

STRUGGLING AROUND THE “NATURAL” DIVIDE:
THE PROTECTION OF TANGIBLE AND INTANGIBLE
INDIGENOUS PROPERTY

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I would like to thank Professors Gustavo Ghidini, Jerome H. Reichman, and James Thomas for their comments on previous drafts of this article. I also would like to thank the editors and staffers of the *Cardozo Arts & Entertainment Law Journal* for their precious contribution toward the publication of this article. Any errors or inaccuracies are solely attributable to me. ©2007 Emanuela Arezzo.

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INTRODUCTION

During a century in which access to information represents the key to doing business, big companies have come to realize that Developing Countries,¹ whose economies are still mainly based on agriculture and textiles, possess invaluable treasures worth billions of dollars. Their varieties of plants and trees, mostly indigenous to the Southern Hemisphere, amount to a huge collection of genetic material with countless potential applications. Moreover, the value of these vast collections of plants and herbs is enhanced by the knowledge of the local communities, which have long studied

¹ The term “Developing Countries” is intended to include “Least Developed Countries” (“LDCs”), as designated by the United Nations. More information on the status of Developing Countries and LDCs can be found on the official World Trade Organization (“WTO”) website. WTO, Who Are the Developing Countries in the WTO?, http://www.wto.org/english/tratop_e/devel_e/dlwho_e.htm (last visited Feb. 3, 2007).

and experimented with their medicinal and other scientific properties. Shamanic knowledge, for example, has in some cases led to precise and effective results toward curing disease.

While indigenous communities do have legal systems and mores regulating how resources—both tangible and intangible—are produced and enjoyed, Developed Countries often view traditional knowledge through the lenses of modern intellectual property systems. Thus, companies located in Developed Countries look for the person who might hold exclusive rights on that subject matter. When they find no author/inventor and no right, they reason that the information lies in the public domain and simply assume the right to appropriate it without giving anything in return.

This article analyzes the current normative framework and the international debate surrounding the protection of traditional knowledge, as well as the ecosystems from which such knowledge is derived. The objective of this article is to provide critical thought toward a tentative solution as to how to best protect this knowledge and its environment. The article begins with a comprehensive review of the international legal framework and the on-going proposals in several international situations. The article next discusses how a misappropriation system might be implemented. Fashioned as a sort of negative entitlement system, this system would protect owners of traditional knowledge against illicit misuse or misappropriation. Together with the amendment of current national and international patent laws, such a system could provide the level of protection that would satisfy the interests of both the creators of traditional knowledge and foreign companies.

I. TRADITIONAL KNOWLEDGE AND BIODIVERSITY: A CONCEPTUAL FRAMEWORK

The beneficial properties of *azadirachta indica*, commonly known as the Indian neem tree, have been known and employed by Indian farmers for centuries.² A few decades ago, the neem tree attracted the interest of foreign biotechnology and pharmaceutical companies, interested in its manifold practical applications.³ In the early 1970s, biologists and ethnobotanists

² For a complete overview of the neem tree story, see Vandana Shiva, *The Neem Tree: A Case History of Biopiracy*, THIRD WORLD NETWORK, available at <http://www.twinside.org.sg/title/pir-ch.htm> (last visited Mar. 22, 2007).

³ The term *azadirachta indica* is known in Sanskrit as *sarva-rōga nīvarini* or “curer of all ailments” because the tree and its seed-oil have been used to produce chemicals with pesticidal, agricultural, medicinal, contraceptive, cosmetic, and dental applications. Olufunmilayo B. Arewa, *The First Ten Years of the TRIPS Agreement: TRIPS and Traditional*

moved to India to investigate the neem tree's attributes, observing and studying how local people utilized the tree. Thus, the fruits of the scientists' work—based on local heritage, i.e., the indigenous species and the community's traditional knowledge—led to the patenting of a wide variety of products.⁴ However, not a single penny went to Indian farmers or to the Indian government.⁵

The neem tree is probably the most well-known case of biopiracy—perhaps better termed biosquatting⁶—but is not the only one.⁷ Indeed, not only have Western companies come to understand the value of resources that indigenous communities have studied and cherished over centuries,⁸ but they have come to comprehend the value of the communities' traditional knowledge.

A. *Traditional Knowledge and Its Economic Value in Market Economies*

Scholars have used the term “traditional knowledge” (“TK”) to refer to a broad range of “indigenous works” ranging from

Knowledge: Local Communities, Local Knowledge, and Global Intellectual Property Frameworks, 10 MARQ. INTELL. PROP. L. REV. 155, 170 (2006); Pollyanna E. Folkins, *Has the Lab Coat Become the Modern Day Eye Patch? Thwarting Biopiracy of Indigenous Resources by Modifying International Patent Systems*, 13 TRANSNAT'L L. & CONTEMP. PROBS. 339, 344 (2003).

⁴ It is interesting to note that when the first patents were filed abroad, Indian patent law expressly excluded agricultural products from patentability. Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy*, 37 IDEA 371, 372 (1997); Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279, 283 (1999).

⁵ Shiva, *supra* note 2.

⁶ The term “biosquatting” is better suited than “biopiracy” to indicate the misappropriation of “intangible components of genetic sources and/or of traditional knowledge that could be in the public domain as well as the unauthorized claiming of traditional knowledge that is in control of Indigenous people and local communities.” N. Pires de Carvalho, *From the Shaman's Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent*, 17 WASH. U. J.L. & POL'Y 111, 116 n.11 (2005).

⁷ For other famous examples, see the turmeric patent case and the quinoa patent case. See GRAHAM DUTFIELD, *INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY: SEEDS AND PLANT VARIETIES* 65, 67 (1999). In a recent report, Jay McGown provides a long and detailed list of African genetic resources that he alleges have been misappropriated by foreign investors. JAY MCGOWN, *OUT OF AFRICA: MYSTERIES OF ACCESS AND BENEFITS SHARING* (Jan. 2006), <http://www.edmonds-institute.org/outofafrica.pdf>.

⁸ The term “biodiversity” is used broadly to encompass both biological diversity and biological resources as they are described in the Convention on Biological Diversity (“CBD”). The CBD agreement was promulgated by the United Nations at the 1992 Earth Summit in Rio de Janeiro. As explained below, the CBD has three main goals: the preservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits accruing from the use of genetic resources. The CBD defines “biological diversity” as “the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part” and “biological resources” as “genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.” Convention on Biological Diversity art. 2, June 5, 1992, 31 I.L.M. 818, *available at* <http://www.biodiv.org/convention/convention.shtml> [hereinafter CBD].

folklore to shamanic knowledge.⁹ TK is characterized by being jointly created and shared by the members of local communities. It is the fruit of an intergenerational process, whereby generations pass on their cultural heritage which, as time passes, continuously grows. Another notable feature of TK is its “unfixed” character.¹⁰ Shamanic knowledge, rituals, dances, and songs are often handed down orally. As there is no need to commercially trade TK within the indigenous communities, there is no fear of such knowledge being stolen, and thus local people have not been compelled to codify it in a written form.¹¹

For the purpose of this article, a distinction must be made between TK in the strict sense and *expressions* of TK, such as “traditional cultural expressions” (“TCEs”) and folklore. As the secretariat of the World Intellectual Property Organization (“WIPO”) has pointed out, TCEs are akin to copyrightable subject matter (e.g., as performances and designs), while strict-sense TK is more akin to industrial property (e.g., patents and trade secrets).¹² While acknowledging that different forms of TK sometimes overlap, WIPO defines TK as “*ideas* developed by traditional communities and indigenous people, in a traditional and informal way, as a response to the needs imposed by their physical and

⁹ See the definition of traditional knowledge (“TK”) provided by Martha Johnson, who describes it as a “body of knowledge built by a group of people through generations living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment, and a system of self management that governs resource use.” Martha Johnson, *Research on Traditional Environmental Knowledge: Its Development and Its Role*, in LORE: CAPTURING TRADITIONAL ENVIRONMENTAL KNOWLEDGE 3, 3-4 (Martha Johnson ed., 1992).

¹⁰ For a description of the features of TK, see generally Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT’L L. 233 (2001). See also Jerzy Koopman, *Bumps and Bends in the Road to Intellectual Property for Traditional Knowledge*, in INTELLECTUAL PROPERTY LAW 2004 247, 247-48 (F. W. Grosheide & J.J. Brinkhof, eds., 2004).

¹¹ Indeed, in patent law, the requirements of written description and enablement serve the purpose of solving a paradox posed by Kenneth Arrow. According to the well-known economist “without a property right, the inventor is in a pickle: if in trying to strike a deal she discloses her idea . . . she has nothing left to sell, but if she does not disclose anything the buyer has no idea what is for sale.” Once the invention is formally embedded in the patent grant, due to the description, specification and claims, the inventor can trade her knowledge in the market without fearing that the latter may be stolen by a third party who, in turn, might claim to be the owner. Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY, 609-25 (R.R. Nelson ed., 1962). Likewise, in American copyright law, the requirement of fixation is aimed at proving that the work has in fact been created, and fixation is fundamental to being able to attribute the creation to the author and reward him with exclusive rights.

¹² WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Document Prepared by the Secretariat: Consolidated Survey of Intellectual Property Protection of Traditional Knowledge*, WIPO/GRTKF/IC/5/7 (July 7-15, 2003), available at http://www.wipo.int/documents/en/meetings/2003/igc/pdf/grtkf_ic_5_7.pdf.

cultural environments.”¹³ WIPO notes, “Those ideas contrast with the respective expressions, such as folk tales, poetry, and riddles, folk songs and instrumental music, dances, plays, etc.”¹⁴

The subject of TCEs—folklore and cultural intangible heritage—lies outside the scope of this article, which analyzes TK in the strict sense. More specifically, this article is concerned with medical and “scientific” knowledge associated with germplasm¹⁵ and biodiversity. In addition, as the purpose of this article is to find a balanced way to protect indigenous communities’ economic interests from unfair conduct and appropriation by the corporations of Developed Countries, it considers the related issue of biodiversity, since it is impossible to analyze the protection of TK without considering biodiversity.

B. *The Stringent Bond Between Traditional Knowledge and Biodiversity*

Biodiversity and TK, although separate concepts, are entwined.¹⁶ Biopiracy cases usually involve the misappropriation of both genetic resources and the associated TK. The plant and animal varieties present in Brazil, Peru, and Australia comprise a treasure trove of immeasurable value, in that there exists billions of compounds with perhaps countless practical applications. Because of the huge quantity of potentially valuable molecules, the process of screening all of them for possible usefulness would be prohibitively time-consuming and costly. Therefore, the role of traditional and shamanic knowledge is crucial. Such TK can minimize search costs and drive researchers toward the most promising therapeutic paths. Without this TK, the native ecosystems long cherished by Developing Countries might remain unexplored, or in the best case scenario, biotechnology companies would expend enormous resources to obtain applications, passing those costs—in dollars and in time—on to consumers.¹⁷

¹³ *Id.*

¹⁴ *See id.*

¹⁵ The term germplasm was introduced by the German biologist Weismann, with regard to the “hereditary substance contained in the germ-cells.” *See* AUGUST WEISMANN, *THE GERM-PLASM, A THEORY OF HEREDITY* (New York, Charles Scribner’s Sons 1893), available at <http://www.esp.org/books/weismann/germ-plasm/facsimile/title3.html>. Today the term is commonly used in medicine to refer to the genetic resources located in the DNA of animals and plants.

¹⁶ *See generally* Gertrui Van Overwalle, *Protecting and Sharing Biodiversity and Traditional Knowledge: Holder and User Tools*, 53 *ECOLOGICAL ECON.* 585 (2005).

¹⁷ In a recent article Charles McManis reported the results of a joint research project (the ICBG-Peru Project) between the Aguaruna people of Peru and three American universities. The report describes the critical role played by the Aguaruna’s traditional knowledge in identifying antimalarial species; without such knowledge it would have taken decades for university researchers to achieve the same results. Charles McManis, *Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally*, 11 *CARDOZO J. INT’L & COMP. L.* 547 (2004).

Biotechnology and pharmaceutical companies are unwilling to invest such huge capital in research projects whose outcomes are so drastically uncertain.¹⁸

From this viewpoint, TK solves a market failure problem by providing incentives to invest in potential paths of research. Furthermore, as long as these companies do not reward any party for the production of TK, and hence do not bear any cost for it, TK represents a positive externality. In addition, indigenous creation of TK is not driven by the incentives of a market economy; local communities do not aim at obtaining exclusive rights to exploit their innovations, as such knowledge is generally shared within the community. So, one might ask, what is the problem with the unauthorized taking of TK?

The problems are numerous. On the one hand, because misappropriation often includes TK *and* biological resources, there are serious environmental risks associated with unregulated and unmonitored taking of biodiversity. On the other hand, the unauthorized and unrewarded taking of both kinds of resources—tangible and intangible—by foreign companies severely damages the Developing Countries’ economy. First, Developing Countries are deprived of the right to trade their biodiversity with foreign companies and make a profit. Similarly, when foreign companies succeed in patenting inventions based on TK in their own countries, these companies deprive indigenous communities of the right to export their knowledge abroad and, again, to profit from it. Moreover, as Professor James Boyle has pointed out, TK often flows out of Developing Countries free of legal constraints and yet returns embedded in foreign patents.¹⁹ When this occurs, there is a strong risk that indigenous people lose any opportunity to retain and exploit their collective knowledge in their own country.²⁰

¹⁸ See Arti K. Rai et al., Pathways Across the “Valley of Death:” Novel Intellectual Property Strategies to Solve the Small Molecule Puzzle (2006), available at <http://www.law.harvard.edu/programs/petrie-flo/rairai%20Pathways.pdf>.

¹⁹ “[C]urare, batik, myths, and the dance ‘lambada’ flow out of Developing Countries, unprotected by intellectual property rights, while Prozac, Levis, [and] Grisham . . . flow in protected by a suite of intellectual property laws which in turn are backed by the threat of trade sanctions.” JAMES BOYLE, SHAMANS, SOFTWARE AND SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY 125 (1996).

²⁰ Almost all Developing Countries are WTO members; hence they have adhered to the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”). TRIPS, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter TRIPS]. Least Developed Countries who are TRIPS signatories are required to comply with TRIPS by 2016. See Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members*, IP/C/40 (Nov. 2005), available at http://www.tripsagreement.net/documents/GATTdocs/Decision_of_the_Council_for_T

The protection of biodiversity and TK presents another conflict of interest between Northern Hemisphere (often Developed) and Southern Hemisphere (often Developing) countries. The former are the technology-rich industrialized countries, and the latter are the biodiversity-rich Developing Countries. Cooperation between these two groups could bring about significant innovation in products ranging from drugs to agricultural products to cosmetics. However, only rarely has such cooperation resulted in revenue for Developing Countries. In the best case scenario, the unequal bargaining power of the contracting parties tends to lead to biased licensing schemes whereby indigenous communities are rewarded only for the biological resources and are not compensated for the intellectual resources they provide.²¹ Furthermore, the indigenous communities are typically excluded from sharing in the results of the subsequent research. Often, no agreement between the countries takes place at all.²²

C. *The Need for a Joint Solution*

There is almost always a bond between TK and genetic resources (although the bond might not be apparent to an investigating scientist). In some cases, the connection is clear, as indigenous communities have come to realize the specific

RIPS_of_29_November_2005_E.doc [hereinafter *Extension of the Transition Period*]. Many Developing Countries have already complied with TRIPS and have introduced national patent laws. Therefore, although indigenous people in such countries often do not seek patent protection, foreign companies who have already obtained a TK-based patent in their own countries can file for protection even in the same Developing Countries from where they have taken, with no authorization, the biodiversity and TK associated with it.

²¹ McManis reports several examples of cooperation between companies located in Developed Countries and entities representing indigenous communities located in Developing Countries. From the information he has collected, it seems that the majority of such agreements have taken the form of “bioprospecting” contracts whereby indigenous communities are rewarded for the biodiversity provided to foreign companies for screening purposes; often, they are entitled to further royalties for subsequent products embedding the germplasm they have provided (i.e., the agreement signed between INBio, a private non-profit organization located in Costa Rica, and Merck). In such cases, it seems that compensation comes mainly from access to the germplasm rather than TK. However, McManis also reports cases such as the agreement between the U.S. National Cancer Institute, the New York Botanical Garden, and the Awa people of northwest Ecuador, in which the former will pay the indigenous community for its researchers to study medicinal botany with shamans. Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255, 270-75 (1998).

²² Notwithstanding the numerous examples of agreements between foreign companies and entities representing indigenous communities provided by McManis, *supra* notes 17, 21, the reported cases of biopiracy remain much larger in number. See MCGOWN, *supra* note 7. There have also been cases in which Developing Countries, incapable of trading their own biodiversity, have destroyed their natural resources to feed their people. For example, Madagascar appears to be one of the richest countries in terms of biodiversity (it should have about five percent of the world’s species), but it has leveled most of its forests to feed its people. BOYLE, *supra* note 19, at 128.

applicability of the germplasm. In such a case, foreign companies simply isolate the molecules, embed them in a commercial product, and file for patent protection.²³ Other times, the link is not apparent. It may happen, for example, that indigenous people have used a certain natural substance for certain purposes, but have not precisely found out its therapeutic properties. In the latter instance, foreign scientists have more work to do, depending on how advanced the local practice is.²⁴

Notwithstanding the close link between the two, biodiversity and TK differ in that the former is material while the latter is abstract and intangible. Biodiversity, however, presents a very peculiar case. Biological resources, like all genetic resources, represent a set of codes, with each piece carrying specific information that deals with a certain function. Once the relation between a portion of the code and its function has been revealed, the genetic resource acquires value.²⁵ Conversely, TK has value only in connection to that specific biological resource. When a germplasm is transferred, and not necessarily stolen, parties' unequal bargaining powers tend to lead to unfair licensing agreements in which companies compensate local communities only for the genetic resources through lump sums or royalties.²⁶ The value of TK goes unacknowledged. Although there could be contractual schemes envisioning “grant back” provisions or granting foreign companies non-exclusive licenses for “research use” and (derivative) innovations based on TK, such arrangements are rare.²⁷

²³ For example, Quechua Indians (from Peru) have grown a certain root called *maca* for hundreds of years, which has properties relating to the boosting of stamina and sex drive. In 2001, PureWorld Botanicals, a company based in New Jersey, obtained a patent for the exclusive distribution of a maca extract with active libido-enhancing properties. The product has been called MacaPure. See Rick Vecchio, *Peruvian Root in Bioprospecting Dispute*, USA TODAY, JAN. 5, 2007, available at http://www.usatoday.com/tech/science/2007-01-05-bioprospecting-peru_x.htm. This is one of the classic cases of biopiracy where the link between TK and genetic resources is apparent, as the product derived from the biodiversity is directly used in connection with the scientific knowledge of local communities.

²⁴ Indeed, it may also be that scientists begin examining a certain molecule because of certain properties associated with it and then further refine such properties or find different ones. This may be the case with the African cactus *hoodia*, used by African tribes to suppress hunger and thirst during hunt. Today, scientists are investigating *hoodia*'s properties as a dietary complement. See MCGOWN, *supra* note 7.

²⁵ Although, in theory, biodiversity could be stolen even in its raw state for the search costs described above, it is unlikely that pharmaceutical companies would simply take hundreds of samples to screen without any notion of the likely properties of the genetic resources.

²⁶ Gustavo Ghidini, *Equitable Sharing of Benefits from Biodiversity-Based Innovation: Some Reflections Under the Shadow of a Neem Tree*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 695 (Jerome H. Reichman & Keith E. Maskus eds., 2005).

²⁷ McManis has praised the way the aforementioned ICBG-Peru Project was shaped, in terms of guarantees and safeguards afforded to the Peruvian community, but so far this is

II. THE NORMATIVE INTERNATIONAL FRAMEWORK FOR THE PROTECTION OF BIODIVERSITY AND THE PROTECTION OF TRADITIONAL KNOWLEDGE

The need to spur cooperation between Northern and Southern countries is reflected in the provisions of the United Nations Convention on Biological Diversity (“CBD”).²⁸ The CBD recognizes the value of biodiversity as *world* heritage and stresses the need for all contracting parties, regardless of whether they are in possession of such resources, to enact measures aimed at protecting and safeguarding this heritage.²⁹ The CBD aims to foster such cooperation while maintaining the globally shared interest in preserving biodiversity and the interests of contracting parties.

The CBD can be conceptually divided into three subsections. The first set of provisions imposes on *all* contracting parties a list of duties to promote sustainable uses and conservation (*in-situ* and *ex-situ*)³⁰ of biological resources, and encourages them to “create conditions to facilitate access to genetic resources for *environmentally sound uses*.”³¹ A second set of provisions recognize states’ sovereignty over natural resources and their right to give access to third parties.³² Therefore, although the CBD clearly aims to encourage the sharing of biological resources, it firmly recognizes states’ prerogatives. The CBD further establishes that access to genetic sources must be subject to prior informed consent (“PIC”) of the party providing such resources, and that once consent has been given, terms of access must be mutually agreed upon.³³ Lastly, the CBD promotes “the fair and equitable sharing of the benefits arising from the utilization of genetic resources.”³⁴ Specifically, the CBD establishes that each contracting party shall take appropriate measures in order to afford (to the party providing the biological resources) equitable sharing of the *results* of research and development and the *benefits*

the only known example. McManis, *supra* note 17.

²⁸ CBD, *supra* note 8 *passim*.

²⁹ Some countries are holders *ex situ* of genetic resources, including many European countries where botanic gardens and large depositories of genetic resources are located. Those countries similarly share the duty to preserve biodiversity.

³⁰ CBD, *supra* note 8, at arts. 6, 8-9.

³¹ *Id.* at art. 15.2.

³² *Id.* at art. 15.1.

³³ *Id.* at arts. 15.4, 15.5.

³⁴ *Id.* at arts. 1, 8(j), 15.7, 19.2. The principle is also supported by the United Nations Food and Agriculture Organization (“FAO”), International Treaty on Plant and Genetic Resources for Food and Agriculture art. 9, Nov. 3-4, 2001, available at <ftp://ftp.fao.org/ag/cgrfa/res/c3-01e.pdf>. See also Michael Blakeney, *Protection of Plant Varieties and Farmers’ Rights*, 24 EUR. INTEL. PROP. REV. 9 (2002); Council Directive 98/44, ¶ 56, 1998 O.J. (L 213) 13 (EC).

arising from the commercial and other utilization of genetic resources.³⁵

While the CBD rightly devotes a great deal of attention to the issue of access to biological resources, it affords much less consideration to the equally important matter of traditional knowledge. Sharing of benefits arising from TK is, however, expressly conceptualized as instrumental to promoting *in-situ* conservation of biological resources in article 8(j) of the CBD.³⁶ Concern for the practices of indigenous and local communities prompted the Conference of the Parties (the governing body of the CBD) to create a working group specifically to address the implementation of article 8(j).³⁷ Subsequently, in 2002, the Conference of the Parties also adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.³⁸

The Bonn Guidelines provide voluntary measures for contracting parties for drafting legislative, administrative, or policy measures aimed at access-and-benefits sharing (“ABS”).³⁹ Specifically, the Guidelines strengthen the importance of PIC as a means to prevent misappropriation of genetic resources.⁴⁰ Thus, PIC should be granted for certain specific uses of a biological resource provided that any change in use prompts a new application for PIC and that competent local authorities are involved in the process of PIC certification.⁴¹ The Guidelines also propose that the country of origin of the genetic resource should be disclosed in patent applications as a means of tracking compliance with PIC.⁴²

³⁵ CBD, *supra* note 8, at art. 15.7. Article 15.7 further specifies that “[s]uch sharing shall be upon mutually agreed terms.” *Id.*

³⁶ The CBD establishes in article 8(j) that Contracting Parties shall:

[s]ubject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities . . . and promote . . . 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, innovation and practices.”

Id. at art. 8(j) (emphasis added). Note that this provision does not compel countries to enact new legislation to pursue the goals outlined above (as it does in most of the other provisions).

³⁷ For more information, see Convention on Biological Diversity, Article 8(j): Traditional Knowledge, Innovations and Practices: Introduction, <http://www.biodiv.org/programmes/socio-eco/traditional/default.asp> (last visited Feb. 6, 2007).

³⁸ Adoption of the Bonn Guidelines was approved in decision VI/24 of the Conference of the Parties in 2002. See Convention on Biological Diversity, Decision VI/24: Access and Benefit-Sharing as Related to Genetic Resources, <http://www.biodiv.org/decisions/?lg=0&dec=VI/24> (last visited Feb. 6, 2007).

³⁹ *Id.* See in particular articles 8(j), 10(c), 15, 16, and 19.

⁴⁰ *Id.*

⁴¹ *Id.* For example, by handling access applications.

⁴² *Id.*

Notwithstanding the important principles set forth in the CBD, international measures for protecting biodiversity remain uncertain. Harmonization on the international level seems far away. Although contracting parties do have an obligation to comply with CBD provisions under international law, the CBD has not been ratified by some of the most economically significant countries, such as the United States.⁴³ Even the Bonn Guidelines are not mandatory for contracting parties to implement. Moreover, the fact that the CBD was developed outside the realm of the WTO and TRIPS makes practical enforcement difficult, if not impossible.⁴⁴

The necessity of reconciling the provisions set forth in the CBD with the TRIPS Agreement was acknowledged during the Doha Declaration, when the TRIPS Council was appointed to examine, *inter alia*, the relationship between the TRIPS Agreement and the CBD and the protection of TK and folklore.⁴⁵ Several proposals to give effect to the provisions set forth in the CBD are currently being discussed. An ad hoc committee also has been created within WIPO to address TK and folklore issues.⁴⁶ In addition, other proposals for complying with the provisions of the CBD have been suggested within the Conference of the Parties,⁴⁷ and still others have come from academics and other eminent scholars. The following Part will examine some of these ongoing proposals.

⁴³ The United States signed the Convention on June 1993 but did not ratify it. Parties to the CBD/Cartagena Protocol on Biosafety, <http://www.biodiv.org/world/parties.asp> (last visited Feb. 12, 2007). See *id.* for the complete list of member states.

⁴⁴ Indeed, for this reason, the CBD cannot benefit by the WTO dispute settlement procedure. See Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994), available at http://www.wto.org/english/docs_e/legal_e/28-dsu_e.htm.

⁴⁵ See World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002), available at http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_e.htm (instructing the TRIPS Council to examine the relationship between the TRIPS Agreement and the CBD, particularly in light of TRIPS articles 7 and 8). See generally DUTFIELD, *supra* note 7, at chs. 3-6.

⁴⁶ In October 2000, WIPO created an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. It was meant to create an international forum for discussion of the interplay between intellectual property rights and traditional knowledge, genetic resources, and expressions of folklore and cultural indigenous knowledge. WIPO General Assembly, *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WO/GA/26/6 (Aug. 25, 2000). Moreover, similar discussions were recently held by another WIPO working group, the Working Group on the Reform of the Patent Cooperation Treaty. See *infra* note 52.

⁴⁷ See Eighth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Mar. 20-31, 2006, available at <http://www.biodiv.org/doc/meeting.asp?lg=0&mtg=cop-08>.

III. EFFECTUATING COMPLIANCE WITH CBD OBLIGATIONS THROUGH DISCLOSURE OF THE ORIGIN OF THE SOURCE

Many countries have proposed amending international patent treaties and corresponding domestic laws to require mandatory disclosure in patent applications of the origin of genetic resources and TK. Use of genetic resources is rarely recognizable by merely looking at the final product. Even under a close analysis, indigenous people would not know that biological resources had been taken without prior informed consent, not to mention access and benefit sharing; the same applies for TK. Only when the innovation consists of the very same use of the plant that is known in the indigenous community is the link between the biological resource and the patent apparent. Sometimes, however, traditional scientific knowledge only provides useful leads that “bioprospectors” use for prioritizing the screening of certain plants. The isolated molecules and compounds of these plants may reveal properties beyond those identified by indigenous communities, or the properties already known by indigenous communities are studied for new purposes. In the latter case, the link between TK and the final product gets blurred along the way to the patent office, and indigenous people are unable to find out about—and hence oppose—biosquatting.⁴⁸

Implementation of the disclosure of origin requirement would increase transparency and help Developing Countries to monitor actual compliance with the provisions set forth in the CBD. Implementation of such a requirement at a *supranational* level, and by Developed Countries first, is compelling because it very often happens that biotechnology and pharmaceutical companies coming from these countries exploit biodiversity and related TK to make products to sell to their own markets (and not to sell them back to Developing Countries).⁴⁹ Thus, even though this requirement has been adopted by several Developing Countries who are contracting parties of the CBD, it is

⁴⁸ This is confirmed in a WTO Communication document in which Peru discusses its difficulties in screening Japanese patent applications to filter out patents that might be based on traditional knowledge. Council for Trade-Related Aspects of Intellectual Property Rights, *Analysis of Potential Cases of Biopiracy*, IP/C/W/458 (Nov. 7, 2005), available at grain.org/rights_files/W458.doc.

⁴⁹ This point is stressed in a document submitted to the WTO by a group of Developing Countries which argued that “bio-piracy is a global problem and . . . involves the acquisition of material in one country and seeking of a patent in another country. This means that relying on national measures alone is not sufficient to address the bio-piracy problem.” Council for Trade-Related Aspects of Intellectual Property Rights, *Elements of the Obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge Used in an Invention*, IP/C/W/429/Rev.1 (Sept. 27, 2004), available at <http://commerce.nic.in/ip-c-w-429R1.pdf>. This document will be analyzed in detail in Part III.B.

fundamental that Developed Countries implement the requirement first.⁵⁰

A. *Introducing the Disclosure of Origin Requirement into the Patent Cooperation Treaty*

Many negotiations on the disclosure of origin requirement are taking place in various international *fora*. In the last session of the working group on the reform of the Patent Cooperation Treaty (“PCT”) held by WIPO,⁵¹ Switzerland reiterated its proposal to amend some of the rules accompanying the PCT to allow national patent systems to require disclosure of origin of both genetic resources and related TK.⁵² Swiss delegates have presented the same proposal to the “Ad Hoc Open-Ended Working Group on Access and Benefits-Sharing” organized by the Conference of the Parties.⁵³ The proposal is aimed at satisfying the so-called

⁵⁰ Understandably, many Developing Countries (Bolivia, Colombia, Costa Rica, Ecuador, Egypt, India, Peru, and Venezuela) have amended their patent laws in such a way as to establish the disclosure requirement as one of the patentability obligations. Other countries, such as the European Community members, have included the requirement only as a recommendation. See de Carvalho, *supra* note 6, at 123.

⁵¹ The Patent Cooperation Treaty makes it possible for nationals of contracting parties to file for patent protection simultaneously in several adhering countries (nationals can choose the number of countries in which they want their patent to be effective). Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 116 U.N.T.S. 231, available at <http://www.wipo.int/pct/en/texts/articles/atoc.htm>.

⁵² See WIPO, Working Group on the Reform of the Patent Cooperation Treaty, *Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, PCT/R/WG/4/13 (May 5, 2003), available at http://www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_4/pct_r_wg_4_13.pdf [hereinafter *Proposals by Switzerland*]; WIPO, Working Group on the Reform of the Patent Cooperation Treaty, *Further Observations by Switzerland on Its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, PCT/R/WG/7/9 (Apr. 5, 2005), available at www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_7/pct_r_wg_7_9.doc [hereinafter *Further Observations by Switzerland*].

The contents of these documents have been summarized in another WIPO document. WIPO, Working Group on the Reform of the Patent Cooperation Treaty, *Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, PCT/R/WG/8/7 (May 8-12, 2006), available at www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_8/pct_r_wg_8_7.doc [hereinafter *Declaration of the Source of Genetic Resources*]. This document is currently the most up-to-date summary. The Ninth Session of the Working Group on the Reform of the PCT is scheduled for April 23-27, 2007 in Geneva, but at the time of this article’s completion, the documents had not yet been published on the WIPO website. See WIPO, PCT Union-Working Group on the Reform of the Patent Cooperation Treaty: Ninth Session, Geneva, Apr. 23-27 2007, *Draft Agenda*, PCT/R/WG/9/1, available at http://www.wipo.int/meetings/en/details.jsp?meeting_id=12542.

⁵³ See CBD, Ad Hoc Open Ended Working Group on Access and Benefit Sharing, *Measures to Support Compliance With Prior Informed Consent of the Contracting Party Providing Genetic Resources and Mutually Agreed Terms on Which Access Was Granted in Contracting Parties with Users of Such Resources Under Their Jurisdiction*, UNEP/CBD/WG-ABS/4/INF/12 (Jan. 17, 2006), available at www.biodiv.org/doc/meetings/abs/abswg-04/information/abswg-04-inf-12-en.doc.

The same proposal had been presented for informational purposes to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“IGC”). WIPO, WIPO/GRTKF/IC/7/INF/5 (Oct.

“four Ts”: 1) *transparency*, as the disclosure obligation within the patent system would surely increase transparency in access and benefit sharing with regard to genetic resources and TK; 2) *traceability*, as the obligation would allow providers of genetic resources and TK to keep track of the use of their tangible and intangible resources as well as the development resulting in patentable inventions; 3) *technical prior art*, as the disclosure obligation would also assist patent examiners and judges in the establishment of prior art with regard to inventions that relate to genetic resources and related TK; and 4) *mutual trust*, as the disclosure of the source of origin would increase mutual trust among the various stakeholders in access and benefit sharing.⁵⁴

In practice, the core of the proposal concerns the insertion of new provisions to rule 51*bis*(1) of the PCT Regulation,⁵⁵ allowing contracting states to amend national patent laws in such a way as to require applicants to furnish: “(i) a declaration as to the source of a specific genetic resource to which the inventor has had access, if the invention is directly based on such a resource”⁵⁶ and “(ii) a declaration as to the source of TK related to genetic resources, if the inventor knows that the invention is directly based on such knowledge.”⁵⁷ The proposal defines the term “source” as “the entity competent (1) to grant access to genetic resources and TK, and/or (2) to participate in the sharing of the benefits arising out of their utilization.”⁵⁸

Because of the great divergence in views on such transparency measures, Switzerland has decided to leave the adoption of the requirement optional in its proposal.⁵⁹ However,

18, 2004), *available at* www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_inf_5.pdf.

⁵⁴ See *Declaration of the Source of Genetic Resources*, *supra* note 52, ¶ 14.

⁵⁵ WIPO, Regulations under the Patent Cooperation Treaty (Apr. 1, 2007), *available at* http://www.wipo.int/pct/en/texts/pdf/pct_regs_april_2007.pdf.

⁵⁶ In particular, according to the proposed new Rule 51*bis*.1(g)(i), the obligation would arise when the invention makes *immediate* use of the genetic resource. This means that the timing depends on the specific properties of the resource, and the inventor must have had *physical access* to the resource, intended as “its possession or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the invention.” *Declaration of the Source of Genetic Resources*, *supra* note 52, ¶ 22.

⁵⁷ Also, according to the proposed new Rule 51*bis*.1(g)(ii), the inventor must know that the invention is strictly based on the relevant traditional knowledge, in the sense that the inventor “must consciously derive the invention from this knowledge.” *Id.* ¶ 23.

⁵⁸ See *Further Observations by Switzerland*, *supra* note 52, ¶ 14. The proposal further distinguishes between primary and secondary sources. On one side there is the Contracting Party who provides genetic resources and the indigenous and local communities, and on the other side there are *ex situ* collections such as gene banks, botanical gardens, databases containing genetic resources and traditional knowledge, and scientific literature. The proposal gives a detailed explanation regarding what sources must be disclosed and under what circumstances. *Id.* ¶15.

⁵⁹ The proposal is aimed at amending the PCT Regulations in order to give contracting parties the possibility, if they wish, to amend domestic patent legislation and

due to minor adjustments to rules 4.17 and 48.2, once a country implements this requirement within its domestic patent laws, the disclosures become part of the international application; hence, they would be published internationally as part of the international patent application.⁶⁰

Failure to declare the source or wrongful declaration of the source of origin of genetic resources and TK would trigger the application of the sanctions currently allowed under the PCT and the WIPO's Patent Law Treaty ("PLT").⁶¹ Therefore, in contracting states which have amended national patent laws to implement the disclosure requirement, the patent office shall invite the applicant to comply with the requirement within a strict time limit.⁶² In the case of non-compliance, the office may refuse the application or consider it withdrawn.⁶³

Nonetheless, if after the patent is granted it is discovered that the patentee has failed to declare the source or has submitted false information, the proposal establishes that such failure *may not* be a ground for revocation or invalidation of the patent.⁶⁴

B. *A Second Proposal Advanced by Developing Countries*

A second proposal has been presented by a group of Developing Countries,⁶⁵ namely Brazil, Cuba, Ecuador, India, Peru, Thailand, and Venezuela. This proposal, consisting of three

introduce a national norm that would require patent applicants to disclose the place of origin of genetic resources and traditional knowledge. *See Declaration of the Source of Genetic Resources, supra* note 52, ¶ 24.

⁶⁰ Indeed, the proposed Rule 48.2(a)(xi) provides that the pamphlet of the international publication shall contain any declaration as referred to in the proposed Rule 4.17(vi). The latter, in turn, requires a declaration regarding the source of a specific genetic resource and/or traditional knowledge related to genetic resources, as referred to in the proposed Rule 51*bis*.1(g). For an in-depth explanation of the proposal, see *Further Observations by Switzerland, supra* note 52, ¶ 12.

⁶¹ According to the Swiss delegates, pursuant to the direct reference in the Patent Law Treaty ("PLT") in article 6.1 of the PCT, the proposed amendments to the PCT would also apply to the PLT. *Declaration of the Source of Genetic Resources, supra* note 52, ¶¶ 16, 27.

⁶² Pursuant to the proposed amended Rule 51*bis*.3(a), the invitation should be sent at the beginning of the national phase, and the time limit set to comply with the invitation should be no less than two months from the date of invitation. *See id.* ¶ 28.

⁶³ *Id.* However, according to the new proposed Rule 51*bis*.2(d), if the applicant has submitted the declaration relating to the source of origin and TK within the international application or even later during the international phase, the designated office must accept it and may not require any further document or evidence relating to the source declared. *Id.*

⁶⁴ There is no protection for fraudulent intention. WIPO PLT art. 10, June 1, 2000, 39 I.L.M. 1047; *see also Declaration of the Source of Genetic Resources, supra* note 52, ¶ 29.

⁶⁵ These countries first submitted a checklist of issues to be dealt with in order to prevent misappropriation of biodiversity and associated traditional knowledge, and to permit the fulfillment of the other remaining goals of the CBD, such as access and benefits sharing. Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity: Checklist of Issues*, IP/C/W/420 (Mar. 2, 2004), available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W420.doc> [hereinafter *Checklist*].

subparts, aims at amending the patent provisions of TRIPS so that Developing Countries benefit from related WTO enforcement procedures.

Although the first obligation under the proposal concerns the disclosure of the source and the country of origin, the proposal goes far beyond the Bonn Guidelines requirement.⁶⁶ Like Switzerland, these countries posit that the source disclosure requirement would help solve a range of patent-related problems, from mere patentability issues to such issues as disputes on inventorship, entitlement to claim an invention and the determination of infringements.⁶⁷ Their proposal aims to be even more effective in that it specifies that the obligation of extra disclosures would be triggered even by a *minimal* use of tangible or intangible resources and envisions a detailed set of legal consequences in case of wrongful or lack of disclosure.⁶⁸ In particular, the proposal distinguishes between cases where the wrongful or missing disclosure is discovered before the patent has been granted and circumstances where the lack of compliance is found at a later stage, when the title of protection has already been issued. In the former case, the patent application would not be processed further until the applicant complies.⁶⁹ In the latter case, three sets of consequences are envisioned: 1) revocation of the patent (in cases in which proper disclosure would cause the application to be denied for lack of novelty or reasons of *ordre public* or morality);⁷⁰ 2) full or partial transfer of the rights (if proper disclosure would show that the applicant was not the true inventor);⁷¹ and 3) narrowing the scope of the claims (in cases in which the proper disclosure would cause the use to be curtailed).⁷²

⁶⁶ *Id.*; see also Council for Trade-Related Aspects of Intellectual Property Rights, *Elements of the Obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge Used in an Invention*, IP/C/W/429/Rev.1 (Sept. 27, 2004), available at <http://commerce.nic.in/ip-c-w-429R1.pdf> [hereinafter *Disclosure of Source and Country of Origin*].

⁶⁷ *Checklist*, *supra* note 65.

⁶⁸ The proposal states in relevant part:

[A]ny use, the disclosure of which is necessary to determine the existence of prior art, inventorship or entitlement to the claimed invention, the scope of the claim and/or is necessary for understanding or carrying out the invention, would be sufficient to trigger the disclosure obligation. In this regard, even where the use was only incidental, it would be sufficient to trigger the obligation if the disclosure of the source and country of origin is relevant for prior art, inventorship or entitlement determinations, the scope of the claim and/or for understanding or carrying out the invention.

Disclosure of Source and Country of Origin, *supra* note 66, ¶ 8.

⁶⁹ *Id.* ¶ 12. The applicant would have also a limited time to comply with the disclosure requirement to avoid withdrawal of the patent application. *Id.*

⁷⁰ *Id.* ¶ 13.

⁷¹ *Id.*

⁷² *Id.*

The second part of the Developing Countries' proposal addresses disclosure of evidence of PIC under the relevant national regime.⁷³ Patent applicants should bear the burden of providing evidence that the national authorities of the country of origin and/or the local or indigenous community have approved the taking of their tangible and/or intangible resources.⁷⁴ For cases of non-compliance with this disclosure requirement, a set of legal measures are proposed, similar to the ones for the disclosure of source of origin already analyzed above.⁷⁵

The third and final part of the Developing Countries' proposal requires inclusion in the patent application of documents that provide evidence of benefit-sharing.⁷⁶ Such a requirement is meant not only for "ensuring that there is benefit-sharing per se but that sharing of benefits is fair and equitable among the parties, taking into account the circumstances of each particular case."⁷⁷ Such further proof would be satisfied by documents showing an arrangement among the parties for the fair and equitable sharing of any benefit that may arise out of the utilization of the resources.⁷⁸ In case of non-compliance with this requirement, the legal consequences would be similar to those outlined above for erroneous or missing disclosures.

Recently, a second group of Developing Countries have summarized the ideas expressed above and codified them into a draft provision for a new article to be inserted into TRIPS.⁷⁹

⁷³ Checklist, *supra* note 65; see Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge: Elements of the Obligation to Disclose Evidence of Prior Informed Consent Under the Relevant National Regime*, IP/C/W/438 (Dec. 10, 2004), available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W438.doc> [hereinafter *PIC document*].

⁷⁴ The communal action problem is beyond the scope of this article.

⁷⁵ In case of non-compliance before the granting of the patent, the application would not be processed any further until the requested documentation is provided. If a specific time limitation has been set and the inventor does not comply with it, the application would be withdrawn. In case of non-compliance after the patent has been granted, legal measures could include the revocation of the patent or criminal and/or civil sanctions. *PIC document*, *supra* note 73, ¶ 13.

⁷⁶ See generally Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge: Elements of the Obligation to Disclose Evidence of Benefit-Sharing Under the Relevant National Regime*, IP/C/W/442 (Mar. 18, 2005), available at <http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/IP/C/W442.doc>.

⁷⁷ *Id.* ¶ 3.

⁷⁸ *Id.* ¶ 10.

⁷⁹ In July 2006, Brazil, China, Colombia, Cuba, India, Pakistan, Peru, Thailand, and Tanzania presented a proposal to insert a new provision: article 29bis, "Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge." Trade Negotiations Committee of the Council for Trade-Related Aspects of Intellectual Property Rights, *Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge*, WT/GC/W/564/Rev.2 (July 5, 2006), available at <http://docsonline.wto.org/DDFDocuments/t/ip/c/w474.doc>.

Accordingly, new article 29*bis* establishes that whenever the subject matter of the patent application concerns, is derived from, or developed with biological resources and/or traditional knowledge associated therein, applicants will be required to disclose both the country providing the resources and the country of origin;⁸⁰ further, applicants shall provide information ensuring that they have complied with national provisions concerning PIC for ABS.⁸¹ In addition, the new article 29*bis* envisions strong enforcement measures providing that administrative or judicial authorities shall have the power to stop the further processing of a patent application or its grant, to revoke it (pursuant to the provisions contained at Article 32 of TRIPS) or render unenforceable the title of protection.⁸²

This provisional article was presented once again at the meeting of the TRIPS Council in Geneva, on February 13, 2007. However, the proposal has been opposed by several countries.⁸³

C. *The Position of the European Union*

The European Union is both a user and producer of biological resources. Not only has the EU been exploiting biological resources for the research and development of a vast range of products, but it also possesses a variety of genetic resources. The biodiversity of the Mediterranean area is home to a wealth of resources, and many institutions, such as botanic gardens, which grow large collections of biological resources. This might explain the European proactive involvement in the conservation and protection of such heritage at the international and national level.⁸⁴

⁸⁰ More precisely, article 29*bis*, ¶ 2, expressly requires the disclosure of: “the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin.” *Id.*

⁸¹ *Id.*

⁸² *Id.* ¶ 5. The patent may be rendered unenforceable only when the applicant has knowingly failed to comply with disclosure obligations set forth above (or when it had reasonable grounds to know), and when he has produced false or fraudulent information. *Id.*

⁸³ See *Disclosure of Origin Again on the TRIPS Council Agenda*, 7 BRIDGES, TRADE BIORES 2 (Feb. 16, 2007), available at <http://www.ictsd.org/biores/07-02-16/BioRes7-3.pdf>. See also Tove Iren S. Gerhardsen, *TRIPS Meeting: Boost to IP Issues as Part of Resumed Trade Talks*, US Submits Enforcement Proposal, INTELL. PROP. WATCH, (Feb. 14, 2007), <http://www.ip-watch.org/weblog/index.php?p=531&res=1024&print=0>.

⁸⁴ In 1995, the European Community funded a study on the best possible measures to implement articles 15 and 16 of the CBD. The results of this study were presented at the third Conference of the Parties of the Convention on Biological Diversity. The EU was very active during the negotiation leading to the adoption of the Bonn Guidelines, implemented in 2003. See Communication from the Commission to the European Parliament and the Council, *The Implementation by the EC of the “Bonn Guidelines” on Access to Genetic Resources and Benefit-Sharing Under the Convention on Biological Diversity*, COM (2003) 821 final (Dec. 23, 2003), available at <http://europa.eu.int/eur>

Nonetheless, the European Union has been less than straightforward regarding its position on the proposed extra-disclosure burden for patent applications. The EU claims that many of the proposed provisions already exist within EU laws and are therefore in line with the proposed requirement. For example, article 13(1)b of directive 98/44/CE establishes that where an invention involves the use of biological material that is not accessible to the public and cannot be described in such a way to enable the person skilled in the art to practice it, the description of the invention is deemed not *sufficient* unless, *inter alia*, the application contains all relevant information on the characteristics of the biological material at issue.⁸⁵ Therefore, disclosing information regarding the source of origin is requested in some cases by the EU directive itself. The same directive states, “if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application *should*, where appropriate, include information on the geographical origin of such material, if known.”⁸⁶ Similarly, article 50 of Council Regulation 2100/94 on community plant variety rights requires applicants to state the geographic origin of the variety.⁸⁷

The EC recognizes, however, that these provisions do not impose an overall obligation to disclose the country of origin. Indeed, recital 27 conditions the disclosure obligation on the contingency that it does not prejudice the processing of the patent application or the validity of the rights arising from the granted patents.⁸⁸ Furthermore, the disclosure obligation contained in article 50 is limited to the variety itself and does not cover the parent material from which the variety might have been developed.⁸⁹

Accordingly, the EC has examined the possibility of inserting a more extensive disclosure requirement.⁹⁰ Like the South American countries, the EU advocates the implementation of the mandatory requirement at the international and national level;⁹¹ nonetheless, as is the case with the Swiss proposal, the EU’s

lex/lex/LexUriServ/site/en/com/2003/com2003_0821en01.pdf [hereinafter *Implementation by the EC of the “Bonn Guidelines”*].

⁸⁵ Council Directive 98/44/EC, art. 13(1)(b), 1998 O.J. (L 213) 13-21 (EC) (on the legal protection of biotechnological inventions).

⁸⁶ *Id.* at recital 27. Recitals are not mandatory for Member States to implement and serve only to explain the rationale of the provisions contained in the Directive’s articles.

⁸⁷ Council Regulation 2100/94, art. 50, 1994, O.J. (L 227) 1 (EC), *available at* http://eurlex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31994R2100&model=guichett.

⁸⁸ Council Directive 98/44/EC, recital 27, 1998 O.J. (L 213) 13-21 (EC).

⁸⁹ Council Regulation 2100/94, *supra* note 87, at art. 50.

⁹⁰ *Implementation by the EC of the “Bonn Guidelines,” supra* note 84, at 19-20.

⁹¹ *Id.*

disclosure requirement is limited to the disclosure of the country of origin, and such disclosure is contingent on the invention being directly based on such resources and the inventors being aware of that fact.⁹² Moreover, the EU shares, at least partially, the American fears regarding the effects of noncompliance with patent law. Therefore, the EU members explicitly ask that the disclosure requirement not amount, *de facto* or *de jure*, to a formal patentability criterion, and in the case of incorrect or incomplete information, “effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law.”⁹³

IV. WHY A DEFENSIVE MECHANISM BY ITSELF IS NOT SUFFICIENT

The proposal to amend international patent laws to include the extra-disclosure burdens has met strong opposition by the United States and Japan.⁹⁴ Although the United States is an ardent promoter of anti-piracy laws aimed at those who do not respect its own intellectual property regime,⁹⁵ the United States seems unreceptive to enforce any legal mechanism that could

⁹² According to the Swiss proposal for new Rule 51*bis*.1(g)(iii), the inventor can also declare that he doesn't know the source of origin of the resources employed in his invention. Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Further Observations by Switzerland on Its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO/GRTKF/IC/7/INF/5 (Oct. 18, 2004).

⁹³ Proposal of the European Community and Its Member States to WIPO, *Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications*, ¶ 8(g), (Dec. 16, 2004), available at http://www.wipo.int/tk/en/genetic/proposals/european_community.pdf; see also Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the European Communities and Their Member States*, IP/C/W/383 (Oct. 17, 2002), available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W383.doc>.

The EC has recently restated its position in a document submitted to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications*, ¶ 5, WIPO/GRTKF/IC/8/11 (May, 17 2005), available at www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_8/wipo_grtkf_ic_8_11.pdf (clarifying that national patent offices must not be required to make an assessment on the extra-disclosure information submitted nor must they be obliged to check whether the applicant has gained access to the relevant material in a way that is compatible with the CBD principles of benefit-sharing and prior informed consent).

⁹⁴ See Council for Trade-Related Aspects of Intellectual Property Rights, *Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, IP/C/W/434 (Nov. 26, 2004), IP/C/W/449 (June 10, 2005) [hereinafter *Communications from the United States*].

⁹⁵ It is well known, indeed, that the United States pushed many Developing Countries to sign the TRIPS Agreement by implementing section 301 of the Trade Act of 1974. Section 301 is the principal statutory authority under which the United States may impose trade sanctions against foreign countries that maintain acts, policies and practices that violate or deny U.S. rights or benefits under trade agreements, or are unjustifiable, unreasonable or discriminatory, and burden or restrict U.S. commerce. See Trade Act of 1974, 19 U.S.C. § 2411 (2006).

grant indigenous people some measure of protection.⁹⁶ Accordingly, U.S. delegates strongly oppose the introduction of a further disclosure requirement, asserting that its introduction would perilously destabilize the patent system by rendering the application mechanism excessively burdensome and the validity of its protection uncertain.⁹⁷

It is perhaps true that a tripartite disclosure requirement, such as the Developing Countries' proposal discussed above, would be too cumbersome for patentees and would go well beyond the certification function that patent offices can perform. Patent officers do not have the skills or the time necessary to evaluate agreements on access and sharing of resources in order to determine whether indigenous communities are truly granted a fair share of the returns and benefits. However, there is no serious obstacle to amending international patent provisions to include a requirement that the source of origin of genetic resources and TK be disclosed. Such an amendment also would not be contrary to TRIPS because although article 29 of the TRIPS Agreement is silent about the possibility of requesting further disclosures,⁹⁸ article 62.1 of TRIPS expressly states that member states can condition the acquisition or maintenance of patents on compliance with *reasonable* procedures and formalities, provided that they are consistent with the provisions of the Agreement.⁹⁹ Numerous examples already exist of national patent laws that require supplementary disclosure burdens, such as the U.S. best mode requirement¹⁰⁰ and the European duty to deposit a sample of the biological material at an accredited institution.¹⁰¹ A requirement to specify the country of origin would not amount to an excessive burden but rather accords with the *reasonableness* standard requested by article 62.¹⁰² In addition, the risk of patent invalidation following a lack of disclosure represents a necessary

⁹⁶ At the last WTO meeting, held in Geneva on February 2007, the United States presented a communication called "Enforcement of Intellectual Property Rights: Experiences of Border Enforcement," in which it expressed its fears of foreign infringement of American IP rights. Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/488 (Jan. 30, 2007), *available at* http://www.strtrade.com/wti/2007/february/26/ipr_submission.pdf. Reportedly, at the meeting, the United States opposed the Developing Countries' proposal of inserting a new provision in TRIPS about disclosure of origin of tangible and intangible indigenous resources. *Cf.* Gerhardsen, *supra* note 83.

⁹⁷ *See Communications from the United States*, *supra* note 94.

⁹⁸ TRIPS, *supra* note 20, at art. 29.

⁹⁹ *Id.* at art. 62(1).

¹⁰⁰ 35 U.S.C. § 112.

¹⁰¹ Council Directive 98/44, art. 13, 1998 O.J. (L 213) (EC), *available at* http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0044&model=guichett.

¹⁰² TRIPS, *supra* note 20, at art. 62.

remedy because a pecuniary sanction would almost certainly never amount to a credible or effective threat.

It is worth noting, however, that although the disclosure of origin requirement may be a valuable *defensive* instrument to protect indigenous people, it is not in itself a sufficient means to solve the biopiracy problem and ensure ABS. Disclosure on patent applications—although a significant step—does not fix anything if the research does not result in a patent. Thus, the provisions of the CBD, quite appropriately, are aimed at ensuring that indigenous peoples benefit at large from the fruits of the research conducted on their intellectual and genetic resources, regardless of whether those benefits eventually result in an intellectual property right or a retained trade secret.

V. TOWARDS A FAIR AND EQUITABLE SHARING OF THE BENEFITS ASSOCIATED WITH BIODIVERSITY AND TRADITIONAL KNOWLEDGE

The provisions set forth in the CBD call for empowering indigenous communities with two fundamental rights: namely, the right to be protected from having their resources stolen and the right to benefit from any exploitation of such resources by third parties.¹⁰³ The latter is subdivided into: 1) *access* to the results of research conducted on biological resources and TK, and 2) equitable *sharing* of economic benefits flowing from the exploitation at large of the research results.¹⁰⁴ In addition to the general provisions on equitable sharing results and benefits in article 15(7), the CBD also provides that:

[E]ach Contracting Party shall take . . . measures . . . with the aim that Contracting Parties, *in particular those that are developing countries*, which provide genetic resources[,] are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, *including technology protected by patents and other intellectual property rights*.¹⁰⁵

Furthermore, the CBD underlines the need to grant the countries providing genetic resources *effective participation in biotechnological research activities*¹⁰⁶ and *priority access* on a fair and equitable basis to the *results and benefits arising from biotechnology based upon genetic resources*.¹⁰⁷

The latter set of rights is firmly grounded in the recognition of the indigenous community's entitlement to its own tangible and

¹⁰³ CBD, *supra* note 8, at arts. 15(1) and 15(7).

¹⁰⁴ *Id.* at art. 15(7).

¹⁰⁵ *Id.* at art. 16(3) (emphasis added).

¹⁰⁶ *Id.* at art. 19(1).

¹⁰⁷ *Id.* at art. 19(2).

intangible resources. In particular, the community has the right to economic compensation for the commercial exploitation of its biological resources, and this right stems from the property rights local communities have in their own genetic resources.¹⁰⁸ Conversely, the right to access the results of the research is based on the view that Developed Countries merely borrow scientific knowledge from indigenous people, and according to logic that resonates with the open source movement, the indigenous community should not be excluded from benefiting from applications of their knowledge.

The intangible character of TK makes the recognition of rights to TK more difficult. Indigenous people have their own system and traditions for the use and application of their knowledge. However, foreign companies filter traditional medical knowledge through the lens of industrialized intellectual property systems, which results in the perception that TK is free to be exploited.

VI. CRAFTING AN ENTITLEMENT SYSTEM FOR PROPRIETORS OF TRADITIONAL KNOWLEDGE

Two proposals have been presented for crafting an entitlement system for those who originate and possess TK. The first, prepared by academics in the field, is the result of a marriage of legal and economic expertise. The second, prepared by the WIPO secretariat, was presented in Geneva at the April 2006 session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge.

A. *Liability Rules for Indigenous Communities: Pros and Cons*

Proponents of strong protection for intellectual property rights tend to emphasize that compensation for TK is incompatible with current IP regimes. Conversely, “public-interest advocates” fear the introduction of any form of proprietary rights in TK because of the likely adverse effects on the public domain.¹⁰⁹ An intermediate stance has been recently put forward by Professors Jerome Reichman and Tracy Lewis as a tentative attempt to regulate TK under a *compensatory liability regime* (“CLR”).¹¹⁰ According to their model, TK owners would be

¹⁰⁸ Such rights, further affirmed in the CBD, should be easily recognizable by Developed Countries because of the tangible character of the resources.

¹⁰⁹ Thomas Cottier & Marion Panizzon, *Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection*, in INTERNATIONAL PUBLIC GOODS, *supra* note 26, at 565, 577.

¹¹⁰ Jerome H. Reichman & Tracy Lewis, *Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge*, in INTERNATIONAL PUBLIC

provided, for a limited time, the following rights: 1) to prevent second comers from entering TK owners' product market with a wholly unoriginal imitation of their product; 2) to reasonable compensation from follow-on innovators who make improvements upon the scientific knowledge of the TK owners; and 3) to make use of second comers' own technical improvements for purposes of further improving the TK owners' original products.¹¹¹

The authors explain that Developing Countries could greatly benefit from an entitlement system based on liability rules rather than property rights for at least two reasons.¹¹² First, Developing Countries' industries often consist of small and medium-sized enterprises rather than large and powerful companies, and in such an industrial environment, titles of protection such as patents, which are costly to obtain and to litigate, may not be the best option to spur technological progress. India and South Korea, for example, have largely benefited from imitation rather than original creation.¹¹³ Secondly, the authors, agreeing with the Developed Countries' perspectives, stress the nature of TK as *sub-patentable* subject matter; they define TK as *technical know-how* that does not meet both copyright and patent eligibility requirements. Therefore, they think this TK would otherwise be left in the public domain. Conversely, a CLR system would place genetic resources and TK in a *semi-common* pool where scientific information can be easily shared because access is permitted, although free-riding is expressly forbidden.¹¹⁴

The Reichman-Lewis proposal is one of the most interesting suggestions advanced so far. Indeed, such a system would entitle indigenous people to procure compensation from third party

GOODS, *supra* note 26, at 337; see also Jerome H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUMBIA L. REV. 2432 (1994); Jerome H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743 (2000).

¹¹¹ Reichman & Lewis, *supra* note 110, at 349. The core of the proposal closely resembles what I have suggested elsewhere for computer programs. Indeed the proposal closely resembles the scheme laid out by article 31(l) of the TRIPS Agreement, which established a cross-licensing mechanism for high-profile innovations whereby only truly innovative second comers are entitled to a license on the first blocking patent and, in turn, are compelled to grant access to their dependent innovation to first inventors. I have examined the possibility of implementing such a scheme with regard to computer-implemented inventions. See Gustavo Ghidini & Emanuela Arezzo, *Patent and Copyright Paradigms vis-à-vis Derivative Innovation: The Case of Computer Programs*, in 36-2 INT'L REV. OF INTELL. PROP. AND COMPETITION LAW 159, 160 n.2 (2005).

¹¹² Reichman & Lewis, *supra* note 110, at 354.

¹¹³ Developed Countries have referred to this as free-riding but are reluctant to see the parallel to biosquatting.

¹¹⁴ See Jerome H. Reichman, *Saving the Patent System from Itself, Informal Remarks Concerning the Systemic Problems Afflicting Developed Intellectual Property Regimes*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 289, 292-94 (F.S. Kieff ed., 2003).

exploitation; however, it would not grant them the right to block access to third parties. Hence, it would favor the advancement of biotechnological sciences based on indigenous resources.

Although this system may spur innovation and enrich Developing Countries, such a system carries some significant limitations. From a normative point of view, a CLR system seems to conflict with the very aims of the CBD, which expressly refers to the Developing Countries' sovereignty over genetic resources as a fundamental right as well as provides negotiating tools for properly dealing with Developed Countries' firms. From a practical point of view, it is not clear how a CLR regime could coexist with traditional intellectual property regimes either inside or outside Developing Countries' territories. Developing Countries (at least most of them) have adhered to the TRIPS Agreement, and sooner or later, they will all be compelled to shift from their local IP system towards internationalized IP standards.¹¹⁵ This means that a CLR system, adopted in a Developing Country, would have to coexist with traditional intellectual property regimes, most significantly with patent law. Arguably, this should not be a problem because patent law is supposed to have a higher standard of protection, filtering out only truly nonobvious innovations.¹¹⁶ However, at least in the United States, this higher standard has been lessened.¹¹⁷ It is not clear how the two regimes could dissect separate spheres of application. In addition, even assuming that such a separation could actually be feasible, it is not clear what would happen if, for example, an inventor provided compensation for appropriating TK from the semi-common pool and then, due to a breakthrough discovery, succeeded in patenting his invention.¹¹⁸

Moreover, the coexistence of a CLR system in other countries with their own IP systems is even more worrisome. Reichman and Lewis state that, lacking any treaty obligation, "members would not be entitled to demand for their citizens that foreign countries reciprocally provide similar CLR protection abroad."¹¹⁹ This circumstance is not as troubling as it may initially seem because

¹¹⁵ At the end of November 2005, the Council for Trade-Related Aspects of Intellectual Property Rights decided to extend Least Developed Countries' transition period for the implementation of IP provisions (which was set to expire on January 1, 2006) by seven and a half years. *See Extension of the Transition Period, supra* note 20.

¹¹⁶ 35 U.S.C. § 103(a) (2006).

¹¹⁷ This trend has been described by Jerome H. Reichman. *See supra* note 114, at 294. However, this trend could change following the much awaited Supreme Court decision about motivation to combine in non-obviousness analysis. *See infra* note 175.

¹¹⁸ In particular, it seems that the exclusive rights conferred by a patent would entitle the patentee to impede TK originators from using the TK put in the pool, not to mention the improvement invention based on TK.

¹¹⁹ Reichman & Lewis, *supra* note 110, at 364.

both the Paris Convention and TRIPS would allow Developing Countries' citizens to claim patent and utility model rights abroad in countries that do not have a similar CLR system.

This is certainly true, but the problem is not how to foster Developing Countries' industries through the exploitation of TK. Indeed, indigenous people (if their countries are TRIPS signatories) are already entitled to ask for patents or utility model protection abroad once their innovations fulfill the requirements set forth by foreign legislation. Rather, the concern here is preventing biopiracy, i.e., how to impede foreign third parties from collecting Developing Countries' biological resources and TK, bringing it back to their own countries, and obtaining IP protection to manufacture and distribute products embedding biodiversity and TK in their own markets. In addition, the third parties might ask for IP protection in Developing Countries in such a way as to impede indigenous communities from using their own resources.

In conclusion, the problem is centered around the implementation of *supranational* provisions that protect local communities against misappropriation that usually takes place abroad.¹²⁰ Although the CLR is attractive as an entitlement system for TK, this regime falls short in that it is not suited to address the issue of biopiracy and misappropriation of TK.

B. *The Draft of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*

Since 2001, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“IGC”) has periodically met to draft provisions expressly meant to enhance protection of TK and traditional culture against misappropriation and misuse.¹²¹ The

¹²⁰ The author's point of view is shared by Cottier and Panizzon, *supra* note 109, at 581, who explain that: “Protection of TK is only effective if it binds industrialized and Developing Countries alike. This is only possible with a global-scale protection.”

¹²¹ The most updated document was presented during the tenth session of the IGC, held in Geneva from November 30 to December 8, 2006. See WIPO, *Protection of Traditional Knowledge: Draft Objectives and Principles*, WIPO/GRTFK/IC/10/5 (Oct. 2 2006), available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_10/wipo_grtkf_ic_10_5.doc [hereinafter *Draft Objectives and Principles*].

TRIPS, *supra* note 20, at art. 2(1), adopted the unfair competition provisions contained in article 10*bis* of the Paris Convention. Although the list of acts contained in article 10*bis*(3) is not exhaustive, and article 10*bis*(2) explains that “any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition,” the lack of an express mention of misappropriation has led to different shaping of unfair competition in different countries. Paris Convention for the Protection of Industrial Property art. 10, Sept. 28, 1979, 21 U.S.T. 1583, 828 U.N.T.S. 305, available at http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html [hereinafter

IGC draft document is comprised of three parts. The first part consists of *policy objectives* and is intended to provide a consistent policy framework for protection.¹²² The second part contains general guiding principles aimed at ensuring consistency, balance, and effectiveness of the substantive principles contained in part three.¹²³ The last part is a set of substantive provisions which define the concept of TK, delineate the scope, duration, and formalities of protection, and establish who should be the entitled owner of such protection.¹²⁴

While the stakeholders participating in the meetings promoted by the Committee have largely agreed on the policy objectives and guiding principles for protection, there remains some disagreement as to the specific form of protection to be implemented (i.e., part three of the document).¹²⁵

1. Protection of Traditional Knowledge in the IGC Document

The IGC has framed an ample definition of TK as the content of knowledge resulting from “intellectual activity in a traditional context” consisting of the know-how, skills, innovations, practices, and knowledge that form part of the lifestyle of indigenous and local communities.¹²⁶ Further, traditional knowledge is defined as a system of *ongoing innovation*,¹²⁷ not limited to any specific technical field, from agriculture to environment and medicine.¹²⁸ The intergenerational character of TK, and in general, its collective nature, is also stressed insofar as it represents the requirement to filter out which TK deserves protection and who should be designated as its proprietor.¹²⁹ To this end, Article 5 of

Paris Convention].

¹²² Among the most relevant policy objectives are: the recognition of the holistic nature of TK, the acknowledgment that TK systems are frameworks of “ongoing innovation and distinctive intellectual and creative life,” the importance of meeting the actual needs of TK holders, and the conservation and preservation of TK itself. *Draft Objectives and Principles*, *supra* note 121, annex, pt. I, at (i).

¹²³ The more relevant guiding principles include: recognition of rights, effectiveness and accessibility of protection, equity and benefit-sharing, and consistency with existing legal systems governing access to associated genetic resources. *Id.* annex, pt. II.

¹²⁴ *Id.* annex, pt. III.

¹²⁵ *See id.*

¹²⁶ *See id.* annex, pt. III, at art. 3, ¶ 2.

¹²⁷ *Id.* annex, pt. III, at art. 3, ¶ 1.

¹²⁸ *Id.* annex, pt. III, at art. 3, ¶ 2.

¹²⁹ Article 4 holds that protection should be extended at least to TK that is:

(i) generated, preserved and transmitted in a traditional and intergenerational context; (ii) distinctively associated with a traditional or indigenous community or people which preserves and transmits it between generations; and (iii) integral to the cultural identity of an indigenous or traditional community or people which is recognized as holding the knowledge through a form of custodianship, guardianship, collective ownership or cultural responsibility. This relationship may be expressed formally or informally by customary or traditional practices, protocols or laws.

the IGC document establishes that protection may benefit entire communities that collectively possess TK as well as individuals within these communities.¹³⁰

As for the requirements for protection, it is worth pointing out that the proposal has established what characteristics TK needs to show to deserve protection,¹³¹ and it has firmly established that there be no barrier of formalities for the recognition of such protection,¹³² which will automatically arise and shall endure as long as the TK maintains the features listed in article 4.¹³³

2. Conduct Amounting to Misappropriation of Traditional Knowledge

As for the definition of TK, the concept of misappropriation has been defined quite broadly. The provision that outlines protection against misappropriation is divided into three sections. First, misappropriation is defined as any acquisition, appropriation or utilization of traditional knowledge by “*unfair or illicit means*.”¹³⁴ Further, the provision notes that misappropriation may also include:

[D]eriving commercial benefit from the acquisition, appropriation or utilization of traditional knowledge when the person using that knowledge knows, or is negligent in failing to know, that it was acquired or appropriated by unfair means; and other commercial activities contrary to honest practices that gain inequitable benefit from traditional knowledge.¹³⁵

It is interesting to note that in both cases, the provision does not ban the acquisition or utilization of TK by foreign third parties, or the gain of commercial benefits *per se*. Indeed, the document is not aimed at foreclosing access and employment of TK by foreign companies, but simply at facilitating a fair exchange and negotiation that benefit all interested parties. Accordingly, all mentioned conduct becomes an act of misappropriation only

Id. annex, pt. III, at art. 4.

¹³⁰ *Id.* annex, pt. III, at art. 5.

¹³¹ *Id.*

¹³² As explained, the misappropriation right should arise and last as long as the requirements listed in article 4 are fulfilled. In contrast to patent law, 35 U.S.C. § 111(a) (2006), indigenous communities should not have to file an application in order to receive protection. Like copyright law, protection immediately arises when the elements listed in article 4 are met. However, this misappropriation differs even from the latter because neither fixation nor registration (*via* deposit of a copy of the materials to be protected at an accredited institution) is required as an element for protection. Although registration is not needed for copyright protection to arise, registration is necessary to file a complaint and sue for copyright infringement. See 17 U.S.C. § 408(a).

¹³³ *Draft Objectives and Principles*, *supra* note 121, annex, pt. III, at arts. 9, 11.

¹³⁴ *Id.* annex, pt. III, at art. 1, ¶ 2.

¹³⁵ *Id.*

insofar as access to TK has been obtained through *unfair means*. In this regard, it should be added that the IGC document has expressly held that third parties seeking access to TK should respect and conform to the principle of prior informed consent.¹³⁶

The provision continues with a list of conduct which is unlawful *per se* and should always be banned. Interestingly, the list is quite heterogeneous and contains unfair conduct,¹³⁷ acquisition through violation of PIC obligation,¹³⁸ exploitation of TK without appropriate compensation for TK owners,¹³⁹ and even willful offensive use of TK.¹⁴⁰ Further, the list expressly mentions false assertion of IP rights over TK-related subject matter “when those intellectual property rights are not validly held in the light of that traditional knowledge and any conditions relating to its access.”¹⁴¹

Article 1 eventually concludes with a broad provision stating that TK holders should be protected, in general, against all forms of unfair competition conduct, including practices specified in Article 10*bis* of the Paris Convention.¹⁴²

Complementary to the misappropriation provisions

¹³⁶ *Id.* annex, pt. III, at art. 7. In addition, the IGC document also envisaged a tentative insertion of a moderate disclosure of origin obligation in Article 6, ¶ 3, in stating that third parties using TK beyond their traditional context should mention its source, acknowledge its holders, and use it in a manner that respects the cultural values of its holders. *Id.* annex, pt. III, at art. 6, ¶ 3.

¹³⁷ Article 1, ¶ 3(i) states that legal means should be provided to prevent acquisition of traditional knowledge by theft, bribery, coercion, fraud, trespass, breach or inducement of breach of contract, breach or inducement of breach of confidence or confidentiality, breach of fiduciary obligations or other relations of trust, deception, misrepresentation, the provision of misleading information when obtaining prior informed consent for access to traditional knowledge, or other unfair or dishonest means.

Id. annex, pt. III, at art. 1, ¶ 3(i).

¹³⁸ Article 1, ¶ 3(ii) states that legal means should be provided to prevent: acquisition of traditional knowledge or exercising control over it in violation of legal measures that require prior informed consent as a condition of access to the knowledge, and use of traditional knowledge that violates terms that were mutually agreed as a condition of prior informed consent concerning access to that knowledge.

Id. annex, pt. III, at art. 1, ¶ 3(ii).

¹³⁹ Article 1, ¶ 3(iv) further states that

if traditional knowledge has been accessed, commercial or industrial use of traditional knowledge without just and appropriate compensation to the recognized holders of the knowledge, when such use has gainful intent and confers a technological or commercial advantage on its user, and when compensation would be consistent with fairness and equity in relation to the holders of the knowledge in view of the circumstances in which the user acquired the knowledge.

Id. annex, pt. III, at art. 1, ¶ 3(iv).

¹⁴⁰ Article 1, ¶ 3(v) states that legal means should be provided to prevent “willful offensive use of traditional knowledge of particular moral or spiritual value to its holders by third parties outside the customary context, when such use clearly constitutes a mutilation, distortion or derogatory modification of that knowledge and is contrary to ordre public or morality.” *Id.* annex, pt. III, at art. 1, ¶ 3(v).

¹⁴¹ *Id.* annex, pt. III, at art. 1, ¶ 3(iii).

¹⁴² *Id.* annex, pt. III, at art. 1, ¶ 4.

contained in Article 1, the provisions contained in Article 6 call for fair and equitable sharing of benefits stemming from the commercial or industrial use of TK¹⁴³ and, when the latter are employed for non-commercial purposes, they ask for compensation in the form of access to research outcomes and involvement of the source community in research and educational activities.¹⁴⁴

3. Implementation Measures and Legal Status of the Misappropriation Regime

Article 2 of the IGC document explains that protection of TK against misappropriation may be implemented through a different set of legal measures including, *inter alia*, a special law on traditional knowledge, intellectual property laws, including unfair competition, and contract laws.¹⁴⁵ The second prong of this Article clarifies that the form of protection need not be through the creation of new exclusive property rights, although it recognizes that the latter may be an option.¹⁴⁶

Eventually, it seems that the effectiveness of the adoption of this form of misappropriation regime hinges on the legal status it will receive once implemented. In this regard, however, the IGC proposal leaves open the issue of how the misappropriation regime should be implemented nationally, as there are a number of legal measures available. In other words, the document drafted by the Committee would simply set some international standards that countries are free to implement.¹⁴⁷ The document only envisages a flexible form of a national treatment principle whereby foreign TK holders should be entitled to protection against misappropriation and misuse of their TK, provided that they are located in a country which is considered eligible.¹⁴⁸ National treatment, however, can be a loose standard if countries are allowed to implement the regime with discretion; this would afford foreign TK holders treatment that is at least as favorable as

¹⁴³ *Id.* annex, pt. III, at art. 6, ¶ 1.

¹⁴⁴ *Id.* annex, pt. III, at art. 6, ¶ 2. This Article further requires that TK holders should be granted legal means to claim fair and equitable sharing of benefits pursuant to what is established at paragraphs 1 and 2 of the Article. *Id.* annex, pt. III, at art. 6, ¶ 4.

¹⁴⁵ *Id.* annex, pt. III, at art. 2, ¶ 1.

¹⁴⁶ *Id.* annex, pt. III, at art. 2, ¶ 2.

¹⁴⁷ *See id.* annex, pt. III, at art. 2, ¶ 1.

¹⁴⁸ Article 14 of the IGC document establishes:

[T]hese international standards should be available to all eligible traditional knowledge holders, who national or habitual resident of a prescribed country as defined by international obligations or undertakings. Eligible foreign holders of TK should enjoy the benefits of protection to at least the same level as traditional knowledge holders who are nationals of the country of protection.

See id. annex, pt. III, at art. 14.

the treatment the country at issue would grant to its own TK holders. However, if the country decides to grant to its own residents a low degree of protection, perhaps because it is a Developed and not a Developing Country, then TK holders would not receive sufficient protection abroad.¹⁴⁹

The IGC document will be the subject of further analysis in the last Part of this article.

VII. A COLONIALIST MODEL OF INTELLECTUAL PROPERTY?

Why is it so difficult to envisage a form of proprietary rights for local communities regarding their intangible works? There are many possible answers. First, the type of intellectual works protected and rewarded by modern intellectual property regimes appears quite different from the model embraced by local indigenous communities. For example, Developed Countries' patent and copyright paradigms respond to the needs of market economies and enable the commercial exploitation of intellectual creations. Although not purposely, these systems therefore set rules with which indigenous people's creations must comply—and in most cases, compliance is difficult or impossible. Second, it has been observed that industrialized intellectual property systems reward only creative efforts and the transformation of raw inputs, giving no value to the raw materials themselves which have represented Developing Countries' competitive advantage.¹⁵⁰ This, in theory, should not be criticized. Intellectual property regimes arose to protect intangible works, and therefore it is no surprise that within IP paradigms there is no reward for producing raw materials. But the system doesn't work the way it does because raw materials have no value. Rather, raw materials, being tangible, should be subject to traditional property rights.

Nevertheless, genetic resources are different from traditional property.¹⁵¹ While Developing Countries lack measures to efficaciously prevent the unauthorized taking of their resources, the close relationship between genetic resources and related TK makes the status of genetic resources very peculiar and close to that of intangible property itself.¹⁵²

¹⁴⁹ The TK stolen from its owners is often used in market products that are almost exclusively sold in Developed Countries' markets; therefore, it is extremely important that TK owners receive protection abroad.

¹⁵⁰ BOYLE, *supra* note 19, at 126.

¹⁵¹ *See supra* Part I.C.

¹⁵² *See supra* Parts I.B-C.

A. *Alleged Barriers to Creating an Entitlement Regime for Intangible TK*

As some scholars have observed, western intellectual property systems are specifically framed to reward and protect the innovator of the industrial revolution and disfavor Developing Countries' ways of contributing to science and culture.¹⁵³ According to Professor James Boyle, the first sign of this imbalance is found in the concept of authorship (or alternatively, “inventorship”) which “stands as a gate through which one must pass in order to acquire intellectual property rights.”¹⁵⁴ A significant passage from the Bellagio Declaration, a statement addressing the expansionist trends in intellectual property laws that was signed in 1992 by lawyers, anthropologists, environmentalists, computer experts, literary critics, and activists, states:

Contemporary intellectual property law is constructed around the notion of the author, the individual, solitary and original creator Those who do not fit this model—custodians of tribal culture and medical knowledge, collectives practicing traditional artistic and musical forms, or peasant cultivators of valuable seed varieties, for example—are denied intellectual property protection.¹⁵⁵

Allegedly, Developing and Developed Countries differ in that the collaborative creative process of the former (as opposed to the individualistic process typical of the latter) makes it hard to identify and reward, through the granting of an exclusive right, the true author/inventor. Furthermore, this collaborative process has a highly cumulative character and gradually advances through generations. Usually, many members of the community

¹⁵³ As Professor Blakeney has vividly pointed out, traditional knowledge (and folklore) is at odds with all common intellectual property principles: “Authorship is replaced by a concept of *interpretation through initiation*. Ownership yields to a concept of custodianship of dreamings, or legend. Alienation is contradicted by the concept of immutable communal property. Exploitation is subject to cultural restraints and taboos.” Micheal Blakeney, *The Protection of Traditional Knowledge Under Intellectual Property Law*, 6 EUR. INTELL. PROP. REV. 251 (2000).

¹⁵⁴ BOYLE, *supra* note 19, at 125.

¹⁵⁵ The Bellagio Declaration is like a *manifesto*, which was signed by a heterogeneous group of renown people (lawyers, anthropologists, environmentalists, computer experts, and literary critics) at the end of the Conference “Cultural Agency/Cultural Authority: Politics and Poetics of Intellectual Property in the Post-Colonial Era,” held in March 1993. *Id.* at 192. The Declaration addresses a growing worldwide concern regarding the expansionist trend of intellectual property laws and its perilous consequences on the “public domain,” intended as the intellectual and cultural commons from which future works will be originated. Among other things, the Declaration condemns the fact that although IP laws have profound effects, *inter alia*, on biodiversity, access to information, and the culture of indigenous tribes, too often these laws “are constructed without taking such effects into account, constructed around a paradigm that is *selectively blind* to the scientific and artistic contributions of many of the world’s cultures and constructed in fora where those who will be most directly affected have no representation.” *Id.* at 193.

contribute in different amounts and in different moments to the enlargement of the knowledge, so that no significant breakthrough can be identified at a certain time, but rather there is a continuous flow of small innovations. This difficulty in identifying a creator is increased by the ephemeral character of the innovations that are orally passed from one generation to the next,¹⁵⁶ so that it is impossible to discern, within the group, who discovered what in any precise moment.¹⁵⁷

It has been further argued that TK holders cannot protect their knowledge or its practical application through current patent laws because the fruit of indigenous people's intellectual labor would not meet the requirements of novelty and non-obviousness.¹⁵⁸ Moreover, from a European perspective, the type of innovations brought about by indigenous people could never receive patent protection because they would amount to mere discoveries.¹⁵⁹ While this obstacle would probably be easier to overcome through the American "product of nature"/"human-made inventions" dichotomy,¹⁶⁰ these objections to patent protection depend on the assumption that indigenous people indeed *want* such protection. However, this assumption is highly misleading as indigenous people have their own social and legal *mores* regulating the creation and enjoyment of biodiversity and TK. Although they surely look for protection against misappropriation of their tangible and intangible resources, it is not clear that they are willing to get rid of their legal customs and are ready to implement a strong IP-like legal system.¹⁶¹

¹⁵⁶ For both patent and copyright paradigms, the fixation of the subject matter represents, for different reasons, a precondition for the granting and/or recognizing of protection.

¹⁵⁷ This requirement may represent a further obstacle. Even if patent law envisages some form of collective inventorship, it strictly requires that all inventors contributed to the innovation and that each individual contribution is discernable. *See* Van Overwalle, *supra* note 16, at 594.

¹⁵⁸ *See* Koopman, *supra* note 10, at 261; Van Overwalle, *supra* note 16, at 593; Reichman & Lewis, *supra* note 110, at 356-57 (noting that TK can be analogized to present-day applications of *know-how* to industry, and that, in a similar fashion to *know-how*, the TK origination mechanism also proceeds mostly by trial and error).

¹⁵⁹ Koopman, *supra* note 10, at 261.

¹⁶⁰ As acknowledged by the European Patent Convention, it is commonly accepted in European patent law that discoveries cannot be patented because they do not amount *per se* to inventions. Convention on the Grant of European Patents art. 52.2(a), Oct. 5, 1973, *available at* <http://www.european-patent-office.org/legal/epc/e/ma1.html> [hereinafter EPC].

American patent law does not ban discoveries as patentable subject matter, 35 U.S.C. § 101 (2006). However, with regard to biotechnological inventions, the Supreme Court has drawn a distinction between naturally occurring things, which are hence not patentable, and "product of human ingenuity having a distinct name, character and use." *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (citing *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)).

¹⁶¹ In fact, quite often, notwithstanding the fact that their countries have implemented intellectual property regimes, local communities respond to their oral traditions and rules

Conversely, to start an analysis with that assumption in mind may be dangerous from the perspective of indigenous communities' interests because it leads foreign researchers to assume that what is not subject to their intellectual property scheme is free, and therefore they have the right to appropriate it. In other words, because foreign enterprises view TK through the lens of industrialized intellectual property systems, the absence of any patents or patent-like rights leads these companies to view TK as in the public domain. Furthermore, western ethnobotanists and biologists often publish the results of their studies based on investigations of indigenous communities' scientific knowledge without obtaining any authorization. Obviously, such knowledge is then deemed to be in the public domain according to the bias of Developed Countries.¹⁶²

B. *Protectionist Measures*

In the recent American case *In re Cruciferous Sprout Litigation*, the United States Court of Appeals for the Federal Circuit affirmed the district court's decision invalidating three patents on the ground of anticipation.¹⁶³ The patents concerned methods of processing sprouts that contain certain enzymes that have a chemoprotective effect—in other words, the enzymes protect against cancer. The court found that the inventions were not novel because the alleged properties claimed by the applicant were *inherent* to the sprouts, regardless of whether persons skilled in the method of processing the sprouts were aware of it.¹⁶⁴ The principle underlying the decision was that it was inappropriate to grant a patent on a plant whose alleged benefits had already been acquired by society—in other words, anticipated.¹⁶⁵

This principle does not apply, however, if the beneficial properties belong to a plant growing on a Developing Country's soil. The U.S. patent system establishes that anticipation, which invalidates a patent application, can be caused only by what was “known or used by others in [the United States] or patented or described in a printed publication in this or a foreign country,

and do not ask for patent protection.

¹⁶² Indeed, such knowledge is often subjected to the *local* IP-like property system. An unauthorized publication should not be considered by Western countries as putting the innovation in the public domain; rather, as happens with the publication of patent applications, such disclosure should have the effect of preserving the knowledge contained therein but clarifying its belonging to the state of the art.

¹⁶³ *In re Cruciferous Sprout Litig.*, 301 F.3d 1343 (Fed. Cir. 2002).

¹⁶⁴ This is the “inherency doctrine” which is part of the novelty inquiry. See Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371 (2005).

¹⁶⁵ 35 U.S.C. § 102 (2006).

before the invention thereof.”¹⁶⁶ This means that no matter how well-known the indigenous scientific knowledge may have been abroad, no protection whatsoever can be granted if the foreign information is not documented in a formal publication. Thus, an indigenous community’s knowledge of the uses of a native plant remains unpatentable, unprotectible, and entirely vulnerable to exploitation by foreign interests, who may themselves publish documentation about the plant’s uses and become eligible to secure a patent on the applications.

This overly protectionist attitude can no longer be justified in today’s environment, in which technology not only allows people to travel extensively but also allows knowledge to travel even faster, without the need of publication by a formal scientific journal. This does not mean that each piece of knowledge somewhere in the globe must necessarily constitute prior art and, consequently, be capable of invalidating a patent; simply, TK should be subject to general anticipation rules.¹⁶⁷

Conversely, if such knowledge is not prevalent throughout society but is nevertheless well known by the experts in the field, there is no reason why it should not be deemed part of the state of the art and be taken into account when evaluating the obviousness of the invention.¹⁶⁸

A different approach has been implemented in European countries where the state of the art comprises “everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the . . . patent application.”¹⁶⁹ India recently applauded the decision by the

¹⁶⁶ *Id.* § 102(a).

¹⁶⁷ According to well-settled American case law, anticipation occurs when the prior art has been sufficiently disclosed and circulated among the public. *See Gayler v. Wilder*, 51 U.S. 477 (1850). However, depending on the circumstances of the case, even “the prior knowledge and use by a single person is sufficient.” *Coffin v. Ogden*, 85 U.S. 120 (1873); *see* 35 U.S.C. § 102. The anticipation inquiry does not allow combination of prior art. To have anticipation, one single prior art must anticipate the whole invention. 35 U.S.C. § 102. A proposal has been made to amend U.S. patent law to broaden the prior art analysis to all knowledge “otherwise known before the effective filing date of the application.” Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005), *available at* <http://patentlaw.typepad.com/patent/DraftPatentStatuteDDC.pdf>.

¹⁶⁸ 35 U.S.C. § 103.

¹⁶⁹ EPC, *supra* note 160, at art. 54, ¶ 2. Although this article does not expressly mention foreign publication and prior uses, their inclusion in novelty inquiry is made clear in the European Patent Office (“EPO”) guidelines, where it is stated that “there are no restrictions whatever as to the geographical location where or the language or manner in which the relevant information was made available to the public.” *See Guidelines for Examination in the European Patent Office*, pt. C, ¶ 5.1 (June 2005), *available at* http://www.european-patent-office.org/legal/gui_lines/e/index.htm.

Moreover, another confirmation of the different European attitude can be found in the text of the U.K. and Italian patent laws which expressly include foreign prior arts. Article 2(2) of U.K. Patents Act reads:

The state of the art in the case of an invention shall be taken to comprise all

Board of Appeal of the European Patent Office to turn down a patent application based on the chemical properties of *azadirachta indica* (i.e., a method for controlling fungi on plants with the aid of the extracted hydrophobic neem oil).¹⁷⁰ The Opposition Division of the EPO, pursuant to article 102(1), found that public prior use had been proven on the basis of the testimony and related affidavit of Abhay Dattaray Phadke, managing director of Ajay Bio-Tech Ltd., in India,¹⁷¹ and that the patent therefore had been anticipated.¹⁷² The Opposition Division also held that the patent lacked the inventive step.¹⁷³ Although the Board of Appeal did not further investigate whether Phadke’s testimony could be part of the prior art and rejected the Opposition Division’s finding on novelty, it nonetheless confirmed that the invention lacked inventiveness.¹⁷⁴ Such a result would not be possible under U.S. patent law, where prior arts cannot be combined for non-obviousness purposes lacking an express motivation.¹⁷⁵

matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (*whether in the United Kingdom or elsewhere*) by written or oral description, by use or in any other way.

Patents Act 1977 art. 2(2), *available at* <http://north.patent.gov.uk/patentsact1977.pdf> (emphasis added).

Similarly, Italian patent law, now codified in the new Italian Code of Industrial Property establishes that “the state of the art comprehends everything made accessible to the public within the territory of the State or in foreign countries, before the patent application has been filed and deposited, in written form or through oral transmission, use or in whatever other means (that implies its accessibility).” Italian Code of Industrial Property, Decree-Law No. 30/2005, art. 46(2) (Emanuela Arezzo, trans.).

¹⁷⁰ Thermo Trilogy Corp. et al. v. Aelvoet Magda. MEP, the Green Group in the European Parliament et al., Case No. T-0416/01, Bd. of Appeal, Eur. Patent Office (2005), *available at* <http://legal.european-patent-office.org/dg3/pdf/t010416eu1.pdf>.

¹⁷¹ Phadke testified that he had conducted tests on the fungicidal effect of the neem tree with two farmers in the summers of 1985 and 1986. *Id.* ¶ IV.

¹⁷² *Id.* ¶ XVI.

¹⁷³ After having defined the state of the art, the Opposition Division defined the technical problem as the finding of alternative methods for controlling fungi or protecting plants. Given that the neem tree’s properties in that sense were already known, the EPO found the invention obvious because the skilled person would have easily turned to a lower concentration of neem oil extract as an obvious less expensive alternative to the known formulations. *Id.* ¶ IV.

¹⁷⁴ The Board of Appeal did not rule out the possibility for oral prior art to form the “state of the art” for novelty and inventiveness analysis; rather, the Board preferred not to inquire further because the appellant argued that such prior use was not sufficiently documented. Since the affidavit confirmed what was contained in the oral testimony, the Board decided not to investigate the issue further. *Id.* at Reason 4.3.

¹⁷⁵ According to well-settled case law, to establish obviousness based on a combination of elements disclosed in the prior art, there must be some motivation for the applicant making the specific combination. *See In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000); *In re Dance*, 160 F.3d 1339, 1343 (Fed. Cir. 1998); *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984); *see also* 35 U.S.C. § 103(a) (2006) (conditions for patentability). Nonetheless, the Court of Appeals for the Federal Circuit recently has endorsed a more relaxed approach toward obviousness standards. *See Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276-77 (Fed. Cir. 2004) (holding that the motivation to combine the teaching in the prior art may come from the nature of a problem to be solved, even when there is not an express written teaching that suggests such a combination). In 2006, the Supreme

VIII. DOWNSIDES OF THE COLONIALIST APPROACH AND
POSSIBLE WAYS OUT

Article 16(5) of the CBD provides that

[t]he Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights *are supportive of and do not run counter to* its objectives.¹⁷⁶

Yet, the way modern intellectual property law is shaped *seems* to put TK-holders at a disadvantage.

Nonetheless, the obstacles presented by the concepts of authorship, the impossibility of attributing an innovation to its actual inventor, and the lack of written form could conceivably be overcome. For example, the concepts of authorship and originality have, at least in American copyright law, a constitutional value and basis.¹⁷⁷ The bond between the author and his work is crucial in that the rewarding mechanism which spurs the creation of intellectual works depends on the assumption that compensation goes to the *original author*. This ideal, however, has been implemented so that today, corporations can be attributed with authorship of software programs, motion pictures, musical compositions, and so on via the Work for Hire doctrine.¹⁷⁸ If corporations can be attributed authorship for works created by their employees, why shouldn't indigenous communities be deemed authors of the TK collectively produced by their members?¹⁷⁹

At first glance, the hurdles of patentability requirements might seem more complex, but even here the obstacles are not insurmountable.¹⁸⁰ However, once again, it must be remembered

Court granted certiorari on a patent case which could radically change the approach towards non-obviousness analysis in patent cases, especially with regard to the possibility of combining prior arts. *See KSR v. Teleflex*, 126 S. Ct. 2965 (2006).

¹⁷⁶ CBD, *supra* note 8, at art. 16(5) (emphasis added).

¹⁷⁷ The copyright clause reads: "Congress shall have the power . . . to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writing and Discoveries." U.S. CONST. art. 1, § 8, cl. 8.

¹⁷⁸ 17 U.S.C. § 201(b) (2006).

¹⁷⁹ Copyright law further envisions forms of collective ownership when the creative work is the fruit of a collective effort. *See id.* §§ 101, 201(c).

¹⁸⁰ If an indigenous community decided to "sell" its collective knowledge in capitalist markets, nothing could prevent it from returning to patent protection, provided that the community's country has adopted a patent system and that the community's innovations, like any other, conform to patentability requirements. Indeed, as shown by Charles McManis, the Aguaruna people, in the mentioned ICBG-Peru project, have been granted the opportunity to file for patents in the United States, and they have successfully obtained several titles of protection as exclusive inventors; in other cases they have been recognized as contributors within the patent application. McManis, *supra* note 17, at 574.

that the purpose of this article is not to analyze whether the small-scale innovations of indigenous people can satisfy patent eligibility standards. Rather, this article starts from the assumption that these indigenous communities have their own legal systems which regulate the sharing of genetic resources and TK *within* each community. What they need is a legal instrument that enables them to prevent others from taking and profiting from their resources with no authorization.

Within this framework, patent protection is a possible option for protecting such knowledge, but it would not always be a feasible one. This is because patent protection is very expensive to obtain, and thus it seems very unlikely that an indigenous community would hire patent agents to codify their knowledge into patent applications and file for patent protection locally and abroad. In addition, although the combination of TK and genetic resources can give rise to innovations which are already suitable for patent protection,¹⁸¹ this combination can also simply point out promising research paths which require more in-depth study and experimentation to reach a valuable economic result.

A. *The Adoption of a Misappropriation Regime*

The recognition of some form of entitlement for TK owners is fundamental to their ability to share in the results of the application of their resources. It is crucial both that they be allowed to derive economic compensation from whatever use their knowledge leads to, regardless of whether it is patented,¹⁸² and that innovations also be returned to common research pools so that the resources remain available for their own ongoing use. Nonetheless, framing a (legal) instrument capable of granting TK owners protection against biopiracy and, at the same time, guaranteeing compensation from and access to follow-on innovations created by third parties, has proven to be particularly difficult.

In this complex scenario, a balanced proposal may be represented by the introduction of an *ad hoc* misappropriation regime similar to the one framed by the WIPO Committee and discussed above.¹⁸³

¹⁸¹ For example, shamans could discover that the leaves of a certain plant, when boiled for a certain time and then dried in the sun, acquire healing properties to cure a certain disease; such a discovery would be in itself an invention.

¹⁸² See generally Ghidini & Arezzo, *supra* note 111.

¹⁸³ See *supra* Part VI.B.

1. Misappropriation in the Form of a Negative Entitlement and Its Advantages over an Exclusive Right

The misappropriation right sketched out in the IGC document has several potentials to bring about the first best solution to the biopiracy and TK issue. Looking closely at the IGC document, it appears that the misappropriation right would take the form of a *negative entitlement*. In fact, different from an absolute intellectual property right, the TK holder would not have an unconstrained right to exclude all third parties from whatever use of its resource. Rather, TK owners would be vested with the power to defend their TK in a wide set of circumstances where third parties' access to TK has occurred, broadly speaking, through unfair and illicit means.¹⁸⁴ In other words, the misappropriation regime does not expressly recognize property rights for TK owners towards their intellectual resources but it nevertheless grants them the right to defend their intangible properties once it has been appropriated and used without their consent. In addition, the normative framework envisions a positive right towards a fair and equitable sharing of the benefits stemming from the commercial or industrial use of TK.¹⁸⁵

For this reason, such a regime would be able to satisfy the interests of parties located in both Developed and Developing countries. The creation of new strong IP rights on TK is undesirable for both third parties seeking access and for TK owners. Indeed, on the one hand, Developed Countries surely would not want TK owners to be vested with the exclusive right to foreclose access to scientific indigenous knowledge. As long as indigenous communities might be capable of closing off use of their resources for scientific innovation, society overall might be worse off. On the other hand, it is interesting to note that even indigenous people have expressed the desire that their intangible knowledge not be embedded in strong exclusive property rights. This is because they probably fear that such a regime, if implemented even locally, might prevent the free circulation of knowledge within their own community.¹⁸⁶

The *sui generis* misappropriation regime may prove successful in that without vesting TK owners with a strong exclusive right, it

¹⁸⁴ In fact, this form of entitlement would not condemn the behavior of third parties who make profits from TK as long as the acquisition, appropriation, or utilization of that TK was not the fruit of illicit or unfair means. See *Draft Objectives and Principles*, *supra* note 121, annex, pt. III, at art. 1.

¹⁸⁵ *Id.* annex, pt. III, at art. 6, ¶ 1.

¹⁸⁶ See *id.* annex, pt. III, at art. 2 cmt. Think what would happen if DCs implemented a strong regime of protection for TK and then foreign companies appropriated all TK under that regime.

would spur third parties' incentives to negotiate access to TK, to the benefit of society at large and of indigenous communities.

2. Implementation Measures and Legal Status of the Misappropriation Regime

For this proposal to work, it is essential that its status of *sui generis* misappropriation regime be maintained and implemented by both Developed and Developing Countries in the form of an *ad hoc* legislation regulating access and employment of TK. In particular, in contrast to what the IGC document says in Article 2,¹⁸⁷ it is necessary that the provisions contained in the overall proposal give rise to an autonomous piece of legislation and shall not end up either serving as a basis for the creation of new IP rights, or being absorbed by existing national unfair competition laws.

As mentioned above, the creation of new strong IP rights on TK is unwelcome by both third parties seeking access to TK and by the very same TK owners. For different reasons, the recourse to national unfair competition norms is also undesirable. In such a case, indeed, there is a strong risk that each country would apply the provision differently, affording a broader or smaller scope of protection according to the degree of protection afforded by its national misappropriation statutes. In this regard, it is important to mention that in some countries, e.g., the United States, the misappropriation doctrine has a narrow scope of protection. To the contrary, this risk would be slight if adhering countries were required to strictly implement the provisions of the *sui generis* misappropriation regime. As will be explained in the following paragraph, the form of a negative entitlement towards TK is a fundamental key in ensuring harmonization and peaceful coexistence among indigenous regimes and IP rights.

3. Commonalities and Differences with the Compensatory Liability Regime

Clearly, shaped in this way, this misappropriation model would have some commonalities with CLR.¹⁸⁸ In both cases, the system would grant TK owners an entitlement which does not vest TK owners with the power to foreclose access to third parties.¹⁸⁹ Moreover, in both cases, access would be permitted in exchange

¹⁸⁷ Article 2 gives countries the possibility to implement the provisions the way in which they prefer, including IP legislation. See *supra* Part IV.B.3.

¹⁸⁸ See *supra* Parts VI.A-B.

¹⁸⁹ See CLR described *supra* Part VI.A; Reichman & Lewis, *supra* note 110, at 349; *Draft Objectives and Principles*, *supra* note 121, annex, pt. III, at art. 1, ¶¶ 1-3.

for some form of compensation.¹⁹⁰ Yet, significant differences between the misappropriation model and CLR emerge, which suggest the former as a better suited system to spur TK-based research while preserving TK owners' interests.

First, unlike the CLR regime, the misappropriation model would grant TK owners protection and a right to monetary compensation even from wholesale imitations.¹⁹¹ This is a crucial difference between the two models. In the CLR discussed above, TK owners would have the right to impede foreign companies from manufacturing and distributing a "wholly unoriginal imitation of their product," but they would be entitled to monetary compensation only from innovators who use TK as a basis for improvement products.¹⁹² Under this system, foreign companies would be allowed to legally take TK out of the common pool belonging to indigenous people only for improvement purposes, provided that they pay for it. However, one may reasonably ask what kind of protection TK owners would have against (the taking of TK and) manufacturing of products which simply embed TK, without any further amelioration? The model tells us that TK owners should be able to stop the distribution of such products but it does not envisage that the owners receive any form of monetary compensation or sharing of the profits that the foreign company might have made in the meantime.

The CLR proves unsatisfactory under this perspective because, on the one hand, it does not provide TK owners with a feasible instrument to get compensation for the marketing of products merely implementing their scientific knowledge; on the other hand, the system grants them the possibility to stop the commercialization of such products, to the damage of society at large.¹⁹³ Conversely, these problems would be easily overcome

¹⁹⁰ Compare Reichman & Lewis' proposal, *supra* note 110, at 349, according to which TK owners should be entitled to get a "reasonable compensation from follow-on innovators who make improvements upon the scientific knowledge of the TK owners" with *Draft Objectives and Principles*, *supra* note 121, annex, pt. III, at art. 6, which expressly held that TK owners should be entitled to receive "fair and equitable sharing of benefits arising out the of the commercial or industrial use of that traditional knowledge," and in case of implementation of TK for non-commercial purposes, "non monetary benefits, such as access to research outcomes and involvement of the source community in research and educational activities."

¹⁹¹ Reichman & Lewis, *supra* note 110, exclude whole sale imitation from their model. See *supra* Part VI.A. Yet, to the contrary, misappropriation is broadly defined to encompass any illicit appropriation of TK, regardless of whether third parties use TK for wholesale imitation or as an input for follow-on innovation. Cf. *Draft Objectives and Principles*, *supra* note 121, annex, pt. III, at art. 1.

¹⁹² The mechanism should work so that foreign parties could take TK from the common pool not for wholesale imitation but only to build and improve upon it.

¹⁹³ Think, for example, about a plant which indigenous tribes use to cure diarrhea. Assume that the plant extracts are particularly effective in curing the symptoms immediately (i.e., they do not need any special chemical treatment in order to be

with the *sui generis* misappropriation regime where the misappropriation defense generally covers acts of illicit and unfair taking of TK, regardless of their subsequent use.¹⁹⁴ Similarly, the right to fair and equitable compensation envisaged by Article 6 of the IGC proposal is not conditioned on the fact that TK be used for follow-on innovation, but it generally covers all commercial and industrial uses.¹⁹⁵

A second area in which the misappropriation regime seems to surpass the CLR is harmonization with both indigenous regimes for the origination and employment of TK, and with IP regimes in Developed and Developing Countries.¹⁹⁶

First, the *ad hoc* misappropriation regime appears the best possible solution to harmonize with and safeguard local indigenous regimes for TK protection. Indeed, as explained above, indigenous communities would not have to comply with any formalities in order to get protection;¹⁹⁷ therefore, the coexistence of the two regimes (namely, the misappropriation right and the indigenous system regulating the creation and enjoyment of TK) would be smooth and peaceful, as there would be no need to compel countries that provide TK to substitute a new legal regime for their own indigenous one.

Second, because the misappropriation would take the form of a negative entitlement actionable only against illicit and unfair acquisition and use of TK, and because protection is not conditioned on any formalities, this model also appears well-suited

effective), but the indigenous tribes do not have the capacity (or the financial capital) to make a commercial product out of it. Indeed, the tribes simply use the plant within the community. Society at large would be much better off if a foreign company with the skill and capacity would put the plant extract in tablets, turn it into a finite product and distribute it on the market. However, in such a case, the conduct of the foreign company could not be considered an improvement because the company only arranged for the mass production and distribution of the product already known and largely used by the indigenous tribe. If the CLR system were implemented as is, indigenous groups might be able to compel the company to take the product off the market (because it would not amount to an improvement), but they would not share whatsoever in the profits the company has already realized.

¹⁹⁴ *Draft Objectives and Principles*, *supra* note 121, annex, pt. III, at art. 1, ¶¶ 2-3.

¹⁹⁵ *Id.* annex, pt. III, at art. 6, ¶ 1. Indeed, the provision establishes that TK owners are always entitled to compensation for the use of their resources; however, it distinguishes between the situation where TK is taken for commercial and industrial purposes from circumstances where TK is taken for non-commercial reasons. In the former case, TK owners are entitled to monetary compensation (art. 6, ¶ 1), while in the latter case they must be granted access to research outcomes and must be involved in the research and educational activities (art. 6, ¶ 2).

¹⁹⁶ *See supra* Part VI.A.

¹⁹⁷ *See Draft Objectives and Principles*, *supra* note 121, annex, pt. III, at art. 11. The WIPO Committee acknowledges that a registration system for TK may provide greater predictability and makes it easier to enforce the rights. However, registration may also impose a severe burden on communities who might lack capacity or resources to take specific steps within a limited time frame and, consequently, risk losing the benefits of protection. *See id.* cmt on art. 11.

to coexist with IP regimes. Indeed, while misappropriation protection would always apply, indigenous groups would always be free, if they wish, to ask for patent protection in their country or abroad, provided that the innovation meets patent eligibility requirements.

B. *Traditional Knowledge and Open Source: Why Not?*

Another difficulty with granting TK owners protection for their intangible “property” concerns the cumulative and incremental process which produces indigenous scientific culture. However, this process is not entirely distinct from the process of innovation in industrialized countries which has a rather sequential and cumulative character.¹⁹⁸ Even in Developed Countries, the single innovator has almost vanished, and has been replaced by research teams where a group of people work together, bringing about “slivers of innovation” (which often come under patent protection).¹⁹⁹

The *collective* and cumulative model of TK creation resembles, even more closely, the *viral effect* underlying *open source software* (“OSS”).²⁰⁰ The OSS licensing mechanism allows for the creation of a pool of common technical knowledge open to everybody. Each interested person can have access to such knowledge and can use it freely,²⁰¹ provided that—roughly speaking—he agrees to license the derivative innovation under the same terms, hence bringing the derivative knowledge back to the pool.²⁰² The

¹⁹⁸ See Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (1991); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

¹⁹⁹ See Reichman, *supra* note 114, at 289; see generally Reichman & Lewis, *supra* note 110.

²⁰⁰ The open source phenomenon has attracted interest from different spheres of the academic world. Some of the most interesting legal articles include: Christian H. Nandan, *Open Source Licensing: Virus or Virtue?*, 10 TEX. INTEL. PROP. L. J. 349 (2002); Severine Dusollier, *Open Source and Copyleft: Authorship Reconsidered?*, 26 COLUM. L.J. & ARTS 281 (2003); Matthew D. Satchwell, *The Tao of Open Source: Minimum Action for Maximum Gain*, 20 BERKELEY TECH. L.J. 1757 (2005); Joseph Eng, *From Software to Life Sciences: The Spreading of the Open Source Production to New Technological Areas*, 24 TEMP. J. SCI. TECH. & ENVTL. L. 419 (2005). Economic and sociological analyses seem to have merged in Josh Lerner & Jean Tirole, *The Scope of Open Source Licensing*, 21 J.L. ECON. & ORG. 20 (2005). A significant economic study about open source has been performed by Paola Giuri, Gaia Rocchetti and Salvatore Torrisci, *Open Source Software: From Open Science to New Marketing Models, an Inquiry into the Economics and Management of Open Source Software* (LEM Working Paper Series, 2002), available at <http://www.lem.sssup.it/WPLem/files/2002-23.pdf>.

²⁰¹ As pointed out by Stallman, in this case, the word “free” has to be interpreted like “free speech” and not like “free beer.” RICHARD M. STALLMAN, *FREE SOFTWARE, FREE SOCIETY: SELECTED ESSAYS OF RICHARD M. STALLMAN* 41 (2002).

²⁰² Nowadays there are several forms of open source software licensing. The most well known licensing model is represented by the GNU General Public License (or simply “GPL”) written by Richard Stallman for the GNU project. This licensing model is based upon four fundamental freedoms: to run the program for any purpose; to study the functioning of the program and adapt it to users’ needs; to redistribute copies of the program; and to improve the program and release program improvements to the public.

mechanism for the origination of TK closely resembles that of OSS, as many people contribute to different extents and in different moments, to the enrichment of the common pool of scientific knowledge. However, the introduction of a misappropriation regime—shaped as the combination of a negative right towards the protection of intangible knowledge and a positive right toward compensation from the use of such resources—may bring this mechanism a step further. Indeed, the misappropriation model could work in a way to open the pool of TK knowledge to foreign companies and have them freely take the resources, provided that the latter remain available for use by the community of TK owners, who shall be compensated monetarily for the taking and use of such resources, but shall also be granted back access to improvements and other developments.

OSS works because of the fictitious stretch of copyright law to cover technical subject matter such as computer programming.²⁰³ Copyright law today, in practice, affords narrow protection to software, but it successfully grants programmers entitlements to the know-how embedded in their innovations.²⁰⁴ Because of this modicum of protection,²⁰⁵ programmers are able to create and share a common pool of resources which they all advance with mutual effort but also common enjoyment.

While the choice of a copyright paradigm to protect a utilitarian subject matter like software may be questionable,²⁰⁶ a licensing scheme based on the recognition of a limited entitlement has doubtlessly brought great results for innovation in

While these freedoms do not imply gratuity (freedom to redistribute the program or the program's improvement does not imply that such copies should be licensed for free), they all require access to the source code as a precondition. See GLU General Public License, <http://www.gnu.org/licenses/gpl.html> (last visited Mar. 30, 2007) for a copy of the license.

²⁰³ Ghidini & Arezzo, *supra* note 111, at 159, arguing that computer programming is a technical subject matter which should only be regulated through patent law.

²⁰⁴ While copyright protection for software was quite broad at the beginning, this trend sensibly slowed in the nineties. See Stuart J.H. Graham & David C. Mowery, *Intellectual Property Protection in the U.S. Industry*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 217 (W.M. Cohen & S.A. Merrill eds., 2003).

²⁰⁵ Today, it is very common for commentators to praise the beneficial features of the OSS model as compared to closed proprietary models based on IPRs. It is important to remember that the OSS model depends on a complex licensing scheme whereby authors decide not to enforce some of their exclusive rights (i.e., the exclusive right to reproduce and copy the work, the right to modify or change it) on their intellectual work, provided that the users comply with some obligations too (i.e., license the derivative work under the same conditions). If authors were not entitled to exclusive ownership over their intellectual creations in the first place, the whole licensing scheme could not be built. Therefore, OSS needs copyright to exist. See also Gustavo Ghidini & Emanuela Arezzo, *One, None or a Hundred Thousand: How Many Layers of Protection for Software Innovation?*, in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND COMPETITION LAW (Josef Drexler ed.) (forthcoming 2007) (on file with author).

²⁰⁶ Ghidini & Arezzo, *supra* note 111, at 159.

the software industry. Similarly, the entitlement granted by the misappropriation regime would confer to TK owners just the modicum of protection they need to benefit from third parties' exploitation of their resources and, at the same time, creates a common pool of knowledge that third parties can exploit, provided that they compensate for their taking.

C. *Misappropriation Right and the Anticommons over Genetic Resources*

It has been argued that a potentially infinite *sui generis* right,²⁰⁷ like that fashioned by the WIPO Committee, might have the ultimate effect of bolstering the formation of an "anticommons" over the genetic resources owned by indigenous communities.²⁰⁸ The term "anticommons" was introduced by Michael Heller to refer to the opposite of the tragedy of the commons.²⁰⁹ The tragedy of the anticommons would occur when too many (often overlapping) rights have been granted over certain scarce resources, and this situation ends up impeding each entitled party from fully exploiting her property due to the huge transaction costs necessary for implementing any use whatsoever of her interest.²¹⁰

Is it possible that a negative right like the one proposed by WIPO would enable local communities to privatize their intangible scientific heritage and impede access to foreign firms?²¹¹ The misappropriation right would not vest TK owners with the right to prevent others from having access to their intangible "property," as noted earlier. Rather, it should function as a mechanism to defend TK owners when neither access nor compensation has been negotiated. The potentially infinite term

²⁰⁷ The proposal requires the protection to endure as long as there is compliance with the requirements listed in article 4. See *Proposals by Switzerland*, *supra* note 52.

²⁰⁸ According to Koopman, *supra* note 10, at 274, "The proprietary regime for traditional knowledge envisaged by WIPO applies to knowledge that may be solely a resource, and is not yet "applied" in any way."

²⁰⁹ The so called tragedy of the commons refers to a situation where a certain resource is at the disposal of a vast group of people. Because each person receives an immediate benefit from the exploitation of the resource which greatly exceeds the cost he should bear to maintain the resource, the tragedy will occur in that the resource is destined to be overexploited and will eventually die off. See Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968).

²¹⁰ Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998).

²¹¹ The problem has been misconstrued from the beginning. The anticommons issue refers to a situation in which many parties have been granted overlapping rights over the same resources, so that if each of them wants to use her share, she needs to separate her property from others. In the case of TK this could not happen. Even if indigenous communities were granted a strong exclusive right (which is not envisioned by WIPO), there would be no overlapping rights. Moreover, the anticommons problem refers to a situation in which owners of the rights have to negotiate between themselves. This, again, would not be the case for TK, because indigenous communities, as the exclusive holders of their intangible knowledge, would have to negotiate with foreign firms.

of protection might raise concerns as well, but it must be remembered that the misappropriation right, as shaped by WIPO, is closer to unfair competition laws than intellectual property paradigms. As unfair competition laws generally do, the model suggested would afford a lesser degree of protection in terms of exclusive and excluding powers. Like unfair competition laws whose principles are strongly connected to a sense of natural justice and fairness, such form of protection exists as long as there are interests to protect.²¹²

The anti-commons problem will occur soon if the phenomenon of “bad patenting” is not stopped. If modern patent laws are not amended in such a way to include widespread TK with novelty and non-obviousness inquiries, there is a substantial risk that more and more exclusive rights will be granted over each tiny bit of knowledge, with the ultimate effect that the very same indigenous communities will be prevented, with no compensation, from using their own scientific heritage.

CONCLUSION

The objective of this article has been to analyze the issues stemming from the widespread misappropriation of genetic resources and TK belonging to indigenous people by the corporations of Developed Countries. The issue is purposely framed in terms of misappropriation because, even in cases where a negotiation takes place, the unequal bargaining strength of the parties often leads to biased agreements where indigenous people are compensated for the use of their tangible resources but not for the related TK.

As explained above, a normative international framework was established in 1992 with the Convention on Biological Diversity. However, for several reasons, including the status of the Convention as being outside WTO negotiations, this set of rules has proven to be inadequate or, at least, insufficient to deal with the problem.

Over time, the biopiracy issue has attracted more attention and several proposals have been advanced simultaneously in different international *fora*. Many countries, often those that are developing, have proposed a solution based on the amendment of patent laws to compel future patent applicants to disclose the

²¹² From a pure IP perspective, it could be further argued that much legislation has recently been advanced that aims to extend the terms of protection of copyright law far beyond its original terms. In addition to the Sonny Bono Copyright Term Extension Act, 17 U.S.C. §§ 101, 302-305 (2006), there are also anticircumvention measures contained in the Digital Millennium Copyright Act, 17 U.S.C. §§ 1201-1204, which allow for infinite control of both copyrighted and not-copyrighted material.

source of origin of the genetic material and TK. Because it is very complex, time-consuming, and expensive for indigenous people to screen patent applications and grant patents for stolen tangible or intangible property, compulsory disclosure has been deemed useful in that it could surely facilitate this task.

This proposal has attracted significant criticism from the United States and Japan, however. They strongly oppose the insertion of an extra disclosure requirement, fearing that the legal consequences that would arise when patentees fail to comply with such a requirement would hamper the stability and certainty of patent law, with enormous consequences for economic progress as a whole.

Moreover, this measure alone would not be sufficient to solve the problem faced by indigenous communities. In particular, even if such measures were adopted and indigenous people were able to discover which patents are based on their misappropriated property, there is little chance of ensuring proper compensation pursuant to CBD's principles. This is because many patent laws have very protectionist requirements regarding novelty (in particular, the problem of anticipation) and non-obviousness which neglect to take into account TK. Given the mobility of foreign biologists and researchers, and the widespread reach of the Internet as a carrier of information, it would be desirable to have TK considered as prior art, capable of anticipating a patent as well as a piece of knowledge that could be considered state of the art.

However, such changes by themselves would only achieve half of the goal outlined by the CBD. In fact, CBD provisions intend for indigenous people both to benefit from third parties' exploitation of their resources and to have access to the research outcomes achieved through the employment of their resources. The benefits envisaged by the CBD include access as well as both monetary and non-monetary benefits that derive from utilization of the goods produced.

The amendment of national patent laws would not guarantee TK owners access to research outcomes or monetary benefits. In order for the indigenous communities to participate in the benefits flowing from the exploitation of subsequent innovations based on their own TK and genetic resources, those communities need to have some sort of legal entitlement. Given the nature of TK as falling between scientific know-how and inventions, it seems appropriate to confer on TK owners an entitlement that is less stringent than a true exclusive right, but enables them to prevent the illicit misuse and misappropriation of their intangible

knowledge.

In conclusion, TK owners would greatly benefit from the adoption of a misappropriation regime modeled on a negative entitlement (almost comparable to a liability rule scheme), like the one framed by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The adoption of such a regime by Developed Countries would grant TK owners the right to sue not only the improper taker of intangible resources, but also anyone who derives a commercial benefit from such acquisition, appropriation, or utilization when she should have known that such resources were acquired through unfair means. Therefore, the misappropriation right has been shaped in a way that complements the safeguards provided by the aforementioned amendments to national patent laws, especially those of the United States, because it seems to permit indigenous people to share in the benefits flowing from subsequent application or implementation of indigenous TK. However, because biopiracy acts are committed by companies, located in rich Developed Countries, who then exploit such resources mainly in their own markets, it is crucial that the Developed Countries be compelled to adopt the new legal measures.

Eventually, it is of crucial importance that the IGC work hard to find mutual consensus on the substantive provisions examined above, and on determining the international status of such provisions in such a way that they be substantially implemented by all member states, including both Developed and Developing Countries. This is critical because the misappropriation doctrine has a different scope of application in each country. A simple implementation of the principle that TK and the misappropriation of genetic resources be protected through national misappropriation regimes might not be sufficient in granting TK holders enough protection in foreign countries. Rather, the best possible solution would be offered by compelling each nation to implement the misappropriation in the form of a negative entitlement, as shaped by the IGC document. As explained, this legal status would carry manifold substantive benefits for all interested parties because it would spur voluntary negotiation between foreign companies and indigenous communities, while preserving the rights of the indigenous communities to access and benefits sharing of the results of research activities based on their own tangible and intangible property.