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THE AYAHUASCA PATENT REVOCATION: RAISING QUESTIONS ABOUT CURRENT U.S. PATENT POLICY

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Abstract: This Note explores the discriminatory effect of U.S. patent law and policy on indigenous communities in developing countries. For years, Western researchers have relied upon local people to point them to useful regional plants and animals so that they could then isolate, develop and patent the chemical compounds found in the organisms. Yet, the U.S. patent system does not recognize or value the traditional knowledge of indigenous groups regarding their regional biodiversity. Rather, the researchers who isolate the compounds can obtain a patent with no recognition for the indigenous knowledge upon which they relied. Recently, the World Trade Organization has succeeded at globalizing Western intellectual property systems through international treaties. These efforts have met with significant resistance in several developing countries. The controversy over the ayahuasca patent is one example of developing countries' opposition to Western-style intellectual property rights. By implementing the suggestions described in this Note, the United States could ensure that indigenous knowledge would be recognized and thus could avoid future controversies like the one surrounding the ayahuasca patent.

INTRODUCTION

In 1986, Loren Miller, an American scientist and entrepreneur, obtained a U.S. patent on a strain of the ayahuasca vine.¹ Ayahuasca, a vine native to the Amazon Rain Forest, has been used by healers and religious leaders throughout the Amazon for generations.² For hundreds of years, shamans have used ayahuasca to treat sicknesses, contact spirits, and foresee the future.³ Many indigenous Amazon tribes also view the plant as a sacred symbol of their religion.⁴

* Managing Editor, BOSTON COLLEGE THIRD WORLD LAW JOURNAL (2000–2001).

¹ See Glenn M. Wiser, *PTO Rejection of the "Ayahuasca" Patent Claim: Background and Analysis* § 2, at <http://ciel.org/ptorejection.html> (Nov. 1999).

² *Id.* § 1.

³ *Id.*

⁴ *Id.*

Several years after its issuance, tribal leaders learned of Miller's patent.⁵ They were understandably angry and incredulous that a foreigner had patented a plant that they had been using and worshiping for hundreds of years.⁶ Voicing his countrymen's frustration, Antonio Jacanamijoy, the leader of a council representing more than 400 indigenous tribes and groups in South America, stated, "[o]ur ancestors learned the knowledge of this medicine and we are the owners of this knowledge."⁷ In 1999, Jacanamijoy's council applied for and obtained a rejection of the ayahuasca patent from the U.S. Patent and Trademark Office.⁸ The controversy over the patent generated considerable hostility between the United States and Ecuador and eventually led Ecuador's legislature to forgo signing a bilateral intellectual property rights agreement with the United States.⁹

The ayahuasca patent and the controversy it evoked is quite typical of the issues facing the biotechnology industry.¹⁰ Today, researchers from the United States travel to distant, resource-rich regions of the world, such as the Amazon, for the express purpose of gleaned scientific knowledge from indigenous populations regarding the var-

⁵ *Id.* § 2.

⁶ See Wisner, *supra* note 1, § 2; CTR. FOR INT'L ENVTL. LAW (CIEL), COMMENTS ON IMPROVING IDENTIFICATION OF PRIOR ART: RECOMMENDATIONS ON TRADITIONAL KNOWLEDGE RELATING TO BIOLOGICAL DIVERSITY SUBMITTED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE § IV(D), at <http://ciel.org/bwp.html> (Aug. 1999) [hereinafter CIEL]. Under the U.S. Patent Act, applicants cannot patent medicinal plants in their natural state. See ALAN L. DURHAM, PATENT LAW ESSENTIALS: A CONCISE GUIDE 80 (1999). However, if a Western researcher separates the plant's chemical compounds in a fashion that is not naturally occurring, it becomes eligible for patent protection. See Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH. J. INT'L L. 919, 938 (1996).

⁷ See Bill Lambrecht, *Amazon Tribal Leaders Challenge U.S. Patent: They Say American Has No Right to Plant Used in Healing*, ST. LOUIS POST-DISPATCH, Mar. 31, 1999, at A5 (quoting Antonio Jacanamijoy).

⁸ See Wisner, *supra* note 1, §§ 3, 5.

⁹ See CIEL, *supra* note 6, § IV(D).

