
Monopolizing Medicinal Methods: The Debate Over Patent Rights for Indigenous Peoples

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The 1994 Draft Declaration of the Rights of Indigenous Peoples states:

Indigenous peoples have the right ... to their traditional medicines and health practices, including the right to the protection of vital medicinal plants, animals, and minerals ... [and] to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, [and] knowledge of the properties of flora and fauna¹

Nonetheless, many argue that there exists a growing problem of biopiracy of the traditional knowledge (TK) of indigenous peoples, as developers of new medicines

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¹ Draft U.N. Declaration on the Rights of Indigenous Peoples, adopted Aug. 26, 1994, U.N. Sub-Comm. on Prevention of Discrimination & Protection of Minorities, 46th Sess., 105, U.N. Doc. E/CN.4/Sub.2/1994/56 (1994).

obtain patent protection and commercialize products based upon TK² without sharing the proceeds with the indigenous peoples from whom they obtained such knowledge.³ The diverse plant life of many developing countries, combined with the traditional natural remedies of indigenous peoples, is at the head of many pharmaceutical companies' research and development of medicinal compounds.⁴ The National Research Council notes that "[i]ndigenous knowledge is being lost at an unprecedented rate, and its preservation ... must take place as quickly as possible."⁵

Biopiracy, as it relates to TK, is defined as the uncompensated taking of the indigenous peoples' information concerning the medicinal effects of plants or other naturally occurring substances and developing it into a patented drug, seed or cell line.⁶

Using the native ethnobiological knowledge, researchers have insight into not only the identity of the plant, but also the specific part of the plant that contains the substance, the time of year during which the substance is present in the plant, the method of preparing the substance, and the symptoms the substance will alleviate.⁷

Such knowledge reduces research costs by concentrating on substances that are already known to be effective.⁸

Indigenous peoples claim that their TK is being pirated because "existing intellectual property schemes do not address the subject matter of traditional knowledge."⁹ TK "has not been recognized as being either 'scientific' or valuable to the dominant culture and so has been freely appropriated by others."¹⁰ Additionally,

² Among other things, traditional knowledge has aided in the development of certain cancer, ulcer, and fertility treatments, pesticides, therapeutic ointments, diet suppressants, and non-sugar sweeteners. *See, e.g.*, STEPHEN A. HANSEN & JUSTIN VANFLEET, AM. ASSOC. FOR THE ADV. OF SCIENCE (AAAS), TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY: A HANDBOOK ON ISSUES AND OPTIONS FOR TRADITIONAL KNOWLEDGE HOLDERS IN PROTECTING THEIR INTELLECTUAL PROPERTY AND MAINTAINING BIOLOGICAL DIVERSITY 3, 5, 11, 14 (2003), available at <http://shr.aaas.org/tek/handbook/handbook.pdf> [hereinafter AAAS HANDBOOK].

³ *See, e.g.*, Audrey R. Chapman, Approaching Intellectual Property as a Human Right: Obligations Related to Article 15(1)(c), 29, prepared for the United Nations Economic and Social Council, Committee on Economic, Social and Cultural Rights, U.N. DOC E/C.12/2000/12, 29 (Oct. 3, 2000) (providing several examples where "individual prospectors and corporate developers have expropriated [traditional] knowledge through filing patents in their own name without any form of remuneration"); *See also* DARRELL A. POSEY & GRAHAM DUTFIELD, BEYOND INTELLECTUAL PROPERTY: TOWARD TRADITIONAL RESOURCE RIGHTS FOR INDIGENOUS PEOPLES AND LOCAL COMMUNITIES 14, 27-28 (1996).

⁴ Laurie Ann Whitt, *Indigenous Peoples, Intellectual Property & the New Imperial Science*, 23 OKLA. CITY U. L. REV. 211, 218 (1998).

⁵ NAT'L RESEARCH COUNCIL, CONSERVING BIODIVERSITY: A RESEARCH AGENDA FOR DEVELOPING AGENCIES 45 (1992).

⁶ AAAS HANDBOOK, *supra* note 2, at 5.

⁷ Lester I. Yano, Comment, *Protection of the Ethnobiological Knowledge of Indigenous Peoples*, 41 UCLA L. REV. 443, 448 (1993).

⁸ *Id.* at 448-49.

⁹ Miriam Latorre Quinn, *Protection for Indigenous Knowledge: An International Law Analysis*, 14 ST. THOMAS L. REV. 287, 289 (2001).

¹⁰ Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical*

they claim that intellectual property treaties and legislation destroy their cultural heritage.¹¹ Some cases of alleged biopiracy include:

Neem tree: The extract of the neem tree was patented in the U.S.¹² as an environmentally-safe insecticide and fungicide, although its medicinal and pesticidal qualities have been well-established in India for many years.¹³ The multi-national corporation, W.R. Grace, which obtained a patent for an insecticide based on neem, dismissed the Indian people's discovery of the plant's uses as "folk medicine" has stated that it has no plan to compensate anyone in India.¹⁴

Turmeric: Expatriate Indian inventors obtained a patent¹⁵ for the method of administering turmeric to wounds for healing purposes. The Indian Council for Scientific and Industrial Research challenged the patent in re-examination proceedings claiming that such use had been in the public domain for thousands of years.¹⁶ The United States Patent and Trademark Office (USPTO) cancelled the patent and various other applications pending that involved turmeric.¹⁷

Rosy periwinkle plant: This plant, which is only found in Madagascar, contains properties that combat certain cancers.¹⁸ Ely Lilly has \$100 million in annual sales of the anti-cancer drugs vincristine and vinblastine, which are derived from the periwinkle, but does not share this bounty with Madagascar.¹⁹

Avahuasca: Amazon Basin tribes have used this plant to make a ceremonial drink for centuries, but a U.S. citizen obtained a patent on it as a new and unique plant variety.²⁰ Amazonian leaders filed for re-examination on the basis that the plant variety

Knowledge of Indigenous and Local Communities, 17 MICH. J. INT'L L. 919, 920 (1996).

¹¹ See generally World Trade Organization, Indigenous Peoples' Seattle Declaration on the Occasion of the Third Ministerial Meeting of the World Trade Organization, Nov. 30 – Dec. 3, 1999, available at http://www.treatycouncil.org/section_21171.htm (explaining threats posed by a WTO Agreement to indigenous peoples' access and control over biological diversity, intellectual heritage, and traditional knowledge).

¹² U.S. Patent No. 5,298,251 (filed July 21, 1993); U.S. Patent No. 5,356,628 (filed Dec. 2, 1993); U.S. Patent No. 5,372,817 (filed Dec. 13, 1993); U.S. Patent No. 5,405,612 (filed Dec. 2, 1993); and U.S. Patent No. 5,409,708 (filed Jan. 31, 1994).

¹³ Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy*, 37 IDEA 371, 375 (1997) [hereinafter Kadidal, *Neem Patent Controversy*].

¹⁴ Roht-Arriaza, *supra* note 10, at 922.

¹⁵ U.S. Patent No. 5,401,504 (filed Dec. 28, 1993).

¹⁶ Quinn, *supra* note 9, at 290

¹⁷ *Id.* at 290, n.6.

¹⁸ Elizabeth Pennisi, *Hairy Harvest: Bacteria Turn Roots into Chemical Factories*, 141 SCIENCE NEWS 366, 366 (1992).

¹⁹ Shayana Kadidal, Note, *Plants, Poverty, and Pharmaceutical Patents*, 103 YALE L.J. 223, 224 (1993) [hereinafter Kadidal, *Plants and Poverty*].

