *taonga*-derived works only offensive public uses might be prevented by the Māori community.¹⁴¹⁸ The Tribunal thus recommended the establishment of a body of experts, which would, on a case-by-case basis, consider whether a given use of *taonga*-derived works or *mātauranga* Māori derived works is offensive with regard to the customary norms of Māori community. According to the Tribunal, what is essential is that Māori should be given the opportunity to raise their concerns and have the opportunity to actively participate in “an independent adjudicatory process”.¹⁴¹⁹

With respect to *taonga* works that have already entered into the public domain, the Tribunal considered that these are entitled to protection from offensive and derogatory public use.¹⁴²⁰

The Tribunal also recognised that much of *mātauranga* Māori about *taonga* species¹⁴²¹ is already in the public domain. However, while exclusive ownership rights are not justified in *mātauranga* Māori about *taonga* species,¹⁴²² the rights of consent and participation shall be respected and their required degree will be analysed on a case-by-case basis, depending on the degree of the *kaitiaki* relationship. For instance, the tribunal ruled that any subsequent use of *taonga* works for *commercial* purposes¹⁴²³ shall entail the following extensive rights:

- (i) the right of the *kaitiaki* to be acknowledged as the source of such knowledge.
- (ii) the right of the *kaitiaki* to have a reasonable degree of control over their *mātauranga* Māori.

¹⁴¹⁸ Wai 262 Report I, p. 47.

¹⁴¹⁹ Wai 262 Report I, p. 49.

¹⁴²⁰ Wai 262 Report I, p. 50.

¹⁴²¹ Wai 262 Report I, pp. 65 and 66 (the Tribunal defines *taonga* species as the species of flora and fauna for which are *kaitiaki* responsibilities. For instance, whales act as a spiritual guardians for certain tribes. Another example is provided by the plant Mānuka, a New Zealand's tree, which components have been used by tribes for its healing properties. In 2008, German researchers claimed to have isolated the main active compound, without acknowledging any debt to *mātauranga* Māori).

¹⁴²² The Tribunal argued that Māori did not create *taonga* species.

¹⁴²³ Wai 262 Report I, p. 50 (The Tribunal also makes a distinction between private, non-commercial and commercial uses. Thus, private and non-commercial uses shall be permitted or tolerated. The Tribunal justifies this distinction on the basis that “the Māori concern has always been around derogatory or offensive public use and commercial exploitation of *mātauranga* Māori and *taonga* works, and this is the area on which the law should focus”).

- (iii) there shall be a legal duty to consult, and to obtain the consent of the *kaitiaki*. However, the Tribunal stressed that consent will not be required systematically whenever *mātauranga* Māori is used in any way. This will depend on a case by case analysis of all the interests at stake. For instance, the level of control will vary with the degree of relevance of *mātauranga* Māori in the invention, and the balancing of the *kaitiaki* relationship against other interested parties.¹⁴²⁴

Second, the tribunal recommended that a genuine balancing of all valid interests has to occur at an early stage – before a patent is granted. In the overall discussions regarding the protection of Māori traditional knowledge, there are three categories of stakeholders: the Māori, the intellectual property rights holders and the public in general.¹⁴²⁵ For the Tribunal, any solution has to find the right balance between these interests. This balance has to be found on a case by case basis depending, fundamentally on the *kaitiaki* relationship with the *mātauranga* Māori. Another fundamental assessment is whether the use of *mātauranga* Māori is offensive or derogatory to Māori values. The Tribunal merely provides some examples of what might be offensive or derogatory for Māori,¹⁴²⁶ and concludes that this assessment has to be determined by experts and the appropriate authorities established under the new system of protection. In addition, the Tribunal did not clarify to whom the use of *mātauranga* Māori must be offensive. Should it be offensive to all Māori, to some *iwi* (tribes) or only to *kaitiaki*.¹⁴²⁷ This question is probably also left open to a case-by-case analysis by the competent authorities. The question as to whom the use of *mātauranga* Māori is offensive has to be distinguished from the question of who is the *kaitiaki* of *mātauranga* Māori or *taonga* works. The Report proposed to identify the *kaitiaki* by means of a public register in respect of a given *taonga* work. The *kaitiaki* applicant might be an individual or a community, namely a tribe or various tribes. Applications for registration would be public in order to allow for any objections.¹⁴²⁸ The registration will also help to demonstrate the degree of relationship

¹⁴²⁴ Wai 262 Report I, pp. 87- 88; see also the same line of argument in, CARPENTER et al., “Clarifying Cultural Property”, 2010, pp. 586-587.

¹⁴²⁵ The public interest relates to the interest of preserving a rich and diverse public domain.

¹⁴²⁶ Wai 262 Report I, p. 48 (the Report provides the example of *kaitiaki* who would probably take offence at the placing of a chief’s *tā moko* (traditional tattoo) on toilet seats).

¹⁴²⁷ LAI, *Indigenous Cultural Heritage and Intellectual Property Rights – Learning from the New Zealand Experience?*, 2014, p. 245.

¹⁴²⁸ Wai 262 Report I, p. 54.

between the *kaitiaki* and the *taonga* work. The Tribunal also recommended that registration should not be a condition for the *kaitiaki* to object to a patent application.

This brings us to the third recommendation, relating to the Crown's proposition to establish a Māori Advisory Committee. The Tribunal noted that the proposal "is a good start, but it needs to go further if the Crown is serious about giving reasonable protection to the interest of *Kaitiaki*".¹⁴²⁹ According to the Tribunal, the Committee should be able to bring a case in front of the Commissioner rather than being involved only on the initiative of the Commissioner of Patents, as proposed by the Crown.¹⁴³⁰ This is because, patent examiners are either trained in law or science but are neither ethicists nor experts in *mātauranga* Māori. It further recommended that the investigating work of the Committee should be supported by an "executive unit" in order to be effective. Finally, it proposed that the Committee should have a mandate in two distinct areas. Firstly, it should be able to instruct the Patent Commissioner on the link between the invention and the *mātauranga* Māori. Secondly, the Committee should advise the Commissioner on whether *kaitiaki* interests are at risk, even if the patentability criteria are satisfied, namely novelty and inventiveness. This second mandate is directly linked with one of the exceptions under the patent system. In conformity with Article 27.2 of the TRIPS Agreement, Member States have the possibility "to exclude from patentability inventions the commercial exploitation of which is necessary to protect order public or morality".¹⁴³¹ Hence, the Tribunal strongly recommended that a specific reference to Māori be included within the provision related to morality exception of the Patents Act. The Tribunal also added that the protection of Māori values are not only related to morality, but may also be related to questions of *ordre public*¹⁴³² in the context of New Zealand. Indeed, issues between Māori and the Crown are resolved and negotiated by reference to the fundamental principles of the Treaty of Waitangi that is of constitutional status. In other words, Māori concerns are fundamental in the societal structure of New Zealand. Consequently, the Tribunal considered that the failure to disclose *mātauranga* Māori in the invention is also contrary to *ordre public*.

¹⁴²⁹ Wai 262 Report I, p. 91.

¹⁴³⁰ Wai 262 Report I, p. 91.

¹⁴³¹ TRIPS Agreement, Article 27.2.

¹⁴³² For a definition of *ordre public*, see Part II, Chapter, 2; see also, GERVAIS, *The TRIPS Agreement: Drafting History and Analysis*, 2012, p. 149.

Finally, the Report recommended a mandatory disclosure requirement. The Tribunal is clear in what should trigger the obligation to disclose. The patent applicant will have to disclose “any use of *mātauranga* Māori that has contributed to the research process or invention”.¹⁴³³ According to the Tribunal, a disclosure requirement will not only help to balance the different interests at stake at an early stage, before the patent is granted, but will also help in assessing whether the *kaitiaki* and/or Māori values are affected. It will also assist the patent examiner in the determination of the prior art. Ideally, the disclosure requirement will help parties to reach an agreement on access and benefit-sharing. However, the Tribunal leaves the consequences of a failure to disclose up to the Commissioner and the Māori Advisory Committee to decide. This discretionary approach is compatible with the case-by-case approach of the Report.¹⁴³⁴

In conclusion, in order to provide an extensive protection to traditional knowledge - that goes beyond the prohibition of offensive use - the key criterion for the Tribunal was the extent of the *kaitiaki* relationship with *mātauranga* Māori. Indeed, this relationship may still exist even though the TK is in the public domain. The greater the impact of bioprospecting projects or patents on the *kaitiaki* relationship, the greater the right of the Maori to participate in the decision-making process.

The following paragraphs will now examine the newly amended Patents Act and discuss whether it has incorporated the recommendations of the Wai 262 Report. It should be noted that the Wai 262 Report was released when the Patent Bill was still pending in the Parliament. At the time of writing, the New Zealand Government has still to react officially to the Report.

3.3.2 The Patent Act and the Māori Patents Advisory Committee

New Zealand in its newly adopted Patents Act (hereafter, the Patents Act 2013) has taken a different approach to the Swiss and Peruvian legislation studied previously.¹⁴³⁵ One of the purposes of the Patents Act is “to address Māori concerns relating to the granting of patents for inventions derived from indigenous plants and animals or from Māori traditional

¹⁴³³ Wai 262 Report I, p. 93.

¹⁴³⁴ Wai 262 Report I, p. 92.

¹⁴³⁵ The New Zealand Patents Act, enacted 13 September 2013, entered into force September 2014 (the NZ Patents Act 2013).

knowledge”.¹⁴³⁶ The following will only focus on Māori traditional knowledge, also called *mātauranga* Māori.

Under the newly amended Patents Act 2013, a Māori Advisory Committee (MAC) has been created.¹⁴³⁷ A similar body had been established under the Trade Marks Act in 2002.¹⁴³⁸ Members of the MAC are appointed by the Commissioner of Patents and they must have knowledge of *mātauranga* Māori and *tikanga*.¹⁴³⁹ Māori.

Section 226 of the Patents Act 2013 states that “the function of the Māori advisory committee is to advise the Commissioner (on request) on whether”: a claimed invention derives from Māori traditional knowledge or from indigenous plants or animals and, if so, if the commercial exploitation of the said invention is likely to be contrary to Māori values.¹⁴⁴⁰

At this point, a comparison should be made between the Patents Act 2013 and the Wai 262 Report. In contrast to the Report, the Patents Act makes no distinction between *taonga* works and *taonga*-derived works, but refers to Māori traditional knowledge and indigenous plants or animals. In that sense, the scope of the Patents Act is wider as to the subject matter deemed to be protectable under the Report.

It seems that it is only at the discretion of the Commissioner that the MAC may become involved. In other words, for the Māori Advisory Committee to enter into play there should first be a suspicion from the Commissioner that the patent application may have been derived from Māori traditional knowledge.¹⁴⁴¹ This will prove to be difficult as the experts in Māori knowledge are located precisely within the MAC. This conclusion should be nuanced. First, the fact that the words “on request” have been inserted within parenthesis needs further clarification. Second, Section 228 of the Patents Act 2013 states that “the Māori advisory committee may regulate its own procedure, subject to any direction given by the

¹⁴³⁶ NZ Patents Act 2013, S. 3.

¹⁴³⁷ NZ Patents Act 2013, S. 225-228.

¹⁴³⁸ New Zealand Trade Marks Act, enacted 4 December 2002, entered into force 20 August 2003 (the NZ Trade Marks Act 2002).

¹⁴³⁹ NZ Patents Act 2013, S. 225 translates *tikanga* Māori as Māori protocol and culture.

¹⁴⁴⁰ NZ Patents Act 2013, S. 15(3) and 226.

¹⁴⁴¹ See LAI, “Māori Traditional Knowledge and New Zealand Patent Law”, 2014, p. 38.

Commissioner”. This provision might constitute an opening for the MAC to make recommendations or warn the Commissioner about a suspicious case.

As far as the mandates of the MAC are concerned, four comments shall be made. First, the mandates the MAC is assigned with are cumulative, in the sense that the Commissioner will take into account the recommendations of the MAC if and only if the two conditions are met. Those are: derivation from Māori traditional knowledge and contrary to Māori values.

Second, the process of determination whether the invention derives from Māori traditional knowledge can lead to certain uncertainty. Indeed, there might be a considerable difference between an invention that is directly based on traditional knowledge and an invention that is remotely related to that knowledge, namely in the assessment as to the novelty or inventiveness of the invention. While the task of the MAC will only consist in determining if the invention derives from *mātauranga* Māori, the Commissioner will assess, on a case-by-case analysis, the novelty of the invention compared to the *mātauranga* Māori. This is in contrast to what had been recommended by the Tribunal, which considered that the Commissioner shall seek advice from the MAC in order to assess the patentability of the invention as far as its novelty and inventiveness are questioned.¹⁴⁴² It is questionable how this task is feasible without a requirement that patent applicants should disclose whether they have used *mātauranga* Māori and to what extent.¹⁴⁴³

Third, with respect to the second mandate of the MAC is to assess whether commercial exploitation is contrary to Māori *values*, this requirement seems to make a direct link to Section 15(1) of the Patents Act 2013, which states that inventions contrary to public order or morality are not patentable. Paragraph 3 of this provision further adds that “[the] Commissioner may, for the purpose of making a decision under this section, seek advice from the Māori advisory committee or any person that the Commissioner considers appropriate”.¹⁴⁴⁴ The question is whether the commercial exploitation of an invention that is likely to be contrary to Māori values is contrary to *ordre public* and morality? This task will prove to be difficult, as the MAC is expected to identify what falls into the broad concept of Māori “values”. According to the Wai 262 Report, Māori values are affected when not only

¹⁴⁴² Wai 262 Report I, p. 86.

¹⁴⁴³ Wai 262 Report I, p. 92.

¹⁴⁴⁴ NZ Patents Act 2013, S. 15.

the fundamental relationship the *kaitiaki* maintains with the *mātauranga* Māori is damaged but also when the *mātauranga* Māori is offensively used.¹⁴⁴⁵ The Report further notes that “the place of Māori interests in IP law is an issue of *ordre public*”.¹⁴⁴⁶

Fourth, Section 227 of the Patents Act 2013 states that while the Commissioner is not bound by the advice provided by the MAC, it must take it into consideration.¹⁴⁴⁷ It is not clear either whether the decision of the Commissioner might be subject to an appeal by the MAC or other interested parties.

While the government has not yet reacted officially to the Wai 262 Report, it is undeniable that the Patent Act is a crucial step forward towards acknowledging the importance of the Maori traditional knowledge in New Zealand.

In conclusion, the Patents Act 2013 makes specific reference to the Māori as recommended by the Wai 262 Report. This is an important step compared to the Patents Act of 1953. Under the latter, whilst the Commissioner of Patents could also reject a patent if it was contrary to morality, it did not make any reference to Māori.¹⁴⁴⁸ However, a criticism that can be addressed to the Patent Act is the requirement for an assessment whether “commercial exploitation” of an invention derived from Māori traditional knowledge might be contrary to Maori values. On the contrary, what is relevant is the appropriation of Maori traditional knowledge without their prior informed consent.

Finally, and as already mentioned, any new framework aimed at protecting *mātauranga* Māori must interface with existing intellectual property laws. This is important so as to ensure that the two regimes do not defeat each other.¹⁴⁴⁹ Thus, when balancing both regimes, there

¹⁴⁴⁵ Wai 262 Report I, p. 86 (the Tribunal states the following: “[w]e say that to give proper legal recognition to the kaitiaki interest would benefit Māori development and guard against exploitation that is contrary to Māori values”).

¹⁴⁴⁶ Wai 262 Report I, p. 92.

¹⁴⁴⁷ NZ Patents Act 2013, S. 227 reads: “[t]he Commissioner must consider, but is not bound by, the advice given by the Māori advisory committee”.

¹⁴⁴⁸ New Zealand Patents Act 1953, Act No. 64 of November 26, 1953 (hereafter, Patents Act 1952), S. 17 reads: “[i]f it appears to the Commissioner in the case of any application for a patent that the use of the invention in respect of which the application is made would be contrary to morality, the Commissioner may refuse the application”.

¹⁴⁴⁹ FRANKEL, “Traditional Knowledge and Innovation as a Global Concern” 2015, p. 232.

shall be a presumption of recognition of the *kaitiaki* relationship with *mātauranga* Māori unless it can be proven that other interests deserve priority.

Chapter 4 Final Reflections

The present chapter brings together the conclusions that have been reached in the previous chapters to provide some reflections and recommendations for the continuing endeavour to protect traditional medicinal knowledge of indigenous peoples and local communities.

1 International Minimum Standards

Chapter One of Part III has shown that, at present, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) is the main forum that has established a general consensus amongst States on the need to tackle the issue of the protection of traditional knowledge. This is notwithstanding the fact that most developing countries would rather prefer that this issue be addressed within the WTO system, as it possesses an efficacious formal dispute mechanism to assure compliance with the agreements. However, given the deadlock at the WTO with regard to the issue of protection of traditional knowledge, the WIPO IGC constitutes the more appropriate forum to address this matter. It presents two main advantages. First, while the WIPO is open to indigenous representatives as observers, the WTO is exclusively reserved to Member States. Generally speaking, indigenous peoples present at the WIPO IGC negotiations support an international treaty as long as “the primary objective of the international legal instrument is to protect indigenous peoples’ rights and interests as custodians¹⁴⁵⁰ and guardians of traditional knowledge” and that “the instrument recognises the principle of free, prior and informed consent of indigenous peoples”.¹⁴⁵¹ Second, the latest version of the Draft Articles, issued at its 31st session of 2016, has made substantive advances compared to the first version, issued at its seventh session in 2004. Indeed, the work of the WIPO IGC has evolved from purely

¹⁴⁵⁰ WIPO IGC, ‘Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions’, the Secretariat, 19-23 September 2016, WIPO/GRTKF/IC/31/INF/7, p. 8 (“[t]he term “custodian” in the context of traditional knowledge and cultural expressions refers to those communities, peoples, individuals and other entities which, according to customary laws and other practices, maintain, use and develop the traditional knowledge and cultural expressions. It expresses a notion that is different from “ownership”, since it conveys a sense of responsibility to ensure that the traditional knowledge or cultural expressions are used in a way that is consistent with community values and customary law”).

¹⁴⁵¹ WIPO IGC, ‘Report’, adopted by the IGC, Geneva, 9 - 13 May 2011, WIPO/GRTKF/IC/18/11, para. 380, p. 58.

capacity building activities, passing through a sole focus upon a defensive approach, to culminate in a more positive protection approach, i.e. the tiered approach.

Chapter Two has also shown that a wide variety of issues still remain unresolved within the WIPO Draft Articles on the protection of traditional knowledge. The principal issues at stake include the subject matter of protection, beneficiaries, the scope of protection and the recognition and application of customary laws of indigenous peoples. Some countries have also already enacted legislation for the protection of traditional knowledge and these laws vary considerably from one country to another. This situation alone justifies an international answer encompassing minimum standards. Indeed, an international binding instrument will force Member States to include these minimum standards in their national law if ratified.

At this point, it is still unknown whether the current negotiations will lead to any international instrument within WIPO IGC, not to mention a legally binding instrument.¹⁴⁵² Any success in this endeavour will depend on the right balance between an appropriate degree of flexibility and sufficient legal effectiveness. Even though an international agreement may be enacted within WIPO, it also has to be somehow supported by the WTO system in order to produce some legal effects at the national level.

2 Subject Matter, Beneficiaries of Protection and Scope of Rights

While Part I of this analysis has highlighted the difficulties related to defining the term “traditional knowledge”, Part III has shown that it is crucial to define the subject matter that a legal document aims to protect. The holistic understanding of traditional knowledge by indigenous communities cannot be wholly caught within a provision of a legal instrument, and it would be counterproductive to proceed in this way. As proposed, the all-encompassing vision could be encapsulated into the preamble of the legal document. In addition, the present author has reached the conclusion that the distinction applied by the WIPO IGC with regard to traditional cultural expressions and traditional knowledge *stricto sensu*¹⁴⁵³ is a good

¹⁴⁵² The especially so considering the fact that the WIPO IGC was very close to being abandoned at one stage. See, WIPO GA, ‘Report’, adopted by the 46th session of the GA, 15 January 2015, WO/GA/46/12, para. 173, p. 46 (the GA did not renew the mandate of the IGC for the next biennium).

¹⁴⁵³ WIPO IGC, ‘Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions’, 19-23 September 2016, WIPO/GRTKF/IC/31/INF/7, p. 40 (traditional knowledge *stricto sensu* is defined as “the content or substance of knowledge resulting from intellectual activity in a traditional context, the know-how, skills, innovations, practices and learning that

compromise between an extremely broad concept encompassing all traditional knowledge and a categorisation of traditional knowledge into various sub-categories, including traditional medicinal knowledge, traditional agricultural knowledge and traditional ecological knowledge for instance. We have seen that the WIPO IGC approach provides protection to traditional knowledge *stricto sensu* that fulfils certain minimum eligibility criteria. We have argued that the set of eligibility criteria will have to be determined on the basis of what is unique or common to the knowledge systems of indigenous peoples.

Accordingly, Article 1 of the WIPO IGC Draft Articles should be drafted as follows:

“The subject matter of protection is traditional knowledge:¹⁴⁵⁴

- (a) that is created, and maintained in a collective context, by indigenous peoples and local communities;
- (b) that is distinctively associated with the cultural identity¹⁴⁵⁵ and cultural heritage of indigenous peoples and local communities;
- (c) that is transmitted from generation to generation, whether consecutively or not;
- (d) which may subsist in codified, oral or other forms; and [or]
- (e) which may be dynamic and evolving.”¹⁴⁵⁶

The author considers that paragraphs (c) and (e) are not so pertinent. For instance, transmission from one generation to another is inherent in the term “traditional”. Logically it is dynamic and evolving, otherwise, it would simply disappear.

Chapter Two of Part III also concluded that, first and foremost, any rights relating to the protection of traditional knowledge shall be vested in indigenous and local communities who

form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources”).

¹⁴⁵⁴ As defined in WIPO IGC, ‘Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions’, 19-23 September 2016, WIPO/GRTKF/IC/31/INF/7, p. 40.

¹⁴⁵⁵ See discussion on cultural identity in Part I, Chapter 3, 3.1.1.1; see also WIESSNER, “The Cultural Rights of Indigenous Peoples: Achievements and Continuing Challenges”, 2011, p. 139.

¹⁴⁵⁶ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, The Secretariat, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5, Article 1, p. 7.

are the developers and guardians of the traditional knowledge. The responsibility and authority to determine the beneficiaries shall be equally conferred on indigenous and local communities themselves. For example, there may be historical reasons that could justify a specific group benefiting from protection rather than another group. For instance, in New Zealand, the situation of the Māori, as colonised peoples, places them in a different position compared to other ethnic or minority groups in the country.

As it has been proposed, States home to indigenous and local communities shall permit the establishment of, and provide the administrative support to, a body representing indigenous and local communities' interests.¹⁴⁵⁷ For the author, a Council gathering indigenous experts, recognised and legitimized by the members of each indigenous community at the national level, is the first important step towards any solution for the protection of traditional knowledge. The establishment of such a body is justified by the right of active participation of indigenous peoples recognised in international human rights and environmental law instruments and by courts. This right encompasses the right of prior informed consent, without which any discussion on the protection of traditional knowledge would be voided of all meaning.

Another key role of the Council would be to act as a point of first contact between third parties interested in the use of traditional knowledge, and specifically traditional medicinal knowledge, and the holders or guardians of a given traditional knowledge. Indeed, in the majority of cases, scientists do not know who to approach. It might also be possible that they could enter into discussions with an individual or a community that is not vested with the authority to decide on the modalities for the disclosure of traditional knowledge.

