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Contents

1	Introduction	4
1.1	Overview	4
2	Traditional Knowledge	6
2.1	Background	6
2.1.1	Definition	8
2.1.2	Beneficiaries	11
2.2	Commercial Value	13
2.2.1	Relationship to Occidental Science	16
3	Protection of Traditional Knowledge	18
3.1	Overview	18
3.2	Non-Legislative Options for Protection	25
3.3	Selected Arguments in Favour of Protection	25
3.4	Selected Arguments Opposed to Protection	26
4	Municipal Legislative Responses	29
4.1	General	29
5	International Law and Policy	30
375.1	World Trade Organization (TRIP's Council)	30
5.2	Convention on Biological Diversity	31
5.3	World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore	34
5.4	United Nations	38
6	Indigenous Peoples Declarations	40
6.1	Overview	40
7	Contract Approach	41
7.1	Overview	41
7.2	Material Transfer Agreements	42
7.3	Bio-prospecting Agreements	42
7.4	Know-How Licensing Agreements	43
7.1.1	Selected Arguments in Favour of a Contract Approach	43

7.1.2	Selected Arguments Opposed to a Contract Approach	45
8	Case studies	48
8.1	San Hoodia Benefit Sharing Trust	48
8.2	Kerala Kani Samudaya Trust	52
8.3	Confederacion de Nacionalidades Amazonicas del Peru (CONAP)Fund	55
9	Selected Issues Surrounding Case Studies	59
9.1	Ownership of Traditional Knowledge	60
9.2	Prior Informed Consent and Disclosure	64
10	Concluding Remarks	72
	Bibliography	74
	Table of Cases	89

1 Introduction

1.1 Overview

There are estimated to be over 500 million tribal or indigenous peoples residing in over seventy countries whose social, political, economic and cultural orders predate the modern nation state.¹ These peoples also possess diverse knowledge systems and various types of knowledge and applications to include knowledge in relation to food and agriculture, biological and other materials, medicine and medical treatment, design, literature, music and other artistic manifestations. Indigenous knowledge systems and associated knowledge are diverse, as are the nomenclature. For example, the Nunavummiut (Inuit) of Canada refer to their knowledge system and associated knowledge as *Qaujimajatuqangit*.² In municipal and international parlance, they are referred to collectively as traditional knowledge systems (TKS) and associated traditional knowledge (TK).

TK in relation to genetic resources has taken on increasing economic, scientific and commercial value due in part, to modern biotechnology. Other forms of indigenous creative expression, such as oral tradition, songs, crafts and methods of farming, now have an increased potential for commercial value, largely a result of globalization and the Internet. With the expansion of this commercial value comes an expanded possibility for exploitation, which brings up the question of intellectual property rights (IPRs)

While it is fair to say that most indigenous communities are marginalized in every sense, they are rich in knowledge. However this knowledge remains largely unprotected and has led the Special Rapporteur of the Sub-Commission on the Prevention of Discrimination and Protection of Minorities (as it then was) and Chairperson of the Working Group on Indigenous Populations (as she was then), Mme. Daes to remark, “[T]he fact that many of these peoples are in jeopardy has been advanced as a justification for acquiring their knowledge even more rapidly.”³ Therefore, there is need for measures for indigenous peoples to control their intellectual capital. In this respect various proposals exist including the preservation of the *status quo*, consideration of TK as protectable subject matter through the development of national, regional and international *sui generis* regimes, a moratorium on all bioprospecting activities until an acceptable solution is found (in what is known colloquially as the “rights first, access later

¹ Julian Burger, *The Gaia Atlas of First Peoples: A Future for the Indigenous World* (London; Gaia Books, Ltd., 1990) p. 18.

² Gartner Lee Limited, *2004 Inuit Qaujimajatuqangit (Traditional Knowledge) Baseline: Nunavut Research Institute Permit Report* (December 2004), see also Pauktuutit Inuit Women’s Association, *Inuit Women’s Traditional Knowledge Workshop on the Amauti and Intellectual Property Rights Rankin Inlet, Nunavut May 24-27, 2001 Final Report* (Ottawa 2002).

³ Commission on Human Rights Sub-Commission on Prevention of Discrimination and Protection of Minorities *Study on the protection of the cultural and intellectual property of indigenous peoples*, (E/CN.4/SUB.21993/28) 28 July 1993 para. 20.

campaign”), a system of certification that would identify the country of origin, source or legal provenance of resources and associated TK as well as evidence of prior informed consent (PIC) as a precondition for the granting of patents and recognition of foreign patents⁴ and the development of an indigenous customary law solution.⁵

Any resolution remains to be seen however. And in the absence of protective measures however constituted, traditional knowledge holders may try to negotiate benefit-sharing arrangements, as some already do with companies, research institutions, other entities and individuals acquiring and using genetic resources and traditional knowledge. This paper will discuss three of these contractual arrangements namely: *San Hoodia Benefit Sharing Trust of Southern Africa*, *Kerala Kani Samudaya Trust of India* and *Confederacion de Nacionalidades Amazonicas del Peru (CONAP)* (Indigenous partner of four organizations of Aguaruna communities and peoples) of Peru and the unique issues they present for indigenous peoples there and specifically ownership of the subject matter TK, prior informed consent and disclosure and the need for capacity building in the negotiation of these arrangements. Before addressing the issue in the main, this paper will present an overview of preliminary considerations regarding traditional knowledge such as a definition, beneficiaries and commercial values. Attention is drawn to issues surrounding its protection including select arguments and counter-arguments for protection. Finally national and international responses to traditional knowledge generally is provided.

At the outset, this paper’s limitations must be noted. A critical and detailed examination on the appropriateness of the application of conventional or

⁴ Of necessity this requires international cooperation between user/recipient countries to control the importation, transfer and commercial use of genetic resources and related TK. See United Nations University Institute of Advanced Studies (UNU-IAS) *User Measures Options for Developing Measures in User Countries to Implement the Access and Benefit Sharing Provisions of the Convention on Biological Diversity* (UNU-IAS Japan 2003) 2nd.

⁵ See WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, *Traditional Knowledge and Folklore Sixth Session* Geneva, March 15 – 19, 2004. (WIPO/GRTKF/IC/6/14) 14 April 2004. Statement of the Kaska Dene on behalf of the indigenous representatives at this meeting. “The organizations were supportive of the development of an international regime on the precondition that the following fundamental principles were included therein: Indigenous peoples were recognized as custodians and owners of their knowledge, TCEs and natural resources and had the exclusive right to control and manage their knowledge, expressions and resources; States should affirm that the land and territorial rights of Indigenous Peoples were fundamental to the retention of Indigenous Knowledge and cultural practices pursuant to the implementation of relevant international obligations; an international regime should expressly affirm the right of Indigenous Peoples to restrict and/or exclude access to their knowledge, TCEs and natural resources; an international regime must ensure that the right to prior informed consent of Indigenous peoples was guaranteed and protected, as a fundamental principle in the exercise of self determination and sovereignty of Indigenous Peoples; the right of prior informed consent must be maintained throughout any access and benefit sharing arrangements where there was potential change of permitted use or third party involvement; an international regime must enable the effective implementation, application and enforcement of Indigenous customary laws and cultural practices; and in circumstances where there was a conflict, Indigenous customary laws and cultural practices should prevail over domestic law or an international regime.”

mainstream IPR to TK is beyond the scope of this paper and the reader is directed to sources in that respect.⁶ Nevertheless the issue will be addressed summarily here for contextual purposes. Likewise TK as a protectable subject matter through *sui generis* regimes (national, regional or international) is also the focus of literature and the reader is also directed to those sources.⁷ This too is beyond the scope of this paper. Finally, while a significant issue and particularly in the light of the Commission on Human Rights Sub-Commission on the Promotion and Protection of Human Rights resolution 2000/7, the interface between human rights and intellectual property will not be addressed.⁸ The issue is far too important for summary treatment (as in the case of the application of conventional IPRs to TK) and thus deserving of separate treatment. Again the reader is directed to sources in that area.⁹

2 Traditional Knowledge

2.1 Background

Knowledge has been identified as a corporation's most valuable resource, the ultimate substitute for raw materials, labour, capital and inputs.¹⁰ A growing level of appreciation of indigenous or traditional knowledge

⁶ See for example David R. Downes, 'How Intellectual Property Could Be a Tool to Protect Traditional Knowledge' 25 *Colum. J. Envtl. L.* 253 (2000), Daniel J. Gervais, 'The Internationalization of Intellectual Property: New Challenges from the Very Old and the Very New' 12 *Fordham Intell. Prop. Media & Ent. L.J.* 929 (2002); Christopher Heath and Sabine Weidlich, 'Intellectual Property: Suitable For Protecting Traditional Medicine,' 1 *I.P.Q.* 2003, 69

⁷ See for example Michael Halewood, 'Indigenous and Local Knowledge in International Law: A Preface to *Sui Generis* Intellectual Property Protection' 44 *McGill L. J.* (1999) 953, WIPO, *Elements for a Sui Generis System for the Protection of Traditional Knowledge*, (WIPO/GRTKF/IC/4/8) 30 September 2002.

⁸ The resolution entitled *Intellectual property rights and human rights* and adopted at its 52 session (E/CN.4/Sub.2/Res/2000/7) 2000 reads in part "[Noting] . . . that actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights in relation to, inter alia, impediments to the transfer of technology to developing countries, the consequences for the enjoyment of the right to food, of plant variety rights and the patenting of genetically modified organisms, "biopiracy" and the reduction of communities' (especially indigenous communities') control over their own genetic and natural resources and cultural values, and restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health, Declares . . . that since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights . . . there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other."

⁹ See for example David Weissbrodt and Kell Schoff, 'Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7,' 5 *Minn. Intell. Prop. Rev.* 1 (2003); Laurence R. Helfer, 'Human Rights and Intellectual Property: Conflict or Coexistence,' 5 *Minn. Intell. Prop. Rev.* 47 (2003); Audrey R. Chapman, 'Approaching Intellectual Property as a human right: obligations related to Article 15 (1) (c),' *Copyright Bulletin* vol. xxxv, no. (3 July – Sept. 2001); WIPO *Intellectual Property and Human Rights* (Geneva, WIPO, 1999).

¹⁰ See Seth Shulman, *Owning the Future*, (Boston, Houghton Mifflin, 1999) p. 4.

(IK/TK)¹¹ finds its corollary in a growing assertiveness on the part of indigenous peoples to prevent the appropriation of their knowledge without their consent or even knowledge.

The growing awareness about TK has also opened up new debates such as a 'historical debt' owed to indigenous peoples globally for past appropriations without compensation.¹² The current debate is also changing corporate behaviour for better or worse. Researchers from the Royal Botanic Gardens Kew claim "that the [Convention on Biological Diversity's] focus on fair and equitable partnerships has resulted in research in fewer countries and particularly in research projects with potential commercial applications in part because of lack of resources and oversight to avoid the risk of costly missteps and damaging accusations of biopiracy... [and]...the increasing application of intellectual property protection and development of the rights of countries of origin and other stakeholders present challenges."¹³ According to researchers at Bristol-Myers Squibb and SmithKline Beecham, it seems unlikely that those companies would even consider making a heavy financial investment beyond the sample fees, given the uncertainty of product development.¹⁴ And while inventors have a duty of candour, good faith and honesty to patent examiners during the process of obtaining a patent, they are advised to take specific actions to avoid becoming the focus of an inequitable conduct defence.¹⁵

¹¹ The terms "indigenous" and 'traditional' are used interchangeably for the purposes of this paper.

¹² See Suman Sahai, 'Protection of Indigenous Knowledge and Possible Methods of Sharing Benefits with Local Communities,' (ICTSD International Centre for Trade and Sustainable Development and CPD Centre for Policy Dialogue – Background Paper Prepared for the Multi-stakeholder Dialogue on Trade, Intellectual Property and Biological Resources In Asia, Bangladesh 19-21 April 2002) p. 11 writes "Shahnaz Hussain, a leading Ayurvedic cosmetics firm which has a large domestic and export market and others like it, should be required to pay back to communities at least some part of the money they have made using their [tribals in India] knowledge." See also UNU-IAS Report *infra* note 37 p. 56 "Compensation of indigenous peoples for past unapproved diffusion, misappropriation or expropriation of their knowledge will need to be adjudged through appropriate mechanism. This will undoubtedly be a lengthy process."

¹³ See Kate Davis and China Williams, *Biodiversity, Botanical Institutions and Benefit-Sharing – comments on the impact of the Convention on Biological Diversity* (Washington University School of Law Conference Biodiversity and Biotechnology and the Protection of Traditional Knowledge 4-6 April 2003) <<http://law.wustl.edu/centeris/Confpapers/>> (visited 14 May, 2004); See also Brad Sherman, 'Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery,' *E.I.P.R.* 2003, 25(7) pp. 301-308 and citing *Access to Biological Resources in Commonwealth Areas* (2000) (often known as the 'Voumard Inquiry') "noted a decline in the use of traditional knowledge because of a fear that [that] any use would be seen to be inequitable."

¹⁴ See Mulholland *infra* note 50.

¹⁵ Phillip Jones, 'How to avoid losing your patent: inequitable conduct verdicts hurt; protect your patent with these eight steps (BioBusiness)' *The Scientist* v.17, i21 p. 34 (November 7, 2005) <www.the-scientist.com> (visited 10 November 2005). The eight steps include:

- Disclose prior art
- Update the examiner about prior art discovered in related applications
- Don't submit partial translations for foreign references
- Update examiners about developments in related patent litigation

There is a growing, albeit minor, commercial practice whereby users of genetic resources (as well as products and substances derived from those resources) refuse to deal with a company if it cannot guarantee the provenance of the biologically based products it is selling.¹⁶ Other organizations are incorporating their professional codes of conduct into bioprospecting contracts¹⁷ and developing “best practices” related to indigenous knowledge.¹⁸

2.1.1 Definition

Traditional knowledge encompasses various types of knowledge and applications and is considered a living knowledge, evolving from the past to the present.¹⁹ TK is not static. The “traditional” in TK means that TK is developed according to the rules, protocols and customs of a certain community and not that it is old.²⁰ In other words, the adjective “traditional” qualifies the method of making TK and not the knowledge itself.²¹ TK manifests in any number of ways and some TK like *Ayurveda* (traditional medicine in India) is codified. A great part of TK, however, is non-codified or tacit such as most tribal or indigenous medicinal knowledge.²²

-
- Disclose data even if it undercuts patentability arguments
 - Help your patent representative to identify inventors
 - Ensure that affidavits present the truth
 - Don't write prophetic examples in the past tense

¹⁶ See Sherman *supra* note 13, pp. 304, 307.

¹⁷ See David J. Stephenson Jr., ‘CONTRACTS AND LICENSES FOR GENETIC INFORMATION: An Introduction to Alternative Mechanisms for Protecting the Intellectual Property of American Indians in The Context of the Human Genome Project’ (A Paper Presented for the UCHSC ELSI Working Group Aspen, Colorado USA April 6, 2001). “The International Society of Ethnobiology has adopted a Code of Ethics and is drafting accompanying Standards of Practice that should be consulted and incorporated into any bioprospecting contract whenever feasible (International Society of Ethnobiology 1998) pp. 9-10.

¹⁸ UNESCO Management of Social Transformations Programme (Most), Nuffic (Netherlands Organization for International Cooperation in Higher Education), *Best Practices on Indigenous Knowledge* (1999); UNESCO Management of Social Transformations Programme (Most), Nuffic (Netherlands Organization for International Cooperation in Higher Education), *Best Practices using Indigenous Knowledge* (2002); UNESCO Management of Social Transformations Programme (Most), Nuffic (Netherlands Organization for International Cooperation in Higher Education), *Register of Best Practices on Indigenous Knowledge* (1999-2002) <www.unesco.org/most/bpikreg.htm> (visited 10 November 2005).

¹⁹ See Robert T McFetridge and Geoff Howell, ‘Linking Western Sciences and Traditional Knowledge’ February 28, 2001, *Canadian Information System for the Environment* p.3 <www.cise> (visited 14 March 2004).

²⁰ See *Elements of a Sui Generis System for the Protection of Traditional Knowledge supra* note 6, para. 27.

²¹ Nuno Pires de Carvalho, ‘From the Shaman’s Hut to the Patent Office: In Search of Effective Protection for Traditional Knowledge,’ 17 *Wash.U.J.L. & Pol’y* (2005) p. 111 asserts, “This idea logically misspells the myth that because TK is old, it cannot be captured by its creators and therefore may not be the subject of intellectual property protection.”

²² See Carlos M. Correa, ‘Protection and Promotion of Traditional Medicine Implications for Public Health in Developing Countries’ (August 2002) p.4

TK may be produced by individuals, by groups of individuals or by local or indigenous communities. Some of this knowledge may be kept confidential to the originator(s) and their descendants and may be accessed only with restrictions. Some may be disseminated locally, but may, nonetheless, be restricted in scope or in terms of accessibility; and some of this knowledge may be shared widely within a community and with outsiders, so that the knowledge becomes public domain TK.²³ Some TK has commercial value (through the sale of TK based products) while other TK has no such value. The latter form of TK may have spiritual components and community custom and mores admonish against commercialization.²⁴

There are sub-sets of TK²⁵ for example traditional ecological knowledge (TEK)²⁶ and traditional medicinal knowledge (TMK).²⁷ As presently

www.southcentre.org/publications/traditionalmedicine/traditionalmedicine> (visited 15 March 2004)

²³ See Anil K. Gupta, *The Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Traditional* (WIPO and UNEP Geneva 2005) pp. 26 – 29.

²⁴ See The Lakota Summit V, an international gathering of US and Canadian Lakota, Dakota and Nakota Nations, passed a "Declaration of War Against Exploiters of Lakota Spirituality" on June 10, 1993 and the following resolution "We especially urge all our Lakota, Dakota and Nakota people to take action to prevent our own people from contribution to and enabling abuse of our sacred ceremonies and spiritual practices by outsiders; for as we all know, there are certain ones among our own people who are prostituting our spiritual ways for their own selfish gain, with no regard for the spiritual well-being of the people as a whole." www.thepeoplespaths.net/articles/ladecwar.htm> (visited 14 October 2004)

²⁵ See de Carvalho *supra* note 21, pp. 5 – 7, characterizes TK into two main areas. "TK consists of knowledge itself, that is, ideas developed by traditional communities and Indigenous peoples, in a traditional and informal way, as a response to the needs imposed by their physical and cultural environments and that serve as means of cultural identification. This is what we may call 'TK *stricto sensu*' and it contrasts with 'expressions of TK,' also named 'expressions of folklore' or 'expressions of traditional culture,' such as verbal instructions (tales, poetry, riddles), musical expressions (songs and instrumental music), expression by action or performances (dances, plays and artistic forms or rituals), expressions by action or performances (dances, plays and artistic forms or rituals), whether or not reduced to a material form, and tangible expressions (productions of art, such as drawings, paintings, carvings), musical instruments and architectural forms. Both categories constitute TK *lato sensu*. However, see Daes *supra* note 3 paras. 21-23 who eschews compartmentalizing TK and regards the distinction between cultural and intellectual property as an artificial construct and that "Indigenous peoples regard all products of the human mind and heart as interrelated, and as flowing from the same source: the relationships between people and the land, their kinship with other living creatures that share the land, and with the spirit world." The Special Rapporteur goes on to suggest "that it is both simpler and more appropriate to refer to the collective 'heritage' of each indigenous people, rather than make distinctions between 'cultural property' and 'intellectual property.'" See also Johanna Gibson, *Intellectual Property Systems, Traditional Knowledge and the Legal Authority of Community E.I.P.R.* 2004, 26(7), 280-90.

²⁶ Martha Johnson, *Research on Traditional Environmental Knowledge: Its Development and Its Role, Lore: Capturing Traditional Environmental Knowledge*, (International Development Research Centre (IDRC Ottawa 1992) lists several ways that TEK is generated, recorded, and transmitted, distinguishing it from occidental or western scientific knowledge.

defined, TK's scope is vast; its boundaries ambiguous suggesting a need to circumscribe it rationally.²⁸ However, difficulty in defining (or establishing parameters) TK has not impeded further work on it at the national or international levels. Indeed, the World Intellectual Property Organization (WIPO) observes, "[G]iven this highly diverse and dynamic nature of traditional knowledge it may not be possible to develop a singular and exclusive definition of the term. However, such a singular definition may not be necessary in order to delimit the scope of subject matter for which protection is sought. This approach has been taken in a number of international instruments in the field of intellectual property."²⁹ Bearing this in mind, WIPO has adopted a working or operational definition:

"traditional knowledge be considered as encompassing traditional and tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other traditional and tradition- based

²⁷ World Health Organization & Zhang X, 'Integration of Traditional and Complementary Medicine Into National Health Care Systems,' 23 *J. Manipulative & Physiological Therapeutics* p. 140 (2000) provides the following conceptualization of traditional medicine, "[O]n the basis of a community's or a country's culture, history and beliefs, traditional medicine came into being long before the development and spread of western medicine that originated in Europe after the development of modern science and technology. The knowledge of traditional medicine is often passed on verbally from generation to generation. Nevertheless, in some cases a sophisticated theory and system is involved." See also World Health Organization, *The Legal Status of Traditional and Complementary/Alternative Medicine: A Worldwide Review* (2001), (WHO/EDM/TRM/200.2) <www.who.int/medicines/library/trm/who-edm-trm2001/2/legalstatus.html> (visited 20 December 2004) for a summary of the legal status of the general practices in traditional or alternative medicine in 123 countries. A distinction is drawn between traditional medicine (TM) and complementary alternative medicine. The WHO use the term TM when referring to Africa, Latin America, South East Asia and Western Pacific while it uses the terms complementary alternative medicine to depict the same concept with reference to Europe and/or North America including Australia.

²⁸ But see Padmashree Gehl Sampath *Defining an Intellectual Property Right on Traditional Medicinal Knowledge: A Process-Oriented Perspective* (United Nations University, Institute for New Technologies Maastricht, The Netherlands July 2003), pp. 37, 23-24 seeks to establish boundaries through evidence of a causal relationship between the contributed TK and an invention "successful attempts to define traditional knowledge ought to focus on demarcating the nature of the contribution that such knowledge could have rather than on the physical attributes of the right itself...[V]iewed this way, traditional knowledge on its own does not attract intellectual property rights protection. It must be shown to make a contribution to cumulative innovation to trigger an intellectual property right."

²⁹ WIPO, *Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge 1998-1999* (Geneva 2001) (and hereinafter 'WIPO FFM') was carried out between June 1998 and November 1999 and included 9 fact-finding missions to 28 countries in the South Pacific, Southern and Eastern Africa, South Asia, North America, Central America, West Africa, the Arab countries, South America and the Caribbean. It was never meant to be a definitive exposition but rather "the FFMs were designed to enable WIPO to identify, as far as possible, the needs and expectations of TK holders...as part of its explorative study of current approaches to, and future possibilities for, the protection of the IP rights of holders of TK." p. 17.

innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

In this regard:

(a) “Traditional” and “tradition-based” refer to knowledge systems, creations, innovations which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are continually evolving in response to a changing environment;

(B) Categories of traditional knowledge could include: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; biodiversity-related knowledge; and, elements of languages, such as names, geographical indications and symbols.”³⁰

2.1.2 Beneficiaries

Any definition of TK becomes more complex once further distinctions such as that proposed between TK and what has been termed indigenous knowledge (IK) is taken into consideration. IK has been defined as knowledge that specifically belongs to indigenous peoples while TK is defined more broadly to include the knowledge held by both indigenous peoples and non-indigenous peoples or local communities living within a geographical boundary or region. Thus, “[i]ndigenous knowledge fits into the traditional character, but traditional knowledge is not necessarily indigenous. That is to say indigenous knowledge is traditional knowledge, but not all traditional knowledge is indigenous.”³¹

The Convention on Biological Diversity (CBD)³² refers to both ‘indigenous and local communities’ but defines neither. A universally accepted definition of ‘indigenous peoples’ eludes current discussions at the United Nations and other international organizations.³³ For practical purposes the

³⁰ This definition was used for the purpose of the WIPO *Survey on Existing Forms of Intellectual Property Protection for Traditional Knowledge* (WIPO/GRTKF/IC/2/5) 10-14 December 2001, paras. 32-33.

³¹ WIPO FFM supra note 29.

