

Traditional Knowledge and Global Lawmaking

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I. INTRODUCTION

¶1 The value and significance of traditional knowledge (TK)¹ has been widely recognized. According to the study of the World Intellectual Property Organization (WIPO), TK has tremendous merits in various respects, generating cultural, social, ecological, biological, agricultural, and industrial values.²

¶2 In short, TK refers to the knowledge, innovations and practices of indigenous and local communities in the world. Yet there seems to be no definite and universally approved definition of TK.³ The concept of TK may be reflected in the work of the WIPO, which outlines its general scope as follows:

[T]he term “traditional knowledge” refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part

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¹ The alternative term of ‘Indigenous Knowledge’ has also been used for the description of this knowledge. See CHIDI OGUAMANAM, *INTERNATIONAL LAW AND INDIGENOUS KNOWLEDGE: INTELLECTUAL PROPERTY, PLANT BIODIVERSITY, AND TRADITIONAL MEDICINE* 20 (2006); Suman Sahai, *Indigenous Knowledge and Its Protection in India*, in *TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY* 174 (Christophe Bellmann et al. eds. 2003).

² Intergovernmental Committee (IGC), *The Protection of Traditional Knowledge: Revised Objectives and Principles*, Eighth Sess., WORLD INTELLECTUAL PROPERTY ORGANIZATION, INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE, Geneva, June 6-10, 2005, WIPO/GRTKF/IC/8/5 [hereinafter IGC Eighth Sess. Doc.]; IGC, *The Protection of Traditional Knowledge: Revised Objectives and Principles*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE, Ninth Sess., Geneva, Apr. 24-28, 2006, WIPO/GRTKF/IC/9/5, Revised Provisions for the Protection of Traditional Knowledge: Policy Objectives and Core Principles, Annexes to both WIPO/GRTKF/IC/8/5 and WIPO/GRTKF/IC/9/5, I. Policy Objectives, Annex 3 (2006) [hereinafter WIPO DRAFT, *TK Objectives and Principles*].

³ Peter Drahos, *A Networked Responsive Regulatory Approach to Protecting Traditional Knowledge*, in *INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS-PLUS ERA* 396 (Daniel J. Gervais ed. 2007).

of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations.⁴

¶3 From an ownership perspective, TK could arguably be classified as a form of intellectual property. In contrast to the normal entitlements of intellectual property that individuals normally enjoy, however, the property elements of TK are quite unique. TK is generated *collectively*, and processed and preserved by indigenous peoples or local communities.⁵ TK is thus distinctively associated with a group of people who may regard their body of TK as being beyond that of a personal or proprietary nature.

¶4 TK is often transmitted orally from generation to generation,⁶ and it typically is not codified within any modern system of documentation. TK is also not limited to any precise form, “tak[ing] the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, community laws, local language, and agricultural practices, including the development of plant species and animal breeds.”⁷ The uniquely communal sense in which TK is possessed might estrange it from modern intellectual property rights.⁸

¶5 Due to TK’s conservation value, its preservation can make a great contribution to sustainable development of biodiversity.⁹ Thus, such a robust body of law governing TK may involve complex considerations of environmental, developmental and social elements.

¶6 Further, given the close linkages between TK and its holders, TK holders become the most indispensable stakeholder in designing any legal structure concerning TK.¹⁰ Certainly, the

⁴ WIPO DRAFT, *TK Objectives and Principles*, *supra* note 2, art. 3(2). Drahos considers the WIPO’s ‘open-ended, inclusive approach to the subject matter of TK’ an adequate model. Drahos, *supra* note 3.

⁵ See *Introduction*, CONVENTION ON BIOLOGICAL DIVERSITY, <https://www.cbd.int/traditional/intro.shtml> (last visited Nov. 16, 2011).

⁶ *Id.*

⁷ *Id.*

⁸ One study shows that modern intellectual property rights systems, such as patents, copyright, trade secrets, and trademarks seem not really available to TK holders, in spite of few national practices using intellectual property rights for TK protection. See GRAHAM DUTFIELD, *INTELLECTUAL PROPERTY, BIOGENETIC RESOURCES AND TRADITIONAL KNOWLEDGE* 100-09 (2004); ALEXANDRA XANTHAKI, *INDIGENOUS RIGHTS AND UNITED NATIONS STANDARDS: SELF-DETERMINATION, CULTURE AND LAND* 225 (2007) (arguing that intellectual property rights are inadequate for the protection of indigenous bio-diversity rights). Cf. Nuno Pires de Carvalho, *From the Shaman’s Hut to the Patent Office: A Road Under Construction*, in *BIODIVERSITY & THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE* 257-58 (Charles R. McManis ed. 2007) (indicating national protection of TK by using existing IP systems); David R. Downes, *How Intellectual Property Could be a Tool to Protect Traditional Knowledge*, 25 *COLUM. J. ENV’T L.* 253 (2000) (speculating the feasibility of articulating intellectual property rights over TK).

⁹ It is observed that TK “commonly refers to knowledge associated with the environment” DUTFIELD, *supra* note 8, at 91. The Convention on Biological Diversity (CBD) recognizes that many indigenous and local communities that are TK holders “have cultivated and used biological diversity in a sustainable way for thousands of years. Some of their practices have been proven to enhance and promote biodiversity at the local level and aid in maintaining healthy ecosystems.” *Introduction*, CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 5.

¹⁰ The instruments of WIPO and the U.N. on TK have addressed the needs of TK holders. See *infra* Part III. B. D.

promotion and recognition of the rights of indigenous peoples will be instrumental in pressuring national authorities to take necessary measures to protect TK, especially when such actions entail the conclusion of binding treaties.¹¹

¶7 As TK is created, applied, and preserved by local and indigenous communities, its protection used to be a national or local matter and concern. Nonetheless, there are significant reasons for the international community to pay due regard to TK protection as well, and there is a growing global movement to promote the international status of indigenous peoples, who possess most TK. For one, given its intrinsic value, the protection and preservation of TK benefits humankind as a whole, and should accordingly be of interest to the international community. In particular, because TK access and utilization has been exercised in boundary-crossing ways, the theft of TK has been and should continue to be strongly intolerant to international society. Misappropriation of TK has led to the granting of undesirable patents on inventions based directly on TK related to local bio-diversity, resulting in a form of TK piracy.¹²

¶8 To date, the international community has responded to the issue of TK by formulating a variety of documents with differential legal implications. The Convention on Biological Diversity (CBD)¹³ appears to be the first international agreement that obliges State parties to protect bio-related TK. The CBD has mandated the use of TK to comply with access and benefit-sharing devices. After intense debate and study, the WIPO, based on a defensive approach, has drafted an unprecedented instrument exclusively for the protection of TK. The World Trade Organization (WTO) has been negotiating the relationship between its intellectual property agreement, namely the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),¹⁴ and the CBD, in which a proposal to revise patent disclosure so as to add certain CBD mandates has aroused heated debate.¹⁵ Following decades of effort, the General Assembly of the United Nations has finally adopted a Declaration on the Rights of Indigenous Peoples¹⁶ in which

¹¹ Drahos, *supra* note 3, at 393-94.

¹² TK has been misappropriated occasionally without just cause, either through failure to gain the approval of the holders of such knowledge, or failure to share any benefits with the holders. A number of infamous bio-piracy cases not only refer to misappropriation of national genetic resources but also associated TK. For an illustration of piracy on TK, *see generally* GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY 65-67 (2000) (outlining patents on turmeric, neem and quinoa that were erroneously granted).

¹³ The Convention on Biological Diversity, *opened for signature* June 5, 1992, 1760 U.N.T.S. 79 (entered into force Dec. 1993) [hereinafter CBD].

¹⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C to the Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, *in* WORLD TRADE ORGANIZATION, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 321 (1999) [hereinafter TRIPS].

¹⁵ *See generally* Kuei-Jung Ni, *The Incorporation of the CBD Mandate on Access and Benefit-Sharing into TRIPS Regime: An Appraisal on the Appeal of Developing Countries with Rich Genetic Resources*, 1 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 433, 446-54 (2006) (summarizing and analyzing the conflicting views and rational among WTO members regarding the disclosure proposal).

¹⁶ U.N. Declaration on the Rights of Indigenous Peoples, G.A. Res. 61/295, U.N. Doc. A/RES/61/295 (Sept. 13, 2007) [hereinafter U.N. Declaration]. The U.N. Declaration was adopted by a majority of 143 states in favor, with 4 votes against (Australia, Canada, New Zealand and the United States) and 11 abstentions (Azerbaijan, Bangladesh,

the rights of peoples regarding TK has been squarely recognized. The CBD, WIPO, and the Declaration on the Rights of Indigenous Peoples, all sub organs of the U.N., as well as the WTO, have become the major contributors towards global TK lawmaking.¹⁷

¶9 This article aims to explore how these key global legal systems engage in the protection of TK by formulating rules of either hard law or soft law. The study will preliminarily analyze the legal implications and effect of those instruments. Part II examines the relevance of global lawmaking to TK. Part III reviews the present global legal frameworks dealing with the protection of TK. Then, Part IV assesses the feasibility of establishing a coherent and integrated instrument for TK protection when individual international legal devices are presumed to be of only limited function. Part V presents the conclusion.

II. THE RELEVANCE OF GLOBAL LAWMAKING TO TRADITIONAL KNOWLEDGE: WHY INTERNATIONAL LAW MATTERS

¶10 As indicated above, TK is developed by local indigenous communities. Management of TK was long a local matter. Yet, in recent years, the protection of TK has become a growing concern in the international community. The achievement of the international endeavor to protect such intellectual and cultural heritage may contribute to the welfare of human kind as a whole.

¶11 Apart from local peoples, TK has also been acquired and employed by foreign entities, including foreign individuals, research academics, and multinational companies. The transnational nature of modern TK use underscores the need to create legal frameworks to regulate such transnational activities not only through national authorities but also through international mechanisms as well.¹⁸ In addition, there has been an international movement to promote and recognize the rights of indigenous peoples who hold most TK. TK protection can be viewed as an imminent international matter, especially from the perspective of international human rights.¹⁹

¶12 International lawmaking could be conducive to TK protection, if employed effectively. With respect to crafting substantial international rules, relevant international institutions may

Bhutan, Burundi, Colombia, Georgia, Kenya, Nigeria, Russian Federation, Samoa, and Ukraine). See Office of the United Nations High Commissioners for Human Rights, *Declaration on the Rights of Indigenous Peoples*, <http://www2.ohchr.org/english/issues/indigenous/declaration.htm> (last visited Nov. 16, 2011). But, those four objecting nations recently have shifted their position to support the declaration. See U.N. Permanent Forum on Indigenous Issues website: <http://www.un.org/esa/socdev/unpfii/en/news.html> (last visited Nov. 16, 2011).

¹⁷ These forums have often been noted by legal scholarship. See, e.g., GRAHAM DUTFIELD & UMA SUTHERSANEN, *GLOBAL INTELLECTUAL PROPERTY LAW* 338-45 (2008); Carvalho, *supra* note 8; Drahos, *supra* note 3, at 385-86. Nonetheless, apart from the above-mentioned regimes, there are other U.N. forums that also pay regard to the TK issue, such as the U.N. Conference on Trade and Development (UNCTAD) and the U.N. Food and Agriculture Organization (FAO). See *Introduction, CONVENTION ON BIOLOGICAL DIVERSITY*, *supra* note 5.

¹⁸ As an aside, note that Professor Jessup's notion of transnational law can be fairly applied to TK regulation. PHILIP JESSUP, *TRANSNATIONAL LAW* (1956).