Foremost, the Council will constitute the tool through which indigenous peoples will regain control over the access and use of their traditional knowledge, particularly, and their cultural identity, generally. In other words, the Council will be vested with the responsibility to protect their cultural heritage. However, the Council will need to be supported by State institutions to be efficient. As suggested earlier in this work with regard to the recognition and implementation of customary law into a national order, the State shall adopt an approach supporting a certain degree of legal pluralism within its borders. The study of the selected

¹⁴⁵⁷ This Council could be linked to the United Nations Permanent Forum on Indigenous Issues, see UNPFII website at: <https://www.un.org/development/desa/indigenouspeoples/> [accessed September 2016].

national approaches has shown that this approach is feasible. Peru is one rare country example of having adopted the widest manifestation of legal pluralism.¹⁴⁵⁸ The pluralistic approach of New Zealand is founded on the Treaty of Waitangi that governs the relationship between the Māori and the Crown.¹⁴⁵⁹ Finally, Switzerland as a user country, has also adopted a certain degree of legal pluralism by promoting respect for foreign national laws regarding access to genetic resources and associated traditional knowledge. In other words, Swiss legislation considers that access has been illegal if it has not respected foreign rules on access to genetic resources and/or associated traditional knowledge.¹⁴⁶⁰

Last but not least, the interaction between the Council representing indigenous interests and national bodies has to be based on a partnership.¹⁴⁶¹ Full autonomy is not feasible because other interests have to be put into balance. Again, a case by case approach is preferable in conflicts arising between traditional knowledge holders and patent holders, for instance. Additionally, for such a Council to be workable and effective, it has to interact with other areas of law, namely the intellectual property regime. In other words, there needs to be bridges between them. As suggested throughout this work, the disclosure requirement constitutes a first step towards this goal.

Accordingly, Article 2 of one of the latest WIPO IGC draft¹⁴⁶² should be drafted as follows:

2.1 Beneficiaries of protection are indigenous peoples and local communities.

2.2 Where the subject matter is not claimed by indigenous peoples or local communities, the permanent Council of indigenous peoples or local communities shall pronounce itself within a reasonable time in determining the beneficiaries of the subject matter.

2.3 If no beneficiaries are identified, the Council shall act as custodian of the protected subject matter. Benefits arising from the use of traditional knowledge will be deposited into a fund that the Council will keep in trust.

¹⁴⁵⁸ Political Constitution of Peru, 1993, Article 149.

¹⁴⁵⁹ Treaty of Waitangi Act.

¹⁴⁶⁰ NCHA, Article 23 n.

¹⁴⁶¹ See the principle of partnership in the Treaty of Waitangi.

¹⁴⁶² WIPO IGC, 'The Protection of Traditional Knowledge: Draft Articles', 7-9 July 2014, WIPO/GRTKF/IC/28/5, Article 2.

2.4 The identity of the Council established under paragraph 2 shall be communicated to the International Bureau of the World Intellectual Property Organisation and the United Nations Permanent Forum on Indigenous Issues.

As mentioned earlier in this work,¹⁴⁶³ even with the establishment of a central body of indigenous peoples' experts and representatives, it would not be an easy task to monitor any access and utilisation of traditional knowledge by third parties, above all, across borders.

Finally, it has been shown that the latest WIPO IGC Draft Articles have undergone substantial changes compared to the previous drafts that were essentially based on a misappropriation approach. Article 3 of the Draft refers to the scope of protection and reflects a “tiered approach”; this approach consists of a system of differentiated protection set out in three levels according to the degree of diffusion of traditional knowledge and to the close cultural link between the traditional knowledge and the community practicing or holding it.¹⁴⁶⁴ The author, while recognising that this new approach has the merit of recognising the positive rights of indigenous peoples in the sense of providing them with control over access and use of their knowledge, considers that this new approach has the main shortcoming of only providing this enhanced degree of protection to secret traditional knowledge. The author has argued throughout this work that the scope of rights shall ideally also extend to traditional knowledge that is no longer secret, but that is distinctively held by the indigenous community. In other words, when there is still a close link between the knowledge and the indigenous community.

The author agrees that this criterion is very fluent and flexible. This link has to be determined on a case-by-case analysis by national and regional courts who, in making their decision, will have to take into account the practice and customary rules of indigenous peoples by actively consulting the representative authorities of indigenous communities.

3 Transparency, Prior Informed Consent and Monitoring

In Chapter Three, Part III, the benefits of both establishing a database and introducing a disclosure requirement in the patent system have been analysed with the view to their ability

¹⁴⁶³ Part III, Chapter 2, 2.

¹⁴⁶⁴ WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, 7-9 July 2014, WIPO/GRTKF/IC/28/5, Article 3. The present author considers that the Article should rather be entitled the “scope of rights” instead of “scope of protection”.

to effectively address the main demand of indigenous peoples, that is a regaining of control over the access and use of their traditional knowledge.

For the holder of traditional knowledge, “adequate protection of TK is not necessarily compatible with requirements of dissemination but rather, depends upon restriction of access and use, ideally regulated through the free and prior informed consent of the community, and according to its shared values and relationship to the knowledge in question”.¹⁴⁶⁵

In that sense, databases aim at providing proof of the existence of traditional knowledge and its relationship with a given indigenous community. While databases might prove to be useful to a certain point, their utilisation shall be optional and voluntary and not constitutive of rights. Fundamentally, their adoption has to be in conformity with the customary laws and practices of indigenous peoples whose approval shall be sought. The main risk inherent in the establishment of any database is, in general, the enhanced possibility of losing control over the content and its eventual placing into the public domain.

A disclosure requirement fundamentally aims at assisting indigenous peoples in monitoring the access to, and the use of, their traditional knowledge. As we have seen, this requirement may be designed as either voluntary or mandatory. In contrast to the establishment of databases, however, the disclosure requirement shall be mandatory. A voluntary disclosure requirement will be meaningless and constitute a loss of time.

Fundamentally, for the sake of harmonization and coherence, a disclosure requirement shall be given an international dimension in order to assure a consistent worldwide application.¹⁴⁶⁶ This can be performed either within the context of the WIPO IGC negotiations and/or through the amendment of the TRIPS Agreement.

Even if the disclosure requirement is dealt with internationally, patent offices and courts will still be required to decide whether the access or use of traditional knowledge in another country forms a legitimate basis for a patent application or a granted patent in their jurisdiction. In other words, an international solution will also require states to give domestic

¹⁴⁶⁵ GIBSON, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, 2005, p. 3.

¹⁴⁶⁶ See generally, CORREA and SARNOFF, “Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications”, 2006.

legal effects to foreign jurisdiction's laws and court decisions. Particularly, they will have to determine which jurisdictions' laws should be applied in the assessment of the legitimacy of access and use of traditional knowledge.¹⁴⁶⁷ Ideally, they shall equally take into consideration the customary laws of the holders of traditional knowledge.

This Chapter has also shown that providing and user countries diverge considerably as to the contours and content of the obligation to disclose. These divergences mainly concern three questions.

- (i) What triggers a disclosure requirement?
- (ii) What information shall be disclosed?
- (iii) What are the consequences of a failure to disclose?

As to the first question, we have argued that when an invention is directly based on traditional knowledge, this must be disclosed. In other words, the traditional knowledge must be disclosed when the invention would not exist without the use of traditional knowledge.¹⁴⁶⁸

As to the question relating to the information that shall be disclosed in the patent application, we argued that the applicant must disclose the origin of the traditional knowledge, i.e. the community holding the traditional knowledge.¹⁴⁶⁹ If this information is not known by the

¹⁴⁶⁷ See generally, CHIAROLLA, "The Role of Private International Law under the Nagoya Protocol", 2013, pp. 423-449.

¹⁴⁶⁸ WIPO IGC, 'Initial Draft Report', The Secretariat, 21 March 2016, WIPO/GRTKF/IC/29/8 Prov., para. 232, p. 58 (for the Delegation of Switzerland, the notion of "directly based on" was supposed to describe the relationship between the invention, and the GRs or the TK. An invention which was "directly based on" this would mean an invention that would not exist without the GR or the TK"); see however, WIPO IGC, 'The Declaration of the Source of Genetic Resources and Traditional Knowledge in the Swiss Patent Act and Related Swiss Regulations on Genetic Resources – Submission by Switzerland in Response to Document WIPO/GRTKF/IC/30/9, 19-23 September 2016, WIPO/GRTKF/IC/31/8, para. 25, p. 7 (in this recent document submitted by Switzerland to the WIPO IGC, the representative of Switzerland explained that "[i]n the context of "traditional knowledge", "directly based on" means that the inventor must know that the invention is based on traditional knowledge, that is, that the inventor must have consciously derived the invention from this knowledge").

¹⁴⁶⁹ WIPO IGC, 'The Declaration of the Source of Genetic Resources and Traditional Knowledge in the Swiss Patent Act and Related Swiss Regulations on Genetic Resources – Submission by Switzerland in Response to Document WIPO/GRTKF/IC/30/9, 19-23 September 2016, WIPO/GRTKF/IC/31/8, para. 16, pp. 6-7 (the Swiss Delegation notes that in order to be "[i]n line with UNDRIP and the NP, it seems more

applicant, then he/she must disclose the source from which they have obtained the information. Furthermore, because any solution to protect traditional knowledge has to include the requirement to obtain the prior informed consent of the communities from which the traditional knowledge has originated, their PIC has to be ideally disclosed in the patent application.

Here, the responsibility is placed on the country home to indigenous communities to require third parties to obtain their PIC. This might be problematic if the rights of indigenous communities are not recognised by their homeland. Notwithstanding, the obligation to obtain prior informed consent is enshrined within the obligations of the Nagoya Protocol.¹⁴⁷⁰ This requirement can also be fulfilled, as provided for in the Swiss legislation, at the stage of market authorisation.¹⁴⁷¹

Finally, and probably the most contentious matter, concerns the sanctions in cases of non-compliance with the disclosure requirement. Broadly speaking, the debates can be reduced to the question of whether the sanctions must be provided within or outside the patent system. As highlighted, the solutions adopted by countries are very diverse. While industrialised countries are in favour of civil, administrative or no sanctions at all, the non-industrialised countries are more likely to favour a solution within the patent system. We have argued that the post-grant revocation of a patent is the most effective means to avoid undue appropriation of traditional knowledge. However, as this solution might prove to be difficult to realise, at

appropriate [...] to require patent applicants to disclose the indigenous peoples and local communities holding such knowledge [...] as the primary source”).

¹⁴⁷⁰ Nagoya Protocol, Article 5.5 obliges parties to take measures to share benefits arising from the utilisation of traditional knowledge with no mention of “in accordance with domestic legislation”. The obligation to share the benefits must be done through mutually agreed terms (MAT), which in turn encompasses the requirement of PIC. There would be no MAT without the PIC of indigenous peoples and local communities; Nagoya Protocol, Article 16 calls upon State Parties to “take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located”.

¹⁴⁷¹ NCHA, Article 23o encompasses the obligation to notify when a product uses traditional knowledge.

least in a short to medium term, a compromise solution could be based on an approach distinguishing between pre-grant and post-grant sanctions.

In conclusion, while databases presuppose a remodelling of traditional knowledge to fit the standards of the patent system, namely the International Patent Classification (IPC), the disclosure requirement reflects an attempt to find a certain balance and interdependence between both systems of knowledge.

CONCLUSION

Drawing upon the previous analysis, the legal protection of traditional medicinal knowledge, in particular, and traditional knowledge, in general, should not be defensible solely by virtue of a utilitarianism justification. That is, traditional knowledge, generally, and traditional medicinal knowledge, particularly, should not be protected solely because of their role in the conservation of biological diversity and sustainable use, and even less because they might have some useful industrial application. A large amount of this knowledge might not have any instrumental and commercial potential whatsoever, but this does not make it any less worthy of respect and protection.¹⁴⁷² Indeed, it can be argued that traditional knowledge is a distinct value in itself.¹⁴⁷³ This would otherwise mean that other cultures, as it is the case for traditional communities, are merely valued for the inputs they yield to the dominant culture.¹⁴⁷⁴

The problem faced by indigenous peoples and local communities with regard to the utilisation of their traditional knowledge will not be solely solved with the adoption of national and international instruments. They are, however, an inevitable start. The process towards an effective protection is a progressive one. The key element for this process to reach its goal is the recognition of customary laws and practices of indigenous peoples and local communities both within national laws and by national courts. Any regime that seeks to protect and preserve traditional knowledge must place equal emphasis on indigenous and non-indigenous sources of law. The WIPO Draft *sui generis* protection of traditional knowledge calls on Member States to pay due regard to indigenous peoples customary laws when adopting national laws for the protection of their traditional knowledge.

At the time of writing these conclusions, discussions are principally ongoing within the World Intellectual Property Organization and, marginally, within the World Trade Organization. So far and generally speaking, the deliberations in the IGC have not yet produced any concrete

¹⁴⁷² DUTFIELD, “The public and private domains – Intellectual property rights in traditional knowledge”, 2000, p. 289.

¹⁴⁷³ Wai 262 Report I, p. 89.

¹⁴⁷⁴ NEWMAN, *Community and Collective Rights: A Theoretical Framework for Rights Held by Groups*, 2011, p. 32 (arguing for the existence of moral rights held by groups and a resulting account of how to reconcile group rights with individual rights and with the rights of other groups).

results in the form of an international instrument on the protection of traditional knowledge. Nevertheless, what has been achieved is an awareness among indigenous and local communities about the value of their knowledge assets. In the words of two scholars, “[w]hile significant efforts are taking place towards the development of internationally harmonised approaches, it is not impossible to envisage a break-down of negotiations on the subject due to developed country manoeuvring, widening differences among developing countries, or a realisation among the developing countries that the economic stakes are not as high as they have been led to believe.”¹⁴⁷⁵

The legal protection of traditional knowledge, generally, and the rights of indigenous peoples to their traditional knowledge, particularly, shall receive due consideration from both developing and developed States, independently of their diverging interests. Although the relationship between genetic resources and traditional knowledge has been settled in the Convention on Biological Diversity and crystallized in the Nagoya Protocol, the status of genetic resources and traditional knowledge is far from being equal, and the policy objectives for their protection are not the same. Traditional knowledge, unlike genetic resources before the adoption of the CBD, was not a common property of mankind. It “pertained” to the indigenous community. Similarly, traditional knowledge, unlike genetic resources after the adoption of the CBD and the TRIPS Agreement, is neither subject to State sovereignty, nor in the public domain, but pertains to traditional knowledge holders. While biodiversity taken as a whole has become a valuable resource that is already the subject of international trade, the same shall not be true for traditional knowledge that is a fundamental component of indigenous cultural rights and identity. Why not consider traditional knowledge of indigenous peoples as a part of their collective right to personality, i.e. as an attribute of their dignity, instead of simply knowledge that has fallen into the realm of the public domain?

This study has also intended to demonstrate that use of publicly available traditional knowledge shall not have the same legal consequences as publicly available knowledge in the context of the intellectual property system. While publicly available common knowledge is freely available to be used, this shall not be the case for publicly available traditional

¹⁴⁷⁵ McMANIS and TERÀN, “Trends and Scenarios in the Legal Protection of Traditional Knowledge”, 2011, p. 139; See also WIPO GA, ‘Report’, adopted by the 46th session of the GA, 15 January 2015, WO/GA/46/12, para. 173, p. 46 (the GA made did not renew the mandate of the IGC for the next biennium).

knowledge that continues to be under the stewardship of indigenous communities or the so-called *kaitiaki* relationship.¹⁴⁷⁶

The protection of traditional knowledge will not be solely achieved through exclusive ownership rights as known in Western legal frameworks. As we have seen, the concerns of indigenous peoples are directed towards the use of their traditional knowledge and the cultural components of their identity and integrity without their acknowledgement, let alone their proper consent. This work has argued that any solution directed at protecting indigenous peoples interests shall be first directed towards the right of indigenous peoples to provide prior informed consent. In the context of the intellectual property system, generally, and patents, particularly, only an international mandatory disclosure requirement with minimum standards of application will constitute an effective first step toward the achievement of this goal.

The author admits that a mandatory disclosure requirement, as proposed in this work, might add some burden to patent applicants in a short term. This potential constraint has to be weighed against the long term advantages of such a solution, which will prove to enhance legal security and partnership among stakeholders. Indeed, the empowerment of indigenous peoples with regard to their knowledge will restore a climate of confidence among indigenous groups toward States, private entities and research institutions, and will act as an incentive to unveil knowledge and facilitate its wider utilisation, including for the discovery of new medicines.¹⁴⁷⁷

¹⁴⁷⁶ See Part III, Chapter 3, Section 3.3.

¹⁴⁷⁷ See also BIBER-KLEMM et al., *Access and Benefit-Sharing in Latin America and the Caribbean – A science-policy dialogue for academic research*, 2014, p. 16.

REFERENCES

Books and Articles

A

ABBOTT Frederick, "Protecting the First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework", *Vanderbilt Journal of Transnational Law*, 1989, vol. 22(4), pp. 689-745.

ABBOTT Frederick, COTTIER Thomas and GURRY Francis, *The international intellectual property system: commentary and materials*, Kluwer Law International, The Hague, vol. I and II, 1999 (ABBOTT et al., *The international intellectual property system: commentary and materials*, 1999).

ABRAMOWICZ Michael and DUFFY John, "The Inducement Standard of Patentability", *Yale Law Journal*, 2011, vol. 120(7), pp. 1590-1897.

ADDOR Félix, "Switzerland's Proposals for Disclosure of the Source of Genetic Resources and Traditional Knowledge in Patent Applications; and Views on Prior Informed Consent and Benefit Sharing in Patent Applications", in CHOUCHENA-ROJAS Martha et al., (eds.), *Disclosure Requirements: Ensuring Mutual Supportiveness Between the WTO TRIPS Agreement and the CBD*, IUCN, Gland, 2005, pp. 35-41.

ADDOR Félix and GIRSBERGER Martin, "How to Address the Disclosure Requirement at the International Level", 2005, *ICTSD Bridges Review*, No. 9, pp. 18-19.

AGGARWAL Bharat et al., "Synthesis, characterization and *in vitro* anticancer activity of C-5 curcumin analogues with potential to inhibit TNF-alpha-induced NF-KappaB activation", *Biomed Research International*, vol. 2014, 10 pages. Available on open access: <http://www.hindawi.com/journals/bmri/2014/524161/> [accessed September 2016].

AGRAWAL Arun, "Indigenous Knowledge and the Politics of Classification", *International Social Science Journal*, 2002, vol. 54(173), pp. 287-297.

AHRÉN Matthias, “Indigenous peoples’ culture, customs, and traditions and customary law: The Saami people’s perspective”, *Arizona Journal of International and Comparative Law*, 2004, vol. 21(1), pp. 63-112.

ALSTON Philip, “Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann”, *European Journal of International Law*, 2002, vol. 13(4), pp. 815-844.

AKHONDZADEH et al., “*Crocus sativus* L. in the treatment of mild to moderate depression: a double-blind, randomized and placebo-controlled trial”, *Phytotherapy Research*, 2005, vol. 19(2), pp. 148-151.

AMIOTT Jennifer, Investigating the Convention on Biological Diversity’s Protection for Traditional Knowledge, *Missouri Environmental Law and Policy Review*, 2011, No. 11, pp. 3-37.

ANAYA James, *Indigenous Peoples in International Law*, Oxford University Press, Oxford, 1996.

ANAYA James and WILLIAMS Robert, “The protection of indigenous peoples land and resource rights under the Inter-American Human Rights System”, *Harvard Human Rights Journal*, 2001, vol. 14, pp. 33-86.

ANAYA James, *International Human Rights and Indigenous Peoples*, Wolters Kluwer Law & Business, Austin, 2009.

ANGHIE Anthony, *Imperialism, sovereignty and the making of international law*, Cambridge University Press, Cambridge, 2009.

ARAB FERNANDEZ Teresa, *Cultural Identity Revisited: Early Twentieth-Century Women’s Work of Cultural Preservation*, Ph.D., University of Kansas, 2007. (Mourning Dove)

AREWA Olufunmilayo, “Piracy, Biopiracy and Borrowing: Culture, Cultural Heritage and the Globalization of Intellectual Property”, *The Berkeley Electronic Press (bepress) Legal Series*, 2006, paper 1114, pp. 1-85.

ARORA Ashih et al., “Markets for technology, intellectual property rights, and development”, in MASKUS Keith and REICHMAN Jerome (eds.), *International Public*

Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime, Cambridge University Press, 2005, pp. 321-336.

AUBERTIN Catherine and MORETTI Christian, “La biopiraterie, entre illégalité et illégitimité” in AUBERTIN Catherine et al. (eds.), *Les marchés de la biodiversité*, IRD, Paris, 2007, pp. 91-120.

AUSTIN Graeme, “Re-Treating Intellectual Property? The Wai 262 Proceeding and the Heuristics of Intellectual Property Law”, *Cardozo Journal of International and Comparative Law*, 2003, vol. 11, pp. 333-363.

B

BAGLEY Margo, “Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World”, *Minnesota Law Review*, 2003, vol. 87(3), pp. 679-742.

BAGLEY Margo, “The New Invention Creation Activity Boundary in Patent Law”, *William & Mary Law Review*, 2009, vol. 51(2), pp. 577-608.

BAGLEY Margo, *International Patent Law and Policy*, West Academic, St. Paul, Minnesota, 2013.

BAGLEY Margo, “Of Disclosure “Straws” and Patent System “Camels”: Patents, Innovation, and the Disclosure of Origin Requirement”, in ROBINSON, ABDEL-LATIF and ROFFE (eds.), *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge Press, forthcoming 2016).

BAGLEY Margo and RAI Arti, “The Nagoya Protocol and Synthetic Biology Research: A Look at the Potential Impacts, University of Virginia School of Law”, *Public Law and Legal Theory Research Paper Series*, 2014-05, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2388794 [accessed September 2016].

BALICK Michael, “Ethnobotany and the Identification of Therapeutic Agents from the Rainforest”, in DHADWICK Derek and Marsh Joan (eds.), *Bioactive Compounds from Plants*, John Wiley and Sons, New York, 1990, pp. 22-31.

BARELLI Mauro, “The Role of Soft Law in the International Legal System: The Case of the United Nations Declaration on the Rights of Indigenous Peoples”, *International and Comparative Law Quarterly*, 2009, vol. 58(4), pp. 957-983.

BARELLI Mauro, “The United Nations Declaration on the Rights of Indigenous Peoples: A Human Rights Framework for Intellectual Property Rights”, in RIMMER Matthew (ed.), *Indigenous Intellectual Property – A Handbook of Contemporary Research*, Edward Elgar, Cheltenham, 2015, pp. 47-63.

BARSH Russel Lawrence, “The Epistemology of Traditional Healing Systems”, *Human Organization*, 1997, vol. 56(1), pp. 28-37.

BARSH Russel Lawrence, “How do you patent a landscape? The perils of dichotomizing cultural and intellectual property”, *International Journal of Cultural Property*, 1999, vol. 8(1), pp. 14-47.

BAUD Sébastien et GHASARIAN Christian, *Des plantes psychotropes - Initiations, thérapies et quêtes de soi*, Imago, Paris, 2013.

BEDERMAN David, *Custom as a Source of Law*, Cambridge University Press, New York, 2010.

BEITER Klaus, “Establishing Conformity between TRIPS and Human Rights: Hierarchy in International Law, Human Rights Obligations of the WTO and Extraterritorial State Obligations under the International Covenant on Economic, Social and Cultural Rights”, in ULLRICH, HILTY et al. (eds.), *TRIPS plus 20: From Trade Rules to Market Principles*, Springer, Heidelberg, 2016, pp.445-505.

BELCARO Gianni et al., “Efficacy and safety of Meriva, a Curcumin-phosphatidylcholine Complex, during Extended Administration in Osteoarthritis Patients”, *Alternative Medicine Review*, 2010, vol. 15(4), pp. 337-344.