³² Convention on Biological Diversity (CBD), opened for signature on June 5, 1992, and entered into force on December 23, 1993. The text of the Treaty as well as an introductory guide to its provisions can be found on the CBD secretariat website <www.biodiv.org>

³³ See Secretariat of the Permanent Forum on Indigenous Issues *THE CONCEPT OF INDIGENOUS PEOPLES* (PFII/2004/WS.1/) 19-21 January 2004 para. 1 “In the thirty-year history of indigenous issues at the United Nations, and the longer history in the ILO on this question, considerable thinking and debate have been devoted to the question of definition of “indigenous peoples”, but no such definition has ever been adopted by any UN-system body. One of the most cited descriptions of the concept of the indigenous was given by Jose R. Martinez Cobo, the Special Rapporteur of the Sub-Commission on Prevention of Discrimination and Protection of Minorities, in his famous Study on the Problem of Discrimination against Indigenous Populations. The Working Group on Indigenous Populations since 1982 has held significant discussions on the subject within

United Nations Permanent Forum on Indigenous Issues accepts the definition provided by Jose R. Martinez Cobo, Special Rapporteur of the Sub-Commission on Prevention of Discrimination and Protection of Minorities in a *Study on the Problem of Discrimination against Indigenous Populations*.³⁴

While there may be more discussion about the term “indigenous peoples,” discussion on the definition of the term “local community” is less so. Oguamanam suggests the use of the term “local community” in the CBD is designed to “avoid the [inexactitude] associated with ‘indigeneity’ and the desire to incorporate other segments of people in far-flung places who live traditional lifestyles but whose fitness to the indigenous label may be contested or contestable”³⁵ or whose recognition as ‘indigenous’ is dependent upon state recognition..³⁶ On its face, questions surrounding

the context of the preparation of a Draft Declaration on the Rights of Indigenous Peoples. An understanding of the concept of “indigenous and tribal peoples” is contained in article 1 of the 1989 Convention concerning Indigenous and Tribal Peoples in Independent Countries, No. 169, adopted by the International Labour Organization.”

³⁴ *Id para. 2* “Indigenous 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.

“This historical continuity may consist of the continuation, for an extended period reaching into the present of one or more of the following factors:

- a) Occupation of ancestral lands, or at least of part of them;
- b) Common ancestry with the original occupants of these lands;
- c) Culture in general, or in specific manifestations (such as religion, living under a tribal system, membership of an indigenous community, dress, means of livelihood, lifestyle, etc.);
- d) 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);
- e) Residence on certain parts of the country, or in certain regions of the world;
- f) Other relevant factors.

“On an individual basis, an indigenous person is one who belongs to these indigenous populations through self-identification as indigenous (group consciousness) and is recognized and accepted by these populations as one of its members (acceptance by the group).

“This preserves for these communities the sovereign right and power to decide who belongs to them, without external interference”.

³⁵ Chidi Oguamanam, ‘Between Reality and Rhetoric: The Epistemic Schism in the Recognition of Traditional Medicine in International Law,’ 16 *St. Thomas L. Rev.* 59 (2003). See also Naomi Roht-Arriaza, ‘Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities,’ 17 *Mich. J. Int’l L.* 919 (1996) p. 964 who argues that although “local communities somewhat overlap with ‘indigenous peoples,’ the former is introduced into official international discourse in order to avoid endless debate over which people qualify as indigenous or tribal. ‘Local Communities’ is a term which includes several categories of peoples who derive large part of their livelihood directly from the natural world.”

³⁶ WTO Council for Trade-Related Aspects of Intellectual Property Rights – (IP/C/W/404) 26 June 2003 *TAKING FORWARD THE REVIEW OF ARTICLE 27.3(b) OF THE TRIPS AGREEMENT* Joint Communication from the African Group proposes reserving the

distinctions between IK and TK and their intended beneficiaries appear insignificant. However, these distinctions become extremely important when addressing issues as conferring rights, seeking prior informed consent (PIC) for use of TK, dealing with benefit-sharing arrangements and dealing with commercialization and conservation activities.³⁷

2.2 Commercial Value

Accurately estimating the value of TK in monetary terms is difficult for a number of reasons. TK is of genuine importance to indigenous peoples, traditional communities and impoverished populations as an alternative to non-existing or inaccessible public health systems in developing countries³⁸ and in development strategies.³⁹ Some TK is also likely to have cultural or spiritual values that cannot be quantified in any money sense. It is also claimed that advances in biotechnology and new drug discovery research techniques will in the long term reduce industrial interest in natural products and associated TK.⁴⁰ In any event, placing a monetary value *a priori* may well be premature and letting the market decide is considered the obvious option.⁴¹ Be that as it may, the range of the global market for TK derived products is predicted to be an incredible USD five trillion by the year 2020

definition of Indigenous peoples to State Parties “(a) ... (c) For purposes of this Decision, traditional knowledge includes folklore unless the context requires otherwise or it is provided otherwise; and local communities includes indigenous peoples subject to definitions that Member may adopt within their domestic laws.” *See also* Draft Principles *infra* note 142, para. 6 where the Government of Niger observed that the absence of a definition of “indigenous people” invited subjective interpretations, which poses dangers for those emerging nations-States in Africa that face recurrent tribal conflicts.

³⁷ UNU-IAS Report, *The Role of Registers and Databases in the Protection of Traditional Knowledge a Comparative Analysis* (United Nations University Institute of Advanced Studies) 2003 p. 10.

³⁸ *See* Correa *supra* note 22.

³⁹ *See generally* Sanjaya Lall, *Indicators of the Relative Importance of IPRs in Developing Countries* International Centre for Trade and Sustainable Development (ICTSD) and United Nations Conference on Trade and Development (UNCTAD) 2003; (PCIPD/4/2) WIPO Permanent Committee on Cooperation for Development Related to Intellectual Property, *Overview of Policy Directions, Priority Areas and Projects in WIPO’s Support of the Development Objectives of Developing Countries* (14-15 April 2005)

⁴⁰ Gerard Bodeker, ‘Traditional Medical Knowledge, Intellectual Property Rights and Benefit Sharing,’ 11 *Cardozo J. of Int’l & Comp. Law* 785 (2003) p. 793 suggests a number of reasons for this shift including “ethnobotanical research is no longer seen to be commercially viable, rapid screening of medicinal plants has yielded few important commercial leads, marine exploration has yielded important and novel substances and as natural products of the seas are not owned and therefore not subject to intellectual property laws and finally long term market trends point to gene therapy as the next new medical and commercial frontier.”

⁴¹ *See* de Carvalho *supra* note 21, p. 18. *See also* Rick Cannell, *The Value of Biodiversity*, Financial Times, July 21, 1998: “Even if we acknowledge that biodiversity has great value can we ever put any kind of figure on its worth? It is perhaps impossible. First, we do not even know roughly how many species there are: estimates range from about 5m to 30m. Second, we cannot even begin to predict the ways an organism may be of use. As we learn more about diseases, we have more ways of looking for useful chemicals. That is to say, organisms that are of no apparent use may be tomorrow’s saviours.”

⁴² in the open market and of no consequential value within an indigenous community. Consider de Koning who suggests “[I]t follows automatically that knowledge that cannot be utilised beyond its communal context has little or no commercial value, as concepts of private property and profits do not play a dominant role in traditional indigenous communal life”⁴³

Quantifying values becomes more complex when considering the distinction between commercial and non-commercial values. This issue was dealt with in the US case of *Madey v. Duke University* where the court held “that ordinary research work conducted by Duke University was classed as ‘commercial’ because a research university attracts better faculty, students and grants than a non-research one; it can therefore be considered as commercial an enterprise as any firm listed on the stock exchange.”⁴⁴ It is nevertheless questionable whether all university research outcomes will result in the reported “bonanza” profits.⁴⁵

⁴² See Sahai *supra* note 12, “The late Alwyn Gentry, senior curator with the Missouri Botanical Gardens, once estimated that tropical medicines, once fully developed, will add \$900 billion to Third World economies” See also Steven M. Rubin, Stanwood C. Fish, ‘Biodiversity Prospecting: Using Innovative Contractual Provisions to Foster Ethnobotanical Knowledge, Technology, and Conservation,’ 5 *Colo. J. Int’l Envtl. L. & Pol’y* 23 (1994) (citing Kevin Krajick, Sorcerer’s Apprentices, *Newsweek Focus*, Jan. 18, 1993, at 2). See also Sampath *supra* note 28, p. 39 “...annual growth rates for the botanical industry are between 10-20% in most countries. According to figures cited therein, the global consumer sales for botanical medicines are estimated to be as high as US\$40 billion and the largest global markets for botanical medicine are found in Germany, China, Japan, France, Italy, UK, USA and Spain. Of these, Germany is the largest consumer of botanical medicines and in 1996, the combined markets for Germany (US\$3.6 billion) and France (US\$1.8 billion) accounted for 75% of EU consumption.”

⁴³ See Martine de Koning, ‘Biodiversity Prospecting and the Equitable Remuneration of Ethnobiological Knowledge: Reconciling Industry and Indigenous Interests’ 12 *I.P.J.* 261 (1997)

⁴⁴ See David Vaver, ‘Canada’s Intellectual Property Framework: A Comparative Overview,’ 17 *I.P.J.* 125 (2004) quoting from the U.S. Federal Court of Appeals for the Federal Circuit 307 F. 3d 1351 (Fed. Cir. (2002), cert. den. June 27, 2003 (U.S.S.C.) p. 167; see also William Kingston, ‘Intellectual Property Needs Help from Accounting’ *E.I.P.R.* 2002, 24(11) p. 510 expresses concern about issuing patents to university research outcomes (a way of protecting ‘science’ and also stifling free discussion and exchange of ideas by researchers) and by allowing private companies to “free ride” on publicly funded research

⁴⁵ Civil Society Organizations & Participation Programme (CSOPP): ‘Conserving Indigenous Knowledge – Integrating New Systems of Integration’. <www.undp.org/csopp/CSO/NewFiles/dociknowledge4.html> (visited 26 January 2004) Research Corporation (a US non-profit agency with a mandate to work with public universities to patent and commercialize academic research) provides an overview of the potential licensing royalties that could arise from patentable research. In the North (or industrialized nations) “every million dollars in research is expected to yield one publishable paper. One in every hundred such papers leads to a patent application; one in every hundred patents might produce notable revenue and only one out of a thousand patents brings bonanza profits.” See also Prabudda Ganguli, ‘Intellectual Property Rights: Mothering Innovations to Markets,’ *World Patent Information* 22 (2000) p. 48, “The state of knowledge in any fields especially those evolved in communities over considerable length of time may have wide gaps and defy quantification and exactness. Innovations based on such empirical knowledge often require extensive work with remote or variable chance of success... Thus it is not just a question of borrowing knowledge but also

Domestic policy has considerable influence upon the value placed on TK. Consider, for example, a recent report revealing US plans to limit the future patent rights of all foreign recipients of US government grants and contracts to the awardees own country and to have the US National Institutes of Health (NIH) retain the rights elsewhere⁴⁶ namely, in the US where most value is generated.

Other values attributed to TK include reduction in research and development (R & D) through the application of ethnobotanical research. In a of study randomly collected plants tested by the US based National Cancer Institute (NCI) for anti-HIV activity showed only six percent activity whereas ethnobotanically collected plants illustrated 25% activity.⁴⁷ The value of this collection technique is the reduction of product lead-time thus creating obvious competitive advantages.

TK has spawned other values such as proposals for the creation of IP management consulting services and bio-collecting societies. It is suggested that these may obviate the need for international protection of TK.⁴⁸ An examination of intellectual property rights issues into “products of archaeological research” is also underway. Archaeologists are urged to examine whether and in what ways intellectual-property-related issues are relevant to their research, particularly when claims to such rights may be made by indigenous peoples affected by that research.⁴⁹

substantially adding value to transform it to meaningful applications or marketable products.”

⁴⁶ Jocelyn Kaiser, ‘NIH to Limit Scope of Foreign Patents,’ *Science*, vol. 296 (28 June 2002). The policy change eliminates the possibility of TK as a protectable subject matter at least in the context of the NIH effectively.

⁴⁷ See Rubin *supra* note 42.

⁴⁸ J. H. Reichman and David Lange, ‘Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions,’ 9 *Duke J. Comp. & Int’l L.* 11 (1998) p. 54 proposes a private non-interested party to facilitate agreements, encourage compliance with bioprospecting and like agreements and mediate disputes. The authors see the International Forum for Intellectual Property Initiatives (IFIPI) at the Duke University Law School Centre for Global Information Technologies Group as serving the functions described above. See also Bodeker *supra* note 40, p. 809 proposal for a Global IP, Benefit Sharing and Traditional Medical Database a network of legal centres, scholars and NGOs working to develop this kind of clearing house including data on best practice, case law, model contracts, reference material, international legislation, IP and benefit sharing, advocacy, research and facilitating partnerships. See also Peter Drahos, ‘Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer,’ *E.I.P.R.* 20000, 22(6), 245 p. 249 proposal for a national global bio-collecting society (GBS) open to both industry and indigenous groups. The GBS would serve many functions including owner of a bank of community registers of TK to assist indigenous communities with contract negotiations, monitoring the use of TK from R & D to the filing of a patent and to the eventual marketing of the final product, dispute resolution and a standard setting function

⁴⁹ See George P. Nicholas & Kelly P. Bannister, ‘Copyrighting the Past,’ *Current Anthropology* 45(3): 327-350 (2004) 329 p. 330 archaeological products “include site reports, site, artefact, and feature descriptions and classifications, radiocarbon debates, and faunal remains, among other materials.” See also Claire Smith, ‘On Intellectual Property Rights and Archaeology,’ *Current Anthropology* 45(4): 527 (2004) for a discussion about

2.2.1 Relationship to Occidental Science

Screening the earth's biological diversity for genetic information is not a new trend in pharmaceutical research, although the last decade has seen resurgence in interest. Since the 1950s, at least twenty-one pharmaceutical companies have been active to some degree in prospecting the tropical forests for sources of medicinal products. It is estimated that at least one quarter of all prescriptions dispensed in the United States use active ingredients that have been extracted or developed from plants. While interest in the screening of natural resources waned in the 1970s (as pharmaceutical research relied more heavily on synthetic chemical production), the last decade has seen a renewal of interest in biodiversity prospecting. According to Mulholland, this phenomenon is attributable to three separate forces that have emerged in the last ten years. First, it is due to the number and severity of currently incurable diseases, such as AIDS, cancer and Alzheimer's disease, for which chemical synthesis has not generated a cure. Second, technological improvements over the last twenty years that have significantly improved the ability to quickly identify compounds that may possess the genetic characteristics that scientists need to develop treatments and cures for diseases. Third, the CBD Article 1 has provided for both the fair and equitable sharing of benefits derived from genetic resources and the recognition of rights over these resources.⁵⁰

shared intellectual property rights, remuneration, and control over publication of the products of research relating to Indigenous knowledge. Academic acclaim or professional advancement is not eligible for sharing.

⁵⁰ D. Mulholland and E. A. Wilman, 'Bioprospecting and Biodiversity Contracts,' (Prepared for the Seventh Annual Conference Canadian Resource and Environmental Economics Study Group/Septième Réunion Annuelle Groupe d'Etudes Canadien sur les Ressources et l'Environnement-Natural Resources in an Era of Deregulation, McMaster University, Hamilton, Ontario, Oct. 4-5, 1997) p. 4. *See also* CSSOPP *supra* note 45. Includes two appendices: appendix A includes a list of more than 100 instances where indigenous or local knowledge has made or is making a contribution to agriculture, food processing or pharmaceutical development and appendix B includes a sampling of potentially patentable products or processes. Examples include:

- Glaxo's Natural Products Discovery Department is investigating medicinal plants in Africa and Latin America [follow this up in the internet]
- Rosy Periwinkle – two drugs from Madagascar's Rosy Periwinkle earn pharmaceutical companies more than \$100 million per annum as anti-cancer and childhood leukaemia. Allelix (a Canadian biotech firm) is working with Mitsui Pharmaceutical to develop 'natural' periwinkle compounds that will not need Madagascar's.
- Tecoma (Latin America) is a plant used in traditional medicine and is being studied for its' potential use against diabetes.
- Stevia (Latin America) plant is widely used as a sweetener and as an antacid and diuretic. It also appears to reduce tooth decay and is being studied for its use in a weight loss regime
- Quassia (Latin America) is widely used by indigenous peoples as a disinfectant, a stimulant to appetite and to kill intestinal worms. It is being studied for similar uses in North America.
- Muir Pauma is a plant used by indigenous communities in Brazil to cure impotency and to regulate the menstrual cycle. The plant is also being studied as to reduce cholesterol.
- Tikluba plant, long used by the Ure-eu-Wau-Wau people of the Brazilian Amazon is being developed by Merck as an anti-coagulant
- D-tubocurarine plant (Amazon) used as a poison, is being developed as a muscle-relaxant

The need for genetic resources arises at two stages in the drug R & D (in the pharmaceutical sector) process: preclinical and clinical testing and for large-scale production of the end product. In these two stages, wherever the laboratory synthesis of the discovered compounds is not possible, the drug R & D process requires huge amounts of raw genetic material to produce minimal quantities of the drugs in question.⁵¹ Such sourcing of genetic resources for R & D is done with the help of several collector intermediaries in source nations, which may range from university-based plant collections, to private individuals/ brokers who collect for small-time profits to public research institutes or small firms.⁵²

In the botanical sector, almost all herbal medicinal preparations are in the public domain, i.e. medicines that have been in use for a long time already and are described in written documentation. These are not patentable since patent law does not allow patenting of known compounds or known preparations. In the few cases in which a patent is issued, this is usually directed to a new form of pharmaceutical preparation.⁵³ Although these products are based on modern scientific findings, the information is mostly derived from/based on traditional systems of medicine. As a result, they are largely comprised of homeopathic products or factory-based traditional medicinal preparations. Generally speaking, the main stages involved in research and development of botanical medicines include⁵⁴ gathering information on useful properties of plants and is usually based upon TK and in many cases, the entire product may be based on the traditional usage itself.⁵⁵ In this case TK plays a major role in proving safety and efficacy of

•Monsanto agreement with Missouri Botanical Gardens for bio-prospecting throughout the “Third World”

•Barbasco plant (Mexico) – Syntex used Barbasco roots to make steroid hormones ultimately used in birth control pills.

See also BioGaia, a Swedish biotechnology company that conducts research, development and manufacturing of probiotic systems. The Company sells licenses and products on the international market that include a probiotic called *Lactobacillus reuteri* (Reuteri™). One of the products is a yoghurt drink containing the substance (which improve digestion and prevent diarrhoea). The substance is naturally occurring in breast milk but is more effective in an anaerobic (oxygen challenged) environment. In 1985, Bio Gaia researchers visited a lactating Indian woman in the Peruvian Andes and extracted her breast milk. From her milk the strain of *Lactobacillus Reuteri* (Reuteri™) was isolated. (On file with the author)

⁵¹ Padmashree Gehl Sampath and Richard G. Tarasofsky, *Study on the Inter-Relations Between Intellectual Property Rights Regimes and the Conservation of Genetic Resources* (Ecologic – Institute for International and European Environmental Policy Berlin December 2002) <www.Ecologic.de> (visited 15 December 2004) p. 34

⁵² *Id.* p. 35.

⁵³ *Id.* p. 25.

⁵⁴ *Id.* p. 39.

⁵⁵ While the useful characteristic(s) of a plant may be known to an indigenous community, its chemical or molecular properties may not. See Lord Hoffman of the British House of Lords who makes the point in *Merrell Dow Pharmaceuticals Inc and Another v. HN Norton & Co. Ltd* in the case of quinine: “The Amazonian Indians have known for centuries that cinchona bark can be used to treat malarial and other fevers. They used it in the form of powdered bark. In 1820, French scientists discovered that the active ingredient, an alkaloid called quinine, could be extracted and used more effectively in the form of sulphate of quinine. In 1944, the structure of the alkaloid molecule (...) was

botanical medicines.⁵⁶ The plant is then tested to check if the activity can be found in a chemical or chemical group present in an herb, or if known chemicals in the herb possess certain pharmacological properties. If this turns out to be the case and the plant does contain pharmacological properties of commercial interest, development of the botanical medicine requires large quantities of raw plant material⁵⁷

3 Protection of Traditional Knowledge

3.1 Overview

The range of concerns about traditional knowledge and its' protection include loss of traditional lifestyles and as a consequence of traditional knowledge (including inter-generational loss), lack of respect for traditional knowledge and holders of traditional knowledge, misappropriation of traditional knowledge including use of traditional knowledge without any recompense and lack of recognition of the need to preserve and promote the further use of traditional knowledge.⁵⁸ Other considerations behind the desire to protect traditional knowledge lies in equity considerations, conservation, cultural appreciation, the prevention of misuse or appropriation and the promotion of its use and its importance to development.⁵⁹

Numerous internal and external forces are also identified as changing the lives and societies of indigenous communities and consequently threatening TK. Some of these influences include: ⁶⁰

- Changing work practices;
- Assimilation into dominant cultures;
- Insecurity over territorial land rights;

discovered...Does the Indian know about quinine? My Lords, under the description of a quality of the bark which makes it useful for treating fevers, he obviously does. I do not think it matters that he chooses to label it in animistic rather than chemical terms. He knows that the bark has a quality which makes it good for fever and that is one description of quinine. On the other hand, in a different context, the Amazonian Indian would not know about quinine. If shown pills of quinine sulphate, he would not associate them with the cinchona bark. He does not know quinine under the description of a substance in the form of pills. And he certainly would not know about the artificially synthesized alkaloid." 33 Intell. Prop. Rep. 10, R.P.C. 76 (1996)

⁵⁶ See Valerie A. Assinewe, 'The science of traditional medicine,' *Biodiversity* 3(3) August 2002 p. 20 "Since most traditional medicines contain a mixture of elements rather than a single component, the variability may be the result of inconsistent ratios of ingredients. Or it may be the consequence of collecting plants from a location with different nutrients, a lack or excess of water, a lack or excess of light, too much predation, or any of a wide range of stressors. This link between efficacy and environment explains the strong emphasis in traditional medicine on the importance of time, place, and method of collection to maximize the effectiveness of treatments. Phytochemical analyses have shown levels of metabolites vary depending on a plant's age and its environmental stresses."

⁵⁷ Sampath *supra* note 51.

⁵⁸ See WIPO FFM *supra* note 29.

⁵⁹ See Correa *supra* note 22, pp. 5-8.

⁶⁰ See Tobin *infra* note 148, p. 51

- Agricultural assistance programmes, including introduction of ‘improved crop varieties;’
- Promotion of the use of pesticides;
- Educational systems which disparage traditional culture and promote loss of language;
- Replacement of traditional medicinal services by State health programmes;
- Political violence and displacement;
- Death of knowledgeable elders without leaving record of knowledge;
- Loss of indigenous languages; and
- Influence of organized religion and its erosion of traditional beliefs and rites.

Misappropriation of TK⁶¹ and traditional cultural expressions by third parties, such as the use of traditional designs, songs and dances by the entertainment and fashion industries are the more widely reported concerns. In some cases, an act of appropriation is usually discovered through serendipity and happenstance. Such was the case in the appropriation of the

⁶¹ Sometimes also referred to as “biopiracy” and while there is no accepted definition of “biopiracy,” the Action Group on Erosion, Technology and Concentration (ETC Group) defines it as “the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually patents or plant breeders’ rights) over these resources and knowledge.” <www.etcgroup.org/> (visited 9 February 2004). See also Commission on Intellectual Property Rights, *Integrating Intellectual Property Right and Development Policy Report of the Commission on Intellectual Property Rights* (London February 2003 (3rd ed.)) p. 83 <www.iprcommission.org/> (visited 14 May 2004) where following has also been described as “biopiracy.”

- a) **The granting of ‘wrong’ patents.** These are patents granted for inventions that are either not novel or are not inventive having regard to traditional knowledge already in the public domain. Such patents may be granted due either to oversights during the examination of the patent or simply because the patent examiner did not have access to the knowledge. This may be because it is written down but not accessible using the tools available to the examiner, or because it is unwritten knowledge. A WIPO led initiative to document and classify traditional knowledge seeks to address some of these problems.
- b) **The granting of ‘right’ patents.** Patents may be correctly granted according to national law on inventions derived from a community’s traditional knowledge or genetic resources. It could be argued this constitutes “biopiracy” on the following grounds:
 - Patenting standards are too low. Patents are allowed, for instance, for inventions, which amount to little more than discoveries. Alternatively, the national patent regime (for example, as in the US) may not recognise some forms of public disclosure of traditional knowledge as prior art.
 - Even if the patent represents a genuine invention, however defined, no arrangements may have been made to obtain the prior informed consent (PIC) of the communities providing the knowledge or resource, and for sharing the benefits of commercialisation to reward them appropriately in accordance with the principles of the CBD.

