International Organizations and Their Proper Roles in Creating Mechanisms for Recognizing the Rights of Holders of Indigenous Knowledge and Traditional Medicines

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Introduction: From the International Year of Indigenous Peoples (1983) To the International Year of Biodiversity (2010)

On 18 December 1990, the U.N General Assembly proclaimed 1993 the International Year of the World's Indigenous Peoples. Sixteen years later, on 20 December 2006, the United Nations General Assembly declared this year, 2010, the International Year of Biodiversity.[1] Is there a connection? The co-dependence (indeed, co-evolution) of traditional healing practices and belief systems of indigenous peoples and the world's biodiversity is now clearly recognized.[2] Efforts toward recognition of the legal rights of indigenous healers, both moral and economic, over their traditional knowledge and practices within their indigenous environments have now been under discussion in numerous international organizations, both governmental and non-governmental, for several decades.

What are the connections (if any) between the discussions in the United Nations General Assembly [UNGA], UN specialized agencies (such as the Conference of the Parties [COP] of the Convention on Biological Diversity [CBD], Food and Agriculture Organization [FAO] and Consultative Group on International Agricultural Research [CGIAR], World Health Organization [WHO], and World Intellectual Property Organization [WIPO]) as well as other international organizations outside of the UN system, such as the World Trade Organization [WTO]? To what extent have these

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[1] U.N.G.A. Res. 45/164 (1990) and 61/203 (2006)

[2] "In discussing the relationship between traditional knowledge and genetic resources, the history of co-evolution (of biological and cultural systems) reinforces the inseparability of traditional knowledge and genetic resources. Furthermore, co-evolution suggests that there is traditional knowledge which is highly specific, and traditional knowledge which is of a more general nature as the result of co-evolved, bio-cultural systems. Research shows that human ecosystem management and traditional knowledge promotes biological diversity and thus genetic diversity." *see* Report on the First Part of the Ninth Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing UNEP/CBD/WG-ABS/9/3 26 April 2010 [hereinafter ABS Report"] Para. 10

discussions evolved, if at all, over the years? Have they influenced one another? And ultimately, are those discussions likely to lead to the creation of international norms of behavior accepted by nation states at very different stages of economic and political development, including both developed and developing countries? Or are they more likely merely to shift a "political football" from one regime to another, depending on the perceived self-interests of individual states or groups of states?[3]

As early as 1982, in preparation for the United Nations International Year for the World's Indigenous Peoples (1983), the U.N. Economic and Social Council decided to establish the U.N. Working Group on Indigenous Populations under the U.N. Sub-Commission on Prevention of Discrimination and Protection of Minorities of the Commission on Human Rights.[4] In its charge to the U.N. High Commissioner for Human Rights, the Council took special notice that "the plight of indigenous peoples is of a serious and pressing nature and… special measures are needed to promote and protect the human rights and fundamental freedoms of indigenous populations." The Working Group proceeded over the course of a decade to formulate a *Draft Declaration on the Rights of Indigenous Peoples*, which it promulgated in 1994.[5] Four provisions of the *Draft Declaration* are relevant to this discussion.

Article 12 of the *Draft Declaration*, as adopted in 1994 by the Sub-Commission, reads:

> Indigenous peoples have the right to practise 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 the restitution of cultural, intellectual, religious and spiritual property taken without their free and informed consent or in violation of their laws, traditions and customs.[6]

Article 20 of the *Draft Declaration* reads:

> Indigenous peoples have the right to participate fully, if they so choose, through procedures determined by them, in devising legislative or administrative measures that may affect them.
> States shall obtain the free and informed consent of the peoples concerned before adopting and implementing such measures.

Article 29 of the *Draft Declaration* reads:

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[3] *see*, e.g., Laurence R. Helfer, "Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking", 29 Yale J. Int'l L. 2, 10-26 (2004)

[4] "Study of the problem of discrimination against indigenous populations". ECOSOC Res. 1982/34, May 7, 1982 *see also* Michael A. Blakeney, "The International Framework of Access to Plant Genetic Resources" *in* (__ed.) Intellectual Property Aspects of Ethnobiology (London 1999) p. 15

[5] *Draft United Nations Declaration on the rights of Indigenous Peoples* E/CN.4/Sub.2/1994/56 http://www.unhchr.ch/Huridocda/Huridoca.nsf/e06a5300f90fa0238025668700518ca4/95a1f896bc21cba9c1256a9a005a49c3/$FILE/G0114202.pdf

[6] http://www.unhchr.ch/huridocda/huridoca.nsf/%28Symbol%29/E.CN.4.SUB.2.RES.1994.45.En?OpenDocument http://www.unhchr.ch/huridocda/huridoca.nsf/%28Symbol%29/E.CN.4.SUB.2.RES.1994.45.En

> 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 the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts. [7]

Finally, Article 37 of the *Draft Declaration* reads:

> States shall take effective and appropriate measures, in consultation with the indigenous peoples concerned, to give full effect to the provisions of this Declaration. The rights recognized herein shall be adopted and included in national legislation in such a manner that indigenous peoples can avail themselves of such rights in practice.