BELL Catherine, STATT Graham and the Mookakin Cultural Society, “Repatriation and Heritage Protection: Reflections on the Kainai Experience” in BELL Catherine and VAL Napoleon (eds.), *First Nations Cultural Heritage and Law – Case Studies, Voices and Perspectives*, UBC Press, Toronto, 2008, pp. 203-257.

BENSAMOUN Alexandra, LABARTHE Françoise, TRICOIRE Agnès, *L'Oeuvre de l'esprit en question(s) – Un exercice de qualification*, Actes de colloque, Mare & Martin, 2015.

BERKES Fikret, "Traditional Ecological Knowledge in Perspective", in INGLIS Julian (ed.), *Traditional Ecological Knowledge: Concepts and Cases*, International Development Research centre, Ottawa, 1993, pp. 1-9.

BESSA APARECIDA Adriana, *Traditional Local Communities in International Law*, PhD Thesis, European University Institute, Florence, 2013.

BIBER-KLEMM Susette, et al., "The current law of plant genetic resources and traditional knowledge", in BIBER-KLEMM Susette and COTTIER Thomas (eds.), *Rights to plant genetic resources and traditional knowledge: Basic issues and perspectives*, CABI, Cambridge, 2006, pp. 56-111.

BIBER-KLEMM Susette et al., *Access and Benefit-Sharing in Latin America and the Caribbean – A science-policy dialogue for academic research*, DIVERSITAS, ICSU-ROLAC, SCNAT, IUBS, 2014.

BIRKBECK Carolyn, *The World Intellectual Property Organization (WIPO) – A Reference Guide*, Edward Elgar, Cheltenham, 2016.

BLAKENEY Michel, "The Protection of Traditional Knowledge under Intellectual Property Law", *European Intellectual Property Review*, 2000, vol. 22(6), pp. 251-261.

BODEKER Gerard, "A Public Health Agenda for Traditional Complementary, and Alternative Medicine", *American Journal of Public Health*, October 2002, vol. 92(10), pp. 1582-1591.

BODEKER Gerard, "Traditional Medical Knowledge, Intellectual Property Rights and Benefit-Sharing", *Cardozo Journal of International and Comparative Law*, 2003, vol. 11, pp. 785-813.

BOIS-MARIAGE Frédérick, "Ayahuasca: Une Synthèse Interdisciplinaire", *Psychotropes*, 2002, vol. 8(1), pp. 79-113.

BOLDRIN Michele and LEVINE David, "The Case Against Intellectual Property", *the American Economic Review*, 2002, vol. 92(2), pp. 209-212.

BOLDRIN Michele and LEVINE David, “Perfectly Competitive Innovation”, *Journal of Monetary Economics*, 2008, vol. 55(3), pp. 435-453.

BONADIO Enrico, “Patents and Morality in Europe”, in CALBOLI Irene and RAGAVAN SRIVIDHYA (eds.), *Diversity in Intellectual Property – Identities, Interests, and Intersections*, Cambridge University Press, Cambridge, 2015, pp. 149-168.

BOYLE Alan and CHINKIN Christine, *The Making of International Law*, Oxford University Press, Oxford, 2007.

BOYLE James, *Shamans, software, and Spleens – Law and the Construction of the Information Society*, Harvard University Press, Cambridge, 1996.

BOYLE James, “The Second Enclosure Movement and the Construction of the Public Domain”, *Law and Contemporary Problems*, 2003, vol. 66(1-2), pp. 33-74.

BOYLE James, *The Public Domain – Enclosing the Commons of the Mind*, Yale Press University, New Haven, 2008.

BOZA Rafael, “Chester James Taylor 2007 Award Winner: Protecting Andean Traditional Knowledge and Biodiversity Perspectives under the US – Peru Trade Promotion Agreement”, *International Trade Law Journal*, 2008, vol. 16(3), pp. 76-93.

BOZICEVIC Karl, “Distinguishing Products of Nature from Products Derived from Nature”, *Journal of the Patent and Trademark Office Society*, 1997, vol. 69, pp. 415-426.

BRADFORD Simon, “Intellectual Property and Traditional Knowledge: A Psychological Approach to Conflicting Claims of Creativity in International Law”, *Berkeley Technology Law Journal*, 2005, vol. 20(3), pp. 1613-1684.

BROWN Michael, “Can culture be copyright?”, *Current Anthropology*, 1998, vol. 39(2), pp. 193-222.

BROWN Michael, *Who owns native culture?*, Harvard University Press, Cambridge, 2004.

BROWN Michael, “Culture, Property, and Peoplehood: A Comment on Carpenter, Katyal, and Riley’s “In Defense of Property”, *International Journal of Cultural Property*, 2010, vol. 17, pp. 569-579.

BRENDLER Thomas and WYK van, Ben-Erik, “A Historical, Scientific and Commercial Perspective on the Medicinal Use of *Pelargonium Sidoides* (Geraniaceae)”, *Journal of Ethnopharmacology*, 2008, vol. 119(3), pp. 420-433.

BRUSH Stephen, “Whose Knowledge, Whose Genes, Whose Rights?”, in BRUSH Stephen and STABINSKY Doreen (eds.), *Valuing Local Knowledge – Indigenous People and Intellectual Property Rights*, Island Press, Washington D.C., 1996, pp. 1-23.

BURELLI Thomas, “De la conservation de la biodiversité à l’émergence des droits de la propriété intellectuelle autochtones : la reconnaissance progressive de l’apport des savoirs autochtones et leur protection en droit international”, in KROLIK Christophe and NADAUD Séverine (eds.), *L’environnement au secours du développement économique et social*, Les chroniques de l’OMIJ, PULIM, 2015, pp. 181-199.

BURGER Julian, “The UN Declaration on the Rights of Indigenous Peoples: From Advocacy to Implementation”, in ALLEN Stephen and XANTHAKI Alexandra (eds.), *Reflections on the UN Declaration on the Rights of Indigenous Peoples*, Hart Publishing, Oxford, 2010, pp. 41-59.

BURK Dan and LEMLEY Mark, “Fence Posts or Sign Posts? Rethinking Patent Claim Construction”, *University of Pennsylvania Law Review*, 2009, vol. 157 (6), pp. 1743-1799

BURTON Geoff, “Implementation of the Nagoya Protocol in JUSCANZ Countries: The Unlikely Lot”, in MORGERA, TSIOUNMANI and BUCK (eds.), in MORGERA, TSIOUNMANI and BUCK (eds.), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges*, Brill, 2013, vol. 1, pp. 295-329.

C

CABRERA MEDAGLIA Jorge, “The Implementation of the Nagoya Protocol in Latin America and the Caribbean: Challenges and Opportunities” in MORGERA, TSIOUNMANI and BUCK (eds.), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges*, Brill, 2013, vol.1, pp. 331-368.

CAENEGEM Van, William, “The Public Domain: Scientia Nullius?”, *European Intellectual Property Review*, 2002, vol. 24(6), pp. 324-330.

CANDEIRA LAGO Alejandro and SILVESTRI Luciano, “Challenges in the Implementation of the Nagoya Protocol from the Perspective of a Member State of the European Union: The Case of Spain”, in MORGERA, TSIOUNMANI and BUCK (eds.), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges*, Brill, 2013, vol.1, pp. 270-294.

CARMEN Andrea, “The Right to Free, Prior, and informed Consent – A Framework for Harmonious Relations and New Process for Redress” in JOFFE and PRESTON (eds.), *Realizing the UN Declaration on the Rights of Indigenous Peoples*, Purich Publishing, 2010, p. 120.

CARPENTER Kristen, KATYAL Sonia and RILEY Angela, “In Defense of Property”, *Yale Law Journal*, 2009, vol. 118, pp. 1022-1125.

CARPENTER Kristen, KATYAL Sonia and RILEY Angela, “Clarifying Cultural Property”, *International Journal of Cultural Property*, 2010, vol. 17, pp. 581-598.

CARR Jonhathan, “Agreements that Divide: TRIPS v. CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications”, *Journal of Transnational law & policy*, 2008, vol. 18(1), p. 131-154.

CARVALHO DE Nuno Pires, “From the Shaman’s Hut to the Patent Office: How Long and Winding is the Road?”, *Review of the Brazilian Association of Intellectual Property*, 1991, vol. 41, pp. 3-17.

CARVALHO DE Nuno Pires, “Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution”, *Washington University Journal of Law & Policy*, 2000, vol. 2, pp. 371-395.

CARVALHO DE Nuno Pires, “From the Shaman’s Hut to the Patent Office: In search of Effective Protection for Traditional Knowledge”, Paper presented at the Conference Biodiversity and Biotechnology and the Protection of Traditional Knowledge, Washington University School of Law Center for Interdisciplinary Studies, 4-6 April 2003.

CARVALHO DE Nuno Pires, “From the Shaman’s Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent”, *Washington University Journal of Law & Policy*, 2005, vol. 17, pp. 111-186.

CARVALHO DE Nuno Pires, “From the Shaman’s Hut to the Patent Office: A Road Under Construction”, in McMANIS Charles (ed.), *Biodiversity and the Law – Intellectual Property, Biotechnology and Traditional Knowledge*, Earthscan, London, 2007, pp. 241-279.

CARVALHO DE, Nuno Pires, *The Trips Regime of Patents and Test Data*, Kluwer Law International, The Hague, 2014, 4th ed.

CASSESE Antonio, *Self-Determination of Peoples: A Legal Reappraisal*, Cambridge University Press, Cambridge, 1995.

CHAMBERS David and GILLESPIE Richard, “Locality in the History of Science: Colonial Science, Technoscience, and Indigenous Knowledge”, *Osiris*, 2000, vol. 15, pp. 221-240.

CHANDER Anupman and SUNDER Madhavi, “The Romance of the Public Domain”, *California Law Review*, 2004, vol. 92, pp. 1331-1373.

CHARTER and STAVENHAGE, “The UN Declaration on the Rights of Indigenous Peoples: How it Came to be and What it Heralds”, in CHARTERS and STAVENHAGEN (eds.), *Making the Declaration Work: The United Nations Declaration on the Rights of Indigenous Peoples*, IWGIA, Copenhagen, 2009, pp. 10-15.

CHEN Jim, “There’s No Such Thing as Biopiracy ... And It’s a Good Thing Too”, *McGeorge Law Review*, 2006, vol. 37(1), pp. 1-32.

CHENNELLIS Roger, “Strengthening Partnership between States and Indigenous Peoples: Treaties, Agreements and other Constructive Arrangements: The Hoodia Case”, UN OHCHR, Geneva, 16-17 July 2012, UN Doc. HR/GENEVA/SEM/EXPERT/2012/BP.8.

CHENNELLIS Roger, “Traditional Knowledge and Benefit Sharing after the Nagoya Protocol: Three Cases from South Africa”, *Law Environment and Development Journal*, 2013, vol. 9(2), pp. 163-185.

CHIAROLLA Claudio, “The Role of Private International Law under the Nagoya Protocol”, in MORGERA, TSOUNAKIS and BUCK (eds.), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges*, Brill, 2013, vol. 1, pp. 423-449.

CLARK Susanna, RUIZ Manuel, and LAPEÑA Isabel, “The Protection of Traditional Knowledge in Peru: A Comparative Perspective”, *Washington University Global Studies Law Review*, 2004, Vol. 3(3), pp. 755-796.

CLAVERO Bartolomé, “The Indigenous Rights of Participation and International Development Policies”, *Arizona Journal of International & Comparative Law*, 2005, vol. 22(1), pp. 41-51.

CLIFT Charles, “Is Intellectual Property Protection a Good Idea?”, in SILLITOE Paul (ed.), *Local Science vs. Global Science: Approaches to Indigenous Knowledge in International Development*, Studies in Environmental Anthropology and Ethnobiology, vol. 4, Berghahn Books, New York, 2007, pp. 191-208.

CLIFT Charles, “Why IPR Issues were Brought to GATT: A Historical Perspective on the Origin of TRIPS”, in CORREA (ed.), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO*, Vol. I, Edward Elgar, Cheltenham, 2010, pp. 3-21.

COHEN Julie E., “Copyright, Commodification, and Culture: Locating the Public Domain” in GUIBAULT Lucie and HUGENTHOLTZ Bernt (eds.), *The Future of the Public Domain – Identifying the Commons in Information Law*, Kluwer Law International, 2006, pp. 121-166.

CONFORTO David, “Traditional and Modern-Day Biopiracy: Redefining the Biopiracy Debate”, *Journal of Environmental Law & Litigation*, 2004, vol. 19(2), pp. 358-397.

CONSTANZA Jennifer, “Indigenous Peoples’ Right to Prior Consultation: Transforming Human Rights from the Grassroots in Guatemala”, *Journal of Human Rights*, 2015, vol. 14(2), pp. 260-285.

COOMBE Rosemary, *The cultural life of intellectual properties: authorship, appropriation, and the law*, Duke University Press, Durham, 1998.

COOMBE Rosemary, “Comments” on the Article written by BROWN Michael, “Can culture be copyright?”, *Current Anthropology*, 1998, vol. 39(2), pp. 193-222.

CORNISH William, LLEWELYN David, and APLIN Tanya, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, Sweet & Maxwell, London, 2013, 8th ed.

CORREA Carlos, *Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries*, South Centre, Geneva, 2002.

CORREA Carlos, “Update on International Developments Relating to the Intellectual Property Protection of Traditional Knowledge including Traditional Medicine”, South Centre Working Paper, 2004, No. 18.

CORREA Carlos and SARNOFF Joshua, *Analysis of options for implementing disclosure of origin requirements in intellectual property applications*, UNCTAD, Geneva, 2006.

CORREA Carlos, *Trade Related Aspects of Intellectual Property – A Commentary on the TRIPS Agreement*, Oxford University Press, 2007.

CORREA Carlos, *A Guide to Pharmaceutical Patents*, The South Centre, Geneva, 2012.

CORSON Timothy and CREWS Craig, “Molecular Understanding and Modern Application of Traditional Medicines: Triumphs and Trials”, *Cell*, vol. 130(5), pp. 769-774.

COTTIER Thomas and PANIZZON Marion, “Legal perspectives on traditional knowledge: The case for intellectual property protection”, in MASKUS KEITH and REICHMAN JEROME (eds.), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime*, Cambridge University Press, 2005, pp. 565-594.

COTTIER Thomas and PANIZZON Marion, “A new generation of IPR for the protection of traditional knowledge in PGR for food, agricultural and pharmaceutical uses”, in BIBER-KLEMM Susette and COTTIER Thomas (eds.), *Rights to plant genetic resources and traditional knowledge: Basic issues and perspectives*, CABI, Cambridge, 2006, pp. 203-238.

COTULA Lorenzo and MAYERS James, *Tenure in REDD: Start-Point or Afterthought?*, International Institute for Environment and Development, 2009.

COYLE Sean, “Property rights, environmental justice and worldly order – lessons from natural law”, in GREAR Anna and KOTZÉ Louis (eds.), *Research handbook on human rights and the Environment*, Edward Elgar, Cheltenham, 2015, pp. 102-120.

CRAGG Gordon and NEWMAN David, “Natural Products as sources of new drugs over the last 25 years”, *Journal of Natural Products*, 2007, vol. 70(3), pp. 461-477.

CRAGG Gordon and NEWMAN David, “Natural Products: A Continuing Source of Novel Drug Leads”, *Biochimica et Biophysica ACTA*, 2013, vol. 1830(6), pp. 3670-3695.

CRAIG Richard, “Intellectual Property Protection of *Pelargoniums*”, *HortTechnology*, 1993, vol. 3(3), pp. 284-290.

CULLET Philippe, “Patents and medicines: the relationship between TRIPS and the human right to health”, *International Affairs*, 2003, vol. 79(1), pp. 139-160.

CULLET Philippe, *Intellectual Property Protection and Sustainable Development*, Butterworths, New Delhi, 2005.

CULLET Philippe et al., “Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge”, in BIBER-KLEMM Susette and COTTIER Thomas (eds.), *Rights to plant genetic resources and traditional knowledge: Basic issues and perspectives*, CABI, Cambridge, 2006, pp. 112-154.

CULLET Philippe, “Human Rights and Intellectual Property Protection in the TRIPS Era”, *Human Rights Quarterly*, 2007, vol. 29(2), pp. 403-430.

CULLET Philippe, “Environmental Justice in the Use, Knowledge and Exploitation of Genetic Resources”, in EBBESSON Jonas and OKOWA Phoebe (eds.), *Environmental Law and Justice in Context*, Cambridge University Press, Cambridge, 2009, pp. 371-389.

CUSKELLY Katrina, *Customs and Constitutions: State Recognition of Customary Law around the World*, International Union for Conservation of Nature (IUCN), Bangkok, 2011.

D

DAES Erica-Irene, ‘On the concept of “indigenous people”, Working Paper by the Chairperson-Rapporteur’, 10 July 1996, UN Doc. E/CN.4/Sub.2/AC.4/1996/2.

DAES Erica-Irene, ‘Indigenous Peoples’ Permanent Sovereignty Over Natural Resources’, Final Report of the Special Rapporteur, Erica-Irene Daes, 12 July 2004, UN Doc. E/CN.4/Sub.2/2004/30/Add.1.

DAES Erica-Irene, “The Contribution of the Working Group on Indigenous Populations to the Genesis and Evolution of the UN Declaration on the Rights of Indigenous Peoples”, in CHARTERS and STAVENHAGEN (eds.), *Making the Declaration Work: The United Nations Declaration on the Rights of Indigenous Peoples*, IWGIA, Copenhagen, 2009, pp. 48-77.

DALY Angela, “Legislation on biopiracy in Europe: too little, too late?”, in RIMMER Matthew (ed.), *Indigenous Intellectual Property – A Handbook of Contemporary Research*, Cheltenham, Edward Elgar, 2015, pp. 365-381.

DEMSETZ Harold, “Towards a theory of property rights”, *The American Economic Review*, 1967, vol. 57(2), pp. 347-359.

DESSEMONTET François, *La propriété intellectuelle et les contrats de licence*, CEDIDAC, Lausanne, 2011, 2nd ed.

DIAZ-POLANCO Hector, *Elogio de la diversidad: globalizacion, multiculturalismo y etnofagia*, Siglo xxi editors, Mexico, 2002.

DIMASI Joseph and PAQUETTE Cherie, “The Economics of Follow-on Drug Research and Development: Trends in Entry Rates and the Timing of Development”, *Pharmaeconomics*, 2004, vol. 22(2), pp. 1-14.

DJIMS Milius, “Justifying Intellectual Property in Traditional Knowledge”, *Intellectual Property Quarterly*, 2009, No. 2, pp. 185-216.

DOLDER Fritz, “Analysis of the European Patent Law – Traditional knowledge and patenting: the experience of the neemfungicide and the hoodia case”, *Biotechnology Law Report*, 2007, vol. 26(6), pp. 583-590.

DOLDER Fritz, “Patente auf der Grundlage traditioneller Kenntniss indigener Gemeinschaften”, in CHRISTOPH et al. (eds.), *Materialles Patentrecht – Festschrift für Reimar König zum 70. Geburtstag*, Carl Heymanns Verlag KH, Berlin, 2002, pp. 81-100.

DOMÉIJ Bengt, *Pharmaceuticals Patents in Europe*, Kluwer Law International, The Hague, 2000.

DOSI Giovanni and STIGLITZ Joseph, “The Role of Intellectual Property Rights in the Development Process, with Some Lessons from Developed Countries: An Introduction”, in CIMOLI et al. (eds.), *Intellectual Property Rights – Legal and Economic Challenges for Development*, Oxford University Press, Oxford, 2014, pp. 1-53.

DOWNES David, “How Intellectual Property could be a Tool to Protect Traditional Knowledge”, *Columbia Journal of Environmental Law*, 2000, vol. 25, pp. 253-282.

DRAHOS Peter, *A philosophy of intellectual property*, Ashgate, Hampshire, 1996.

DRAHOS Peter, “Indigenous Knowledge and the Duties of Intellectual Property Owners”, *Intellectual Property Journal*, 1997, vol. 11, pp. 170-201.

DRAHOS Peter, “Biotechnology Patents, Markets and Morality”, *European Intellectual Property Review*, 1999, vol. 21(9), pp. 441-449.

DRAHOS Peter, *The Global Governance of Knowledge – Patent Offices and their Clients*, Cambridge University Press, 2010.

DRAHOS Peter, *Intellectual Property, Indigenous People and their Knowledge*, Cambridge University Press, Cambridge, 2014.

DREWS Jürgen, “Drug Discovery: A Historical Perspective”, *Science*, 2000, vol. 287(5460), pp. 1960-1964.

DROSS Miriam and WOLF Franziska, *New Elements of the International Regime on Access and Benefit-Sharing of Genetic Resources – The Role of Certificates of Origin*, Federal Agency for Nature Conservation, Bonn, 2005.

DUCOULOMBIER Peggy, “Interaction between human rights: Are all human rights equal?” in GEIGER Christophe (ed.), *Research Handbook on Human Rights and Intellectual Property*, Cheltenham, Elgar, 2015, pp. 39-51.

DUCOR Philippe, “New Drug Discovery Technologies and Patents”, *Rutgers Computer and Technology Law Journal*, 1996, vol. 22, pp. 369-477.

DUNAND Jean-Philippe, SCHMIDLIN Bruno and WINIGER Bénédict, *Droit privé romain*, Helbing Lichtenhahn, Basel, 2012, 2nd ed.

DUSOLLIER Séverine, “Inclusivity in intellectual property” in DINWOODIE Graeme (ed.), *Intellectual Property and General Legal Principles – Is IP a Lex Specialis?*, Edward Elgar, Cheltenham, 2015, pp. 101-118.

DUTFIELD Graham, “Rights, Resources and Responses” in POSEY Darrell (ed.), *Cultural and Spiritual Values of Biodiversity*, United Nations Environment Programme, Nairobi, 1999, p. 505-515.

DUTFIELD Graham, “The Public and Private Domains – Intellectual Property Rights in Traditional Knowledge”, *Science Communication*, 2000, vol. 21(3), pp. 274-295.

DUTFIELD Graham, “TRIPS-Related Aspects of Traditional Knowledge”, *Case Western Reserve Journal of International Law*, 2001, vol. 22(2), pp. 233-275.

DUTFIELD Graham, *Protecting Traditional Knowledge and Folklore. A Review of Progress in Diplomacy and Policy Formulation*, ICTSD, Geneva, 2003, p. 47.

DUTFIELD Graham, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, Earthscan, London, 2004.

DUTFIELD Graham, ‘Harnessing Traditional Knowledge and Genetic Resources for Local Development and Trade’, International Seminar on Intellectual Property and Development, WIPO, Geneva, 2005.

DUTFIELD Graham, “Legal and Economic Aspects of Traditional Knowledge”, in MASKUS KEITH and REICHMAN JEROME (eds.), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime*, Cambridge University Press, 2005, pp. 495-520.

DUTFIELD Graham, “Protecting the Rights of Indigenous Peoples: Can Prior Informed Consent Help?” in WYNBERG Rachel et al. (eds.), *Indigenous Peoples, Consent and Benefit-Sharing: Lessons from the San-Hoodia Case*, Springer, New York, 2009, pp. 53-68 (DUTFIELD, “Protecting the Rights of Indigenous Peoples: Can Prior Informed Consent Help?”, 2009).

DUTFIELD Graham, “A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-Based Biopiracy”, *European Intellectual Property Review*, 2011, vol. 33(4), pp. 38-244.

E

EBERMANN Petra, *Patents as Protection of Traditional Medicinal Knowledge? A Law and Economic Analysis*, European Studies in Law and Economics, Intersentia, Cambridge, 2012.