But see supra de Carvalho note 21, p. 15, “[T]he term “biosquatting” seems...more accurate to identify illegal or otherwise illegitimate IP practices related to genetic resources and associated TK.” See also Gavin Stenton, ‘Biopiracy within the Pharmaceutical Industry: A Stark Illustration of How Abusive, Manipulative and Perverse the Patenting Process Can Be Towards Countries of the South,’ *E.I.P.R.* 2004, 26(1) for a censorious discussion on biopiracy.

Ami”Song of Joy” by the rock band Enigma. The disfigurement of tribal religious figures and icons by toy company Lego drew the indignation of the Maori. The estate of Crazy Horse (a well regarded Lakota warrior) and the Rosebud Tribe of South Dakota successfully challenged a brewing company’s use of the name “Crazy Horse” for a malt liquor product.⁶² Similar challenges are becoming known in the appropriation of indigenous medicinal knowledge. The cases of the appetite suppressant *Xhoba* or *Hoodia* of the San in South Africa⁶³ and *Ayahuasca* of the indigenous people of the Amazon basin are other recent examples.⁶⁴ Similarly, farmers who utilize traditional methods both use and conserve genetic resources through utilization for planting, seed production and continuous selection of the best-adapted farmers’ varieties. However, many of these resources have been collected, researched and developed into commercial products by seed companies, who are then able to utilize intellectual property law to protect their profits. These farmers, however, are not compensated for the input, which they provided in the development of the product.⁶⁵

⁶² See Rosemary J. Coombe, ‘Fear, Hope, and Longing for the Future of Authorship and a Revitalized Public Domain in Global Regimes of Intellectual Property,’ 52 *DePaul L. Rev.* 1171 (2003) pp. 1187-90. See also Kara Josephberg et al., ‘Taiwan Considers Draft Bill to Protect Aboriginal IP’ 15 No. 2 *J. Proprietary Rts.* 20. Taiwan’s Council of Indigenous Peoples (CIP) recently approved draft legislation to protect their intellectual property. The draft law called “Law for the Protection of Intellectual Creations of Indigenous Peoples” will protect intellectual creations that are recognized and registered with the CIP. The legislation offers protection to many kinds of traditional arts including folk skills, religious rites, dances, songs, sculpture and costumes. Under the law as drafted, representatives of a specific group of people, a tribal settlement or a family could make applications. Where no qualified applicant can be identified, the application can be made on behalf of all Taiwanese indigenous peoples. The law would provide the registrants with perpetual exclusive rights to use such creations, as well as moral rights.

⁶³ See discussion on San Hoodia Benefit Sharing Trust below at section (P) (1) below.

⁶⁴ See Commission on Intellectual Property Rights *supra* note 61, pp. 84-85. “For generations, shamans of indigenous tribes throughout the Amazon Basin have processed the bark of *Banisteriopsis caapi* to produce a ceremonial drink known as “ayahuasca”. The shamans use ayahuasca (which means, “vine of the soul”) in religious and healing ceremonies to diagnose and treat illnesses, meet with spirits, and divine the future. An American, Loren Miller obtained US Plant Patent 5,751 in June 1986, granting him rights over an alleged variety of *B. caapi* he had called “Da Vine”. The patent description stated that the “plant was discovered growing in a domestic garden in the Amazon rain-forest of South America.” The patentee claimed that Da Vine represented a new and distinct variety of *B. caapi*, primarily because of the flower colour. The Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) – an umbrella organisation representing over 400 indigenous groups – learned of the patent in 1994. On their behalf, the Center for International Environmental Law (CIEL) filed a re-examination request on the patent. CIEL protested that a review of the prior art revealed that Da Vine was neither new nor distinct. They argued also that the granting of the patent would be contrary to the public and morality aspects of the Patent Act because of the sacred nature of *Banisteriopsis caapi* throughout the Amazon region. Extensive, new prior art was presented by CIEL, and in November 1999, the USPTO rejected the patent claim agreeing that Da Vine was not distinguishable from the prior art presented by CIEL and therefore the patent should never have been issued. However, further arguments by the patentee persuaded the USPTO to reverse its decision and announce in early 2001 that the patent should stand. “

⁶⁵ Carlos M. Correa, *Traditional Knowledge and Intellectual Property Issues and Options Surrounding the Protection of Traditional Knowledge* (QUNO Geneva 2001)
<www.geneva.quno.info/pdf/tkmono1.pdf> (visited 15 May 2004)

Appropriation (or misappropriation) is defended on many grounds. Coombe, for example argues that some acts of appropriation may serve a wider social purpose:

“[T]he rights of Western authors to access cultural forms for the purposes of creative transformation need to be balanced with other human rights, if only because there may be no more of such music to sample from in the very near future, given the circumstances in which most of the world’s indigenous peoples find themselves. In short, Western arts of appropriation might be practiced so as to further the maintenance of, or at least stem, the on-going destruction of cultural diversity.”⁶⁶

The US patent office is criticized for encouraging appropriation by its “tendency for instant patent gratification: issue first and ask subject-matter questions later.”⁶⁷ Coombe charges the same office with abetting appropriation; “[F]rom the internal incentive structures which reward examiners financially for granting patents and penalize them for conscientious examination of prior art, to the restricted forms of prior art considered in the search process and the complete lack of any obligation to respect the public interest, the practices of this office have brought the regime of intellectual property into extensive disrepute.”⁶⁸ Without more evidence it remains to be seen whether a direct and causal relationship exists between the claimed USPTO *laissez faire* practices and resultant increase in patents issued⁶⁹ and appropriation.

Coombe however, raises the important issue regarding the desirability of a disclosure requirement in patent applications as it relates to genetic resources (GR) and TK and although there is no one single disclosure scenario that captures all the existing concerns about GR and TK relevant to patented inventions, this matter is the subject of discussion and study at the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.⁷⁰

⁶⁶ See Coombe *supra* note 62, p. 1189. For a less sanguine view see Angela Riley, ‘Recovering Collectivity: Group Rights to Intellectual Property in Indigenous Communities,’ 18 *Cardozo Arts & Ent. L. J.* (2000)

⁶⁷ See Vaver *supra* note 44, p. 59.

⁶⁸ Rosemary J. Coombe, ‘The Recognition of Indigenous Peoples’ and Community Traditional Knowledge in International Law,’ 14 *St. Thomas L. Rev.* 275 (2001) p. 281.

⁶⁹ The OECD reports that from 1990-2000, the number of patents granted in biotechnology rose 15% a year at the United States Patent and Trademark Office (USPTO) and 10.5% at the European Patent Office (EPO), against a 5% a year increase in overall patents. See *The Role of Intellectual Property Rights in Access and Benefit Sharing Arrangements, including National and Regional Experiences*, (UNEP/CBD/WG-ABS/2/3) (20 October 2003) para. 15.

⁷⁰ See WIPO *Technical Study on Disclosure Requirements in Patent Systems Related to Genetic resources and Traditional Knowledge* <www.wipo.int/tk/en/publications/technical_study.pdf> (visited 10 November 2005). This study concerns requirements in patent law to disclose information about genetic resources and TK. It was prepared by the Intergovernmental Committee at the request of the COP to CBD at its sixth meeting at the Hague from April 7-19, 2002 (Decision V1/24C). The preparation of the study was based upon responses to a questionnaire circulated to member states of WIPO. The study was presented to the seventh meeting of COP at Kuala Lumpur,

The public domain remains the dominant justification for appropriation of TK. This is because features germane to TK places it into the public domain, removing any opportunity for protection. For example, the sociality or communality of control over knowledge equates to lack of a known author, its' oral transmission means lack of codification and finally its early origins and continuous innovation connote lack of novelty and originality.⁷¹ Similarly it is often claimed that because TK is collectively held and generated, patent law is fundamentally incompatible because of the fiction of the lone genius inventor. But as Ganguli points out “[E]ffective research is no longer a loner’s paradise. It needs symphony-like teamwork and harmonized networking with diverse groups and organizations.”⁷² And as Charles Kettering of General Motors observed in 1941 “a one-man invention isn’t very possible these days,” and argued that it would be unfair to reward individuals for what are basically collective endeavours.⁷³

These occidental constructs, it is argued, trump non-dominant knowledge systems drawing similarities to Columbus’ original letters patent to the Americas.⁷⁴ In a similar vein Van Caenegem observes:

Malaysia from February 9-20, 2005 and was received with appreciation. The study adopts a structured approach to reviewing the range of possible disclosure requirements, based on the following questions:

- (i) What would be the relationship between the claimed invention and the GR/TK; or what would be a sufficient link between the two to trigger a disclosure requirement?
- (ii) What legal principle would form the basis of the requirement?
- (iii) What would be the nature of the obligation placed on the applicant?
- (iv) What would be the consequence of failure to comply with the requirement?
- (v) How would the requirement be implemented, verified or monitored?

⁷¹ See Graham Dutfield, ‘The Public and Private Domains Intellectual Property Rights in Traditional Knowledge’ 21: 3 *Science Communication* (March 2000), 274-295 pp. 281-282. He challenges the orthodox perception of indigenous peoples’ communal ownership and prompts the need for a wider review of customary law and practice.

⁷² See Ganguli *supra* note 45, p. 44. *But see* Correa *supra* note 22, p. 28 for a discussion on a single act of discovery through the use of a selection patent. A selection patent is a patent under which a single element or a small segment within a larger known group is ‘selected’ and independently claimed based on a particular feature not mentioned in the large group. If the large group of elements is already patented, the patent owner may use the selection patent to extend the term of protection beyond the expiration of the original patent, at least for the selected subset.

⁷³ See Graham Dutfield, ‘Trips-Related Aspects of Traditional Knowledge’ 33 *Case W. Res. J. Int’l L.* 233 (2001) (citing Larry Owens, ‘Patents, the ‘Frontiers’ of American Invention, and the Monopoly Committee of 1939: Anatomy of a Discourse,’ 32 *Tech. and Culture* 1076, 1081 (1991)).

⁷⁴ See Roger Chennells, ‘Ethics and Practice in Ethnobiology and Prior Informed Consent with Indigenous Peoples regarding Genetic Resources’ p. 4. Paper presented at Washington University in St. Louis Conference on Biodiversity and Biotechnology and the Protection of Traditional Knowledge, April 4-6, 2003 <www.law.wustl.edu/centeris/confpapers/> (visited 19 December 2004), “Just as the original letters patent issued to Christopher Columbus modern patents strive to justify conquest of economies. Patents in the global patent system are viewed by a largely third world coalition, including indigenous peoples’ movement, as effective tools of recolonisation. Arguments supporting this recolonisation revolve around the relatively new battlefield, namely knowledge, or “intellectual property”...”

“For those who in fact have a claim to that knowledge construed on the basis of different normative structures, this amounts to an expropriation of knowledge. To coin a phrase, the public domain is the *scientia nullius* of intellectual property law; just as the now discredited theory of *terra nullius* was really a theory justifying unwarranted dispossession of land, the theory of *scientia nullius* can be conceived as a justification for the dispossession of knowledge.”⁷⁵

According to Barsh very few patents are derived directly from indigenous medical or ecological knowledge and those that do exist were inspired by data already placed in the public domain through the publications of academic researchers.⁷⁶ Thus claims of appropriation often directed towards largely occidental pharmaceutical corporations maybe erroneous writes Barsh:

“University-based authors account for an overwhelming 82 percent of the publications. Furthermore, contrary to the popular perception that rich countries are extracting knowledge from poorer ones, a majority (58 percent) of the host institutions represented by these publications are located in developing and transitional societies. A greater threat to indigenous knowledge systems, this data suggest, is internal intellectual colonialism.”⁷⁷

Similarly Coombe notes, “the assumption that transnational corporations or more developed countries are unfairly exploiting local communities is exaggerated in comparison to the exploitation by the political-economic elites of less developed countries who are far more likely to be engaged in commercial extraction resulting in the resource degradation that impoverishes local communities.”⁷⁸ Noting recent trends in drug development Bodeker suggests “[T]he key figures become local pharmaceutical companies or government agencies looking to exploit the national pool of traditional medical knowledge for the purposes of drug development.”⁷⁹

Assigning responsibility for appropriation is beside the point and may be moot when considering the application of new bioinformatics⁸⁰ data-mining systems. It is now possible to “read” historical herbal texts to identify novel

⁷⁵ See William Van Caenegem, ‘The Public Domain: Scientia Nullius,’ *E.I.P.R.* 2002, 24 (6), 324 p. 329.

⁷⁶ See Russell Lawrence Barsh, ‘Who Steals Indigenous Knowledge,’ *95 Am. Soc’y Int’L. Proc.* 154 (2001).

⁷⁷ *Id.* p.157. But even if university-based researchers account for 82% of publications, the relationship between academia and large pharmaceutical companies exists. For example, the Bayh-Dole Act in the United States permits universities to patent inventions based on federally funded research on the basis that this would facilitate the commercialization of research and hasten invention. See also Commission on Intellectual Property Rights *supra* note 61, p. 123.

⁷⁸ Rosemary J. Coombe, ‘Intellectual Property, Human Rights and Sovereignty,’ *6 Ind. J. Global Leg. Stud.* (1998) 59 p. 78

⁷⁹ See Bodeker *supra* note 40, p. 794.

⁸⁰ Bioinformatics is the application of computer science and information technology to the management and analysis of biological data or bio-prospecting electronic texts.

pharmaceutical leads for bioactive compounds.⁸¹ Bioprospecting electronic texts are not subject to the many controversies that surround classical bioprospecting and thus according to Buenz, “the use of herbal texts avoids many of these issues [allegations of exploitation and issues of profit sharing], while still derivatively using the knowledge of traditional healers.”⁸²

3.2 Non-Legislative Options for Protection

International and national legal systems are slow to respond to the challenges TK brings and thus TK remains largely unprotected. In the absence of other common law or statutory protection, traditional knowledge holders may try to negotiate benefit-sharing arrangements, as some already do with large biopharma.⁸³ Other measures include the creation of registers and databases.⁸⁴ In this regard, the paradox faced by indigenous peoples is that in order to protect knowledge about medicinal and other uses of plants; they must put them in the public domain.⁸⁵ Restricted use data bases⁸⁶ could

⁸¹ See Eric J. Buenz et al. “Techniques: Bioprospecting historical herbal texts by hunting for new leads in old tomes Trends,” *Pharmacological Sciences* Vol. 25, No. 9 September 2004. <www.sciencedirect.com> (visited 15 December 2004). The protocol involves identifying the historical text, extracting information through an manual read or an automated read, updating the information through plant name confirmation, pharmacological extrapolation from symptoms and/or disorders and comparing this information to reported functions in NAPRALERT™

⁸² *Id.* p.494. “The relevant information gathering must race against the generational losses of traditional knowledge, which is particularly true with respect to knowledge of the medicinal properties of plants. The impact of such loss is inestimable, although it is likely to be significant from a pharmacological perspective because more than half of the current chemotherapeutic cancer drugs and >100 marketed pharmaceuticals have been derived from plant sources.”

⁸³ United Nations University Institute for New Technologies (INTECH) *International workshop: Building (Bio) pharmaceutical systems in developing countries*, Maastricht: 26-27 February 2003 <www.scielo.br/scielo.php?script=sci_arttext&pid=S0074-02762003000400028> (visited 12 May 2004) coined the phrase “Bio pharma” and is used in a wider context which includes traditional therapies using local plants and biological ingredients, bio-prospecting, modern pharmaceutical industry base on organic chemistry synthesis and recombinant DNA (rDNA), and hybridoma technologies. See Barsh *supra* note 76 p. 154 whose reference to “Big Pharma” includes two dozen large, well established, vertically integrated, publicly traded multinational corporations that are capable of taking pharmaceuticals from “lab bench to bottle.” Emerging Pharma refers to numerous research and technical services firms that concentrate on making and marketing on-patent innovations, and rely heavily on venture capital financing.

⁸⁴ UNU-IAS Report *supra* note 37, pp. 11 – 12, (citing D. Dowd and S. Laird et al et al, *Community Registers of Biodiversity Related Knowledge: Role of Intellectual Property in Managing Access and Benefit-Sharing*, 1999, UNCTAD Biotrade Initiative) “A registry is not merely a list or database designed to provide information to users. It is a database to place information in order to gain legal rights relating to that information. ‘Registering’ something in a registry ‘puts it on the record’ and puts the public ‘on notice’ that the registrant asserts a claim.” See also Thomas J. Krumenacher, ‘Protection for Indigenous Peoples and Their Traditional Knowledge: Would a Registry System Reduce the Misappropriation of Traditional Knowledge?’ *8 Marq. Intell. Prop. L. Rev.* 143 (2004)

⁸⁵ *Id.* UNU-IAS Report urges national governments and international organizations to:

- Review existing laws and policies to develop more culturally sensitive search procedures related to traditional knowledge

be an option in this regard bearing in mind the firms that have huge patent portfolios have also developed biotech databases and sometimes on the public dime.⁸⁷

3.3 Selected Arguments in Favour of Protection

An oft-cited reason for protection *sui generis* or otherwise concerns the limitation of conventional IPRs to protect TK in copyright⁸⁸ and patents.⁸⁹ In addition, while intellectual property law recognizes individuals or corporations as the producers of intellectual property, traditional knowledge, it is claimed, is often collective, held by an entire group, or by selected

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- Require that companies demonstrate prior informed consent as a condition for scientific or commercial use of traditional knowledge
 - Ensure that intellectual property rights are supportive of the UN Convention on Biodiversity and of international human rights
 - Engage indigenous peoples in developing traditional knowledge registers worldwide and a regime for protecting the information

⁸⁶ Dutfield *supra* note 71, p. 259 An experimental project based in Ecuador and supported by the Inter-American Development Bank is currently trying to protect TK as trade secrets. The project, entitled “transforming traditional knowledge into trade secrets,” aims to enable traditional peoples and communities to benefit from bio-prospecting through effective trade secret protection of their knowledge. An NGO called Ecociencia is documenting the botanical knowledge of the participating indigenous groups, and registering it in closed-access databases. Checks are made to see whether each entry is not already in the public domain and whether other communities have the same knowledge. If an entry is not in the public domain, the community or communities with the knowledge have a trade secret. The trade secret can then be disclosed to companies with benefit sharing guaranteed by a standardized contract. These benefits can then be distributed among the trade secret-holding communities and the Ecuadorian government. To date, the database contains 8,000 entries provided by six participating indigenous groups. Sixty percent of the uses appear so far not to have been disclosed through publications. Already, three companies have expressed interest in accessing the database.

⁸⁷ Kingston *supra* note 44, p. 510.

⁸⁸ Dutfield *supra* note 71 p. 250. “[F]irst whereas copyright requires an identifiable author, the notion of authorship is a problematic concept in many traditional societies. Second, copyright has a time limit, whereas folkloric expressions that are important elements of a people’s cultural identity should have permanent protection. Third, copyright normally requires works to be fixed. However, among some traditional groups, folkloric expressions are not fixed but are passed on orally from generation to generation. This normally excludes such expression from eligibility for copyright expression.”

⁸⁹ *Id.* at 254 “The most commonly expressed reservations to the patent approach include traditional knowledge is collectively held and generated while patent law treats inventiveness as an achievement of individuals; patent applicants must supply evidence of a single act of discovery; patent applications must be written in a technical way that examiners can understand and applying for patents and enforcing them once awarded is expensive. “ See also Nuno Pires de Carvalho, ‘From the Shaman’s Hut to the Patent Office: How Long and Winding is the Road?’ 41 *Rev. ABPI* [Brazilian Association of Intellectual Property] 3 (1999). Several features of patent law that are commonly seen as obstacles for the use of the patent system for the protection of indigenous knowledge are rather the result of misunderstandings and misperceptions and not actual shortcomings of patent law. In addition, he proposes that, in spite of being possible to cover several elements of indigenous knowledge by resorting to the traditional mechanisms of intellectual property, such as copyright and related rights, patents, trademarks, geographical indications and trade secrets, any attempt in that direction would divest indigenous knowledge from its holistic nature, and therefore would not be entirely adequate.

individuals who pass on knowledge through oral traditions, for example. Thus copyrights and patents give individuals ownership rights that are thereby denied to the other members of their society, which presents unique conflicts inter-societally. Furthermore, intellectual property laws are generally intended to reward innovation, and consequently are meant for new knowledge, not for knowledge that already exists. As pointed out earlier, not all of traditional knowledge is ancient and much is still evolving and it is embedded in traditional systems, which each community has developed and maintained in its local context over hundreds of years. Finally, IP laws confer rights on a temporary basis, after which the knowledge becomes public, and can be utilized by anyone, for commercial uses or otherwise. This is particularly problematic for communities whose knowledge is held in perpetuity.

Another argument for the protection of traditional knowledge lies in the belief that such information is valuable for purposes of environmental conservation. But as Sampath points out “[I]t must be acknowledged ...that there are many who are sceptical about these assertions. At present, there is no data that convincingly links IPRs to improved conservation of genetic resources. There is not even convincing data that situates IPRs into a more effective policy environment to conserve genetic resources.”⁹⁰

It is also suggested that by vesting legally recognized ownership of knowledge in communities through intellectual property rights, it will raise awareness of that knowledge and encourage respect for it. This could encourage inter-generational transfer, particularly with the added incentive of the possibility of economic return.⁹¹ Certainly, protection is not the panacea for the transmission and preservation of TK. However, the possible loss, not only of biodiversity (assuming IPRs conserve biodiversity), but also of language and culture, provides an added incentive to utilize intellectual property rights in rectifying the situation.

3.4 Selected Arguments Opposed to Protection

Opposition to TK as a protectable subject matter under conventional IPR regimes is sometimes grounded in the belief that the main beneficiary is the industrialized north. Nwabueze suggests the purpose of presumably occidental IP law is “to ensure a steady, unhindered and available supply of South’s biological resources, by acknowledging developing countries sovereignty over their resources and obliging them to conserve such resources for the pharmaceutical and biotechnological needs of developed countries, in exchange for a clearly delineated and limited technological consideration.”⁹² On different grounds, Canadian Christie suggests

⁹⁰ See Sampath *supra* note 28, p. 63.

⁹¹ See Gupta *supra* note 23.

⁹² See Remigius Nwabueze, ‘Ethnopharmacology, Patents and the Politics of Plants’ Genetic Resources,’ 11 *Cardozo J. Int’l & Comp. L.* 585 (2003) p. 604. For similar views see Michael H. Davis, ‘Some Realism About Indigenism,’ 11 *Cardozo J. Int’l & Comp. L.* pp. 815, 825, 828 (2003) “The irony, therefore, of suggesting an IP based remedy as an

mechanisms for protection are better left to aboriginal communities and not the state and even where there is no or very little institutional mechanism. He urges aboriginal communities to return to traditional ways of controlling traditional knowledge and culture.⁹³ The irony is that the lack of TK protection facilitates its' appropriation. Christie paradoxically eschews conventional IPR protection of intellectual products as such, preferring instead protection for values, beliefs and principles that give meaning to intellectual.⁹⁴

Argued differently, some oppose the commercialization or "commodification" of TK. But as de Carvalho points out IP protection:

"...does not 'commodify' TK per se: to the contrary, one immediate consequence can be to empower TK holders against the distorting use of elements of their identity, or against unauthorized commodification of their TK. TK holders may, if they wish so, not only to refrain from giving a commercial dimension to their TK, but they may also prevent others from doing so. On the other hand, an IP regime will be of crucial interest for those TK holders who have the legitimate aspiration of 'commodifying' their knowledge or at least certain selected parts of it they choose to commercialize."⁹⁵

A similar view is voiced by Lars Anders Baer, vice president of the SAAMI Council in Jokkmokk, Sweden, at the WIPO Roundtable on Intellectual Property and Indigenous Peoples, Geneva:

"I believe that most [indigenous peoples] welcome changes and development, but on the clear condition that it take place in accordance to our needs and desires, and it is not imposed upon use...in my view, the future challenge is the conceptualization of ways of organizing and managing the globalized economy and its mechanism."⁹⁶

apparently costless solution, is that IP is a major source of indigenous poverty... it is simply baffling how the assurance of IP protection in a country with little or no existing manufacturing or marketing facilities could be a decisive incentive...this argument is but a ruse to encourage expansion of IP...so that the inauguration of an ever-increasing outward drain of precious domestic resources can be legitimized." J. Gibson, 'Justice of Precedent, Justness of Equity: Equitable Protection and Remedies for Indigenous Intellectual Property,' *AILR* (2001) 42 <www.austlii.edu.au/au/journals/AILR/2001/42.html> (visited 15 December 2004) asserts "[T]o attempt to define and delimit intellectual property and the requirements for protection within conventional regimes is to further the process of colonisation and to trivialise the significance of what must be protected."