²⁰ David R. Downes, *How Intellectual Property Could Be a Tool to Protect Traditional Knowledge*, 25 COLUM. J. ENVTL. L. 253, 279 (2000).

was not novel, prompting the USPTO to cancel the patent.²¹

Hoodia: The San people of South Africa, commonly known as the Bushmen, had used the hoodia plant as an appetite suppressant for hundreds of years.²² The South African Council for Scientific and Industrial Research (CSIR) patented the hoodia plant under the name P57, without informing the San tribe.²³ In 1997, Phytopharm, a British biotech company, entered into a licensing agreement with CSIR to further develop and commercialize P57.²⁴ After the San brought a case against CSIR, a benefit-sharing program was developed between CSIR and the San, in which the San will receive a percentage of royalties Phytopharm received on the commercial sales of pharmaceuticals containing P57.²⁵

This paper examines the issue of patents and TK. Part I defines the terms “indigenous peoples,” “indigenous medicinal knowledge,” and “traditional knowledge.” Part II analyzes whether indigenous peoples’ TK would be eligible for patent protection in the current world patent system and the appropriateness of extending patent protection. Finally, Part III examines possible solutions.

I. DEFINING INDIGENOUS PEOPLE AND TRADITIONAL KNOWLEDGE

A threshold question is how to define the terms “indigenous people” or “indigenous knowledge.” Scholars have struggled for decades to define these terms.²⁶

A. Indigenous People

The term “indigenous people” has evolved over time.²⁷ For example, anthropologist, Stephen Brush argues that the term “is best used in regions with a colonial history that has left a predominant national culture and autochthonous cultures that coexist and compete for limited resources, especially land.”²⁸ He argues that this definition “is not suited for large parts of Asia and Africa, where a

²¹ *Id.* at 280.

²² Susan Kling Finston, *Relevance of Genetic Resources to the Pharmaceutical Industry* *7 (Dec. 2, 2004) (presented at D.C. Bar Conference on Convention on Biological Diversity) (unpublished manuscript, on file with author).

²³ *Id.*

²⁴ *Id.*

²⁵ Press Release, Council for Scientific and Industrial Research, *The San and the CSIR announce a benefit-sharing agreement for potential anti-obesity drug* (Mar. 23, 2003), available at http://www.csir.co.za/plsql/ptl0002/PTL0002_PGE013_MEDIA_REL?MEDIA_RELEASE_NO=7083643.

²⁶ Trevor W. Purcell, *Indigenous Knowledge and Applied Anthropology: Questions of Definition and Direction*, 57 HUM. ORG. 258, 259 (1998).

²⁷ John L. Trotti, *Compensation Versus Colonization: A Common Heritage Approach to the Use of Indigenous Medicine in Developing Western Pharmaceuticals*, 56 FOOD DRUG L.J. 367, 368 (2001).

²⁸ *Id.* at 368 (citing Stephen B. Brush, *Whose Knowledge, Whose Genes, Whose Rights?*, VALUING LOCAL KNOWLEDGE 1, 5 (1996)).

single hybrid culture (e.g., European-Native) is not dominant.”²⁹ This definition would exclude areas that are no longer colonized. By contrast, a more flexible definition is “people living in tribal societies and peoples of aboriginal cultures in nation states ... thus including both tribal peoples and peasant peoples.”³⁰ Another flexible definition suggests that indigenous peoples are “existing descendants of non-Western peoples who in general continue to occupy their ancestral lands even after conquest by Westerners, or who have been relocated forcibly in the process of colonization.”³¹

This paper will adopt the second definition because it is consistent with the writings of activists and peoples concerned with indigenous knowledge and international treaties and declarations such as the Convention on Biodiversity, which includes “local communities embodying traditional lifestyles.”³² The Convention addressed the relationship between biodiversity and development and is notable for vesting sovereign rights in developing countries for access to their genetic resources.³³

“Indigenous groups are semi-autonomous collectives or ‘nations within.’”³⁴ Due to their unique political status, indigenous peoples have been granted substantive rights and are now viewed as “subjects of international law”³⁵ and have unique political relationships with their host states.³⁶

B. Traditional Knowledge and Indigenous Medicine

Indigenous medicinal knowledge is generally defined as a subset of TK “consisting of the medicinal and curative properties of plants in indigenous culture,” including genetic resources.³⁷ Therefore, TK must be defined.

One scholar defines TK as “the body of historically constituted knowledge instrumental in the long-term adaptation of human groups.”³⁸ Another scholar notes

²⁹ *Id.*

³⁰ Stephen B. Brush, *A Non-Market Approach to Protecting Biological Resources*, INTELLECTUAL PROPERTY RIGHTS FOR INDIGENOUS PEOPLES: A SOURCE BOOK 133, 137, n.1 (Tom Greaver, ed., Society for Applied Anthropology 1994).

³¹ Purcell, *supra* note 26, at 260.

³² U.N. Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, art. 8(j), 31 I.L.M. 818, 826.

³³ David S. Tilford, *Saving the Blueprints: The International Legal Regime for Plant Resources*, 30 CASE W. RES. J. INT’L L. 373, 414-17 (1998).

³⁴ Erik B. Bluemel, *Substance Without Process: Analyzing TRIPS Participatory Guarantees in Light of Protected Indigenous Rights*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 671, 682 (2004) (citing VINE DELORIA, JR. & CLIFFORD M. LYTLE, *THE NATIONS WITHIN: THE PAST AND FUTURE OF AMERICAN INDIAN SOVEREIGNTY* (Univ. of Texas Press 1994)).

³⁵ See generally Russell Lawrence Barsh, *Indigenous Peoples: An Emerging Object of International Law*, 80 AM. J. INT’L L. 369, 372-373 (1986) (noting three international conferences which endorsed recognizing rights of indigenous people such as the right “to maintain their traditional structure of economy and culture, including their own language, and also recognize[d] the special relationship of indigenous peoples to their land and stresse[d] that their land, land rights and natural resources should not be taken away from them”).

³⁶ Bluemel, *supra* note 34, at 682.

³⁷ Trotti, *supra* note 27, at 369.

³⁸ Purcell, *supra* note 26, at 260.

that TK can be “defined by its general characteristics: creation through a long period of time which has been passed down from generation to generation; new knowledge is integrated to the existing, as knowledge is improved; improvement and creation of knowledge is a group effort; and ownership of indigenous knowledge varies between indigenous peoples.”³⁹ TK generally encompasses two forms of indigenous knowledge or resources: medicinal or plant knowledge and traditional cultural expressions or folklore.⁴⁰ Folklore, although an important contribution to the world heritage, is outside the scope of this paper, as any possible relationship between intellectual property and the protection of traditional cultural expressions falls closer to the realm of copyright law or trademark law, than patent law.⁴¹

Portugal’s law defines TK as:

All intangible elements associated with the commercial or industrial utilization of local varieties and other autochthonous material developed in a non-systematic manner by local manner by local populations, either collectively or individually, which form part of the cultural and spiritual traditions of those populations. That includes, but is not limited to, knowledge of methods, processes, products and designations with applications in agriculture, food and industrial activities in general, including traditional crafts, commerce and services, informally associated with the use and preservation of local varieties and other spontaneously occurring autochthonous material⁴²

II. PATENT PROTECTION FOR INDIGENOUS MEDICINAL KNOWLEDGE?

There is currently no patent protection for indigenous medicinal methods and pharmaceutical companies commonly utilize the knowledge in the development of new patentable medicines.⁴³ Proposals have been made to reform this supposed inequity and “to place patents for indigenous peoples as a means to empowerment and recognition of their intellectual contributions.”⁴⁴ However, Western patent systems appropriately exclude TK from patent protection. Additionally, intellectual property rights are not reconcilable with the traditional beliefs of indigenous peoples.

³⁹ Quinn, *supra* note 9, at 292.

⁴⁰ Hansen & VanFleet, *supra* note 2, at 3.