The "plight" of indigenous peoples, as recognized by these documents in the 1980s and 1990s, is evidently not just a sad remnant of the history of colonization and enslavement by the European powers in Africa and Asia for centuries, but also a by-product of the creation of modern "new" nation-states as a result of decolonization in the 1960s and 1970s based upon a European model.[8] The *Draft Declaration* makes clear that the responsibilities and obligation of states toward indigenous peoples are borne not just by the former colonial powers, but by the "new" post-colonial states as well. Beyond the question of what developed countries must do to repair the damage of their past exploitation is the question of how are the governments of poor, developing countries to shoulder the burdens they also share toward their own indigenous peoples.

Twenty-four years after that beginning, on 7 September 2007, the U.N. General Assembly finally adopted the *Declaration*. Of particular note are the obligations and responsibilities of U.N. Member States toward their own indigenous populations. These obligations are more specific in the 2007 *Declaration* than in the 1994 *Draft Declaration*. For example, Article 11 of the *Declaration* as adopted in 2007, the following final text taken from Article 12 of the *Draft*:

> 1. Indigenous peoples have the right to practise 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, artefacts, designs, ceremonies, technologies and visual and performing arts and literature.
> 2. States shall provide redress through effective mechanisms, which may include restitution, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs.[9]

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[7] http://www.unhchr.ch/huridocda/huridoca.nsf/%28Symbol%29/E.CN.4.SUB.2.RES.1994.45.En

[8] In most of the Western Hemisphere, decolonization generally took place much earlier - in the 18th Century for the United States and the early 19th Century for French, Spanish and Portuguese colonies. Decolonization of the British Caribbean colonies mostly has occurred in the 20th Century.

[9] U.N.G.A. Res. A/61L.67 (7 September 2007) For a recent review of the history of the *Declaration*, its problematic status in the relationship between modern African governments and their indigenous peoples, such as the Hadzabe (Tanzania), Ogiek (Kenya), Batwa (Ruanda/Burundi), Ogoni (Nigeria), and the Bagyeli (Cameroun), and the interaction of indigenous, law and international and national law, *see*, Willem van Genugten, "Protection of Indigenous Peoples on the African Continent: Concepts, Position Seeking, and the Interaction of Legal Systems", 104 Am. J. Int'l Law, 29 (2010) In particular, van Genugten (at p.,

Likewise, Articles 18 and 19 of the 2007 *Declaration* provide separately for the provisions of Article 20 of the 1994 *Draft*, and impose on states an obligation to consult and cooperate with their own indigenous peoples, as follows:

> *Article 18*
> Indigenous peoples have the right to participate in decision-making in matters which would affect their rights, through representatives chosen by themselves in accordance with their own procedures, as well as to maintain and develop their own indigenous decision-making institutions.
>
> *Article 19*
> States shall consult and cooperate in good faith with the indigenous peoples concerned through their own representative institutions in order to obtain their free, prior and informed consent before adopting and implementing legislative or administrative measures that may affect them.

Article 31(1) of the 2007 *Declaration*, based on Article 29 of the *Draft*, reads:

> 1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.[10]

Finally, and most interestingly, Article 38 of the 2007 *Declaration*, based on Article 37 of the *Draft*, reads:

> States in consultation and cooperation with indigenous peoples, shall take the appropriate measures, including legislative measures, to achieve the ends of this Declaration.

In a recent article, Professor van Genugten calls specific attention to Article 38 of the 2007 *Declaration* and its "mandatory" language, and observes that "states that do not live up to this provision are doing more than simply neglecting a political or moral commitment. Asking states to abide by their promise could surely not be brought before [international judicial bodies], but on the national level Article 38 can be instrumental, for example in developing procedures for domestic decision making in indigenous issues."[11]

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50) notes the language of Article 38 of the *Declaration* that " States in consultation and cooperation with indigenous peoples, shall take the appropriate measures, including legislative measures, to achieve the ends of this Declaration.

[10] U.N.G.A. Res. A/61/295 (7 September 2007)

[11] van Genugten at p. 50 It should be noted that there are several national and regional mechanisms in place on ABS standards, such as the Andean Pact Decision 391/96, the Common Regime on Access to Genetic Resources of Peru including legislation on traditional knowledge, the African Union's Model Law for the Protection of the Rights of Local Communities Farmers and Breeders. *see* Carl-Gustaf Thronstrom, "Access and Benefit Sharing: Understanding the Rules for Collection and Use of Biological Materials, The Handbook, Chapter 16.2, p. 1462.