¹⁹ See *infra* Part III.D.

engage in the negotiations regarding common conditions and standard-setting among States with a view to providing either a minimal or basic level of protection or a strict universally applied requirement. In pursuing the latter option, imposing clear obligations upon contracting parties generates a legally binding force that makes the non-compliance of parties a serious matter.²⁰ However, States are usually inclined to resist entering into binding agreements that might deprive them of their discretion over protected matters. Accordingly, States may reach compromise by opting instead for a minimum level of protection in the form of relatively weak guidelines or recommendations.²¹ In spite of the soft law character of these non-binding agreements, empirical studies have underlined their essential role in the international legal system.²²

¶13 In order to strengthen protection measures, international institutions have a wide range of options available to them. First, international institutions can formulate enforcement mechanisms to ensure national implementation of treaty obligations and to enforce compliance through rules governing procedure and remedy. For example, the U.N. Security Council is empowered with very strong enforcement authority by which coercive or non-coercive measures may be taken to redress violations.²³ The compliance system operative in the Montreal Protocol, which regulates compliance with environmental regulations, also represents an effective model.²⁴

¶14 Second, if no binding agreement or solid enforcement mechanism has yet been established, international institutions may avail themselves of non-legally binding resolutions or recommendations to persuade violators to correct their impermissible behavior.²⁵ Ideally, a

²⁰ PATRICIA BIRNIE, ALAN BOYLE & CATHERIN REDGWELL, *INTERNATIONAL LAW & THE ENVIRONMENT* 245-46 (3d ed. 2009).

²¹ See Bonn Guidelines *infra* Part III. A.3.a.

²² For a thorough study on the role of non-binding norms, including an environmental perspective, *See generally* COMMITMENT AND COMPLIANCE: THE ROLE OF NON-BINDING NORMS IN THE INTERNATIONAL LEGAL SYSTEM (Dinah Shelton et al. eds. 2000). Soft law instruments can constitute a dynamic part of the multilateral treaty-making process. ALAN BOYLE & CHRISTINE CHINKIN, *THE MAKING OF INTERNATIONAL LAW* 216-20 (2007).

²³ U.N. Charter arts. 41, 42.

²⁴ The Montreal Protocol on Substances that Deplete the Ozone Layer, Sep. 16, 1987 [hereinafter Montreal Protocol]. In Annex IV of the Montreal Protocol, entitled "Non-compliance Procedure," an Implementation Committee was established in order to supervise the national implementation of the Protocol. According to paragraph 9 of the Annex, the Committee shall report to the Meeting of Parties (MOP) of the Protocol, including any recommendations it considers appropriate. Then, based upon the report, the Parties may decide upon and call for necessary measures to enforce full compliance with the Protocol. In order to avoid controversy and to confine the extent and content of the measures the Parties may take, Annex V of the Protocol sets up a list of available measures in a straightforward manner. Apart from non-coercive and incentive means, in paragraph C of the Annex, suspension of trade is clearly specified. *See also* BIRNIE ET AL., *supra* note 20, at 246-48, 353-54.

²⁵ For instance, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) has not yet built an enforceable compliance mechanism as effective as that of the Montreal Protocol. However, in response to the trade on endangered rhinos and tigers during the mid-1990's, CITES called upon contracting parties to use trade restriction measures against countries that failed to obey its resolutions. Following the non-binding resolutions, the U.S. soon invoked the Pelly Amendment to impose trade sanctions on Taiwan. For a description of the episode, see Christine Crawford, Note, *Conflicts Between the Convention on International Trade in Endangered Species and the GATT in Light of Actions to Halt the Rhinoceros and Tiger Trade*, 7 *GEO. INT'L ENVTL. L. REV.* 555, 560-70 (1995).

dispute settlement mechanism should be established to provide remedies for the breach of obligations. The dispute settlement body of the WTO has been generally considered effective and useful because it adopts compulsory jurisdiction and authorizes sanctions to make effective its adjudications.²⁶

¶15 Apart from the lawmaking process, international institutions often also engage in national capacity building by providing technical and financial support and assisting in national implementation of standards. Of course, international cooperation should be mandated or encouraged, such as informational and technical exchanges and technology transfers.²⁷

¶16 As mentioned, the use of TK frequently involves transnational actions of foreign entities. It is difficult to deny the limits and probable deficiencies of international regulations on TK; “international law based upon the regulation of state behavior is ill-equipped to respond to corporate behavior, or that of other non-state actors.”²⁸ It is uncertain to what extent the making of TK-related international law may progress, and the effectiveness of these tools also remains to be seen.²⁹ Yet certainly the ongoing lawmaking process may provide an impetus for the protection, preservation, and development of TK at the international level.

¶17 The following text will examine the present and ongoing lawmaking activities for TK initiated by a variety of international institutions.

III. HOW DO THE MAJOR INTERNATIONAL INSTITUTIONS RESPOND TO THE PROTECTION OF TRADITIONAL KNOWLEDGE?³⁰

A. *The Convention on Biological Diversity*

1. The Convention on Biological Diversity Context

¶18 Adopted in 1992, the Convention on Biological Diversity (CBD) is one of the most prominent multilateral environmental agreements dealing with the conservation and sustainable use of the earth’s biodiversity.³¹ TK, in a general sense, has played a significant role in

²⁶ See *infra* Part III.C and accompanying text. Cf. BIRNIE ET AL., *supra* note 20, at 250 (noting unsatisfactory resolution of disputes by the WTO mechanism).

²⁷ See generally PHILIPPE SANDS, *PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW* 1037-43 (2d ed. 2003).

²⁸ BOYLE & CHINKIN, *supra* note 22, at 21.

²⁹ Experts have cautioned that treaties on TK may turn out to be ‘dead letters’ if they fail to coordinate the enforcement of existing norms. See Drahos, *supra* note 3, at 386-87.

³⁰ The current status of international legal instruments on the protection of traditional knowledge is elaborated in Annex I, *infra*.

³¹ Apart from the CBD, there are other multilateral environmental agreements relevant to the conservation of wildlife, such as the 1971 Convention on Wetlands of International Importance (Ramsar Convention); the 1972 Convention for the Protection of the World Cultural and Natural Heritage (World Heritage Convention); the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); and the 1979 Convention on the Conservation of Migratory Species of Wild Animals (Bonn Convention). BIRNIE ET AL., *supra* note 20, at 652.

contributing to the conservation and sustainable use of this biodiversity.³² In its preamble, the CBD recognizes indigenous and local peoples' close and traditional dependence on biological resources. In its text, the CBD places the preservation of bio-related TK as one of the contracting parties' obligations under the "In-situ Conservation" of Article 8. Article 8(j) provides that every State Party shall:

Subject to its national legislation, *respect, preserve and maintain* knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and *promote their wider application with the approval and involvement of the holders* of such knowledge, innovations and practices and *encourage the equitable sharing of the benefits* arising from the utilization of such knowledge, innovations and practices.³³

¶19 Thus, State Parties' obligations under Article 8(j) include three aspects. First, each Party is required to preserve TK in its territories. Second, the CBD respects the rights of TK holders to the extent that the utilization of TK is not allowed without the approval of TK holders. Third, any contracting Party to the CBD is expected to formulate a system to ensure that TK holders enjoy the benefits that flow from the utilization of their TK. The first element is derived from a conservation perspective. The latter two mandates are designated to oblige Parties to establish suitable legal regimes upon which the application and benefit-sharing of TK can be fairly managed.

¶20 Irrespective of CBD's resolve to protect TK and its holders, the normative binding force on Parties seems tenuous. The mandate on States under Article 8(j) is "subject to its national legislation," which may result in multiple interpretations and outcomes. One commentator seems not to worry about the problem of this expression, arguing that the usage "was included in order to protect the existing relationships between some States and their indigenous populations, and should not be interpreted as affording each Contracting Party discretion as whether or not to implement the provision."³⁴ Others argue, however, that obligations under Article 8(j) are eviscerated by inserting this phrase; arguably, national law, to some extent, may prevail over the CBD mandate.³⁵ Moreover, opening passage of Article 8 qualifies this "mandate" by including the phrase "as far as possible and as appropriate."

³² See Introduction, CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 5.

³³ CBD, *supra* note 13, art. 8(j).

³⁴ Michael I. Jeffery, *Bioprospecting: Access to Genetic Resources and Benefit-Sharing under the Convention on Biodiversity and the Bonn Guidelines*, 6 SING. J. INT'L & COMP. L. 747, 782 (2002).

³⁵ Aguilar considers the commitment of Art. 8(j) weak, contending that "without national legislation to implement

¶21 In addition to Article 8(j), the CBD includes other provisions related to the protection of TK. Article 10(c), which deals with sustainable use of TK on biodiversity, requires States to “protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.”³⁶ According to the CBD section concerning ‘Exchange of Information,’ indigenous and traditional knowledge is explicitly placed in the category of information to be exchanged.³⁷ On the deployment of techniques to facilitate the fulfillment of the CBD objectives, such as ‘Technical and Scientific Cooperation,’ Article 18 requires parties to engage in cooperation for the development of technologies, which includes the aspect of TK.³⁸ Lastly, it is evident that certain TK has been misappropriated, and then exploited to obtain intellectual property rights. Thus, TK issues should be covered by the CBD’s work to reconcile the protection of intellectual property rights with CBD’s objectives.³⁹

2. The Conference of the Parties and the Working Group on Article 8(j)

¶22 Regardless of CBD provisions that set out lofty goals to protect TK and to promote the interests of TK holders, the treaty’s effectiveness hinges largely on the willingness and ability of States to perform their duties. The Conference of the Parties (COP), as the supreme decision-making body of the CBD, is competent to monitor the implementation of the Convention.⁴⁰ In addition, the COP also plays a significant role in assisting Contracting Parties to carry out their obligations. To fulfill the mandate, the COP shall “[e]stablish such subsidiary bodies, particularly to provide scientific and technical advice, as are deemed necessary for the implementation of this Convention.”⁴¹ At its fourth annual meeting, the COP, in decision IV/9, established an Ad Hoc Open-ended Inter-sessional Working Group to address the implementation of Article 8(j) and related provisions.⁴²

the article, this is merely an expression of goodwill.” Grethel Aguilar, *Access to Genetic Resources and Protection of Traditional Knowledge in Indigenous Territories*, in *TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY* 176 (Christophe Bellmann et al. eds. 2003).

³⁶ CBD, *supra* note 13, art. 10(c).

³⁷ *Id.* art. 17(2).

³⁸ *Id.* art. 18(4). It is argued that the inclusion of TK into the broader range of “technologies” in the CBD means that “there is no justification for assuming (as many tend to do) that such technologies have a lower status than other technologies relevant to the Convention; nor should they be any less morally entitled to legal protection.” GRAHAM DUFIELD, *INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY* 35 (2000).

³⁹ Article 16(5) of the CBD provides, “The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.” CBD, *supra* note 13, art. 16(5).

⁴⁰ CBD, *supra* note 13, art. 23(4).

⁴¹ *Id.* art. 23(4)(g).

⁴² Convention on Biological Diversity, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Fourth Meeting*, Bratislava, Slovakia, May 4-15, 1998, COP Decision IV/9, ¶ 1, U.N. Doc. UNEP/CBD/COP/4/20, Annex 1 (1998), available at <http://www.cbd.int/doc/decisions/COP-04-dec-en.pdf>

¶23 The primary mission of this working group is to provide the COP with advice relating to the implementation of such provisions.⁴³ Based on the structure of the elements proposed in the Madrid workshop report,⁴⁴ the Working Group formulated a programme of work on Article 8(j), which was subsequently adopted at the COP-5 in May 2000.⁴⁵

¶24 The programme of work aims to help Parties fulfill their commitments under Article 8(j) by highlighting a number of elements under which further specific tasks are listed. The programme constitutes a blueprint for the implementation of TK protection within the CBD context. First of all, considering the indispensable role of indigenous peoples and local communities in TK protection, the work programme places the full and effective participation of those groups at all stages and levels of its implementation as its key objective.⁴⁶

¶25 Secondly, the programme initiated the study and survey of status and trends of TK in question. Shortly thereafter, in 2002, an outline of a composite report was endorsed at the COP-6.⁴⁷ In the report, the Working Group was requested to explore the possibility of developing technical guidelines for recording and documenting TK, and to analyze the potential threats posed by documentation to the rights of TK holders.⁴⁸ Further, in order to facilitate and assist Parties and governments in the fulfillment of their commitments under Article 8(j) and related provisions, the Working Group has been assigned to engage in the elaboration of several sets of guidelines.⁴⁹

[hereinafter COP decision IV/9].