¹⁰ See, e.g., James O. Odek, *Bio-Piracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. INTELL. PROP. L. 141, 145-49 (1994); Valentina Tejera, Note, *Tripping over Property Rights: Is It Possible to Reconcile the Convention on Biological Diversity with Article 27 of the TRIPS Agreement?*, 33 NEW ENG. L. REV. 967, 972 (1999); Craig Benjamin, *Biopiracy and Native Knowledge: Indigenous Rights on the Last Frontier*, NATIVE AMERICAS, June 30, 1997, available at 1997 WL 15895006; Vandana Shiva, *The U.S. Patent System Legalizes Theft and Biopiracy*, THE HINDU, at <http://www.purefood.org/Patent/USpatsys.cfr> (July 28, 1999). In 1997, corporations and government agencies were researching 1000 traditional plants and their uses. Benjamin, *supra*. For instance, in a period of five years the National Cancer Institute collected 10,000 plant specimens from six countries. *Id.* Although it is a publicly funded organization, the Institute obtains patents on discoveries that have potential commercial value. *Id.*

ied uses of local plants and animals.¹¹ These researchers are free to return to their countries with their plant or animal samples, isolate a chemical compound, and subsequently obtain a patent.¹² Protected by their patents, the researchers are not bound to share in the profits from their patented items with the indigenous tribes from whom they gained the critical knowledge.¹³ This activity has come to be known as "biopiracy."¹⁴

Biopiracy has been on the rise ever since a 1980 U.S. Supreme Court decision held that people could patent biological living organisms.¹⁵ In response, many developing countries have enacted legislation designed to protect their natural resources, often by drastically cutting foreign-researchers' access to some of the most diverse ecosystems in the world.¹⁶

Exacerbating the situation, the United States does not recognize prior foreign use of an "invention" as a bar to obtaining a patent unless such foreign use has been published and is available for all to find.¹⁷ In contrast, prior domestic use of an "invention" is enough, without publication, to preclude issuance of a patent.¹⁸ This differing treatment of domestic and foreign use dates back to a time when inventors in this country likely would not have known that an invention

¹¹ See Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279, 279 (1999); Tejera, *supra* note 10, at 971; see also Lakshmi Sarma, Note, *Biopiracy: Twentieth Century Imperialism in the Form of International Agreements*, 13 TEMP. INT'L & COMP. L.J. 107, 108 (1999).

¹² See Marden, *supra* note 11, at 279; Roht-Arriaza, *supra* note 6, at 938.

¹³ See Scott Holwick, Note, *Developing Nations and the Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1999 Y.B. COLO. J. INT'L ENVTL. L. & POL'Y 49, 57-58 (2000); Sarma, *supra* note 11, at 108; see also Roht-Arriaza, *supra* note 6, at 938. See generally Odek, *supra* note 10, at 145-49 (discussing examples of uncompensated appropriation of plant genetic resources).

¹⁴ See David R. Downes, *How Intellectual Property Could Be a Tool to Protect Traditional Knowledge*, 25 COLUM. J. ENVTL. L. 253, 263 (2000); Odek, *supra* note 10, at 145; Sarma, *supra* note 11, at 117; Tejera, *supra* note 10, at 971; Shiva, *supra* note 10; see also Marden, *supra* note 11, at 280.

¹⁵ See *Diamond v. Chakrobarty*, 447 U.S. 303, 309 (1980); Andrew J. Pollack, *Biological Products Raise Genetic Ownership Issues: Governments Are Demanding Share of Profits*, N.Y. TIMES, Nov. 26, 1999, at C4.

¹⁶ See Pollack, *supra* note 15, at C4. For instance, Brazilian environmentalists sued a non-governmental organization alleging that it stole traditional knowledge from indigenous peoples. See Mario Osava, *Brazil-Biodiversity: Crackdown on Eco-Pirates*, INTER. PRESS SERVICE, Aug. 14, 1997, available at 1997 WL 13256081. Since the suit, legislative proposals have been put forth in an attempt to protect Brazil's biodiversity by imposing harsh penalties on biopirates claiming rights to biological materials taken from the rain forests. See *id.*

¹⁷ See 35 U.S.C. § 102 (1994).