Professor van Genugten observes that the four states that voted against the *Declaration* (Australia, Canada, New Zealand and the United States) explained their votes partly as resistance to the legal character of the *Declaration.*[12] In characteristic fashion, these four former "emigrant" British colonies remain adamant in not recognizing international "obligations" they supposedly bear toward their own indigenous populations – obligations with which they believe they cannot comply in good faith.[13] In this, the West is not alone. Resistance to international standards recognizing traditional knowledge is also is encountered in non-Western countries, for example, in some Islamic countries regarding the use of Islamic belief systems by traditional healers.[14]

In 2002, I proposed a human rights conceptual framework for *national* recognition of rights to identification, information, participation, benefit sharing, conservation, and preservation for the holders of traditional knowledge and folklore.[15] In 2007, at the first Global Summit on HIV/AIDS, Traditional Medicine, and Indigenous Knowledge held here in Ghana, I posed the question of whether domestic laws need to be enacted first in the states, with a view toward creating a viable international regime (or regimes.)[16] And at the Second Summit in Accra in 2008, I introduced an important practical resource for helping developing nations to begin their work to build national legal systems to recognize the rights of indigenous peoples in traditional knowledge, the Handbook of Best Practices: Intellectual Property Management in Health and Agricultural Innovation.[17]

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[12] Australia's explanation of why it refused to sign the *Declaration* was as follows: "As the *Declaration* did not describe current State practice or actions that States considered themselves obliged to take as a matter of law, it could not be cited as evidence of the evolution of customary international law." U.C. Doc. GA/10612 (Sept. 13, 2007) cited in van Genugten, at p. 51.

[13] "Every treaty in force is binding upon the parties to it and must be performed by them in good faith." Article 26, Vienna Conv. on the Law of Treaties (May 23, 1969) 1155 U.N.T.S. 331

[14] For example, traditional healers are approved to use Islamic religion in Saudi Arabia, allowed but not recognized in Egypt, and prohibited as completely illegal in Tunisia *see* M. Fakhr Es-Islam, "Islamic Religious and Traditional Healers' Contributions to Mental Health and Well-being", in M. Incayawar *et al*, Psychiatrists and Traditional Healers: Unwitting Partners in Global Mental Health (Wiley-Blackwell 2009) 197, 199

[15] William Hennessey, Toward a Conceptual Framework for Recognition of Rights for the Holders of Traditional Knowledge and Folklore, Proceedings of the WIPO Caribbean Symposium on Indigenous Knowledge and Folklore, Port of Spain, Trinidad & Tobago (February 2002) *see* http://www.faculty.piercelaw.edu/hennessey/RghtsfrHldrs.pdf This "human rights" approach seems to be in accord with the view of the African Commission on Human and Peoples' Rights on the *Declaration*. *see* Advisory Opinion of the African Commission on Human and Peoples' Rights on the United Nations Declaration on the Rights of Indigenous Peoples, 41st Ordinary Session (May 16-30, 2007) *cited in* van Genugten, p. 36

[16] William Hennessey, "Enacting International Laws and Implementing Public Policies To Protect The Rights of Indigenous Peoples to Knowledge and Biodiversity: Challenges and Opportunities" http://www.piercelaw.edu/assets/pdf/hennessey-enacting-international-laws-and-implementing-public-policies.pdf

[17] William Hennessey," Enacting International Laws and Implementing Public Policies to Protect the Rights of Indigenous Peoples to Knowledge and Biodiversity: Challenges and Opportunities" http://www.piercelaw.edu/assets/pdf/hennessey-enacting-international-laws-and-implementing-public-policies.pdf

What I intend to attempt in this paper is to review briefly some current international efforts to define substantive standards for the protection of "traditional knowledge associated with genetic resources" being formulated in various international organizations, and to speculate on the extent to which those activities are likely to produce results in the form of real and effective protection for both indigenous peoples and the biodiversity upon which they so dearly rely. How are states doing in their efforts at protecting the rights of indigenous peoples over their traditional knowledge? How can they do better? How can the work of international regimes assist all states to develop norms, standards, and best practices for the protection of indigenous knowledge and traditional medicines against misappropriation?

Part II: The Difficulty in Defining an International Standard for Basic Terms: What is "Traditional Knowledge Associated with Genetic Resources" and What is "Misappropriation"

The relationship of indigenous peoples to their natural environment, including plants and animals, earth, weather, and water, is a complex one. Common to both traditional hunter-gatherer cultures and traditional agricultural societies based upon domestication of plants and animals, the natural world is a seamless web of Being.[18] One modern dichotomy not found among indigenous peoples is that between human "physical" and "spiritual" wellbeing, or between human cultures and the natural environment.

> "The development of traditional medicines has been influenced by the different cultural and historic conditions in which they were first developed. Their common basis is a holistic approach to life, equilibrium between the mind, body and environment, and an emphasis on health rather than on disease. Generally, the treatment focuses on the overall condition of the individual patient, rather than on the ailment or disease.[19]

Another modern dichotomy is that the means of human sustenance are sometimes divided analytically (and artificially) into "foods" and "medicines." Foods fill our bellies and medicines cure our ills. But for indigenous peoples, the distinction is not so clear.

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[18] Deloria's classic description of the Native American worldview is representative of the belief systems of indigenous peoples:

> Instead of isolating things, Indians encompassed them; togetherness, synthesis, and relatedness characterized their experiences of the universe. The ordinary distinctions between mind and matter, human and other life forms, nature and human beings and even our species and the divinity were not considered valid ways of understanding experience. Life was a complex matriz of entities, emotions, revelations, and cooperative enterprises and any abstraction was considered stupid and dangerous, destructive of spirit and reductionist in the very aspects that made life important.