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ Convention on Biological Diversity, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Fifth Meeting*, Nairobi, Kenya, May 15-26, 2000, *Programme of Work on the Implementation of Article 8(j) and Related Provisions of the Convention on Biological Diversity*, Annex to COP Decision V/16, U.N. Doc. UNEP/CBD/COP/5/23, Annex III, available at <http://www.cbd.int/doc/decisions/cop-05/full/cop-05-dec-en.pdf> [hereinafter *Programme of Work*].

⁴⁶ *Id.* at 143. The COP has continuously encouraged Parties to include TK holders in their delegations for the Working Group to promote consultations among the groups on issues covered by the Working Group. See COP decision IV/9, *supra* note 42, ¶¶ 3, 4, 12; *Programme of Work*, *supra* note 45, ¶¶ 5, 18. Recently, the COP at its ninth meeting paid more attention on the “participatory mechanisms for indigenous and local communities in the Convention.” The Ninth Meeting of the Conference of the Parties to the Convention on Biological Diversity, *Bonn, Ger.*, May 19-30, 2008, COP Decision IX/13E, at 67-68, U.N. Doc. UNEP/CBD/COP/9/29 (June 30, 2008), available at <http://www.cbd.int/doc/decisions/COP-09-dec-en.pdf>.

⁴⁷ Convention on Biological Diversity, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Sixth Meeting*, The Hague, Neth., Apr. 7-19, 2002, *Outline of a Composite Report on the Status and Trends regarding Knowledge, Innovations and Practices of Indigenous and Local Communities relevant for the Conservation and Sustainable Use of Biological Diversity, and the Plan and Timetable for its Preparation*, Annex I to COP Decision VI/10, UNEP/CBD/COP/6/20, available at <http://www.cbd.int/doc/decisions/cop-06/full/cop-06-dec-en.pdf>.

⁴⁸ Convention on Biological Diversity, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Eighth Meeting*, Curitiba, Braz., Mar. 20-31, 2006, COP Decision VIII/5BI, ¶ 5, U.N. Doc. UNEP/CBD/COP/8/31 (June 15, 2006), available at <http://www.cbd.int/doc/decisions/COP-08-dec-en.pdf>.

⁴⁹ See *Programme of Work*, *supra* note 45, at 145-46, Element 3, Task 6, 13, 14, 15 at 145-46 (including the respect, preservation, and maintenance of TK; efforts to strengthen the use of TK; the establishment of national incentive schemes for indigenous peoples to preserve and maintain their TK and for the application of such TK; and the facilitation of repatriation of TK information).

¶26 Thirdly, with respect to regulations to ensure fair TK access, one of the focal points of the programme has been the development of guidelines to ensure the utilization of TK with the consent of the holders and to ensure they can obtain an equitable share of benefits arising from the utilization.⁵⁰ To effectively protect such interests, the Article 8(j) Working Group's programme emphasizes prevention measures regarding the misappropriation of TK.⁵¹

¶27 In practice, many States have adopted specific laws to implement the programme of work on Article 8(j). For instance, Peruvian law requires that people who are interested in having access to the knowledge must apply for the prior informed consent of TK holders.⁵² In an effort to document TK, Peruvian law also initiates systems of registration of TK.⁵³

¶28 The more recent and prominent progress and achievement of the CBD lawmaking on Article 8(j) are found in the drafting of a text on "elements of a code of ethical conduct," which were finally adopted at COP-10 in 2010.⁵⁴ The elements of the code are designed to provide guidance to assist Parties in building their national legal frameworks to fulfill their commitments on respect, preservation, and maintenance of TK.⁵⁵

¶29 The context of the code elaborates and expands the original TK protection mandate enunciated in Article 8(j). The document manages to cover any activities and interactions with indigenous and local communities that are relevant to the conservation and sustainable use of biological diversity.⁵⁶ Further, regarding the place where the activities are operative, and considering the integral connection between TK and the environment where they traditionally exist, the code specifies that the geographic coverage of protection may extend to sacred sites, culturally significant sites, and lands and waters in which such activities may occur.⁵⁷

⁵⁰ *Id.* at 144, Element 4, Task 7.

⁵¹ *Id.* at 146, Element 6, Task 10.

⁵² Ley N° 27811, art. 6 del 24 de julio de 2002, mediante la cual se establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos (Peru) [Law N° 27811, art. 6. of July 24, 2002] [Law Establishing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources], available at <http://www.wipo.int/wipolex/en/details.jsp?id=3420> [hereinafter Peruvian Law N° 27811].

⁵³ *Id.* arts. 15-24.

⁵⁴ Convention on Biological Diversity, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Tenth Meeting*, Nagoya, Japan, Oct. 18-29, 2010, *The Tkarihwaieri Code of Ethical Conduct on Respect for the Cultural and Intellectual Heritage Indigenous and Local Communities Relevant to the Conservation and Sustainable Use of Biological Diversity*, Annex to COP Decision X/42, at 3, U.N. Doc. UNEP/CBD/COP/DEC/X/42 (Oct. 29, 2010), available at <http://www.cbd.int/doc/decisions/cop-10/cop-10-dec-42-en.pdf> [hereinafter Code of Ethical Conduct]. For a previous draft of the code, see Convention on Biological Diversity, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Ninth Meeting*, Bonn, Ger., May 19-30, 2008, *Draft Elements of A Code of Ethical Conduct to Ensure Respect for the Cultural and Intellectual Heritage Indigenous and Local Communities Relevant to the Conservation and Sustainable Use of Biological Diversity*, Annex to COP Decision IX/13G, at 70, U.N. Doc. UNEP/CBD/COP/9/29 (June 30, 2008), available at <http://www.cbd.int/doc/decisions/COP-09-dec-en.pdf>.

⁵⁵ Code of Ethical Conduct, *supra* note 54, ¶ 3.

⁵⁶ *See id.* ¶ 1 (emphasis added).

⁵⁷ *Id.* ¶¶ 3, 17.

¶30 The major part of the code underlines several ethical principles applicable to the activities and interactions in questions. Some of them tend to confirm the privileges of indigenous peoples, although the passage carefully avoids using terms that indicate group rights. The privileges consist of claims on intellectual property relevant to TK, the right to know (keeping the operation of the activities transparency), the right to give prior informed consent, and the right to claim benefit-sharing.⁵⁸ As the term ‘rights’ has yet to be clearly specified in Article 8(j),⁵⁹ other principles underline the burdens imposed on entities engaging in relevant activities, without producing concrete commitments regarding TK protection.⁶⁰

¶31 More importantly, apart from delivering general ethical principles, the code also provides ‘specific consideration,’ which arguably incorporates human rights aspects under the rubric of TK protection. The approach clearly indicates the attempt to link TK protection to certain indigenous peoples’ human rights which have already been promoted by other instruments of international human rights,⁶¹ such as recognition of rights to lands and waters occupied or used by indigenous peoples, rights to traditional resources, and the right not to be removed.⁶²

¶32 Indeed, the code emphasizes that it “should not be construed as altering or interpreting the obligations of Parties to the Convention . . .”⁶³ Such inclusion appears to be an indication of minimizing the legal effect of the document. Nevertheless, when viewing the document as a whole, its elaboration and amplification of the original mandate of TK protection specified in the wording of Article 8(j) is simply in line with the usual model developed in the lawmaking process of multilateral treaties.⁶⁴

3. Protection of Genetic Resources and the Access and Benefit-Sharing Regime

i) *The Bonn Guidelines’ Device on TK*

¶33 One of the objectives of the CBD aims to ensure the fair and equitable sharing of benefits arising out of the utilization of biodiversity resources,⁶⁵ especially genetic resources.⁶⁶ The goal reflects grave concerns over the protection of genetic resource-providing countries from the

⁵⁸ *Id.* ¶¶ 8, 10, 11, 14. In paragraph 11, the terms “prior informed consent (PIC)” and/or “Approval and Involvement” of TK holders are placed together.

⁵⁹ See BIRNIE ET AL., *supra* note 20, at 627.

⁶⁰ *E.g.*, Code of Ethical Conduct, *supra* note 54, ¶¶ 7, 12, 15.

⁶¹ *Id.* ¶ 17. For instance, ILO 169’s standard and the recent U.N. Declaration touch on the land rights of indigenous peoples and carry similar implications to that of the CBD Code.

⁶² *Id.* ¶¶ 17, 18, 19.

⁶³ *Id.* ¶ 1.

⁶⁴ It is not uncommon that a soft law form of an instrument delivered after a previously concluded treaty may constitute a tool of interpretation for provisions of treaties. See generally BOYLE & CHINKIN, *supra* note 22, at 216-17.

⁶⁵ CBD, *supra* note 13, art. 1.

⁶⁶ CBD defines genetic resources as genetic material of actual or potential value. *Id.* art. 2.

unauthorized, uncompensated activities of bioprospectors, particularly bio-piracy.⁶⁷ Article 15 of the CBD provides the basic elements upon which State Parties may establish their access regimes for genetic resources. This provision first confers upon States sovereign rights over the resources, so that States have the authority to regulate access to their genetic resources.⁶⁸ More importantly, the law requires that any Party wanting such access must obtain Prior and Informed Consent from Parties and also mandates the sharing of benefits arising from authorized genetic resource bioprospecting, which is based upon mutually agreed upon terms.⁶⁹

¶34 Since the inception of the CBD regime, contracting parties have attempted to build the Access and Benefit-Sharing (ABS) regime. Meanwhile, many of them require capacity building and technical support for the construction of their related legal and administrative frameworks. The CBD thus established an Ad Hoc Open-ended Working Group on Access and Benefit Sharing (ABS) in an attempt to facilitate parties' implementation of Article 15 and related provisions.⁷⁰ In 2002, at its sixth meeting, the COP, in decision VI/24, adopted the work prepared by the Working Group in this regard, namely the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization."⁷¹

¶35 Apart from genetic resources, the Guidelines extend the ABS elements to cover associated traditional knowledge, innovations, and practices.⁷² Thus, access to national genetic resource-related TK and its benefit-sharing could be guided by the Bonn instrument.⁷³ Of course, the Bonn Guidelines specify a number of guiding principles for TK in each sector.

¶36 For instance, competent national authorities are expected to provide advice on a "mechanism for the effective participation of indigenous and local communities."⁷⁴ The users of TK should "respect customs, traditions, values, and customary practices of indigenous and local communities."⁷⁵ State Parties, who discover that genetic resource users are under their

⁶⁷ For a description of bio-piracy on bio-resources, see DUTFIELD, *supra* note 8, at 52-59; Jeffery, *supra* note 34, at 757, n.53. For the genetic resources-providing countries' attempt to revoke undesirable patents obtained by bio-piracy, see also Ni, *supra* note 15, at 437-38.

⁶⁸ CBD, *supra* note 13, art. 15(1).

⁶⁹ *Id.* art. 15(5)(7).

⁷⁰ Convention on Biological Diversity, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Fifth Meeting*, Nairobi, Kenya, May 15-26, 2000, Annex III to COP Decision V/26A, at 197, U.N. Doc. UNEP/CBD/COP/5/23, available at <http://www.cbd.int/doc/decisions/COP-05-dec-en.pdf> [hereinafter CBD COP-V decision].

⁷¹ Convention on Biological Diversity, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Sixth Meeting*, The Hague, Neth., Apr. 7-19, 2002, *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*, Annex to COP Decision VI/24A, at 263, U.N. Doc. UNEP/CBD/COP/6/20, available at <http://www.cbd.int/doc/decisions/COP-06-dec-en.pdf> [hereinafter *Bonn Guidelines*].

⁷² *Id.* ¶ 9.

⁷³ Given the relevance of the Bonn Guidelines to the work of the Working Group on Article 8(j), the COP requests the Ad Hoc Open-Ended Working Group on Article 8(j) and Related Provisions to consider the Guidelines as relevant to its ongoing work. See *Bonn Guidelines*, *supra* note 71, at 263.

⁷⁴ *Bonn Guidelines*, *supra* note 71, ¶ 14(g).

⁷⁵ *Id.* ¶ 16(b)(ii).

jurisdiction, “could” consider adopting measures to encourage the disclosure of the origin of TK while applying for intellectual property rights.⁷⁶ In accessing biodiversity-related TK, the prior informed consent of TK holders should be obtained in accordance with their traditional practices, national access policies, and subject to domestic laws.⁷⁷ With regards to the mutually agreed upon terms between users and providers, the Guidelines provide an indicative list of typical terms, including “whether relevant TK has been respected, preserved and maintained, and whether the customary use of biological resources in accordance with traditional practices has been protected and encouraged.”⁷⁸

¶37 The practice of some developing countries hosting TK has been consistent with the Bonn Guidelines. In Brazil, applicants for intellectual property rights must disclose the origin of the genetic material and the associated traditional knowledge.⁷⁹ This is distinct from the Peruvian practice regarding the requirement of prior informed consent mentioned above.

¶38 Although the informative and detailed Guidelines have contributed greatly to the field, the instrument remains a voluntary commitment, rather than a binding obligation.⁸⁰ In effect, the Guidelines give Parties much discretion in managing access to genetic resource-associated TK without undertaking real international obligations.

ii) *The Nagoya Protocol’s Device on TK*

¶39 Responding to the call of the 2002 World Summit on Sustainable Development,⁸¹ the CBD has been engaging in the elaboration and negotiation of an international regime with a view to strengthening the enforcement of ABS requirements under the CBD.⁸² A preliminary draft on the regime was formulated and revealed at the eighth meeting of the COP in 2006.⁸³ According to the draft, the scope of the international regime is in line with the Bonn Guidelines and applies

⁷⁶ *Id.* ¶ 16(d)(ii).

⁷⁷ *Id.* ¶ 31.

⁷⁸ *Id.* ¶ 44(g).

⁷⁹ Provisional Measure No. 2.186-16, art. 31, Braz., Aug. 23, 2001, available at <http://www.grain.org/brl/?docid=850&lawid=1768>.

⁸⁰ *Bonn Guidelines*, *supra* note 71, ¶ 7.

⁸¹ World Summit on Sustainable Development, Aug. 26–Sept. 4, 2002, *Plan of Implementation of the World Summit on Sustainable Development*, ¶ 42(o), adopted in U.N. Doc. A/CONF.199/20, at 139 (Jan. 1, 2002), available at http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf.

⁸² See CBD website, *International Regime on Access and Benefit-Sharing*, <http://www.cbd.int/abs/regime.shtml> (last visited Nov. 16, 2011). For a general overview of the CBD’s lawmaking progress on international regimes see Kuei-Jung Ni, *Legal Aspects of Prior Informed Consent on Access to Genetic Resources: An Analysis of Global and Local Implementation towards an Optimal Normative Construction*, 42 VAND. J. TRANSNAT’L L. 227, 242-50 (2009).

⁸³ Convention on Biological Diversity, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Eighth Meeting*, Curitiba, Brazil, Mar. 20-31, 2006, *International Regime on Access and Benefit-Sharing*, Annex to COP Decision VIII/4A, at 53, U.N. Doc. UNEP/CBD/COP/8/31 (June 15, 2006), available at <http://www.cbd.int/doc/decisions/COP-08-dec-en.pdf>.

both to genetic resources and associated TK. The draft clearly seeks to enforce the interests of TK holders.

¶40 In effect, the 2006 draft proposes to contain measures to ensure compliance with the prior informed consent of TK holders.⁸⁴ The inclusion of measures to prevent misappropriation and unauthorized access and use of TK is also under deliberation.⁸⁵ The draft further requires that Parties take enforcement measures, such as sanctions, to prevent uses of TK that fail to comply with provisions of the international regime.⁸⁶

¶41 At its ninth meeting in 2008, the COP adopted a more detailed agenda on the negotiations of the international regime.⁸⁷ Regarding the protection of TK in the context of the ABS system, the agenda provides components to be negotiated, which fulfill and elaborate the mandate of ABS disclosed in Article 8(j). However, it should be noted that Article 8(j) actually does not use identical terms as those in Article 15 of the CBD.⁸⁸ To expand and apply the ABS regime originating in Article 15 to cover TK protection requires further study and political will. In order to assist the ABS Working Group, the COP decided to establish a group of technical and legal experts on genetic resource-related TK to study and examine relevant issues, such as the definition of associated TK, the applicability of ABS in Article 15 to TK and the legal basis of prior informed consent for TK holders.⁸⁹

¶42 The result of the seventh meeting of the Working Group on ABS reveals more specific elements on TK's ABS device,⁹⁰ which elaborates and amplifies Article 8(j) and the Bonn Guidelines in this regard. It manages to define clearly the rights and obligations of both TK holders and national authorities. The draft tends to promote the status of indigenous and local communities with regard to TK access by confirming their right to be consulted by authorities, including on the matters of prior informed consent, mutually agreed terms in benefit-sharing, and effective participation.⁹¹ To allow them to actively and meaningfully engage, Parties hosting TK

⁸⁴ *Id.* at 134.

⁸⁵ *Id.* at 135.

⁸⁶ *Id.*

⁸⁷ Convention on Biological Diversity, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Ninth Meeting*, Bonn, Ger., May 19-30, 2008, *International Regime*, Annex I to COP Decision IX/12, at 53, U.N. Doc. UNEP/CBD/COP/9/29 (June 30, 2008), available at <http://www.cbd.int/doc/decisions/COP-09-dec-en.pdf> [hereinafter *Biological Diversity Ninth Mtg.*].

⁸⁸ For instance, the CBD prior informed consent requirement of Art. 15 is not specified in Art. 8(j).

⁸⁹ Convention on Biological Diversity, Bonn, Ger., May 19-30, 2008, *Terms of Reference of the Expert Groups Established in Paragraph 11 of Decision IX/12*, Annex IIC to COP Decision IX/12, at 61, U.N. Doc. UNEP/CBD/COP/9/29 (June 30, 2008), available at <http://www.cbd.int/doc/decisions/COP-09-dec-en.pdf>.

⁹⁰ Convention on Biological Diversity, Paris, Fr., Apr. 2-8, 2009, *Report of the Seventh Mtg. of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing*, U.N. Doc. UNEP/CBD/WG-ABS/7/8, Annex, at 21 (May 5, 2009), <http://www.cbd.int/doc/meetings/abs/abswg-07/official/abswg-07-08-en.pdf>.

⁹¹ *Id.* at 31-32.

are required to provide capacity building, to ensure appropriate participation, and to provide assistance in giving prior informed consent and forming mutually agreed terms.⁹²

¶43 At the eighth meeting of the Working Group on ABS, under the insistence and advocacy of genetic resource-rich countries, an agenda to negotiate a binding protocol for the international regime prevailed.⁹³ Meanwhile, more draft texts to uphold the rights of TK holders in ABS continued to be produced.⁹⁴

¶44 At the last ABS working group meeting prior to the COP-10, a revised draft protocol on ABS was then formulated in the form of a treaty.⁹⁵ The draft largely reflects the genuine expectations of indigenous and local communities by requiring TK hosting Parties to grant TK holders the right to prior informed consent and benefit-sharing while genetic resource-related TK is accessed and utilized.⁹⁶ Parties' obligation to support capacity building for TK holders has also been confirmed.⁹⁷ However, some phrases are still subject to deliberation and final approval. Moreover, Parties' obligations, such as those concerning TK access, are to some extent also weakened by the addition of compromising language, such as "with the aim of" and "as appropriate."⁹⁸

¶45 At its tenth meeting, held in Japan in October 2011, the COP eventually adopted the Nagoya Protocol on ABS⁹⁹ to finalize the six years of negotiation for creating an international ABS regime. Most elements concerning TK that were negotiated in the previous drafts have been reflected in the Protocol. As such, the treaty seems to oblige both TK hosting and user countries to ensure that TK holders' rights to benefit-sharing and prior informed consent are enforced. However, the obligatory level of certain items remains deferential. For instance, each Party's obligation to fulfill TK holders' entitlement to share benefits is abated by inserting "as appropriate."¹⁰⁰ Furthermore, with respect to TK access, indigenous groups' exercise of prior informed consent rights must be in accordance with domestic law.¹⁰¹ In other words, Parties'

⁹² *Id.* at 32-33.

⁹³ Convention on Biological Diversity, Montreal, Can., Nov. 9-15, 2009, *Report of the Eighth Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing*, ¶¶ 32, 49, U.N. Doc. UNEP/CBD/WG-ABS/8/8 (Nov. 20, 2009), <http://www.cbd.int/doc/meetings/abs/abswg-08/official/abswg-08-08-en.pdf>.

⁹⁴ *Id.* Annex I.

⁹⁵ Convention on Biological Diversity, Cali, Colom, Mar. 22-28, 2010, *The Ninth Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing*, U.N. Doc. UNEP/CBD/WG-ABS/9/CRP.1, Annex I (Mar. 25, 2009).

⁹⁶ *Id.* art. 4, ¶ 4; art. 5.

⁹⁷ *Id.* art. 9, ¶ 3 (Parties are required to support the development of community protocols, minimum requirements and model contractual clauses on ABS); art. 18, ¶ 3.

⁹⁸ *Id.* art. 4, ¶ 4; art. 5.

⁹⁹ Convention on Biological Diversity, Nagoya, Japan, Oct. 18-29, 2010, *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity*, COP Decision X/1, U.N. Doc. UNEP/CBD/COP/DEC/X/1, Annex I, at 5 (Oct. 29, 2010), available at <http://www.cbd.int/doc/decisions/COP-10-dec-en.pdf> [hereinafter Nagoya Protocol].

¹⁰⁰ *Id.* art. 5(5).

¹⁰¹ *Id.* art. 7.

obligation to enforce prior informed consent rights of TK holders hinges on whether domestic law affirms such a right. Without such domestic law, no Party would be held responsible for treaty violation. Such an arrangement indicates the unwillingness of Parties, at the current stage, to allow the new treaty to change their national level of protection for TK holders.

¶46 The Nagoya Protocol will remain open for signature by Parties to the Convention from February 2, 2011 until February 1, 2012, at the United Nations Headquarters in New York. Because the Protocol is still in the signature stage, it remains to be seen how many countries ultimately ratify the protocol and what effect it will have on international TK protection. What is clear is that, without changes in domestic law, the Protocol has not yet established a strong mandate to require Parties to observe ABS elements for TK holders below the international level.

4. Reflection and Comments on the CBD's Progress

¶47 Presently, it may be safe to say that the CBD is the most dynamic international legal system for promoting the protection of TK, although its mandate is confined to the context of biodiversity-related areas. In effect, the regime constitutes one of the most significant international institutions that pay due regard to TK holders. While no precise and definite obligations of Parties are specified in Article 8(j) of the CBD in terms of TK preservation, it remains to be seen how nations may seriously implement Article 8(j) in its broader sense. Nonetheless, while recognizing the indispensable role of TK holders in the fulfillment of the mandate of Article 8(j), the CBD's continuous efforts to make indigenous peoples and local communities involved in relevant lawmaking and deliberation processes cannot be underestimated.¹⁰²

¶48 The CBD has finished a preliminary study and survey on the status of TK and proposed certain means for its preservation, such as documentation of TK. Currently, at least one soft law character of guidance in assisting implementation has been formulated and adopted.¹⁰³

¶49 Indeed, the current work of guidelines and principles is not of a binding nature, but is instead voluntary. Nonetheless, as observed, some international soft law instruments do go beyond the status of a simply non-binding force and may be transformed into binding form while having dynamic interaction with related treaty regimes.¹⁰⁴ It would thus be premature to predict how far the Working Group's efforts on Article 8(j) may go in terms of influencing national TK

¹⁰² It is submitted that the CBD "will provide the forum within which such communities can participate and thus influence the parties when developing policies, guidelines or protocols impinging upon their interests..." BIRNIE ET AL., *supra* note 20, at 628.

¹⁰³ Code of Ethical Conduct, *supra* note 54.

¹⁰⁴ For an explanation on how soft law instruments interact with treaty regimes and how the law goes beyond non-binding force, *see generally* BOYLE & CHINKIN, *supra* note 22, at 216.

policy. However, it should be noted that, as mentioned above, some developing countries have already begun implementing such instruments.

¶50 The attempt to formulate a code of ethical conduct is an indication of the CBD's broader perspective on TK protection, which is not limited to the knowledge itself, but manages to extend to the geographic and ecological environment where TK originates and develops. The move should be justifiable and desirable given the close and inalienable linkage between them. In particular, the incorporation of a human rights approach for TK protection could further the legal status of TK holders and safeguard TK from undesirable activities. Thus, in contrast to some observations,¹⁰⁵ the progress of TK working groups has actually moved towards the clarification of the rights of TK holders, in spite of its voluntary nature.

¶51 Apart from calling for the submission of national reports regarding Parties' implementation, the CBD on Article 8(j) makes little progress with respect to monitoring mechanisms. Given the weak commitments imposed on Parties in this regard, at the current stage it would be politically infeasible to incorporate any compliance mechanism from the perspective of TK preservation into the CBD framework. Nevertheless, despite lacking real teeth, the CBD COP/Working Group on Article 8(j) can regularly keep Parties informed of the significance of TK protection by signaling international concern at all levels of the CBD forums.

¶52 On the other hand, relatively visible progress has been made concerning the ABS mechanism that has covered bio-related TK, evidenced in the Bonn Guidelines and the newly adopted Nagoya Protocol on ABS. As indicated above, the soft law character of the Bonn Guidelines may weaken their effectiveness. Attempts to establish an ABS treaty regime do demonstrate the CBD's resolve to enforce one of its objectives on a global basis. In terms of obliging Parties to protect TK in the context of ABS, the eventual establishment of the Nagoya Protocol may be a repetition of an episode on how a soft approach of the Bonn Guidelines can be transformed into a more consolidated form.¹⁰⁶ The new treaty does expand the realm of ABS to include TK protection. As indicated above, however, the Parties' commitment on international level remains uncertain due to the wide margin of national discretion. Thus, in spite of its legally binding form, it remains to be observed whether and to what extent the newly developed ABS treaty regime, in the form of the Nagoya Protocol, may make substantial contribution to TK enforcement after its inception.¹⁰⁷

¹⁰⁵ Some scholars are not convinced that presently "the COP will provide the vehicle for further clarification of indigenous and local communities' rights." BIRNIE ET AL., *supra* note 20, at 628.

¹⁰⁶ For instance, the binding form of non-compliance procedure set in the Montreal Protocol is preceded by a non-binding resolution. *See* BOYLE & CHINKIN, *supra* note 22, at 218.

¹⁰⁷ According to Art. 30 of the Nagoya Protocol, the meeting of the Parties to this Protocol would adopt procedures and mechanisms to promote compliance with the Protocol. Nagoya Protocol, *supra* note 99, art. 30.

¶53 Furthermore, irrespective of its non-intellectual property rights treaty nature, the CBD appears to call on other intellectual property rights-related international institutions, such as the WIPO and WTO, to pay due regard to the protection of biodiversity-related TK in terms of property rights.¹⁰⁸ Particularly in light of this push for multilateral approaches to TK protection, the CBD has become pivotal in initiating and promoting TK protection amongst relevant international legal regimes.

B. The World Intellectual Property Organization

1. Background

¶54 The World Intellectual Property Organization (WIPO), a subsidiary organ of the United Nations that supervises global intellectual property treaties, appears to be relatively attentive to the grave concern of the CBD regarding the impact of intellectual property rights on the implementation of the access and benefit-sharing (ABS) system. At its sixth meeting, the COP to the CBD in 2002 adopted a decision on the “Role of intellectual property rights in the implementation of access and benefit-sharing arrangements.”¹⁰⁹ With respect to the issue of TK protection, Parties are invited to encourage the disclosure of the origin of bio-related TK. The COP has signaled that TK-related intellectual property rights fall under the competence of other international institutions, such as the WIPO. It thus invited WIPO to prepare a technical study on disclosure requirements of associated TK and its sources, where they are utilized in the development of the claimed inventions.¹¹⁰ The WIPO was also encouraged Parties to consider means by which they could collaborate to protect TK.¹¹¹

¶55 In 2000, in response to the increasing global concern over the impact of intellectual property rights on the protection of genetic resources, TK, and traditional cultural expressions, WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Since then, especially with the CBD’s urging, the IGC has been conducting a substantial and comprehensive study on the legal and policy options for the protection of TK.¹¹² The task involves “analyses of existing national and

¹⁰⁸ See notes 105-07 *infra* and accompanying text. CBD/COP Decision X/1, I: Adoption of the Nagoya Protocol, ¶ 6, at 3.

¹⁰⁹ Convention on Biological Diversity, The Hague, Apr. 7-19, 2002, *Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Sixth Meeting*, U.N. Doc. UNEP/CBD/COP/6/20, Annex I, at 284, available at <http://www.cbd.int/doc/decisions/COP-06-dec-en.pdf>.

¹¹⁰ *Id.* ¶ 4.

¹¹¹ *Id.* ¶ 10.

¹¹² The Protection of Traditional Knowledge: Revised Objectives and Principles, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Ninth Sess., Apr. 24-28, 2006, WIPO/GRTKF/IC/9/5, ¶ 1 (Jan. 9, 2006) [hereinafter IGC Ninth Sess. Doc.]. IGC reviewed then existing *sui generis* TK laws during its fifth session in July 2003. See WIPO/GRTKF/IC/5/INF/4, WIPO/GRTKF/IC/5/INF/6 and WIPO/GRTKF/IC/5/INF/7.

regional legal mechanisms, certain core elements of TK protection, cases studies, ongoing surveys of international policy and law as well as certain previously supported key principles and objectives of TK protection.”¹¹³

¶56 From an intellectual property perspective, the WIPO considers TK protection as comprising both defensive and proactive approaches.¹¹⁴ After an extensive review on legal and policy options, the IGC, at its eighth session in 2005, finalized a document, entitled “Draft Provisions for the Protection of Traditional Knowledge: Policy Objectives and Core Principles.”¹¹⁵ Instead of creating positive rights for TK holders, the instrument is confined to deterring the illicit uses and misappropriations of TK.¹¹⁶ The draft includes three parts: Policy Objectives, Guiding Principles and Substantive Provisions.

2. The Implications of the Draft Objectives and Principles on TK Protection

i) *Overview*

¶57 The Policy Objectives underline “common general directions for [TK] protection and provide a consistent policy framework.”¹¹⁷ Despite its presumed status of a preamble¹¹⁸ that normally lacks definite legal configuration, this sector delivers significant messages on TK protection. The value of TK recognized in the task appears to be fairly extensive and holistic.¹¹⁹ More importantly, the Policy Objectives indicate the goal of recognizing and promoting the status of TK holders, which makes the WIPO work one of the most attentive international instruments for the interest of TK holders. Furthermore, given that the ABS initialed by the CBD has been considered to be an effective tool against the illicit use of genetic resources and associated knowledge, the Policy Objectives are intended to incorporate the CBD mandates into its text, such as prior informed consent and benefit-sharing.¹²⁰ To deter the erroneous grant of intellectual property rights over TK to unauthorized parties, the Objectives expect patent

¹¹³ IGC Ninth Sess. Doc., *supra* note 112, ¶ 1.

¹¹⁴ World Intellectual Property Organization, Traditional Knowledge, <http://www.wipo.int/tk/en/tk> (last visited Nov. 3, 2011).

¹¹⁵ See WIPO DRAFT, *TK Objectives and Principles*, *supra* note 2.

¹¹⁶ IGC Ninth Sess. Doc., *supra* note 112, ¶ 5; Reproduction of Doc. WIPO/GRTKF/IC/9/5 “The Protection of Traditional Knowledge: Revised Objectives and Principles,” Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Twelfth Sess., Feb. 25-29, 2008, ¶ 18, WIPO/GRTKF/IC/12/5(c) (Dec. 6, 2007) [hereinafter IGC Twelfth Sess. Doc.]; In the earlier sessions of IGC, discussion focused more on defensive protection with a view toward the prevention of illegal granting of intellectual property rights, which covered the proposal on disclosure of origin of TK. See DUTFIELD & SUTHERSANEN, *supra* note 17, at 342.

¹¹⁷ IGC Ninth Sess. Doc., *supra* note 112, ¶ 4(i).

¹¹⁸ IGC Eighth Sess. Doc., *supra* note 2, Annex, at 6.

¹¹⁹ *Id.* at 3.

¹²⁰ *Id.* at 4.

applicants to disclose the country of origin of TK, as well as the evidence of compliance with prior informed consent and benefit-sharing arrangements required by the country of origin.¹²¹

¶158 General Guiding Principles are designed to “ensure that the substantive provisions concerning protection are equitable, balanced, effective and consistent, and appropriately promote the objectives of protection.”¹²²

¶159 Several Guiding Principles do invoke a mandate to address the needs and rights of TK holders.¹²³ Also, certain elements of ABS have been confirmed as part of the Principles.¹²⁴ The inclusion of the ABS elements simply reflects the harmonization with the CBD mandate that confers national authority to regulate the matter in this regard.¹²⁵ In particular, the Principles declare that the rights of TK holders should be recognized and respected. While the CBD has not yet endorsed the “rights” of TK holders, the WIPO’s design represents remarkable progress in this direction. Nevertheless, according to the commentary on the Principles, such rights would not be on a comprehensive basis. Rather, the rights seem to be narrowed to a defensive nature, which are applied only to the protection against misappropriation.¹²⁶ The principle of recognizing the specific characteristics of TK (traditional, collective or communal, inter-generational and constantly evolving) is specified.¹²⁷ The capacity building for TK holders is of grave concern to the WIPO task.¹²⁸

ii) *Legal Framework*

¶160 Arguably the most important contribution of the draft to TK protection is the formation of a set of substantive provisions that are largely legal in nature. The draft provisions consist of fourteen articles that constitute a systematic legal framework for the protection of TK.

¶161 As mentioned, it is not the intention of the IGC to adopt a positive-rights approach toward TK protection. Thus, no exclusive or monopolistic property rights are created for TK.¹²⁹ Article 1 explicitly declares that the protection is limited to rights against misappropriation or misuse. Respecting existing national legal systems concerning TK protection, Article 2 gives nations much discretion and flexibility regarding the legal form of protection.¹³⁰

¹²¹ *Id.* at 4-5.

¹²² *Id.* at 8.

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.* at 10-11.

¹²⁶ *Id.* at 9. *See also* the discussion of Peruvian legislation, *infra* note 147 and accompanying text, for an example of how prior informed consent and benefit sharing should be implemented to prevent misappropriation.

¹²⁷ *Id.* at 11.

¹²⁸ *Id.*

¹²⁹ *Id.* at 14.

¹³⁰ *Id.* at 17.

¶62 Articles 3 to 5 tend to clarify the realm of both TK and its holders. Given the diverse definitions and scope of TK in national legal systems, Article 3, titled “General Scope of Subject Matter,” “does not seek to apply one singular and exhaustive definition” of TK.¹³¹ Rather, it simply underlines a general description and then an illustrative list of elements within the scope of TK.¹³² “Eligibility for the protection,” specified in Article 4, manages to propose what qualities TK should have, mainly: (i) a traditional, intergenerational character; (ii) a distinctive association with its traditional holders; and (iii) a sense of linkage with the identity of the TK holding community.¹³³ Article 5 defines which TK holders are entitled to such protection. The beneficiaries comprise the indigenous and traditional communities that generate, preserve and transmit the knowledge, or individuals within these communities and peoples.¹³⁴

¶63 Articles 6 and 7 incorporate the mandate of ABS that has been adopted and implemented within the CBD and many national regimes.¹³⁵ Article 8 provides exceptions and limitations to the TK protection with a view to reconciling with public interests and policy.¹³⁶ In contrast to general intellectual property rights setting the duration of protection, Article 9 considers TK protection should last as long as the TK meets the criteria of eligibility for protection defined in Article 4.¹³⁷ Article 10 deals with transitional measures, which give fair treatment to third parties who acquired TK in good faith before the implementation of the protection measures.¹³⁸ According to Article 11, the formalities of protection are not required. Countries are allowed to maintain a system of TK registers. Yet, the system should not prejudice undisclosed TK or the interests of TK holders.¹³⁹ Article 12, titled “Consistency with the General Legal Framework,” requires that access to bio-diversity related knowledge be consistent with national laws governing the matter.¹⁴⁰

¶64 Article 13 mainly provides the content of competency for each national authority in order to assist the administration and enforcement of such protection.¹⁴¹ The provision also mandates that enforcement mechanisms “should be fair and equitable, [and] should be accessible[,] [a]ppropriate and not burdensome for holders of traditional knowledge, and should provide safeguards for legitimate third party interest and the public interest.”¹⁴²

¹³¹ *Id.* at 20.

¹³² *Id.*

¹³³ *Id.* at 22-23.

¹³⁴ *Id.* at 24.

¹³⁵ *Id.* at 27-32.

¹³⁶ *Id.* at 33-34.

¹³⁷ *Id.* at 35-36.

¹³⁸ *Id.* at 37-38.

¹³⁹ *Id.* at 39-40.

¹⁴⁰ *Id.* at 41-42.

¹⁴¹ *Id.* at 44-45.

¹⁴² *Id.* at 44.

¶165 In terms of the status of national TK holders in foreign countries, Article 14 on international and regional protection adopts the principle of national treatment. Consequently, foreign TK holders enjoy no fewer benefits than those who are nationals of the country offering protection.¹⁴³

3. An Assessment of the WIPO Task

¶166 It may be fair to contend that the current WIPO/IGC draft is the most systematic international instrument for TK protection, at least in terms of IP protection. It not only provides lofty objectives and principles, but also a definite and well-structured legal foundation. If widely accepted and implemented, it would to a certain degree promote TK protection on a global basis and advance the rights and interests of TK holders as well. Not surprisingly, the WIPO has been considered to be the appropriate forum for formulating relevant rules on TK protection.¹⁴⁴

¶167 Although the IGC work has not yet been finalized, the influence of the draft over international legislative progress cannot be underestimated. Indeed, several regional and national processes have availed themselves of the draft WIPO provisions in developing and designing their TK protection measures.¹⁴⁵

¶168 In spite of the above accomplishment, it should be noted that the TK protection provided by the draft instrument is a defensive mechanism in that it only applies to action against misappropriation of TK.¹⁴⁶ With respect to national practice, the Peruvian legislation represents the leading practice of allowing TK holders, *inter alia*, to enjoy the right of protection against unauthorized use, which echoes the WIPO's approach.¹⁴⁷

¶169 Further, certain deficiencies embodied in the WIPO work are evident. These provisions, irrespective of WIPO's well-organized structure, fall short of crystalline obligations upon States given that the WIPO avoids using the term "shall" as much as possible.¹⁴⁸ As a result, no definite and strong commitments are established for States, and they still can maintain extensive discretion and latitude in regulating TK protection. More importantly, the final form and status of

¹⁴³ *Id.* at 47-49.

¹⁴⁴ Weerawit Weeraworawit, *International Legal Protection for Genetic Resources, Traditional Knowledge and Folklore: Challenges for the Intellectual Property System*, in *TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY* 157, 164-65 (Christophe Bellmann et al. eds. 2003).

¹⁴⁵ IGC Twelfth Sess. Doc., *supra* note 116, ¶¶ 33-35 (pointing out how the CBD, Mongolia, the African Regional Intellectual Property Organization and the South Asian Association for Regional Cooperation have used part of the draft as a reference to develop their agendas).

¹⁴⁶ *E.g.* DUTFIELD & SUTHERSANEN, *supra* note 17, at 349-51.

¹⁴⁷ Peruvian Law N° 27811, *supra* note 52, arts. 42, 43. It should be noted that the WIPO document would not prevent States from adopting a more positive approach for TK protection. Actually, positive protection had been discussed at the WIPO forum. See DUTFIELD & SUTHERSANEN, *supra* note 17, at 338-39.

¹⁴⁸ The term 'shall' is rarely applied. Arts. 1 and 9(2) are the only two instances; the wording 'should' or 'may' is frequently used instead.

the document has not yet been settled.¹⁴⁹ It is observed that most WIPO members, either developed or developing nations, now lack strong political will and momentum to take the task in a serious manner.¹⁵⁰ Accordingly, there is a high possibility that the instrument may turn out to be similar to the voluntary Bonn Guidelines.

¶70 Of course, the IGC will continue to seek international consensus on TK protection with a view to setting up a minimum standard. Even if the text may result in a binding instrument, the inherent flaw of the WIPO that weakens its effectiveness, is the lack of a decent enforcement mechanism.¹⁵¹

C. *The WTO/TRIPS*

¶71 The international protection of intellectual property rights should fall under the competence of the WIPO. However, unsatisfied with the poor enforcement mechanism of the WIPO, developed countries proposed an intellectual property rights agenda under the Uruguay Round of Multilateral Trade Negotiations between 1986 and 1994. The final conclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) within the WTO regime represents the triumph of developed countries, led by the United States (U.S.), which had long appealed for an effective and universal enforcement of intellectual property rights protection.¹⁵² Since then, the WTO has acquired parallel competence over intellectual property rights protection, irrespective of the existence of the WIPO.

¶72 The present TRIPS context does not cover TK protection.¹⁵³ TK draws the attention of the WTO as a result of the CBD's call for relevant international organizations, including the WTO, to be aware about the impact of intellectual property rights policy on access and benefit-sharing of genetic resources and associated knowledge.¹⁵⁴ Developing countries have especially sensed the gravity of the piracy and misappropriation of bio-diversity related TK, mostly occurring in their territories.¹⁵⁵ Since 1999, the TRIPS Council has accordingly begun to debate and review the interrelationship between the TRIPS and the CBD.¹⁵⁶

¹⁴⁹ IGC Ninth Sess. Doc., *supra* note 112, ¶ 14 (outlining five possible options of binding or non-binding arrangements. The latter covers declaration, recommendation, or guidelines).

¹⁵⁰ DUTFIELD & SUTHERSANEN, *supra* note 17, at 343.

¹⁵¹ See MICHAEL J. TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE* 409 (3d ed. 2005).

¹⁵² *Id.* at 409-10.

¹⁵³ See DUTFIELD & SUTHERSANEN, *supra* note 17, at 344; Jakkrit Kuanpoth, *Intellectual Property Protection after TRIPS: An Asian Experience*, in *INTERPRETING AND IMPLEMENTING THE TRIPS AGREEMENT: IS IT FAIR?* 71, 78 (Justin Malbon & Charles Lawson eds. 2008).

¹⁵⁴ CBD, *supra* note 13, decision V/16, ¶ 14; V/26 B, ¶ 2 (inviting the WTO alike to deal with the relationship between TRIPS and CBD).

¹⁵⁵ UNCTAD-ICTSD, *RESOURCE BOOK ON TRIPS AND DEVELOPMENT* 398 (2005).

¹⁵⁶ See generally Sabrina Shaw and Risa Schwartz, *Trade and Environment in the WTO: State of Play*, 36 J. WORLD TRADE 129, 138-39 (2002).

¶73 At its fourth Ministerial Conference held in Doha in November 2001, the WTO adopted the Doha Development Agenda,¹⁵⁷ in which the issue of TRIPS' relation with the CBD (including TK) continued to be included in the WTO new round negotiations. Paragraph 19 of the Doha Development Agenda provides:

We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to *examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore*, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by *the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension*.¹⁵⁸

Initially there had been different views on whether the WTO is the right forum for TK negotiations. Developed countries had insisted that the WIPO/IGC is the more suitable forum. In contrast, developing countries support the protection of TK through negotiations at the WTO, partly due to the insufficient enforcement power of the WIPO.¹⁵⁹ Currently, however, the WTO has made no progress on positive TK protection.¹⁶⁰

¶74 TK protection, however, has been negotiated under the context of the TRIPS-CBD relationship since 2002. The central deliberations in the TRIPS Council have focused on the proposals of many bio-resource-rich developing countries regarding the disclosure of origin, which has also been a focal debate at the CBD and WIPO.¹⁶¹ They appeal the revision of the TRIPS Agreement to add further disclosure obligations. The proposed amendment requires that patent applicants shall provide, as a condition to acquiring patent rights, the following evidence:

¹⁵⁷ The World Trade Organization, Ministerial Declaration of 14 November 2001, The Fourth Ministerial Conference, Doha, Nov. 9-14, 2001, The Doha Development Agenda, WTO Doc. WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

¹⁵⁸ *Id.* ¶ 19.

¹⁵⁹ See generally UNCTAD-ICTSD, *supra* note 155, at 399.

¹⁶⁰ Some are skeptical of the appropriateness of the WTO/TRIPS establishing new norms on positive TK protection. DUTFIELD & SUTHERSANEN, *supra* note 17, at 345. See also Daniel Gervais, *Traditional Knowledge and Intellectual Property: A TRIPS-Compatible Approach*, 2005 MICH. ST. L. REV. 137, 149-59 (2005) (discussing whether these proposed norms are adequate to deal with communally-held TK).

¹⁶¹ DUTFIELD & SUTHERSANEN, *supra* note 17, at 342, 344.

- (i) disclosure of the source and country of origin of the biological resource and of the *traditional knowledge* used in the invention;
- (ii) evidence of prior informed consent through approval of authorities under the relevant national regime; and
- (iii) evidence of fair and equitable benefit-sharing under the relevant national regime.¹⁶²

Developing countries contend that the disclosure requirements, if made mandatory, would be useful to deter the undesirable grant of patents for inventions that misappropriate or illicitly acquire bio-resources or associated TK.¹⁶³ Further, such revision aims to ensure that TRIPS is implemented in a manner supportive of the CBD objectives.¹⁶⁴

¶75 Nonetheless, the proposal has met the strong opposition of some developed members. For example, the U.S. consistently objects to the amendment. The U.S. argues that the requirement would create an unnecessary burden upon national patent authorities,¹⁶⁵ and that the more effective means to curb bio-piracy is through solid enforcement of national ABS laws and contract arrangements.¹⁶⁶ Switzerland, although sympathetic to the concern raised by developing countries, proposes the amendment of the WIPO Patent Cooperation Treaty as an alternative.¹⁶⁷

¶76 Since the release of the disclosure proposal, both groups have been engaging in a very heated debate.¹⁶⁸ Given the significant controversy of the amendment and the persistent opposition by developed world, especially the U.S., there seems to be no sign that the stalemate will be solved in the near future or that the disclosure revision will reach consensus among WTO members.¹⁶⁹

¹⁶² Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela, *The Relationship between the TRIPS Agreement and The Convention on Biological Diversity and the Protection of Traditional Knowledge*, WTO Doc. IP/C/W/403, ¶ 1 (June 24, 2003) [hereinafter Developing Countries, IP/C/W/403] (emphasis in original), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

¹⁶³ *Id.* ¶ 8.

¹⁶⁴ *Id.* ¶ 3.

¹⁶⁵ Communication from the United States, *Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, WTO Doc. IP/C/W/434, ¶ 15 (Nov. 26, 2004).

¹⁶⁶ Communication from the United States, *Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, WTO Doc. IP/C/W/449, ¶¶ 19-21, 26, 39, 41 (June 10, 2005).

¹⁶⁷ Communication from Switzerland, *Review of Article 27.3(b), the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge*, WTO Doc. IP/C/W/400/Rev.1 (June 18, 2003).

¹⁶⁸ Developing countries are represented by Brazil and India. The U.S. continues to play the major role in opposition to the proposal. See generally Ni, *supra* note 15, at 449-52, 53.

¹⁶⁹ In order to reach a compromise, Ni suggests that such a disclosure requirement could be of a discretionary instead of compulsory nature for WTO members. In effect, the discretion allows nations to decide whether patent applicants are required to submit necessary information in this regard. While many developing countries have linked the grant of patents to the compliance with their ABS laws, this approach ensures the consistency of such national laws with TRIPS. Ni, *supra* note 15, at 457-58.

¶77 If the developing countries' proposal succeeds, the amendment would become obligatory upon each WTO member, and national relevant IP laws must be revised accordingly. The implementation of the mandate would be under the supervision of the TRIPS Council. The non-compliance of the presumed obligations would be subject to the WTO dispute settlement mechanism that provides a relatively effective procedure.¹⁷⁰ Were such an amendment to pass, TRIPS would mandate compulsory disclosure of TK origin and it would allow TK-hosting-countries who are WTO members to sue countries like the U.S. (also a WTO member) if U.S. agents (such as the U.S. Patent and Trademark Office) fail to require intellectual property rights applicants to disclose the information. This would be a dispute between WTO members instead of between indigenous groups and States. Of course, the local groups may pressure their hosting countries to resort to the WTO dispute settlement mechanism. Therefore, not surprisingly, developing countries are convinced that the WTO is the appropriate forum to effectively solve the problem of the misappropriation of bioresources and related knowledge.

D. The U.N. Declaration on the Rights of Indigenous Peoples:¹⁷¹ The Protection of TK Holders from a Human Rights Perspective

¶78 Most TK holders are from indigenous communities. As TK holders constitute the most important stakeholder in the context of TK protection, their TK rights should be fairly protected and recognized.

¶79 The promotion and recognition of indigenous peoples' rights have become important international issues. In addition to the efforts of the International Labor Organization (ILO),¹⁷² the U.N., during the past several decades, has engaged in lawmaking to protect the rights of indigenous peoples in many fora. For example, the discussion of issues pertaining to indigenous peoples was initiated by the Sub-Commission on the Prevention of Discrimination and Protection of Minorities under the Human Rights Commission of the Economic and Social Council of the U.N. However, a serious deliberation of protecting indigenous peoples' rights had not taken

¹⁷⁰ See generally MITSUO MATSUSHITA ET AL., *THE WORLD TRADE ORGANIZATION: LAW, PRACTICE, AND POLICY* 103-39 (2d ed. 2006). Disputes between WTO members are governed by "Understanding on Rules and Procedures Governing the Settlement of Disputes," of which Art. 23 is to be interpreted to grant the WTO exclusive jurisdiction over disputes among members. JOHN H. JACKSON, *THE WORLD TRADING SYSTEM: LAW AND POLICY OF INTERNATIONAL ECONOMIC RELATIONS* 124 (2d ed. 1999).

¹⁷¹ In addition to the U.N. lawmaking for the rights of indigenous peoples, the International Labor Organization (ILO) had concluded two conventions for the protection of indigenous peoples: the 1957 Convention No. 107 and the 1989 Convention No. 169. However, these treaties have not been widely ratified by countries with indigenous populations. See BIRNIE ET AL., *supra* note 20, at 626.

¹⁷² Convention Concerning Indigenous and Tribal Peoples in Independent Countries (I.L.O. No. 169), June 27, 1989, 28 I. L.M.S 1382 [hereinafter ILO Convention No. 169].

place until the creation of the Working Group on Indigenous Populations, a sub-organ under the Sub-Commission, in 1982.¹⁷³

¶180 The mandate of the Working Group aims to: (i) annually review recent developments pertaining to the promotion and protection of human rights and fundamental freedoms of indigenous peoples, and (ii) develop international standards regarding the human rights of indigenous peoples.¹⁷⁴ Following a resolution of the Sub-Commission stating that a special instrument, in the form of a declaration, was needed, the Working Group first formulated certain generally agreed-upon principles. Over time, it eventually completed the draft Universal Declaration on the Rights of Indigenous Peoples in 1993.¹⁷⁵

¶181 In accordance with a resolution of the Commission on Human Rights,¹⁷⁶ the draft had been further developed during eleven sessions between 1995 and 2006. The newly established Human Rights Council finally approved the United Nations Declaration on the Rights of Indigenous Peoples on June 29, 2006¹⁷⁷ and recommended it to the General Assembly for adoption. Given the opposition by countries with large indigenous peoples to the declaration,¹⁷⁸ the Third Committee of the General Assembly in November of 2006 voted to defer further action on the declaration.¹⁷⁹ Eventually, the U.N. General Assembly adopted the Declaration on September 13, 2007.¹⁸⁰

¶182 The U.N. instrument contains several provisions upholding the rights of indigenous peoples on TK. Article 11 recognizes the rights of the peoples to maintain, protect and develop the past, present, and future manifestations of their cultures.¹⁸¹ With respect to the remedy for misappropriation of their cultural, intellectual, religious and spiritual property, States are

¹⁷³ See XANTHAKI, *supra* note 8, at 102-03.

¹⁷⁴ E.S.C. Res. 1982/34, 1st Regular Sess., U.N. Doc. E/1982/82, at 26-27 (May 7, 1982).

¹⁷⁵ E.S.C. Rep. of the Sub-Commission on Prevention of Discrimination and Protection of Minorities on Its Forty-Sixth Sess., Aug. 1-26, 1994, at 103-04, U.N. Doc. E/CN.4/1995/2, E/CN.4/Sub.2/1994/56 (Oct. 28, 1994).

¹⁷⁶ Commission on Human Rights Res. 1995/32, 51st Sess., E/CN.4/RES/1995/32 (Mar. 3, 1995).

¹⁷⁷ Human Rights Council Res. 2006/2 (June 29, 2006), Working group of the Commission on Human Rights to elaborate a draft declaration in accordance with paragraph 5 of the General Assembly resolution 49/214 of 23 December 1994, U.N. GAOR, 11th Sess., A/HRC/RES/2006/2 (June 29, 2006), <http://www.gcc.ca/pdf/INT000000021.pdf>. Adopted by a recorded vote of 30 votes to 2, with 12 abstentions. See *Declaration on the Rights of Indigenous Peoples*, OFFICE OF THE U.N. HIGH COMMISSIONERS FOR HUMAN RIGHTS <http://www2.ohchr.org/english/issues/indigenous/declaration.htm> (last visited Nov. 6, 2011).

¹⁷⁸ The U.S. then joined Australia and New Zealand to strongly criticize the declaration. *Contemporary Practice of the United States Relating to International Law*, 101 AM J. INT'L L. 212 (2007).

¹⁷⁹ Press Release, Third Committee, Third Committee Approves Draft Resolution on Right to Development; Votes to Defer Action Concerning Declaration on Indigenous Peoples, U.N. Doc. GA/SHC/3878 (Nov. 28, 2006), <http://www.un.org/News/Press/docs/2006/gashc3878.doc.htm> (last visited May 10, 2007).

¹⁸⁰ See U.N. Declaration, *supra* note 16.

¹⁸¹ *Id.* art. 11(1).

required to provide an effective mechanism.¹⁸² This mandate coincides with the WIPO's TK instrument, which focuses on legal protection against misappropriation.¹⁸³

¶83 More importantly, Article 31 explicitly recognizes their right to TK in the context of cultural development, including intellectual property rights to TK:

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, *traditional knowledge* and traditional cultural expressions, . . . They also have the right to maintain, control, protect and develop their *intellectual property* over such cultural heritage, *traditional knowledge*, and traditional cultural expressions.¹⁸⁴

Furthermore, the declaration demands that States, in conjunction with indigenous peoples, take effective measures to recognize and protect the exercise of the rights listed in the declaration.¹⁸⁵ In contrast to previous international instruments concerning the duty of States regarding TK protection, this provision seems to send a relatively strong message to States hosting indigenous peoples.

¶84 This instrument also declares certain rights that are relevant to the preservation of TK as a whole. Article 25 recognizes the distinct relationship between indigenous peoples and their traditionally owned or occupied lands, territories, and resources.¹⁸⁶ Additionally, their right to own, use, develop, and control these areas has been affirmed.¹⁸⁷ Article 29 bestows upon indigenous peoples the right to conserve and protect the environment.¹⁸⁸ As mentioned above, these rights to some extent have been incorporated into the current CBD lawmaking process in Article 8(j).¹⁸⁹

¶85 The declaration, irrespective of its adoption and possible influence, is not legally binding. But, multilateral declarations are able to generate a variety of lawmaking effects, which can be evaluated on a case-by-case basis.¹⁹⁰ It has been observed that the degree of support for a declaration matters.¹⁹¹ In effect, a consensus declaration or a unanimous adoption amounts to a sign of strong expectations of compliance.¹⁹² By contrast, “[d]issenting minorities may

¹⁸² *Id.* art. 11(2).

¹⁸³ See WIPO DRAFT, *TK Objectives and Principles*, *supra* note 2, arts. 1, 2, 7, 13.

¹⁸⁴ U.N. Declaration, *supra* note 16, art. 31(1) (emphasis added).

¹⁸⁵ *Id.* art. 31(2).

¹⁸⁶ *Id.* art. 25.

¹⁸⁷ *Id.* art. 26.

¹⁸⁸ *Id.* art. 29.

¹⁸⁹ U.N. Environment Programme, *supra* notes 54-60 and accompanying text.

¹⁹⁰ They may constitute evidence of existing law, or of the *opinion juris* necessary for new law, or of the practice of states. See BIRNIE ET AL., *supra* note 20, at 31.

¹⁹¹ *Id.*

¹⁹² *Id.* at 32.

undermine the authority and lawmaking significance of a resolution, particularly if they comprise states most affected.”¹⁹³ Indeed, the U.N. declaration was not approved by consensus or by unanimous vote. The four negative votes on the Declaration thus may presumably have a significant diminishing effect. Nonetheless, indicating that those objecting States actually accepted core principles and values of the Declaration during the debates and negotiations, Wiessner argues that “the four states in opposition to the Declaration have demonstrated an *opinio juris*—a willingness to be bound if all of the provisions were formulated to agree with their detailed policy preference.”¹⁹⁴

¶86 The instrument has actually become so dynamic and influential as to shape States’ behavior and policy.¹⁹⁵ It can be expected that the U.N. articulation may create further impetus for States to protect the rights of indigenous peoples regarding TK.

¶87 It is worth noting that the Declaration tends to strengthen its implementation and effectiveness by requesting the U.N. system, including the Permanent Forum on Indigenous Issues (UNPFII),¹⁹⁶ and States to promote respect for and full application of the content of the Declaration.¹⁹⁷ Literally speaking, the UNPFII would be competent to monitor and supervise the progress and compliance of the Declaration.¹⁹⁸ It remains to be seen how far and to what extent each nation would implement the U.N. mandate, and how seriously the U.N. regime may ensure the effectiveness and observance of the rules.

IV. DO WE NEED A SINGLE FORUM TO CREATE A COMPREHENSIVE AND INTEGRAL INTERNATIONAL INSTRUMENT ON TRADITIONAL KNOWLEDGE?

¶88 The above study indicates the active and diverse global lawmaking on TK. The development of course will continue to evolve and progress. The proliferation of international TK lawmaking reflects the broad spectrum of TK, including, *inter alia*, the concern of nature

¹⁹³ *Id.*

¹⁹⁴ Siegfried Wiessner, *Indigenous Sovereignty: A Reassessment in Light of the United Nations Declaration on the Rights of Indigenous Peoples*, 41 VAND. J. TRANSNAT’L L. 1141, 1165 and n.153 (2008).

¹⁹⁵ It is shown that the adoption of the Declaration has influenced many countries’ statutes or policies on indigenous affairs, such as those of the Philippines and some Latin American countries. *Id.* at 1162. The U.S., Canada, New Zealand and Australia recently have shifted their original positions so as to support the U.N. Declaration. Moreover, Bolivia has passed a law (No. 3760) to incorporate the declaration. See INTERNATIONAL WORK GROUP FOR INDIGENOUS AFFAIRS, <http://www.iwgia.org/sw37643.asp> (last visited Nov. 16, 2011).

¹⁹⁶ The U.N. Permanent Forum on Indigenous Issues (UNPFII) serves an advisory role to the U.N. Economic and Social Council, providing advice and reports concerning indigenous affairs while the Council is in session. *About Us/Mandate*, UN PERMANENT FORUM ON INDIGENOUS ISSUES, http://www.un.org/esa/socdev/unpfii/en/about_us.html (last visited Nov. 16, 2011); *Background Information*, U.N. ECONOMIC AND SOCIAL COUNCIL, <http://www.un.org/ecosoc/about> (last visited Nov. 16, 2011).

¹⁹⁷ U.N. Declaration, *supra* note 16, art. 42.

¹⁹⁸ For a discussion of the role of the UNPFII in serving as a monitoring mechanism, see Viniyanka Prasad, *The United Nations Declaration on the Rights of Indigenous Peoples: An Approach to Addressing the Unique Needs of Varying Populations*, 9 CHI. J. INT’L L. 297, 314-15 (2008).

conservation, cultural expression, intellectual property and the protection and recognition of indigenous peoples' rights. Usually a multilateral lawmaking process on the same subject matter may generate incoherent or even conflicting normative implications. Drahos points out that multiple international efforts to protect TK and the application of a variety of norms to TK protections that are already being enacted at state level would make TK regulations lose coherence and produce a clash of cultures, legal approaches, and enforcement strategies.¹⁹⁹ In order to avoid such circumstances, the international community should promote harmony and coherence amongst the regimes at stake.

¶89 The CBD appears to be the most dynamic global institution on the protection of TK. The CBD currently focuses on building an ABS international regime that would cover the enforcement of genetic resource-associated TK. The newly adopted Nagoya Protocol reflects the determination of the CBD Parties to eliminate bio-piracy and misappropriation of such genetic resources and associated knowledge. Overall, the lawmaking has been an international movement to consolidate and enhance the efforts in combating the illegal monopoly of such items, and to ensure that genetic resources and TK holders may benefit from the commercialization of these valuable objects. In spite of the promising effort, the CBD arrangement has its own limitations. The CBD, by its mandate, cannot govern the protection of TK beyond the bio-diversity related sphere and accordingly lacks expertise and competence to effectively address TK-related intellectual property rights. Without the cooperation of the U.S. (which has long been blamed for bio-related piracy) especially, the future international regime on ABS hardly can thoroughly redress the violation of provider parties' national law concerning the preservation of bio-related TK. Because the U.S. is not a party to the CBD, the treaty body would be incapable of monitoring the U.S. patent policy concerning TK.

¶90 The property and commercial orientation of the WIPO and WTO probably make them insufficient instruments in terms of governing TK protection. Also, it remains uncertain whether the U.N. Indigenous Forum can effectively supervise and enforce its TK mandate.

¶91 Indeed, TK is not the only cross-cutting issue facing the international community. For instance, as noted by Boyle and Chinkin, there have been a variety of U.N. bodies governing the development of forest-related rules,²⁰⁰ and "no single forum is self-evidently the right one to undertake the development of new laws."²⁰¹ Given the limitation embodied in the present TK lawmaking regimes, similar to the forest scenario, no single forum currently proves to be available and competent to manage TK thoroughly.

¹⁹⁹ Drahos, *supra* note 3, at 414.

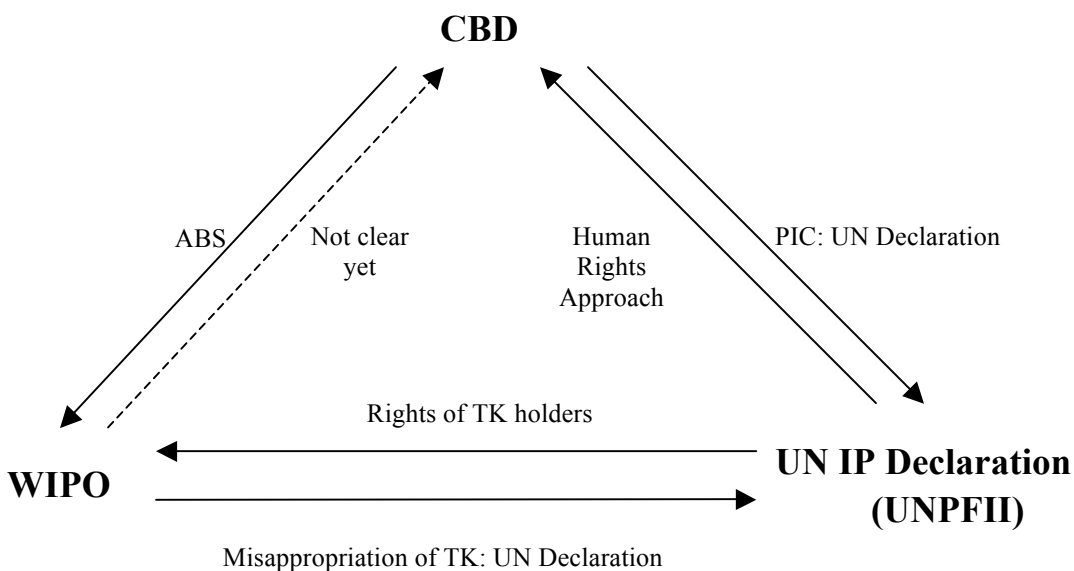
²⁰⁰ BOYLE & CHINKIN, *supra* note 22, at 117 (including FAO, International Tropical Timber Organization, The World Heritage Convention adopted UNESCO, Convention on Biological Diversity, UNEP, and Convention on Climate Change, etc).

²⁰¹ *Id.*

¶192 Ideally, the international community needs a coherent and integrated instrument or institution on TK to formulate binding rules and effective enforcement mechanisms. The diverse merits of TK make it difficult to decide which single international institution or treaty body, and in what form, should govern the matter. Drahos proposes the establishment of a Global Bio-Collecting Society (GBS) regime to co-ordinate multiple international institutions, and argues the agenda of enforcement should be placed as the first priority.²⁰² Yet, the question remains unsettled as to which international institution should be in charge of the matter.

¶193 Constructing a single institution on TK lawmaking would likely not be realistic in the near future. Nevertheless, in light of the lawmaking process of those institutions mentioned above, it is worth noting that, the U.N.-related institutions (CBD, WIPO, and U.N. Human Rights' mechanisms) to some extent have already been engaging in harmonization of lawmaking activities. Not only do they have cross-culture dialogue²⁰³ and cooperation,²⁰⁴ but they are also seeking mutual incorporation and integration in the TK context (see Figure 1 below for a graphic representation of this concept). The constant sharing of common values could alleviate the adverse effect of fragmentation of international TK lawmaking and help promote coherence among these regimes. Certainly, trans-institutional cooperation and mutual supportiveness for TK protection among the relevant international TK instruments will be essential as the respective TK instruments become operative and mature in the future.

¶194 Figure 1: The Mutual Integration of Components among TK Regimes



²⁰² Drahos, *supra* note 3, at 412-15.

²⁰³ OGUAMANAM, *supra* note 1, at 191-222 (observing the cross-cultural dialogue between the CBD and WIPO).

²⁰⁴ See BIRNIE ET AL., *supra* note 20, at 628, n.214 (noting the close cooperation between the CBD and the UNPFII).

V. CONCLUSION

¶95 The protection of TK is no longer a matter of national context. Rather, there has been a growing international movement to structure TK in a more normative form. Of course, the lawmaking process of relevant international legal regimes is still ongoing. Presently, it remains premature to predict the eventual outcome. Given the largely soft law character of most international instruments on TK, it seems far from clear whether States may seriously conform to the rules. The effect of those “laws” may be even less prominent, especially when a powerful mechanism to supervise or monitor the national enforcement of TK mandates is still scant. Yet, the adoption of a binding ABS by the CBD may make things different.

¶96 The uncertain international legal status of those TK holders, mainly indigenous peoples, would leave the protection of TK to the discretion of each State. Indeed, the ABS Protocol of the CBD, if run successfully, would uphold the protection of biodiversity-related TK and preserve the interest of indigenous and local groups holding such TK. Its effectiveness is nevertheless confined to matters of ABS regarding associated TK.

¶97 The significance of the WIPO document on TK protection cannot be overemphasized. The work can be deemed as international consensus to protect TK from the perspective of a defensive approach. However, as indicated, it would not be possible to make the document legally binding, partly because the expressions used in the draft have indicated that it may turn out to be a form of voluntary guidelines.

¶98 The WTO agreements, including the TRIPS, are the most mandatory of the current international regimes. Their enforcement and dispute settlement mechanisms are also relatively effective. The current Doha Round Negotiations, however, do not create a particular agenda for TK protection. There has also been strong resistance against the approach to add the CBD elements into the disclosure requirement for patent applications. It is thus highly unlikely that the WTO may actively contribute to the protection of TK at the present stage.

¶99 Most of current TK lawmaking remains in a preliminary stage and the proposed documents are largely of soft law character. However, their draft form and non-binding nature, such as the WIPO and U.N. instruments, do not prevent them from providing useful reference for national TK legislation. It is also predictable that the elaboration and finalization of these TK instruments may help promote and enhance the awareness and political will to engage in domestic TK law- and policy-making. It may thus be premature to cast a definite judgment on the achievement of the current international lawmaking on TK. Whether the movement would be a useful vehicle or just an empty box awaits further assessment.

¶100 On the other hand, the proliferation of global TK lawmaking reveals a potential contradiction amongst relevant international norms. To enhance mutual supportiveness and to

avoid conflict, it is highly desirable to articulate a mechanism to harmonize and reconcile those lawmaking vehicles. While the formation of a single comprehensive international institution for the development of TK law probably remains remote or unrealistic, the present and continuous harmonization among TK lawmaking mechanisms proves to be essential and must be strengthened.

Annex I: The Current Status of International Legal Instruments on the Protection of Traditional Knowledge

Int'l Institutions	The Legal Status of Instruments	Compliance Mechanism	Dispute Settlement
CBD	Art. 8(j): binding but weak	Weak	Weak
	Code of Ethical Conduct: Non-binding	N/A	N/A
	Bonn Guidelines: Non-binding	N/A	N/A
	Int'l Regime on Access and Benefit-sharing: Nagoya Protocol is binding upon effectiveness	To be developed under the Protocol	N/A
WIPO	Draft Provisions for the Protection of Traditional Knowledge: uncertain (binding or non-binding to be negotiated)	N/A	N/A
WTO/TRIPS	The Proposal to amend the disclosure requirement for patent application: binding if the revision becomes mandatory	Yes	Yes
United Nations/ General Assembly/ UNPFII	The UN Declaration on the Rights of Indigenous Peoples: Non-binding but with potential influence	To be developed under UNPFII	N/A