⁴¹ See World Intellectual Property Organization, *Intellectual Property and Traditional Cultural Expressions/Folklore*, WIPO Publication No. 913(E), 8 (2004), available at <http://www.wipo.int/tk/en/folklore> (describing the legal and policy issues raised by the relationship between intellectual property and folklore [also known as traditional cultural expressions], and describing the ways in which, although TK overlaps with this relationship, it has been given a distinct focus in WIPO’s work, which includes developing a model for the IP-type protection of folklore).

⁴² Intergovernmental Comm. on Intellectual Property and Genetic Resources, *Traditional Knowledge and Folklore*, Note by Portugal: Ministry of Agric., Rural Dev., and Fisheries, Decree-Law No. 118/2002, WIRO/GRTKF/IC/8/13, art. 3 (Apr. 20, 2002).

⁴³ Trotti, *supra* note 27, at 370; Lester I. Yano, Comment, *Protection of the Ethnobiological Knowledge of Indigenous Peoples*, 41 UCLA L. REV. 443, 486 (1993).

⁴⁴ Trotti, *supra* note 27, at 370.

A. The World Patent System

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),⁴⁵ a portion of the agreement that amended the General Agreement on Trade and Tariffs (GATT) and created the World Trade Organization (WTO), set international procedural and substantive standards for patent protection.⁴⁶ Any country wishing to join the WTO must comply with the intellectual property requirements of TRIPS.⁴⁷ Article 27 of TRIPS defines as patentable “any product or process ... provided they are new, involve an inventive step and are capable of industrial application.”⁴⁸ TRIPS codified pre-existing standards of member states with strong patent systems, which many critics view as primarily benefiting the Western world.⁴⁹

The requirements of novelty, inventive step (non-obviousness), and industrial application (utility), the legal definition of joint inventorship, and the ban on patenting products of nature are barriers serve as barriers to the patentability of indigenous medicinal knowledge.⁵⁰

1. Novelty

By definition, indigenous TK is not novel by patent standards. Novelty is a requirement that the claimed invention cannot be too similar to an existing invention. “Because indigenous medicine normally has been used for millennia as part of an oral tradition, the novelty requirement acts as a bar to patenting it.”⁵¹

TRIPS requires Member States to adopt patent laws to protect inventions that are “new, involve and inventive step and are capable of industrial application,”⁵² but TRIPS never defines what “new” means.⁵³ Under Article 54 of the European Patent Convention (EPC), “an invention shall be considered to be new if it does not form part of the state of the art.”⁵⁴ State of the art is defined as “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.”⁵⁵

The United States’ novelty requirement is similar to that of the EPC but excludes inventions “known or used by others in this country, or patented or described in a

⁴⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Apr. 15, 1994, 33 I.L.M. 1125, 1197 [hereinafter TRIPS Agreement].

⁴⁶ See *id.* at 1198-99 (describing scope and nature of obligation of member states under TRIPS).

⁴⁷ *Id.* at 1130.

⁴⁸ *Id.* at 1208.

⁴⁹ Finston, *supra* note 22, at 1; Trotti, *supra* note 27, at 370.

⁵⁰ See generally TRIPS Agreement, *supra* note 45, at 1208-09 (outlining the requirements for obtaining a patent).

⁵¹ Trotti, *supra* note 27, at 371-72.

⁵² TRIPS Agreement, *supra* note 45, Art. 27(1), at 1208.

⁵³ Dennis S. Karjala, Biotech Patents and Indigenous Peoples 8 (September 17, 2003) (unpublished manuscript circulated at conference entitled Intellectual Property and Biotechnology in the Age of Globalization: Challenges, Opportunities and Risks, Sept. 19-20, 2003 at the University of British Columbia, on file with author).

⁵⁴ Convention on the Grant of European Patents art. 54(1), Oct. 5, 1973, 13 I.L.M. 271 (1974) [hereinafter *Grant of European Patents*].

⁵⁵ *Id.*

printed publication in this or a foreign country,”⁵⁶ and inventions “patented or described in a printed publication or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.”⁵⁷ Thus, disclosures made outside the United States must be written to constitute prior art.⁵⁸

One scholar argues that the requirement that disclosures outside the United States must be written means that indigenous oral traditions outside the United States would not constitute prior art, a fact which “could be advantageous to indigenous peoples because they would not automatically face a novelty bar for oral disclosures made beyond United States territory.”⁵⁹ However, this would only hold true as long as the particular person seeking a patent in the United States is the actual inventor of the subject-matter.

Section 102(f) of the Patent Act states that “a person shall be entitled to a patent unless...he did not himself invent the subject-matter sought to be patented.”⁶⁰ Therefore, if the TK has been passed down for generations orally, the indigenous peoples would not be eligible to obtain a patent since they themselves were not the actual inventors. Only if the actual indigenous peoples who are seeking patent protection themselves invented the method of using the TK would they be meet the requirement of actual inventorship stipulated in § 102(g).⁶¹ For example, if a medicine man or shaman outside the United States derived a particular application thirty years ago and has orally disclosed this knowledge only to his fellow tribesmen, then this disclosure and use of the TK would not pose a novelty bar under U.S. law as long as he personally applies for the patent. If however this same shaman applies for patent protection for a TK invention that has been used for millennia by his forefathers, then he would not be eligible to obtain patent protection due to the § 102(g) bar. Likewise, if a pharmaceutical company patents a plant medicinal method based on oral indigenous TK although such uses have been well-established in the other country, without refining or isolating the extraction or adding further ingredients, the patent is invalid under §102(g) because the actual inventors were the ancestors of the indigenous peoples, not the pharmaceutical company.

Finally, the novelty requirement “means that inventors must seek a patent at the earliest possible moment; if they do not, they cannot later ‘catch up.’”⁶² One scholar argues that this system unfairly penalizes indigenous peoples who “had no practical opportunity to participate in the development of world intellectual property systems and that are now only beginning to debate and to demand a place in those systems
...”⁶³

⁵⁶ 35 U.S.C.A. § 102(a) (2004).

⁵⁷ *Id.* at § 102(b).

⁵⁸ Trotti, *supra* note 27, at 372.

⁵⁹ *Id.*

⁶⁰ 35 U.S.C.A. § 102(g) (2002).

⁶¹ *See id.* (extending patent protection only to the actual inventor, and not those individuals that the inventor passed the information to through oral tradition or any other means of conveyance).

⁶² Roht-Arriaza, *supra* note 10, at 937.

⁶³ *Id.*

2. *Inventive Step (Nonobviousness)*

Patentability of TK faces a barrier in the inventive step or nonobviousness requirements because of the way it is developed. Indigenous peoples' knowledge is gathered over time and builds upon layers of prior TK and trial and error.⁶⁴

The TRIPS Agreement requires that patentable subject matter "involve an inventive step."⁶⁵ Under Article 56 of the EPC, "an invention shall be considered as involving an inventive step if ... it is not obvious to a person skilled in the art."⁶⁶ Other Western patent regimes, such as the United States and Japan, have similar requirements.⁶⁷

In the United States, this concept is known as "nonobviousness."⁶⁸ Section 103(a) of the U.S. Patent Act states that "a patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."⁶⁹ The nonobviousness or inventive step requirement would not pose a bar to Western pharmaceutical companies, on the other hand, if they isolate and identify "previously unidentified bioactive substances."⁷⁰

3. *Industrial Application (Utility)*

Indigenous medicine is often unrefined, which many observers might consider as not being useful. Under TRIPS, an invention must have an "industrial application."⁷¹ United States patent law requires that the application be "useful," or "utility."⁷² While indigenous TK is arguably extremely useful in "developing pharmaceuticals through identification of plants with healing properties,"⁷³ the USPTO has suggested that utility in aiding drug development is not the test, but rather focuses on proven medical applications of a particular fragment or plant.⁷⁴

⁶⁴ Trotti, *supra* note 27, at 372.

⁶⁵ TRIPS Agreement, *supra* note 45, art. 27.1, at 1208.

⁶⁶ See Grant of European Patents, *supra* note 54, art. 56 (defining the "inventive step" requirement to patentability under the European Patent Convention).

⁶⁷ Trotti, *supra* note 27, at 372.

⁶⁸ 35 U.S.C.A. § 103.

⁶⁹ *Id.* § 103(a).

⁷⁰ Trotti, *supra* note 27; at 372, *see also* Kadidal, *Plants, Poverty*, *supra* note 19, at 238 (generally, the patent laws of most nations exclude the mere discovery of a chemical substance from patentability, however there is an exception when the substance was "previously unknown in its purified and isolated form," thus allowing for a patent of the actual substance).

⁷¹ TRIPS Agreement, *supra* note 45, Art. 27, at 1208. Footnote 5 to Article 27 states that "the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively."

⁷² 35 U.S.C.A. § 101.

⁷³ Trotti, *supra* note 27, at 373.

⁷⁴ *Id.* (discussing the prosecution history of the attempt by the National Institutes of Health to patent gene fragments that aid development of gene therapy through their use in mapping gene sequences); *see also* Josephine R. Axt, et. al, BIOTECHNOLOGY, INDIGENOUS PEOPLES, AND INTELLECTUAL PROPERTY RIGHTS, No. 93-478A, at 55-56 (1st sess. 1993) (noting that the USPTO rejected the National Institute of Health's attempt to patent gene markers because these markers had no proven application in medical treatment); Elaine Elisabetsky, *Folklore, Tradition, or Know-How?*, CULTURAL SURVIVAL Q. 9,10

4. *Joint Inventorship*

One author posits that indigenous contributions to modern medicine may be protected under a claim of joint inventorship.⁷⁵ Joint inventorship is a status applicable to inventions that are made by two or more persons jointly⁷⁶ working in collaboration toward the same end with each inventor actually contributing to the inventive thought.⁷⁷ “The collaboration requirement is flexible enough to accommodate the relationships between indigenous people and researchers. It does not require that joint inventors work together or at the same time, or that they make the same type or amount of contribution, or make a contribution to every claim ...”⁷⁸

However, much medicinal TK is considered to be in the public domain, thus rendering the “intellectual contribution of indigenous people ... [perhaps] not ... worthy of inventorship status.”⁷⁹ A further barrier is that most indigenous people “understand their medicine within the context of their culture.”⁸⁰ It may be difficult for them to prove a “conceptual connection between their contribution and the medicine’s ultimate use in Western medicine.”⁸¹

5. *Product of Nature*

Indigenous medicines often consist of unaltered or minimally altered raw plant material.⁸² As such, they may be subject to a “products of nature” rejection. Substances naturally occurring in nature, without alteration, are not patentable.⁸³

The legislative history of the United States Patent Act states that patentable subject matter “include[s] anything under the sun that is made by man.”⁸⁴ Article 3 of the EPC prohibits inventors from obtaining patents on “plant and animal varieties.”⁸⁵

Such requirements may be applied “to the detriment of indigenous medicine in patent applications.”⁸⁶ For example, the European Patent Office rejected a claim for genetically altered herbicide-resistant plant cells on the grounds that the plant was a product of nature.⁸⁷ On the other hand, the German Supreme Court stated it would

(Summer 1991) (discussing ethnopharmacology, detailed ethnographic research, particularly of indigenous cultures, that aids in the understanding of traditional drug uses).

⁷⁵ Michael J. Huft, Comment, *Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights*, 89 NW. U. L. REV. 1678, 1724 (1995).

⁷⁶ 35 U.S.C.A. § 116.

⁷⁷ *Monsanto Co. v. Kamp*, 269 F.Supp. 818, 824 (D.C. Cir. 1967).

⁷⁸ Trotti, *supra* note 27, at 373.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*; see also Craig Jacoby and Charles Weiss, *Recognizing Property Rights in Traditional Biocultural Contribution*, 16 STAN. ENVTL. L.J. 74, 98 (1997) (highlighting problems with including traditional biocultural knowledge holders as joint inventors).

⁸² Trotti, *supra* note 27, at 371.

⁸³ *Id.*

⁸⁴ S. Rep. No. 1979, at 5 (1952), reprinted in 1952 U.S.C.A.N. 2394, 2399.

⁸⁵ *Grant of European Patents*, *supra* note 53, at 271.

⁸⁶ Trotti, *supra* note 27, at 371.

⁸⁷ Decision T356/93 Plant Genetic Systems/Glutamine Synthetase Inhibitors, 1995 E.O.P.R. 357, 5367.

allow a patent for a “product of nature” if the plant resulted from the “systematic application ... of biological forces of nature.”⁸⁸ Likewise, since *Diamond v. Chakrabarty*,⁸⁹ U.S. courts have held that patents may be granted for artificially created living things, including plant life.⁹⁰ In *Ex Parte Hibberd*,⁹¹ the Board of Patent Appeals and Interferences held that plants were patentable under § 101. However, “the level of human intervention required for patent protection is so demanding,”⁹² that many types of indigenous medicines utilizing plants may be excluded, as naturally existing wild plants are often used in indigenous medicines.⁹³

B. PATENT RIGHTS IN THE CONTEXT OF INDIGENOUS PEOPLES

The differences between indigenous societies and Western states raise questions as to whether patent protection for indigenous medicinal knowledge would be desirable or even a feasible solution.

1. *Can indigenous peoples conceive of private rights?*

Private property rights in indigenous knowledge may actually be abhorrent to indigenous peoples who adhere to traditional beliefs.⁹⁴ Indigenous peoples often object to the use of their TK on ethical grounds, arguing that intellectual property should be treated as a pure public good.⁹⁵ This is a question of fundamental cultural values, and thus neither right nor wrong. At least one scholar questions whether “any group following this belief should retain exclusive rights to use information they discover with respect to people outside the group.”⁹⁶ This scholar continues:

If the information is freely available simply by visiting the group and observing their lifestyle, and if a visitor does this without fraud or duplicity, saying that the visitor cannot use the information as a basis for creating a new, and perhaps patentable, product is equivalent to recognizing exclusive, perhaps group, rights in the information. Maybe such recognition can be justified on the ground that the group’s culture should be respected by outsiders, but if this is the claim, it should be articulable in terms of even western

⁸⁸ Geertrui Van Overwalle, *Patent Protection for Plants: A Comparison of American and European Approaches*, 39 IDEA 143, 173-174 (1999) (discussing the *Rote Taube* case).

⁸⁹ 447 U.S. 303, 310-11 (1980) (holding that genetically engineered micro-organism was patentable under § 101 as a “manufacture” or “composition of matter”).

⁹⁰ Amy Sun, Note, *Ag Supply, Inc. v. Pioneer Hi-Bred Int’l Inc.: Statutory Construction and Plant Patents*, 43 JURIMETRICS J. 473, 481 (2003).

⁹¹ 227 U.S.P.Q. (BNA) 443, 445-46 (B.P.A.I. 1985).

⁹² Trotti, *supra* note 27, at 371.

⁹³ Jacoby & Weiss, *supra* note 80, at 97.

⁹⁴ Karjala, *supra* note 52, at 11.

⁹⁵ Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 WAKE FOREST L. REV. 89, 122 (1993); Whitt, *supra* note 4, at 252-53 (discussing a type of knowledge that the Maori call “tapu” and regard as sacred, believing that its misuse would cause the knowledge to lose its power); Melissa L. Sturges, Note, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 AM. U. INT’L L. REV. 219, 244 (1997).

⁹⁶ Karjala, *supra* note 52, at 11.

notions like breach of confidence or privacy rights. *Something* besides “We discovered it so it’s ours” is necessary unless one takes the extreme step of embracing a full-fledged natural rights basis for intellectual property or one simply has a preference for economic inefficiency over economic efficiency.⁹⁷

This lack of conception regarding intellectual property rights in indigenous societies tends to aid the uncompensated use of TK “because it implies that the knowledge is considered properly to be in the public domain.”⁹⁸ However, there has been no comprehensive study of the intellectual property rights concept among indigenous peoples.⁹⁹ In fact, studies suggest that rights similar to patents, trademarks, and copyrights exist in some indigenous societies.¹⁰⁰

Some indigenous medicines may be seen as a form of trade secret, rather than public domain knowledge.¹⁰¹ One scholar notes that while most herbal medicine may be seen as public domain, “the renowned herbalists ... guarded their knowledge ... in great secrecy.”¹⁰²

2. *How to compensate?*

If patent regimes were adapted to include patents on indigenous peoples’ medicinal methods, a question would arise as to who would receive royalties. One critique of applying Western intellectual precepts to indigenous societies is that the developed nations’ focus of “vesting rights only in individuals ... marginalizes the interests and contributions of indigenous and traditional communities.”¹⁰³ This critique crystallizes the debate: Should an individual healer receive royalties, despite the fact that his discovery may have come from a general body of knowledge in the indigenous community derived over time?¹⁰⁴ One possibility would be to compensate towns or communities for use of the TK in drug development.¹⁰⁵ This approach might, however, affect the relationships between the communities, ultimately adding to the problem.¹⁰⁶ Indigenous communities may even begin to

⁹⁷ *Id.*

⁹⁸ Trotti, *supra* note 27, at 375.

⁹⁹ *Id.*; David A. Cleveland & Stephen C. Murray, *The World’s Crop Genetic Resources and the Rights of Indigenous Farmers*, 38 CURRENT ANTHROPOLOGY 477, 483 (1997).

¹⁰⁰ Trotti, *supra* note 27, at 375 (citing Candace S. Green & Thomas Drescher, *The Tipi with Battle Pictures: The Kiowa Tradition of Intangible Property Rights*, 84 TRADEMARK REP. 418, 423-24 (1994); Cleveland & Murray, *supra* note 98, at 483 (discussing the concept of “wou” in the Madang society of New Guinea which grants the exclusive right to make certain pots and plant certain species of yams)).

¹⁰¹ Gelvina Rodriguez Stevenson, Note, *Trade Secrets: The Secret to Protecting Indigenous Ethnobiological (Medicinal) Knowledge*, 32 N.Y.U. J. INT’L L. & POL. 1119, 1153 (2000).

¹⁰² Komla Tsey, *Traditional Medicine in Contemporary Ghana: A Public Policy Analysis*, 45 SOC. SCI. & MED. 1065, 1071 (1997).

¹⁰³ Roht-Arriaza, *supra* note 10, at 948.

¹⁰⁴ Janet McGowan and Iroka Udeinya, *Collecting Traditional Medicines in Nigeria: A Proposal for IPR Compensation*, INTELLECTUAL PROPERTY RIGHTS FOR INDIGENOUS PEOPLES: A SOURCE BOOK 59, 62 (Tom Greaver, ed., Society for Applied Anthropology 1994).

¹⁰⁵ Trotti, *supra* note 27, at 376.

¹⁰⁶ *Id.*

charge other tribes for use of their medicinal knowledge.¹⁰⁷ “Thus, patent protection could become an instrument for the concentration of wealth and the creation of a new indigenous elite rather than a means to achieve distributive justice.”¹⁰⁸

Additionally, there is a fear that an influx of monetary compensation may threaten or destroy indigenous societies.¹⁰⁹ Intellectual property rights are part and parcel of capitalist systems.¹¹⁰ Indigenous societies, on the other hand, have community-based economies where “no transactions occur outside the group.”¹¹¹ One scholar argues that introducing patent rights would “lead to economic transformation of adoption of the market form exactly among those people whom it is said to protect.”¹¹² Additionally, there is the possibility that “national governments may interfere with the rewards of patent compensation.”¹¹³

Lastly, even if the patent protection was granted to indigenous peoples’ TK, there is no assurance that tribes would receive timely compensation.¹¹⁴ Despite the existence of such groups as Public Interest Intellectual Property Advisors,¹¹⁵ many indigenous peoples have no access to patent attorneys or other attorneys.¹¹⁶ Furthermore, tribes would not receive royalties for years, because it typically takes between 10-to-20 years to get drugs approved and commercialized.¹¹⁷ Indigenous cultures are rapidly disappearing,¹¹⁸ and thus, this time lag may be injurious to indigenous peoples who rely on the royalties from TK medicines “to save endangered indigenous communities.”¹¹⁹

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* (citing Ajay K. Sharma, *The Global Loss of Biodiversity: A Perspective in the Context of the Controversy over Intellectual Property Rights*, 4 U. BALT. INTELL. PROP. L.J. 1, 15 (1995); Stephen Gudeman, *Sketches Qualms and Other Thoughts on Intellectual Property Rights*, in VALUING LOCAL KNOWLEDGE 102, 118 (Stephen B. Brush & Doreen Stabinsky eds., 1996)).

¹⁰⁹ See, e.g., Jan McGirk, *A Tribe Goes Into Battle Over the 'Evil Twins' of Colombia*, INDEPENDENT (London), Sept. 6, 1999 (exploring the impropriety of offering monetary compensation to indigenous peoples, particularly the U’wa tribe of Colombia).

¹¹⁰ See Trotti, *supra* note 27, at 376 (contrasting individualized intellectual property rights inherent in market economics with indigenous peoples’ communal view of intellectual property).

¹¹¹ Gudeman, *supra* note 108, at 105.

¹¹² *Id.* at 104.

¹¹³ Trotti, *supra* note 27, at 377.

¹¹⁴ *Id.*

¹¹⁵ Public Interest Intellectual Property Advisors (PIIPA) “is an international non-profit organization that makes intellectual property counsel available for developing countries and public interest organizations that seek to promote health, agriculture, biodiversity, science, culture, and the environment.” Public Interest Intellectual Property Advisors, <http://www.piipa.org> (last visited Jan. 7, 2007).

¹¹⁶ Trotti, *supra* note 27, at 377 (citing Robert Weissman, *Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT’L ECON. L. 1069, 1090 (1996)).

¹¹⁷ Elisabetsky, *supra* note 74.

¹¹⁸ KATY MORAN, *Toward Compensation Returning Benefits from Indigenous Medicinal Drug Discovery to Native Peoples*, in ETHNOECOLOGY: SITUATED KNOWLEDGE/LOCATED LIVES 249, 252 (Virginia D. Nazarea ed., Univ. of Arizona Press 1999) (“Because of poverty, acculturation, outside encroachment, and loss of habitat, extinction has been the fate of one indigenous culture each year in the Amazon region alone”).

¹¹⁹ Trotti, *supra* note 27, at 377.

III. PROPOSALS AND POTENTIAL SOLUTIONS

It is unlikely that the current patent regimes can protect indigenous TK. While extension of the patent laws through TRIPS may be the “most efficient way to protect and compensate for the use of [traditional] knowledge,”¹²⁰ other ways of recognizing indigenous peoples’ contributions to science may also be possible. Examples of possible options are the use of contract law, *sui generis* legislation, treaty protection, and an international framework similar to the United States Bayh-Dole Act.