Vine Deloria, "Civilization and Isolation", in ____, For this Land: Writings on Religion in America (19991 35-144

[19] http://www.who.int/intellectualproperty/studies/en/ ["WHO TM Report"] p. 5 The concept of harmony between human society and nature is pervasive in Eastern philosophy, although in modern East Asian societies such as China, Japan, and India, where a belief in rapid economic development has taken hold, that concept is more honored in the breach.

> "Before manufactured drugs came into widespread use, herbal medicines played an important role in human health. Reviewing the history of the development of medicines, we see that most herbal medicines were originally derived from foods. Most manufactured drugs were developed from medicinal plants. The influence of culture and history on the use of herbal medicines differs from country to country and region to region, and they still have a major impact on the use of herbal medicines in modern societies. There are great differences between Member States in the categorization of herbal medicines. A single medicinal plant may be defined as a food, a functional food, a dietary supplement or a herbal medicine in different countries…This makes it difficult to define the concept of herbal medicines for the purposes of national drug regulation, and also confuses patients and consumers.[20]

Indigenous belief systems are impervious to these so-called dichotomies, looking at the world not just holistically, but beyond mere symbolism.[21] Traditional farmers and traditional healers rely on their reservoirs of biodiversity to practice their livelihoods, and the conservation of those biological reservoirs depends on the diligence of its guardians. The knowledge systems of traditional healers are inextricably linked to the genetic resources of the plants and animals their craft has evolved with.

Nevertheless, in a global society (as reflected by this meeting and the U.N. Declaration), traditional healers have a personal incentive to invest their time and efforts into protecting the resources they rely on for their craft. Modern "Western" agricultural and pharmaceutical companies may speak a different language – the language of "new" and the language of "intellectual property." But human nature (whether a business executive in a multinational corporation or traditional healer among his or her villagers) does not recognize such a distinction; in both the traditional and modern worlds, the practical and functional power of the term "incentive to invest" means just about the same thing.

The multiplicity of international organizations working on identifying substantive standards for the protection of "traditional knowledge" includes the WHO-CIPIH , FAO-ITPGRFA, CBD-COP, and WIPO-IGCTK. To what extent are these organizations working collaboratively in formulating such standards? While these discussions overlap in subject matter, different organizations use different terms. Can a clear distinction be made between "Traditional Knowledge Associated With Genetic Resources", "Indigenous Knowledge", and "Traditional Medicine" as used in these negotiations? Should such a distinction be made?

A. International Success Stories: WHO and FAO

1. WHO-CIPIH

In 2003, the World Health Assembly of the WHO established its Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), with the following mission:

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[20] *id.*

[21] A good example of a vibrant non-symbolic belief system that survives in modern Western cultures is the key transubstantive role that "bread and wine" play in some Christian religions.

> "…to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries…"[22]

In 2005, the Commission published its first Global Survey of National Policies on traditional and complementary/alternative medicines [TM/CAM].[23] The Commission has also published a rich series of freely available studies on issues concerning the interface between IP systems and traditional medicines.[24] And its ground-breaking 2006 Report "Public Health: Innovation and Intellectual Property Rights", devoted an entire chapter to "Fostering Innovation in Developing Countries."[25] Proposals for protection of traditional medicines was treated skeptically in this report, but the need to prevent misappropriation of indigenous knowledge was clearly recognized:

> In respect of traditional knowledge generally, and traditional medical knowledge in particular, there is an ongoing debate about how intellectual property rights might be responsible for unfairly depriving communities of the benefits of their knowledge (e.g. when a company uses such knowledge to create commercial value, none of which flows back to the community from which the knowledge originated). Such practices are sometimes called biopiracy or misappropriation. Nevertheless it is also argued that patenting is essential to the commercialization of inventions based on legitimately accessed traditional knowledge, or associated genetic resources, and measures to restrict it would be harmful to the effort to develop new products that benefit public health. Intimately linked to this debate is the question of how benefits should be shared between traditional knowledge holders (whether individuals or communities) and those who make use of their knowledge. … Much of this debate raises issues far beyond our terms of reference. Our own perspective is rather narrower – what measures might (a) seek to promote innovation and (b) promote access to new products derived from traditional medical knowledge.
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> …The purpose of intellectual property protection should be to stimulate new invention and innovation. However, in practice, regimes being considered for traditional knowledge principally seek to address the question of equitable benefit sharing, not that of stimulating innovation derived from traditional knowledge. The risk is that introducing a form of intellectual property protection for traditional knowledge may actually have the effect of restricting access by others, thereby inhibiting downstream innovation. …
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> There is [still] a need to guard against misappropriation of genetic resources and associated knowledge, to ensure that the commercial benefits derived from traditional knowledge are fairly shared with the communities that discovered those resources and their possible medical uses, and to promote the use of such knowledge for the benefit of public health New measures may be required for equity reasons, and also to provide incentives for the transfer of traditional knowledge to those who can exploit it.[26]

The WHO Commission takes a very modest approach to the issues of IP protection, access, and benefit sharing, clearly seeking to strike a balance between the

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[22] http://www.who.int/intellectualproperty/en/
[23] http://apps.who.int/medicinedocs/en/d/Js7916e/9.1.html#Js7916e.9.1
[24] http://www.who.int/intellectualproperty/studies/en/ ["WHO TM Report"]
[25] www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf ["WHO IP Report"]
[26] WHO IP Report, at p. 164

need for access to genetic resources and traditional knowledge in the creation of modern medicines with global application, and benefit-sharing with local indigenous peoples.