⁹³ See Gordon Christie, 'Aboriginal Rights, Aboriginal Culture, and Protection,' 36 *Osgoode Hall Law Journal* (1998) 448 p. 483.

⁹⁴ *Id.* at 483 and also suggests, "that the solution of the problem of outside appropriation is to restrict access to knowledge to those who come searching with proper motives."

⁹⁵ See de Carvalho *supra* note 21, p. 20.

⁹⁶ *Roundtable on Intellectual Property and Indigenous Peoples Geneva, July 23 and 24, 1998 Initiatives for Protection of Rights of Holders of Traditional Knowledge, Indigenous Peoples and Local Communities* (WIPO/INDIP/RT/98/4A) July 23-24, 1998

A more cautious approach however, calls for a more thorough analysis of its (protection) impact on other forms of intellectual property⁹⁷ and the impact of IPRs on the control and sharing of benefits from specific uses of TK and associated genetic resources.⁹⁸ Others oppose protection on ideological grounds if for no other reason. Heald's proposal would "require former biopirates to secure large tracts of land for donor communities in return for the right to make withdrawals."⁹⁹ Indigenous communities become the 21st century sharecroppers so to speak. A preference for non-IPR approaches to protect TK through contract, trade secrets and trademark is also suggested.¹⁰⁰ Others are concerned about the potential negative affects such a regime may have on innovation or creativity particularly in the area of digital technology.¹⁰¹

A lack of a cohesive definition is often raised, making it difficult to agree on precisely what must be protected. This lack of definition, however, may not entirely be a hindrance to the protection of traditional knowledge through intellectual property law. Patent law only defines the requirements for protection, and does not necessarily list the types of items, which can be protected; the items often found protected under patent law can range from mechanical to biological. Similarly, trade secrets are defined as involving any secret and commercially valuable information, and no further definition about their content is required for their legal protection. However, it is important to keep in mind that since traditional knowledge and folklore generally cover a wide variety of cultural expressions and natural resources, any intellectual property law which attempts to protect them must be sufficiently comprehensive - a goal which a definition could facilitate. Be that as it may one is reminded that intellectual property laws "are exercises in building fences around intangible assets, and that such fences are inherently imperfect and approximate."¹⁰²

⁹⁷ See Gervais *supra* note 6, p. 976.

⁹⁸ See *supra* Downes note 6 who express the view that "...the sharing of benefits with a community as a whole is no guarantee that the people who are working to conserve traditional knowledge and associated biodiversity will gain the rewards they deserve for their efforts."

⁹⁹ See Paul J. Heald, 'The Rhetoric of Biopiracy,' 11 *Cardozo J. Int'l & Comp. L.* 519 (2003).

¹⁰⁰ See Robert K. Paterson and Dennis S. Karjala, 'Looking Beyond Intellectual Property in Resolving Protection of the Intangible Cultural Heritage of Indigenous Peoples,' 11 *Cardozo J. Int'l & Comp. Law* (2003) 633 p. 634 concluding that "a reinterpretation of existing contract, privacy and unfair competition laws, or minor statutory amendments or national courts aimed at levelling the playing field can accomplish much of what indigenous communities are claiming."

¹⁰¹ See Mark Perry, Digital Propertization of the New Artifacts: 'The Application of Technologies for "Soft" Representations of the Physical and the Metaphysical,' 11 *Cardozo J. Int'l & Comp. L.* (2003) 671 p. 705 writes, "[T]he legal system is rightly slow to respond to changes in society, or at least take measured response to the shifting environment. Hopefully, in the realm of artifacts and software, we can avoid the temptation for instant cures and instead develop a finely tuned approach to protecting or even restoring culture without killing innovation or creativity."

¹⁰² See Reichman *supra* note 48, p. 50 (citing Ejan Mackaay, 'Legal Hybrids: Beyond Property and Monopoly?' 94 *Colum. L. Rev.* 2630, 2636 – 38 (1994))

4 Municipal Legislative Responses

4.1 General

At the municipal level, few states have legislation recognizing and protecting TK and those that do are usually from the developing or least developed countries where a majority of the world's biodiversity lies.¹⁰³ As an industrialized nation, Canada for example, sees no need for a *sui generis* or any other regime to protect TK, preferring instead that indigenous people there resort to conventional IPRs for protection.¹⁰⁴ Canada does see however, a need for "other measures...to complement the existing legal system and...is currently seeking the views of national Aboriginal organizations and specifically soliciting examples where existing intellectual property mechanisms have not provided protection for traditional knowledge but arguably should have."¹⁰⁵ Interestingly, Canada's Office of Natural Health Products (ONHP), now known as the Natural Health Product Directorate proposes the development of a regulatory framework for natural health products that includes criteria that identify and regulate traditional healers/practitioners.¹⁰⁶ This possibility raises challenges

¹⁰³ See generally *Report on the Review of Existing Intellectual Property Protection of Traditional Knowledge*, (WIPO/GRTKF/IC/4/7) 5 November 2002; *Consolidated Survey of Intellectual Property Protection of Traditional Knowledge* (WIPO/GRTKF/IC/5/7) 4 April 2003, See also Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore *Comparative Summary of Existing National SuiGeneris Measures and Laws for the Protection of Traditional Knowledge*, Fifth Session Geneva, July 7 to 15, 2003 (WIPO/GRTKF/IC/5/INF/3) and Johanna Gibson, 'Intellectual Property Systems, Traditional Knowledge and the Legal Authority of Community,' *E.I.P.R.* 2004, 26(7), 280-290 for a summary of these national approaches.

¹⁰⁴ See *id.*, *Report on the Review of Existing Intellectual Property Protection of Traditional Knowledge* at annex 1. See also Canada, Department of Indian Affairs and Northern Development, *Intellectual Property and Aboriginal People* (Ottawa: Research and Analysis Directorate, 1999) (Contractors: S. Brascoupé and K. Endemann), <www.ainc-inac.gc.ca/pr/ra/intpro/intpro_e.html> (visited 8 August 2004). A study produced for the Canadian government in 1999 provides an overview of areas of Canadian intellectual property law of most relevance to Aboriginal people. It sets out brief examples of Aboriginal peoples' use of, and their perspectives on, copyright, industrial design, trademarks, and patent and trade secrecy protection. See generally H. Mann, *Indigenous Peoples and the Use of Intellectual Property Rights in Canada: Case Studies Relating to Intellectual Property Rights and the Production of Biodiversity*, (Ottawa: International and Environmental Law and Policy 1997. See also Industry Canada (Intellectual Property Policy Directorate) *Report on the Presentation to the British Columbia First Nations Vancouver British Columbia March 10 - 11 2003* <www.strategis.ic.gc.ca/epic/internet/inipppd.bs/en/ip01075e.html> (8 August 2004),

¹⁰⁵ *WIPO Survey on Existing Forms of Intellectual Property Protection for Traditional Knowledge Preliminary Analysis* (WIPO/GRTKF/IC/2/) 3 December 2001 para. 9

¹⁰⁶ Office of Natural Health Products, *A Fresh Start: Final Report of the ONHP Transition Team* (Ottawa: Government of Canada 2000) p. 54. 'Criteria that identify and regulate traditional practitioners must be developed in concert with provincial, territorial and First Nation authorities. These criteria should include the following considerations: historical origins and underpinning philosophy, traditional body of knowledge, scope of practice, traditional references and standards of evidence, educational standards, adherence to traditional philosophy and practitioner cohesiveness.'

for traditional medicine practitioners and their patients and with the government of Canada:

“Another common theme throughout the discussions is Elders’ apprehension about the government regulating traditional medicine or in some way controlling their activity. The Elders/healers highlighted the fact that it was in their recent history that these ways were outlawed, and perhaps now, the government is finding another way to control their spirituality, healing and ceremonies. The legal issues arising from insurance from malpractice of traditional healers are a very current and real challenge for Aboriginal health facilities that have traditional medicine as a public service. Also they felt threatened by any documenting of traditional medicine in health facilities.”¹⁰⁷

5 International Law and Policy

5.1 World Trade Organization (TRIPs Council)

Intellectual property rights became concerns of international trade in the Uruguay Round of GATT, when the World Trade Organization (WTO) was established, and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) was concluded.¹⁰⁸ Acceptance of TRIPs is mandatory for any country wishing to be a member of the WTO. Thus, intellectual property rights and enforcement continue to be an important part of the ongoing trade rounds of the WTO, particularly in the light of the Ministerial Declaration (DOHA Declaration) adopted on 14 November 2001, in Doha. The Doha Declaration includes a review of the relationship between the TRIPs Agreement and the CBD, the protection of traditional knowledge and folklore as topics of the work programme to be pursued by the Council for TRIPs under the review of Article 27.3(b).¹⁰⁹ de Carvalho observes, “...according to paragraph 52 of the Ministerial Declaration, the work programme does not necessarily entail negotiations on new standards. The TRIPs Council may, therefore (and it probably will) keep its focus on TK at the level of discussions and exchange of views.”¹¹⁰ It has remained so.¹¹¹

¹⁰⁷ Canada, *Canadian Biodiversity Strategy, Canada’s Response to the Convention on Biological Diversity* (Ministry of Supply and Services Ottawa, Canada 1995)

¹⁰⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO], Annex 1C; LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPs Agreement] <www.wto.org/english/docs_e/legal_e/27-trips.pdf> (visited 19 December 2004).

¹⁰⁹ Ministerial Declaration Adopted on 14 November 2001, WTO document WT/MIN (01)/DEC/1, of November 20, 2001 para. 19.

¹¹⁰ See de Carvalho *supra* note 21, p. 209.

¹¹¹ WTO document (IP/C/W/368) 8 August 2002. For a summary of the issues raised and the points made by delegations in the Council for TRIPs in regard to the relationship between the TRIPs Agreement and the Convention on Biological Diversity.

A more controversial issue surrounds the introduction of a requirement that patent applications be accompanied by disclosures regarding source of origin, any related traditional knowledge, evidence of prior informed consent (PIC) of the country of origin and evidence of fair and equitable benefit sharing. This polarizing issue has the member states clearly divided with the north (industrialized) opposed to the requirement and the south (developing and least developed countries) in favour of it.¹¹² A clear resolution remains to be seen but it does raise the spectre of a deeper policy conflict over whether patent officials should be tasked with this level of examination and whether contractual arrangements are to be preferred to a system of institutionalized PIC.

5.2 Convention of Biological Diversity

While the TRIPs agreement does not specifically address TK holders (the terms of that agreement concentrating solely on the rights, authority, and capacity of states or national governments),¹¹³ the CBD Preamble makes the agreement between the contracting parties subject to the recognition of:

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

The only provision of the Convention that relates directly to intellectual property rights is stated in Article 16, whose title is "Access to and transfer of technology". Article 16 (5) states as follows:

“The Contracting Parties, recognising that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall co-operate 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.”

Another key CBD provision concerns Article 8(j), which relates to traditional knowledge. This provision calls for Parties to:

¹¹² See generally WIPO *supra* note 70. See also Martha Chouchena-Rojas, Manuel Ruiz Muller, David Vivas and Sebastian Winkler (eds.), *Disclosure Requirements: Ensuring mutual supportiveness between the WTO TRIPs Agreement and the CBD*. (IUCN, Gland, Switzerland and Cambridge, UK and ICTSD, Geneva, Switzerland November 2005) <www.iprsonline.org> (visited 10 December 2005).

¹¹³ But see Weerawit Weeraworawit, ‘Formulating an International Legal Protection for Genetic Resources, Traditional Knowledge and Folklore: Challenges for the Intellectual Property System,’ 11 *Cardozo J. Int’l L. & Comp. L.* 769 (2003) suggests that although the TRIPs Agreement is silent on TK, it has certain provisions that could be used to prevent against unfair or abusive exploitation of genetic resources, but they do not confer legal protection to traditional knowledge or genetic resources.

“Subject to 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.”

To facilitate the implementation of Article 8(j), the CBD Conference of the Parties (COP) established a Working Group.¹¹⁴ Based on its recommendations and in 2000, the COP adopted a Programme of Work on the implementation of Article 8(j).¹¹⁵ The programme focuses on the following issues:

- (a) The effective participation and involvement of indigenous and local communities in policy development and decision-making relating to the use of their traditional knowledge and practices relevant to the conservation and sustainable use of biological diversity;
- (b) The development of mechanisms and legislation to foster the effective participation of indigenous and local communities in decision-making, policy planning and development and implementation of the conservation and sustainable use of biological diversity at all levels;
- (c) The preparation of a composite report on the status and trends regarding traditional knowledge of indigenous and local communities;
- (d) The development of guidelines on environmental, cultural and social impact assessment for developments proposed to take place on sacred sites and on lands and waters occupied by indigenous and local communities;
- (e) The development of guidelines on the sharing of benefits arising from the utilization of traditional biodiversity-related knowledge and innovations;
- (f) The development of elements of sui generis systems for the protection of traditional knowledge.

The COP also emphasized that further work is required to develop a common appreciation of the relationship between intellectual property rights, the WTO TRIPS Agreement and the CBD. To that end, the COP has

¹¹⁴ The Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions was established by decision 1V/9 of the COP to the CBD. It held its first meeting in Seville, Spain, from 27 to 31 March 2000. The second and third meetings took place in Montreal from 4 to 8 February 2002 and from 8 to 12 December 2003, respectively. The fourth meeting of the Working Group will take place from 23 – 27 January 2006 in Granada, Spain.

¹¹⁵ The programme of work on article 8 (j) and related provisions is contained in decision V/16. Decisions VI/10 and VII/16 further develop the work programme. All are available at www.biodiv.org/decisions/.

invited both WIPO and WTO to explore the relationship between the TRIPS Agreement and the CBD.¹¹⁶

Despite the recognition of indigenous and local communities, the CBD section 15.1 nevertheless emphasizes the sovereignty of states with respect to the preservation of biological resources, noting that such protection is ultimately the responsibility of states. Similarly, while the CBD provides for *in situ* conservation, consistent with community autonomy and governance, those community interests are to be subject to national laws. Underscoring state sovereignty was done for two reasons; to remove genetic resources out of the “common heritage” of mankind and therefore subject to IPR and as a compromise to developing nations of whom a majority of the world’s genetic resources lie.¹¹⁷ Inescapably ownership of genetic resources between the state and indigenous people over land and resources arises.¹¹⁸

At CBD COP-6, Decision VI/24 on Access and Benefit Sharing as Related to Genetic Resources was adopted. This followed deliberations by an Expert Panel and an Ad Hoc Working Group on the topic. Decision VI/24 includes the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization and a section on the role of intellectual property rights in the implementation of access and benefit-sharing arrangements. Although the Bonn Guidelines are not legally binding, Sampath makes a case that they can be considered as reflecting an authoritative interpretation of the relevant CBD provisions.¹¹⁹

The Bonn Guidelines include several references to IPRs including paragraph 16(d), which states State Parties should consider taking “measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights.” Paragraph 43(c) stipulates several parameters to form the basis of the contractual arrangements between providers and users. These include:

¹¹⁶ Decision IV/15, para. 10 reads in part “...Emphasizes that further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity ... [R]equests the Executive Secretary to enhance cooperation with the World Intellectual Property Organization with respect to the Organization's programme of work;

¹¹⁷ See generally Sampath *supra* note 51 p. 75.

¹¹⁸ See for example Canada Department of Justice, *Biotechnology Conference, Legal and Policy Implications of Advancements in Biotechnology*. (Ottawa February 21-22, 2002). See comments of Violet Ford, Consultant, Inuit Circumpolar Conference <www.canada.justice.gc.ca/en/news/conf/biotech/fs3.html> (visited 12 May 2004) “The nature of state sovereignty over resources, which is recognized by the CBD, needs clarification. Governments often interpret it as absolute, and this is a matter of considerable concern to indigenous peoples in Canada, whether or not they have land rights.”

¹¹⁹ See Sampath *supra* note 51 p. 10.

“[P] rovision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained, to provide licences by common consent” and the “possibility of joint ownership of intellectual property rights, according to the degree of contribution.”¹²⁰

The Decision also lists a number of issues for further examination including:

- Impact of intellectual property regimes on access to and use of genetic resources and scientific research;
- Role of customary laws and practices in relation to the protection of genetic resources and traditional knowledge, innovations and practices, and their relationship with intellectual property rights;
- Consistency and applicability of requirements for disclosure of country of origin and prior informed consent in the context of international legal obligations;
- Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights applications and the re-examination of intellectual property rights granted;
- Efficacy of country of origin and prior informed consent disclosures in monitoring compliance with access provisions;
- Feasibility of an internationally recognised certificate of origin system as evidence of prior informed consent and mutually agreed terms; and
- Role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights.

5.3 World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

At its Twenty-Sixth Session, held in Geneva from September 26th to October 3rd, 2000, the WIPO General Assembly established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (hereinafter the “Intergovernmental Committee”). It is a forum for discussions among Member States on the three primary themes identified during earlier consultations namely, 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.¹²¹

¹²⁰ Decision VI/24 para. 55(c)

¹²¹ See document WO/GA/26/6 para. 14.

The Committee has met eight times, including twice in 2004¹²² and includes participation of indigenous and local communities and approximately 30 indigenous non-governmental organizations accredited with *ad hoc observer* status.¹²³ Industry including the pharmaceutical industry is also represented at the sessions. They include the Biotechnology Industry Organization (BIO) a lobby organization representing over 500 large and emergent biotechnology firms in the United States and in over 40 nations¹²⁴ and International Federation of Pharmaceutical Manufacturers Associations (IFPMA).¹²⁵

To facilitate the work of the Committee, the WIPO Secretariat prepared a number of documents elaborating upon specific tasks assigned to the Committee.¹²⁶ For the Committee's first meeting, the Secretariat prepared a document, providing an overview of the topics for the Committee to discuss, including specific tasks that the Committee might wish to consider with respect to intellectual property issues relating to genetic resources access

¹²² In late 2003, the member States of WIPO decided on a new and extended mandate for the Intergovernmental Committee, which requires the Committee to accelerate its work and to focus in particular on the international dimension of intellectual property and traditional knowledge and traditional cultural expressions (or "expressions of folklore"). The new mandate of the Committee is not limited in the range of possible results that may eventually be achieved, including the possible development of an international instrument or instruments. At the seventh session of the Intergovernmental Committee, which took place in November 2004, the Committee examined the first drafts of two instruments, one dealing with the protection of traditional cultural expressions/expressions of folklore and the other, in a parallel and linked manner, with traditional knowledge. These draft instruments are aimed at recognizing, among other things, collective interest in traditional know-how and expressions of traditional cultures that are innovative or creative and characteristic of a distinct cultural identity, and at strengthening the legal basis for the prevention of the misappropriation and misuse of such knowledge and expressions held by traditional communities, including indigenous peoples. These draft proposals include compliance with the principle of "free, prior and informed consent" and the recognition of customary laws and practices in the protection of traditional knowledge and traditional cultural expressions.

¹²³ See *Participation of Indigenous and Local Communities*, (WIPO/GRTKF/IC/5/11) 28 March 2003 which details various means by which to achieve effective involvement of communities in the current discussions. Strategies include the encouragement of Member States to include community representatives in national delegations as well as funding NGO representatives of communities, the direct financial support of community representatives or leaders of Indigenous or local communities of developing countries, cooperation with the United Nations Permanent Forum on Indigenous Issues, consultations and workshops, provision for submissions of accredited NGOs to the WIPO web site, specific briefings and consultations for NGO representatives, and ongoing consultation with representatives of Indigenous and local communities. At the seventh session (1-5 November) a consensus statement included proposals ranging from a more visible presence at the WIPO Secretariat, procedural modifications and to designated seating areas that clearly distinguished indigenous representatives from NGOs. (WIPO/GRTKF/IC/7/15 Prov.) December 9, 2004. Presumably the request is to signify the indigenous position as owners of its' TK.

¹²⁴ See generally <www.bio.org/>

¹²⁵ The members of IFPMA are national or regional pharmaceutical industry associations in more than 60 countries in both the industrialised and developing countries. See generally <www.ifpma.org/About_Us/about.aspx>

¹²⁶ All working documents, comments, papers, studies, questionnaires and other materials prepared for consideration by the Intergovernmental Committee, as well as comprehensive reports of its sessions are available at <www.wipo.int/tk/en/igc/documents/index.html>

and benefit-sharing, and the protection of traditional knowledge, innovations and creativity.¹²⁷

The first task of the Committee is the development of "guide contractual practices" and model intellectual property clauses for contractual agreements on providing for access to genetic resources and benefit sharing. The second set of tasks the Committee addresses deals with the protection of traditional knowledge and its status as prior art in existing patent systems. A third and more controversial set of tasks and which lacks any consensus as yet (as it also does at the WTO TRIPs Council), relates to the development of appropriate national and international patent measures, including a requirement that applicants for biotechnology patents disclose the origin of relevant genetic resources and associated TK used in the development of a claimed invention, the country of origin, source or legal provenance of such genetic resources and traditional knowledge; and evidence of prior informed consent and equitable benefit-sharing.¹²⁸ The diverse approaches towards such disclosure requirements are discussed in the WIPO Technical Study on Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge¹²⁹ prepared by WIPO at the request of the COP and submitted to the latter in 2004.

The WIPO Standing Committee on the Law of Patents, the Working Group on Reform of the Patent Cooperation Treaty and the Intergovernmental Committee has also considered of the inter-relationship between access to genetic resources and a disclosure requirement. Following a further invitation from the Conference of the Parties to the Convention on Biological Diversity, WIPO is focusing on some specific issues identified as being of relevance to the Convention. A draft examination of these issues has been prepared and will be considered by a special one-day ad hoc meeting in early June 2005.¹³⁰

¹²⁷ *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore – an Overview* (WIPO/GRTKF/IC/1/3) 16 March 16 2001

¹²⁸ *Id.* paras. 32-47.

¹²⁹ See WIPO *supra* note 70.

¹³⁰ Relevant proposals and draft materials are currently available at <www.wipo.int/tk/en/genetic/proposals/index.html>. See also *Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications*. (WIPO/IP/GR/05/3) 12 May 2005. This document examines a range of issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications. It is one step in developing a response to the Conference of Parties (COP) of the Convention on Biological Diversity (CBD), which has (in Decision VII/19) invited the World Intellectual Property Organization (WIPO) to: "examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, inter alia:

- (a) Options for model provisions on proposed disclosure requirements;
- (b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
- (c) Options for incentive measures for applicants;
- (d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties;

The WIPO overview document notes that contractual agreements are the most common legal mechanism for regulating access to genetic resources and benefit sharing. As a follow-up to the overview document, the WIPO Secretariat produced "Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit-Sharing."¹³¹ It provides a sampling of contractual provisions governing the scope of the contract, the respective intellectual property rights and obligations of the provider and recipient of genetic materials and other standard clauses governing such matters as dispute resolution, the term and termination of the contract, entry into force and cancellation. Finally, the document articulates certain operational principles for the development of guide contractual clauses.¹³² As with discussions surrounding a disclosure requirement, the debate here is fractured with developing and least developed countries opposed to an institutionalized (and private) use of contracts in access and benefit sharing¹³³ while a contract approach is supported by the industrialized nations, the European

(e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance.

¹³¹ WIPO/GRTKF/IC/2/3 10 September 2001

¹³² *Id.* paras. 125 – 129. These possible operational principles include:

- The IP-related rights and obligations set out in the Model IP clauses should recognize, promote and protect all forms of formal and informal human creativity and innovation, based on, or related to, the transferred genetic resources.
- The IP-related rights and obligations set out in the Model IP Clauses should take into account sectorial characteristics of genetic resources and genetic resource policy objectives and frameworks.
- The IP-related rights and obligations set out in the Model IP Clauses should ensure the full and effective participation of all relevant stakeholders and address process issues related to contract negotiation and the development of IP clauses for access and benefit sharing agreements, including in particular traditional knowledge holders where traditional knowledge is covered by the agreement.
- The IP-related rights and obligations set out in the Model IP Clauses should distinguish between different kinds of use of genetic resources, including commercial, non commercial and customary uses.

¹³³ See the Committee Report at its seventh session (WIPO/GRTKF/IC/7/15) 10 June 2005 para.175. For example, the delegation from India stated the document “approached the question of access to GR and associated TK from a perspective that bore little relationship to the core responsibility of WIPO, namely international IP law.... Instead of approaching the issue from the IP-law angle, it approached it from the perspective of contract law. Instead of framing the issue in terms of what needs to be done to make IP laws supportive of a fair and equitable access and benefit sharing regime, approaches it from the opposite end. It appears to have turned the issue on its head, by asking instead, how we might ensure that access and benefit sharing concerns do not impact adversely on the global IP system. Acceptance and endorsement of this approach would have the Secretariat working on finding solutions based on private contractual agreements between the provider of the genetic resource and associated TK, and the prospective user of that resource and knowledge. Given the asymmetry of the power relationship between the two parties, there can be little doubt about what the inevitable outcome would be. However carefully any model contract is drafted, however ardently such contracts try to correct the huge imbalance between the provider and the user, such an approach simply cannot lead to anything even remotely resembling a fair and equitable regime. Laws regulating private contractual relationships, combined with carefully crafted model contracts cannot, therefore be the solutions.”

Union and the United States for example ¹³⁴ and industry.¹³⁵ For the moment, the idea is shelved.¹³⁶

5.4 United Nations

The most comprehensive statement of the rights of indigenous peoples to date is the Draft Declaration on the Rights of Indigenous Peoples (and hereinafter the ‘Draft Declaration’).¹³⁷ It proposes standards on the rights in relation to their land, cultural property and identity as well as the rights to education, employment, health, religion and language.

Originally drafted by the Working Group on Indigenous Populations, in 1985, the Draft Declaration was adopted by the United Nations Sub-Commission on the Promotion and Protection of Human Rights by its resolution 1994/45 of 26 August 1994. From there, it was submitted to the Commission on Human Rights, which, by its resolution 1995/32 of 3 March 1995,¹³⁸ established an open-ended inter-sessional working group of the Commission on Human Rights with the sole purpose of elaborating a draft declaration for consideration and adoption by the General Assembly within the International Decade of the World's Indigenous People namely, December 2004.¹³⁹ The Draft Declaration is divided into nine parts and

¹³⁴ *Id* paras. 176 (EU) and 182 (US)

¹³⁵ *Id.* at para. 198. For example, “The representative of the Biotechnology Industry Organization (BIO) commended the effort of the Committee to engage in a constructive discussion of measures that will improve the transparency and accountability in the collection and use of GR. The representative explained that BIO was an international association representing more than 1000 companies, academic institutions and biotechnology centres in over 33 countries.

¹³⁶ *Id* at para. 202. The Chair concluded that there was no consensus on the future work of the Committee in this area and suggested that no decision should be taken at this session but that it should be kept on the agenda for the eighth session of the Committee.

¹³⁷ The Draft Declaration on the rights of indigenous peoples is contained in the 1994 Sub-Commission annual report, document E/CN.4/Sub.2/1994/56. The declaration is annexed to resolution number 45. Consisting of 45 Articles, the draft Declaration is divided into nine parts:

Part 1. Fundamental Rights

Part 2. Life and Security

Part 3. Culture, Religion, and Language

Part 4. Education, Media, and Employment

Part 5. Participation and Development

Part 6. Land and Resources

Part 7. Self Government and Indigenous Laws

Part 8. Implementation

Part 9. Minimum Standards

¹³⁸ E/ CN/ 4 RES /1995/ 32. Establishment of a working group of the Commission on Human Rights to elaborate a draft declaration in accordance with paragraph 5 of General Assembly resolution 49/214 of 23 December 1994.

¹³⁹ Proclaimed by the General Assembly by its resolution 48/163 of 21 December 1993. The General Assembly adopted resolution 59/174 on 20 December 2004 which proclaims a second International Decade of the World’s Indigenous People to commence on 1 January 2005.

while all parts in some way bear directly upon intellectual property rights issues,¹⁴⁰ article 29 of part 6 reads:

“Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property.

They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts;”

By its resolution 1993/44 of 26 August 1993, the Sub-commission on Prevention of Discrimination and Protection of Minorities also endorsed the study of the protection of the cultural and intellectual property of indigenous peoples prepared by the Special Rapporteur Mrs. Erica-Irene Daes¹⁴¹ and requested that she expand the study with a view to elaborating draft principles and guidelines for the protection of indigenous peoples’ heritage. A preliminary report containing draft principles and guidelines was transmitted to the Sub-Commission at its forty-sixth session. The Sub-Commission later adopted the ‘Revised Draft Principles and Guidelines for the Protection of the Heritage of Indigenous Peoples.’¹⁴²

¹⁴⁰ See for example Article 12, “Indigenous peoples have the right to practice and revitalize their cultural traditions and customs. This includes the right to maintain, protect and develop the past, present and future manifestations of their cultures, such as archaeological and historical sites, artifacts, designs, ceremonies, technologies and visual and performing arts and literature, as well as the right to restitution of cultural, intellectual, religious and spiritual property taken without their free and informed consent or in violation of their laws, traditions and customs; ”

¹⁴¹ See Daes *supra* note 3.

¹⁴² The first draft principles can be found in Draft principles and guidelines for the protection of the heritage of indigenous people (E/CN.4/Sub.2/1995/26). The draft contains 10 broad principles and 49 guidelines under general headings as:

- Definitions
- Transmission of heritage
- Recovery and restitution of heritage
- National programmes and legislation
- Researchers and scholarly institutions
- Business and industry
- Artists, writers and performers
- Public information and education
- International organizations

See also *STANDARD-SETTING Review of the draft principles and guidelines on the heritage of indigenous peoples Expanded working paper submitted by Yozo Yokota and the Saami Council on the substantive proposals on the draft principles and guidelines on the heritage of indigenous peoples* E/CN.4/Sub.2/AC.4/2005/3 21 June 2005.

6 Indigenous Peoples Declarations

6.1 Overview

While indigenous peoples have long demanded from states a right to recognition and control over their culture, including traditional knowledge related to biodiversity, medicines and agriculture, perspectives on the issue are far from homogenous, according to Coombe:

“It appears that there is an emerging division of opinion as to the viability of IPRs between representatives of indigenous peoples in "the West" (which appears to encompass New Zealand, Australia, Hawaii, and the Pacific Islands) and representatives of tribal others (Asian and African groups and Southern NGOs representing Third World, rather than Fourth World, interests). The interests of these groups are substantially different and appear to reflect the different social and political contexts in which rights are being recognized and negotiated. Those in the former group have claims as indigenous peoples that are more fully recognized in national and international law. They have made IPRs subsidiary to, and an integral part of, their struggles for self-determination--aspects of their more primary assertions of sovereignty. The latter group of indigenous peoples face more protracted struggles to have their indigenous status recognized, both in the States in which they reside and in the international arena. Legal recognition of their sovereign rights to control territory and resources appears far more remote; consequentially, they have taken a more pragmatic view of the potential short-term benefits of IPRs in alleviating poverty.”¹⁴³

While indigenous communities responses entail diverse approaches, it is arguable that such diversity does not detract from the much broader issue such as the position of indigenous peoples within the wider economy and society in which they live and their access to and ownership of land and resources they traditionally occupy and use. These issues as well as TK are included in numerous indigenous peoples' declarations.¹⁴⁴

¹⁴³ See Coombe *supra* note 78, p. 108. See also Gupta *supra* note 23, pp. 20-21 and pp. 108-109 who assails the “so-called representatives of indigenous communities, often themselves of Western origin, both in identity and in their ways of approaching the issue” of dominating international discourse.

¹⁴⁴ See for example Charter of the Indigenous-Tribal Peoples of the Tropical Forests (CITP) (Malaysia 1992), Indigenous Peoples Earth Charter (Brazil 1992), Mataatua Declaration on the Cultural and Intellectual Property Rights of Indigenous Peoples (New Zealand 1993), Julayinbul Statement on Indigenous Intellectual Property Rights (Australia 1993), the Coordinating Body of the Indigenous Peoples of the Amazon Basin (COICA) Statement (Bolivia 1994) and the Final Statement of the South Pacific Regional Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights (Fiji 1995). See Michael Blakeney, 'Bioprospecting and the Protection of Traditional Medical Knowledge of Indigenous Peoples: An Australian Perspective' *E.I.P.R.* 1997, 19(6), 298 – 303. See also Agrawal Arun, *Indigenous and Scientific Knowledge: Some Critical Comments*, 3(3) *Indigenous Knowledge and Development Monitor* (1995) <www.nuffic.nl/ciran/ikdm/3-3/article/agrawal.html> (visited 15 December 2004) who asserts “...If the primary motive for highlighting the knowledge of the marginalized poor is to find them a greater voice in

7 Contract Approach

7.1 Overview

Contractual agreements are, in the absence of or in addition to legislative forms of protection, often relied upon to bargain around TRIPS and/or the CBD and to capture benefits arising from traditional knowledge¹⁴⁵ and have become the standard practice of a number of corporations that have been accessing biological resources within indigenous and local communities and their traditional biodiversity related knowledge for a decade or more. As agreements they take a wide variety of forms, ranging from letter statements attached to a shipment of germplasm, to memoranda of understanding and to detailed and formally negotiated contracts covering cooperation programmes between the parties and for a transfer of a growing range of genetic resources for commercial or non-commercial purposes, or a

development, then it would seem preferable to foreground this objective, rather than framing it in terms of the confounding rhetoric of indigenous vs. Western/scientific knowledge. If indigenous knowledge systems are disappearing, it is primarily because the pressure of modernization and cultural homogenization, under the auspices of the modern nation-state and the international trade system, threaten the lifestyles, practices and cultures of nomadic populations, small agricultural producers and indigenous peoples. The appropriate response from those interested in preserving the diversity of different knowledge systems, might then lie in attempting to reorient and reverse state policies to permit members of threatened populations to determine their own future, thus facilitating in situ preservation of indigenous knowledge. In situ preservation cannot succeed unless indigenous populations and local communities gain control over the use of the lands on which they dwell and the resources on which they rely. Those who are seen to possess knowledge must also possess the right to decide on how to conserve their knowledge, and how and by whom it will be used.”

¹⁴⁵ Although not negotiated with indigenous people in mind, the INBIO -Merck agreement is often touted as a very good model to follow. InBio, Costa Rica's National Institute of Biodiversity. InBio was created by a small group of entomologists who had discovered the wealth of information located in the tropical forests of Costa Rica. Initially, their goals were to conserve and catalogue all of the genetic resources located in the developing country. The entomologists approached Merck to request a grant to fund their project. Merck had been unaware of the magnitude of genetic information located in Costa Rica's forests until the entomologists informed them of their findings. However critics of the agreement point to its' failing to produce any lasting benefits and that should a conflict arise into the future as to the origin of biological materials, Costa Rica would be hard pressed to enforce its' rights under contract. As to the suitability of this model, see CSSOP *supra* note 45, “The deal requires Costa Rica to provide Merck with roughly 10,000 plant, animal or microbial samples in return for US \$ 1.3 million or \$130 per sample[d]. Costa Rica is estimated to hold five percent of the world's Biodiversity. If the Merck deal were replicated for the developing world as a whole, all of the South's Biodiversity would go for \$20 million. Merck's sales in 1991 alone were \$8,600 million, while Costa Rica's entire Gross National Product that year was less than \$5,200 millions. Merck's research budget in 1991 was roughly \$1,000 million. At present, Merck has three drugs on the market with a sales volume in excess of \$1,000 million each. Since Merck invests an average of \$125 million on research for each new drug, the discovery charge for one single new drug arising from the Costa Rican agreement is barely loose change for Merck. For Merck, the Costa Rica contract is cheap labour. If 10 or 20 years from now, Merck and Costa Rica dispute the origins of a plant-derived active ingredient, the country has comparatively little capacity to appeal to the international courts to resolve such a dispute compared to Merck's army of lawyers.”

combination thereof. An increasing number of stakeholders and access frameworks are using contractual agreements for their genetic resource transfers. Such stakeholders include public sector research institutions and private sector companies in all sectors utilizing genetic resources, indigenous peoples and local communities, as well as gene banks and other *ex situ* collections such as botanical gardens.

Due to the wide variety of forms of contracts, it is only possible to address those most commonly used, namely, material transfer agreements, bio-prospecting agreements and know-how licensing agreements.

7.2 Material Transfer Agreements

This form of bilateral agreement treats genetic material as a commodity rather than as knowledge (in contrast to a “know how” licensing agreement). A contract is reached between buyer and seller based on the potential value of the commodity¹⁴⁶ These contracts generally involve both initial up front or one off payments and a formula for an additional payments if and when the material is commercialized. These agreements are negotiated in situations where both parties realize that the material to be transferred has real and relatively immediate commercial potential.¹⁴⁷ MTAs should not be confused with commercial plant extraction (bioprospecting agreements) agreements where communities are directly involved in plant extraction.

7.3 Bio-prospecting Agreements

Bioprospecting agreements are generally bi-lateral agreements involving a country and/or traditional/indigenous community and provides for access to biodiversity and/or knowledge on agreed terms. It involves exploration of biodiversity for commercially valuable genetic resources and bio-chemicals.

¹⁴⁶ WIPO *Genetic Resources: Draft Intellectual Property Guidelines for Access and Benefit Sharing Contracts* (WIPO/GRTKF/IC/6/5) 3 February 2004; *Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit Sharing*; (WIPO/GRTKF/IC/2/3) 10 September 2001, CBD *The Role of Intellectual Property Rights in Access and Benefit-Sharing Arrangements, including National and Regional Experiences* (UNEP/CBD/WG-ABS/2/3) 20 October 2003 See also WIPO contract database at www.wipo.int/tk/en/databases/contracts/ for a compilation of model and actual agreements.

¹⁴⁷ See CSSOP *supra* 45. Typically an MTA will have the following provisions:

- Up front or one off payment
- Reporting provisions advising the community of the research related to the material
- Transfer of technology arrangements giving both parties access to technologies related to the material
- Third party agreement regarding the conditions (if any) under which the material or research products can be made available to third parties
- Commercialization agreement setting out the terms and conditions under which the material or research product may be commercialized. These provisions could include royalties or other financial arrangements.
- Arbitration agreement establishing dispute settlement procedures; such procedures should ensure that legal costs of dispute settlement or litigation are borne by the corporation.
- Review process, through which either party can have an independent periodic review during the life of the agreement.

It describes a search for resources and the collection of resources with an intention to commercialize the resources. Bioprospecting can also include the collection from local communities of traditional knowledge relating to the use of these resources.

7.4 Know-How Licensing Agreements

A know-how license is a type of industrial agreement that provides the licensee with exclusive or non-exclusive rights to use informal knowledge that is not generally patentable, but is important in the execution or utilisation of an associated technology. The use of a know-how license for ethno-medicinal knowledge in the context of bioprospecting is an innovation credited to legal counsel for the Aguaruna, Brendan Tobin of the Sociedad Peruana de Derecho Ambiental (SPDA). A “know-how” licensing agreement is designed to:

- (a) Secure continuing control by indigenous peoples of their knowledge throughout research and development (R & D) of new medicinal products;
- (b) Increase opportunities for benefit sharing;
- (c) Prevent patents obtained during R & D from being used to impede the use, sharing, transfer, licensing or sale of traditional knowledge or traditional medicinal products, anywhere in the world; and
- (d) Extend control to genetic resources that are the subject of the R & D activities.¹⁴⁸

7.1.1 Selected Arguments in Favour of a Contract Approach

Reliance upon contractual arrangements to capture benefits for indigenous communities is widely thought of as the most practical approach to ensure equitable sharing of benefits referred to in Article 8(j) of the CBD and to protect a community’s intellectual property rights. The WIPO Report on Intellectual Property Needs and Expectations of Traditional Knowledge Holders,¹⁴⁹ observes that traditional knowledge holders who contributed to the Report concluded that “models for contractual arrangements - in the form of licenses, material transfer agreements, access agreements, information transfer agreements and the like - offer practical tools” for indigenous peoples and other traditional knowledge holders in negotiating fair and equitable access and benefit-sharing agreements.¹⁵⁰

The traditional knowledge holders also made several practical suggestions in this respect. They identified a need for:

¹⁴⁸ See Brendan Tobin, ‘Redefining Perspectives in the Search for Protection of Traditional Knowledge: A Case Study from Peru’ *RECIEL* 10 (1) 47 (2001) p. 52. See also Shane Green, ‘Intellectual Property, Resources, or Territory? Reframing the Debate over Indigenous Rights, Traditional Knowledge and Pharmaceutical Bioprospecting’ in *Truth Claims and Human Rights* 229, 232 (M.P. Bradley & P. Petro eds. 2002)

¹⁴⁹ WIPO FFM *supra* note 29.

¹⁵⁰ *Id.* But see Tobin *supra* note 148 p. 59 who cautions against the use of the FFM findings as it “flies in the face of almost consensual conventional wisdom, that existing IPR regimes do not meld with indigenous issues.”

- Assistance and training for TK holders in the negotiation, drafting, implementation, and enforcement of contracts;
- The development and testing, with the close involvement of local communities, of “best contractual practices” and guidelines and model clauses for contracts, as well as the provision of information on and protection against “unfair contract terms.”¹⁵¹

The contractual concept is also considered attractive because most societies are familiar with it and because it is a relatively private bargain involving minimal governmental intervention.¹⁵² Contracts can provide a useful way of allocating IP ownership¹⁵³ and responsibility for its protection and defence.¹⁵⁴ This is especially the case in those national jurisdictions that do not recognize TK as a protectable subject matter.

Contracts may prove beneficial in providing both monetary and non-monetary benefits. Monetary benefits may include, but not be limited to access fees/fee per sample collected or otherwise acquired, up-front payments, milestone payments, payment of royalties, licence fees in case of commercialization, special fees to be paid trust funds supporting conservation and sustainable use of biodiversity, salaries and preferential terms where mutually agreed, research funding, joint ventures and joint ownership of relevant intellectual property rights. Non-monetary benefits may include, but not be limited to sharing of research and development results, collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnology research activities,

¹⁵¹ *Id.*

¹⁵² Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity, *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 Biological Diversity*, (UNEP/CBD/WG8J/1/2) 10 January 2000 para. 22.

¹⁵³ See Sharon L. Tasman, ‘Addressing Intellectual Property Ownership When Drafting Joint Development Agreements,’ 8 No. 7 *Intell. Prop. Strategist* 1 (2002) Agreements must outline three main areas of IP.

1. Each parties’ contributed IP (developed prior to and/or outside the scope of the collaborative agreement);
2. Joint IP (created as a result of the collaborative project); and
3. Modifications or derivatives of either party’s contributed IP.

¹⁵⁴ *Id.* In handling patent prosecution and infringement claims. The contract should set which party will protect IP through patents or trade secrets, filing and prosecuting and maintaining patents and applications, pay for patent prosecution and maintenance expenses, provisions to act when either party is unable or unwilling to do above and take other necessary steps to protect joint IP, provisions re: bankruptcy, who deals with claims that joint IP infringes third parties, can include a proviso that if the real cause of an infringement claim is one party’s underlying contributing IP, that party will bear the burden of the infringement claim, who has the responsibility of prosecuting third party infringers. See also CSSOPP *supra* note 45 “British industry experts have estimated that 8 to 9 percent of corporate R & D budgets is spent up front on legal fees and other costs to ensure protection and undertake litigation. The average cost of litigation in the United States has risen from a quarter of a million dollars 20 years ago to well over a million dollars today...the burden of these expenses rests with the patent holder.”

where possible in the provider country, participation in product development, collaboration, cooperation and contribution in education and training and institutional capacity building.¹⁵⁵ In this regard it is claimed that through contracts indigenous peoples and communities will achieve economic parity with national and international communities.¹⁵⁶

Contracts could also be useful to prevent appropriation and compel the disclosure of origin and associated TK. This however, is not borne out and presumably without a framework of broader intergovernmental arrangements, contracts may not achieve these goals.¹⁵⁷

7.1.2 Selected Arguments Opposed to a Contract Approach

While the contractual approach is considered attractive to most societies familiar with it, it presents unique difficulties for indigenous peoples who it is fair to say are unfamiliar their rights under conventional contract law and the commercial value of the information they are imparting. Other limitations include the private bargain nature of contracts means they are not enforceable against third parties; disparities in bargaining power between contracting parties;¹⁵⁸ high transaction costs; and limited resources, access

¹⁵⁵ See Bonn Guidelines decision V1/24

¹⁵⁶ See David B. Vogt, "Protecting Indigenous Knowledge in Latin America Maintaining Biological Diversity, Creating Relationships, and Returning Benefits to Native Communities for Ethnobotanical Drug Discoveries – Can it be done?" 3 *Or. Rev. Int'l L.* 12 (2001) p. 17. See also Steven King *et al.* 'Issues in the Commercialization of Medicinal Plants,' *HerbalGram* 47 (1999). It remains to be seen whether indigenous people will benefit from the use of their TK. One study found that only one of 100 companies (mainly European herbal or phytomedicine companies) marketing products based on 10 medicinal plants used by indigenous peoples actually provided a benefit to indigenous communities. The plants studied were *Echinacea*, *wild yam*, *goldenseal*, *mate*, *pygeum*, *pau d'arco*, *una de Gato*, *yohimbe*, and *saw palmetto* and *kava kava*.

¹⁵⁷ See WTO, THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE PROTECTION OF TRADITIONAL KNOWLEDGE Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela (IP/C/W/403 24) June 2003 para. 18, "It has been suggested that there should be a separate law for governing aspects of biopiracy, and that PIC and fair and equitable benefit sharing can be done through contracts as well. The CBD mandates its member states to enact national laws that would facilitate PIC and benefit sharing in a fair and equitable manner, prior to access and use of biological resources and traditional knowledge. It is acknowledged that these mechanisms can and should be used, and several countries have already enacted laws to put in place an Access and Benefit Sharing (ABS) regime. However, this in itself, is insufficient to arrest biopiracy and misappropriation of resources. It also does not achieve the central objective of disclosure norms; that is; to stall the reward of a patent for knowledge or information misappropriated from another country."

¹⁵⁸ See for example Rachel Wynberg, 'Bioprospecting, Access and Benefit-Sharing in South Africa: Towards A Strategic Assessment May 2004' (A paper prepared for the National Botanical Institute as a contribution towards the Southern African Biodiversity Support Programme and National Biodiversity Strategy and Action Plan.) "It would appear that the bargaining arm of local institutions or individuals has been far weaker than that of their international collaborators. Unfortunately, South Africa's isolation through the apartheid years is still reflected in the naivety with which local institutions receive foreign commercial collaborations, and the lack of capacity of local institutions to engage with and comprehend the very powerful interests that tend to drive such partnerships. In the absence

to legal advice and negotiating skills among some traditional knowledge holders may disable them from being able successfully to use contracts to regulate access to and secure benefit sharing in their traditional knowledge.¹⁵⁹

Overwhelmingly it cannot be said that a contract negotiated between an indigenous community and public sector research institutions or private sector companies is a contract between equally resourced parties. If a company (or research institution) breaches a term of the contract, the indigenous party will have to bear the cost of seeking enforcement or any other remedy. Experience reduces uncertainty and public sector research institutions and private sector companies have a good deal of experience negotiating contracts for the exploitation of IPRs; an indigenous community by and large, does not.

Another fundamental problem is what Drahos terms 'pervasive imperfect information' (neither party has perfect information).¹⁶⁰ TK may reduce the level of uncertainty in whether or not a product will be the result. But any further reduction of uncertainty will depend upon a company's research facilities, knowledge of the market, its patenting position and procurement and so on; indigenous communities do not have the same capacity (although in theory, they can obtain patents for their innovations).

The ability (or lack of) to absorb risk is another limitation to a contractual approach. Large private and public sector organizations are well resourced and thus able to absorb the costs of risk across their R & D portfolios. Indigenous communities do not have the same ability to spread monetary risk yet also potentially accept new ones resulting in potentially irreversible changes to their communities. For example, Bodeker warns of a serious risk that communities become trapped in a system of exploitation and lose control over their livelihoods and traditional territories.¹⁶¹ This is more troublesome where land security is an issue.¹⁶²

of other options, local chemists or biologists involved in doing the research have been left to fumble through highly complex and legally challenging agreements, the full implications of which were perhaps poorly comprehended and thought through."

¹⁵⁹ See generally *supra* note 146.

¹⁶⁰ See Drahos *supra* note 48, p. 247.

¹⁶¹ See Bodeker *supra* note 40 p. 787, "In 1985 -1991...over-harvesting of bark (11,537 tons) for *Prunus Africana* in Cameroon for use in a European herbal medicine to treat benign prostatic hypertrophy (BPH). Citizens were only paid for the collection of the bark." See also John Hunter & Chris Jones, *Bioprospecting and Indigenous Knowledge in Australia: Valuing Indigenous Spiritual Knowledge and its Implications for Integrated Legal Regimes* referring to *Dubosia* known and used by Aboriginal people as a sedative. It is now commercially harvested with an export industry of Aus. \$1,000,000. Aside from a few seasonal employment opportunities, Aboriginal people receive no other benefit. (Washington University School of Law Conference Biodiversity and Biotechnology and the Protection of Traditional Knowledge 4-6 April 2003 <<http://law.wustl.edu/centeris/Confpapers/>> (visited 14 May 2004)

¹⁶² See Vogt *supra* note 156 p. 17 who observes "[S]hould they become unable to provide for or heal themselves due to increased external demand, indigenous communities are faced with abandoning their ancestral homeland, becoming wards of the state, or adapting to city

Contracts also present challenges to or disruption to social structure. Mme. Daes observed, "...concern has been expressed about the social impact of paying large sums of money directly to indigenous community leaders. Royalty payments might increase traditional leaders' power and reduce their accountability to their own people. They might also provoke conflicts between different clans and communities regarding the ownership of traditional knowledge, for example, if several tribes have traditionally used a medicinal plant, but only one of them sells its knowledge to a pharmaceutical company."¹⁶³ Such was the case with the Kayapo people in Brazil. In 1992, a British company, The Body Shop, entered into a supply contract with Chief Paulinho Paiakan, a respected leader of the Kayapo. Chief Paiakan agreed to supply to The Body Shop 6,000 liters a year of natural oil to use in hair conditioners in exchange for a small percentage of the profits. The Body Shop gave their payment to Chief Paiakan. Stephen Corry, Director General of the non-governmental organization "Survival International" observed, "[t]he project has caused deep divisions amongst the Kayapo exacerbated by the way Paikan has accumulated great personal wealth and power."¹⁶⁴ Contracts can potentially contribute to intra-generational tension in situations where elders perceive knowledge as sacred and non-negotiable while the younger generation may view it as a source of income.¹⁶⁵

A well-crafted contract could include a proviso that an ethnographic impact assessment is conducted prior to, during, and after the completion of any significant bioprospecting in indigenous communities with the results of such assessments made available to persons involved in or potentially

life. Sharing profits in exchange for sharing IK provides indigenous communities with long term protection from the depletion of traditional plants and products."

¹⁶³ See *supra* note 3, para. 156.

¹⁶⁴ See Gelvina Rodriguez Stevenson, 'Trade Secrets: The Secrets to Protecting Indigenous Ethnobiological (Medicinal) Knowledge,' 32 *N.Y.U.J. Int'l L. & Pol.* 1119 (2000) p. 1142.

¹⁶⁵ See Stephen D. Osborne, 'Protecting Tribal Stories: The Perils of Propertization,' 28 *Am. Indian L. Rev.* 203 (2003/2004)pp. 205-206. Similar intra-tribal conflict exist in some Native American reservations. "The so-called 'realists' acknowledge the tribes' partial assimilation into the world market and seek to prosper with that system by exploiting the niches carved for Indians by the dominant culture's laws and the opportunities created by the free market. This group believes that the circulation of cultural property is inevitable, so Indians may as well stake out as much of the profits of such circulation as possible. The traditionalists, meanwhile, are less concerned with money flowing in than with meaning flowing out. They fear that commercial exploitation of traditional symbols, images, stories and ceremonies may drain or dilute traditional cultural resources" and presumably other forms of TK as traditional medicinal knowledge. See also Amina Para Matlon, 'Safeguarding Native American Sacred Art by Partnering Tribal Law and Equity: An Exploratory Case Study Applying the Bulun Bulun Equity to Navajo Sandpainting,' 27 *Colum. J. L. & Arts* 211 (2004) p. 244 writes that limitations on an artist's sand painting could jeopardize creativity and income and further "especially if this were to be seen as primarily supported by an older, conservative contingent of Navaho society, holds a real danger of smothering innovation. Even Navaho who feel strongly about commercial paintings are reluctant to give sanctioning effect to cultural obligations, instead preferring to rely on individual governance."

affected in some significant way by the project.¹⁶⁶ Risk checkpoints could be identified and plans in place to mitigate some risk.

The risks currently identified are very real yet their effects may be lasting and permanent. As more contracts come under scrutiny, a better understanding might develop. In any event, these risks must be plainly laid out, as preliminary as they are. It might well evolve that communities may not consent to projects if they have full disclosure, based on the current state of knowledge and decide not to chance such proposals. It remains to be seen whether contracts are a useful tool to prevent appropriation and compel the disclosure of origin and associated TK. It is clear however, that without a framework of broader national and intergovernmental arrangements, contracts may not achieve these goals.¹⁶⁷

8 Case studies

8.1 San Hoodia Benefit Sharing Trust

The subject of this case study is a benefit-sharing agreement concluded 24 March 2003 between the South African Council for Scientific and Industrial Research (hereinafter "CSIR") and the South African San Council (hereinafter the "San Council") concerning the development of an appetite suppressant derived from species of Hoodia, succulent plants indigenous to southern Africa and long used by the San, indigenous peoples of the region, to stave off hunger and thirst.¹⁶⁸

The CSIR is one of the largest research organizations in Africa accounting for about ten percent of the entire African research and development budget. The San Council was formed in November 2001 with a mandate to represent San peoples of Namibia, Botswana and South African in all benefit sharing negotiations regarding Hoodia.¹⁶⁹

¹⁶⁶ See Stephenson *supra* note 17, p. 14.

¹⁶⁷ See Tobin *supra* note 148 p. 152 asserts it was the lack of a legislative framework and the unequal bargaining power of the parties that led to the dilution of some of the most progressive elements of the initial licensing proposal [referring to the CONAP-Aguaruna Know-How licensing agreement] ... and also demonstrated the need to enact legislation which recognizes and regulates the rights of indigenous peoples to negotiate agreements for the use of their knowledge. See also *Report of the Panel of Experts on Access and Benefit-Sharing* (UNEP/CBD/COP/5/8) 2 November 1999 which observes, "It is now widely accepted that bioprospecting agreements, negotiated in the absence of national access policy and law cannot assure the realization of the CBD's benefit-sharing objectives."

¹⁶⁸ See Rachel Wynberg, "Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of Hoodia Species in the Development of An Appetite Suppressant," 7 *Journal of World Intellectual Property* (2004) 851 for an overview of the ecology and use of Hoodia species and a history of its' commercial development and current market potential for the dietary control of obesity of over USD three billion per annum in the United States alone.

¹⁶⁹ See generally Roger Chennells, Ethics and Practice in Ethnobiology and Prior Informed Consent with Indigenous Peoples regarding Genetic Resources Paper presented at Washington University in St. Louis Conference on Biodiversity and Biotechnology and the Protection of Traditional Knowledge, April 4-6, 2003 www.law.wustl.edu/centeris/confpapers/ (visited 10 November 2005). The San have

Contemporary San live in small settlements in the more remote regions of southern Africa, earning their living through a combination of agriculture, livestock raising, small-scale industries, non-timber forest product harvesting and wage labour. Wynberg observes that the San's history of dispossession and relocation (commencing with their persecution and displacement upon colonization of the region in 1652, their discrimination along with other people of colour during South Africa's apartheid regime and their use by the South African Defence Force in Namibia and Angola for counter-insurgency operations) continues today through evictions and continued political, social and economic marginalization. Many San live below the poverty datum line and face extreme hardship in terms of access to social services, employment and income-generating opportunities. Presently, the San number between 85,000 and 90,000 in southern Africa, the overwhelming majority of who live in the Kalahari Desert and its surrounding regions in Namibia, Botswana and to a lesser extent, in South Africa.¹⁷⁰

Documented use of Hoodia as a food and water substitute in colonial and later botanical accounts led directly to the CSIR including the plant for further investigation in a 1963 project on edible wild plants of the region.¹⁷¹ Laboratory tests on mice revealed Hoodia's potential as a non-toxic appetite suppressant but lack of technology stalled further research until the early 1980s' when CSIR acquired high-field nuclear magnetic resonance spectroscopy which made it possible to elucidate relevant molecular structures of Hoodia.

In 1995 and following nine years of confidential research and development, a patent application was filed in South Africa by the CSIR for use of active components of the plant responsible for suppressing appetite.

In 1998 the CSIR signed a licensing agreement with Phytopharm, a small British company, specializing in the development of phytomedicine, and this was followed in the same year by the granting of international patents in

repeatedly asserted that their heritage is collectively owned and cannot be privately appropriated by any individual or group(s). A Working Group of Indigenous Minorities in Southern Africa (WIMSA) was formed in 1996 and at an annual general meeting it was determined that any benefits derived from their shared heritage are to be shared among all San. The San Council was subsequently formed in November 2001.

¹⁷⁰ See Wynberg *supra* note 168, p. 854-855.

¹⁷¹ There is some dispute as to when San use of Hoodia became first known. According to Wynberg *id* p. 853 the first recorded use of Hoodia was by the botanist Francis Masson (1741-1805), who visited the Cape in South Africa (1772-1774 & 1786-1795), recorded finding '*Stapelia gordonii*' and wrote that the stems of *Trichocaulon piliferum* were eaten by the 'Hottentots'. It was this knowledge, recorded in the literature and combined with field studies, that provided the motivation for the CSIR to include *Trichocaulon spp.* in a research programme aimed at determining the nutritional and possible toxic properties of 'foods from the veld' (forest). *But see* Commission on Intellectual Property Rights *supra* note 61, pp. 76-78 which places recorded use much later and in 1937 and *see also* Chennells *supra* note 169 who claims San knowledge about Hoodia was disclosed to anthropologists about 20 years prior to 1995 (original patent application) and in 1975.

some countries. The agreement granted Phytopharm an exclusive worldwide license to manufacture and market Hoodia-related products and to exploit any other part of CSIR's IPRs relating to Hoodia.

Through a programme called 'P57', Phytopharm developed this drug lead to a more advanced stage, leading to a license and royalty agreement in 1998 with Pfizer, the U.S.-based pharmaceutical giant, for further development and commercialization. During July 2003, however, Pfizer merged with Pharmacia and closed its Natureceuticals group responsible for the development of P57. The company announced it was to discontinue clinical development of the drug and was returning the licensing rights to Phytopharm, leaving Phytopharm free to license P57 to other parties.¹⁷²

Up until 2001 however, the San were unaware of the research and development and commercialization of Hoodia and only became informed through news reports.¹⁷³ Hastily organized and in November 2001, the San Council was mandated to negotiate on the behalf of all San groups.¹⁷⁴ The San Council alleged CSIR non-compliance with the CBD by its failure to obtain PIC. In its defence, Phytopharm claimed extensive enquiries were made but they were unable to find any of the "knowledge holders". To its credit, the CSIR maintained they had planned to inform the San of the research and share the benefits, but first wanted to make sure the drug proved successful.¹⁷⁵

In February 2002, a Memorandum of Understanding (MOU)¹⁷⁶ was reached between the CSIR and the San Council. Key aspects of this agreement include:

- Recognition by the CSIR of the San as originators of the body of traditional knowledge associated with human uses of the Hoodia succulent.
- An acknowledgement by the San of the 'context' in which CSIR first registered the P57 patent, without having first engaged the San in negotiations.

¹⁷² See Wynberg *supra* 168 note pp. 854-857.

¹⁷³ *Id* p.857, "In June 2001, the situation changed dramatically ... [O]ngoing vigilance by a South African-based NGO, Biowatch South Africa, combined with assistance from the international NGO Action Aid, alerted the foreign media to the potentially exploitative nature of the agreement, and a leading story in a British newspaper The Observer was published about the case ... [I]n contrasting images of emaciated San and obese Americans, and reinforcing popular notions of 'biopiracy' by large pharmaceutical companies, the media captured the public's imagination, embarrassed the CSIR and Phytopharm, and this in turn led the CSIR to enter into high-level negotiations with the San."

¹⁷⁴ While the prevalence of Hoodia is endemic, the details of sharing benefits amongst the San in different countries require further consideration.

¹⁷⁵ See Commission on Intellectual Property Rights *supra* note 61, p. 85.

¹⁷⁶ See Wynberg *supra* note 168, pp. 858-859.

- A commitment, on the part of both the CSIR and the San, to a process of negotiating with one another in good faith, in order to arrive at a comprehensive benefit-sharing agreement.
- An additional understanding considered the San and the CSIR to be the primary parties with regard to benefit sharing. The effect of this understanding is to exclude non-San groups, such as the Nama, Damara, and Topnaar, who had historically occupied and still occupy areas where Hoodia grows and had undoubtedly used the plant as a medicinal remedy and as a food and water substitute.

On 24 March 2003 a benefit sharing agreement between CSIR and the San Council was concluded.¹⁷⁷ Key aspects of this agreement include:

- The San will receive six percent of all royalties received by the CSIR from Phytopharm for the duration of the royalty period or for as long as the CSIR received financial benefits from commercial sales of the products.
- The San will also receive eight percent of the milestone payments received by the CSIR from Phytopharm.
- The establishment of a joint CSIR-San Council Trust.¹⁷⁸
- The parties commit to conserve biodiversity and to undertake best-practice procedures for plant collection.
- CSIR to grant the San access to existing study bursaries.
- A joint commitment between CSIR/San for a bioprospecting partnership.
- All intellectual property rights arising from traditional indigenous knowledge of use of Hoodia and related to the CSIR patents for P57 remains vested exclusively with the CSIR. The San Council has no right to claim any co-ownership of the patents or products derived from the patents.
- An undertaking and warranty by the San that, *inter alia*, it is the legal custodian of traditional indigenous knowledge on the use of Hoodia; that it will not assist or enter into an agreement with any third party for the development, research and exploitation of any competing products or patents; and that it will not contest the

¹⁷⁷ *Id* pp. 861-862.

¹⁷⁸ *Id*. In August 2004, the San Trust, formally named the San Hoodia Benefit Sharing Trust, was registered. The content of this agreement was discussed over several meetings, during which San delegates from South Africa, Namibia and Botswana debated issues relating to benefit sharing and agreed upon principles to guide the sharing of benefits. There was unanimous agreement that 75 percent of all Trust income would be equally distributed to the constituted San Councils of Namibia, Botswana and South Africa; that 10 percent would be retained by the Trust for internal and administration purposes; that 10 percent would be allocated to WIMSA as an emergency reserve fund; and that 5 percent would be allocated to WIMSA to cover administration of the San networks. Priorities within the region such as education, leadership empowerment, and land security were agreed upon as non-binding recommendations to the Councils. The WIMSA Annual General Meeting for benefit sharing that would bind the Trust unanimously endorsed principles in December 2003.

enforceability or validity of the CSIR's right, title and interest in the P57 patent and related products.

- A further provision on third-party claims sets out various measures to protect the CSIR against claims by any third party for intellectual property infringement and stipulates that a successful third-party claim against the CSIR may lead to a review of the agreement to accommodate claimants in the sharing of financial benefits. It also requires the San Council to share financial benefits with a third party if they are successful in proving a claim.

8.2 Kerala Kani Samudaya Trust

This case study concerns a benefit sharing arrangement through the creation of a trust in November 1997 at the instigation of the Tropical Botanic Garden and Research Institute (hereinafter "TBGRI") and for the benefit of members of the Kani tribals. The subject matter of this arrangement is the drug *Jeevani*TM,¹⁷⁹ an herbal medicine developed by TBGRI scientists as a restorative, immuno-enhancing, anti-stress and anti-fatigue agent based on the knowledge of the Kani tribe.¹⁸⁰

The TBGRI is a centre for plant research situated in the state of Kerala in southern India.¹⁸¹ It is an autonomous institution for research and development set up by the Government of India.¹⁸² One of the major aims of the centre is to carry out botanical, chemical and pharmacological research for the development of scientifically validated and standardized herbal drugs.

The Kani tribals are a traditionally nomadic community, who now lead a primarily settled life in the forests of the Agasthyamalai hills of the Western Ghats (a mountain range along south-western India), in the

¹⁷⁹ JEEVANITM is a product of the Arya Vaidya Pharmacy which is an Indian company.

¹⁸⁰ See Gupta *supra* note 23 for a detailed overview of the ecology and use of *Jeevani*TM and its' research and development and potential in global markets for natural health care products and sports medicines. Its potential was acknowledged in journals like *Nature* and magazines like *Time*. It has also been included in Chinese/Japanese medicine such as "Shosaikoto" with considerable clinical effect. One company in the United States has also registered a trademark of "Jeevani" for sale of the same drug in the USA. See also R.V. Anuradha "SHARING WITH THE KANIS A case study from Kerala, India available at <www.cbd.org> (visited 1 February 2005); Brooklyn Journal of International Law – Note and Comment, 'Market Realities v. Indigenous Equities,' 26 *Brook. J. Int'l L.* 1147 (2001).

¹⁸¹ See Gupta *id* p. 106. It is a registered autonomous institution under the Travancore-Cochin Literary, Scientific and Charitable Societies Registration Act, 1955. Being the largest botanical garden in Asia, TBGRI plays an important role not just in the country but also at the international level as a member of the Botanical Garden Association. The garden is spread over 300 acres, having 50,000 accessions belonging to 12,000 genetic variants of 7000 tropical plant species.

¹⁸² *Id* The Chairman of its Governing Body is the Chief Minister of Kerala; the Secretary of this body is the Director, TBGRI, in addition to whom there are fourteen members. The Chairman of the Science, Technology and Environment Committee (EC), Government of Kerala chairs the Executive Committee of TBGRI. The Secretary of the EC is the Director, TBGRI, and the EC has four members. Both bodies have representation from other State Departments such as the Forest Department and the Planning Board.

Thiruvananthapuram district of Kerala. Their current population is estimated at approximately 18,000 or about 1.8 percent of the total district. Contemporary Kani live in several tribal hamlets, each consisting of ten to twenty families spread in and around the forest areas of the Thiruvananthapuram district and while now not a cohesive unit, do share certain characteristics and practices.¹⁸³ Most of the areas in and around which the Kanis live have been declared as Reserved Forest under the Indian Forest Act, 1927 thus the Kani survive largely on subsistence farming cultivated on small plots of land given by the Forest Department. They derive most of their livelihood from crafts and gathering and selling of various permitted forest products.¹⁸⁴ Marginalized and dependent, the Kani live in thatched huts built by the Forest Department and the Tribal Department.

Politically, the Kani traditional system of governance is now eroded and their daily governance is either absorbed into a devolved and decentralized *Panchayati Raj* system¹⁸⁵ where they have little or no influence or is determined by the Forest Department whose role according to Gupta “is quite evident even to a casual visitor.”¹⁸⁶

Kani tribal use of *Jeevani*TM was first disclosed to a team of scientists from the All India Coordinated Research Project on Ethnobiology (hereinafter “AICRPE”)¹⁸⁷ during a botanical expedition into the forests of the Western Ghats in December 1987.¹⁸⁸ During the arduous treks across the forests,

¹⁸³ See Anuradha *supra* note 180 “... the Kanis are no longer one cohesive unit or community. Kanis in different areas of Thiruvananthapuram district, even at a distance of around 15 to 20 km from each other have differing opinions and reactions about TBGRI’s role and motive.”

¹⁸⁴ See Gupta *supra* note 23 p. 109 “... all acts not permitted by the Forest Office of the State Government are prohibited. The Forest Department periodically issues a list of minor forest produce, which can be extracted by the tribals living in the forest ... It may seem paradoxical that the original inhabitants of this area are dependent on the state for using the natural resources conserved by them for centuries. But the forests were nationalized and despite the recent constitutional amendment making tribal people the custodians of all minor forest species in their areas, the situation at ground level has not improved.”

¹⁸⁵ See Anuradha *supra* note 180 “This system of governance, referred to as the Panchayati Raj system, is based on the principle of devolution of administrative powers to the local village level and has been institutionalised under the Constitution of India. Each Panchayat area consists of a number of wards under it. Each ward has an assembly of all the adult members called the Gram Sabha (village council). There are 1000 to 2000 members in each Gram Sabha, inclusive of both non-tribal and tribal members, but pre-dominantly non-tribal. Members of the Panchayat’s decision-making body are elected by the members of all the Gram Sabhas constituting the Panchayat.”

¹⁸⁶ See Gupta *supra* note 23 p. 109.

¹⁸⁷ The AICRPE is a project that was set up by the Indian government in 1982 to a) develop a better understanding of the life, culture, customs and traditional knowledge systems of tribals b) to develop sustainable development alternatives which are in sync with the values and ethos of tribals and c) to strengthen the linkages between tribal welfare and the management of the forests. The AICRPE has 27 centres all over the country and has so far documented information about 9500 medicinal plants, 3900 edible plants, 700 plants amongst others. See *id* p. 107.

¹⁸⁸ See generally Anuradha *supra* note 180 for an overview of the first documented use of *Jeevani* by the Kani tribals.

scientists noticed that the Kani guides constantly ate some fruits, which kept them energetic and agile. When the exhausted scientists consumed these, they also felt a “sudden flush of energy and strength.” When asked about the source of the fruit however the guides were reluctant to reveal the same, saying that it was sacred information and a tribal secret, not to be revealed to outsiders.¹⁸⁹ After a great deal of persuasion,¹⁹⁰ the Kani guides led the AICRPE team to the *arogyappacha*.¹⁹¹

TBGRI isolated five compounds in all from *arogyapaacha*, but the detailed characterization of four compounds was delayed due to the lack of adequate technology and equipment.¹⁹² For the one compound for which characterization was possible, the TBGRI without delay and in 1996 filed a process patent application for a process of manufacture of an herbal sport medicine, based on the compounds isolated from *arogyapaacha*. The application describes the invention as “a novel, safe herbal sports medicine, having antifatigue, antistress and stamina boosting properties.” The application does not specifically mention the tribal knowledge of *arogyapaacha*, but it records that “the therapeutic effect of this plant has been established by detailed pharmacological studies.”¹⁹³ On 10 November 1995, the TBGRI licensed the right to manufacture Jeevani to Arya Vaidya Pharmacy (Coimbatore) Ltd. (hereinafter “AVP) for a period of seven years for a license fee of one million rupees, approximately \$25,000 and a two percent royalty fee on any future drug sales. This company has been a manufacturer of Ayurvedic drugs since 1948.¹⁹⁴ A further resolution approved by both the governing body and the executive committee of TBGRI directed that the Kani tribals receive fifty percent of the license fee, as well as fifty percent of the royalty obtained by TBGRI on sale of the drug.¹⁹⁵

¹⁸⁹ The tribal physicians of the Kani, known as *Plathi*, are the exclusive holders of the traditional medicinal knowledge of the tribe. See generally Gupta *supra* note 23 p. 110 for a description of the initiation process for the *Plathi*.

¹⁹⁰ Its claimed the AICRPE scientists offered the Kani guides the half the proceeds of sale of any marketable drug developed from Kani knowledge. See Brooklyn *supra* note 180, p.1166.

¹⁹¹ The term means “the greener of health, that is the one that gives very good health and vitality”. It is claimed by the Kani tribals that one can live for days together without food, and still be able to perform rigorous physical work by eating a few fruits of *arogyappacha* everyday.” See Anuradha *supra* note 180 (citing P.Pushpangadan, “Arogyappacha: The Gensing of Kani Tribes of Agastyar Hills (Kerala) for Evergreen Health and Vitality”, *Ancient Science of Life*, Vol. VII, No.1, (July 1988) 13).

¹⁹² A collaborative research project entitled “Ethnopharmacology of Indian Medicinal Plants” is carried out between the Tropical Botanic Garden and Research Institute, Trivandrum, and the Department of Medical Chemistry at the Royal Danish School of Pharmacy, Copenhagen, Denmark, sponsored by the Danish International Development Agency (DANIDA). The project is undertaken on a mutual understanding that all patents and patent rights developed under this project belong to the Indian partner and all scientific publications resulting from this collaboration are published as joint publications between the two institutes. See Gupta *supra* note 23 p. 112.

¹⁹³ *Id.*

¹⁹⁴ See Anuradha *supra* note 180.

¹⁹⁵ *Id.*

In November 1997 a trust was registered and named the Kerala Kani Samudaya Kshema Trust. The Trust was registered with nine members, all of whom are Kani tribals. The president and vice-president of the Trust are two of three Kanis who first disclosed the traditional knowledge to the TBGRI regarding *arogyapaacha*. The decision to form the Trust was taken in a local meeting of around 40 Kanis. The Trust objectives are:

- Welfare and development activities for Kanis in Kerala.
- Preparation of a biodiversity register to document the knowledge base of the Kanis.
- Evolving and supporting methods to promote sustainable use and conservation of biological resources.¹⁹⁶

At its first meeting held at the Kallar Mattammodhu Kani tribal settlement on March 19, 1999 the original tribal informants were compensated at a rate of between 10,000 Rupees (approximately USD 222.00) to 50,000 Rupees (approximately USD 1110.00).¹⁹⁷

Not all Kanis are trust beneficiaries. The Kanis in the Vithura (the only Panchayat in Kerala with a Kani president) and Peringamala Panchayat areas were largely ignored and only became aware of the Trust through newspaper accounts.¹⁹⁸ The Plathis, exclusive holders of the traditional medicinal knowledge of the Kanis, were similarly ignored.¹⁹⁹ Over time it is anticipated more Kanis will support the trust.²⁰⁰

8.3 Confederacion de Nacionalidades Amazonicas del Peru (CONAP) Fund

This case study concerns a benefit sharing arrangement through the negotiation of a “Know-How” licensing agreement of the International Cooperative Biodiversity Groups (ICBG)-Peru partnership (1997-2002) including Washington University in St. Louis, Missouri, Museo de Historia Natural, Universidad Nacional Mayor de San Marcos in Lima, Peru, and the

¹⁹⁶ See Gupta *supra* note 23 p. 116.

¹⁹⁷ *Id* p.116. Other proposals for disbursement of Trust funds include a telephone booth (a first) in the Kottor area bordering the forest belt, health insurance for pregnant women and accidental health insurance.

¹⁹⁸ TBGRI has primarily been interacting with Kanis from the Kuttichal Gram Panchayat area. Two Kanis disclosed knowledge of *arogyappacha* are from this area and have been retained by TBGRI as consultants. It is through them that TBGRI has been interacting with the Kanis in their area. This section of Kanis has been supportive of and appreciative of TBGRI’s role. See Anurdha *supra* note 180.

¹⁹⁹ *Id* “In September 1995, a group of nine medicine men (called Plathis) of the Kani tribe wrote a letter to the Chief Minister of Kerala, objecting to the sale of their knowledge to “private companies.” They expressed fear that private companies would destroy the available stock of the plant very fast once they start collecting the same with the intention of generating profit. As for TBGRI, it acknowledges that it has not reached out or communicated to all the members of the Kani tribe; but feels that once the Trust to administer the benefit sharing arrangement is constituted, the Kanis would feel more involved.”

²⁰⁰ See Gupta *supra* note 23 p. 117

Departamento de Microbiología, Universidad Peruana Cayetano Heredia (University partners); G.D. Searle & Company, a division of Monsanto Company (corporate partner), and the Confederación de Nacionalidades Amazónicas del Perú (CONAP) (Indigenous partner of four organizations of Aguaruna communities and peoples.)²⁰¹

The ICBG programme was an experimental one and the product of a workshop in 1991 sponsored by the National Institutes of Health (NIH), the National Science Foundation (NSF) and the United States Agency for International Development (USAID). The NIH emerged as the administrator of the programme and announced a competition for large grants for research into the pharmaceutical potential of international biodiversity. These grants are based on collaborative funding, research and mutual benefits relationship between U.S. and developing country institutions, commercial partners and in some cases specific indigenous/local communities.

The purpose of the now completed ICBG-Peru project was to identify new pharmaceuticals based originally on ethnobotanical pre-screening, while also conserving biodiversity in northern Peru by enhancing economic growth among the collaborating Aguaruna people. The focus of the research has been both on globally important diseases particularly anti-malarial extracts used by the Aguaruna.²⁰² In 1992, the principal investigator Dr. Walter H. Lewis, Professor of Biology at Washington University in St. Louis, Missouri catalogued several hundred plants currently used in both modern medicine and pharmacy and by the indigenous peoples of Peru.²⁰³

The Aguaruna peoples reside in the Alto Marañón region of northern Peru and are described as organized into 187 individually titled Aguaruna

²⁰¹ See generally Charles R. McManis, 'Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally,' 11 *Cardozo J. Int'l & Comp. L.* 547 (2003); Joshua P. Rosenthal (Guest ed.), 'Drug Discovery, Economic Development and Conservation: The International Cooperative Biodiversity Groups,' 37 *Pharmaceutical Biology (Supplement)* (1999); Joshua Rosenthal, 'Politics, culture and governance in the development of prior informed consent and negotiated agreements with indigenous communities,' Paper presented at Washington University in St. Louis Conference on Biodiversity and Biotechnology and the Protection of Traditional Knowledge, April 4-6, 2003 <www.law.wustl.edu/centeris/confpapers/> (visited 19 December 2004), Shane Greene, "Indigenous People Incorporated? Culture as Politics, Culture as Property in Pharmaceutical Bioprospecting" *Current Anthropology*, 45(2):211-237. (2004); see also Tobin *supra* note 148.

²⁰² See ICBG website <www.nih.gov/flc/opportunities/icbg.html> See also McManis *id.*, p. 563 (citing Walter H. Lewis et al., *Peruvian Medicinal Plant Sources for New Pharmaceuticals (International Cooperative Biodiversity Group Peru)*. Dr. Lewis and two co-inventors (a senior research associate and a graduate student at Washington University) filed a provisional patent application with the United States Patent and Trademark Office that disclosed certain antiparasitic compounds from American plants that effectively inhibit in vitro the leading cause of malaria, and named the confederation of participating Aguaruna communities and organizations, along with the three participating universities, as assignees (i.e., co-owners) of the application.

²⁰³ *Id.* McManis, (citing Walter H. Lewis, *Plants Used Medically by Indigenous People*, in H.N. Nigg & D. Seigler (eds.), *PHYTOCHEMICAL RESOURCES FOR MEDICINE AND CULTURE* 33-74 (1992)).

communities affiliated with local Aguaruna-run organizations or with other Amazonian ethnic groups. The biological collecting agreement identifies them as those “who live in the collection area,” while the “collection area” is defined as the areas “inhabited by members of the Collaborating Organizations” and namely, “CONAP and affiliates” or those who have signed the agreement. CONAP is described as a pan-Indianist organization that includes other indigenous Amazonians who form a majority. According to Greene, none of them (as the Shipibo and Yaneshá peoples) had anything to do with the ICBG negotiations, but as members of a democratically run organization they would have as much claim to any patented property as the Aguaruna.²⁰⁴ This definition excludes Aguaruna, organized and non-organized who chose not to affiliate themselves with CONAP. These non-participants include Consejo Aguaruna Huambisa (CAH) who constitute a clear majority of Aguaruna.

Originally the ICBG handpicked indigenous communities to partner with. A first partnership with a small clan based Aguaruna organization called Organizacion Comunal De Comunidades Aguarunas del Alto Marañon (OCCAAM) dissolved because of linguistic differences. The ICBG moved on to what appeared to be better organized and coherent NGO, the Consejo Aguaruna y Huambisa (CAH). That relationship failed as well because of the CAH’s objection to the undisclosed license option agreement between Washington University and Searle-Monsanto and the CAH’s earlier assertion of IPR’s. The ICBG finally settle into a partnership with 3 clan based Aguaruna federations under the leadership of CONAP. The now marginalized CAH (dubbed a ‘rival’) was no longer invited to treat.²⁰⁵

The ICBG-Peru project includes a set of interconnected agreements:

- (1) the basic Biological Collecting Agreement, which outlines who is involved in the programme, where and under what circumstances collecting can occur, and what annual collecting fees will be provided to the collaborating Aguaruna organizations by the corporate partner;
- (2) a License Option and a License Option Amendment Agreement between Washington University and G.D. Searle & Company, detailing a basis for their interactions and establishing royalty rates for pharmaceutical products and how these rates are to be shared;²⁰⁶

²⁰⁴ See Greene *supra* note 201, pp. 214-215, 218.

²⁰⁵ See Rosenthal *supra* note 201, pp. 8-9. *But see* McManis *id* (citing Walter H. Lewis et al., Peruvian Medicinal Plant Sources for New Pharmaceuticals (International Cooperative Biodiversity Group Peru) who states CONAP includes four Aguaruna based organizations including the Organizacion Central de Comunidades Aguarunas del Alto Marañon (OCCAAM); Federacion Aguaruna del Rio Domingusa (FAD); Federacion de Cominidades Nativas Aguarunas del Rio Nieva (FECONARIN); and Organizacion Aguaruna del Alto Mayo (OAAM)).

²⁰⁶ G.D. Searle & Company, a division of Monsanto Company, headquartered in St. Louis, Missouri, U.S.A., was eventually forced to withdraw from the ICBG-Peru project due to the acquisition of the Monsanto Company by Pharmacia, Inc. and according to McManis, it did so only after completing all of the annual know-how royalty and milestone payments that it was contractually obligated to make to the final member of the partnership, the Confederacion de Nacionalidades Amazonicas del Peru (CONAP). *See id* McManis p. 564.

- (3) a later negotiated Know-How License Agreement that prescribes an annual license fee to be paid by the corporate partner to the collaborating Aguaruna groups while their knowledge is being used in extraction and screening programs, and also establishes certain milestone payments to be paid by the corporate partner; and
- (4) two subsidiary agreements outlining the nature of the collaborative relationship between Washington University and the two other academic institutions involved.²⁰⁷

Annual collection and know-how license fees paid by the corporate partner are to be deposited into a fund that will make grants to assist the Aguarunas with education and make small grants to ensure the development of new conservation and sustainable development projects within the Aguaruna communities. Milestone payments are specified for each potential commercial product during specified research and development phases, and royalties based on net sales are specified should a commercial product be released to the public. Royalties will be divided equally among the three universities and the Aguaruna peoples, with fully 75% of any royalty income returning to Peru.²⁰⁸

The final report on the ICBG-Peru project explicitly recognize that the medicinal plant knowledge disclosed by the collaborating Aguaruna peoples is valuable know-how owned by them, that all know-how was disclosed subject to prior informed consent and is retained in confidence, and both the original know-how and subsequent research will be protected primarily through the filing of appropriate patents, naming individual Aguarunas as inventors where possible and will, in any event, recognize the Aguarunas as contributors to the invention. On their part, the participating Aguarunas acknowledged the ownership and patrimony of the Peruvian state over the genetic material collected, that samples are permanently deposited and curated at both the Museo de Historia Natural in Lima and the Missouri Botanical Garden in St. Louis and researched for non-commercial purposes at national and international depositories. It was also stipulated that biological collections obtained for the purpose of extracting compounds for commercial purposes remain under the control of the Aguarunas unless released by them and that these materials are held in trust by Washington University as recipient of the grant.²⁰⁹

At the projects conclusion, substantial preliminary data showed strong correlations between high activities in specific screens and targeted plant extracts selected for their use as medicinals by the Aguaruna to treat specific infections. According to McManis, without the Aguaruna ethnobotanical data, it would have taken at least decades to identify the antimalarial species that the ICBG-Peru project accomplished in months.²¹⁰

²⁰⁷ See McManis *supra* note 201, p. 566.

²⁰⁸ *Id* (citing Walter H. Lewis et al., Peruvian Medicinal Plant Sources for New Pharmaceuticals (International Cooperative Biodiversity Group Peru pp. 73).

²⁰⁹ *Id.* 73-74, 80.

²¹⁰ *Id* p. 82

The consent process (over one and a half years) included a series of workshops and meetings in Lima, in villages and in St. Louis and involved 55 (of 187) communities thus “a significant number of Aguaruna clans are not included, nor are the other related Jivara tribes with whom they share some traditions.”²¹¹ In any event, consent was arrived at by consensus through a process called ‘Ipaamamu’ and described as “iterative, redundant process representing multiple layers of Aguaruna society.”²¹²

9 Selected Issues Surrounding a Contract Approach

9.1 Ownership of Traditional Knowledge

It is often claimed that communal property is the prevailing system used in most indigenous/traditional societies to control access to basic resources, and even in cases where TK is the exclusive intellectual property of individuals, families, shamans, clans or lineages, these owners cannot necessarily commercialize the knowledge without the permission of the whole community or tribal elders.²¹³ However to assume that there is a generic form of collective intellectual property rights ignores the intricacies and diversity of indigenous peoples and their respective traditional proprietary systems according to a Canadian non-governmental organization, the Four Directions Council:

“Indigenous peoples possess their own locally-specific systems of jurisprudence with respect to the classification of different types of knowledge, proper procedures for acquiring and sharing knowledge, and the rights and responsibilities which attach to possessing knowledge, all of which are embedded uniquely in each culture and its language.”²¹⁴

Consequently, although TK protection is generally perceived as a matter of collective rights, it may nonetheless be vested in individuals within a traditional knowledge system. Customary law can therefore help establish the attribution of rights and benefits within the community.

While policy discussions surrounding customary laws and TK protection have been extensive, actual reference to customary laws in existing *sui generis* laws have, to date, been fairly limited, although recognition of customary law may be important in their practical implementation.²¹⁵

²¹¹ See Rosenthal *supra* note 201, p. 10.

²¹² *Id* p. 9.

²¹³ See Posey and Dutfield *infra* note 251.

²¹⁴ Four Directions Council, “Forests, indigenous peoples and biodiversity”. Contribution of the Four Directions Council to the Secretariat of the Convention on Biological Diversity, Lethbridge: FDC, 1996.

²¹⁵ See Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore Sixth Session Geneva, March 15 to 19, 2004 *Revised Version of Traditional Knowledge: Policy and Legal Options* (WIPO/GRTKF/IC/6/4 Rev.) February 19, 2004 paras. 46-47. ” A number of existing *sui generis* systems utilize references to customary laws and protocols as an alternative or as a supplement to the

While there is yet consensus on intergovernmental arrangements regarding TK, indigenous representatives at the WIPO Intergovernmental committee meetings generally support such provided they are recognized as custodians and owners of their TK and that an international regime recognize customary laws and practices including their paramountcy over national and international law.²¹⁶

Municipal courts dealing with IPR disputes are hindered from recognizing customary law approaches however. For example, in *Yumbulul v. Reserve Bank of Australia* (1991)²¹⁷ the claim of communal proprietorship in sacred images was rejected by the court because “Australia’s copyright law does not provide adequate recognition of Aboriginal community claims to regulate the reproduction and use of works which are essentially communal in origin” and that these issues are better left to the legislature. Similarly, in the Australian case of *Milpurrurru v. Indofurn Pty Ltd.* (1995) the court was unable to compensate the communities whose images were used in culturally inappropriate ways because “the statutory remedies do not recognise the infringement of ownership rights of the kind which reside under Aboriginal law in the traditional owners of the dreaming stories.”²¹⁸ Nevertheless and according to Blakeney, this case “establishe[d] the principle that where the unauthorized reproduction of such works involved a breach of copyright, customary Aboriginal laws on the subject may be taken into account in quantifying the damage which had been suffered”.²¹⁹

While the Australian cases are restricted to their facts, claims to recognition of customary law as they apply to TK can draw upon analogous arguments in communal Indian title cases. In the Anglo-American and Common Law

creation of modern IP rights over TK. For example, the African Model Law and the sui generis laws of Peru and the Philippines incorporate by reference certain elements of customary laws into the sui generis protection of TK. The relation between modern sui generis laws and customary laws ranges from the principle of independence of the rights granted by the modern and traditional systems (Peru) to the principle that the State protects rights specified in the modern sui generis legislation “as they are enshrined and protected under the ... customary law found in ... the concerned local and indigenous communities, whether such law is written or not” (African Model Legislation). The substantive use of customary laws ranges from obtaining Prior Informed Consent for access to TK “in accordance with customary laws” (Philippines), over the settlement of disputes arising among indigenous peoples in the implementation of TK protection (Peru), to the identification, interpretation and ascertaining of “community, knowledge or technology ... under their customary ... law” (African Model Law).

²¹⁶ See *supra* note 5. See also Amina Matlon, ‘Safeguarding Native American Sacred Art by Partnering Tribal Law and Equity: An Exploratory Case Study Applying the Bulun Bulun Equity to Navajo Sandpainting,’ 27 *Colum. J. L. & Arts* 211 (2004) who suggests a possibility that limitations on artists could run afoul of First Amendment guarantees. A conflict of laws situation may arise should a community member challenge a decision reached by consensus or otherwise.

²¹⁷ See Michael Blakeney, ‘Bioprospecting and the Protection of Traditional Medical Knowledge of Indigenous Peoples: An Australian Perspective,’ *E.I.P.R.* 1997, 19(6), 298-303 (citing I.P.R. 481at 490, 492)

²¹⁸ *Id* (citing 91-116 CCH Australian Intellectual Property Cases 39,051 at 39,077).

²¹⁹ Michael Blakeney, ‘Communal intellectual property rights of indigenous peoples in cultural expressions,’ *Journal of World Intellectual Property* 1998 1 (6), 985-1002.

traditions, there is a longstanding recognition of communal Indian or Aboriginal title. Canadian lawyer McNeil observes:

“[W]hile their communal title obviously has a proprietary aspect, it also has social, cultural, and political dimensions that are beyond the scope of standard conceptions of private property ...A further dimension of aboriginal title is the fact that it is held communally. Aboriginal title cannot be held by individual persons; it is a collective right to land held by all members of an aboriginal nation. Decisions with respect to that land are also made by that community. This is another feature of aboriginal title which is *sui generis* and distinguishes it from normal property interests. That does not mean however that no other interests can be created.”²²⁰

Accordingly, if their own laws so permit, they could create interests in land within their own territories, while retaining their communal title to the whole of their territories.²²¹ It follows that a community’s law can recognize private interests in TK, for example. It works in the converse presumably.

The Inter-American Court of Human Rights has also developed jurisprudence on communal title. In the 2001 case of *Mayagna (Sumo) Awas Tingni Community v. Nicaragua*, at issue was the right to property as found in article 21 of the American Convention on Human Rights. The court made clear that indigenous peoples’ rights to their lands include rights to the resources there and that these rights of ownership are held by the community in their collective capacity and according to their own customary law, values, customs and mores and, “that the State must adopt in its domestic law, pursuant to article 2 of the American Convention on Human Rights, the legislative, administrative, and any other measures necessary to create an effective mechanism ... [for] property of indigenous communities, in accordance with their customary law, values, customs and mores.”²²² The Court also defined property as, “as those material things which can be possessed, as well as any right which may be part of a person’s patrimony; that concept includes all movables and immovables, corporeal and incorporeal elements and any other intangible object capable of having value.”²²³ Building upon the jurisprudence of the Inter-American Court of Human Rights in the *Awes Tingni* case, the Inter-American Commission report in the case of the Maya Indigenous Communities of the

²²⁰ Kent McNeil, *Self-Government and the Inalienability of Aboriginal Title*, 47 McGill L. J. 473 (2002) at 486.

²²¹ See for example Sahai *supra* note 12 p. 13. The Cholanaickan (tribals of Kerala India) have well-defined principles that allow the members to gather and extract minor forest produce within their respective region. There is no restriction on gathering edible tubers, roots, fruits and leaves for self-consumption. One is free to move in the entire forests region and to collect tubers, roots, fruits etc. as and when required. But people usually gather edibles only in their own area. However, there are rigid norms regarding the collection of minor forest produce. Moreover, to trespass the territory of another Cholanaickan to collect minor forest produce is considered an offence.

²²² Inter-Am. Ct. H.R., (Ser. C) No. 79 (2001) available at <www.corteidh.or.cr/index_ing.html>

²²³ *Id.*, para. 144.

Toledo District of Belize, held that indigenous peoples have property rights over their traditional lands and resources under international human rights law, apart from whether or not those rights are recognized under domestic law and that the Belize government violated Maya rights to judicial protection because of the failure of the domestic legal situation to adequately address Maya grievances.²²⁴

While judicial precedent is limited a general principle does emerge namely, that indigenous peoples have rights to their lands and resources and that these rights of ownership are held by the community in their collective capacity and according to their own customary law, values, customs and mores. That community makes decisions with respect to that land. If a community's law so permit, it could create other proprietary interests. These rights exist whether or not they are recognized under domestic law and in any case, states are obligated to adopt in their domestic law, the legislative, administrative, and any other measures necessary to create an effective mechanism for the recognition of property of indigenous communities, in accordance with their customary law, values, customs and mores.

The aforementioned case studies demonstrate in very real practical ways support for the above principle at the least on the part of the indigenous parties. In the San Hoodia Benefit Sharing Trust, the San as a whole asserted that their heritage is collectively owned and cannot therefore, be appropriated by any individual or groups (presumably any group of San residing in Namibia, Botswana and South Africa) and determined that any benefits derived from their collective heritage shall be shared among all San regardless of nationality and frontier.²²⁵ Indeed, the benefit sharing agreement recognizes the San as the legal custodians of traditional indigenous knowledge on the use of Hoodia to the exclusion of non-San groups.

The Kerala Kani Samudaya Trust case is an example however, of lack of reciprocal acknowledgment of a community's views on ownership. There is an irresistible inference that both the Kani guides and the AICRPE researchers were aware the former lacked the competency to disclose community or tribal knowledge regarding Kani usage of *arogyappacha* because it was both sacred information and a tribal secret not to be divulged to 'outsiders.' Actions subsequent and including objections raised by the *Plathis* and the Kani of Vithura and Permingamala appears to support the proposition that TK is collectively owned and any decision with regard to it is a collective one. Appukuttan Kani, President of Vithura Panchayat "... expressed offence at the fact that TBGRI has not made the effort to reach out to the Kanis in his Panchayat area. He feels that this is an instance when a scientific institution has pirated tribal knowledge for its own benefit, and that the benefit sharing proposal is a superficial exercise since the Kanis

²²⁴ Report No. 96/03, Maya Indigenous Communities and their Members (Case 12.053(Belize)), 24 October 2003 para. 141.

²²⁵ See *et seq.* 169.

have neither been consulted nor involved in the exercise.”²²⁶ To be sure, the Trust’s aim to have all adult Kani as members is acknowledgement of collective ownership of tribal knowledge although the existence and the role of the Plathis as exclusive holders of the traditional medicinal knowledge of the tribe is unclear but in any event it is evidence of pre-existing customary law and practice.

The CONAP (Aguaruna) Fund case study experienced a similar challenge. On its’ facts, it can be inferred that ICGB was aware of the Aguaruna as owners of the TK of traditional medicinal plant knowledge and that the ICGB eventually treated with the third (and more agreeable) Aguaruna organization representing a minority of the tribe, does not make this inference any less so. In any event, consent was obtained from the participating Aguaruna through a customary practice called ‘Ipaamamu’ to arrive at a demonstrable consensus as to the ICGB proposal.

The above are far from anomalous situations where customary law and practice were ignored. For example, researchers with the Federal University of Sao Paulo Brazil signed an agreement with representatives of three out of the eighteen Krahò tribes in order to obtain traditional knowledge on the therapeutic use of plants. The rest of the tribes were outraged about being excluded from the agreement and demanded compensation. Under the proposed agreement, the University, the pharmaceutical company and the Indigenous Association owned any patents on medicine. The excluded tribes demanded an immediate end to the research and compensation of USD \$8,000,000 for ‘moral’ damages and bioprospection fees. Their objections included lack of previous informed consent of all the tribes, lack of authorization from the agency responsible for Indian Affairs (FUNAI), lack of payment of bioprospecting fees to the tribes and absence of clear benefit sharing provisions.²²⁷

The unsuccessful ICGB-Maya partnership²²⁸ of the University of Georgia, El Colegio de La Frontera Sur (ECOSUR) in Chiapas and Molecular Nature Ltd, a UK-based natural products pharmaceutical and botanical firm proposed to develop an ‘Asociacion Civil’ or an NGO (later named PROMAYA) to incorporate Maya community participants and manage a trust fund that would distribute any earnings thus by-passing community and recognized traditional healers (the investigators here chose to work on those species cited by individual community members as useful medicinally).

There is no simple catchall explanation for the lack of oversight as these cases demonstrate. One cannot escape a strong element of calculation (or

²²⁶ See Anuradha *supra* note 180.

²²⁷ See Eliana Torelly de Carvalho, ‘Protection of Traditional Biodiversity-Related Knowledge: Analysis of Proposals for the Adoption of a Sui Generis System,’ 11 *Mo. Envtl. L. & Pol’y Rev.* 38 (2003) p. 66.

²²⁸ See Rosenthal *supra* note 201 p. 13. The focus of the project was drug discovery from the plants and macrofungi used by the Highland Maya.

lack of veracity) at the outset. On the other hand, the explanation may lay in lack of political leadership or national oversight to adopt legislative, administrative and any other measures necessary to create an effective mechanism for the recognition of property of indigenous communities, in accordance with their customary law, values, customs and mores.

Without regard to customary law and practices regarding ownership of TK (and distribution of benefits inter and intra-tribally), these arrangements will be fraught with legal uncertainty and questions about their legitimacy. And more importantly, from whom prior informed consent is to be obtained from.

9.2 Prior Informed Consent (PIC) and Disclosure

The right of states to some form of prior informed consent is recognized in a variety of contexts, including the trans-boundary movement of hazardous and toxic materials, genetically engineered organisms, and persistent organic pollutants.²²⁹ Where access to TK and genetic resources is concerned, PIC focus is not on preventing adverse impacts of the movement of materials into a country, but rather the emphasis is on preventing the exploitation and movement out of a country of potentially beneficial materials, as well as on ensuring that the benefits derived from the use of these materials accrue to the holders (providers) of these materials. Accordingly Article 15, paragraph 5, of the CBD requires that:

“Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that party,”

While not expressly worded, the principle of PIC is also embedded in the wording of article 8(j) and indeed PIC is a necessary corollary of the rights of indigenous and other local communities to enable them to participate in the management of the resources found on the lands they occupy, and of all associated traditional knowledge.

The application of the principle of prior and informed consent to the rights of indigenous peoples is acknowledged in several other documents in the field international and human rights law and jurisprudence. The International Labour Organization Indigenous and Tribal Peoples Convention, 1989 (C169) articles 6, 7 and 15 aims to ensure every effort is made by States to fully consult with indigenous peoples in the context of

²²⁹ See for example Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in: International Trade, Sept. 10, 1998, U.N. Doc. UNEP/CHEMICALS/98/17, available at <www.pic.int/en/ViewPage.asp?id=104>; Stockholm Convention on Persistent Organic Pollutants, May 23, 2001, 40 I.L.M. 532, available at <www.pops.int>; Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, Mar. 22, 1989, 28 I.L.M. 657, available at <www.basel.int> Cartagena Protocol on Biosafety, Jan. 29, 2000, 39 I.L.M. 1027, available at <www.biodiv.org>

development, land and resources with the objective of achieving agreement or consent.²³⁰

The Committee on the Elimination of Racial Discrimination (CERD)²³¹ is the body of independent experts that monitors implementation of the Convention on the Elimination of All Forms of Racial Discrimination by its State parties. The Committee also publishes its interpretation of the content of human rights provisions, known as general recommendations (or general comments). To that end the CERD issued Recommendation XXIII, which calls upon all parties to the Convention, “[E]nsure that members of 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.”²³² In its concluding observations on the report of Ecuador in 2003, the CERD noted “[A]s to the exploitation of the subsoil resources of the traditional lands of indigenous communities, the Committee observes that merely consulting these communities prior to exploiting the resources falls short of meeting the requirements set out in the Committee's general recommendation XXIII on the rights of indigenous peoples. The Committee therefore recommends that the prior informed consent of these communities be sought, and that the equitable sharing of benefits to be derived from such exploitation be ensured.”²³³ The Committee also considered the report of Botswana in 2001 and conveyed its trepidation in the following terms, “[T]he Committee expresses concern that the ongoing dispossession of Basarwa/San people from their land and about reports stating that their resettlement outside the Central Kalahari Game Reserve does not respect their political, economic, social and cultural rights. The Committee draws the attention of the State party to its general recommendation XXIII on indigenous peoples and recommends that no decisions directly relating to the rights and interests of members of indigenous peoples be taken without their informed consent. The Committee recommends that negotiations with the Basarwa/San and non-governmental organizations on this issue be resumed, and that a rights-based approach to development be adopted.”²³⁴

In its concluding observations on the report of Colombia in 2001, the Committee on Economic, Social and Cultural Rights noted “with regret that the traditional lands of indigenous peoples have been reduced or occupied, without their consent, by timber, mining and oil companies, at the expense of the exercise of their culture and the equilibrium of the ecosystem.” It subsequently recommended that the State party ensure the participation of indigenous peoples in decisions affecting their lives and particularly urged it

²³⁰ The text of the Convention is available at <www.ilo.org/ilolex/english/convdisp1>

²³¹ The text of the Convention, general recommendations and concluding observations are available at <www.ohchr.org/english/bodies/cerd/index.htm>

²³² General Recommendation XXIII (51) concerning Indigenous Peoples. Adopted at the Committee's 51st Session, 18 August 1997. UN Doc. CERD/C/51/Misc.13/Rev.4, para. 4

²³³ Concluding observations of the Committee on the Elimination of Racial Discrimination : Ecuador (CERD/C/62/CO/2), March 21, 2003, para. 16.

²³⁴ Concluding Observations of the Committee on the Elimination of Racial Discrimination : Botswana (A/57/18), November 1, 2002, para. 304

“to consult and seek the consent of the indigenous peoples concerned prior to the implementation of timber, soil or subsoil mining projects and on any public policy affecting them, in accordance with ILO Convention No. 169.”²³⁵

The Inter-American Commission on Human Rights (IACHR) has developed jurisprudence on PIC. In August 2001, the Inter-American Court concluded that Nicaragua had violated the rights of the Mayagna community of Awas Tingni by granting a logging concession within the community’s traditional territory without its consent and by ignoring the consistent complaints and requests of Awas Tingni urging demarcation of the territory.²³⁶ In 2002, the Commission stated that Inter-American human rights law requires “special measures to ensure recognition of the particular and collective interest that indigenous people have in the occupation and use of their traditional lands and resources and their right not to be deprived of this interest except with fully informed consent.”²³⁷ And most recently, in 2003, the IACHR stated that PIC is generally applicable “to decisions by the State that will have an impact upon indigenous lands and their communities, such as the granting of concessions to exploit the natural resources of indigenous territories.”²³⁸

The draft United Nations declaration on the rights of indigenous people is an important emerging instrument that explicitly recognizes the principle of free, prior and informed consent in its articles 10, 12, 20, 27 and 30.²³⁹ And at present, the draft American declaration on the rights of indigenous people of the Organization of American States (OAS)²⁴⁰ provides that indigenous peoples have the right to determine and develop priorities and strategies for the development or use of their lands, territories and other resources, including the right to require that States obtain their free and informed consent prior to the approval of any project affecting their lands, territories and other resources, particularly in connection with the development, utilization or exploitation of mineral, water or other resources.

The approach adopted by the respective instruments above is consistent with the observations of the UN Centre for Transnational Corporations in a series of reports that examine the activities of multinational corporations on indigenous territories. The final report concluded that multinational companies’ “performance was chiefly determined by the quantity and quality of indigenous peoples’ participation in decision making” and “the extent to which the laws of the host country gave indigenous peoples the

²³⁵ Concluding Observations of the Committee on Economic, Social and Cultural Rights : Colombia. (E/C.12/1/Add.7) November 30, 2001, paras. 12, 13, available at www.unhchr.ch/html/menu2/6/cescr.htm

²³⁶ See *supra* note 222.

²³⁷ *Mary and Carrie Dann v. United States*, case 11.140, Report No. 75/02, Inter-Am. C.H.R., 2002, para. 131.

²³⁸ See *supra* note 224 para. 141

²³⁹ See Draft Declaration *supra* note 137.

²⁴⁰ *Proposed American declaration on the Rights of Indigenous Peoples* (Approved by the Inter-American Commission on Human Rights on February 26, 1997, at its 1333rd session, 95th regular session) <www.cidh.org/Indigenous.htm>

right to withhold consent to development.²⁴¹ Similarly, the recent UN Sub-Commission on the Promotion and Protection of Human Rights' Norms on Transnational Corporations state that: "[T]ransnational corporations and other business enterprises shall respect the rights of local communities affected by their activities and the rights of indigenous peoples and communities consistent with international human rights standards..."²⁴² They shall also respect the principle of free, prior and informed consent of the indigenous peoples and communities to be affected by their development projects.²⁴³

The principle of indigenous peoples' right to PIC is thus clearly recognized under a range of universal and regional human rights instruments as well as under the Convention on Biological Diversity.²⁴⁴ However, the substantive and procedural norms underlying PIC have yet to be developed. Efforts directed to elaborating some core elements to the principle of PIC include the development of realistic and concise methodologies,²⁴⁵ voluntary guidelines²⁴⁶ and 'best practices' identified in PIC procedures.²⁴⁷ The Working Group on Indigenous Populations has begun a preliminary examination of the principle of free, prior and informed consent (FPIC as opposed to PIC) of indigenous peoples in relation to development affecting their lands and natural resources as a part of their standard setting mandate.²⁴⁸ Their preliminary appraisal of the principle is:

²⁴¹ (UN Doc. E/CN.4/Sub.2/1991/49); a report focusing on the Americas (UN Doc. E/CN.4/Sub.2/1992/54) and a report focusing on Asia and Africa, summarizing the findings of all reports and making recommendations "to mitigate the adverse impacts of TNCs on indigenous peoples' lands, and increase indigenous peoples' participation in relevant government and TNC decision-making." (UN Doc. E/CN.4/Sub.2/1994/40)

²⁴² Report of the Commission on Transnational Corporations to the Working Group on Indigenous Populations. UN Doc. E/CN.4/Sub.2/1994/40, at para. 20.

²⁴³ Commentary on the Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights, UN Doc. E/CN.4/Sub.2/2003/38/Rev.2, 2003, para. 10(c).

²⁴⁴ The CBD: Elaboration of Key Terms of Article 8(j) and Related Provisions in Articles 10 (c) and 17.2 and 18.4 lists several subjective factors to consider in appraising the adequacy of PIC. Holders of TK must:

1. feel secure in tenure arrangements regarding their traditional land, forest and marine/inland water estates;
2. feel reassured that they have been accorded equal status to the other members of the partnerships; and
3. be convinced of a common purpose compatible with their cultural and ecological values

This and other elaboration of key terms is available at <www.biodiv.org/indig/tkbd-4e.htm>

²⁴⁵ See Permanent Forum on Indigenous Issues, *Report of the International Workshop on Methodologies regarding Free, Prior and Informed Consent and Indigenous Peoples* (E/C.19/2005/3 17) February 2005.

²⁴⁶ For instance, the Bonn Guidelines provide mechanisms for involving stakeholders; they suggest reasonable timeframes and deadlines; they specify types of use, and links under mutually agreed terms; and provide detailed procedures for obtaining consent as well as a description of general procedures that should be followed to obtain access.

²⁴⁷ See *supra* note 18.

²⁴⁸ See COMMISSION ON HUMAN RIGHTS Sub-Commission on the Promotion and Protection of Human Rights Working Group on Indigenous Populations, *STANDARD-SETTING Preliminary working paper on the principle of free, prior and informed consent*

“Substantively, the principle of free, prior and informed consent recognizes indigenous peoples’ inherent and prior rights to their lands and resources and respects their legitimate authority to require that third parties enter into an equal and respectful relationship with them based on the principle of informed consent. Procedurally, free, prior and informed consent requires processes that allow and support meaningful choices by indigenous peoples about their development path.”²⁴⁹

Preliminary interpretations of the key elements of FPIC including a right to withhold consent)²⁵⁰ are as follows:

Free: It is a general principle of law that consent is not valid if obtained through coercion or manipulation. While no legislative measure is foolproof, mechanisms need to be established to verify that consent has been freely obtained.

Prior: To be meaningful, informed consent must be sought sufficiently in advance of any authorization by the State or third parties or commencement of activities by a company that affect indigenous peoples and their lands, territories and resources.

Informed: A procedure based on the principle of free, prior and informed consent must involve consultation and participation by indigenous peoples, which includes the full and legally accurate disclosure of information concerning the proposed development in a form which is both accessible and understandable to the affected indigenous people(s)/communities regarding, inter alia:

- The nature, size and scope of the proposed development or activity;
- The duration of the development (including the construction phase) or the activity;
- The locality of areas that will be affected;
- A preliminary assessment of the likely impact of the development;
- The reasons/purpose for the development;
- Personnel likely to be involved in both construction and operational phases (including local people, research institutes, sponsors, commercial interests and partners – as possible third parties and beneficiaries) of the development process;
- Specific procedures the development or activity would entail;
- Potential risks involved (e.g. entry into sacred areas, environmental pollution, partial destruction of a significant site, disturbance of a breeding ground);
- The full implications that can realistically be foreseen (e.g. commercial, economic, environmental, cultural);
- Conditions for third-party involvement;
- Provision of misleading or false information should result in a penalty or denial of consent for the proposed development to proceed.

Consent: This involves consultation about and meaningful participation in all aspects of assessment, planning, implementation, monitoring and closure of a project. As such, consultation and meaningful participation are fundamental components of a consent process. There may also be negotiation involved to reach agreement on the proposal as a whole, certain components thereof, or conditions that may be attached to the operationalization of the principle of free, prior and informed consent. At all times, indigenous peoples have the right to participate through their own freely chosen representatives and to identify the persons, communities or other entities that may require special measures in relation to consultation and participation. They also have the right to secure and use the services of any advisers, including legal counsel of their choice.

of indigenous peoples in relation to development affecting their lands and natural resources that would serve as a framework for the drafting of a legal commentary by the Working Group on this concept submitted by Antoanella-Iulia Motoc and the Tebtebba Foundation (E/CN.4/Sub.2/AC.4/2004/4 8) July 2004.

²⁴⁹ *Id* para. 13.

²⁵⁰ *Id* para. 20.

Additional disclosure requirements particularly with respect to TK can include the costs and disadvantages for the people whose consent is being requested, possible alternative activities and procedures, discoveries made in the activity that might affect the willingness of people to continue to collaborate, the destination of the knowledge that is to be acquired, its ownership status, and the rights of local people once it has left the community, any commercial interests the researchers have in the knowledge or material acquired and the legal options available to the community if it refused to allow the activity.²⁵¹ Further requirements can include that researchers must demonstrate that exploitation of an economic, cultural or sexual nature will not occur, researchers must not enter into private economic arrangements and unauthorized negotiations for cultural visits, investigations or exchanges.²⁵²

As a general principle FPIC is *sine qua non* for the constructive engagement of indigenous peoples in bioprospecting or any kind of contract. As a point of departure, FPIC as developed, acknowledges indigenous peoples as custodians and owners of their TK, traditional cultural expressions (TCEs) and resources with the exclusive right to control and manage same in accordance with their own customary laws, values, customs and mores. Indigenous peoples, tribes, and communities as the case may be on the principle of FPIC make any decision with respect to TK, TCEs and resources. 'Free' requires consent obtained voluntarily without coercion, manipulation, and actual or perceived threats of violence, without charge or promises or inducements and that it is verifiable. 'Prior' requires consent obtained before and in any case well in advance of any proposed activity affecting indigenous peoples, their lands and territories, resources and any other proprietary interests. 'Consent' requires genuine and good faith consultation and meaningful participation in all aspects of assessment, planning, implementation, monitoring and closure of a project. In the proper case, consent includes accommodation to take steps to avoid irreparable harm or to minimize adverse effects of a project up to and including a right to withhold consent as the case may be. At all times FPIC includes the right of indigenous peoples to utilize processes in accordance with their own customary laws, values, customs and mores and includes the right to participate through their own freely chosen representatives and to identify the persons, communities or other entities that may require special measures in relation to consultation and participation. They also have the right to secure and use the services of any advisers, including legal counsel of their choice. A corollary to FPIC is a duty upon states to adopt in their domestic law, the legislative, and administrative and any other measures necessary to

²⁵¹ D. Posey and G. Dutfield, *Beyond Intellectual Property. Toward Traditional Resource Rights for Indigenous Peoples and Local Communities* (Ottawa: International Development Research Centre (IDRC) 1996).

²⁵² Yianna Lambrou, 'Control and Access to Indigenous knowledge and Biological Resources,' Biodiversity Convention Office Environment Canada 31 October 1997 p. 9<www.nativemaps.org/abstracts/Control/97 on-line (visited 15 March 2004)

create an effective mechanism for the recognition and implementation of a right to FPIC.

The case studies present challenges to the well established principle of PIC as proposed on both a substantive and procedural level. In all the cases studied, consent was obtained *ex post facto* and usually after the commercial potential is realized, a patent has been issued or when the appropriation is discovered serendipitously. In all of the case studies bioprospecting and R & D occurred years before obtaining PIC, although in fairness PIC was not required until the coming into force of the CBD and in 1992. In any event and after 1992 the PIC requirement is honoured in the breach. For example, in the San Hoodia Benefit Sharing Trust arrangement, R & D occurred first in the 1963 project on edible wild plants and in subsequent R & D from 1986 to 1995, date of the CSIR patent application. Up until 2001, the San were unaware of these developments and only became so through the media.

In the Kerala Kani Samudaya Trust arrangement, it is doubtful the original tribal informants were competent to disclose *arogyapaacha* during the botanical expedition into the forest of the Western Ghats in December 1987. By 1995, it is clear the TBGRI did not obtain the consent of the *Plathis*, the acknowledged exclusive holders of the traditional medicinal knowledge of the Kanis. And certainly at the establishment of the trust in November 1997 to its first meeting in March 1999, the Kanis in the Vithura and Peringamala were ignored altogether and only became aware of these developments through the media. To be sure, the TBGRI neither obtained PIC prior to filing a process patent application in 1996 nor in negotiations with the AVP licensee.

In the CONAP (Aguaruna) Fund arrangement, PIC was not obtained in 1992 when the principal investigator Dr. Walter Lewis first documented use of medicinal plants by the Arguaruna and in any case, it is established that PIC was obtained from the pan-Indianist organization CONAP to the exclusion of a majority of the Arguaruna.

Selecting few individuals and organizations to represent the interests of holders of traditional knowledge (as was the case in the Kerala Trust), with the underlying but unwritten assumption that these individuals will obtain prior informed consent and spread benefits more broadly among the community is equivalent to a two-tier consent process. Such a process, is arguably is not the intention of PIC.

The consequences for the lack of PIC or at the very least, a timely one, meant the indigenous people studied here were denied their capacity and authority to act with respect to their TK and to their detriment. As San lawyer Chenells points out the San Trust arrangement was dictated by exigency rather than by true, considered and deliberate choice and consent and as a result the San were excluded from some important elements not the

least of which was the securing of IPRs regarding Hoodia.²⁵³ Other illustrations include that although the San could receive a considerable amount of money, this will be only a fraction of a percent – between 0.03 percent and 1.2 percent - of net sales of the product. Monies received by the San will be extracted from royalty and milestone payments obtained by the CSIR, whereas profits received by Phytopharm and its partners will, after deduction of the license royalties, remain unchanged.²⁵⁴ Moreover, the agreement explicitly protects Pfizer and Phytopharm from any further financial demands by the San.

The agreement's non-compete clause also prevents the San from using their knowledge of Hoodia in any other commercial applications thus the San are unable to independently pursue less lucrative but perhaps more viable commercialization options based on non-patented herbal medicines (as opposed to patented pharmaceutical drugs or other products). They are also unable to claim any benefits from the dozens of new Hoodia-based products that have recently emerged in the market, which blatantly use San traditional knowledge of Hoodia in their promotion.²⁵⁵ Similarly, the Kani were excluded from negotiating the agreement between TBGRI and the AVP licensees. The CAH's objection to the undisclosed license option agreement between Washington University and Searle-Monsanto led to the CAH's unilateral termination as partner with the ICGB settling with a more agreeable party.

It is readily apparent in all of the case studies, the indigenous parties in all practical sense were deprived of the opportunity to utilize processes in accordance with their customary laws, values, customs and mores or at the very least denied the opportunity to participate through their own freely chosen representatives. For example, the Kani were not involved in the negotiation of any of the fundamental terms of the agreement. In the main, the TBGRI negotiated on behalf of the Kani. It is not realistic to expect local intermediaries such as research institutes to act in the best interests of indigenous communities.²⁵⁶ Nor is it reasonable to assume as some do, that

²⁵³ See *supra* note 169.

²⁵⁴ See Wyberg *supra* note 168.

²⁵⁵ *Id.* " For example, a recent advertisement by the U.S.-based BioMed Pharmaceuticals promotes Trimphetamine as the "first commercially available product containing the revolutionary Hoodia gordonii cactus plant", based on a standardized natural extract of the plant, and another U.S.-based company Hi-Tech Pharmaceuticals markets a similar Hoodia-based product, Lipodrene, citing use of Hoodia as an appetite suppressant by the San. A rather barefaced advertisement for Hoodoba "Hoodia gordonii diet pill" describes the "push by western drug companies" to "sideline the indigenous people and turn this remarkable plant into a synthetic prescription drug", and then goes on to do the same, but through using the image and knowledge of the San to market the product as a natural extract ."

²⁵⁶ See Daes *supra* note 3, paras. 102-113, "...the intermediaries cannot avoid choosing which communities and individual leaders they will support...many indigenous organizations, particularly in Amazonia, have criticized these proposals as creating a kind of neo-colonialism, with Western academics and non-governmental organizations controlling the financial resources flowing to indigenous communities." the intermediaries cannot avoid choosing which communities and individual leaders they will support." "Many indigenous organizations, particularly in Amazonia, have criticized these proposals

international organizations and non-governmental organizations are better able to serve the interests of indigenous communities for the reason that the interests of indigenous peoples and the states in which they live is at odds with those of the state.²⁵⁷

Replicating occidental decision-making methodologies is not a panacea for the constructive engagement of indigenous peoples in bioprospecting or any kind of contract. Wynberg observes, “[I]n the case of the San, intra-community issues are especially complex. Many of the organisations set up to politically represent the San are very new and the introduction of Western values and economies into supposedly traditional communities, already fractured and ‘hybridised’, presents a suite of difficult social and economic problems ...[including] ... the social complexities of contemporary San identity, knowledge and practice, and charts the intra-community divisions and conflict that emerged between self-designated ‘traditionalists’ and ‘Western bushmen’ when San land claims were lodged in the Northern Cape province of South Africa.”²⁵⁸

In part, the solution may lie in recognizing and/or building (as the case may be) on existing and accepted institutions of traditional knowledge holders to ensure their participation and ensure the acceptance of the communities for benefit-sharing arrangements, if they so choose.

10 Concluding Remarks

In the absence of protective or any other measures, TK holders may try to negotiate benefit-sharing arrangements, as some already do with “bio-pharma.” This may solve some inequities but until and unless a market practice develops, the fact that TK holders often have no clear “right” to trade away genetic resources and other forms of TK means that the situation offers too little in terms of guarantees for TK holders. Intellectual property rights are elusive in those areas where indigenous peoples lack territorial recognition and security, where they are not recognized ‘indigenous’ as such or where they lack security overall (under threat of violence by government or their proxies). And in those areas where indigenous peoples with recognized land and resource rights through treaties, agreements or other constructive arrangements with States, were better able to enter into relations with private sector natural resource companies on the basis of free, prior, informed consent than peoples without such recognized rights, there is a significant lack of capacity or the critical mass required to do so. In this

as creating a kind of neo-colonialism, with Western academics and non-governmental organizations controlling the financial resources flowing to indigenous communities.”

²⁵⁷ Joanne Gibson, ‘Traditional Knowledge and the International Context for Protection,’ (2004) 1:1 SCRIPT-ed, on-line @: <http://www.law.ed.ac.uk/ahrb/script-ed/docs/TK.asp> (visited 15 December 2004) writes, “It might also be argued that international organisations, for the most part, serve the interests of indigenous groups better than state organisations. States, not uncommonly, have been opponents of indigenous groups in the context of land claims and rights issues. Political-economic elites wielding the power of the state present the greatest danger to indigenous groups.”

²⁵⁸ See Wynberg *supra* note 168.

regard, indigenous peoples themselves will need to develop new institutions for dealing effectively with outsiders and external financing. Examples of capacity building is strengthening local autonomy including the establishment of community based institutions for supervising research, promoting education and training, conserving collections of important objects and documents and building institutional capacity to permit indigenous communities to pursue conventional IPRs if they choose to do so. State recognition of indigenous customary laws, values, customs and mores regarding ownership and control of IPRs and interpreting these laws flexibly is a necessary precondition as is building capacity for communities to develop and codify laws regarding same, if they so choose.

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