A. Private solutions: Contract-based approaches

One possible solution for the protection of TK lies in contract law. Some pharmaceutical companies and indigenous groups enter into contracts, whereby the indigenous peoples seek compensation for the use of their TK in the development of patented products and to “provide a mechanism through which any new knowledge obtained by the pharmaceutical company will be shared with the indigenous peoples.”¹²¹ As consideration, the pharmaceutical company seeks a monopoly on the TK in return for royalties.¹²²

For example, the Kuna Indians of Panama started the Project for the Study of Management of Wildlife Areas of the Kuna Yala (PEMANSKY), to establish a protected forest area on the edge of their lands.¹²³ PEMANSKY also manages a system where visiting scientists may sample the native flora and fauna in exchange for using native assistants while on the Kuna lands and making all reports freely available to the Kuna.¹²⁴ However, the contracts do not provide for any royalties.¹²⁵

The Merck/INBio Cost Rica agreement of 1991 is an example of a partnership between a developing country and public and private institutions “which led to positive benefit-sharing among all parties involved.”¹²⁶ Prior to the Rio Earth Summit which resulted in the Convention on Biological Diversity (CBD), the National Biodiversity Institute (INBio) of Costa Rica entered into an agreement with Merck whereby INBio provided Merck with short-term exclusive rights to study plant, animal, and soil samples “as well as proprietary rights for any innovative product created from the INBio samples” in exchange for \$1 million United States dollars, 60% of the royalties from products created from the INBio samples, and laboratory equipment.¹²⁷ The government of Costa Rica agreed to use royalty proceeds for biological diversity conservation.¹²⁸ This agreement, while a non-statutory, contract-based approach, foreshadowed many of the objectives later

¹²⁰ Yano, *supra* note 7, at 472.

¹²¹ *Id.* at 473.

¹²² *Id.*

¹²³ *Id.* (citing Mac Chapin, *How the Kuna Keep Scientists in Line*, CULTURAL SURVIVAL Q. 17 (Summer 1991)).

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ Finston, *supra* note 22, at 7.

¹²⁷ Yano, *supra* note 7, at 474.

¹²⁸ Finston, *supra* note 22, at 7.

included in the CBD.¹²⁹ However, there is no provision for direct compensation to the indigenous peoples, thus “[a]ny benefit to the indigenous people must be indirectly derived from the preservation of the biodiversity of the region.”¹³⁰

One commentator posits that “tribal laws could be used to provide contract-like remedies for the uncompensated transfer of ethnobiological knowledge.”¹³¹ Tribal laws could be used to make the “entry of outsiders onto tribal lands conditional, and provide for the punishment of any tribal member who discloses ethnobiological knowledge without tribal consent.”¹³² If the indigenous peoples are treated as separate sovereign peoples within a host state (“nations within”), like Native Americans in the United States, damages could possibly be obtained “if the outsider is prosecuted on the reservation.”¹³³

A problem with such a private solution, however, is that there are no means of ensuring that corporations will engage in benefit-sharing unless an effective enforcement mechanism exists.¹³⁴ There is also the potential shortcoming of under compensation and unequal sharing.¹³⁵ Finally, a contract-based solution would require individual agreements between each indigenous group and each pharmaceutical company, which could result in detrimentally affecting the relationships between indigenous communities and inadvertently creating a class system amongst indigenous groups, as tribes with greater access to lawyers are able to craft better agreements.¹³⁶

B. *Sui Generis* legislation

Several countries provide *sui generis* protection to indigenous TK.¹³⁷ In response to a questionnaire on existing intellectual property protection of TK, twelve members of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (Committee) of the World Intellectual Property Organization (WIPO) indicated that protection for TK is available under the current standards of their intellectual property law.¹³⁸ While almost all of the examples provided focused on appellations of origin and on the protection of handicrafts through copyright and trademark, only Russia and Vietnam

¹²⁹ M. D. Coughlin, Jr., *Using the Merck-INBio Agreement to Clarify the Convention on Biological Diversity*, 31 COLUMB. J. TRANSNAT'L L. 337 (1993).

¹³⁰ *Id.*

¹³¹ Yano, *supra* note 7, at 475.

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ Trotti, *supra* note 27, at 376.

¹³⁷ Canada, Hungary, Italy, Mexico, the Republic of Moldova, the Republic of Korea, Portugal, Romania, the Russian Federation, Switzerland, Uruguay, and Vietnam have indicated that they provide such protection. World Intellectual Property Organization [WIPO], Intergovernmental Comm. on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Report on the Review of Existing Intellectual Property Protection of Traditional Knowledge*, Doc. WIPO/GRTKF/IC/4/7 (Dec. 9-17, 2002) (prepared by the Secretariat), available at http://www.wipo.int/documents/en/meetings/2002/igc/pdf/grtkf_ic_4_7.pdf [hereinafter WIPO Report].

¹³⁸ *Id.*

provided examples of existing patent protection for indigenous TK.¹³⁹ Two members of the Committee, Portugal and Togo,¹⁴⁰ indicated that they adopted a *sui generis* system for protection of TK. According to WIPO, five additional countries enacted *sui generis* national legislation for protection of indigenous TK, pursuant to the Convention on Biological Diversity providing.¹⁴¹

Brazil's Provisional Measure No. 2.186-16¹⁴² protects the TK "of indigenous and local communities relating to the genetic heritage ... against illegal use and exploitation and other actions that are harmful or have not been authorized by the Management Council ... or by an accredited institution."¹⁴³ The Brazilian Provision recognizes the inherent differences between Western intellectual property norms and the collective rights understood in indigenous societies in its statement that, "any traditional knowledge associated with the genetic heritage may be owned by the community, even if only one single member of the community holds that knowledge."¹⁴⁴

The Panamanian Legislative Assembly enacted Law No. 20 on June 26, 2000 in order to:

protect the collective rights of intellectual property and traditional knowledge of the indigenous communities upon their creations such as inventions, models, drawings and designs ... capable of commercial use, through a special registration system, promotion, commercialization of their rights in order to stand out the value of the indigenous cultures and to apply social justice.¹⁴⁵

This law continues by stating that TK "consequently, cannot be object of any form of exclusive right by not authorized third parties under the intellectual property system."¹⁴⁶ Although the statute refers to inventions and TK, the specific provisions set up a protection regime more similar to that of trademark or copyright, and cover the crafts of traditional artisans, fables and stories, and traditional dance.¹⁴⁷

Perhaps the lack of patent-like protection for indigenous medicinal TK stems from many indigenous peoples' understanding of their TK through songs and dance. While this undoubtedly will protect traditional cultural expressions and folklore in Panama, unless the indigenous peoples are able to make a case that their medicinal methods are protected under this *sui generis* regime, this statute may do nothing to ensure that Western companies compensate for the appropriation of TK.

¹³⁹ *Id.*

¹⁴⁰ *See id.* (enacting [laws or regulations] establishing a system of traditional knowledge intellectual property protection especially adapted to its characteristics (that is, a *sui generis* system)."

¹⁴¹ In addition to Portugal and Togo, Brazil, Panama, and Peru have enacted *sui generis* legislation. *Id.*

¹⁴² Provisional Measure No. 2.186-16, Aug. 23, 2001 (Brazil), available at <http://www.grain.org/brl/?docid=850&lawid=1768>.

¹⁴³ *Id.*, art. 8.

¹⁴⁴ *Id.*, art. 9, Sole Paragraph.

¹⁴⁵ Legislative Assembly Law No. 20, art. 1. June 26, 2000 (Panama), available at http://www.digerpi.gob.pa/law_20.html.

¹⁴⁶ *Id.*, art. 2.

¹⁴⁷ *Id.*

Peruvian Law No. 27811, “Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources,”¹⁴⁸ perhaps provides the most protection of the various *sui generis* attempts. Two of its stated objectives are “to ensure that the use of knowledge takes place with the prior informed consent of the indigenous peoples”¹⁴⁹ and “to avoid situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions.”¹⁵⁰

One potential drawback of the legislation is that financial benefit-sharing of royalties from inventions derived from TK does not flow directly to the tribes themselves. While Peru has statutorily imposed a royalty of “no less than ten per cent of the value, before tax, of the gross sales resulting from the marketing of goods developed on the basis of collective knowledge,”¹⁵¹ this royalty is paid to the state, which directs it into the Fund for the Development of Indigenous Peoples and Communities.¹⁵² As this is a collective fund, all indigenous peoples in Peru have the ability to draw on the fund through their representative organizations, regardless of the extent to which their TK resulted in the monies.¹⁵³ Although the royalties do not go directly to the specific groups that provided the knowledge, the fund may ensure that the royalties actually reach indigenous peoples. As a result of the state’s involvement, this regime provides a greater enforcement mechanism than do individual contracts between tribes and Western researchers.

The key apprehension with respect to *sui generis* regimes is their enforceability outside the state implementing the legislation, despite the fact that such statutes allegedly derive from the CBD.¹⁵⁴ “Without an international agreement requiring reciprocity of such protections, *sui generis* protections may prove fruitless for indigenous peoples.”¹⁵⁵

One way of “creating a base for a *sui generis* regime”¹⁵⁶ might be the creation of a worldwide database to serve as a repository of TK.¹⁵⁷ The database could serve to document TK as “prior art” to be used in challenging patent applications, as a means of providing contact information of indigenous groups, or “as a fee-based access service to such knowledge.”¹⁵⁸ For example, In Ecuador, a non-governmental organization (NGO), Eccosciencia, has established a database of over 8,000 entries

¹⁴⁸ Law No. 27811, (published 2002) (Peru).

¹⁴⁹ *Id.*, art. 5(d).

¹⁵⁰ *Id.*, art. 5(f).

¹⁵¹ *Id.*, art. 8.

¹⁵² *Id.*, arts. 37-41.

¹⁵³ *Id.*, art. 38.

¹⁵⁴ Bluemel, *supra* note 34, at 700; see also Gerard Bodeker, *Traditional Medical Knowledge, Intellectual Property Rights, and Benefit Sharing*, 11 *CARDOZO J. INT’L & COMP. L.* 785, 807 (2003) (discussing whether *sui generis* legislation is enforceable outside the state).

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ WIPO Report, *supra* note 137.

¹⁵⁸ Bluemel, *supra* note 34, at 701.

detailing TK of six local groups in an experimental project entitled “Transforming Traditional Knowledge into Trade Secrets.”¹⁵⁹

Databases, unfortunately, have drawbacks. They may “inhibit the ability of indigenous peoples to participate in the management of their traditional knowledge or otherwise undermine the rights of indigenous peoples.”¹⁶⁰ Additionally, some indigenous peoples may be reluctant to disclose their TK in a database, because they might feel that they cannot control the process or that they were coerced into using the database.¹⁶¹ For indigenous peoples, “the idea of disclosure within a public forum over which the individual [TK] holder has no control may be seen to represent a level of risk of exploitation that is unacceptable to many.”¹⁶² Further, databases are not protected under existing intellectual property laws in most of the world.¹⁶³

C. Treaties

Conventions and declarations provide guiding principles for states to follow in launching international norms.¹⁶⁴ “The parties to the conventions negotiate agreements stating broad goals and setting up procedural mechanisms for attaining these goals, but typically the conventions contain few, if any, substantive requirements.”¹⁶⁵ As a result, further agreements are necessary to “provide specific goals and enforcement mechanisms.”¹⁶⁶ One example of this dichotomy, between conventions and further agreements needed to provide enforcement mechanisms, is demonstrated by the inclusion of the various WIPO treaties in the TRIPS agreement of the WTO.¹⁶⁷ Despite their inherent shortcomings, treaties may provide a means for the protection of TK, as long as they evolve to contain legitimate enforcement mechanisms and have widespread support.

1. *Convention on Biological Diversity*

The CBD, which was opened for signature at the United Nations Conference on Environment and Development (popularly referred to as the Rio Earth Summit) in Rio de Janeiro in 1992, was the first “large-scale international recognition of the need to compensate indigenous people for their ethnobiological knowledge.”¹⁶⁸

¹⁵⁹ *Id.* (citing JOSEPH HENRY VOGEL, *THE BIODIVERSITY CARTEL: TRANSFORMING TRADITIONAL KNOWLEDGE INTO TRADE SECRETS* (CARE, Proyecto Subir 2000); Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT’L L. 233, 259 (2001)).

¹⁶⁰ Bluemel, *supra* note 34, at 701.

¹⁶¹ *Id.* at 702.

¹⁶² Bodeker, *supra* note 151, at 804.

¹⁶³ Amol Pachnanda, Comment, *Scientific Databases Should be Protected Under a Sui Generis Regime*, 51 BUFF. L. REV. 219, 229 (2003) (noting that databases are not effectively protected under current United States law); *but see* Mark Schneider, *The European Union Database Directive*, 13 BERKELEY TECH. L.J. 551, 556-60 (1998) (describing the database protection available in the European Union).

¹⁶⁴ Yano, *supra* note 7, at 476; *see also* Pierre-Marie Dupuy, *Soft Law and the International Law of the Environment*, 12 MICH. J. INT’L L. 420, 429-31 (1991) (describing classical and legal categories by which scholars usually describe and explain the creation and authority of international norms).

¹⁶⁵ Yano, *supra* note 7, at 476.

¹⁶⁶ *Id.*

¹⁶⁷ *See* TRIPS Agreement, *supra* note 45.

¹⁶⁸ Yano, *supra* note 7, at 476.

Previous conventions and international declarations had mentioned compensation but did not provide a means of enforcement and lacked widespread support.¹⁶⁹ The impetus for the CBD was the perception by developing countries that the binding intellectual property obligations of TRIPS (which were then being negotiated in the WTO) provided “disproportionate benefits to the West.”¹⁷⁰

The Preamble to the CBD recognizes

“the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components.”¹⁷¹

Although the “primary purpose of the Convention is to arrange for an agreement among the member states to preserve biological diversity,”¹⁷² articles of the CBD address both TK itself and the requirements for providing compensation when TK is used.

Article 16, entitled “Access to and Transfer of Technology,”¹⁷³ states in part: “in the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.”¹⁷⁴ Article 18, entitled “Technical and Scientific Cooperation,” requires member states to “encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies....”¹⁷⁵ Articles 20 and 21 also address compensation.¹⁷⁶ The critical commitment to ensuring that benefits from the commercial development of new products related to bio-diverse resources flow back to developing countries is commonly referred to as “Access and Benefit Sharing” (ABS).¹⁷⁷

The CBD enjoys widespread support. Most the world’s nations are parties (168 signatories and 189 parties).¹⁷⁸ The United States has not yet ratified the treaty, despite becoming a signatory in 1993. One commentator asserts that “concerns about the negative tone of countries on intellectual property protection expressed by key developing countries during the negotiations contributed to the U.S. decision to

¹⁶⁹ *Id.*

¹⁷⁰ Finston, *supra* note 22, at 3.

¹⁷¹ UN Conference on Environ. and Dev.: Convention on Biological Diversity, Rio de Janeiro, Braz., pmbl, *opened for signature* June 5, 1992, 31 I.L.M. 818, 822 (1992), pmbl [hereinafter *Convention on Biological Diversity*].

¹⁷² Yano, *supra* note 7, at 476.

¹⁷³ *Convention on Biological Diversity*, *supra* note 171, art. 16.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*, art. 18.

¹⁷⁶ *Id.*, arts. 20-21.

¹⁷⁷ Finston, *supra* note 22, at 3.

¹⁷⁸ See Parties to the Convention on Biological Diversity, <http://www.biodiv.org/world/parties.asp> (last visited Jan. 7, 2007) (providing statistics of the CBD).

defer ratification of the CBD, notwithstanding that most European and other WIPO/WTO members had adopted and implemented the CBD.”¹⁷⁹ While most U.S. pharmaceutical companies voluntarily follow CBD ABS guidelines,¹⁸⁰ the CBD lacks realistic effectiveness if the leading biotech market¹⁸¹ is not a Party. Finally, an additional problem with reliance on the CBD for protecting TK through benefit-sharing lies in the general nature of its terms.¹⁸²

2. TRIPS Agreement

Currently, TRIPS does not protect indigenous TK.¹⁸³ However, this agreement, one of several comprising the WTO, is a work in progress, as it allows differential deadlines for a state to implement its obligations, depending on its classification as a developed, developing, or least-developed country. There have been subsequent rounds of negotiation since TRIPS’ signing.

Some commentators feel that TRIPS provides the obvious framework for protecting indigenous TK, and that it could potentially:

1. Educate indigenous peoples about different intellectual property protections and their implications;
2. Require patent applications to identify traditional knowledge used in the development process;
3. Make information regarding patent applications more readily available to indigenous populations;
4. Require the equitable sharing of benefits with indigenous peoples where genetic resources or traditional knowledge from their territories are used to develop commercial products¹⁸⁴

However, before TRIPS is likely to accomplish such goals, there may need to be effective indigenous participatory rights in the negotiation of TRIPS. This belief indicates that indigenous peoples’ interests are not being effectively protected by their host states.¹⁸⁵

¹⁷⁹ Finston, *supra* note 22, at 1.

¹⁸⁰ *Id.* at 2.

¹⁸¹ Victoria Griffith, *Biotech Reaches a Turning Point in its Evolution*, FIN. TIMES 16, Dec. 17, 2003 (“The US dominance is clear on virtually any measure. By end-2002 its biotech sector had 10 times the market capitalisation of Europe’s ... and the US spent three times more on research and development. This year the gap has widened. In the US, biotech has once again found favour with venture capitalists, raising \$8.52[billion] so far ... the rest of the world raised \$1.37[billion]”).

¹⁸² Yano, *supra* note 7, at 478.

¹⁸³ See generally, *infra* Part II (noting that indigenous TK often is not able to satisfy TRIPS provisions requiring that the invention be, for example, novel or involve an inventive step. Moreover, TRIPS conceives of property rights in a way that is not commensurate with how indigenous people conceive of property rights, which engenders the problem of how to compensate the indigenous peoples.).

¹⁸⁴ Bluemel, *supra* note 34, at 706.

¹⁸⁵ See generally *id.* at 706 (concluding that the extent to which participatory rights may reach is has not been clearly established by theories of public participation and suggesting methods for which TRIP may adopt to truly protect indigenous interests).

D. International Framework Based on Bayh-Dole Act

One commentator asserts that the current focus on protection of indigenous TK, particularly “the expanding universe of ABS guidelines with the CBD”¹⁸⁶ is stifling the potential of the biotechnology sector.¹⁸⁷ Specifically, she cites the existence of the Bayh-Dole Act as the reason for the low level of investment in biotechnology outside the United States.¹⁸⁸

In the 1960s and 1970s, U.S. policy makers were concerned that industry was commercializing little of the technologies funded by U.S. Government grants.¹⁸⁹ In fact, less than 5% of the 28,000 U.S. Government-held patents were developed into commercial products in 1980,¹⁹⁰ in part due to the time-consuming and difficult process of obtaining exclusive patent protection.¹⁹¹ The non-exclusive rights provided for by U.S. law “failed to encourage companies to invest in the application and development of new products.”¹⁹² To solve this problem and encourage industry to commercialize products developed with taxpayer money, Congress enacted legislation, known as the Bayh-Dole Act of 1980.¹⁹³

Bayh-Dole enabled universities and research institutions to own inventions and work with industry to bring, manufacture, and commercialize products, a process commonly referred to as “technology transfer.”¹⁹⁴ This process allowed exclusive licensing of inventions.¹⁹⁵ Regulations ensured that products “were developed diligently and for the public good.”¹⁹⁶ The university, inventor, and industry all shared in royalties resulting from the invention. The university’s share was used to fund additional research.¹⁹⁷ In fiscal year 2002, more than \$37 billion in total funding was distributed to over two hundred research institutes in the United States.¹⁹⁸ Improved health, as a result of Bayh-Dole, was estimated to be fifteen times the annual investment in NIH research.¹⁹⁹

Private investment in the U.S. biotechnology sector, perhaps as a result of the jumpstart provided by the Bayh-Dole Act, is much higher than anywhere else in the world.²⁰⁰ Investment is drawn to the U.S. “due to the strength of its private rights,

¹⁸⁶ Finston, *supra* note 22, at 8.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* at 10 (quoting Victoria Griffith, *Biotech Reaches a Turning Point in its Evolution*, FIN. TIMES 16, Dec. 17, 2003).

¹⁸⁹ COUNCIL ON GOVERNMENT RELATIONS, THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 1-2 (1999), available at http://www.cogr.edu/docs/Bayh_Dole.pdf [hereinafter BAYH-DOLE ACT].

¹⁹⁰ *Id.* at 2.

¹⁹¹ Finston, *supra* note 22, at 8.

¹⁹² *Id.* at 9.

¹⁹³ BAYH-DOLE ACT, *supra* note 189, at 1-2.

¹⁹⁴ Finston, *supra* note 22, at 9.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ AUTM Licensing Survey, FY 2002 Survey Summary, 1.

¹⁹⁹ U.S. CONGRESS JOINT ECONOMIC COMMITTEE, THE BENEFITS OF MEDICAL RESEARCH AND THE ROLE OF NIH ii (May 2000).

²⁰⁰ Finston, *supra* note 22, at 10.

including intellectual property rights.”²⁰¹ Likewise, WIPO reports very low rates of filing for international patent applications for medicinal substances derived from plants, as opposed to other biotechnology inventions.²⁰² One commentator asserts:

Essentially, the bio-diverse developing countries are facing today the same situation that the U.S. faced in the 1970s. They possess a tremendous unexploited potential value in natural products R&D, but, without the proper legal framework needed to ensure the commercial development of actual products, their economic development and health objectives will not be realized.²⁰³

One requirement for developing countries wishing to foster indigenous biotechnology industries is foreign direct investment.²⁰⁴ A possible solution may be to implement an “International Bayh-Dole,”²⁰⁵ because a clear understanding of patent rights may be necessary to attract investment.

This solution, of course, has its shortcomings. While advantageous to business by providing clear rights to inventions derived from indigenous knowledge and potentially advantageous to developing countries who wish to attract foreign direct investment, the Bayh-Dole system does little to acknowledge the contributions that indigenous peoples make in the derivation of the inventions and to ensure that they will receive the benefits from their TK.

CONCLUSION

The use of TK without compensation is an issue of growing concern among indigenous peoples, developing countries, and activists. However, it is unlikely that a simple solution will be found. Currently patents and treaties are neither successful nor viable means of protecting or providing compensation for the transfer of TK. The most viable current alternative is the formation of private contracts that would serve the same function as patent protection. *Sui generis* legislation implemented by various developing states is another viable alternative, although without a legitimate enforcement mechanism outside the jurisdiction of the particular country, or without a comprehensive database or management system, such legislation will fail to provide meaningful protection on a more far-reaching scale. An international framework based on Bayh-Dole may help stimulate investment in bio-diverse developing countries and ensure that royalties flow back to the governments or indigenous peoples, but such a system would need strong enforcement mechanisms to ensure compensation for the indigenous peoples.

²⁰¹ *Id.*

²⁰² World Intellectual Property Organization [WIPO], Yearly Review of the PCT: 2002 (2002), available at http://www.wipo.int/pct/en/activity/pct_2002.pdf.

²⁰³ Finston, *supra* note 22, at 11.

²⁰⁴ *Id.*

²⁰⁵ *Id.* at 10.