2. ITPGRFA-FAO.

Another very modest, and thus far apparently successful initiative in bridging the gap between the needs of the traditional farmer and those of the modern agricultural corporation has been the United Nations Food and Agriculture Organization's [FAO] International Treaty on Plant Genetic Resources for Food and Agriculture [ITPGRFA] of 2004.[27] The treaty provides for a Multilateral System of Access and Benefit-Sharing, sometimes described as a "limited compensatory liability mechanism" or a "take-and-pay rule."[28] Crops and forages listed in Annex I of the Treaty can be accessed in accordance with a Standard Materials Transfer Agreement [SMTA] that requires recipients of plant material to share a percentage of the commercial benefits eventually generated from the sale of the improved materials, especially if the improved material was patented or the sale was otherwise restricted.[29] Monetary benefit-sharing comes at the end of successful commercialization – not when the material is transferred.[30] Also, because recipients and providers are often the same party, this treaty has drawn wide participation, including prior over 40 countries in Africa, and surprisingly, earlier hold-outs such as Australia and the U.K.[31] In 2007, its scope was extended to cover all accessions in the thirteen international agricultural research centers constituting the CGIAR.[32]

An interesting feature of the ITPGRFA is that it provides a central place for non-monetary benefits that, according to recent reports, may be even more important than monetary benefit-sharing, including information sharing, capacity building, and technology transfer.[33] Non-monetary benefit sharing is critically important for purposes of transparency. Cash payments to national or local governments where traditional farmers reside might be diverted to other uses and never reach the parties most deserving of assistance. Information sharing, capacity building, and technology transfer can bring the skills needed for the creation of value in so-called "new traditional knowledge" – that is, the transformation of traditional knowledge into modern legal rights.[34] The CGIAR

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[27] International Treaty on Plant Genetic Resources for Food and Agriculture, FAO Resolution 3/2003, November 3, 2001 U.N.T.S. I-43345

[28] *see* Christine Frison *et al.* "Intellectual Property and Facilitated Access to Genetic Resources Under the International Treaty on Plant Genetic Resources for Food and Agriculture" [2010] E.I.P.R. 1, 2

[29] *id.* 3

[30] This feature led to some initial (and ongoing) skepticism from some civil society NGOs. *see, e.g.,* International Seed Treaty Comes Into Force Today But Will It Undermine Farmers' Efforts to Conserve Biodiversity?" U.K. Agricultural Biodiversity Coalition Special Report, 29 June 2004 http://www.ukabc.org/itpgrfa29june2004.htm

[31] *see* http://www.fao.org/Legal/treaties/033s-e.htm

[32] Frison, at 6

[33] ITPGRFA Article 13.2 Monetary benefit-sharing has been modest thus far, amounting to a bit less than US$ one million. *id.* at 7 That is insignificant in the overall funding scheme of the Treaty, with a target of US$ 116 million for the period 2009-2014.

[34] *see* William Hennessey, "Changing Traffic Patterns in Technospace" 2005 Mich.St.L.Rev. 201, 216 (2005) citing Yinliang Liu, "IPR Protection for New Traditional Knowledge: With a Case Study of

Centers are engaged in an outreach program to provide assistance in developing countries to increase their capacity to manage their intellectual property assets. A unit of the CGIAR system, the Central Advisory Service on Intellectual Property (CAS-IP) "assists the agricultural research centers of the Consultative Group on International Agricultural Research (CGIAR) with their intellectual property management issues for development purposes."[35] A key link in the value-chain of non-monetary access and benefit sharing for both traditional agriculture and traditional medicine will be the role of research institutes and technology transfer offices in universities in the countries where indigenous peoples live.[36] The CAS has developed a National Partner Initiative [NPI] to bring together scientists, lawyers, and academics in developing countries.[37] CAS also works in parallel with several non-governmental organizations that assist in capacity building for interested parties in developing nations. Among them is the Public Interest Intellectual Property Advisors.[38] Another it the International Technology Transfer Institute at Franklin Pierce Center for Intellectual Property.[39]

Like the activities of the WHO-CIPIH mentioned earlier, those of the FAO-ITGRFA appear to be intended to protect the narrower interests of traditional healers and farmers from encroachment in a comprehensive international agreement. The focus of benefit-sharing in both organizations appears to be primarily non-monetary, and in the form of information sharing, technical cooperation and expert assistance. Both work in tandem with non-governmental organizations to help achieve those goals. By contrast, the focus of discussion in the CBD-COP and WIPO-IGCGRTKF, to be discussed below, appear to be much broader, and with a different agenda.

B. International Initiatives Awaiting Success: CBD and WIPO

Traditional Chinese Medicine," 25 Eur. Intell. Prop. Rev. 194 (2003) available at http://www.faculty.piercelaw.edu/hennessey/MichiganStateLawReview.pdf

[35] *see http://www.cas-ip.org/* The WHO Traditional Medicines Report notes that the need for support from Member States regarding their traditional medicines included assistance with registration of TMs; intellectual property issues; funding to develop a national database of TM and herbs; scientific references and research; equipment; facilities and funding for research; support and funding for the development of national pharmacopoeias, and visits by technical advisors (among others).