¹⁸ See *id.*

that was new in the United States was in fact common knowledge elsewhere.¹⁹ With modern technological and communications advances, the foreign use exclusion has come under increased criticism.²⁰ Unlike in previous centuries, the ease of international travel and research today makes prior foreign use of an invention accessible to U.S. researchers.²¹

Since most of the world's remaining biodiversity is concentrated in underdeveloped southern countries, such as Brazil and India, increasing protectionism on the part of these developing nations could significantly impair research regarding the fight against diseases.²² This result is not in anyone's best interest.²³ In order to reverse this protectionist trend, the United States and other developed nations should consider ways to reform domestic patent laws as well as international patent treaties to reflect more accurately the needs of developing countries and their indigenous populations.

Part I of this Note will discuss the current U.S. patent law regarding prior foreign use or knowledge. In particular, Part I will discuss how the current U.S. policy discriminates against developing nations and their indigenous populations by failing to value traditional knowledge. Part II will then illustrate the detrimental effect U.S. policy has on developing countries by offering a more detailed description of the ayahuasca patent controversy. Finally, Part III will suggest ways to reform current U.S. patent policy. In particular, Part III argues that the U.S. should: (1) enforce the public policy and morality aspects of current patent law so that morally offensive patents are not issued; (2) alter its current patent law to recognize prior foreign use as a bar to issuance of a patent; and (3) urge reform of the Agreement on Trade-Related Aspects of Intellectual Property Rights, so that, like the United Nations Framework Convention on Biological Diversity, it would seek a more equal distribution of the benefits de-

¹⁹ See Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy*, 37 IDEA 371, 386 (1997) (citing Donald S. Chisum, *Foreign Activity: Its Effect on Patentability under United States Patent Law*, 11 INT'L REV. INDUS. PROP. & COPYRIGHT L. 26, 36 (1980)).

²⁰ See Marden, *supra* note 11, at 289; see also Roht-Arriaza, *supra* note 6, at 936. See generally Kadidal, *supra* note 19.

²¹ See Kadidal, *supra* note 19, at 397.

²² See Roht-Arriaza, *supra* note 6, at 926-27; Pollack, *supra* note 15, at A1. A large amount of the Earth's genetic diversity has already disappeared. See Roht-Arriaza, *supra* note 6, at 926-27. For example, ninety percent of all the vegetable types distributed by seed houses in the United States early in the twentieth century are extinct today. *Id.* In the past 100 years, half of Europe's domestic animal species became extinct. *Id.*

²³ See, e.g., Roht-Arriaza, *supra* note 6, at 927; Pollack, *supra* note 15, at A1.

rived from biodiversity between developed and developing nations. This Note concludes that, by implementing the three measures mentioned above, the United States would improve considerably its relations with resource-rich developing nations. It further concludes that these measures would help to ensure that biologically diverse ecosystems and traditional knowledge systems are preserved so that they continue to be available in the future as a source for the discovery and development of new pharmaceutical and agricultural products.

I. CURRENT U.S. PATENT LAW AND POLICY

A. Requirements for Patentability

In order to receive a patent under U.S. law, an individual must demonstrate the (1) novelty; (2) non-obviousness; and (3) utility of her invention.²⁴ Although these are useful measures for determining whether an inventor deserves an exclusive property right, as presently applied, these criteria result in discrimination toward indigenous groups in developing nations.²⁵

1. Novelty

Federal law requires that, in order to obtain a patent on an invention or discovery, the invention or discovery must be new.²⁶ Section 102(a) of the Patent Act provides that a person can obtain a patent unless "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."²⁷ Thus, an important goal of the U.S. Patent Act is to distinguish claimed inventions from prior inventions to ensure that patents are only granted for products and processes that are actually new.²⁸ When deciding whether or not to issue a patent, patent examiners look to

²⁴ See 35 U.S.C. §§ 101–103 (1994).

²⁵ See Sarma, *supra* note 11, at 130; CIEL, *supra* note 6, § II; see also Roht-Arriaza, *supra* note 6, at 936–40.

²⁶ See 35 U.S.C. § 102(a); DURHAM, *supra* note 6, at 80.

²⁷ 35 U.S.C. § 102(a). In addition to § 102(a)'s prior art categories that preclude issuance of a patent, § 102(b) states that a person shall be entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . ." *Id.* § 102(a)–(b).

²⁸ See DURHAM, *supra* note 6, at 80.

the existence of any prior art references.²⁹ Prior art references include: prior inventions, patents, patent applications, and publications discussing prior inventions.³⁰ The specific types of prior art references upon which the Patent and Trademark Office (PTO) relies are listed in 35 U.S.C. § 102.³¹ In particular, § 102(a) identifies four categories of prior art references that preclude issuance of a patent: (1) prior knowledge of the invention by others in the United States; (2) prior use of the invention in the United States; (3) prior patent of the invention in any country; and (4) the printed publication of the invention in any country.³²

As § 102(a) demonstrates, prior use or knowledge of an invention in this country is enough to preclude issuance of a patent, while the same prior use or knowledge in a foreign country has no effect on patentability.³³ The reason for this apparent double standard is that, historically, U.S. patent laws have based prior art references on accessibility.³⁴ In other words, the use or knowledge of a prior invention, must be accessible to the public in this country.³⁵ While foreign publications or patents meet this criteria, unpublished foreign use or knowledge do not.³⁶ This distinction has the effect of discriminating against indigenous populations in foreign countries because their traditional knowledge is rarely published.³⁷ Furthermore, such a distinction is not useful in the bio-piracy arena: biopirates who “discover” new species of plants and animals are able to pass the novelty requirement, even though indigenous people have often led them to the “new” species and imparted to them information about its traditional use.³⁸ Thus, by granting patents in this type of situation, U.S.

²⁹ See *id.* at 80–81.

³⁰ See *id.*

³¹ 35 U.S.C. § 102(a).

³² *Id.*

³³ See *id.*; Kadidal, *supra* note 19, at 380, 385. To prove prior use one must show that the prior user had a physical embodiment of the claimed invention, used the invention as the current applicant intends, and did not conceal his use of the invention. See *id.* at 381–82. Prior knowledge requires that there was a model or written procedure that if reduced to practice would have worked in the way that the current applicant intends. *Id.* at 381.

³⁴ See DURHAM, *supra* note 6, at 82.

³⁵ See *id.* at 83.

³⁶ See 35 U.S.C. § 102(a).

³⁷ See Sarma, *supra* note 11, at 130; see also Downes, *supra* note 14, at 277–78.

³⁸ See Roht-Arriaza, *supra* note 6, at 926, 928; Sarma, *supra* note 11, at 116–17. Bio-prospectors who inquire from indigenous people about useful plants can increase the success ratio of their trials for useful substances from 1 in 10,000 to 1 in 2. See Roht-Arriaza, *supra* note 6, at 928.

patent law seems to violate the very goals that underpin the novelty requirement.³⁹

2. Non-Obviousness

In addition to the novelty requirement, § 103 of the Patent Act also requires that an invention or discovery be non-obvious in order to be patentable.⁴⁰ The non-obviousness requirement precludes any invention that would have been obvious at the time of invention to a person with ordinary skill in the particular art.⁴¹

As under the novelty requirement, the prior art relied upon to determine whether an invention is obvious would not cover prior knowledge or use in a foreign country.⁴² As a result, the “person with ordinary skill in the particular art” would not include a member of an indigenous population in a foreign country.⁴³ Therefore, the non-obviousness requirement discriminates against indigenous persons in the same way as the novelty requirement.⁴⁴ In addition, this effect on indigenous persons is often exacerbated when the invention involves chemical compounds because indigenous use of a plant does not require isolation of the chemical compounds that make up the plant.⁴⁵ If prior art references show that a compound likely contains certain

³⁹ See 35 U.S.C. § 102(a); DURHAM, *supra* note 6, at 82; Roht-Arriaza, *supra* note 6, at 921, 926, 928.

⁴⁰ 35 U.S.C. § 103.

⁴¹ See *id.* 35 U.S.C. § 103(a) reads:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, 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.

Id. § 103(a). For a helpful case, see *Graham v. John Deere Co.*, which holds that obviousness or non-obviousness of subject matter is to be determined by looking to the scope and content of prior art, the differences between prior art and claims at issue, and the level of ordinary skill in the pertinent art. See 383 U.S. 1, 17 (1966); see also Roht-Arriaza, *supra* note 6, at 937. An inventor who simply examines prior knowledge and follows the next logical step to solve a problem, has not met the nonobviousness requirement of the Patent Act. See *Graham*, 383 U.S. at 17; see also Roht-Arriaza, *supra* note 6, at 937.

⁴² See 35 U.S.C. §§ 102(a), 103.

⁴³ See *id.*; Sarma, *supra* note 11, at 130.

⁴⁴ See Sarma, *supra* note 11, at 129–30.

⁴⁵ See Roht-Arriaza, *supra* note 6, at 937.

qualities, patent applicants must rebut the presumption of obviousness.⁴⁶

A common method of rebutting the presumption is to show that the new compound displays "unexpectedly improved properties."⁴⁷ Because plants are made up of biochemical compounds, the isolation of these compounds must prove that the new genetic configuration displays "unexpected properties."⁴⁸ Therefore, it is nearly impossible for indigenous groups to obtain patents on their own innovations because their unprocessed uses of medicinal plants would be considered obvious.⁴⁹ Furthermore, indigenous communities have no means and no need to improve the chemical compounds of plants in order to meet the non-obviousness requirement.⁵⁰ Unlike Western research companies, indigenous peoples have no need to isolate compounds for mass marketing; rather, they rely on these plants mainly for local subsistence.⁵¹

3. Utility

The third major requirement for patentability is utility.⁵² As the term suggests, the utility requirement mandates that an invention or discovery must be useful in order to be patented.⁵³ This requirement is set out in § 101 of the Patent Act, and is based on Article I, Section 8 of the U.S. Constitution, which grants Congress the power to promote the progress of science and the *useful arts*.⁵⁴ The utility requirement is a relatively easy one for a patent applicant to fulfill: an invention can be quite trivial, but if it has any fathomable use it will generally pass the utility requirement.⁵⁵ In fact, even if an invention is inferior to a prior invention that serves the same purpose it can still be patented.⁵⁶

The only kinds of inventions or discoveries that have been precluded from patentability on the grounds of non-utility are those for

⁴⁶ See *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990); Roht-Arriaza, *supra* note 6, at 937.

⁴⁷ See *Dillon*, 919 F.2d at 692-93; see also Roht-Arriaza, *supra* note 6, at 937.

⁴⁸ See *Ex parte Gray*, 10 U.S.P.Q.2d (BNA) 1922, 1924 (Bd. Pat. App. & Interf. 1989); Roht-Arriaza, *supra* note 6, at 937.

⁴⁹ See Roht-Arriaza, *supra* note 6, at 937.

⁵⁰ See *id.*

⁵¹ See *id.* at 938, 940.

⁵² See 35 U.S.C. § 101 (1994).

⁵³ See *id.*

⁵⁴ See U.S. CONST. art. I, § 8; 35 U.S.C. § 101 (emphasis mine).

⁵⁵ See DURHAM, *supra* note 6, at 64.

⁵⁶ See *id.*

purposes deemed illegal or immoral.⁵⁷ For example, any invention useful only in committing a crime or fraud, such as a method of counterfeiting currency, could be unpatentable for public policy reasons.⁵⁸

B. Current U.S. International Patent Policy

In addition to maintaining domestic patent laws that discriminate against foreign indigenous knowledge, the United States also supports international agreements which impose traditional Western patent systems on less-developed, resource-rich countries.⁵⁹ One such agreement involving intellectual property rights is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), a result of the Uruguay Round of trade agreements.⁶⁰ While fully supporting TRIPS, the United States has failed to ratify the 1992 Convention on Biological Diversity (Biodiversity Convention) which, unlike TRIPS, lists the sharing of benefits arising from the use of traditional knowledge as a goal.⁶¹

1. TRIPS

The goal of TRIPS is to “reduce distortions and impediments to international trade [by] taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade”⁶²

⁵⁷ See *id.*

⁵⁸ See *id.*

⁵⁹ See Roht-Arriaza, *supra* note 6, at 936; Holwick, *supra* note 13, at 52–53; Sarma, *supra* note 11, at 107, 124; see also VANDANA SHIVA, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE* 81 (1997). