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Advancing Science While Protecting Developing Countries from Exloitation of Their Resources and Knowledge

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NOTE

Advancing Science While Protecting Developing Countries from Exploitation of Their Resources and Knowledge

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INTRODUCTION

Increasing accessibility to the world's resources stimulates innovation. The scientific community is no longer confined to its nation's soil but may employ the world's resources and techniques when approaching almost any challenge. Advancements that benefit one nation's livelihood, however, may come at the expense of countries whose soil and inhabitants provide the basis for those developments. Accordingly, in recent years this exploitation of developing nations by some unscrupulous privately held companies has become an area of increasing international concern. Scholars and legislatures have advanced various laws and proposals striving to fortify the rights that source countries[1] have over their resources. Inconsistencies in their approaches, however, abridge the ability to enforce these rights.

This Note discusses how to appropriately allocate rights over the use of a nation's natural resources and traditional knowledge without discouraging scientific innovation. Part I of this Note provides a background to this conflict, demonstrating the ability of patent law to provide intellectual property protection for scientific

[1] "Source countries" refer to the countries providing the relevant resources and knowledge.

innovations. It then addresses how developing nations have been exploited in the obtainment of intellectual property rights for innovations derived from their knowledge and resources. Part I also discusses the prevailing national and international laws showing the varying approaches legislative bodies have taken to equitably allocate rights. Part II addresses the conflicts presented between advancing science and recognizing developing countries' sovereign rights over the use of their resources. It then discusses various policy considerations and proposed solutions offered to resolve these conflicts and the need for a unified and internationally accepted approach. Part III proposes documenting traditional knowledge as "prior art," establishing an internationally accepted definition of prior art, implementing an international online search system to retrieve traditional knowledge documentation, and using Material Transfer Agreements for access to a country's resources.

I. BACKGROUND

A. Intellectual Property Protection for Products Derived from Use of a Country's Biodiversity and Traditional Knowledge

Scientific advancements often derive from use of a country's biodiversity and traditional knowledge and are then patented to obtain legal rights through intellectual property law. Biodiversity has been defined as "the total variety of genetic strains, species, and ecosystems."[2] Traditional knowledge has been described as "knowledge systems, creations, innovations which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are continually evolving in response to a changing environment."[3]

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[2] Rosemary J. Coombe, *Intellectual Property, Human Rights and Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conversation of Biodiversity*, 6 IND. J. GLOBAL LEGAL STUD. 59, 89 (1998).

[3] Intergov'tal Comm. on Intell. Prop. and Genetic Resources, Traditional Knowledge and Folklore, *Survey on Existing Forms of Intellectual Property Protection for Traditional Knowledge*, World Intellectual Property Organization [WIPO] Doc. GRTKF/IC/2/5, at 10 (Aug. 8, 2001) [hereinafter WIPO Survey] (explaining that categories of traditional knowledge may include agricultural knowledge, scientific

In other words, traditional knowledge is developed from the cultural traditions of a given community or nation.[4] While there are presently no legally binding international intellectual property standards for protecting traditional knowledge alone, this knowledge is often intrinsically tied to the use of a country's biodiversity, making it of great value to foreign researchers looking to patent their discoveries.[5]

Conditions for obtaining a patent vary among nations but often must fulfill three requirements: (1) novelty, (2) non-obviousness or inventiveness, and (3) utility.[6] First, novelty necessitates that the invention be something "truly new, above and beyond what already exists" to prevent patents from being granted for inventions that already exist.[7] Depending on the national law, an invention may lack novelty if it was published or used publicly by its inventor or someone else before filing for a patent.[8] Some countries allow a grace period from when the invention was used publicly prior to the filing of a patent application.[9] Second, an invention must meet the requirement of non-obviousness[10] or inventiveness, meaning it must not be obvious to someone with ordinary skill in the art and it must involve an inventive step.[11] Patent offices examine "prior art" to ascertain whether these two

knowledge, technical knowledge, ecological knowledge, medicinal knowledge, biodiversity-related knowledge, and elements of languages (such as names, geographical indications, and symbols)), http://www.wipo.int/eng/meetings/2001/igc/doc/grtkfic2_5.doc.

4 *See id.*

5 *See id.*

6 *See* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 323, 514, 707 (2d ed. 2001); CRAIG JOYCE ET AL., COPYRIGHT LAW 7–8 (5th ed. 2001).

7 JOYCE ET AL., *supra* note 6, at 7; *see also* CHISUM ET AL., *supra* note 6, at 323.

8 *See* JOYCE ET AL., *supra* note 6, at 7.

9 *See id.*

10 If "it would be 'obvious' to a person of ordinary skill in the art to assemble these elements in the form of the claimed invention . . . it could reasonably be said that the claimed invention was in the public domain, albeit not in one single prior art reference." CHISUM ET AL., *supra* note 6, at 514.

11 JOYCE ET AL., *supra* note 6, at 8 (explaining that for U.S. patents, *Graham v. John Deere Co.*, 383 U.S. 1 (1966), sets forth the three factors that determine non-obviousness: (1) the scope and content of the prior art; (2) the differences between the prior art and the claim; and (3) the level of ordinary skill of the worker in the pertinent discipline). Secondary considerations may also be considered such as commercial success, long-felt needs, and failure of others to make the discovery. *Id.*

requirements are met.[12] Prior art is a term used in patent law that refers to the body of technical knowledge available to the public prior to the filing of a patent application.[13] The existence of this knowledge may prevent the ability to receive intellectual property protection.[14] Patent applicants therefore usually search prior art to avoid the high costs associated with preparing a patent application for what could be an unpatentable invention.[15] Third, an invention often must fulfill the requirement of utility. Accordingly, it must be publicly disclosed, operate "in accordance with its intended purpose or a purpose discernible by a person of ordinary skill in the art," work as described in the patent application, and benefit the world in some technological way.[16]

Through these requirements, patent law both encourages new intellectual creations and discloses those creations to the world.[17] By temporarily issuing exclusive rights to the inventor, patents reduce the expense of protecting scientific creations.[18] Absent intellectual property protection many innovators may lack the incentive to invest the time and money required for scientific advancement.[19] Research supporting this conclusion demonstrates a strong link between patent protection and economic growth.[20] Requiring public disclosure then allows society to reap the benefits

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12 Intergov'tal Comm. on Intell. Prop. and Genetic Resources, Traditional Knowledge and Folklore, *Progress Report on the Status of Traditional Knowledge as Prior Art* at 3, WIPO Doc. GRTKF/IC/2/6 (July 1, 2001) [hereinafter WIPO Comm. Progress Report], http://www.wipo.int/eng/meetings/2001/igc/doc/grtkfic2_6.doc.

13 *See* CHISUM ET AL., *supra* note 6, at 93; WIPO Comm. Progress Report, *supra* note 12, at 3.

14 *See* CHISUM ET AL., *supra* note 6, at 93.

15 *See id.* (noting that a thorough search "may also help give the applicant an opportunity to make informed arguments about the patentability of the invention, and to present the written description and claims in a way favorable to patentability").

16 CHISUM ET AL., *supra* note 6, at 707. *See also* WIPO Comm. Progress Report, *supra* note 12, at 3.

17 *See* Bibek Debroy, *The Compulsory Licensing Anomaly*, International Policy Network (July 2001), *at* http://www.policynetwork.net/IPhealth/rethinking_the_debate_0701_debroy.htm.

18 *See* WIPO Survey, *supra* note 3, at 4–5; Debroy, *supra* note 17.

19 *See* Debroy, *supra* note 17, at 3.

20 *See id.*

of patented experiments and to use the underlying knowledge for further inventive endeavors.[21]

To distribute the benefits of scientific advancements, a large amount of time and economic resources must be invested to ensure the highest quality and quantity of products.[22] Patents are particularly necessary for drug companies because it often takes more than a decade and costs hundreds of millions of dollars to develop a drug.[23] Without intellectual property protection, test drugs could be easily copied once on the market.[24] Because of the costs involved, only economically advanced nations have the means necessary to develop and distribute products globally. If developing countries, often rich in biodiversity, were able to hoard their natural resources and knowledge, countless medical treatments would remain unknown to the rest of the world. The ability of economically advanced countries to provide channels of development and distribution, however, may come at a price to the people of developing nations.

B. The Exploitation of Indigenous and Local Communities Through the Use of Their Natural Resources and Traditional Knowledge

Indigenous and local communities in developing nations have often been exploited for the use of their natural resources and traditional knowledge. Such exploitation, often referred to as "biopiracy," occurs if the source country is not afforded any *control over* or *compensation for* the use of their resources.[25] Various examples demonstrate the link between biopiracy and the

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21 *See id.*

22 *See* Andrew Pollack, *Defensive Drug Industry: Fueling Clash Over Patents*, N.Y. TIMES, Apr. 20, 2001, at A6.

23 *Id.*

24 *Id.*

25 *See* Nuno Pires de Carvalho, *International and Comparative Law Issues: Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS: The Problem and the Solution*, 2 WASH. U. J.L. & POL'Y 371, 375 (2000) (explaining that biopiracy may occur when local community members lead researchers to genetic resources and are then not compensated for their cooperation).

obtainment of patents, and the need for an internationally recognized method of legal protection.

In Latin America, for example, the Amazonian Indians for centuries used *tamate* (a small cylindrical tomato) from the jungle in Ecuador for its cancer-fighting properties. A multi-national pharmaceutical company then isolated the tomato's active ingredient, lycopene, and now sells it as a cutting-edge product in cancer treatment.[26] Neither the country nor its people received any benefit from "what should have been their industrial property rights to these items of traditional knowledge."[27]

A patent was also issued to the owner of a United States pharmaceutical laboratory, the International Plant Medicine Corporation, based on the use of a plant called *Ayahuasca*, found in the Amazon region.[28] Issuance of this patent was condemned by the Coordinating Secretariat of Organizations of Indigenous Peoples from the Amazon (COICA).[29] COICA did not oppose development or research but emphasized the need for governmental permission or prior informed consent from the local indigenous people due to the plant's spiritual significance.[30] COICA emphasized "the magnitude of the offense to indigenous peoples for a single person to purport to appropriate, assert proprietary rights in, and derive monetary benefit from such a sacred symbol."[31]

There are also examples of how the failure to satisfy intellectual property law requirements can prevent pharmaceutical companies from exploiting local communities. Teaching traditional uses of natural resources, for example, may constitute prior art, making subsequent inventions that build upon such teaching unable to satisfy the novelty requirement of patent law.[32]

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[26] *See* Frank J. Penna & Coenraad J. Visser, *Cultural Industries and Intellectual Property Rights*, *in* DEVELOPMENT, TRADE, AND THE WTO: A HANDBOOK 400 (Bernard M. Hoekman et al. eds., 2002).

[27] *Id.*

[28] Coombe, *supra* note 2, at 88.

[29] *See id.*

[30] *Id.* at 88–89 (noting that a vast amount of literature substantiated its sacred character).

[31] *Id.* at 89.

[32] *See* WIPO Comm. Progress Report, *supra* note 12, at 3.

This occurred in India, where a fungicide that appeared naturally in the bark of the neem tree was used by the country's people for many years.[33] A foreign pharmaceutical company identified the bark's active ingredient and patented it in the European Patent Office.[34] Neither the country nor its people were to receive any compensation.[35] The patent's registration was challenged and the Technical Board of Appeal revoked the patent, ruling that "the patented invention fell foul of the absolute novelty requirement" because the bark's properties were known in India for many years.[36] More complex issues like distribution of control and compensation need not be addressed in situations such as this where the resource's traditional use qualifies as prior art.

These examples demonstrate the importance of maintaining the prior art requirement, facilitating access to prior art, and adopting internationally uniform procedures for the use of a country's resources and/or knowledge. Doing so will establish standards for foreign scientific innovators and provide source countries with consistent enforcement measures, thereby reducing the potential for exploitation.

C. Applicable International Laws

Inconsistencies in national and international legislation obstruct efforts to prevent exploitation of developing countries' resources and knowledge. Nonetheless, it is important to analyze the varying approaches and how countries implement and perceive existing forms of intellectual property protection. Four areas of law of particular relevance come from the Community of Andean Nations (CAN), the Convention on Biological Diversity (CBD), the World Intellectual Property Organization (WIPO), and the World Trade Organization (WTO). These organizations address a wide range of issues including intellectual property rights and the distribution of rights surrounding use of a country's resources. Variations in their approaches, however, may subject nations to conflicting

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33 *See* Penna & Visser, *supra* note 26, at 400.

34 *See id.* (noting that the pharmaceutical company even offered the patented product for sale to the Indians).

35 *Id.*

36 *Id.*

obligations. After analyzing the laws and policies behind each organization, it is necessary to extract an internationally uniform procedure that can properly address the use of a source country's resources and traditional knowledge.

1. The Community of Andean Nations

Patented inventions developed from the knowledge and resources of the CAN must comply with international, Andean Community, and national law, making the decisions of the CAN of particular legal importance.[37] The Andean Community is a subregional organization with international legal status now comprising Bolivia, Columbia, Ecuador, Peru and Venezuela.[38] The member countries possess twenty-five percent of the planet's biological diversity, making the Andean subregion "one of the world's best endowed regions."[39] The countries are also part of the Amazon dominion, the main watershed of the Amazon River Basin, which is the largest river basin in the world and the greatest tropical rain forest.[40] As a result, the Andean countries have developed extensive and sophisticated laws, extending beyond pure trade and economic issues to include social and environmental issues.[41] Two CAN decisions of particular importance are the Common Regime on Access to Genetic Resources and the Common Industrial Property System of the Andean Community.

a) The Common Regime on Access to Genetic Resources

The centerpiece of environmental regulation in the Andean Community is the Common Regime on Access to Genetic Resources for the protection of biodiversity (hereinafter

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[37] *See* The Common Intellectual Property Regime, Andean Comm. of Nations Decision 486 (Dec. 1, 2000) [hereinafter CAN Decision 486], http://www.comunidadandina.org/ingles/treaties/dec/D486e.htm.

[38] Victor Tafur-Dominguez, *International Environmental Harmonization—Emergence and Development of the Andean Community*, 12 PACE INT'L L. REV. 283, 285–86 (2000).

[39] *Id.* at 288 n.27.

[40] *Id.* at 288 n.30. The Andes form a continuous axis, stretching over more than 7,000 kilometers. *Id.* at 288 n.28. The Andes' natural resources are one of the region's most notable aspects. *Id.* at 287.

[41] *See id.* at 286.

"Regime"). The Regime was approved by the Commission of the Cartagena Agreement through passage of Decision 391[42] of the Andean Community and became law in all five member states in July 1996.[43] It recognizes the historic contribution made by native people of African descent and indigenous communities to biological diversity.[44] It guarantees the fair and equitable participation of the Andean Community countries in the benefits stemming from the use of their genetic resources.[45] Prior to the enactment of the Regime, access to such resources was not legislated, preventing member countries and local communities from receiving their equitable share of such benefits.[46]

Under the Regime, member countries have sovereignty over their resources. Those who wish to use the active components of member countries' plants and microorganisms must first secure the necessary authorization and sign an access contract with the state.[47] Under article 32 of Decision 391, the parties to the access contract are the state, represented by a competent national authority, and the

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[42] *See* The Common Regime on Access to Genetic Resources, Andean Comm. of Nations Decision 391 (July 2, 1996) [hereinafter CAN Decision 391] (explaining that this principle was also ratified by the Agreement on Biological Diversity, signed in Rio de Janeiro in June 1992 and ratified by all member countries), http:www.comunidadandina.org/ingles/treaties/dec/d391e.htm.

[43] *See Economic Policies/Intellectual Property*, Andean Comm. of Nations [hereinafter Andean Comm. Policies], *at* http://www.comunidadandina.org/ingles/politics/intelec.htm (last visited Apr. 21, 2003).

[44] *See* Tafur-Dominguez, *supra* note 38, 306. This Regime was established by the Andean Committee on Genetic Resources. *Id.* at 307.

[45] *See* Andean Comm. Policies, *supra* note 43; Tafur-Dominguez, *supra* note 38, at 306. The four purposes of Decision 391 are: (1) to regulate access to genetic resources; (2) to establish the conditions for just and equitable participation in the benefits of access to genetic resources; (3) to lay the foundation for recognition and valuation of genetic resources and their by-products; (4) to strengthen the negotiating capacity of the member countries. *Id.*

[46] *See* Andean Comm. Policies, *supra* note 43; Coombe, *supra* note 2, at 104.

[47] *See* Andean Comm. Policies, *supra* note 43; *see also* CAN Decision 391, *supra* note 42 (stating that the Common Regime on Access to Genetic Resources defines an access contract under article 1 as an "agreement between Competent National Authority in representation of the State, and a person that establishes the terms and conditions for access to genetic resources, their by-products and, if applicable, the associated intangible component," and explaining that this principle was also enumerated by the United Nations Convention on Biological Diversity [CBD], June 5, 1992, U.N. Doc. DPI/1307 (1992), *reprinted in* 31 I.L.M. 818 (1992), *available at* http://www.biodiv. org/doc/legal/cbd-en.pdf).

applicant requesting access.[48] Under article 16, all access procedures "require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding Resolution and the declarative registration of the acts connected with that access."[49] This requirement "expressly recognizes" the local communities' rights over the uses of their traditional knowledge and genetic resources.[50] Despite such recognition, however, no explicit provision mandates the prior informed consent of the actual local communities.[51] This may derive from the difficulties that would be involved in trying to obtain consent from a whole community, which would clearly be a costly and timely procedure. As a result, however, the competent national authority may grant such consent without any input from the locals responsible for the existence of those resources and knowledge.[52]

b) The Common Industrial Property System

The Common Industrial Property System of the Andean Community aims to improve intellectual property procedures while also granting adequate protection to local communities. It became effective on December 1, 2000, through the passage of Decision 486.[53] It regulates the issuance of patents and trademarks and provides protection for various areas of intellectual property including industrial secrets, appellations of origin,[54] and unfair competition.[55] Decision 486 improved intellectual property protection by creating "more expeditious and transparent

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48 *See* CAN Decision 391, *supra* note 42, art. 32.

49 *Id.* art. 16.

50 Andean Comm. Policies, *supra* note 43.

51 *See, e.g.*, Coombe, *supra* note 2, at 106.

52 *See id.*

53 *See* Andean Comm. Policies, *supra* note 43.

54 Appellation of origin of products refers to "the geographical name of a county, region or locality which has come to be generally known to designate a product originating therein the quality and characteristics of which are due exclusively or essentially to the geographical environment, including natural and human factors." Industrial Property Office of the Czech Republic, Law Concerning the Protection of Appellations of Origin of Products, Dec. 12, 1973, http://www.upv.cz/english/z150-73.htm.

55 *See id.*; Tafur-Dominguez, *supra* note 38, at 303.

procedures" for the issuance of patents and trademark registration, thereby encouraging both national and foreign investors.[56]

Decision 486 also seeks to protect the ecological resources and knowledge associated with the intellectual property rights. Under article 3, for example, member countries must safeguard and respect "their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities."[57] Article 3 is enforced by the various conditions and limitations Decision 486 sets forth for obtaining patents within the Andean Community. Articles 14 and 20, for example, define the subject matter of patentability. Under article 14, member countries may issue patents for inventions of both products and procedures, provided they are (1) new, (2) involve an inventive step, and (3) are able to be put to industrial use.[58] Article 20 lists limitations that preclude patentability. Accordingly, the following are not patentable: (1) inventions where the prevention of commercial exploitation is necessary to protect public order or morality; (2) inventions where the prevention of commercial exploitation is necessary to protect human or animal life or health or to avoid serious prejudice to plant life and the environment; and (3) plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes.[59] These limitations explicitly recognize the need to protect against commercial exploitation and to respect a country's extracted resources.

Decision 486 procedures further guard against commercial exploitation by demanding the obtainment of either a contract for

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[56] Andean Comm. Policies, *supra* note 43; *see also* CAN Decision 486, *supra* note 37. Under article 1 of Decision 486, each member country

> shall accord the nationals of other members of the Andean Community, the World Trade Organization, and the Paris Convention for the Protection of Industrial Property, treatment no less favorable than it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in articles 3 and 5 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and in article 2 of the Paris Convention for the Protection of Industrial Property.

Id.

[57] CAN Decision 486, *supra* note 37, art. 3.

[58] Tafur-Dominguez, *supra* note 38, at 304.

[59] *See* CAN Decision 486, *supra* note 37, art. 20.

access to genetic material or a document authorizing the use of traditional knowledge before a patent may be issued.[60] Article 75(g) allows invalidation of a patent if the products derived from genetic resources or their byproducts originating in one of the member countries and the applicant failed to submit a copy of the contract for access to the material.[61] A patent may also be invalid under article 75(h) if it is based on traditional knowledge and the applicant failed to submit a copy of the document certifying the existence of a license or authorization for use of that knowledge.[62]

Decision 486 also recognizes the value of information systems. Under article 270, member countries were to set up an Andean information system of the intellectual property rights registered in their countries and interconnect their respective databases by December 31, 2002.[63] These databases will ensure that traditional uses of ecological resources are properly documented as prior art. They will thereby secure the Andean Community's sovereign rights over its natural resources by reducing the number of illegitimate patents granted for products derived from its resources.

2. The Convention on Biological Diversity

The CBD was formulated by the United Nations to protect developing countries from the exploitation of their biological resources and to help conserve natural resources. It opened for signature on June 5, 1992, at the United Nations Conference on Environment and Development (the Rio "Earth Summit") and entered into force on December 29, 1993.[64] One hundred and thirty countries have ratified the CBD.[65]

Article 1 of the CBD sets forth its three main objectives: (1) the conservation of biological diversity; (2) the sustainable use of its components; and (3) the fair and equitable sharing of benefits arising from utilization of genetic resources, including appropriate

60 *Id.* art. 26(h)–(i).
61 *See id.*
62 *See id.*
63 *See id.*
64 *See* CBD, *supra* note 47; Pires de Carvalho, *supra* note 25, at 371 n.2.
65 *See* Coombe, *supra* note 2, at 71–72.

access to genetic resources and transfer of relevant technologies.[66] The CBD "mandates a recognition of indigenous knowledge and the use of intellectual property protections in a manner congruent with that end."[67] The signatories agreed that while access to biological resources should be provided, it should require national permission since biodiversity is a sovereign national resource.[68] Article 2 of the CBD broadly defines biological diversity as "the variability among living organisms from all ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems."[69] Because the CBD includes provisions compensating source countries for use of their natural resources, Rosemary J. Coombe described it as providing an "opportunity to break the obvious nexus between biodiversity and poverty."[70]

The CBD embodies the rationale that indigenous communities should be compensated not only based on concepts of fairness and equity, but also because their knowledge and techniques are essential to preserving biodiversity and sustainable development.[71] Article 8 requires states to respect and preserve the knowledge, innovations, and practices of indigenous and local communities and to promote the wider application of traditional knowledge with both the approval and involvement of such communities.[72] Under article 10(c), contracting parties must protect and encourage traditional uses of biological resources compatible with conservation or sustainable use requirements.[73] These provisions

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66 CBD, *supra* note 47, art. 1.

67 *Id.*

68 Michael A. Gollin & Sarah A. Laird, *Global Policies, Local Actions: The Role of National Legislation in Sustainable Biodiversity Prospecting*, 2 B.U. J. SCI. & TECH. L. 16 (1996).

69 CBD, *supra* note 47, art. 2.

70 Coombe, *supra* note 2, at 90. *See also* Annie O. Wu, *Surpassing the Material: The Human Rights Implications of Informed Consent in Bioprospecting Cells Derived from Indigenous People Groups*, 78 WASH. U. L.Q. 979, 989 (2000).

71 *See, e.g.*, Coombe, *supra* note 2, at 90.

72 *See id.* at 92, 102. The provisions of article 8 are also in accordance with principle 22 of the Rio Declaration which mandates state recognition of indigenous and local communities' identity, culture, and interests. *Id.* It also mandates the effective participation of these communities in achieving sustainable development. *Id.* at 104; *accord* CBD, *supra* note 47, art. 8.

73 CBD, *supra* note 47, art. 10(c).

recognize the vital role local communities play in achieving scientific advancements and that "preservation of biodiversity and cultural diversity are integrally related."[74]

Despite the aspirations underlying the CBD, it faces much criticism. The CBD has been criticized for containing vague provisions that fail to fully detail all necessary requirements.[75] Article 8(j), for example, only requires contracting parties to "encourage" the equitable sharing of benefits derived from the knowledge, innovations, and practices of indigenous and local communities.[76] This lack of any mandatory sanction leaves moral persuasion as the only real means of enforcement.[77]

The CBD faces further criticism for failing to contain "any explicit requirement for the consent or participation of indigenous peoples" for access to their resources or use of their knowledge.[78] The CBD's provisions mainly refer to the "Contracting Parties," which seem to refer to a state authority and the patent applicant.[79] All the power therefore appears to rest in the state's hands; the rights of the local people may be completely overlooked, which is likely due to the procedural burdens of obtaining their consent. Article 15.1 on Access to Genetic Resources, for example, while recognizing the sovereign rights of states over their natural resources, grants the national governments authority to determine access to those resources, not the communities.[80] While it would appear that consent from local communities, not just the government, is necessary to fulfill the CBD's objectives, its failure to explicitly require consent renders its goals merely advisory and thus difficult to enforce.[81] States implementing article 15 should

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74 Coombe, *supra* note 2, at 92.

75 *E.g.*, Gollin & Laird, *supra* note 68, ¶ 14.

76 Wu, *supra* note 70, at 989.

77 *See* Gollin & Laird, *supra* note 68, ¶ 13.

78 Coombe, *supra* note 2, at 99.

79 *See generally* CBD, *supra* note 47. Article 15.5, for example, requires that access to genetic resources "be subject to prior informed consent of the [c]ontracting [p]arty providing such resources, unless otherwise determined by that Party." *Id.* art. 15.5. *See also* Coombe, *supra* note 2, at 99.

80 *See* CBD, *supra* note 47, art. 15.1.

81 *See* Coombe, *supra* note 2, at 99.

consider local community interests even though the CBD appears to mandate responsibilities only to the state.[82]

3. World Intellectual Property Organization

WIPO is the specialized United Nations agency responsible for the promotion of intellectual property protection worldwide.[83] It was established in 1967 by convention and became a United Nations agency in 1974.[84] WIPO historically emphasized individual creation and public diffusion.[85] For over 100 years, it and its predecessor, the United International Bureau for the Protection of Intellectual Property (BIRPI),[86] have administered international agreements that provide patent standards, such as the Paris Convention of 1884,[87] Berne Convention of 1886, and other international unions.[88]

To address concerns of indigenous peoples, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (hereinafter the

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[82] *Id.* at 101–02.

[83] WIPO, *Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore*, WIPO Global Issues, *at* http://www.wipo.int/globalissues/index-en.html (last visited Apr. 24, 2003).

[84] *See id.*; Gollin & Laird, *supra* note 68, ¶ 27.

[85] *See* Coombe, *supra* note 2, at 75.

[86] *See* WIPO, *General Information*, *at* http://www.wipo.org/about-wipo/en/index.html (last visited Apr. 24, 2003). The United International Bureau for the Protection of Intellectual Property was created when the two small bureaux of the Convention of Paris for the Protection of Industrial Property, Mar. 20, 1883 (as revised July 14, 1967), 21 U.S.T. 1583, 828 U.N.T.S. 305, and the Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, 25 U.S.T. 1341, 828 U.N.T.S. 221, united to form this international organization. *Id.*

[87] One international agreement administered by WIPO is the Convention of Paris for the Protection of Industrial Property, Mar. 20, 1883 (as revised July 14, 1967), 21 U.S.T. 1583, 828 U.N.T.S. 305. Under the Paris Convention, signature states must accord foreign patent applicants and owners the same intellectual property protection as they would to their domestic applicants and owners. *See* Gollin & Laird, *supra* note 68, ¶ 24. The procedure outlined by the Patent Cooperation Treaty [PCT], June 19, 1970, 28 U.S.T. 7645; 1160 U.N. T. S. 231, requires that a single application be filed which can subsequently be reviewed by most national patent offices. *See id.* Although the Paris Convention affords such reciprocal protection to both domestic and foreign applicants, it fails to provide any real substantive international intellectual property rights. *Id.*

[88] *See* WIPO, *supra* note 86. *See also* Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, 25 U.S.T. 1341, 828 U.N.T.S. 221.

"Committee") was established in 2000 by the WIPO General Assembly with the primary objective of preserving common heritage.[89] One main concern of the Committee was that inventors would use elements of this heritage, like traditional knowledge, to acquire intellectual property rights even if it fell within the public domain.[90] It therefore focused on "the adequate recognition of traditional knowledge as prior-art during the examination of patent applications for traditional knowledge-based inventions."[91] To do this, the Committee recognized the need to draft a definition of prior art that could be implemented internationally.[92]

a) Draft Substantive Patent Law Treaty Proposed to Resolve Conflicting Definitions of Prior Art

In its "Progress Report on the Status of Traditional Knowledge as Prior Art," the Committee discussed using a patent law treaty that would harmonize variances in patent legislation existing at regional and national levels.[93] A draft of a substantive patent law treaty was submitted to and supported by the fifth session of the Standing Committee on the Law of Patents, held in Geneva from May 14 to 19, 2001.[94]

This draft treaty seeks to resolve conflicting national definitions of prior art. Presently, some countries define prior art broadly to include everything "made available to the public, anywhere in the world" by any means.[95] In other countries, however, oral disclosures, or uses outside their jurisdictions, do not constitute prior art.[96] The draft provisions contained alternate definitions of prior art, each essentially providing that:

any information made available to the public, anywhere in the world, in any form, including in written form, by oral communication, by display and through use, shall constitute prior

89 Penna & Visser, *supra* note 26.
90 *Id.*
91 *Id.* (explaining that expressions of folklore are a subset of traditional knowledge).
92 *See* WIPO Comm. Progress Report, *supra* note 12, at 17.
93 *Id.*
94 *Id.*
95 *Id.*
96 *Id.*

art, if it has been made available to the public before the filing date, or, where applicable, the priority date.[97]

Some countries, however, may feel that learning of and enforcing restrictions based on oral communications from a foreign country is unrealistic. Gaining international acceptance of this definition may therefore be difficult.

Varying definitions of prior art can be found in three International Searching Authorities of particular importance, namely the European Patent Office (EPO), the Japanese Patent Office (JPO), and the United States Patent and Trademark Office (USPTO). These three offices administered 89.7% of the international searches for international applications (or 81,650 international searches) in the year 2000.[98]

The European Patent Convention (EPC) defines prior art as comprising "everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing of the European patent application."[99] This definition lacks any limitation based on geographical location, language used, or manner in which the information was made accessible to the public.[100] All traditional knowledge falling under this definition is therefore recognized by the EPO as prior art. The EPO has also initiated measures to facilitate faster and more thorough access to sources of non-patent literature.[101]

Similar to the EPC, Section 29 of the Japanese Patent Law (JPL) also provides a requirement for absolute novelty.[102] The JPL's definition of prior art includes publicly known inventions, publicly worked inventions, and inventions described in a

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97 *Id.*

98 *Id.*

99 *Id.* at 18.

100 *See id.*

101 *See, e.g.*, *id.* Such measures include: (1) loading copies of commercial databases in-house at the European Patent Office [EPO] (such as INSPEC, ELSEVIER, BIOSIS, COMPENDEX, etc.); (2) an annual subscription to 1,400 journals from which 120,000 articles are copied and added yearly to the classified collection; and (3) cooperation within Europe by the EPO and member states to forge consortium contracts with publication houses and commercial hosts for access to their non-patented literature databases. *Id.*

102 *See, e.g.*, *id.*

distributed publication or made available to the general public through telecommunication lines, either in Japan or elsewhere prior to the filing date or priority date.[103] Such telecommunication lines include information disclosed on the Internet.[104] Prior art can also be found by searching a traditional knowledge database made available to the general public.[105]

Unlike the EPC and the JPL, the U.S. Patent Act fails to define "prior art." Instead, it establishes certain limitations under 35 U.S.C. § 102 that prevent the ability to obtain patents.[106] Under this statute a patent is unattainable if:

> the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.[107]

Unlike Europe and Japan, whose definitions protect traditional knowledge and foreign oral communications as prior art, the U.S. does not protect any foreign activity unless it was described in a printed document.[108]

U.S. patent examiners must search thoroughly for any prior art that would make the claimed invention unpatentable.[109] A library

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[103] *See id.* at 19. The "general public" is defined as "unspecified persons in general." "Available to the general public" means information that is in a state where "it can be seen by unspecified persons without necessarily implying that it must have actually been accessed." *Id.*

[104] *See id.*

[105] *See id.* Online traditional knowledge databases are available to the general public if "linked with any other site on the Internet, registered with any search engine, or the URL of the site is published in a means providing information to the general public (for example, a widely-know newspaper or magazine), and if, at the same time, public access to the site is not restricted." *Id.*

[106] *See id.* at 20.

[107] *Id.*; *see also* 35 U.S.C. § 102 (2000).

[108] *See* 35 U.S.C. § 102; WIPO Comm. Progress Report, *supra* note 12.

[109] WIPO Comm. Progress Report, *supra* note 12, at 20. This requirement is found under the Code of Federal Regulations. *Id.* 37 C.F.R. § 1.104 (2003) provides that national applications must be subject to an international search if filed on or after June 1, 1978, to attain any written disclosures made available to the public anywhere in the

of scientific and other works and periodicals, foreign and domestic, is therefore maintained in the USPTO.[110] Nonetheless, patent examiners can not always determine whether any relevant traditional non-patent literature exists at the time of application.[111] In response, the USPTO suggested creating "more easily accessible" non-patent literature databases and classifying them to facilitate searches.[112]

b) Draft Material Transfer Agreements

In the Committee's second session, on Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit-Sharing, member states mandated that the Committee develop guideline procedures and model intellectual property clauses for contract agreements on access to genetic resources and equitable distribution of benefits.[113] These contractual agreements are referred to as Material Transfer Agreements (MTAs). MTAs are enforceable agreements creating rights and obligations for both the provider and recipient of transferred genetic material.[114] Because MTAs are subject to the law of contracts, parties transferring

world, including drawings and other illustrations, and to determine whether the invention meets the requirements of novelty or inventive step. WIPO Comm. Progress Report, *supra* note 12, at 21.

[110] WIPO Comm. Progress Report, *supra* note 12, at 20.

[111] *See id.* at 4, 21.

[112] *Id.* at 20–21.

[113] Intergov'tal Comm. on Intell. Prop. and Genetic Resources, Traditional Knowledge and Folklore, *Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit-Sharing*, WIPO Doc. GRTKF/IC/2/3, at 5 (Sept. 10, 2001) [hereinafter WIPO Operational Principles], http://www.wipo.int/eng/meetings/2001/igc/doc/grtkfic2_3.doc. Member states also requested that WIPO closely coordinate its work with other intergovernmental fora active in the field of genetic resources, such as the CBD and the United Nations Food and Agriculture Organization, "to avoid duplication of work and maintain a comprehensive view of the multi-dimensional aspects of genetic resource policies before the Committee . . . ." *Id.* at 7.

[114] *Id.* at 6. Contracts that take the provisions of the CBD into account are usually referred to as "access" or "benefit-sharing agreements" or "contractual agreements on access to genetic resources and benefit-sharing." *Id.*

genetic resources have a large degree of discretion in arranging their agreements according to their specific needs.[115]

The Committee was specifically asked to develop guideline provisions accounting for the different stakeholders,[116] genetic resources, and transfers within the various sectors of genetic resource policy.[117] Because of the nearly limitless variety of possible provisions, the requirements for mutually agreed contract terms must entail a degree of flexibility.[118] Contractual arrangements may differ according to the parties involved, the varying types of genetic material being transferred, and whether the desired use of genetic resources is "'scientific or commercial, and, within each of these categories, according to the specific nature of the use.'"[119] Flexibility is also necessary due to the complex involvement of multiple actors in such transactions, so that the contract provisions create transferable rights and responsibilities that extend beyond the duration of the contract.[120]

MTAs may even benefit countries that already have access and benefit-sharing legislation by clarifying the processes involved and reducing transaction costs. Model MTAs for Equitable Bioprospecting already address intellectual property rights surrounding traditional knowledge.[121] These agreements recognize that traditional knowledge "is transferred with the genetic material as the intellectual property of the indigenous and local communities concerned."[122] A Panel of Experts on Access and Benefit-Sharing (hereinafter "Panel of Experts") concluded in its first meeting, in October 1999, that contractual agreements were presently the main mechanism for accessing genetic resources and

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115 *See id.* at 23.

116 Types of stakeholders may include government institutions, the public sector research community, the private sector, and civil society (including non-governmental organizations, indigenous and local communities, and other traditional knowledge holders). *Id.* at 48.

117 *Id.* at 4.

118 *See id.* at 5.

119 *Id.* at 49 (quoting UNEP/CBD/COP/5/8, ¶ 102).

120 *See id.* at 6.

121 *See, e.g.*, *id.* at 30.

122 *Id.*

arranging benefit-sharing agreements.[123] The Panel of Experts also noted that standardized MTAs would reduce transaction costs that may otherwise significantly impact the use of genetic resources.[124]

In the Panel of Experts' second meeting in March 2001, it considered the executive secretary's proposals addressing model agreements for creating fair and equitable contractual arrangements.[125] These included (1) using standard MTAs to reduce transaction costs to allow for repeat access under expedited procedures; (2) including provisions regarding user obligations: (3) varying contractual arrangements in relation to different resources and uses of those resources and anticipating commercial arrangements based on those variances; (4) including the full range of biotechnology applications and genetic resources used to ensure the fair and equitable sharing of benefits arising from commercialization of derivatives from those resources; (5) using a flexible approach that reflects the interests of all parties; and (6) ensuring parties are aware of prior relevant agreements.[126] In accordance with article 10(c) of the CBD, the Panel of Experts also recommended that contract provisions ensure that the continued customary use of biological resources and related traditional knowledge be protected and encouraged.[127] Contractual arrangements for access to genetic resources also often require parties to obtain prior informed consent from indigenous and local communities.[128] Provisions such as these broaden the available protection for biodiveristy and traditional knowledge as a sovereign national resource.

MTAs use trade secrets to protect traditional knowledge by allowing consenting local communities to require that knowledge

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123 *Id.* at 11. The Committee's Conference of Parties established the Panel of Experts on Access and Benefit-Sharing.

124 *Id.*

125 *See id.* at 12.

126 *Id.*

127 *See id.* at 39. Such model provisions would require that "any holder or licensee of an intellectual property right which concerns traditional knowledge of the community, shall not act to restrict any customary and non-customary use, production or practices involving the transferred genetic material in the source country." *Id.*

128 *See id.* at 32.

be kept confidential by both the provider and the recipient.[129] This strategy may prove beneficial where elements of traditional knowledge fail to fulfill requirements for intellectual property protection, such as novelty and inventive step for patents.[130] Problems may arise, however, with keeping such knowledge secret when it is known among an entire community or multiple communities. In such instances, documenting the knowledge as prior art may be a useful alternative for its protection and conservation.

c) Survey on Existing Forms of Intellectual Property Protection for Traditional Knowledge

In the Committee's first session held in Geneva from April 30 to May 3, 2001, member states sought to ascertain whether new measures were necessary to integrate traditional knowledge more effectively into searchable prior art.[131] Some states expressed concern over patents granted for traditional knowledge-related inventions because these patents failed to satisfy the requirements of novelty and inventive step since the knowledge could qualify as prior art.[132] Although most parts of the world conserve traditional knowledge through documentation, such information "is not orderly arranged" and "there are no effective search tools" for its retrieval.[133] Consequently, these patents were granted because of the lack of access to traditional knowledge information when examining patent applications.[134]

In the Committee's second session in Geneva on December 10 to December 14, 2001, preliminary conclusions were offered based on a survey the Secretariat issued inviting member states to provide information and case studies on existing forms of intellectual property protection for traditional knowledge.[135] The

[129] *See id.* at 31–32.
[130] *See id.* at 32.
[131] *See* WIPO Comm. Progress Report, *supra* note 12, at 3.
[132] *See id.* at 3–4.
[133] *Id.* at 4.
[134] *See id.* at 3–4.
[135] WIPO Survey, *supra* note 3, at 2. The survey contained twenty-seven questions addressing four distinct but interrelated topics. *See id.* Question 1 asked about experiences in using existing intellectual property mechanisms to protect traditional

responses demonstrated that many members believed adequate mechanisms for such protection existed.[136]

The survey asked member states to comment on the adequacy of existing intellectual property laws and procedures for protecting traditional knowledge and the possibilities of new legislative standards.[137] Three types of responses were received. First, some countries, such as Kazakhstan and Latvia, perceived no deficiencies in the use of existing intellectual property law mechanisms to protect traditional knowledge.[138] Second, countries such as Australia, Canada, and Norway expressed a "dual, supplementary approach," indicating that although existing intellectual property mechanisms already protect some or most traditional knowledge, further measures may be needed to complement the existing legal system.[139] Third, other responses demonstrated various examples of how existing intellectual property standards will always suffer from limitations in the protection of traditional knowledge.[140] Traditional knowledge, for example, may fail to meet the criteria of novelty and originality, as

knowledge. *Id.* at 13. Questions 2–25 focused on aspects of systems specifically devised to protect traditional knowledge. *Id.* at 15–31. Question 26 addressed the assistance available to traditional knowledge holders for determining how to acquire, exercise, manage, and enforce rights over their traditional knowledge. *Id.* at 32. The last question dealt with the general perception of intellectual property law's ability to adequately protect traditional knowledge. *Id.* at 33.

136 *See id.* at 3; Intergov'tal Comm. on Intell. Prop. and Genetic Resources, Traditional Knowledge and Folklore, *Survey on Existing Forms of Intellectual Property Protection for Traditional Knowledge—Preliminary Analysis and Conclusions*, WIPO Doc. GRTKF/IC/2/9, at 6 (Dec. 31, 2001) [hereinafter WIPO Survey Analysis] (explaining and analyzing the responses to the WIPO Survey), http://www.wipo.int/eng/meetings/2001/igc/doc/grtkfic2_9.doc. The European Union, Hungary, Switzerland, and Turkey identified several existing mechanisms, implying that "eligibility for traditional knowledge protection depends almost exclusively on meeting previously established legal conditions." *Id.* Kazakhstan and the Russian Federation both identified examples of how grants of patents protect technical traditional knowledge. *Id.* at 5.

137 *See* WIPO Survey Analysis, *supra* note 136, at 7.

138 *Id.*

139 *Id.* Guatemala expressed that the "combination of existing standard intellectual property mechanisms with cultural heritage legislation provides for the necessary and effective legal framework." *Id.*

140 *Id.* at 8.

established by internationally adopted standards.[141] It may also be difficult to identify individual creators of such knowledge, therefore eliminating the chance of obtaining communal benefits.[142] Some members also felt that limits on duration of protection pose problems because traditional knowledge should be afforded indefinite protection.[143] Furthermore, because traditional knowledge is difficult to quantify and is in the public domain, it is not possible to privately appropriate it.[144]

Despite these concerns, the Committee noted that existing intellectual property standards already contain answers to the perceived list of limitations. For example, although difficulties exist in identifying inventors of traditional knowledge, this does not necessarily eliminate the application of current intellectual property standards.[145] The Committee pointed out that collective entities own most intellectual property assets. It offered General Motors as an example of an entity that owns intellectual property rights "on behalf of a community of shareholders that is much larger and more diffuse than most identified traditional communities."[146] The Committee further remarked that patent law "is not necessarily about protecting *inventors*, but about appropriating *inventions*," and, therefore, even if the inventor cannot be identified, many national laws acknowledge that patent offices should not be prevented from issuing patents.[147]

Three member countries (Guatemala, Panama, and Peru) provided information on their national laws, or sui generis systems, specifically adopted to protect traditional knowledge.[148] Guatemala protects traditional knowledge through a national

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[141] *See id.* (Bhutan, Guatemala, Indonesia, Panama, Peru, and the Russian Federation expressed this concern.).

[142] *See id.* (Bhutan, Gambia, Panama, Samoa, and Singapore acknowledged the potential for this problem.).

[143] *See id.* (Bhutan, Gambia, the Russian Federation, and Singapore asserted the need to protect traditional knowledge indefinitely.).

[144] *See id.* (Singapore noted this problem.).

[145] *See id.* at 9.

[146] *Id.*

[147] *Id.* However, this would not apply to the U.S. because under article 1, section 8 of the Constitution, the inventor must be identified. U.S. CONST. art. I, § 8.

[148] WIPO Survey Analysis, *supra* note 136, at 5.

cultural heritage approach.[149] Under this approach, the "Culture Goods registry" includes expressions of national culture, including traditions and medicinal knowledge, under the state's protection.[150] This prevents parties from selling such rights through the use of contractual arrangements.[151] Under Panama's regime, traditional knowledge is protected "to the extent it provides for the cultural identification of indigenous peoples and is susceptible to commercial use."[152] Moreover, exclusive rights may be collectively owned for registered elements of traditional knowledge, or even co-owned by various communities, allowing for the sharing of benefits.[153] Peru does not have a system to protect traditional knowledge. It does, however, have a draft law to protect indigenous knowledge concerning properties, uses, and characteristics of biological diversity.[154] Under this draft law, knowledge holders must give consent for access to and use of their knowledge.[155] If the intended use is commercial or industrial in nature, a license agreement that provides for equitable sharing of the benefits must be entered.[156] The draft law also describes enforcement measures such as injunctions, seizures, and criminal sanctions, such as fines.[157] It remains to be seen if this ambitious draft law will be implemented.

Another survey question addressed whether the legislation of member states had special measures "to assist traditional knowledge holders to acquire, exercise, manage and enforce their rights."[158] Some answers demonstrated that some form of institutional assistance could provide these measures.[159] The

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149 *Id.*

150 *Id.* (The Ministry of Cultural Affairs manages this system which follows a "public good approach, in the sense that traditional knowledge is to be identified, recorded and preserved by the State for the benefit of the entire society.").

151 *Id.*

152 *Id.* at 6.

153 *See id.* at 6.

154 *See, e.g.*, *id.*

155 *See id.*

156 *See id.*

157 *See id.*

158 *Id.*

159 *See generally id.* at 6–7 (including answers from Australia and Tanzania).

majority of responses, however, indicated that no such measures were in place.[160]

Although less than twenty percent of member states responded to the survey, it is useful in understanding the perceived limitations of existing intellectual property procedures and the resources needed to more adequately protect traditional knowledge holders.[161] The survey may help "clarify whether governments should embark on a coordinated effort to promote the protection of traditional knowledge through available intellectual property mechanisms—either in anticipation of or in addition to a future exercise of developing a new, *sui generis* system for the protection of traditional knowledge, or as its substitute."[162]

4. The World Trade Organization and the Agreement on Trade-Related Aspects of Intellectual Property Rights

While the WIPO administers international agreements providing patent standards, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) takes a new approach to executing these standards.[163] In 1994, intellectual property was brought under jurisdiction of the WTO when member states signed the General Agreement on Trade and Tariffs (GATT) Uruguay Round Agreements, including TRIPS.[164] All WTO members are bound by TRIPS.[165]

TRIPS requires nations to meet minimum standards[166] for protecting patents, copyrights, trademarks and trade secrets, and

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[160] *Id.* at 7 (Norway acknowledged the possibility of introducing those measures in the future.).

[161] *See id.* at 9–10.

[162] *Id.* at 9.

[163] *See* Penna & Visser, *supra* note 26, at 9–10.

[164] *Id.*; *see also* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

[165] *See* TRIPS, *supra* note 164.

[166] TRIPS sets forth minimum standards by laying down "basic principles, specific rules for various rights, and rules on enforcement of rights, on maintaining rights, and on transitional arrangements." CRUCIBLE GROUP, PEOPLE, PLANTS, AND PATENTS: THE IMPACT OF INTELLECTUAL PROPERTY ON TRADE, PLANT BIODIVERSITY AND RURAL

failure to meet these standards is recognized as a barrier to legitimate trade.[167] All member countries must have systems in place for patenting products by January 1, 2006.[168] TRIPS allows developing nations up to ten years to come into compliance with its standards, depending on their economic status.[169] All but the least developed countries must implement protection for pharmaceutical patents by 2005.[170]

Under TRIPS, patents run for twenty years from the time the creator files the application.[171] Patent benefits must also be "shared equally, on a most-favored-nation basis, so that the benefits enjoyed by foreign inventors and firms doing business in the U.S. must be reciprocated in their home markets."[172] Many countries may therefore be forced to accelerate their intellectual property reform under TRIPS by entering into bilateral negotiations to ensure such reciprocal treatment.[173] TRIPS faces much criticism, however, because of the conflicting obligations it presents in relation to the CBD and its failure to adequately address the rights of indigenous people.

a) Critique of TRIPS

Scholars criticize TRIPS stating that it so interferes with the ability of member states to reach social policy objectives that "any attempt" to use intellectual property rights "to meet the goals espoused by the CBD is effectively foreclosed."[174] They argue that indigenous peoples' rights cannot be adequately addressed because of the restrictive stipulations the CBD is subject to under

SOCIETY 98 (1994), *available at* http://www.idrc.ca/books/725/append.html; *see also* TRIPS, *supra* note 164.

167 *See* Gollin & Laird, *supra* note 68, at 18; *see also* TRIPS, *supra* note 164.

168 Julian Morris, *Introduction and Summary*, *in* TRIPS AND HEALTHCARE: RETHINKING THE DEBATE 1 (2001) (unpublished symposium piece, on file with the *Fordham Intellectual Property, Media & Entertainment Law Journal*), *available at* http://www.policynetwork.net/pdfs/rethinking_the_debate_0701.pdf.

169 Gollin & Laird, *supra* note 68, at 22.

170 *See* Penna & Visser, *supra* note 26.

171 TRIPS, *supra* note 164, art. 33; *see also* Pollack, *supra* note 22, at 6 (Patents award an inventor exclusive rights to make or sell a product for a set period of time.).

172 Penna & Visser, *supra* note 26, at 10; *see also* TRIPS, *supra* note 164, art. 27.

173 Gollin & Laird, *supra* note 68, at 22.

174 Coombe, *supra* note 2, at 91.

TRIPS.[175] In the Committee on Trade and Environment within the WTO, the Indian Delegation noted two main ways in which TRIPS contradicted the CBD.[176] First, TRIPS fails to require the disclosure of the origin of resources or traditional knowledge when submitting patent applications.[177] Second, TRIPS lacks any requirement of prior informed consent from the source country or from the knowledge holders in order to obtain a patent.[178] TRIPS was also described by Jim Keon, the president of a trade group representing generic drug companies in Canada, as "'probably the greatest political economic achievement that the pharmaceutical industry ever had.'"[179]

Negotiations in the formation of TRIPS revealed that parties to GATT sought procedures that were "simple, short, and cheap so that certainty as to the grant and enforcement of patent rights were increased, and at the same time the length and the burden of administrative procurement were reduced."[180] According to Professor Drahos, developing countries were often not party to TRIPS negotiations between the United States and Europe, and therefore lacked access to the same level of information as the U.S. and Europe.[181] This professor criticized TRIPS as "less a negotiation and more a convergence of processes" because of the United States efforts to bring developing countries closer to the American position.[182] International respect for biodiversity and traditional knowledge as a sovereign national resource requires the active participation of source countries in the protection of their rights, even if it increases burdens on the patent application process.

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175 *See id.* at 91–92.
176 *See* Pires de Carvalho, *supra* note 25, at 390.
177 *Id.*
178 *Id.* at 390–91.
179 Pollack, *supra* note 23, at 6.
180 Pires de Carvalho, *supra* note 25, at 383.
181 *See* Penna & Visser, *supra* note 26, at 16.
182 *Id.*

II. RELEVANT LEGAL CONFLICTS

A. Encouraging Scientific Innovation While Respecting Source Countries' Rights over the Use of Their Resources and Knowledge

All too often, the areas with the greatest domesticated and wild biological diversity are also the areas of greatest economic poverty, exploitation, and biological degradation.[183] Although already plagued by economic devastation, communities further suffer from exploitation if they are not compensated for the use of their resources. Unscrupulous foreign companies and the developing countries' own local governments are often responsible for this exploitation. An anthropologist estimated that less than 0.001 percent of profits from drugs originating from traditional medicines have ever reached the indigenous people responsible for leading researchers to them.[184] This calculation, however, fails to clarify the percentage of profits received by the "political-economic elites" of their countries.[185]

Continuing to subject these communities to such dual forms of exploitation may affect the evolution of traditional knowledge. Their rights may be inadvertently overlooked in efforts to advance science or may derive from prejudicial notions of unworthiness, based on their economic status or ethnic background. Perhaps the communities are just the most vulnerable targets for self-interested seekers of economic profit. Whatever the explanation, the issue arises of whether the marginalization of these communities will

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[183] *See, e.g.*, Coombe, *supra* note 2, at 94 (citing Steven B. Brush, *Whose Knowledge, Whose Genes, Whose Rights?*, *in* VALUING LOCAL KNOWLEDGE 4–5 (S.B. Brush & D. Stabinsky eds., 1996)).

[184] *Id.* at 96.

[185] *Id.* at 95–96 (arguing that the political-economic elite of less developed countries "are far more likely to be engaged in commercial extraction resulting in the resource degradation that impoverishes local communities" than are transnational corporations or more developed countries). For example, national governments justify logging concessions to corporations that negatively impact biodiversity conservation as benefiting the national economy. *Id.* at 95. The local communities, however, never receive these benefits. *Id.*; *see also supra* notes 51–52 and accompanying text.

cause them to abandon traditional practices that provide an essential foundation for scientific development.[186]

To preserve traditional knowledge, source countries and their local communities should maintain a certain amount of control over and receive compensation for the use of their traditional knowledge and natural resources. By imposing such a requirement, a variety of issues will need to be resolved. The amount that would be adequate for economically challenged communities whose traditional knowledge may have passed down many generations would need to be determined. The proper authority to measure the adequacy of this compensation would also need to be identified. Additionally, the recipient of the compensation would need to be ascertained, whether it is the government, the local communities, or both. It should be noted that if only the government is compensated, it could hoard its recompense away from its local communities.

Another issue that remains unresolved is how much control source countries should be able to maintain. If developing countries are given strict control over their resources, they could control the patented developments by refusing to license them, which would impede scientific development. If industrial companies are required by international law to obtain consent before using another country's resources, they may become discouraged from exploring potential scientific discoveries. On the other hand, if source countries receive no control or compensation, companies may continue to exploit their resources. It is a continuing challenge for lawyers and legislative bodies to create laws that ensure sufficient control and compensation are provided to source countries and their communities while nonetheless encouraging scientific advancement.

B. Proposals that Strive to Resolve These Conflicts

Many proposals have been offered on how industrial companies can pursue scientific innovations while still respecting the right of indigenous communities to receive control and compensation for use of their resources and knowledge.

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[186] *See, e.g.*, *id.* at 97.

Inconsistencies in these proposals illustrate the need for a unified internationally accepted approach that ensures consistent enforcement.

1. Protection of Traditional Knowledge through Industrial Property Rights

a) Relying on Patent Law Protection

Frank J. Penna, from the Policy Sciences Center, Inc. and Coenraad J. Visser, from the University of South Africa, advocated that protections afforded to indigenous peoples should consist of both: (1) protection *against* the industrial property rights acquired by "outsiders" over the use traditional knowledge; and (2) protection *by* industrial property for traditional knowledge holders.[187] The first form of protection entails two requirements: (1) establishing a notification requirement for patentability; and (2) preventing the unauthorized acquisition of industrial property rights, particularly patents, over traditional knowledge by facilitating the documentation and publication of traditional practices as searchable prior art.[188] This would eradicate the possibility of fulfilling the novelty requirement, thereby preventing unauthorized users from obtaining patents. The second form of protection, "by industrial property," aims to secure economic revenue for knowledge holders by encouraging them to exploit their traditional knowledge, such as by obtaining patents over its uses.[189]

While this approach appears advantageous by demonstrating how indigenous people can be protected both *against* and *by* the intellectual property system, its application may prove unrealistic. "One basic problem [with encouraging indigenous groups to obtain patents] is that a patent protects active ingredients that have been isolated and tested. Such isolation and testing cost hundreds of millions of dollars and so is [sic] only possible for multi-national pharmaceutical companies, not for developing countries, or

[187] Penna & Visser, *supra* note 26, at 10–11.
[188] *Id.* at 11.
[189] *Id.*

certainly not for their indigenous peoples."[190] This proposal also fails to recognize that an invention's novelty may have been destroyed by its prior use in the local community, depending on the nation's patent law standards.[191] Most importantly, these two forms of protection may prove mutually incompatible. Documenting traditional knowledge as prior art, for example, would prevent community members from asserting any intellectual property rights over use of that knowledge. Consequently, although this approach is aspirational in seeking to take full advantage of the intellectual property system, it may prove unattainable.

b) Transfer of Technology Approach

As an alternative to knowledge holders using patent law for obtaining economic gain, these authors also advanced a transfer of technology approach. Under this approach plant samples and information on biological resources are sent to a company with the resources to test the received materials in return for some form of compensation.[192] This approach therefore requires an organized body of knowledge and an identifiable entity to transfer such knowledge.[193] Such an approach was used in 1991, when a contract was signed between the Instituto Nacional de Biodiversidad (INBio), a non-profit organization in Costa Rica, and Merck, a global research pharmaceutical company.[194] Under their agreement, INBio sent nearly 10,000 plant samples to Merck over a two-year period with information on their traditional uses in return for 1.35 million dollars and an agreement to pay a two to three percent royalty.[195] If any sample became a billion-dollar drug, Merck would pay INBio twenty to thirty million dollars in royalties, which could potentially earn INBio more than 100 million dollars each year.[196]

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190 *Id.* at 12; *see also supra* notes 22–24 and accompanying text.
191 *Id.* at 12 n.27; *see also supra* notes 6–15 and accompanying text.
192 *Id.* at 12.
193 *See id.*
194 *Id.*
195 Penna & Visser, *supra* note 26, at 12.
196 *Id.*

Despite the potential to earn substantial profits, this approach requires that royalties be paid to an official body, as opposed to a non-government official or privately held corporation. As such, the profits "may disappear into the general state revenue account and may not 'trickle down' to the relevant communities or individuals."[197]

c) Relying on Trade Secret Law Protection

Trade secret law was also offered as a possible form of protection. Trade secrets are usually disclosed and licensed to someone in return for an undertaking of confidentiality, and remuneration, usually in the form of a royalty.[198] Trade secrets may include "any formula, pattern, device, or compilation of information which is used in one's business, which gives [that person] an opportunity to obtain an advantage over competitors who do not know or use it."[199] Information is considered secret if it is not "generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; has commercial value because it is secret; and has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret."[200] The value created from the information's secrecy is clearly the driving force of this approach.

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[197] *Id.*; *see also supra* notes 184–185 and accompanying text.

[198] *See* Penna & Visser, *supra* note 26, at 12. The Policy Sciences Center is experimenting with a trade secret approach by making a grant to Otro Futuro, a non-governmental organization in Venezuela. *Id.* Otro Futuro will use the grant to protect the Dhekuana Indians' intellectual property rights by establishing a community foundation to document the ethnobotanical knowledge as trade secrets. *Id.* This knowledge may only be disclosed to private companies who pay royalties to the foundation. *Id.* at 13. The Policy Sciences Center, Inc. is a non-profit, public, tax exempt foundation seeking to advance the policy sciences relating to decision-making processes. *See* The Policy Sciences, *at* http://www.policysciences.org/policy_sciences_center.htm (last visited Apr. 25, 2003).

[199] JOYCE ET AL., *supra* note 6, at 11 (citing the RESTATEMENT (FIRST) OF TORTS § 757 cmt. b (1939), which defines a trade secret as "a formula for a chemical compound; a process of manufacturing, treating or preserving materials; a pattern for a machine or other device; or a list of customers").

[200] Penna & Visser, *supra* note 26, at 13.

The stringent requirements of trade secret law make its application to a community's traditional knowledge impractical for various reasons. First, requiring that the proprietor take measures to maintain secrecy and that this secrecy remains substantial within the owner's industry may prove impossible because "secrecy often flows only from the fact that few people have access to the information concerned."[201] Traditional knowledge, however, is often shared within and among entire local communities.[202] Second, trade secret protection can only be enforced against improper appropriation, such as "theft by an industrial spy or breach of a contractual commitment not to divulge the trade secret."[203] It is unlikely that traditional knowledge holders from indigenous communities have the means to become aware of such misappropriation enabling them to enforce their rights under this approach. Third, trade secret law varies nationally and "international attempts at harmonization have not yielded much."[204] Some countries lack any trade secret legislation. This lack of international harmonization disrupts the ability to consistently protect ethno-botanical knowledge in both the country of origin and foreign countries.

d) Compensatory Liability Approach

The compensatory liability approach was described as "loosely derived from classical trade secret law and from antitrust principles applicable to two-party transfers of unpatented industrial know-how."[205] This regime seeks to reward both indigenous communities, described as 'first comers,' and 'second comers' who build on the communities' cultural heritage.[206] This approach allows 'second comers' to commercially exploit ethno-botanical knowledge, even without prior authorization, as long as a designated person or institution is paid a reasonable royalty.[207] It therefore seeks to encourage scientific development based on

[201] *Id.*; *see also* JOYCE ET AL., *supra* note 6.
[202] *See supra* notes 3–4 and accompanying text.
[203] JOYCE ET AL., *supra* note 6.
[204] Penna & Visser, *supra* note 26, at 13.
[205] *Id.* at 14.
[206] *Id.* at 15.
[207] *See id.*

indigenous knowledge without depriving knowledge holders of their equitable share of the benefits.[208]

Three problems are presented by this approach. First, it fails to define a reasonable royalty. If the royalty were a monetary payment, a neutral authority would need to be identified to make determinations of reasonableness based on some form of established guidelines. Second, it does not specify who would be compensated—an individual, community, or government. Third, by failing to require prior authorization, this approach ignores the importance of recognizing biodiversity and traditional knowledge as a sovereign national resource.

2. Requiring Indications of Origin and Prior Informed Consent for Patent Approval

Nuno Pires de Carvalho proposed that the origin of the genetic resources and prior informed consent from the government, local authorities, and traditional knowledge holders should be indicated when submitting patent applications (the "Requirement") to prevent biopiracy.[209] The Requirement derives from article 15 of the CBD, regarding access to genetic resources[210] and has been incorporated into Andean Decision No. 391 and the Biodiversity Law (No. 7788) of Costa Rica, enacted on May 27, 1998.[211] The author conceded that the Requirement fails to comply with TRIPS[212] but addressed three ways it can be adopted by WTO members without infringing TRIPS.[213]

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[208] *See id.*

[209] *See* Pires de Carvalho, *supra* note 25, at 374. Nuno Pires de Carvalho received her LL.M. from Washington University and serves in the Global Intellectual Property Issues Division of WIPO. *Id.* at 371 n.*.

[210] *See id.* (stating that under CBD, *supra* note 47, article 15, paragraph 5, access "shall be on mutually agreed terms and subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party").

[211] *See* Pires de Carvalho, *supra* note 25, at 375–76. Under both statutes, patent applicants must provide the origin of the genetic resource and proof of prior informed consent from both governmental authorities and the traditional knowledge holders if the resource was obtained based on their traditional know-how. *Id.* at 376.

[212] *See id.* at 379 ("The Requirement quote obviously is not compatible with article 27.1.").

[213] *Id.* at 380.

The Requirement is inconsistent with several provisions of TRIPS concerning the availability of patent rights.[214] First, it is not compatible with article 27.1, which requires that patentable subject matter meet the three conditions of: i) novelty; ii) inventiveness; and iii) industrial applicability.[215] By addressing how the manner of obtaining resources affects patentability the author's Requirement extends beyond what TRIPS requires. Second, TRIPS's conditions for disclosure are limited to those established by article 29.[216] Accordingly, an invention's disclosure need only be in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.[217] Requiring the indication of origin and prior informed consent clearly exceeds TRIPS minimal disclosure requirements.[218] Third, the Requirement appears incompatible with article 62 of TRIPS.[219] Article 62 mandates that members comply with "reasonable procedures" when acquiring patents, but fails to define this term.[220] "Reasonable procedures" appears to mean procedures that assist patent administrators in determining whether inventions satisfy substantive patent requirements, such as novelty, inventive step, and industrial applicability, not procedures on how source materials are obtained.[221]

The author offered three alternative solutions to eliminate the inconsistencies between TRIPS and the Requirement. First, source countries could implement the CBD, which would entitle them to receive equitable compensation for use of their resources.[222] Second, TRIPS could be amended to include the Requirement.[223] The author recognized, however, the high improbability of

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214 *See id.* at 379.

215 *See, e.g.*, *id.* at 389; *supra* Part I.A.

216 *See, e.g.*, *id.* at 380.

217 *See id.*; TRIPS, *supra* note 164, art. 29.

218 *See* Pires de Carvalho, *supra* note 25, at 380.

219 *Id.* at 381; *see also* TRIPS, *supra* note 164, art. 62.

220 *Id.*

221 *See* Pires de Carvalho, *supra* note 25, at 382. Article 62.2 specifies that the procedures subject to compliance with article 27.1 should grant the rights established by article 27.1 within a reasonable period of time to avoid unwarranted curtailment of the period of protection. *Id.*

222 *See id.* at 371–72.

223 *See id* at 390.

obtaining the international consensus necessary to reach such an amendment in the near future.[224] Third, compliance with the Requirement could be mandated, not as a condition for obtaining a patent, which would be inconsistent with TRIPS, but as a condition for the "enforceability" of patent rights.[225] The author demonstrated that TRIPS does not prohibit WTO members from adopting patent laws "intended to secure compliance" with the CBD.[226]

The author supported her third proposal by addressing article 8 of TRIPS and applying the fraudulent procurement doctrine. Paragraph 1 of article 8 authorizes WTO members to adopt measures "necessary to promote the public interest in sectors of vital importance to their socio-economic and technological development," as long as such measures are consistent with TRIPS.[227] The author therefore concluded that "if the implementation of benefit sharing under the CBD framework is a matter of vital importance both from an economic and a technological perspective, then . . . the Requirement may be adopted by national patent laws" as a condition for enforcing patent rights.[228] Paragraph 2 of article 8 also authorizes WTO members to adopt measures that prevent the abuse of intellectual property rights.[229] Enforcing an illegitimately obtained patent could therefore be prohibited even if the WTO could not actually revoke the patent as a sanction.[230]

Using these loopholes of article 8, the author applied the fraudulent procurement doctrine to support the measure proposed.[231] This doctrine only allows patents to be invalidated if the substantive conditions of patent applications were illegitimate. Illegitimacy on non-essential matters, however, such as failing to obtain prior informed consent, could be sanctioned by non-

224 *See id.* at 390–95.
225 *Id.* at 372.
226 *Id.* at 395.
227 *Id.*; *see also* TRIPS, *supra* note 164, art. 8.
228 *See* Pires de Carvalho, *supra* note 25, at 395–96.
229 *Id.* at 396; *see also* TRIPS, *supra* note 164, art. 8.
230 *See* Pires de Carvalho, *supra* note 25, at 395.
231 *See id.* at 396.

enforceability.[232] Before enforcing patent rights against alleged infringers, patent owners would have to disclose the origin and prior informed consent of the authorized stakeholders—including governments, local authorities and traditional knowledge holders.[233]

While the Requirement appears to circumvent the obstacles presented by TRIPS, it suffers various inadequacies that must be addressed. First, obtaining the prior informed consent from governments, local authorities, and traditional knowledge holders may prove extremely difficult, if not impossible.[234] Situations may arise, for example, where the knowledge holders wish to consent but the government or local authorities do not, and vice versa. Potential scientific advancements would be thwarted if consent could not be obtained from all three sources. Additionally, requiring such consent would greatly attenuate the patent application process, further impeding scientific innovation.[235] As with many of the earlier mentioned approaches, the Requirement also fails to clarify who would receive the compensation and how such compensation would be measured. These areas must be addressed and clarified to adequately account for the rights of all parties involved.

These varying approaches illustrate the ongoing struggle to find a method that protects source countries and their local communities from commercial exploitation without discouraging scientific development. Only an internationally adopted procedure can provide the uniformity needed to overcome this struggle.

III. PROPOSED SOLUTION

An internationally uniform procedure must be adopted that recognizes source countries' sovereign rights over their resources and knowledge and that allows parties to structure arrangements

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[232] *See id.* at 397—98.

[233] *See id.* at 399.

[234] *See generally id.* at 383, 392 (discussing the need for procedures that do not overly burden the patent application process).

[235] *See id.* at 392 (noting the arguments made by the United States delegation against amending TRIPS).

for access to resources according to each party's specific needs and the desired uses of the resources and knowledge involved.

A. Documenting Traditional Knowledge as Prior Art and Using Online Search Systems

Documenting traditional knowledge as prior art and creating online traditional knowledge databases recognizes the sovereign rights of knowledge holders by providing them with control over the use of their resources and knowledge. This will encourage them to document their knowledge and enable intellectual property offices to integrate this documentation into their patent application procedures.[236] These measures will also "facilitate the electronic exchange and dissemination of public domain traditional knowledge data within intellectual property information systems" worldwide.[237] To achieve these goals, intellectual property offices and traditional knowledge initiatives must make various joint endeavors.

1. Documenting Publicly Disclosed Traditional Knowledge as Prior Art

Documenting publicly disclosed traditional knowledge as prior art will prevent subsequent inventions that build upon this knowledge from satisfying the novelty requirement of patent law.[238] This will allow knowledge holders to retain control over the use of their resources even if they themselves cannot exert intellectual property rights because the knowledge is already in the public domain or because it is too costly to perform the necessary experiments.[239] Accordingly, local communities, not just governmental authorities, will be provided with control because they decide if their knowledge should be documented. Knowledge holders will therefore be encouraged to document their knowledge to prevent others from asserting rights over uses of their resources. This will ensure the conservation of traditional knowledge by

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[236] This proposal is derived from resolutions advocated by the WIPO Committee. *See* WIPO Comm. Progress Report, *supra* note 12, at 21.

[237] *Id.* at 21.

[238] *See supra* notes 6–15 and accompanying text.

[239] *See supra* text accompanying notes 8, 22.

decreasing the potential for knowledge holders to abandon their practices for fear of exploitation.[240]

Encouraging the documentation of knowledge as prior art will not reduce scientific discovery because it merely supports exerting a lawful measure established to protect against illegitimate patents. Many organizations and national laws already recognize documented knowledge as prior art.[241] To consistently protect source countries' interests, however, limitations created by prior art must be internationally uniform. This can be achieved by establishing an internationally accepted definition of prior art.

2. The Need for an Internationally Accepted Definition of Prior Art

Consistent intellectual property protection for traditional knowledge holders requires an internationally adopted definition of "prior art." Because traditional knowledge is intrinsically related to a nation's biodiversity, treating it as prior art will protect the resources involved as well. This Note advocates the following definition: "any information available to the public, anywhere in the world, in written form, if it was made available to the public before the filing date, or, where applicable, the priority date." This definition is similar to that proposed by the Committee in its Draft Substantive Patent Law Treaty but excludes oral communications and communications by display or use because they would prove extremely difficult to enforce.[242] It would be very difficult for a United States company, for example, to learn of all oral communications in India that may qualify as prior art. Including only written communications will ensure consistent enforcement and thereby encourage documentation. Moreover, this definition accounts for foreign documented knowledge, uses, or inventions, which will protect knowledge holders from foreign industrial companies. This will encourage all nations to act more responsibly towards one another when extracting the world's resources by

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240 *See supra* note 186 and accompanying text.

241 *See infra* Part III.A.4.

242 *Cf.* WIPO Comm. Progress Report, *supra* note 12, at 17; *see also supra* Part I.C.3.a.

forcing them to learn of and respect the rights surrounding another country's resources.

Harmonizing definitions of prior art will help unify patent application procedures among national patent-granting authorities. This will benefit developing nations, particularly those who lack the economic resources to process patent applications and instead "maintain cooperation agreements with large national or regional patent-granting authorities" to conduct their substantive patent examinations.[243] Local communities will therefore gain more stability in the results of documenting their knowledge because uncertainties that come with inconsistency will be reduced.

3. Using Online Search Systems or Digital Libraries to Retrieve Traditional Knowledge

Online search systems are widely recognized as systems that can protect against granting patents for traditional knowledge-related inventions that fail to satisfy the requirements of novelty and inventive step because the underlying knowledge qualifies as prior art.[244] To prevent insufficient access to this non-patented literature when examining patent applications, an orderly and internationally accessible information system that is efficiently classified with effective search tools must be implemented worldwide.

a) Traditional Documentation Initiatives by Local and Indigenous Communities

Many indigenous communities, economically unable to continually process applications for intellectual property rights, instead developed traditional knowledge documentation initiatives.[245] These initiatives organize, preserve, and protect their historic yet constantly evolving knowledge by entering it into registers, such as databases.[246] As explained by the Committee, a registry does not merely provide a compilation of retrievable

[243] WIPO Comm. Progress Report, *supra* note 12, at 17.
[244] *See infra* Part III.A.4; *supra* note 63 and accompanying text.
[245] WIPO Comm. Progress Report, *supra* note 12, at 33.
[246] A registry is defined as an ordered collection or repository of information. *Id.*

information, but by implication, confers legal status onto the information it contains.[247] They therefore help secure the rights local communities have over their invaluable knowledge by systematically organizing it in documented form.[248] The documentation is proof of the origin of the traditional uses of any given resource.[249] This will reduce the potential for situations such as that seen in India where a patent was granted illegitimately because the well-known use of the natural resource among India's people qualified it as prior art.[250] Local communities benefit from these initiatives because they determine what gets documented. Requiring patent application examiners to retrieve all information available from these initiatives will ensure their rights are respected. Consequently, the interchangeability of information between documentation initiatives and existing intellectual property information systems is necessary for achieving a legal status for traditional knowledge that evokes international recognition.

b) Connecting Intellectual Property Offices and Traditional Documentation Initiatives by Creating Traditional Knowledge Databases

With the increasing use of traditional documentation initiatives, the Committee recognized the need to create "operational links," or connections, between intellectual property offices and these initiatives.[251] This can be achieved by administering a system of internationally accessible traditional knowledge databases. According to the Committee, these links would serve three objectives: (1) allow the initiatives to make their documented traditional knowledge from the public domain available to intellectual property offices; (2) allow intellectual property offices

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[247] *See id*. Registration of information in a registry "puts that information 'on the record' and records the fact that the registrant asserts a claim to that information." *Id.* Various initiatives in India, Peru, the Philippines, and by the Inuit of Nunavik and the Dene in Canada have developed widely acclaimed traditional knowledge registries/databases. *Id.*

[248] *See id.*

[249] *See id.*

[250] *See supra* note 33–36 and accompanying text.

[251] *See* WIPO Comm. Progress Report, *supra* note 12, at 4, 33.

to integrate that knowledge into their patent application process; and (3) assist the electronic exchange and dissemination of this documentation.[252] This system would ensure all documented traditional knowledge is retrievable by patent examiners worldwide.[253] It would therefore further reduce the potential for illegitimate patents granted due to insufficient access prior art. Moreover, it would enhance the international recognition of traditional knowledge as prior art, originating from even the smallest indigenous communities.

Concerned that a lack of traditional knowledge documentation was permitting the wrongful issuance of patent rights, the WIPO Standing Committee on Information Technology (SCIT) proposed the establishment of Traditional Knowledge Digital Libraries (TKDLs).[254] Under its proposal, the

> TKDL portal should have a web-based search interface providing full text search and retrieval of traditional knowledge. The TKDL portal should have full data on traditional medicine and practices including the pertinent scientific literature. Such a portal should include cross references, key words, comprehensive search interfaces, indexing and retrieval and it should have a secured access on the web. In the future, TKDL can increase its canvas beyond traditional medicine and include other innovations based on traditional knowledge. The methodology and standards used in the creation of the TKDL portals should be the same as those established by several of I[ntellectual] P[roperty] offices such as USPTO, European Patent Offices or WIPO's Intellectual Property Digital Library (IPDL).[255]

To assist in this proposal, WIPO identified measures governments should take to facilitate the recognition of traditional knowledge as prior art. These measures illustrate appropriate and attainable standards all nations should follow. Four measures of particular relevance included: (1) assisting in the documentation

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[252] *Id.* at 4.
[253] *See id.*
[254] *See id.* at 7, 27.
[255] *Id.*

and publication of traditional knowledge as searchable prior art; (2) properly classifying traditional knowledge documentation; (3) using "minimum documentation" lists for non-patent literature that contains traditional knowledge information; and (4) increasing the inclusion of traditional knowledge databases and digital libraries in existing intellectual property information systems.[256] Establishing an international definition of prior art and using online search systems will not be sufficient if the documented knowledge can not be efficiently accessed. These guidelines are therefore crucial to implementation of this proposal and to the international recognition of traditional knowledge as prior art.

Assisting in the Documentation and Publication of Traditional Knowledge as Searchable Prior Art

Providing traditional knowledge holders with proper assistance will help them overcome any potential reluctance to document their knowledge.[257] This reluctance is likely if people from indigenous/local communities, who may be in charge of the documentation initiatives, are not thoroughly educated on the intellectual property implications of their documentation work.[258] If, for example, disclosure of traditional knowledge preempts its protection as an intellectual property right, it becomes essential to advise that only knowledge already in the public domain be disclosed.[259] If those in charge of the initiatives receive the proper training, they will become more competent in their documentation work. This will increase knowledge holders' confidence in the use of intellectual property offices and traditional documentation initiatives. Intellectual property offices, such as the USPTO, EPO, and JPO, should therefore be required to offer traditional knowledge holders and documentation initiatives "practical advice and assistance in developing and implementing intellectual property strategy during their documentation work," to ensure all

[256] *See id.* at 9, 22.
[257] *Id.* at 31.
[258] *See id.* at 31–32. Disclosure of traditional medicine documentation, for example, may destroy the novelty of a formulation and thereby foreclose the ability to obtain patent protection. *Id.* at 32.
[259] *See id.* at 31–32.

interests are adequately protected.[260] This assistance can take many forms such as intermediate training programs, informational packets, and/or periodic visits to local initiatives. It is clearly an attainable measure with end results that will far outweigh any administrative burdens.

The Classification of Traditional Knowledge Within Databases

Establishing a classification system that easily and accurately retrieves information is essential for an efficient database. Otherwise, the documented traditional knowledge will be unorganized and disorderly, rendering the use of these databases meaningless. An International Patent Classification (IPC) system already exists for establishing a search tool to identify and retrieve patented documents.[261] National and regional patent offices publish over one million patent documents worldwide each year, approximately 95% of which bear IPC classification symbols.[262] Because technology is divided into nearly 69,000 subdivisions under the IPC, it appears flexible enough to account for regional variances in biodiversity.[263] This Note supports the Committee's proposal that a system similar to the IPC be initiated to facilitate access to traditional knowledge documentation.[264]

The government of India formed a task force to create such a classification system for traditional Indian medicine documentation.[265] The task force developed a draft Traditional Knowledge Resource Classification (TKRC), which was largely influenced by the structure of the IPC. [266] As a result, the Committee of Experts of the Special Union for the International Patent Classification (IPC Union) created a special task force to advise and expand the TKRC to include documentation of other

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260 *Id.*; *see also supra* Part I.C.3.a.

261 *See* WIPO Comm. Progress Report, *supra* note 12, at 22.

262 *Id.*

263 *Id.* Each subdivision is identified by a separate symbol and before publication, each patent document is "classified," according to the technical fields to which the invention relates, which is then printed on the front page of the published document. *Id*.

264 *See id.*

265 *Id.*

266 *Id.*

countries.[267] The IPC Union recognized that the TKRC could be linked or partially integrated into the IPC.[268] The more nations take such initiatives, the greater the potential for achieving an international system for the classification of traditional knowledge. All source countries will benefit from such an achievement because the effective retrieval of traditional knowledge documentation fortifies their ability to prevent illegitimate patents.

Searching Procedures that Retrieve Traditional Knowledge Documentation Based on the "Minimum Documentation" Standard

a) International Searches

In addition to a classification system, international searching procedures are necessary to retrieve traditional knowledge documentation from online databases. Accordingly, the Committee encouraged using the standard found under article 15(4) of the Patent Cooperation Treaty (PCT).[269] Article 15(4) states that international searching authorities "'shall endeavor to discover as much of the relevant prior art as its facilities permit, and shall, in any case, consult the documentation specified in the Regulations.'"[270] This documentation is referred to as the PCT "minimum documentation." It includes, under rule 34, certain national patent documents, published international and regional applications, published regional patents and inventors' certificates, and other published items of non-patent literature as agreed upon by the international searching authorities. The international availability of traditional knowledge documentation would also be enhanced by the "integration of periodicals, gazettes and newsletters which document traditional knowledge into the minimum documentation list."[271] This will ensure recognition of prior art that may not yet be documented in an online database but may have been recognized in some form of local report. At the

[267] *Id.* at 23. This task force was created in its thirtieth Session, held in Geneva from February 19 to 23, 2001. *Id*.

[268] *Id.*

[269] *Id.*; *see also* PCT, *supra* note 87, art. 15(4).

[270] WIPO Comm. Progress Report, *supra* note 12, at 23 (quoting PCT, *supra* note 87, art. 15(4)).

[271] *Id.* at 24.

very least, international law should require all nations to meet the "minimum documentation" standard to ensure the most thorough searches are performed for each patent application.[272] Without such minimum guidelines, the potential for mere cursory searches will increase the chance of inadvertently overlooking prior art.

An example of an initiative taken based on the PCTs minimum documentation list is the *Journal of Patent Associated Literature* (*JOPAL*). This journal was established and published in paper form in 1981 based on the international cooperation of national and regional authorities.[273] *JOPAL* aimed to create a centralized database for intellectual property offices to search for prior art of technical and scientific non-patent literature.[274] This database is now available through the Internet from WIPO Intellectual Property Digital Libraries (IPDL) site and is updated monthly.[275] *JOPAL* gathers the "bibliographic details and classification of selected articles as a by-product of the systematic maintenance of their search files" and submits that information to the Secretariat of WIPO to be included in the database.[276] Creation of the *JOPAL* demonstrates the importance nations must place on thoroughly examining a full range of documentation when assessing prior art. Nations must continue expanding the *JOPAL* and making further similar initiatives to increase access to non-patent literature as prior art.[277]

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[272] PCT, *supra* note 87, art. 34; WIPO Comm. Progress Report, *supra* note 12, at 23. Currently the International Searching Authorities have agreed that such published items of non-patent literature should be the items published in 134 periodicals during the five-year period preceding the time at which the international search report is established. *Id.* It is understood, however, that the International Searching Authority is not precluded from consulting issues of these publications published prior to the beginning of this five-year period. *Id.* at 23–24.

[273] WIPO Comm. Progress Report, *supra* note 12, at 24.

[274] *Id.*

[275] *Id.*

[276] *Id*.

[277] *See id.* at 24–25. The results of a survey distributed to intellectual property offices revealed the consensus view that the *JOPAL* should continue. *Id.* Forty-one offices responded to the survey. *Id.* The results of the survey were presented in a status report to the sixth Plenary Session of the WIPO Standing Committee on Information and Technology, held in Geneva from January 22 to 26, 2001. *Id.* The Committee concluded, however, that further steps are needed for intellectual property offices to adequately

b) National Searches

National searches should adhere to international searching procedures. Unlike the minimum documentation standard for international applications, the documentation search for national applications "varies widely according to the law and practice of national and regional patent-granting authorities."[278] This variation perpetuates the problems that arise from insufficient access to prior art and creates the potential for haphazard documentation searches. Under article 15(5)(a) of the PCT, upon the applicant's request an international-type search *may* be carried out on national applications subject to the national law of the contracting state.[279] National offices of contracting states may also choose to subject national applications to "international-type" searches and in some jurisdictions examiners are obligated to do so.[280] Most jurisdictions, however, do not require such a procedure.[281] This Note advocates administering international searches for all patent applications. The increased efficiency created by integrating all traditional knowledge databases would make this a feasible requirement and will thereby harmonize inconsistent national procedures.

Implementing the Online Search System

Efficiency requires that traditional knowledge databases be available through online search systems. A WIPO survey on *computerized* search systems indicated that they are more suitable for general orientation searches, while *online* search systems would more efficiently search non-patent literature.[282] An online

access non-patent literatures as prior-art and to determine how the *JOPAL* could be used to achieve that goal. *Id*. at 25.

[278] *Id.* (recommending that examination procedures for national patent applications should more effectively integrate guidelines for "international-type searches").

[279] *Id.*; *see also* PCT, *supra* note 87, art. 15(5).

[280] WIPO Comm. Progress Report, *supra* note 12, at 25–26; PCT, *supra* note 87, art. 15(5).

[281] *See* WIPO Comm. Progress Report, *supra* note 12, at 26.

[282] *See id.* The productivity of online systems in non-patent literature searches is partially due to (1) generally satisfactory coverage of backlog files, (2) extensive experience in the computerization of non-patent literature searching, (3) more lenient patent office requirements for non-patent literature documentation, in comparison to patent documentation. *Id.* The survey indicated the following problems with use of computerized systems: "a lack of confidence and reliability with regard to the

traditional knowledge database should be established that entails a variety of the following features:[283]

The database should be established and administered by WIPO, due it its expertise and technical capacity, in close cooperation with other relevant international bodies, particularly the CBD.[284]

The database should be established at the international level to "ensure that all national, regional and international patent authorities and relevant judicial authorities have adequate access to information on traditional knowledge."[285] An international system will help eliminate the inconsistencies found among national patent application procedures.

To reduce the costs of creating one international database, existing regional, national, and local databases should be electronically linked. This would allow an international database to "function as a gateway to these other databases."[286] This can be achieved through use of the standardized classification system previously discussed.[287]

Information should be consistently updated to ensure that "traditional knowledge, which is constantly created and improved, is always recorded in its newest form."[288] Up-to-date recording clearly proves easier and less costly for electronically linked regional, national, and local databases, rather than updating one large international database.[289]

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completeness of coverage of documents; limited coverage in time of computerized systems (this will be a particularly grave problem in the case of traditional knowledge-related N[on-]P[atent]L[iterature]); lack of standardization, in particular with regard to command language and the recording of data elements; overlaps of subject areas by subject-related search systems combined with difficulties in cross-file searching; absence of illustrations and drawings online; regular training-needs for examiners involved in online searching; and the fact that many computerized NPL databases are not specific enough from the point of view of patent search." *Id.*

283 Some of these features were proposed in a recent communication submitted to the TRIPS Council. WIPO Comm. Progress Report, *supra* note 12, at 28.

284 *See id.*

285 *Id. See* discussion *supra* Part III.A.3.b.3.

286 WIPO Comm. Progress Report, *supra* note 12, at 28.

287 *See id.*; *supra* Part III.A.3.b.2

288 WIPO Comm. Progress Report, *supra* note 12, at 28.

289 *Id.*

The general public should have access to this database. Although there may be harm in allowing the public to learn of medical treatments derived from foreign products to which they lack access (i.e., people may lose faith in their own nation's medical industry), the ability to educate the public overrides this concern. No nation would benefit by limiting its people's knowledge of foreign scientific and medical methods. In fact, allowing broad latitude in people's ability to research foreign techniques will motivate any scientific community to explore and stay abreast of relevant advancements, thereby stimulating innovation. Traditional knowledge holders should, however, be allowed to request limitations on the general public's access to some elements of their knowledge if necessary to respect and preserve their community's sacred use of its resources.[290]

Recorded information should be translated in several languages.[291] Problems may arise, however, when trying to disclose microbiological inventions to the public in words, as required by patent law or when updating digital libraries.[292] Terms used for chemical processes may vary regionally and cause even skilled translations of the published material to contain inadvertent inaccuracies. The Committee should be responsible for carefully monitoring documented material for possible inaccuracies.

The date and time of all publications and updates must be recorded.[293] Accurately documenting the time of disclosure of traditional knowledge may prove problematic because it is constantly evolving and may have been passed on for many years. To avoid inconsistencies, the date the knowledge is presented for documentation as prior art should be the recorded disclosure date.

All recordings should be made voluntarily after knowledge holders receive the appropriate assistance and guidance.[294]

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[290] *Id*.

[291] *See id.*

[292] Interview with John Richards, Esq., Adjunct Professor of Law, Fordham University School of Law, New York, N.Y. (Apr. 16, 2002).

[293] WIPO Comm. Progress Report, *supra* note 12, at 6. For patent applications, it is necessary to record the appropriate time of disclosure in relation to the filing date of a patent application or, if priority is claimed, the priority date of the application. *Id.*

[294] *Id.* at 28.

4. Organizations Supporting Treating Traditional Knowledge as Prior Art and Using Online Search Systems

The international support already present for the treatment of traditional knowledge as prior art and the use of online databases demonstrates both the importance and attainability of this proposal. The Committee noted a variety of organizations and legislation supporting this proposal. WTO members, for example, noted that documenting traditional knowledge in the public domain as prior art would ease difficulties patent examiners face when assessing patent applications.[295] The WTO also reviewed several cases of bio-piracy of traditional knowledge in India and argued that a digital database containing prior art would prevent such occurrences by disseminating information to patent examiners worldwide.[296]

The World Bank also sought to mainstream traditional indigenous knowledge to "optimize the benefits of development assistance, especially to the poor" by creating a database with over 200 case studies.[297] The database summarizes all traditional knowledge techniques and contains references, through hyperlinks or bibliographic references, to more detailed descriptions and to organizations or individuals.[298] This system thereby allows patent application examiners to efficiently review documented traditional knowledge and to access contacts or more thorough information on any documentation deemed relevant to an application.

The United Nations Conference on Trade and Development (UNCTAD), in an Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices, noted that documenting traditional knowledge in ordered collections or databases can help conserve and protect such knowledge and demonstrate the existence of prior art.[299] A WHO Inter-Regional Workshop on Intellectual Property Rights in

[295] *See id.* Such discussions occurred in the Committee on Trade and Environment and in the TRIPS Council. *Id.*

[296] *Id.* As discussed *supra* Part III.A.3.b, such an endeavor has already been initiated in India through the establishment of Traditional Knowledge Digital Libraries.

[297] *Id.* at 13.

[298] *Id.*

[299] *Id.* at 12 (This meeting was held in Geneva from October 30 to November 1, 2000.).

the Context of Traditional Medicine also recommended that public domain traditional knowledge be documented in traditional knowledge digital libraries.[300] They believed that WIPO, along with their assistance, could create such a system to facilitate the exchange and dissemination of traditional knowledge.[301] Under the United Nations Convention to Combat Desertification (UNCCD), parties are to make inventories of their knowledge and practices and their potential uses in coordination with local communities, and, where appropriate, disseminate such information in cooperation with relevant organizations.[302]

Support for this proposal is also found in the CBD. Article 17.2, for example, contains a provision on the exchange of information.[303] Additionally, the CBD Programme of Work on the Implementation of article 8(j) and Related Provisions of the Convention provides that an ad hoc working group "develop standards and guidelines for the reporting and prevention of unlawful appropriation of traditional knowledge and related genetic resources." [304] They advised that this work be carried out in collaboration with other relevant organizations, such as WIPO.[305]

These are only a few examples of the support that can be found internationally for implementation of this proposal. Because it

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[300] *See id.* at 10 (This workshop was held in Bangkok, Thailand from December 6 to 8, 2000.).

[301] *Id.*

[302] *Id.* at 11.

[303] *Id.* at 10; *see also* CBD, *supra* note 47, art. 17.2 ("Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.").

[304] WIPO Comm. Progress Report, *supra* note 12, at 10–11. *See also* CBD, *supra* note 47, art. 8(j). Under article 8(j), contracting parties shall, "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." *Id.*

[305] WIPO Comm. Progress Report, *supra* note 12, at 11.

already evicts such international recognition, its goals are more attainable than many other proposals. Increasing this international consensus is necessary to ensure science is advanced without exploiting sources countries.

B. Requiring Material Transfer Agreements for Access to Resources

While recognizing traditional knowledge as prior art prevents outsiders from obtaining illegitimate intellectual property rights, it is also important to address situations where foreign access to a country's resources is sought regardless of the intellectual property rights involved. In such situations, parties should be required to enter into MTAs to allocate control and compensation arrangements properly.[306] Pending the Committee's establishment of guideline procedures and model intellectual property clauses for contract agreements, parties should refer to samples of actual contracts, codes of conduct, and voluntary guidelines when entering MTAs.[307] This will facilitate stakeholders in achieving mutually agreed terms on access to genetic resources and equitable distribution of benefits.[308] MTAs will allow contracting parties to arrange their agreements specifically according to their needs and to determine how to allocate compensation among the government, local authorities, and traditional knowledge holders. All MTAs should require the obtainment of prior informed consent by indigenous and local communities of source countries. Contractual arrangements should also account for potentially extreme variances in bargaining power among the respective parties. Guidelines or technical assistance should therefore be provided to ensure all parties are treated equally.[309] The flexibility of MTAs makes them the most practical means for addressing the complex issues involved in obtaining access to national resources.

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306 *See supra* Part I.C.3.b.

307 WIPO Comm. Progress Report, *supra* note 12, at 11. *See also supra* Part I.C.3.b.

308 *Id.*

309 *See* WIPO Operational Principles, *supra* note 113, at 48.

CONCLUSION

In a world eager for scientific advancement, every country can expect the benefits of their resources to be maximized. Biodiversity and traditional knowledge are therefore subjected to countless foreign uses. Source countries' sovereign rights over their resources and knowledge, however, must not be sacrificed in the name of scientific exploration. Variances in existing national laws and international obligations prevent the proper enforcement and allocation of these rights, creating the potential for exploitation. To address these discrepancies, this Note has proposed documenting publicly disclosed traditional knowledge under an international definition of prior art, using online databases to retrieve prior art, and requiring MTAs for access to resources. This proposal resolves complications concerning intellectual property rights, allocation of compensation, and prior informed consent. Moreover, its procedures necessitate the active involvement of local communities, illustrating respect for their contributions to scientific advancement. The conservation of their traditional practices is therefore reinforced because the potential for abandoning their customs from fear of exploitation is reduced. Existing support for this proposal demonstrates its potential for international acceptance. Ultimately, the international uniformity achieved by this proposal will promote scientific discovery by optimizing the efficiency of intellectual property procedures worldwide.