[36] A fine example of such cooperation is the work of Nigeria's National Institute of Pharmaceutical Research and Development reported by Dr. Charles Wembebe at the 2d Meeting of this Summit in 2008 *see* Wembebe, "A Herbal Medicine:Niprisan/Nicosan, For the Management of Sickle Cell Anemia" Wembebe notes that consent and patient information forms were developed in conformity with WHO requirements and patents were taken out in 46 countries (including the U.S. and U.K.) with a grant from the UNDP.

[37] *see* http://www.cas-ip.org/projects/npi/

[38] " PIIPA (Public Interest Intellectual Property Advisors, Inc.) is the global nonprofit resource for developing countries and public interest organizations seeking expertise in intellectual property matters to promote health, agriculture, biodiversity, science, culture, and the environment. PIIPA provides worldwide access to the IP Corps -- IP professionals who can advise and represent such clients pro bono publico (as a public service). www.piipa.org.

[39] ITTI is a global innovation development clinic. information about ITTI is available at http://www.piercelaw.edu/itti/projects.phphttp://www.piercelaw.edu/assets/pdf/magazine-2009-vol13-no2-summer-kowalski-19-20.pdf
http://www.piercelaw.edu/assets/pdf/magazine-2009-vol13-no1-winter-global-interest-33-34.pdf
http://www.piercelaw.edu/assets/pdf/magazine-2008-vol12-no2-summer-globalinterest-50-51.pdf
http://www.piercelaw.edu/assets/pdf/magazine-2009-vol13-no1-winter-itti-20-21.pdf

1. CBD-COP The Convention on Biological Diversity was finalized in Nairobi and signed in 1992 at Rio de Janeiro, Brazil. The CBD provides for "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources." Article 15 of the Convention sets out principles and obligations of Parties related to this objective, on the basis of prior informed consent and mutually agreed terms.[40] Article 8(j) refers to the rights of the holders of TK. Some progress has been made on articulating the substantive standards these two provisions refer to.

The CBD's Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing was established in 2004. Its Ninth Meeting was held in Cali Colombia in March 2010.[41] Ninety-one countries (including twenty-seven African countries) and eighty-nine NGOs participated. [42] After years of negotiations among the parties, this meeting was to attempt to finalize a negotiating text for an "International Regime on Access and Benefit-Sharing," to be adopted as a Protocol (the Nagoya Protocol) to the CBD by the tenth meeting of the COP in October 2010.[43] While the focus of the Protocol is on genetic resources, an important part of the ongoing discussion concerns what is called "traditional knowledge associated with genetic resources." The Report includes a draft Article 9 of the Protocol which states:

> 1. In implementing their obligations under this Protocol, Parties shall give due consideration of indigenous and local community laws, customary laws, community protocols and procedures, of indigenous and local communities, as applicable, with respect to traditional knowledge associated with genetic resources.[44]

But there is no definition in the draft of what is meant by "traditional knowledge associated with genetic resources."[45] The 2009 Working Group had heard from an Expert Group on the nature of "traditional knowledge associated with genetic resources."[46] However, while that Expert Group provided descriptions and characterizations of the term, it did not provide any definitions. Among the common characteristics of "traditional knowledge associated with genetic resources" suggested by legal and technical experts to the Working Group were:

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[40] *see* http://www.cbd.int/abs/ *see generally* The Handbook, Chapter 16.

[41] Report on the First Part of the Ninth Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing UNEP/CBD/WG-ABS/9/3 26 April 2010 [hereinafter ABS Report"]

[42] Angola, Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Congo, Egypt, Gabon, Guinea, Liberia, Madagascar, Malawi, Mali, Morocco, Mozambique, Namibia, Niger, Senegal, South Africa, Sudan, Togo, Uganda, Tanzania, Yemen, and Zambia

[43] *see* Report of the First Part of the Ninth Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, UNEP/CBD/WG-ABS/9/3 (26 April 2010) This would be the second protocol to the CBD, the first being the Cartagena Protocol on Biosafety finalized at the Montreal Conference of the Parties (COP-5) of the CBD in January of 2000 *see* http://www.cbd.int/biosafety/background/

[44] *id.* p. 48

[45] ABS Report Para. 26 The WHO, by contrast, produced a definition for "traditional medicine." "Traditional medicine is the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illnesses." http://www.who.int/intellectualproperty/studies/en/ ["WHO TM Report"] p. 3

[46] id. Para 19

(a) A link to a particular culture or people – knowledge is created in a cultural context;
(b) A long period of development, often through an oral tradition, by unspecified creators;
(c) A dynamic and evolving nature;
(d) Existence in codified or uncodified (oral) forms;
(e) Passed on from generation to generation – intergenerational in nature;
(f) Local in nature and often embedded in local languages;
(g) Unique manner of creation – (innovations and practices);
(h) It maybe difficult to identify original creators.[47]

Ironically, these very characteristics suggested by the Experts point not just to the difficulty of coming up with any textual definition of "traditional knowledge associated with genetic resources" - even a very fluid one that might apply equally to different local circumstances, but the futility of doing so. As Deloria reminds us in so many words, to define traditional knowledge is to destroy it.