EGEA Vincent, “Innovation et droits fondamentaux: un conflit de valeurs?” in CERVETTI Pierre-Dominique (ed.), *L’innovation à l’épreuve de la mondialisation – Réflexions autour d’un droit de l’innovation en devenir*, Presse Universitaires d’Aix-Marseille, 2015, pp. 187-195.

EISENBERG Rebecca and HELLER Michael, “Can patents Deter Innovation? The Anticommons in Biomedical Research”, *Science*, 1998, vol. 280, pp. 698-710.

EISENBERG Rebecca, “Pharma’s Nonobviousness Problem”, *Lewis & Clark Law Review*, 2008, vol. 12(2), pp. 375-430.

ENGLE Karen, *The Elusive Promise of Indigenous Development – Rights, Culture and Strategy*, Duke University Press, London, 2010.

ETKIN Nina and ROSS Paul, “Recasting Malaria, Medicine, and Meals: A perspective on Disease Adaptation”, in Romanucci-Ross et al. (eds.), *The Anthropology of Medicine*, Praeger, New York, 1991, pp. 230-258. (trouver l’article)

F

FARNSWORTH Norman et al, “Medicinal Plants in Therapy”, *Bulletin of the WHO*, 1985, vol. 63(6), pp 965-981.

FARNSWORTH Norman and FABRICANT Daniel, “The Value of Plants Used in Traditional Medicine for Drug Discovery”, *Environmental Health Perspectives*, 2001, vol. 109(1), pp. 69-75 (FARNSWORTH and FABRICANT, “The Value of Plants Used in Traditional Medicine for Drug Discovery”).

FECTEAU Leanne, “The Ayahuasca Patent Revocation: Raising Questions About Current U.S. Patent Policy”, *Boston College Third World Law Journal*, 2001, vol. 21(1), pp. 69-104.

FEHER Miklos and SCHMIDT Jonathan, “Property distributions: Differences between Drugs, Natural Products, and Molecules from Combinatorial Chemistry”, *Journal of Chemical Information and Computer Sciences*, 2003, vol. 43 (1), pp. 218-227.

FINETTI Claudia, “Traditional Knowledge and the Patent System: Two Worlds Apart?”, *World Patent Information*, 2011, vol. 33, pp. 58-66.

FISHER William, “Theories of Intellectual Property”, in MUNZER (ed.), *New Essays in the Legal and Political Theory of Property*, Cambridge University Press, Cambridge, 2001.

FITZMAURICE Malgosia, “The question of indigenous peoples’ rights: a time for reappraisal?”, in FRENCH Duncan (ed.), *Statehood and Self-Determination – Reconciling Tradition and Modernity in International Law*, Cambridge University Press, Cambridge, 2013, pp. 349-376.

FRANKEL Susy and Richardson Megan, “Cultural Property and the Public Domain Case Studies form New Zealand and Australia” in ANTONS Christophe (ed.), *Traditional Knowledge, Traditional Cultural Expressions and Intellectual Property Law in the Asia-Pacific Region*, Kluwer Law International, The Netherlands, 2009, pp. 275-292.

FRANKEL Susy, “‘Ka Mate Ka Mate’and the protection of traditional knowledge”, in DREYFUSS Rochelle and GINSBURG Jane (eds.), *Intellectual Property at the Edge – The Contested Contours of IP*, Cambridge University Press, 2014, pp. 193-214.

FRANKEL Susy, “Traditional Knowledge and Innovation as a Global Concern”, in GERVAIS Daniel (ed.), *International Intellectual Property – A Handbook of Contemporary Research*, Elgar, Cheltenham, 2015, pp. 217-245.

FRANKEL Susy, “Using Intellectual Property Rules to Support the Self-Determination Goals of Indigenous Peoples” in GEIGER Christophe (ed.), *Research Handbook on Human Rights and Intellectual Property*, Cheltenham, Elgar, 2015, pp. 627-640.

FRANKEL Susy and GERVAIS Daniel, *Advanced Introduction to International Intellectual Property*, Edward Elgar, Cheltenham, 2016.

FROW John, “Public Domain and Collective Rights in Culture”, *Intellectual Property Journal*, 1998, vol. 13, pp. 39-52.

FROW John, “Public Domain and the New World Order in Knowledge”, *Social Semiotics*, 2000, vol. 10(2), pp. 173-185.

G

GASNIER Jean-Pierre, “Innovation, culture et patrimoine mondial” in CERVETTI Pierre-Dominique (ed.), *L’innovation à l’épreuve de la mondialisation – Réflexions autour d’un droit de l’innovation en devenir*, Presse Universitaires d’Aix-Marseille, 2015, pp. 217-239.

GEORGE Alexandra, *Constructing Intellectual Property*, Cambridge University Press, 2014.

GERVAIS Daniel, “Spiritual but not intellectual? The Protection of Sacred Intangible Traditional Knowledge”, *Cardozo Journal of International and Comparative Law*, 2003, vol. 11, pp. 467-495.

GERVAIS Daniel, “Traditional Knowledge & Intellectual Property: A TRIPS-Compatible Approach”, *Michigan State Law Review*, 2005, pp. 137-166.

GERVAIS Daniel, *L’Accord sur les ADPIC*, Larcier, Bruxelles, 2010.

GERVAIS Daniel, *The TRIPS Agreement: Drafting History and Analysis*, Sweet & Maxwell, London, 2012, 4th ed.

GEX Maude, “Le divin profane par Da Vine? La contestation du brevet sur l’ayahuasca et les débats autour de la biopiraterie”, *Political Science Working Paper Series*, No 46, University of Lausanne, 2010.

GIBSON Johanna, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, Ashgate Publishing, 2005 (GIBSON, *Community Resources – Intellectual Property, International Trade and Protection of Traditional Knowledge*, 2005).

GIBSON Johanna, “Audiences in Traditions: Traditional Knowledge and the Public Domain” in WAEDELDE Charlotte and MACQUEEN Hector (eds.), *Intellectual Property – The Many Faces of Public Domain*, Edward Elgar, 2007, pp. 174-188.

GIBSON Johanna, “Community Rights to Culture: The UN Declaration on the Rights of Indigenous Peoples”, in ALLEN Stephen and XANTHAKI Alexandra (eds.), *Reflections on the UN Declaration on the Rights of Indigenous Peoples*, Hart Publishing, Oxford, 2010, pp. 433-453.

GIRSBERGER Martin, *Biodiversity and the Concept of Farmers’ Rights in International Law – Factual Background and Legal Analysis*, Peter Lang, Berne, 1999.

GIRSBERGER Martin, “Transparency Measures under Patent Law Regarding Genetic Resources and Traditional Knowledge – Disclosure of Source and Evidence of Prior Informed Consent and Benefit-Sharing”, *Journal of World Intellectual Property*, 2004, vol. 7(4), pp. 451-489.

GIRSBERGER Martin, *Certificates of Source – Disclosure of Source*, in *Proceedings of the International Expert Workshop on Access to Genetic Resources and Benefit Sharing*, October 24-27 2004, Final Report, Environment Canada and CONABIO, 2004, pp. 141-146.

GIRSBERGER Martin and MÜLLER Benny, “International trade in indigenous cultural heritage: and IP practitioners’ perspective”, in GRABER Christoph, KUPRECHT Karolina and LAI Jessica (eds.), *International Trade in Indigenous Cultural Heritage: Legal and Policy Issues*, Cheltenham, Edward Elgar, 2012, pp. 175-195.

GLOWKA Lyle et al., “A Guide to the Convention on Biological Diversity”, *Environmental Policy and Law Paper* No. 30, IUCN, Gland, 1999, 3rd ed.

GODT Christine, “The Multi-Level Implementation of the Nagoya Protocol in the European Union” in COOLSAET Brendan et al. (eds.), *Implementing the Nagoya Protocol – Comparing Access and Benefit-Sharing Regimes in Europe*, Brill, Leiden, 2015, vol. 3, pp. 308-327.

GOHARI Ahmad Reza et al., “An Overview on Saffron, Phytochemicals, and Medicinal Properties”, *Pharmacognosy Reviews*, vol. 7(13), pp. 61-66.

GOODMAN Ryan and JINKS Derek, “Measuring the Effects of Human Rights Treaties”, *European Journal of International Law*, 2003, vol. 14(1), pp. 171-183.

GORDON Veronica, “Appropriation without Representation? The Limited Role of Indigenous Groups in WIPO’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, And Folklore”, *Vanderbilt Journal of Entertainment and Technology Law*, 2014, vol. 16(39), pp. 629-639.

GORLIN Jacques, *An Analysis of the Pharmaceutical-Related Provisions of the WTO TRIPS Agreement*, IP Institute, London, 1999.

GREENE Shane, “Indigenous People Incorporated? Culture as Politics, Culture as Property in Pharmaceutical Bioprospecting”, *Current Anthropology*, 2004, vol. 45(2), pp. 211-237.

GREENE Shane, *Customizing Indigeneity*, Stanford University Press, 2009.

GREENWOOD D., “The Quinine Connection”, *Journal of Antimicrobial Chemotherapy*, 1992, vol. 30(4), pp. 417-427.

GREER Steven, “What’s Wrong with the European Convention on Human Rights?” *Human Rights Quarterly*, 2008, vol. 30(3), pp. 680-702.

GREENFIELD Michael, ‘Recombinant DNA Technology: A Science Struggling with the Patent Law’, *Intellectual Property Law Review*, 1992, pp. 1051-1094.

GREIBER Thomas, MORENO Sonia Peña, KAMAU Evanson, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing*. Gland: IUCN, 2012.

GRIFFITHS John, “What is Legal Pluralism?” *Journal of Legal Pluralism*, 1986, vol. 24(1), pp. 1-55.

GROTH Stephan, “Negotiating Tradition. The Pragmatics of International Deliberations on Cultural Property”, *Göttingen Studies in Cultural Property*, vol. 4, 2012.

GRUBB Philip and THOMSEN Peter, *Patents for Chemicals, Pharmaceuticals, and Biotechnology – Fundamentals of Global Law, Practice, and Strategy*, Oxford University Press, 5th ed., 2010.

GUIBAULT Lucie and HUGENHOLTZ Bernt, *The Future of the Public Domain: Identifying the Commons in Information Law*, Kluwer Law International, The Netherlands, 2006.

GUILLOD Olivier, *Le consentement éclairé du patient : autodétermination ou paternalisme ?*, Ides et Calendes, Neuchâtel, 1986.

GUILLOD Olivier, *Le consentement dans tous ses états*, Actes du Colloque de Paris, Dalloz, Paris, 2014, pp. 1-15.

GUILLOD Olivier, “Le statut de la médecine traditionnelle chinoise (MTC) en droit suisse”, in LECA, SHEN and JIN (eds.), *Le droit de la Médecine chinoise dite “traditionnelle”*, Les cahiers de droit de la santé No 20, Les Études Hospitalières Éditions, Bordeaux, 2015, pp. 337-355.

GUPTA Ranjan et al., “Nature’s Medicines: Traditional Knowledge and Intellectual Property Management. Case Studies from the National Institutes of Health (NIH), USA”, *Current Drug Discovery Technologies*, 2005, vol. 2(4), pp. 203-219.

GUPTA Vinod Kumar, “India’s TKDL: Definition and Classification of Intangible Cultural Heritage and Traditional knowledge in the Context of Inventory”, in KONO Toshiyuki (ed.), *Intangible Cultural Heritage and Intellectual Property: Communities, Cultural Diversity and Sustainable Development*, Intersenia, Antwerp, 2009, pp. 101-111.

H

HAHN Anja von, *Traditionelles Wissen indigener und lokaler Gemeinschaften zwischen gestiegen Eigentumsrechten und der “Public Domain”*, Springer, Berlin, 2004.

HAHN Anja von and STOLL Peter-Tobias, “Indigenous peoples, knowledge and resources in international law” in LEWINSKI (ed.), *Indigenous heritage and intellectual property – Genetic resources, traditional knowledge and folklore*, Kluwer Law International, The Netherlands, 2008, 2nd ed., pp. 7-58.

HAMBURGER Matthias and HOSTETTMAN Kurt, “Bioactivity in Plants: The Link between Phytochemistry and Medicine”, *Phytochemistry*, 1991, vol. 30(12), pp. 3864-3874.

HART H.L.A., *The concept of Law*, 2nd ed., Clarendon Press, Oxford, 1997.

HARVEY Alan, “Medicines from nature: are natural products still relevant to drug discovery?”, *Trends in Pharmacological Sciences*, 1999, vol. 20(5), pp. 196-198

HARVEY Alan, “Natural Products in Drug Discovery”, *Drug Discovery Today*, 2008, vol. 13(19/20), p. 894-901.

HATHAWAY Oona, “Do Human Rights Treaties Make a Difference?”, *The Yale Law Journal*, 2002, vol. 111(8), pp. 1935-2042.

HAUNSS Sebastian, *Conflicts in the Knowledge Society – The Contentious Politics of Intellectual Property*, Cambridge University Press, 2013.

HAYDEN Cori, *When Nature Goes Public: The Making and Unmaking of Bioprospecting in Mexico*, Princeton University Press, Princeton, 2003.

HAYES Katherine, “Three Years Post-KSR: A Practitioner’s Guide to “Winning” Arguments on Obviousness and a Look at What May Lay Ahead”, *Northwestern Journal of Technology and Intellectual Property*, 2010, vol. 9(3), pp. 243-262.

HARDIN Garrett, “The Tragedy of Commons”, *Science*, 1968, vol. 162(3859), pp. 1243-1248

HEALD Paul, “The Rhetoric of Biopiracy”, *Cardozo Journal of International and Comparative Law*, 2003, vol. 11, pp. 519-544.

HEINRICH Peter, *PatG/EPÜ - Schweizerisches Patentgesetz/Europäisches Patentübereinkommen: Kommentar in synoptischer Darstellung*, 2nd ed., Staempfli, Bern 2010.

HELPER Laurence, “Human Rights and Intellectual Property: Conflict or Coexistence?”, *Minnesota Intellectual Property Review*, 2003, vol. 5(1), pp. 47-61.

HELPER Laurence and AUSTIN Graeme, *Human Rights and Intellectual Property: Mapping the Global Interface*, Cambridge University Press, Cambridge, 2011.

HELLER Michael, “The Tragedy of the Anticommons: A Concise Introduction and Lexicon”, *The Modern Law Review*, 2013, vol. 76(1), pp. 6-25.

HELLIO Hughes, “Le Protocole de Nagoya: reconnaissance internationale du droit des communautés autochtones et locales aux ressources génétiques de leur environnement ou passer à l'impossible application équitable?” in COURNIL Christel et al. (eds.), *Changements environnementaux globaux et droits de l'homme*, Bruylant, 2012.

HENNINGER Thomas, “Disclosure Requirements in Patent Law and Related Measures – A Comparative overview of existing national and regional legislation on IP and Biodiversity”, document presented at Diálogo Centroamericano sobre medidas relacionadas con la biodiversidad y el sistema PI, Costa Rica, 17-19 November 2009, ICTSD.

HERMITTE Marie-Angèle and KAHN P (dir.), *Les Ressources génétiques végétales et le droit dans les rapports Nord/Sud*, Bruylant, 2004.

HEY Ellen, *Advanced Introduction to International Environmental Law*, Edward Elgar, Cheltenham, 2016.

HILTY Reto, “Rationales for the legal protection of intangible goods and cultural heritage”, Max Planck Institute for Intellectual Property, Competition and Tax Law, 2009, Research Paper Series No. 09-10, pp. 1-25.

HOEKMAN Bernard and KOSTECKI Michel, *The Political Economy of the World Trading System: The WTO and Beyond*, Oxford University Press, 2009, 3rd ed.

HOSSEINZADEH Hossein and NASSIRI Marjan, “Avicenna’s (Ibn Sina) the canon of medicine and saffron (*Crocus Sativus*): a review”, *Phytotherapy Research*, 2013, vol. 27(4), pp. 475-483).

HU Albert and JAFFE Adam, “Lessons from the Economics Literature on the Likely Consequences of International Harmonization of IPR protection”, in CIMOLI Mario et al.

(eds.), *Intellectual Property Rights – Legal and Economic Challenges for Development*, Oxford University Press, Oxford, 2014, pp. 89-110.

HUFT Michael, “Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights”, *Northwestern University Law Review*, 1995, vol. 89, pp. 1678-1722.

HUFTY Marc, SCHULT Tobias and TSCHOPP Maurice, “The Role of Switzerland in the Nagoya Protocol Negotiations”, in OBTERTHÜR and ROSENDAL (eds.), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol*, Routledge, New York, 2014, pp. 96-113.

I, J

JANICKE, Paul, “A Commentary on the New Patent Law of the United States”, *Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil (GRUR Int)*, 2011, vol. 11, pages 887-894.

JOHNSON Martha, *LORE: Capturing Traditional Ecological Knowledge*, International Development Research Centre, Ottawa, 1992.

JUSTIN Malbon, LAWSON Charles, DAVISON Mark, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights: A Commentary*, Edward Elgar, Cheltenham, 2014.

K

KADIDAL Shayana, “United States Patent Prior Art Rules and the Neem Controversy: A Case of Subject-matter Imperialism”, *Biodiversity and Conservation*, 1998, vol. 7(1), pp. 27-39.

KAMAU Evanson, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing*, IUCN Gland, 2012.

KAMAU Evanson, “The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and What are the Implications for Provider and User Countries and the Scientific Community”, *Law Environment and Development Journal*, 2010, vol. 6(3), pp. 246-262.

KARI Moyer-Henry, “Patenting Neem and Hoodia: Conflicting Decisions Issued by the Opposition Board of the European Patent Office”, *Biotechnology Law Report*, 2008, vol. 27(1), pp. 1-10.

KIENE Tobias, *The Legal Protection of Traditional Knowledge in the Pharmaceutical Field – An Intercultural Problem on the International Agenda*, Waxmann, Münster, 2011.

KINGSTON David, “Modern Natural Products Drug Discovery and its Relevance to Biodiversity Conservation?”, *Journal of Natural Products*, 2011, vol. 74(3), pp. 49-511.

KISHI Sandra, “PIC in Access to TK in Brazil” in KAMAU Evanson and WINTER Gerd (eds.), *Genetic Resources, Traditional Knowledge and the Law*, Earthscan, London, 2009, pp. 311-325.

KOESTER Viet, ‘The Nagoya Protocol on ABS: Ratification by the EU and its Member States and Implementation Challenges’, IDDRI Study No 03/12 June 2012.

KÖKLÜ Kaya and NÉRISSON Sylvie, “How Public is the Public Domain? The Perpetual Protection of Inventions, Designs and Works by Trademarks?”, in ULLRICH and HILTY et al. (eds.), *TRIPS plus 20: From Trade Rules to Market Principles*, Springer, Heidelberg, 2016, pp.561-579.

KOOPMAN Jerzy, “Bumps and Bends in the Road to Intellectual Property for Traditional Knowledge: On Knowledge Models, Legal Orders and the Anti-commons in Biotechnology”, in GROSHEIDE and BRINKHOF (eds.), *Intellectual Property Law, 2004: Articles on Crossing Borders Between Traditional and Actual*, Intersentia, Antwerp, 2005, pp. 247-277.

KOOPMAN Jerzy, “Amidst Peril and Progress: Conservation of Diversity and Patent Law”, in BOGERS et al. (eds.), *Medicinal and Aromatic Plants: Agricultural, Commercial, Ecological, Legal, Pharmacological and Social Aspects*, Springer, Dordrecht, 2006, pp. 129-154.

KOUTOUKI Konstantia and BIEBERSTEIN von Katarina, “The Nagoya Protocol: Status of Indigenous and Local Communities”, Legal Working Paper Series, CISDL, 2011, pp. 1-19.

KRAUS Daniel, BUNN Tony and MULDER Michel, *Requirements for Access to Affordable and Efficacious Traditional Medicine(s)*, Editions Weblaw, Berne, 2008.

KRAUS Daniel, BUNN Tony and STIRNER Beatrice, “Traditional Medicine(s): Definitions and Terminology”, in KRAUS et al. (eds.), *Requirements for Access to Affordable and Efficacious Traditional Medicine(s)*, Editions Weblaw, Berne, 2008, pp. 5-15.

KRAUS Daniel and GHASSEMI Leila, Commentaire des articles 9 et 9a, 32, 35a et 35b, 36 à 40e et 49a de la Loi sur les brevets d'invention in de WERRA and GILLIERON (eds.), *Commentaire romand de propriété intellectuelle (PI) - Loi sur le droit d'auteur, Loi sur la protection des marques, Loi sur les designs, Loi sur les brevets*, Helbing et Lichtenhahn, Bâle, 2013.

KUEI-JUNG Ni, “Legal Aspects of Prior Informed Consent on Access to Genetic Resources: An Analysis of Global Lawmaking and Local Implementation toward an Optimal Normative Construction”, *Vanderbilt Journal of Transnational Law*, 2009, vol. 42, pp. 227-278.

KUHLEN Rainer, “Universal Access – Wem gehört Wissen?”, in Heinrich-Böll-Stiftung (eds.), *Gut zu Wissen – Links zur Wissensgesellschaft*, Westfälisches Dampfboot, Münster, 2002, pp. 164-197.

KUHLEN Rainer, “Knowledge and Information – Private Property or Common Good? A Global Perspective”, in ANDORNO Roberto et al. (eds.), *Ethics and Law of Intellectual Property – Current Problems in Politics, Science and Technology*, Ashgate, London, 2009 pp. 213-230.

KHUN Tomas, *The Structure of Scientific Revolution*, University of Chicago Press, Chicago, 2012, 4th ed.

KUPRECHT Karolina, *Indigenous Peoples’ Cultural Property Claims – Repatriation and Beyond*, Doctoral Thesis University of Lucerne, Springer, 2014.

KURTH James, “Western Civilization, our tradition”, *Intercollegiate Review*, 2003/2004, vol. 39, pp. 5-13.

L

LAI Jessica Christine, “Māori Traditional Knowledge and the Wai 262 Report: A Coherent Way Forward?”, i-call working paper, *Communications & Art Law Lucerne*, No. 2012/03.

LAI Jessica Christine, *Indigenous Cultural Heritage and Intellectual Property Rights – Learning from the New Zealand Experience?*, Springer, London, 2014.

LAIRD Sarah and TEN KATE Kerry, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, Earthscan, London, 1999.

LAIRD Sarah, “Medicinal Plants in International Trade: Conservation and Equity Issues”, in ELISABETSKY and ETKIN (eds.) *Ethnopharmacology - Encyclopedia of Life Support Systems*, EOLSS Publishers, Oxford, 2005, vol. II, pp. 241-257.

LAIRD Sarah and WYNBERG Rachel, “The Commercial Use of Biodiversity: An Update on Current Trends in Demand for Access to Genetic Resources and Benefit-Sharing, and Industry Perspectives on ABS Policy Implementation”, UNEP, CBD WG-ABS, Granada, 30 January – 3 February 2006, UNEP/CBD/WG-ABS/4/INF/5 (LAIRD and WYNBERG, “The Commercial Use of Biodiversity: An Update on Current Trends in Demand for Access to Genetic Resources and Benefit-Sharing, and Industry Perspectives on ABS Policy Implementation”, 2006, UNEP/CBD/WG-ABS/4/INF/5).

LAIRD Sarah et al., “The Interweave of People and Place: Biocultural Diversity in Migrant and Indigenous Livelihoods around Mount Cameroon”, *International Forestry Review*, 2011, vol. 13(3), pp. 275-293.

LAIRD Sarah, *Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Pharmaceutical Industry*, Secretariat of the Convention on Biological Diversity, 2013.

LANDES William and POSNER Richard, *The Economic Structure of Intellectual Property Law*, The Belknap Press of Harvard University Press, Cambridge, 2003.

LANGE David, “Recognising the Public Domain”, *Law and Contemporary Problems*, 1981, vol. 44(4), pp. 147-178.

LANGE David, “Reimagining the Public Domain”, *Law and Contemporary Problems*, 2003, vol. 66(3), pp. 463-483

LAURIE Graeme, “Patenting Stem Cells of Human Origin”, *European Intellectual Property Review*, 2004, vol. 26(2), pp. 59-66.

LEE Edward, “The Public’s Domain: the Evolution of Legal Restraints on the Government’s Power to Control Public Access through Secrecy or Intellectual Property”, *Hastings Law Journal*, 2003, vol. 55, pp. 91-209.

LEE Roberta and BALICK Michael, “Indigenous Use of Hoodia Gordonii and Appetite Suppression”, *Explore: the Journal of Science and Healing*, 2007, vol. 3(4), pp. 404-406.

LEMLEY Mark, “Reconceiving Patents in the Age of Venture Capital”, *Journal of Small and Emerging Business Law*, 2000, vol. 4(1), pp. 137-148.

LEMLEY Mark and BURK Dan, “The Patent Crisis and How the Courts Can Solve It”, *The University of Chicago Press*, Chicago, 2009.

LEMLEY Mark, MENELL Peter and MERGES Robert, *Intellectual Property in the New Technological Age*, 2016, *Volume I: Perspectives, Trade Secrets and Patents*, Stanford Public Law Working Paper No. 2780190.

LENK Christian, “Exclusive Property Rights in the Biosciences: An Ethical Discussion”, in ANDORNO Roberto et al. (eds.), *Ethics and Law of Intellectual Property – Current Problems in Politics, Science and Technology*, Ashgate, London, 2007 pp. 123-135.

LÉVI-STRAUSS Claude, *La Pensée Sauvage*, Librairie Plon, Paris, 1962.

LEWINSKI von, Silke, *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore*, 2nd ed., Wolters Kluwer, Austin, 2008.

LEWINSKY von Silke, “Comments on Susy Frankel: ‘Ka Mate Ka Mate’ and the protection of traditional knowledge – an international perspective”, in DREYFUSS Rochelle and Ginsburg Jane (eds.), *Intellectual Property at the Edge – The Contested Contours of IP*, Cambridge University Press, 2014, pp. 215-224.

LI Jesse et al., “Drug discovery and Natural Products: End of an Era or an Endless Frontier?”, *Science*, 2009, vol. 325, pp. 161-165.

LI Xuan and LI Weiwei, “Inadequacy of Patent Rgime on Traditional Medicinal Knowledge – A Diagnosis of 13-Year Traditional Medicinal Knowledge Patent Experience in China”, *The Journal of World Intellectual Property*, 2007, vol. 10(2), pp. 125-148.

LINDSAY Mark, “Target Discovery”, *Nature Reviews Drug Discovery*, 2003, vol. 2, pp. 831-838.

LITMAN Jessica, “The Public Domain”, *Emory law Journal*, 1990, vol. 39, pp. 965-1023.

LOCKE John and SHERMAN Charles Lawton, *Treatise of Civil Government and A Letter Concerning Toleration*, Appleton-Century Company, London, 1937.

LONG Doris Estelle, “Traditional Knowledge and the Fight for the Public Domain”, *The John Marshall Review of Intellectual Property Law*, 2006, vol. 5, pp. 317-329.

LUZZATTO Enrico, “Traditional Knowledge and Patents: A Brief Summary of the EPO’s Perspective” *Pacific Studies*, 2013, vol. 36(1/2), pp. 14-28 (LUZZATTO, “Traditional Knowledge and Patents”).

M

MAGALLANES Catherine, “Reflecting on cosmology and environmental protection: Maori cultural rights in Aotearoa New Zealand”, in GREAR Anna and KOTZÉ Louis (eds.), *Research handbook on human rights and the Environment*, Edward Elgar, Cheltenham, 2015, pp. 275-308.

MAHOP Marcelin, *Intellectual Property, Community Rights and Human Rights – The biological and genetic resources of developing countries*, Routledge, New York, 2010.

MAINA Charles, “Power Relations in the Traditional Knowledge Debate: A Critical Analysis of Forums”, *International Journal of Cultural Property*, 2011, vol. 18(2), pp. 143-178.

MAHOP Marcelin, *Intellectual Property, Community Rights and Human Rights – The biological and genetic resources of developing countries*, Routledge, New York, 2010.

MALZBENDER Daniel et al., *Traditional water governance and South Africa's "National Water Act" – Tension or cooperation?*, International Workshop on 'African water laws: plural legislative frameworks for rural water management in Africa', Johannesburg, 26-28 January 2005.

MARINOVA Dora and RAVEN Margaret, "Indigenous Knowledge and Intellectual Property: A Sustainability Agenda", *Journal of Economic Surveys*, 2006, vol. 20(4), pp. 587-605.

MASKUS Keith and REICHMAN Jerome, "The Globalisation of Private Knowledge Goods and the Privatisation of Global Public Goods", *Journal of International Economic Law*, 2004, vol. 7(2), pp. 279-320.

MAY Christopher, "The World Intellectual Property Organisation and the Development Agenda", *Global Society*, 2008, vol. 22(1), pp. 97-113.

MAY Christopher, *The World Intellectual Property Organisation: Resurgence and the Development Agenda*, Routledge, London, 2009.

MAY Christopher, *The Global Political Economy of Intellectual Property Rights: The New Enclosures*, Routledge, London, 2010, 2nd ed.

MAY Christophe, "Towards an Affirmative Public Domain", *Cultural Studies*, 2014, vol. 28(5-6), pp. 997-1021.

McHUGH Paul, *Aboriginal Title: The Modern Jurisprudence of Tribal land Rights*, Oxford University Press, Oxford, 2011.

McMANIS Charles and TERÀN Yolanda, "Trends and Scenarios in the Legal Protection of Traditional Knowledge" in WONG Tzen and DUTFIELD Graham (eds.), *Intellectual Property and Human Development – Current Trends and Future Development*, Cambridge University Press, 2011, p. 139-172.

MEIJKNECHT Anna, *Towards International Personality: The Position of Minorities and Indigenous Peoples in International Law*, Intersentia, Oxford, 2001.

MERGERS Robert and NESLON Richard, "On the Complex Economics of Patent Scope" in RAI Arti (ed.), *Intellectual Property and Biotechnology*, Elgar Research Collection, Cheltenham, 2011, pp. 31-110.

- MEYER Anja, “International Environmental Law and Human Rights: Towards the Explicit Recognition of Traditional Knowledge”, *Review of European, Comparative and International Environmental Law*, 2001, vol. 10(1), pp. 37-46.
- MGBEOJI Ikechi, *Global Biopiracy – Patents, Plants, and Indigenous Knowledge*, Cornell University Press, New York, 2006.
- MIN Yan, “Morality: An Equivocal Area in the Patent System”, *European Intellectual Property Review*, 2012, vol. 34(4), pp. 261-265.
- MONKS N.R. et al, “Natural Products Genomics: A novel approach for the discovery of anti-cancer therapeutics”, *Journal of Pharmacological and Toxicological Methods*, 2011, vol. 64(3), p. 217-225.
- MORGERA Elisa, TSIOUNMANI Elsa, “The Evolution of Benefit-Sharing: Linking Biodiversity and Communities’ Livelihoods”, *Review of European Community and International Environmental Law*, 2010, vol. 19(2), pp. 150-173.
- MORGERA Elisa, TSIOUNMANI Elsa, BUCK Matthias (eds.), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges*, Brill, Leiden, 2013, vol. 2.
- MORGERA Elisa, TSIOUNMANI Elsa, BUCK Matthias, *Unravelling the Nagoya Protocol – A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, BRILL, Leiden, 2014, vol. 1.
- MUELLER Janice, “Chemicals, Combinations, and “Common Sense”: How the Supreme Court’s KSR Decision Is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases”, University of Pittsburgh School of Law, *Legal Studies Research Paper Series*, Working Paper No. 2008-7, December 2007.
- MUNYI Peter and JONAS Harry, “Implementing the Nagoya Protocol in Africa: Opportunities and Challenges for African Indigenous Peoples and Local Communities”, in MORGERA, TSIOUNMANI and BUCK (eds.), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges*, Brill, 2013, vol. 1, pp. 217-246.

N

NARBY Jeremy and HUXLEY Francis, *Anthologie du chamanisme – Cinq cents ans sur la piste du savoir*, Albin Michel, 2002.

NASRI Hamid et al., “Turmeric: A Spice with Multifunctional Medicinal Properties”, *Journal of HerbMed Pharmacology*, 2014, vol. 3(1), pp. 5-8.

NDULO Muna, “African customary law, customs, and women’s rights”, *Indiana Journal of Global Legal Studies*, 2011, vol. 18(1), pp. 87-120.

NELSEN Robert and BISHOP Hans, “New Patent Law Would Trash Disease Cures”, in *FORBES*, 24 March 2015.

NEWMAN Dwight, *Community and Collective Rights: A Theoretical Framework for Rights Held by Groups*, Hart, Oxford, 2011.

NIJAR Gurdial Singh et al., *Framework Study on Food Security and Access and Benefit-sharing for Genetic Resources for Food and Agriculture*, CGRFA Background Study Paper No. 42, Rome, September 2009.

NIJAR Gurdial Singh, “Incorporating Traditional Knowledge in an International Regime on Access to Genetic Resources and Benefit Sharing: Problems and Prospects”, *European Journal of International Law*, 2010, vol. 21(2), pp. 457-475.

NIJAR Gurdial Singh, “The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries”, *South Centre, Research Papers*, No. 36, March 2011.

NIJAR Gurdial Singh, “Traditional Knowledge Systems, International Law and National Challenges: Marginalization or Emancipation”, *European Journal of International Law*, 2013, vol. 24(4), pp. 1205-1221.

NIJAR Gurdial Singh, “An Asian Developing Country’s View on Implementation Challenges”, in MORGERA, TSIOUNMANI and BUCK (eds.), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges*, Brill, 2013, vol. 1, pp. 247-268.

NOIVILLE Christine, “Aspect juridique: droit d’accès aux ressources biologiques et partage des avantages”, in GUEZENNEC Jean, MORETTI Christian, et al. (eds.), *Substances naturelles en Polynésie française*, Institut de Recherche pour le Développement (IRD), Montpellier, 2006, second part.

NOJI Eric, “The Global Resurgence of Infectious Diseases”, *Journal of Contingencies and Crisis Management*, 2001, vol. 9(4), pp. 223-232.

NVAUCHE Enyinna, “The Swakopmund Protocol and community Ownership and Control of Expressions of Folklore in Africa”, *The Journal of World Intellectual Property*, 2014, vol. 17(5-6), pp. 191-201.

O

OBTERTHÜR Sebastian and ROSENDAL Kristin, “Global Governance of Genetic Resources: Background and Analytical Framework”, in OBTERTHÜR and ROSENDAL (eds.), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol*, Routledge, New York, 2014, pp. 1-17.

OGUAMANAM Chidi, *International Law and Indigenous Knowledge: Intellectual Property, Plant Biodiversity and Traditional Medicine*, University of Toronto Press, Toronto, 2006.

OGUAMANAM Chidi, “Patents and Traditional Medicine: Digital Capture, Creative Legal Interventions, and the Dialectics of Knowledge Transformation”, *Indiana Journal of Global Legal Studies*, 2008, vol. 15, pp. 489-528.

OGUAMANAM Chidi, *Intellectual Property in Global Governance. A Development Question*, Routledge, London, 2013.

OLDHAM Paul and BURTON Geoff, “Defusing Disclosure in Patent Applications: A positive strategy to strengthen legal certainty in the Nagoya Protocol and support WIPO’s IGC”, 2010.

OLIVA María Julia, “Private Standards and the Implementation of the Nagoya Protocol: Defining and Putting in Practice Due Diligence in the EU Regulation on ABS”, in

COOLSAET Brendan et al. (eds.), *Implementing the Nagoya Protocol – Comparing Access and Benefit-Sharing Regimes in Europe*, Brill, Leiden, 2015, vol. 3, pp. 280-307.

ORANGE Claudia, *An Illustrated History of the Treaty of Waitangi*, Bridget Williams Books, Wellington, 2004.

OTIS Ghislain, “Territoriality, Personality, and the Promotion of Aboriginal Legal Traditions in Canada”, in Law Commission of Canada (ed.), “Indigenous Legal Traditions”, University of British Columbia Press, Vancouver, 2007, pp. 136-168.

OVIEDO Gonzalo, MAFFI Luisa and LARSEN Peter, *Indigenous and Traditional Peoples of the World and Ecoregion Conservation – An integrated Approach to Conserving the World’s Biological and Cultural Diversity*, WWF, Gland, 2000.

P

PARDO-DE-SANTAYANA and MACIA, “Biodiversity: The Benefits of Traditional Knowledge”, *Nature*, 2015, vol. 518 (7540), pp. 487-488.

PATWARDHAN Bhushan, “Traditional knowledge patents: New guidelines or deterrents?”, *Journal of Ayurveda and Integrative Medicine*, 2013, vol. 4(1), pp.1-3.

PAVONI Riccardo, “The Nagoya Protocol and WTO Law” in MORGERA, TSIOUNMANI and BUCK Matthias (eds.), in MORGERA, TSIOUNMANI and BUCK (eds.), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges*, Brill, 2013, vol. 1, pp. 185-213.

PERRAULT Anne, “Facilitating Prior Informed Consent in the Context of Genetic Resources and Traditional Knowledge”, *Sustainable Development Law & Policy*, 2004, vol. 4(2), pp. 21-26.

PERRY Robin, “Balancing Rights or Building Rights? Reconciling the Right to Use Customary Systems of Law with Competing Human Rights in Pursuit of Indigenous Sovereignty”, *Harvard Human Rights Journal*, 2011, vol. 24, pp. 71-114.

PETERSMANN Ernst-Ulrich, “The WTO Constitution and Human Rights”, *Journal of International Economic Law*, 2000, vol. 3(1), pp. 19-25.

PETERSMANN, “Time for a United Nations “Global Compact” for integrating human rights into the law of Worldwide Organisations: Lessons from European Integration”, *European Journal of International Law*, 2002, vol. 13(3), pp. 621-650).

PILA Justine, *The Requirement of an Invention in Patent Law*, Oxford University Press, Oxford, 2010.

PLOMER, “Human Dignity and Patents”, in GEIGER (ed.), *Research Handbook on Human Rights and Intellectual Property*, Cheltenham, Elgar, 2015, pp. 479-495.

PLOTKIN Mark, “Traditional Knowledge of Medicinal Plants – The Search For New Jungle Medicines” in AKRELE et al., *Conservation of Medicinal Plants*, Cambridge University Press, Cambridge, 1991, pp. 53-64.

POSEY Darrell and DUTFIELD Graham, *Beyond Intellectual Property – Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*, International Research Development Centre, Ottawa, 1996.

POSEY Darrell, DUTFIELD Graham et al., *Traditional Resource Rights: International Instruments for Protection and Compensation for Indigenous Peoples and Local Communities*, IUCN, Gland, 1996.

POSEY Darrell, “Biological and Cultural Diversity: The Inextricable, Linked by Language and Politics”, in MAFFI Luisa (ed.), *On Biocultural Diversity: Linking Language, Knowledge, and the Environment*, Smithsonian Institution Press, 2001, in Part III.

POSEY Darrell, *Indigenous Knowledge and Ethics: A Darrell Posey Reader*, Routledge, New York, 2004.

Q

QUANE Helen, “The UN Declaration on the Rights of Indigenous Peoples: New Directions for Self-Determination and Participatory Rights?”, in ALLEN Stephen and XANTHAKI

Alexandra (eds.), *Reflections on the UN Declaration on the Rights of Indigenous Peoples*, Hart Publishing, Oxford, 2010, pp. 259-287.

R

RAFIEIAN-KOPAEI Mahmoud et al., “Tumeric: A Spice with Multifunctional Medicinal Properties”, *Journal of HerbMed Pharmacology*, 2014, vol. 3(1), pp. 5-8.

RATES, “Plants as Source of Drugs”, *Toxicon*, 2001, vol. 39(5), pp. 603-613.

REID Walter, “Gene Co-ops and the Biotrade: Translating Genetic Resource Rights into Sustainable Development”, *Journal of Ethnopharmacology*, 1996, vol. 51(1-3), pp. 75-92.

REYNOLDS Louisa, “Mayan Law Still Lacks Official Recognition”, Latin America Press, Guatemala, 10 June 2006.

RIMMER Matthew, “Introduction: Mapping Indigenous Intellectual Property”, in RIMMER Matthew (ed.), *Indigenous Intellectual Property – A Handbook of Contemporary Research*, Cheltenham, Edward Elgar, 2015, pp. 1-44.

RINGELHEIM Julie, “L’appréhension juridique de l’identité culturelle – Entre autodéfinition et objectivation” in FOBLETS Marie-Claire et YASSARI Nadjma (eds.), *Approches juridiques de la diversité culturelle*, 2013, Académie de droit international de La Haye, pp. 137-181.

RINGMAN John et al., “Oral Curcumin for Alzheimer’s disease: tolerability and efficacy in a 24-week randomised, double blind, placebo-controlled study”, *Alzheimer’s Research & Therapy*, 2012, vol. 4(5), p. 43-51.

ROBINSON Daniel, *Confronting Biopiracy – Challenges, Cases and International Debates*, Earthscan, London, 2010.

ROHT-ARRIAZA Naomi, “Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities” *Michigan Journal of International Law*, 1996, vol. 17, pp. 919-966.

ROSANOWSKI Sarah, “Protection of traditional cultural expressions within the New Zealand intellectual property framework: a case study of the *Ka Mate* haka”, in RIMMER Matthew (ed.), *Indigenous Intellectual Property – A Handbook of Contemporary Research*, Cheltenham, Edward Elgar, 2015, pp. 264-288.

ROSEN Lawrence, *Law as Culture – An Invitation*, Princeton University Press, 2006.

ROSENTHAL Joshua and KATZ Flora, “Plant-based research among the International Cooperative Biodiversity Groups”, *Pharmaceutical Biology*, 2009, vol. 47(8), pp. 783-787.

ROULAND Norbert, “Custom and the Law” in DEKKER Paul and FABERON Jean-Yves (eds.), *Custom and Law*, Asia Pacific Press, The Australian National University, 2001.

RUIZ Manuel, *Protecting shared and widely distributed traditional knowledge: Issues, challenges and options*, ICTSD, Geneva, 2013, pp. 1-32.

S

SAFRIN Sabrina, “Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life”, *The American Journal of International Law*, 2004, vol. 98, pp. 641-685.

SAMPATH Padmashree Gehl, “Defining an intellectual property right on traditional medicinal knowledge: a process-oriented perspective”, *Journal of World Intellectual Property*, 2004, vol. 7(5), pp. 711-737.

SAMUELSON Pamela, “Enriching Discourse on Public Domains”, *Duke Law Journal*, 2006, vol. 55, pp. 783-834.

SASIDHARAN, S. et al., “Extraction, Isolation and Characterization of Bioactive Compounds from Plants’ Extracts” *African Journal of Traditional, Complementary and Alternative Medicines (AJTCAM)*, 2011, vol. 8(1), pp. 1-10.

SAVARESI, Annalisa, “The International Human Rights Law Implications of the Nagoya Protocol” in MORGERA, Elisa, BUCK Matthias and TSIOUMANI Elsa (eds.), *The 2001*

Nagoya Protocol on Access and Benefit-Sharing in Perspective, Brill, Leiden, 2013, vol. 1, pp. 53-81.

SCHERER Frederic, "Pharmaceutical Innovation", Harvard University, Faculty Research Working Paper Series No. RWP07-004, *SSRN Electronic Journal*, 2007, pp. 1-59.

SCHROEDER Doris, "Informed Consent: From Medical Research to Traditional Knowledge" in WYNBERG, SCHROEDER and CHENNELLIS (eds.), *Indigenous Peoples, Consent and Benefit-Sharing: Lessons from the San-Hoodia Case*, Springer, New York, 2009, pp. 27-52.

SCHROEDER Doris, "Justice in Benefit-Sharing", in WYNBERG, SCHROEDER and CHENNELLIS (eds.), *Indigenous Peoples, Consent and Benefit-Sharing: Lessons from the San-Hoodia Case*, Springer, New York, 2009, pp. 11-26.

SHERER Frederic, "Pharmaceutical Innovation", Harvard University, *Faculty Research Working Paper Series*, No. RWPo7-004, June 2007, pp. 1-40.

SHERIDAN Cornac, "EPO Neem Patent Revocation Revives Biopiracy Debate", *Nature Biotechnology*, 2005, vol. 23(5), pp. 511-512.

SHERMAN Brad and BENTLY Lionel, *The Making of Modern Intellectual Property Law - the British Experience, 1760-1911*, Cambridge University Press, Cambridge, 1999.

SHILLHORN Kerrin, *Kulturelle Rechte indigener Völker und Umweltvölkerrecht – Verhältnis und Vereinbarkeit*, Duncker & Humblot, Berlin, 2000.

SIEDER Rachel, "The Judiciary and Indigenous Rights in Guatemala", *International Journal of Constitutional Law*, 2007, vol. 5(2), pp. 211-241.

SIEDER Rachel, "'Emancipation or Regulation?' Law, globalization and indigenous peoples' rights in post-war Guatemala", *Economy and Society*, 2011, vol. 40(2), pp. 239-265.

SILLITOE Paul, "The Development of Indigenous Knowledge: A New Applied Anthropology", *Current Anthropology*, 1998, vol. 39(2), pp. 223-252.

SILLITOE Paul, "Local Science vs. Global Science: an Overview", in SILLITOE Paul (ed.), *Local Science vs. Global Science: Approaches to Indigenous Knowledge in International*

Development, Studies in Environmental Anthropology and Ethnobiology, vol. 4, Berghahn Books, New York, 2007, pp. 1-22.

SIMONCELLI Tania and PARK Sandra, “Making the Case Against Gene Patents” *Perspectives on Science*, 2015, vol. 23(1), pp. 106-145.

SIMPSON Tony, *Indigenous heritage and Self-Determination: The Cultural and Intellectual Property Rights of Indigenous Peoples*, The Forest Peoples Programme and IWGIA Copenhagen, 1997.

SMOLCZYNSKI Vincent, “Willful Patent Filing: A Criminal Procedure Protecting Traditional Knowledge”, *Chicago-Kent Law Review*, 2010, vol. 85(3), pp. 1171-1198.

SNEADER Walter, *Drug Discovery: A History*, John Wiley & Sons, West Sussex, 2005.

SPOENDIN Kaspar, “Erfindung und Entdeckung“, in INGRES (ed.), *Kernprobleme des Patentrechts: Festschrift zum einhundertjährigen Bestehen eines eidgenössischen Patentgesetzes*, INGRES, Bern, 1988, pp. 35-51.

STAVENHAGEN Rodolfo, “How Strong Are the Rights of Indigenous Peoples?”, *Journal of Human Rights*, 2011, vol. 10(3), pp. 414-421.

SUNDER Madhavi, “The Invention of Traditional Knowledge”, *Law and Contemporary Problems*, 2007, vol. 70(2), pp. 97-124.

SUNDER Madhavi, *From Goods to A Good Life: Intellectual Property and Global Justice*, Yale University Press, 2012.

SWIDERSKA Krystyna, “Banishing the Biopirates: A New Approach to Protecting Traditional Knowledge, IIED, *Gatekeepers Series* 129, 2006.

T

TAUBMAN Antony, “Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge”, in MASKUS KEITH and REICHMAN JEROME (eds.), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime*, Cambridge University Press, 2005, pp. 521-564.

TAUBMAN Antony, “TRIPS Jurisprudence in the Balance: Between the Realist Defense of Policy Space and a Shared Utilitarian Ethic”, in ANDORNO Roberto et al. (eds.), *Ethics and Law of Intellectual Property – Current Problems in Politics, Science and Technology*, Ashgate, London, 2007 pp. 89-120.

TAUBMAN Antony and LEISTNER Matthias, “Analysis of different areas of indigenous resources” in LEWINSKI, Silke von (ed.), *Indigenous heritage and intellectual property – Genetic resources, traditional knowledge and folklore*, Kluwer Law International, The Netherlands, 2008, 2nd ed., pp. 7-58.

TAUBMAN Antony et al., *A Handbook on the WTO TRIPS Agreement*, Cambridge University Press, Cambridge, 2012.

TAYLOR Leslie, *The Healing Power of Rainforest Herbs: A Guide to Understanding and Using Herbal Medicinal*, Square One Publishers, New York, 2005.

THÉRIAULT Sophie, “Environmental justice and the Inter-American court of human rights”, in GREAR Anna and KOTZÉ Louis (eds.), *Research handbook on human rights and the Environment*, Edward Elgar, Cheltenham, 2015, pp. 309-329. (on paper file with the author)

THOMAS Frédéric, “Biodiversité, biotechnologies et savoirs traditionnels - Du patrimoine commun de l’humanité aux ABS (Access to Genetic Resources and Benefit-Sharing)”, *Revue Tiers Monde*, 2006, vol. 188, pp. 825-842.

THORNBERRY Patrick, “Integrating the UN Declaration on the Rights of Indigenous Peoples into CERD Practice”, in ALLEN Stephen and XANTHAKI Alexandra (eds.), *Reflections on the UN Declaration on the Rights of Indigenous Peoples*, Hart Publishing, Oxford, 2010, pp. 61-91.

TIMMERMANNS Karin, “Intellectual property rights and traditional medicine: policy dilemmas at the interface”, *Social Science & Medicine*, 2003, vol. 57, pp. 745-756.

TOBIN Brendan, “Certificates of origin: A Role for IPR Regimes in securing Prior Informed Consent” in MUGABE John (ed.), *Access to Genetic Resources – Strategies for Benefit-Sharing*, ACTS Press, Nairobi, 1997, pp. 329-340.

TOBIN Brendan, CUNNINGHAM David, WATANABE Kazuo, “The feasibility, practicality and cost of a certificate of origin system for genetic resources – Preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme”, United Nations University Institute of Advanced Studies, Working Paper submitted to the ABS WG, 11 January 2005, UN doc. UNEP/CBD/WG-ABS/3/INF/5, p. 3.

TOBIN Brendan, BURTON Geoff and FERNANDEZ-UGALDE Jose, *Certificates of Clarity or Confusion: The search for practical, feasible and cost effective system of certifying compliance with PIC and MAT*, Yokohama, UNU-IAS, 2008.

TOBIN Brendan and TAYLOR Emily, “Across the Great Divide: A Case Study of Complementarity and Conflict between Customary Law and TK Protection Legislation in Peru, SPDA IDRC, Year IV No. 11 May 2009.

TOBIN Brendan, “Bridging the Nagoya Compliance Gap: The Fundamental Role of Customary Law in Protection of Indigenous Peoples’ Resource and Knowledge Rights”, *Law, Environment and Development Journal*, 2013, vol. 9(2), pp. 140-164.

TOBIN Brendan, “Open Access Seeds and Breeds: the Role of the Commons in Protecting Farmers and Livestock keepers”, in SANDERSON Jay and LAWSON Charles (eds.), *The Intellectual Property and Food Project: From Rewarding Innovation and Creation to Feeding the World*, Farnham, Ashgate, 2013, pp. 75-100.

TOBIN Brendan, “Biopiracy by Law: EU Draft Law Threatens Indigenous Peoples’ Rights over their Traditional Knowledge and Genetic Resources”, *European Intellectual Property Review*, 2014, vol. 36(2), pp. 75-146.

TOBIN Brendan, *Indigenous Peoples, Customary Law and Human Rights – Why Living Law Matters*, Routledge, New York, 2014 (TOBIN Brendan, *Indigenous Peoples, Customary Law and Human Rights*, 2014).

TOBIN Brendan, “Traditional Knowledge Sovereignty: The Fundamental Role of Customary Law in the Protection of Traditional Knowledge”, in RIMMER Matthew (ed.), *Indigenous Intellectual Property – A Handbook of Contemporary Research*, Cheltenham, Edward Elgar, 2015, pp. 565-592.

TOBIN Brendan, JOHNSTON Sam and BARBER Charles, *Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity*, Yokohama, UNU-IAS, 2015, 2nd ed.

TORREMANS Paul, “The Construction of the Directive’s Moral Exclusions under the EPC”, in TORREMANS Paul and PLOMER Aurora (eds.), *Embryonic Stem Cell Patents: European Law and Ethics*, Oxford University Press, Oxford, 2009, pp. 141-171.

TRINDADE Antônio, *International Law for Humankind – Toward a New Jus Gentium*, The Hague Academy of International Law Monographs, Martinus Nijhoff, Boston, 2013, vol.8, 2nd ed.

TROLLER Kamen, *Précis du droit suisse des biens immatériels*, Helbing & Lichtenhahn, Bâle, 2006, 2nd ed.

TRUFFIN Barbara, “Le pluralisme juridique en question(s): le cas des droits autochtones en Amérique latine” in FOBLETS Marie-Cjre et YASSARI Nadjma (eds.), *Approches juridiques de la diversité culturelle*, 2013, Académie de droit international de La Haye, pp. 287-409.

TSOSIE Rebecca, “Indigenous Peoples’ Claims to Cultural Property: A Legal Perspective”, *Museum Anthropology*, 1997, vol. 21(3), pp. 5-11.

TSOSIE Rebecca, “Cultural challenges to biotechnology: Native American Genetic Resources and the Concept of Harm”, *Journal of Medical Ethics*, 2007, vol. 35(3), pp. 396-411.

TVEDT Morten, “How Will a Substantive Patent Law Treaty Affect the Public Domain for Genetic Resources and Biological Material?”, *Journal of World Intellectual Property*, 2005, vol. 8(3), pp. 311-344.

TVEDT Moten, “One Worldwide Patent System: What’s in it for developing Countries?”, *Third World Quarterly*, 2010, vol. 31(2), pp. 277-293).

TVEDT Morten and SCHEI Peter, *‘Genetic Resources’ in the CBD: The Wording, the Past, the Present and the Future*, Fridtjof Nansen Institute, 2010.

TVEDT Morten and SCHEI Peter, “The term ‘Genetic Resources’: Flexible and Dynamic While Providing Legal Certainty”, in OBERTHÜR Sebastian and ROSENDAL Kristin (eds.),

Global Governance of Genetic Resources – Access and benefit-sharing after the Nagoya Protocol, Routledge, London, 2014, pp. 18-32.

TVEDT Morten W., “Norwegian Experiences with ABS”, in COOLSAET Brendan et al. (eds.), *Implementing the Nagoya Protocol – Comparing Access and Benefit-Sharing Regimes in Europe*, Brill, Leiden, 2015, vol. 3, pp. 175-193.

U

ULLRICH Hanns, “Traditional Knowledge, Biodiversity, Benefit-Sharing and the Patent System – Romantics v. Economics?”, in FRANCIONI Francesco and SCOVAZZI Tullio (eds.), *Biotechnology and International Law*, Hart Publishing, Oxford, 2006, pp. 201-230.

ULLRICH Hanns, “The Political Foundations of TRIPS Revisited”, in ULLRICH Hanns, HILTY Reto et al. (eds.), *TRIPS plus 20 – From Trade Rules to Market Principles*, Springer, London, 2016, pp. 85-129.

V

VAN COTT Donna Lee, “A Political Analysis of Legal Pluralism in Bolivia and Colombia”, *Journal of Latin America Studies*, 2000, vol. 32, pp. 207-234.

VAN DEN DRIEST Simone, *Remedial Secession: A Right to External Self-Determination as a Remedy to Serious Injustices?*, Intersentia, 2013.

VOGEL Joseph et al, “The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing” *Law Environment and Development Journal*, 2011, vol. 7(1), pp. 54-65.

W

WANG Ying, “Needs for New Plant-derived Pharmaceuticals in the Post-genome Era: An Industrial view in Drug Research and Development”, *Phytochemistry Review*, 2008, vol. 7, pp. 395-406.

WAZIYATAWIN WILSON Angela, “Indigenous knowledge recovery is indigenous empowerment”, *The American Indian Quarterly*, 2004, vol. 28(3), pp. 359-372.

WERRA DE Jacques, “Fighting against biopiracy: does the obligation to disclose in patent applications truly help?”, *Vanderbilt Journal of Transnational law*, 2009, vol. 49(1) pp. 143-179.

WERRA DE Jacques and GILLIERON Philippe (eds.), *Commentaire romand de propriété intellectuelle – Loi sur le droit d’auteur, Loi sur la protection des marques, Loi sur les designs, Loi sur les brevets*, Helbing Lichtenhahn, Basel, 2013.

WEST Simon, “Institutionalised Exclusion: The Political Economy of Benefit Sharing and Intellectual Property”, *Law, Environment and Development Journal*, 2012, vol. 8(1), pp. 19-43.

WIESSNER Siegfried, “Indigenous Sovereignty: a reassessment in Light of the UN Declaration on the Rights of Indigenous Peoples”, *Vanderbilt Journal of Transnational Law*, 2008, vol. 41(4), pp. 1141-1176.

WIESSNER Siegfried and GRAHAM Lorie, “Indigenous Sovereignty, Culture, and International Human Rights Law” *South Atlantic Quarterly*, 2011, vol. 110(2), pp. 403-427.

WIESSNER Siegfried, “The Cultural Rights of Indigenous Peoples: Achievements and Continuing Challenges”, *European Journal of International Law*, 2011, vol. 22(1), pp. 121-140.

WIESSNER Siegfried, “Indigenous self-determination, culture, and land: a reassessment in light of the 2007 UN Declaration on the Rights of indigenous Peoples”, in PULITANO Elvira (ed.), *Indigenous Rights in the Age of the UN Declaration*, 2012, Cambridge University Press, Cambridge, pp. 31-63.

WIESSNER Siegfried and CAREY John, “A New United Nations Subsidiary Organ: The Permanent Forum on Indigenous Issues”, *American Society of International Law*, 2001, vol. 6(8), available at: www.asil.org [accessed September 2016].

WISER Glen, “U.S. Patent and Trademark Office Reinstates Ayahuasca Patent – Flawed Decision Declares Open Season on Resources of Indigenous Peoples”, Center for International Environmental Law (CIEL), 25 June 2001.

WYNBERG Rachel, “Rhetoric, Realism and Benefit-Sharing – Use of Traditional Knowledge of Hoodia Species in the Development of an Appetite Suppressant”, *The Journal of World Intellectual Property*, 2004, vol. 7(6), pp. 851-876.

WYNBERG Rachel and CHENNELLS Roger, “Green Diamonds of the South: An Overview of the San-Hoodia Case”, in WYNBERG, SCHROEDER and CHENNELLS (eds.), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case*, Springer, New York, 2009, pp. 89-126.

WYNBERG Rachel and NIEKERK van Jaci, “The trade in *Pelargonium Sidoides*: Rural Livelihood Relief or Bounty for the ‘Bio-buccaneers’?” *Development Southern Africa*, 2012, vol. 29(4), pp. 530-547.

X, Y

YAMANE Hiroko, *Interpreting TRIPS – Globalisation of Intellectual Property Rights and Access to Medicines*, Hart Publishing, Oxford, 2011 (YAMANE, *Interpreting TRIPS*).

Z

ZANDERS Edward, *The Science and Business of Drug Discovery – Demystifying the Jargon*, Springer, New York, 2011.

ZOGRAFOS Daphne, “New perspectives for the protection of traditional cultural expressions in New Zealand”, *International Review of Intellectual Property and Competition Law*, 2005, vol. 36(8), pp. 928-952.

United Nations / UN Agencies' Documents

Human Rights

Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, 'Study of the Problem of Discrimination Against Indigenous Populations', submitted by Special Rapporteur José Martínez Cobo, 1986, vol. I, UN Doc E/CN. 4/Sub.2/1986/7 (Commission on Human Rights, 'Study of the Problem of Discrimination Against Indigenous Populations', Special Rapporteur José Martínez Cobo, 1986, vol. I, UN Doc E/CN. 4/Sub.2/1986/7) Available at: <http://www.un.org/en/documents/ods/>

Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, 'Study of the Problem of Discrimination Against Indigenous Populations', submitted by Special Rapporteur José Martínez Cobo, 1986, vol. II, UN Doc E/CN. 4/Sub.2/1986/7/Add.1 (Commission on Human Rights, 'Study of the Problem of Discrimination Against Indigenous Populations', Special Rapporteur José Martínez Cobo, 1986, vol. II, UN Doc E/CN. 4/Sub.2/1986/7/Add.1). [definition of indigenous peoples in chapter V, see also conclusions).

Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, 'Study of the Problem of Discrimination Against Indigenous Populations', submitted by Special Rapporteur José Martínez Cobo, 1986, vol. III, UN Doc E/CN. 4/Sub.2/1986/7/Add.2 (Commission on Human Rights, 'Study of the Problem of Discrimination Against Indigenous Populations', Special Rapporteur José Martínez Cobo, 1986, vol. III, UN Doc E/CN. 4/Sub.2/1986/7/Add.2).

Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, 'Study of the Problem of Discrimination Against Indigenous Populations', submitted by Special Rapporteur José Martínez Cobo, 1986, vol. IV, UN Doc E/CN. 4/Sub.2/1986/7/Add.3 (Commission on Human Rights, 'Study of the Problem of Discrimination Against Indigenous Populations', Special Rapporteur José Martínez Cobo, 1986, vol. IV, UN Doc E/CN. 4/Sub.2/1986/7/Add.3).

Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, 'Study of the Problem of Discrimination Against Indigenous

Populations – Conclusions, Proposals and Recommendation’, submitted by Special Rapporteur José Martínez Cobo, 1986, vol. V, UN Doc E/CN. 4/Sub.2/1986/7/Add.4 (Commission on Human Rights, ‘Study of the Problem of Discrimination Against Indigenous Populations – Conclusions, Proposals and Recommendation’, Special Rapporteur José Martínez Cobo, 1986, vol. V, UN Doc E/CN. 4/Sub.2/1986/7/Add.4).

Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, ‘Discrimination against indigenous peoples - Report of the Working Group on Indigenous Populations on its ninth session, by Special Rapporteur Erica-Irene Daes, 3 October 1991, UN Doc. E/CN.4/Sub.2/1991/40/Rev.1.

Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, ‘Discrimination against indigenous peoples - Study on the protection of the cultural and intellectual property of indigenous peoples, by Erica-Irene Daes’, Special Rapporteur of the Sub-Commission on Prevention of Discrimination and Protection of Minorities and Chairperson of the Working Group on Indigenous Populations, 28 July 1993, UN Doc. E/CN.4/Sub.2/1993/28.

Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, ‘Discrimination Against Indigenous Peoples - Report of the Working Group on Indigenous Populations’, eleventh session, Special Rapporteur Erica-Irene Daes’, 23 August 1993, UN Doc. E/CN.4/Sub.2/1993/29 (Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, ‘Discrimination Against Indigenous Peoples - Report of the Working Group on Indigenous Populations’, Special Rapporteur Erica-Irene Daes, 23 August 1993, UN Doc E/CN.4/Sub.2/1993/29).

Commission on Human Rights, ‘*Observaciones y enmiendas a los artículos examinados del proyecto de declaración sobre los derechos de los pueblos indígenas y la introducción de nuevos párrafos en la parte dispositiva, formuladas por el Movimiento Indio Tupaj Katari el Consejo Mundial por la Paz*’, 29 November 2005, UN Doc. E/CN.4/2005/WG.15/CRP.5.

Commission on Human Rights, ‘Report of the Special Rapporteur on the Situation of Human Rights and Fundamental Freedoms of Indigenous Peoples by Dr. Rudolfo Stavehagen’, 21 January 2003, UN Doc. E/CN.4/2003/90.

Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, Report of the Working Group on Indigenous Populations, chairperson-Rapporteur Erica-Irene Daes, 29 July- 2 August 1996, UN Doc. E/CN.4/Sub.2/1996/21.

Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, ‘Intellectual Property and Human Rights’, Resolution 2001/21, 16 August 2001, UN Doc. E/CN.4/SUB.2/RES/2001/21. Available at: http://ap.ohchr.org/documents/alldocs.aspx?doc_id=8220 [accessed September 2016].

Committee on the Elimination of Racial Discrimination (CERD), ‘General Recommendation XXI on the right to self-determination’, adopted 15 March 1996, available at: http://tbinternet.ohchr.org/_layouts/treatybodyexternal/TBSearch.aspx?Lang=en&TreatyID=6&DocTypeID=11 [accessed June 2016].

CERD, ‘General Recommendation XXIII on the Rights of Indigenous Peoples’, General Recommendation 23, 22 August 1997, 51st Session, annex V, at 122, U.N. Doc. A/52/18, reprinted in “Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies”, the Secretariat, 12 May 2003, U.N. Doc. HRI\GEN\1\Rev.6, p. 212, available at: <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G03/417/03/PDF/G0341703.pdf?OpenElement> [accessed September 2016].

CERD, ‘Consideration of Reports Submitted by States Parties under Article 9 of the Convention: Concluding Observations on Ecuador, Committee on the Elimination of Racial Discrimination – Ecuador’, 62nd Session, 3-21 March 2003, UN Doc. CERD/C/62/CO/2.

CERD, Concluding Observations on the Combined seventh to ninth Periodic Reports of the United States of America’, 25 September 2014, UN Doc. CERD/C/USA/CO/7-9.

CERD, ‘Consideration of Reports Submitted by States Parties under Article 9 of the Convention: Concluding Observations on the Eighteenth to Twenty-first Periodic Reports of Peru’, 25 September 2014, UN Doc. CERD/C/PER/CO/18-21, available at: http://tbinternet.ohchr.org/_layouts/treatybodyexternal/TBSearch.aspx?Lang=en&TreatyID=6&DocTypeID=5 [accessed September 2016].

Economic and Social Council (ECOSOC), ‘Establishment of a Permanent Forum on Indigenous Issues’, Resolution 2000/22, 45th Plenary Meeting, 28 July 2000, UN Doc.

E/2000/22, in “Resolutions and decisions adopted by the Economic and Social Council at its substantive session of 2000”, 5 to 28 July 2000, UN Doc. E/2000/INF/2/Add.2, pp. 50-52.

ECOSOC, Permanent Forum on Indigenous Issues (UNPFII), ‘Report of the International Workshop on Methodologies regarding Free, Prior and Informed Consent and Indigenous Peoples’, 17 February 2005, UN Doc. E/C.19/2005/3.

ECOSOC, CESCR, ‘General Comment No. 17 - The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, 7-25 November 2005, UN Doc. E/C.12/GC/17 (12 January 2006) (CESCR, ‘General Comment No. 17’).

ECOSOC, ‘General Comment No 21 – Right of Everyone to Take Part in Cultural Life (art. 15, para. 1 (a), of the International Covenant on Economic, Social and Cultural Rights)’, 21 December 2009, UN Doc. E/C.12/GC/21.

ECOSOC, Permanent Forum on Indigenous Issues, ‘Report on the Ninth Session’, 19-30 April 2010, UN Doc. E/2010/43-E/C.19/2010/15.

ECOSOC, Permanent Forum on Indigenous Issues, ‘Report on the tenth session’, 16-27 May 2011, UN Doc. E/2011/43-E/C.19/2011/14.

Human Rights Committee, ‘General Comment adopted by the Human Rights Committee under Article 40, paragraph 4, of the International Covenant on Civil and Political Rights: General Comment No. 23(50): Article 27’, adopted on 6 April 1994, UN Doc. CCPR/C/21/Rev.1/Add.5 (HRC, ‘General Comment No. 23: Article 27’) (26 April 1994), available at: <http://www.ohchr.org/EN/HRBodies/CCPR/Pages/CCPRIndex.aspx> [accessed September 2016].

Human Rights Council, ‘Report of the Special Rapporteur on the Situation of Human Rights and Fundamental Freedoms of Indigenous Peoples’, James Anaya, Adendum, Summary of cases transmitted to Governments and replies received, 15 August 2008, UN Doc. A/HRC/9/9/Add.1 (Human Rights Council, ‘Report of the Special Rapporteur on the Situation of Human Rights and Fundamental Freedoms of Indigenous Peoples’, James Anaya, 15 August 2008, UN Doc. A/HRC/9/9/Add.1).

Human Rights Council, ‘Expert mechanism on the rights of indigenous peoples’, Resolution 6/36, 6th session, 14 December 2007, UN Doc. A/HRC/RES/6/36.

Human Rights Council, 'Human rights and indigenous peoples: mandate of the Special Rapporteur on the rights of indigenous peoples', Resolution 15/14, 15th Session, 6 October 2010, UN Doc. A/HRC/RES/15/14.

Human Rights Council, 'Report of the Special Rapporteur of indigenous peoples' rights by James Anaya', 1st July 2013, UN Doc. A/HRC/24/41.

Human Rights Council, 'Report of the Special Rapporteur of indigenous peoples' rights by Victoria Tauli Corpuz', 30th session, 6 August 2015, UN Doc. A/HRC/30/41.

Human Rights Council, 'Promotion and Protection of the Rights of Indigenous Peoples with Respect to their Cultural Heritage', Study by the Expert Mechanism on the Rights of Indigenous Peoples, 8th session, 19 August 2015, UN Doc. A/HRC/30/53 (Human Rights Council, 'Promotion and Protection of the Rights of Indigenous Peoples with Respect to their Cultural Heritage', 2015, UN Doc. A/HRC/30/53).

UN General Assembly, 61st Session, 107th Plenary Meeting, Official Records, New York, 13 September 2007, UN Doc. A/61/PV.107 (UN GA, 61st Session, 13 September 2007, UN Doc. A/61/PV.107).

UN General Assembly, 'Report of the Special Rapporteur of the Human Rights Council on the Rights of Indigenous Peoples on the Impact of International Investment and Free Trade on the Human Rights of Indigenous Peoples', Victoria Tauli Corpuz, submitted by the Secretary-General, 70th session, 7 August 2015, UN Doc. A/70/301 (UN GA, 'Report of the Special Rapporteur of the Human Rights Council on the Rights of Indigenous Peoples on the Impact of International Investment and Free Trade on the Human Rights of Indigenous Peoples', Victoria Tauli Corpuz, 7 August 2015, UN Doc. A/70/301).

United Nations Environmental Program

CBD, 'Traditional Knowledge and Biological Diversity', Madrid, 24-28 November 1997, UNEP/CBD/TKBD/1/2.

CBD WG-ABS, 'Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International

Regime on Access and Benefit-Sharing', Montreal, 9-15 November 2009, UNEP/CBD/WG-ABS/8/2.

CBD WG-ABS, 'Technical study on disclosure requirements related to genetic resources and traditional knowledge', submitted by WIPO, Montreal, 1-5 December 2003, UNEP/CBD/WG-ABS/2/INF/4 (23 October 2003).

CBD WG-8J, 'Legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity', Seville, 27-31 March 2000, UNEP/CBD/WG8J/1/2 (10 January 2000).

CBD WG-8J, 'Extracts Covering the Evolution of the Issue of Definitions within the *Sui Generis* Agenda Item from the Working Group on Article 8(j) and Related Provisions', Montreal, 31 October – 4 November 2011, UNEP/CBD/WG8j/7/INF/1/Add.1 (6 July 2011), available at: <https://www.cbd.int/doc/meetings/tk/wg8j-07/information/wg8j-07-inf-01-add1-en.pdf> [accessed September 2016] (p. 11: potentially valuable biological resources, mostly located in the tropical and subtropical regions of the world)

CBD WG-8J, 'Study on how tasks 7, 10 and 12 of the revised programme of work on Article 8(j) and related provisions could best contribute to work under the Convention and the Nagoya Protocol', Montreal, Montreal, 7-11 October 2013, UNEP/CBD/WG8J/8/INF/5, (12 September 2013).

CBD WG-8J, 'Possible elements of *sui generis* system for the protection of traditional knowledge, innovations and practices of indigenous and local communities', Montreal, 7-11 October 2013, UNEP/CBD/WG8J/8/6/Add.1 (4 October 2013).

CBD WG-8J, 'Development of elements of *sui generis* system for the protection, preservation and promotion of traditional knowledge, innovations and practices relating to biological diversity', Montreal, 7-11 October 2013, UNEP/CBD/WG8J/8/6.

CBD WG-8J, 'Report of the expert group on the repatriation of traditional knowledge relevant to the conservation and sustainable use of biological diversity', ninth meeting, Montreal, 4-7 November 2015, UNEP/CBD/WG8J/9/INF/4 (17 August 2015).

CBD WG-8J, 'A Glossary of Relevant Key Terms and Concepts to be Used within the Context of Article 8(j) and Related Provisions', Montreal, 4-7 November 2015, UNEP/CBD/WG8J/9/2/Add.1 (24 September 2015).

CBD COP 3, 'Report of the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity', third meeting, Buenos Aires, 4-15 November 1996, U.N. Doc. UNEP/CBD/COP/3/38, (11 February 1997).

CBD COP 4, 'Report of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity', fourth meeting, Bratislava, 4-15 May 1998, UNEP/CBD/COP/4/27, (15 June 1998).

CBD COP 5 'Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity', fifth meeting, Nairobi, 15-26 May 2000, UNEP/CBD/COP/5/23.

CBD COP 6, 'Report of the sixth meeting, of the Conference of the Parties to the Convention on Biological Diversity', sixth meeting, the Hague, 7-19 April 2002, UNEP/CBD/COP/6/20 (27 May 2002).

CBD COP 7, 'WIPO technical study on patents disclosure requirement related to genetic resources and traditional knowledge', Submission by WIPO, Kuala Lumpur, 15 December 2003, UNEP/CBD/COP/7INF/17.

CBD COP 7, 'Report of the Seventh Meeting of the Conference of the Parties to the Convention on Biological Diversity', seventh meeting, Kuala Lumpur, 9-20 and 27 February 2004, UN Doc. UNEP/CBD/COP/7/21.

CBD COP 10, 'Report of the third part of the ninth meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-sharing', tenth meeting, Nagoya, 17 October 2010, UNEP/CBD/COP/10/5/Add.5 (hereafter, CBD COP 10, 'the Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity', Nagoya, 17 October 2010, UNEP/CBD/COP/10/5/Add.5).

CBD COP 10, 'Report of the Tenth Meeting of the Conference of the Parties to the Convention on Biological Diversity', Nagoya, 18-19 October 2010, UNEP/CBD/COP/10/27.

UNESCO

UNESCO, 'Intellectual Works of Universal Value that have Fallen into the Public domain and are Regarded as Forming Part of the Common Heritage of Humanity', General Conference, Thirtieth Session, Paris, 11 October 1999, UNESCO Doc. 30/c/56.

World Health Organisation

WHO, 'General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine', Geneva, 2000, WHO/EDM/TRM/2000.1, available at: http://apps.who.int/iris/bitstream/10665/66783/1/WHO_EDM_TRM_2000.1.pdf [accessed August 2016].

WHO, 'WHO Traditional Medicine Strategy 2002-2005', WHO, Geneva, 2002, available at: http://www.wpro.who.int/health_technology/book_who_traditional_medicine_strategy_2002_2005.pdf [accessed August 2016]

WHO, 'Report of the Commission on Intellectual Property Rights, Innovation and Public Health: Public Health, Innovation and Intellectual Property Rights', WHO, Geneva, 2006, available at: <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1> [accessed September 2016].

WHO, 'WHO Traditional Medicine Strategy 2014-2023', WHO, Geneva, 2013, available at: http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf?ua=1 [accessed September 2016].

World Intellectual Property Organisation

WIPO, 'Protection of Traditional Knowledge: A Global Intellectual Property Issue', by the International Bureau, Geneva, 1-2 November 1999, WIPO/IPTK//RT/99/2.

WIPO, 'Intellectual Property Needs and Expectations of Traditional Knowledge Holders - WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge 1998-1990', Geneva, April 2001 (WIPO, 'Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge 1998-1999', 2001).

WIPO, Working Group on Reform of the Patent Cooperation Treaty (PCT), ‘Proposals by Switzerland regarding the declaration of source of genetic resources and traditional knowledge in patent applications’, Geneva, 5 May 2003, PCT/R/WG/4/13.

WIPO, ‘Customary Law, Traditional Knowledge and Intellectual Property: An Outline of the Issues, 2013, available at: http://www.wipo.int/tk/en/indigenous/customary_law/ [accessed February 2016].

WIPO, ‘Seminar on Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: Regional, National and Local Experiences’, Geneva, 30 March to 1st April 2015, WIPO/IPTK/GE/15/INF/1 PROV.2, available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=35602 [accessed February 2016].

WIPO GA, ‘Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore’, the Secretariat, 25 September – 3 October 2000, WO/GA/26/6 (document adopted by the GA in WO/GA/26/10).

WIPO GA, ‘Report’, adopted by the Assembly, Geneva, 25 September – 3 October 2000, WO/GA/26/10.

WIPO GA, ‘Participation of Indigenous and Local Communities: Establishment of a Voluntary Fund’, by the Secretariat, Geneva, 5 October 2005, WO/GA/32/6, Annex, p. 1 (adopted by the GA in WO/GA/32, 39).

WIPO GA, ‘Report’ adopted by the 38th session of the GA, Geneva, 1st October 2009, WO/GA/38/20, available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=18641 [accessed September 2016].

WIPO GA, ‘Report, adopted by the 41st GA, Geneva, 1 – 9 October 2012, WO/GA/41/18 (9 October 2012), available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=23138 [accessed September 2016].

WIPO GA, ‘Report’, adopted by the 46th session of the GA, Geneva, 22– 30 September 2014, WO/GA/46/12, available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=33291 (15 January 2015) [accessed September 2016].

WIPO GA, 'Report', adopted by the 47th session of the GA, Geneva, 14 October 2015, WO/GA/47/19, available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=36337 [accessed September 2016].

WIPO GA, 'Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (ICG)', Document prepared by the Secretariat, Geneva, October 2015, WO/GA/47/12.

WIPO GA, 'Conversion of WIPO IGC into a Standing Committee: Proposal by the African Group to the 2015 GA', by the Secretariat, Geneva, 5 – 14 October 2015, WO/GA/47/16.

WIPO GA, 'Matters concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) : Proposal of the United States of America to the WPO GA', the Secretariat, Geneva, 5 – 14 October 2015, WO/GA/47/17.

WIPO GA, 'Matters concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) : Proposal of the Holy See, Kenya, Mozambique, New Zealand, Norway and Switzerland to the WPO GA, the Secretariat, Geneva, 5 – 14 October 2015, WO/GA/47/18.

WIPO GA, 'Report', adopted by the 47th session of the GA, Geneva, 5 – 14 October 2015, WO/GA/47/19.

WIPO IGC, 'Report of the First IGC Session, adopted by the Committee, 30 April- 3 May 2001, WIPO/GRTKF/IC/1/13 (23 May 2001).

WIPO IGC, 'Traditional Knowledge – Operational Terms and Definitions', the Secretariat, 13-21 June 2002, WIPO/GRTKF/IC/3/9 (20 May 2002).

WIPO IGC, 'Report', adopted by the Committee, 13-21 June 2002, WIPO/GRTKF/IC/3/17 (21 June 2002).

WIPO IGC, 'Elements of a *Sui Generis* System for the Protection of Traditional Knowledge', the Secretariat, 9-19 December 2002, WIPO/GRTKF/IC/4/8 (30 September 2002).

WIPO IGC, 'Practical Mechanisms for the Defensive Protection of Traditional Knowledge and Genetic Resources within the Patent System', the Secretariat, 7 – 15 July 2003, WIPO/GRTKF/IC/5/6. (14 May 2003)

WIPO IGC, 'Report' by the Secretariat, Geneva, 7-15 July 2003, WIPO/GRTKF/IC/5/15.

WIPO IGC, 'Comparative Summary of Existing National *Sui Generis* Measures and Laws for the Protection of Traditional Knowledge', the Secretariat, Geneva, 7-15 July 2003, WIPO/GRTKF/IC/5/INF/4. (28 April 2003)

WIPO IGC, 'Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources: The International Dimension', the Secretariat, Geneva, 15-19 March 2004, WIPO/GRTKF/IC/6/6.

WIPO IGC, 'Protection of Traditional Knowledge: Overview of Policy Objectives and Core Principles', the Secretariat, 1–5 November 2004, WIPO/GRTKF/IC/7/5 (20 August 2004).

WIPO IGC, 'Practical Means of Giving Effect to the International Dimension of the Committee's Work', the Secretariat, 6 – 10 June 2005, WIPO/GRTKF/IC/8/6. (4 April 2005)

WIPO IGC, 'Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications', submitted by the European Community and its Member States, 6-10 June 2005, WIPO/GRTKF/IC/8/11 (17 May 2005).

WIPO IGC, 'The Protection of Traditional Knowledge: Revised Outline of Policy Options and Legal Mechanisms, the Secretariat, 27 March 2006, WIPO/GRTKF/IC/9/INF/5 (compilation of national legislation on TK).

WIPO IGC, 'The Protection of Traditional Knowledge: Draft Objectives and Principles', the Secretariat, 30 November – 8 December 2006, WIPO/GRTKF/IC/10/5 (2 October 2006).

WIPO IGC, 'Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposals by Switzerland', Document submitted by Switzerland, 3 – 12 July 2007, WIPO/GRTKF/IC/11/10.

WIPO IGC, 'Patent System and the Fight against Biopiracy – The Peruvian Experience', submitted by Peru, 6-10 June 2005, WIPO/GRTKF/IC/8/12 (30 May 2005).

WIPO IGC, ‘Combating Biopiracy – The Peruvian Experience’, submitted by Peru, 3-12 July 2007, WIPO/GRTKF/IC/11/13 (9 July 2007).

WIPO IGC, ‘The Protection of Cultural Expression: Draft Gap Analysis’, the Secretariat 13-17 October 2008, WIPO/GRTKF/IC/13/4(b) Rev. (11 October 2008).

WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Gap Analysis’, 13-17 October 2008, WIPO/GRTKF/IC/13/5(b) Rev. (11 October 2008).

WIPO IGC, ‘Recognition of Traditional Knowledge within the Patent System’, the Secretariat, 13-17 October 2008, WIPO/GRTKF/IC/13/7. (18 September 2008)

WIPO IGC, ‘Report’, the Secretariat, Geneva, 3 July 2009 WIPO/GRTKF/IC/14/12.

WIPO IGC, ‘Policies, measures and experiences regarding intellectual property and genetic resources: Submission by Switzerland’, 3-7 May 2010, WIPO/GRTKF/IC/16/INF/14 (19 February 2010).

WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, the Secretariat, 3-7 May 2010, WIPO/GRTKF/IC/16/5 (22 March 2010)

WIPO IGC, ‘Note on the Meaning of the Term “Public Domain” in the Intellectual Property System with Special Reference to the Protection of Traditional Knowledge and Traditional Cultural Expressions/Expressions of Folklore’, the Secretariat, 6-10 December 2010, WIPO/GRTKF/IC/17/INF/8 (24 November 2010).

WIPO IGC, ‘List and Brief Technical Explanation of Various Forms in which Traditional Knowledge may be Found’, the Secretariat, 6-10 December 2010, WIPO/GRTKF/IC/17/INF/9 (5 November 2010).

WIPO IGC, ‘The Protection of Traditional Knowledge: Revised Objectives and Principles’, the Secretariat, 9-13 May 2011, WIPO/GRTKF/IC/18/5 (10 January 2011).

WIPO IGC, ‘Report’, adopted by the IGC, Geneva, 9 - 13 May 2011, WIPO/GRTKF/IC/18/11 (Indigenous statement).

WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, the Secretariat, 18-22 July 2011, WIPO/GRTKF/IC/19/5 (20 May 2011).

WIPO ICG, ‘Like-Minded Countries Contribution to the Objectives and Principles on the Protection of Genetic Resources and Preliminary Draft Articles on the Protection of Genetic Resources’, by the Delegation of Indonesia, 18 July 2011, WIPO/GRTKF/IC/19/11.

WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, the Secretariat, 4-8 February 2013, WIPO/GRTKF/IC/23/4.

WIPO IGC, ‘Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources’, Submitted by Canada, Japan, Republic of Korea and the United States of America, 4-8 February 2013, WIPO/GRTKF/IC/23/7.

WIPO ICG, ‘Draft Report, the Secretariat, 4-6 February 2013, WIPO/GRTKF/IC/23/8/PROV. 2.

WIPO IGC, ‘Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources’, 22-26 April 2013, WIPO/GRTKF/IC/24/7 (28 March 2013).

WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, the Secretariat, 22-26 April 2013, WIPO/GRTKF/IC/24/4.

WIPO IGC, ‘Report’, adopted by the IGC, Geneva, 24 March to 4 April 2014, WIPO/GRTKF/IC/27/10.

WIPO IGC, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, the Secretariat, 7 – 9 July 2014, WIPO/GRTKF/IC/28/4 (2 June 2014).

WIPO IGC, ‘The Protection of Traditional Knowledge: Draft Articles’, the Secretariat, 7 – 9 July 2014, WIPO/GRTKF/IC/28/5 (2 June 2014).

WIPO IGC, ‘Proposal for the Terms of References for the Study by the WIPO Secretariat on Measures Related to the Avoidance of the Erroneous Grant of Patents and Compliance with Existing Access and Benefit-Sharing Systems’, submitted by the Delegations of Canada, Japan, Norway, the Republic of Korea, the Russian Federation and the United States of America, 7-9 July 2014, WIPO/GRTKF/IC/28/9 (9 May 2014).

WIPO ICG, 'Initial Draft Report', the Secretariat, 15-19 February 2016, WIPO/GRTKF/IC/29/8 Prov. (21 March 2016).

WIPO IGC, 'Report', adopted by the IGC, 15-19 February 2016, WIPO/GRTKF/IC/29/8 (30 May 2016).

WIPO IGC, 'Report', adopted by the IGC, 30 May – 3 June 2016, WIPO/GRTKF/IC/30/10 (23 September 2016).

WIPO IGC, 'Consolidated Document Relating to Intellectual Property and Genetic Resources', the Secretariat, 30 May – 3 June 2016, WIPO/GRTKF/IC/30/4 (9 March 2016).

WIPO IGC, 'Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions', the Secretariat, 19-23 September 2016, WIPO/GRTKF/IC/31/INF/7 (13 May 2016).

WIPO IGC, 'Seeking a Better Understanding of Switzerland's "Federal Act on the Protection of Nature and Cultural Heritage" and "Federal Act on Patents for Inventions" by Hypothetically Applying them to U.S. Patent Number 5, 137, 870, the Delegation of the United States of America, 30 May – 3 June 2016, WIPO/GRTKF/IC/30/9 (1 June 2016)

WIPO IGC, 'The Declaration of the Source of Genetic Resources and Traditional Knowledge in the Swiss Patent Act and Related Swiss Regulations on Genetic Resources – Submission by Switzerland in Response to Document WIPO/GRTKF/IC/30/9, the Delegation of Switzerland, 19-23 September 2016, WIPO/GRTKF/IC/31/8 (12 September 2016).

WIPO IGC, Technical Review of Key Intellectual Property-Related Issues of the WIPO Draft Instruments on Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions by Professor James Anaya', submitted by the UN PFII, 28 November- 2 December 2016, WIPO/GRTKF/IC/32/INF/8 (3 October 2016).

WIPO IPC Union, 'Development of Classification Tools for Traditional Knowledge', by the International Bureau, 18 February 2002, IPC/CE/31/6.

WIPO PCT Union, 'PCT Minimum Documentation: Traditional Knowledge', the International Bureau, 21-25 February 2005, PCT/MIA/11/5. (26 January 2005)

WIPO Program and Budget Committee (PBC), 'Participation of Representatives of Accredited Indigenous and Local Communities in the Work of the IGC : Proposal for Subsidiary Funding from the Regular Budget of WIPO', Proposal by the Delegations of Australia, Finland, Holy See, New Zealand and Switzerland, Geneva, 1-5 September 2014, WO/PBC/22/24.

WIPO Standing Committee on the Law of Patents (SCP), 'Protection of Biological and Genetic Resources', the Delegation of Colombia, 6 to 14 September 1999, WIPO/SCP/3/10.

WIPO SCP, 'Study on the interface between the SPLT, the PLT and the PCT, prepared by the International Bureau, Geneva, 5-9 November 2001, SCP/6/5 (24 September 2001).

WIPO/UNESCO, 'Model Provisions for National Laws on the Protection of Expression of Folklore Against Illicit Exploitation and Other Prejudicial Actions' (WIPO/UNESCO, Model Provision 1985). (http://www.wipo.int/wipolex/en/text.jsp?file_id=184668)

World Trade Organisation

WTO, 'European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs', complaint by the United States, Report of the Panel, 15 March 2015, WT/DS174/R.

WTO Ministerial Conference, 'Ministerial Declaration', adopted 14 November 2001, Fourth Ministerial Conference, Doha, 9-14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, (20 November 2001) (Doha Declaration).

WTO Trade Negotiations Committee, 'Draft Modalities for TRIPS Related Issues', submitted by Brazil, the EU, India, and Switzerland, 19 July 2008, WTO Doc. TN/C/W/52 (coalition of 110 countries).

WTO Trade Negotiations Committee, 'Draft Decision to Enhance Mutual Supportiveness between the TRIPS Agreement and the Convention on Biological Diversity', Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, ACP Group, and the African Group, 19 April 2011, WTO Doc. TN/C/W/59.

Multilateral Trade Negotiations, The Uruguay Round, Group of Negotiations on Goods (GATT), ‘Negotiating Group on Trade-Related Aspects of Intellectual Property Rights’, Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, 14 May 1990, GATT Doc. MTN.GNG/NG11/W/71.

WTO TRIPS Council, ‘Review of the Provisions of Article 27.3(b) of the TRIPS Agreement’ Submission by the USA, 29 October 1999, IP/C/W/162.

WTO TRIPS Council, Review of the Provisions of Article 27.3(b) of the TRIPS Agreement’ Submission by Kenya on behalf of the African Group, 8 November 1999, IP/C/W/163.

WTO TRIPS Council, ‘Protection of Biodiversity and Traditional Knowledge – The Indian Experience’, Submission by India, 14 July 2000, WT/CTE/W/156 (IP/C/W/198).

WTO TRIPS Council, ‘Review of the Provisions of Article 27.3(b) of the TRIPS Agreement’ Communication from Japan, 11 December 2000, IP/C/W/236.

WTO TRIPS Council, Review of the Provisions of Article 27.3(b) of the TRIPS Agreement’ Submission by the European Communities and their Member States, 13 June 2001, IP/C/W/254.

WTO TRIPS Council, ‘Review of Article 27.3(b): The View of Switzerland’, Communication from Switzerland, 15 June 2001, IP/C/W/284.

WTO TRIPS Council, ‘Review of Article 27.3(b) of the TRIPS Agreement, and the relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore’ Submission by the European Communities and their Member States, 17 October 2002, IP/C/W/383.

WTO TRIPS Council, ‘Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore - Biodiversity, Traditional Knowledge and Intellectual Property: Peru’s Position in Relation to Disclosure of Origin and Legal Provenance’, Communication from Peru, 8 June 2005, IP/C/W/447.

WTO TRIPS Council, ‘Minutes of Meeting’Euro, Centre William Rappard, 14-15 June 2005, IP/C/M/48 (15 September 2005).

WTO TRIPS Council, ‘The Relationship between the TRIPS Agreement and the Convention on Biological Diversity’, Note by the Secretariat, 8 February 2006, IP/C/W/368/Rev.1 (on file with the author).

WTO TRIPS Council, ‘Combating Biopiracy – The Peruvian Experience’, Communication from Peru, 19 September 2007, IP/C/W/493.

WTO TRIPS Council, ‘Minutes of Meeting’, Centre William Rappard, 1st March 2011, IP/C/M/65.

WTO TRIPS Council, ‘Minutes of Meetings’, Centre William Rappard, 5-6 March 2013, IP/C/M/72.

Other Reports

CAPAJ, ‘Document Presented for Consideration by the XXII Session of the IGC’, 2012, available at: <http://www.wipo.int/tk/en/igc/ngo/> [accessed September 2016].

Commission on Intellectual Property rights (CIPR), ‘Integrating Intellectual Property Rights and Development Policy’, Report, London, 2002.

Confédération suisse, *OFEV* (FOEN), ‘*Ordonnance de Nagoya – Rapport explicatif*’ (Ordinance on the Nagoya Protocol – Explanatory Report), 11 December 2015.

DE LA CRUZ Rodrigo, “Customary Law in the Protection of Traditional Knowledge – Regional Study in the Andean Countries”, prepared for WIPO, Quito, 2006, available at: http://www.wipo.int/tk/en/indigenous/customary_law/ [accessed February 2016].

European Parliament Resolution, ‘Development Aspects of Intellectual Property Rights on Genetic Resources: The Impact on Poverty Reduction in Developing Countries (2012/2135(INI))’, 15 January 2013, P7_TA (2013)0007, at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2013-0007+0+DOC+XML+V0//EN> [accessed February 2016].

International Council on Human Rights Policy (ICHRP), 'When Legal World Overlap: Human Rights, State and Non-State Law', 2009, available at: www.ichrp.org [accessed September 2016].

International Council for Science (ICSU), 'Science and Traditional Knowledge', March 2002, available at: www.icsu.org [accessed September 2016].

International Law Association (ILA), Committee on Formation of Customary International Law, London conference 2000, available at: <http://www.ila-hq.org/> [last visited 20 February 2016].

International Law Association (ILA), 'Rights of Indigenous Peoples', Interim Report, The Hague Conference, 2010, available at: <http://www.ila-hq.org/> [last visited 20 February 2016].

International Law Association (ILA), 'Rights of Indigenous Peoples', Final Report, The Sofia Conference, 2012, available at: <http://www.ila-hq.org/> [accessed February 2016].

Pacific Islands Forum Secretariat, 'Guidelines for developing legislation for the protection of traditional biological knowledge, innovations and practices based on the Traditional Biological Knowledge, Innovations and Practices Model Law, Fiji 2010, available at: http://www.spc.int/hdp/index2.php?option=com_docman&task=doc_view&gid=256&Itemid=4 [accessed September 2016]

Swiss Federal Council, *Message du Conseil fédéral suisse concernant la modification de la loi sur les brevets et l'arrêté fédéral portant approbation du Traité sur le droit des brevets et du Règlement d'exécution*, Dispatch of the Federal Council concerning the Amendment to the Patent Act, 23 November 2005, FF 2006 1.

Swiss Federal Council, *Message portant approbation du Protocole de Nagoya sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (Protocole de Nagoya) et sa mise en œuvre (loi fédérale sur la protection de la nature et du paysage)*, Dispatch of the Federal Council concerning the ratification of the Nagoya Protocol, 10 April 2013, FF 2013 2659.

TE PUNI KOKIRI, *He Tirohanga ō Kawa ki te Tiriti o Waitangi: A Guide to the Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal*, Te Puni Kōkiri, Wellington, 2002, available at: <http://www.waitangitribunal.govt.nz/treaty-of-waitangi/principles-of-the-treaty/> [accessed September 2016].

Waitangi Tribunal Report of the Waitangi Tribunal on claims concerning New Zealand law and policy affecting Maori culture and identity, Wai 262, Waitangi Tribunal Report 2011, vol. 1 [hereafter, Wai 262 Report, vol. 1], available at: https://forms.justice.govt.nz/search/Documents/WT/WT_DOC_68356054/KoAotearoaTeneiTT1W.pdf [accessed August 2016].

Waitangi Tribunal, Report of the Waitangi Tribunal on claims concerning New Zealand law and policy affecting Maori culture and identity, Wai 262, Waitangi Tribunal Report 2011, vol. 2 [hereafter, Wai 262 Report, vol. 2].

International Treaties, Conventions, Agreements and Declarations

Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, adopted 15 April 1994, 1869 UNTS 299, 33 ILM 1197 (TRIPS Agreement or TRIPS).

Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal, adopted 22 March 1989, 28 ILM 649, (Basel Convention).

Berne Convention for the Protection of Literary and Artistic Works, opened for signature Sept. 9, 1886, revised at Paris in 1979, 828 UNTS 221 (Berne Convention).

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation, CBD COP Decision VI/24, “Access and Benefit-Sharing as Related to Genetic Resources”, in ‘Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity’, 7-9 April 2002, UN Doc. UNEP/CBD/COP/6/20 (27 May 2002), Annex I, pp. 253-269 (Bonn Guidelines).

Charter of the United Nations, 24 October 1945, 1 UNTS XVI.

Charter of the United Nations and Statute of the International Court of Justice, 26 June 1945, 59 Stat. 1031 [the Charter], 1055 [ICJ Statute], T.S. No. 933 [I.C.J. Statute at 25], 3 Bevans 1153 [I.C.J. Statute at 1179].

Convention Establishing the World Intellectual Property Organisation, Stockholm, 14 July 1967, WO029, as amended in 1979, 828 UNTS 3 (WIPO-Convention).

Convention for the Safeguarding of the Intangible Cultural Heritage, UNESCO, Paris, 17 October 2003, 2368 UNTS 3 (UNESCO Convention 2003).

Convention on Biological Diversity, adopted 5 June 1992, entered into force 29 December 1993, 1760 UNTS 79 (Convention on Biodiversity or CBD).

Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal, adopted 22 March 1989, 1673 UNTS 126 (hereafter, “Basel Convention”).

Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act

revising the EPC of 29 November 2000, OJ EPO 2001, Special edition No. 4, p.55 and OJ EPO 2007, Special edition No. 4, synoptic presentation (EPC).

Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the Legal Protection of Databases, OJ L 77, 20-28 (Directive 96/9/EC).

Directive 98/44/EC of the European Parliament and of the Council of the 6 July 1998 on the Legal Protection of Biotechnological Inventions, (1988) OJ L 213, 13-21 (Directive 98/44/EC).

European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by substantive and procedural additional protocols, Council of Europe, Rome, 4 November 1950, ETS 5, 213 UNTS 221 (hereafter, “ECHR”).

European Union Regulation No 511/2014 of the European Parliament and of the Council of 16 April 2014 on Compliance Measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, Official Journal of the European Union, L 150/59, 20 May 2014, (EU Regulation 511/2014).

Implementing Regulations to the Convention on the Grant of European Patents of 5 October 1973 as amended by the decision of the Administrative Council of the EPO of 7 December 2006, OJ EPO 2007, Special edition No. 5, as last amended by the decision of Administrative Council of EPO of 14 October 2015 amending Rule 147, OJ EPO 2015 (EPC Implementing Regulations).

International Covenant on Civil and Political Rights, 16 December 1966, GA Resolution 2200 (XXI), entered into force 23 March 1976, 999 UNTS 171 (ICCPR).

International Covenant on Economic, Social and Cultural Rights, New York, 16 December 1966, GA Resolution 2200 A (XXI), entered into force 3 January 1976, 993 UNTS 3 (ICESCR).

International Convention on the Elimination of All Forms of Racial Discrimination, 21 December 1966, GA Resolution 2106A (XX), entered into force 4 January 1969, 660 UNTS 195.

International Labour Organisation Convention Concerning the Protection and Integration of Indigenous and Other Tribal and Semi-Tribal Populations in Independent Countries, Geneva, 26 June 1957, 328 UNTS 247 (ILO Convention No 107).

International Labour Organisation Convention Concerning Indigenous and Tribal Peoples in Independent Countries, Geneva, 27 June 1989, 1650 UNTS 383 (ILO Convention No 169).

International Treaty on Plant Genetic Resources for Food and Agriculture, adopted Nov. 3, 2001, Rome, S. Treaty Doc. No. 110–19, <http://www.fao.org/AG/cgrfa/itpgr.htm> (International Treaty or ITPGRFA).

Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples, adopted by the First International Conference on the Cultural and Intellectual Property Rights of Indigenous Peoples, Whakatana, 12-18 June 1993, Aotearoa, New Zealand, UN Doc. E/CN.4/Sub.2/AC.4/1993/CRP.5 (Mataatua Declaration).

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity, CBD COP Decision X/1, “Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation”, in ‘Report of the Tenth Meeting of the Conference of the Parties to the Convention on Biological Diversity’ Nagoya, 18-19 October 2010, entered into force 12 October 2014, UN Doc. UNEP/CBD/COP/10/27 pp. 82 ff.

Paris Convention for the Protection of Industrial Property, adopted in 1883, and revised at Stockholm in 1967, 21 UST 1583, 828 UNTS 305 (Paris Convention).

Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 reprinted in 9 I.L.M. 978 (PCT).

Rio Declaration on Environment and Development, proclaimed 13 June 1992, Agenda 21, Rio de Janeiro, 3-14 June 1992, UN Doc., A/CONF.151/26 (vol. I), 31 ILM 874 (Rio Declaration).

Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the African Regional Intellectual Property Organisation (ARIPO), adopted by the Diplomatic Conference of ARIPO at Swakopmund (Namibia), 9 August 2010 (Swakopmund Protocol).

Treaty Creating the Court of Justice of the Andean Community, 18 ILM 1203, amended by the Cochabamba Protocol, 28 May 1996 (TCCJ).

United Nations Convention to Combat Desertification in Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa, 14 October 1994, Paris, 1954 UNTS 3 (UNCCD).

United Nations Declaration on the Rights of Indigenous Peoples, Resolution 61/295 adopted by the United Nations General Assembly Resolution (UN GA Res), 61st session, 13 September 2007, UN Doc. A/RES/61/295.

Universal Declaration on Cultural Diversity, UNESCO, Paris, 2 November 2001, UNESCO Doc. 31C/Res. 25, Annex I, ILM, vol. 41, 2002, p. 57 (UNESCO Universal Declaration 2001).

Universal Declaration of Human Rights, Paris, 10 Dec. 1948, Resolution 217 A adopted by the UN GA Res, 10 December 1948, UN Doc. A/RES/3/217 A (UDHR).

Vienna Convention on the law of Treaties, Vienna, 23 May 1969, entered into force 27 January 1980 1155 UNTS 331, (VCLT).

Statutes and Legislations

Andean Community Decision 391 Establishing the Common Regime on Access to Genetic Resources, enacted 2 July 1996 (Andean Decision 391 on a Common Regime on Access to Genetic Resources, 1996), available at: <http://www.wipo.int/wipolex/en/details.jsp?id=9446> [accessed March 2016].

Andean Community Decision 486 Establishing the Common Industrial Property Regime, enacted 17 September 2000 (hereafter, Andean Decision 486 on a Common Intellectual Property Regime, 2000), available at: <http://www.wipo.int/wipolex/en/details.jsp?id=9451> [accessed March 2016].

Constitución política *del Perú*, 29 December 1993, [hereafter, Political Constitution of Peru], available at: <http://spij.minjus.gob.pe/CLP/contenidos.dll?f=templates&fn=default-constitucion.htm&vid=Ciclope:CLPdmo>, [accessed 7 January 2016].

Decreto-Lei de Portugal n.º 118/2002 de 20 de Abril sobre Material vegetal autóctone, Portuguese Decree-Law No. 118/2002 of 20 April on Autochthonous plant material [hereafter, Portuguese Law 118/2002], available at: <http://www.wipo.int/wipolex/fr/details.jsp?id=5758> [accessed August 2016].

Directive 98/44/EC of the European Parliament and of the Council Of 6 July 1998 on the legal protection of biotechnological inventions, 1998, OJ L 213/13.

EU Regulation No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, 2014, OJ L 150/59.

Ley de Derecho a la Consulta Previa a los Pueblos Indígenas u Originarios Reconocido en el Convenio 169 de la Organización Internacional del Trabajo (OIT), Ley 29785 (Law on the Right of Consultation of Indigenous Peoples, Peruvian Law 29785), 8 August 2011, available at: <http://ht.ly/6b5HO>, [accessed September 2016].

Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos, Ley 27811 (Protection of Indigenous Peoples' Collective Knowledge Associated with Biological Resources, Peruvian Law 27811), 24 July

2002, available at: <http://www.wipo.int/wipolex/en/details.jsp?id=3420>, [accessed September 2016].

Ley de protección al acceso a la Diversidad Biológica Peruana y los conocimientos colectivos de los pueblos indígenas, Ley 28216 (Protection of Access to Peruvian Biological Diversity and Collective Knowledge of Indigenous Peoples, Peruvian Law 28216), 30 April 2004, available at: <http://www.wipo.int/wipolex/fr/details.jsp?id=5752> [accessed January 2016].

U.S. Patent Law, 35 U.S.C. §§ 1 et seq. (consolidated as of May 2015). This consolidated version of the U.S. Patent Law, contained in Title 35 of the United States Code incorporates the changes made by the Patent Law Treaties Implementation Act of 2012 (Public Law 112-211, 126 Stat. 1527) of December 18, 2012, implementing the Hague Agreement Concerning International Registration of Industrial Designs and the Patent Law Treaty (US Patent Law, U.S.C. Title 35) available at: http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf [September 2016].

Norwegian Patent Act No. 9 of 15 December 1967 (consolidated version of 2010, which takes into account amendments up to the Law No. 8 of 26 March 2010).

New Zealand Patent Act, enacted 13 September 2013, entered into force September 2014 (the NZ Patents Act 2013).

Loi fédérale sur les brevets d'invention (LBI), Swiss Federal Act on Patents for Inventions, 25 June 1954, Systematically Recorded under No. 232.14 (Swiss Patent Act, PatA).

Loi fédérale sur la protection de la nature et du paysage (LPN), Swiss Federal Act on the Protection of Nature and Cultural Heritage, 1 July 1966, Systematically Recorded under No 451 (Swiss Act on the Protection of Nature and Cultural Heritage, NCHA).

Ordonnance sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (ONag), 11 December 2015, Systematically Recorded under No 451.61, Ordinance on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Ordinance, NagO).

Case LawEuropean Patent Office

EPO Technical Board of Appeal, T 84/83 – *Hohe v. Hagus*, 29 September 1983, unpublished.

T 939/92 (chemical structure and biological activity).

EPO Technical Board of Appeal, T0964/92 – *ESAI*, 23 August 1994, unpublished.

EPO Technical Board of Appeal, T 0206/83 - *Herbicides/ICI*, 26 March 1986 (enablement), OJ 1987, 005.

EPO Technical Board of Appeal, T 0020/83 – *Benzothiopyran derivatives*, 17 March 1983, OJ 1983, 419.

EPO Technical Board of Appeal, T 0150/82 – *IFF*, 7 February 1984, OJ 1984, 309.

EPO Enlarged Board of Appeal, G 05/83– *EISAI*, 5 December 1984.

EPO Enlarged Board of Appeal, G 2/88 – *Mobil Oil v. Chevron Research*, 11 December 1989, OJ 1990, 93.

EPO Technical Board of Appeal, T0019/90 – *Onco-Mouse v. Harvard*, 3 October 1990.

EPO Technical Board of Appeal, T 0245/88, *Union Carbide v. Linde*, 12 March 1991, unpublished.

EPO Technical Board of Appeal, T 0270/90 – *Asachi v. General Electric*, 21 March 1991, OJ 1993, 725.

EPO Technical Board of Appeal, T 116/90 – *Beecham v. Hoechst*, 18 December 1991, unpublished.

EPO Technical Board of Appeal, T 513/90 – *JAPAN STYRENE*, 19 December 1991, OJ 1994, 154.

EPO Technical Board of Appeal, T 743/89 – *CIBA-GEIGY v. BORG-WARNER CHEMICALS*, 27 January 1992, unpublished.

EPO Technical Board of Appeal, T 383/88 - *Biomeasure*, 1 December 1992, unpublished.

EPO Board of Appeal, T 328/87 – *Thomson-Brandt v. Electrolux*, 4 April 1991, OJ 1992, 701.

EPO Board of Appeal, T 0356/93 – *Plant Genetic Systems v. Greenpeace*, 21 February 1995, OJ 1995, 545.

EPO Technical Board of Appeal, T 0939/92 – *Triazoles herbicides v. AgrEvo UK*, 12 September 1995, OJ 1996, 309.

EPO Technical Board of Appeal, T 69/94 – *BEECHAM GROUP v. HOECHT*, 18 June 1996, unpublished.

EPO Technical Board of Appeal, T 472/92 – *SEKISUI v. Owens*, 20 November 1996, OJ 1998, p. 161

EPO Technical Board of Appeal, T381/87 – *Research Association v. Brauns*, 10 November 1998.

EPO Technical Board of Appeal, T 314/99 – *ExxonMobil v. Fina Research* (“*Diplomarbeit*”), 21 June 2001, unpublished.

EPO Technical Board of Appeal, T 967/97 – *OVD Kinegram*, 25 October 2001, unpublished.

EPO Technical Board of Appeal, T 479/00 – *Colouring ceramics v. VIGNALI*, 15 February 2002, unpublished.

EPO Technical Board of Appeal, T 186/01 – *DeLaval International v. MAASLAND N.V.*, 25 October 2002, unpublished.

EPO Technical Board of Appeal, T 631/00 – *SANYO v. STARCK*, 5 May 2004, unpublished.

EPO Technical Board of Appeal, T 315/03 – *Onco-Mouse v. Harvard*, 6 July 2004, OJ 2006, 15.

EPO Technical Board of Appeal, T 1081/01 - *New Japan Chemical*, 27 September 2004, unpublished.

EPO Technical Board of Appeal, T 1408/04 – *THE PROCTER & GAMBLE v. Kimberly-Clark*, 17 November 2006, unpublished.

EPO Technical Board of Appeal, T 1020/03 – *GENENTECH*, 29 October 2004, OJ 2007, 204.

EPO Technical Board of Appeal, T 0543/04 – *Appetite suppressant /CSIR*, 27 January 2005, unpublished.

EPO Technical Board of Appeal, T 1212/01 – *Pfizer Limited v. Virus Inc.*, 3 February 2005, unpublished.

EPO Technical Board of Appeal, T 0416/01 – *Thermo Trilog v. Aelvoet*, 8 March 2005 (often referred to as the Neemfungicide case), unpublished, available at: <http://www.epo.org/law-practice/case-law-appeals/recent/t010416eu1.html> [accessed September 2016].

EPO Technical Board of Appeal, T 0211/06 – *NGK INULATORS*, 25 April 2007, unpublished.

EPO Technical Board of Appeal, T 804/05 – *DAL v. CREVAN*, 16 October 2007, unpublished.

EPO Technical Board of Appeal, T 1309/07 – *Mahle International*, 23 June 2009, unpublished.

EPO Enlarged Board of Appeal, G 02/08 – *Abbott Respiratory*, 19 February 2010, OJ EPO 2010, 456.

EPO Technical Board of Appeal, T 0593/09 – *TOKO KOHAN v. TATA STEEL*, 20 December 2012, unpublished.

EPO Technical Board of Appeal, T 1140/09 – *Hitachi-Omron v. Gieseck & Devrient*, 18 January 2012, unpublished.

United States Cases

United States Court of Appeals, Federal Circuit, *In re Lee*, 277 F.3d 1338, 2002.

United States Court of Appeals, Federal Circuit, *Pfizer v. Apotex*, 480 F.3d 1348, 2007, reconsideration denied in United States Court of Appeals, Federal Circuit, *Pfizer v. Apotex*, 488 F.3d 1377, 2007

United States Court of Appeals, Federal Circuit, *Takeda Chemical Industries v. Alphapharm*, 492 F.3d 1350, 2007.

United States Court of Appeals, Federal Circuit, *PHARMASTEM THERAPEUTICS v. VIACELL*, 491 F.3d 1342, 2007, para. 65

United States Court of Appeals, Federal Circuit, *Eisai Co v. Dr. Reddy's Labs*, 533 F.3d 1353, 2008.

United States Court of Appeals, Federal Circuit, *Re Klein*, 647 F.3d 1343, 2011.

United States Court of Appeals, Federal Circuit, *Kinetic Concepts v. Smith & Nephew*, 688 F.3d 1342, 1368, 2012.

United States Court of Appeals, Federal Circuit, *Bristol-Myers Squibb v. Teva Pharm. USA*, 752 F.3d 967, 2014.

United States Court of Appeals, Federal Circuit, *Insite Vision v. Sandoz*, 783 F.3d 853, 2015.

United States Supreme Court (U.S. S.Ct.), *Hotchkiss v. Greenwood*, 52 U.S. 248, 11 How. 248, 13 L.Ed. 683, 1850.

U.S. S.Ct., *Cuno Engineering v. Automatic Devices*, 314 U.S. 84, 62 S.Ct. 37, 86 L.Ed. 58, 1941.

U.S. S.Ct, *William Graham v. John Deere Company Kansas City et al.*, 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed. 2d 545, 1966.

U.S. S.Ct, *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S.Ct. 2204, 65 L.Ed. 2d 144, 1980.

U.S. S.Ct, *KSR International v. TELEFLEX et al.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 2007.

U.S. S.Ct, *Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. __ 2013

USPTO Manual of Patent Examining Procedure, Chapter 2100, Section 2161, available at:
<http://www.uspto.gov/web/offices/pac/mpep/s2161.html>

Other Case Laws

Constitutional Court of South Africa, *Alexkor Ltd v. The Richtersveld Community & Others*, 12 BCLR 1301 (CC), decided on 14 October 2003.

European Court of Human Rights (ECtHR), *Chassagnou and Others v. France* [GC], nos. 25088/94, 28331/95 and 28443/95, 20 April 1999, Reports of Judgments and Decisions 1999-III.

High Court of Australia, *Mabo and Others v. Queensland*, No. 2, 175 CLR 1 F.C 92/014, 107 ALR 1, decided 3 June 1992.

High Court of Australia, *Western Australia v. Ward & Others*, 213 CLR 1; 76 ALJR 1098; 191 ALR 1, decided 8 August 2002.

Inter-American Court of Human Rights (IACHR), *Mayagna (Sumo) Awas tingni Community v. Nicaragua*, Judgement of 31 August 2001, Series C No. 79, IACHR 9.

Inter-American Court of Human Rights (IACHR), *Saramaka People v. Suriname*, Preliminary Objections, Merits, Reparations, and Costs, Judgement of 28 November 2007, Series C No. 172, IACHR 5.

Inter-American Court of Human Rights (IACHR), *Saramaka People v. Suriname*, Interpretation of the Judgement on Preliminary Objections, Merits, Reparations, and Costs, Judgement of 12 August 2008, IACHR 2008.

International Court of Justice (ICJ) Advisory Opinion, *Western Sahara: Advisory Opinion* of 16 October 1975, IJC Rep 12.

Supreme Court of Canada, *R v. Van Der Peet*, 2 SCR 507, decided 21 August 1996.

ABBREVIATIONS

ABS	Access and Benefit-Sharing
ATF	<i>Arrêts du Tribunal Fédéral</i> (Case Law of the Swiss Federal Tribunal)
BCLR	Butterworths Constitutional Law Reports (South Africa)
BGH	Bundesgerichtshof
CBD	Convention on Biological Diversity
CC	Constitutional Court (South Africa)
CERD	Committee on the Elimination of Racial Discrimination
CESCR	Committee on Economic, Social and Cultural Rights
CGRFA	Commission on Genetic Resources for Food and Agriculture
CHM	Clearing House Mechanism
CIPR	Commission on Intellectual Property rights
CISDL	Centre for International Sustainable Development Law
ECHR	European Convention on Human Rights
ECOSOC	The Economic and Social Council (UN)
ECtHR	European Court of Human Rights
EPO	European Patent Office
EPO OJ	Official Journal of the European Patent Office
EPOR	European Patent Office Reports
EU	European Union

FF	<i>Feuille Fédérale</i> (Swiss Federal Gazette)
FOEN	<i>Département fédéral de l'environnement, des transports, de l'énergie et de la communication (OFEV)</i>
FPIC	Free, and Prior Informed Consent
GC	Grand Chamber
GRs	Genetic resources
HRC	Human Rights Council
IACHR	Inter-American Court of Human Rights
ICCPR	International Covenant on Civil and Political Rights
ICERD	International Convention on the Elimination of All Forms of Racial Discrimination
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICHRP	International Council on Human Rights Policy
ICSU-ROLAC	International Council for Science Regional Office for LAC
ICTSD	International Centre for Trade and Sustainable Development
IDRC	International Development Research Centre (Canada)
IIED	International Institute for Environment and Development
ILA	International Law Association
ILCs	Indigenous and Local Communities
ILO	International Labour Organisation
INDECOPI	<i>El Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual</i>
INGRES	<i>Institut für Gewerblichen Rechtsschutz</i>

IPC CE	Committee of Experts of the IPC
IPC Union	Special Union for the International Patent Classification
IPRs	Intellectual Property Rights
ITPGRFA	The International Treaty on Plant Genetic Resources for Food and Agriculture
IUBS	International Union of Biological Sciences
IUCN	International Union for Conservation of Nature
JdT	<i>Journal des Tribunaux</i> (Journal of Tribunals)
IPONZ	Intellectual Property Office of New Zealand
LAC	Latin America and the Caribbean
MAT	Mutually Agreed Terms
NagO	Ordinance on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation
NCHA	Swiss Act on the Protection of Nature and Cultural Heritage
NIH	National Institute of Health
NP	Nagoya Protocol
OHCHR	United Nations Human Rights Office of the High Commissioner
Para.	Paragraph
PatA	Swiss Patent Act
PIC	Prior Informed Consent
RAFI (now ETC)	Rural Advancement Foundation International
REDD	Reducing Emissions from Deforestation and forest Degradation

SCNAT	Swiss Academy of Sciences
SPDA	<i>La Sociedad Peruana de Derecho Ambiental</i> (The Peruvian Society for Environmental Law)
SSRN	Social Science Research Network
TCEs	Traditional Cultural Expressions
TK	Traditional Knowledge
TMK	Traditional Medicinal Knowledge
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNCCD	United Nations Convention to Combat Desertification in Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa
UNCTAD	United Nations Conference on Trade and Development
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNPFII	United Nations Permanent Forum on Indigenous Issues
UNU-IAS	United Nations University – Institute for the Advanced Study and Sustainability
U.S.C.	United States Code
U.S. S.Ct.	United States Supreme Court
WG-ABS	Ad Hoc Open-ended Working Group on Access and Benefit-Sharing
WG-8J	Ad Hoc Open-ended Working Group on Article 8(j) and Related Provisions

WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WIPO GA	WIPO General Assembly
WIPO IGC	WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore Traditional Knowledge
WIPO PBC	WIPO Program and Budget Committee
WIPO PCT Union	WIPO International Patent Cooperation Union
WIPO SCP	WIPO Standing Committee on the Law of Patents
WTO	World Trade Organization