The Nagoya Protocol discussions in the CBD-COP have not gone unnoticed at the FAO. In the Thirty-sixth Session of the FAO Conference in November 2009, the members passed a resolution in which it:

> *Invites* the Conference of the Parties of the Convention on Biological Diversity and its Ad Hoc Open-ended Working Group on Access and Benefit-sharing, to take into account the special nature of agricultural biodiversity, in particular genetic resources for food and agriculture, their distinctive features, and problems needing distinctive solutions; in developing policies they might consider sectoral approaches which allow for differential treatment of different sectors or subsectors of genetic resources, different genetic resources for food and agriculture, different activities or purposes for which they are carried out; [48]

Importantly, the FAO representative at the Cali conference requested the Conference of the Parties to assure that there would be no conflicts between the two regimes.

> "The representative of the International Treaty on Plant Genetic Resources for Food and Agriculture said that the fully functional access and benefit-sharing system of the Treaty, which was in harmony with the Convention on Biological Diversity, was proof of the feasibility of such a regime. He hoped that the complementarity of rules, mutual supportiveness and coherence among legal obligations under the respective legal instruments would be at the centre of the decisions to be taken…[49]

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[47] Report of the Meeting of the Group of Technical And Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing UNEP/CBD/WG-ABS/8/2 (July 2009)
[48] FAO Resolution *18/2009*. Policies and arrangements for Access and Benefit-sharing for Genetic Resources for Food and Agriculture, FAO Conference Report (2009) pp. 71-73 www.fao.org/docrep/meeting/018/k6821E02.pdf
[49] ABS Report Para. 39

In this request, he was supported by developed nations such as Switzerland, Norway, Canada, New Zealand, the European Union, and Australia.[50]

Unlike the FAO and WHO discussions, the focus of the CBD-COP's benefit-sharing" provisions is first and foremost upon financial compensation to the holders of traditional knowledge for commercial use. Annex I of the draft Nagoya Protocol lists (non-exclusively) ten monetary benefits and seventeen non-monetary benefits. The first benefits mentioned in the Annex are for access fees/fee per sample collected, up-front payments, milestone payments and payment of royalties even before commercialization.[51] Without patent-like ownership rights protecting such knowledge, these provisions are not likely to be well accepted by developed states. In the first instance, such provisions will have no obligatory force against non-signatories of the CBD (such as the United States). Furthermore, the Protocol will not bind CBD Member States (such as the European and Western Pacific states mentioned just above) if they choose not to ratify it. This unfortunately creates a high possibility that the Protocol will end up being merely a political, rather than a legal document.[52] This eventuality is reinforced by the fact that it appears that the drive toward completion of the Nagoya Protocol to the CBD before the end of 2010 is directly related to the designation of this year as the International Year for Biodiversity, and the negotiations may be rushed to complete the instrument before then.

Nevertheless, there are several encouraging provisions in the Draft Protocol. One is the creating of an ABS Clearing-House (Article 11) to facilitate information-sharing, including national legislation and decisions, "indigenous and local community laws", and model contract clauses, codes of conduct and best practices.[53] Other welcome measures include provisions encouraging the monitoring and measuring of national compliance with ABS legislation, mutually agreed terms, model contractual clauses, awareness-raising, capacity building, and tech transfer and cooperation.[54] (The Handbook of Best Practices has a wealth of practical information on protection for holders of traditional knowledge.)[55])

2. WIPO-IGCGRTKF

The Inter-Governmental Committee on Genetic Resources, Traditional Knowledge, and Folklore of the World Intellectual Property Organization (WIPO-

[50] ABS Report Paras. 45, 52, 54, 57, 97, 112, and 135

[51] UNEP/CBD/WG-ABS/9/3 p. 59 Annex I, Section 1(a)-(d). Section 1(e) refers to "License fees *in case of commercialization*" which implies that the up-front payments are not limited to successfully commercialized results.

[52] Curiously, the representative of Mexico stressed that among the priority issues in the negotiations should be "the obligations of non-Parties." ABS Report Para. 31

[53] There may be an important rolw for the IP Handbook of Best Practices (mentioned above) in building local capacity to create value (including economic value) from IP "know-how."

[54] Draft Protocol Arts. 12-18.

[55] Stephan A. Hansen, Justin W. Van Fleet, "Issues and Options for Traditional Knowledge Holders in Protecting Their Intellectual Property" http://www.iphandbook.org/handbook/ch16/p06/

IGCGRTKF] was established in 2000.[56] Since that time, it has accomplished a great deal in terms of collecting a wealth of information about knowledge and practices among the Member States in protecting against the misappropriation of TK. Beginning in 2006, it began drafting objectives and principles with a view to creating substantive international standards to further that end.[57] In May 2010, at the Sixteenth Session, the Committee issued its most recent revision of those objectives and principles, with a view toward proposal soon of a negotiating text for an international instrument under the WIPO treaty system for the protection of traditional knowledge.[58] Yet the documents available at present reveal wide differences in understanding of the meaning of such basic terms as "traditional knowledge," "misappropriation", "holder", "commercial use", and "public domain." Many delegations support work to provide clear definitions of such terms, but that effort may be impossible. For example, in the WIPO documents, the term "genetic resources and associated traditional knowledge" (as used by the CBD) was sometimes referred to as "traditional knowledge and associated genetic resources."[59] It is not clear what the nature of the "association" is in either direction, but seems to be dependent on national laws.[60]

The negotiations appear to have had two initial tracks. One, proposed by Norway, would subsume protection of "associated" traditional knowledge under the law of unfair competition as provided by Article 10bis of the Paris Convention for the Protection of Industrial Property as a form of "misappropriation." At its most recent meeting of the IGC, a number of delegations suggested that the term "misappropriation" must be defined.[61] But faced with the challenge of deciding what the terms "unfair" and "misappropriation" mean, and courts in common law countries (and particularly in the United States) have tended to decide on a case-by-case basis rather than to find an articulated legal standard to apply.[62] One (unidentified) observer at the IGC meeting made a similar observation:

> An observer noted that the concept of misappropriation appeared to vary widely. As a fundamental matter, the concept of misappropriation should be linked to notions of appropriate access and benefit-sharing through compliance with national ABS laws. In other words, if there was no violation of the national ABS law, there was no

[56] "The IGC is an ad hoc committee created by the WIPO General Assembly as a result of the political impossibility of discussing and promoting topics related to genetic resources and the protection of traditional knowledge in the negotiations of WIPO's Patent law Treaty in 2000." David Vivas-Eugui, et al, International Negotiations on Biodiversity, Genetic Resources and Intellectual Property: Implications of the WIPO Intergovernmental Committee's New Mandate (IUCN 2004) p. 3 www.iprsonline.org/ictsd/docs/Vivas-Espinosa-WinklerMarch04.pdf

[57] WIPO/GRTKF/IC/7/5

[58] WIPO/GRTKF/IC/16/5, characterized as a revision of an earlier working document WIPO/GRTKF/IC/9/5

[59] WIPO/GRTKF/IC/16/5 passim

[60] for example WIPO/GRTKF/IC/9/5 draft Article 12 says " In case of traditional knowledge which relates to components of biological diversity, access to, and use of, that traditional knowledge shall be consistent with national laws regulating access to those components of biological diversity. Permission to access and/or use traditional knowledge does not imply permission to access and/or use associated genetic resources and vice versa." It does not, however explain the nature of the association in either direction.

[61] id. at p. 18

[62] see., e.g., General Motors Corp. v. Ignacio Lopes de Arriortua et al., 948 F. Supp 684 (E.D. Mich. 1996)

> "misappropriation." When considering how to define specific instances of "misappropriation" under national laws, the following circumstances might be taken into account: (1) whether the relevant TK was communicated directly to the user by traditional holders; (2) whether the relevant TK was not known, disclosed or used anywhere else; (3) whether permission to use the relevant TK was obtained from at least some genuine holders; and (4) whether mutually agreed terms for benefit-sharing existed and were respected. Other circumstances might be considered, but clear rules were needed to determine which conditions were essential. There were many outstanding questions that governments had to consider. Should there be special conditions regarding research or non-commercial use or publication of TK? If the information claimed to be TK had become publicly known or was in use by other – perhaps unrelated – indigenous peoples, would ABS laws still apply? How could a system be designed to put users on notice that published information was not freely available for use (as the patent system does)? If the relevant TK was unpublished, should it be treated in the same way as other proprietary unpublished information – so that, for example, if it was developed independently, it could not be subject to restrictions on use?[63]

The other track (proposed by the African Group); was directed toward creation of a *sui generis* system of protection for traditional knowledge associated with genetic resources rather than protection under the law of misappropriation.[64] But likelihood that a broad or "global" understanding of the nature of traditional knowledge and how to protect it acceptable to developed and developing states emerging from either the CBD or the WIPO seems quite low.

Perhaps a "bottom up" approach – bringing interested stakeholders in states with a wealth of traditional knowledge together to formulate model national laws and regulations for ABS implementation rather than waiting for a consensus on international law standards – would be a better strategy. Most encouraging in this regard is the recent work of WIPO's Development Agenda, which appears to be follow in the footsteps of WHO and FAO, focusing on non-monetary benefit-sharing in the form of technical cooperation and capacity building.[65] For example, WIPO has just announced a request for proposals for provision of patent landscape reports (PLR) in various fields of technology, including public health, climate change/ environment/energy, food and agriculture.[66]

Such modest efforts from experts coming together from international organizations, IP offices, research institutes, universities, and NGO's are likely to be more productive than grandiose treaty regimes in achieving real success, meeting the needs and aspirations of traditional peoples and preserving the biodiversity that they, and all of us, depend upon so greatly.

[63] WIPO/GRTKF/IC/16/5 at p. 18
[64] The Commentary on "Legal Form of Protection" (Article 2) highlighted that different countries may select different national standards, as is the case with some other WIPO treaties.
[65] http://www.wipo.int/ip-development/en/strategies/technology.html
[66] http://www.wipo.int/procurement/en/notices/2010/ptd10007/index.html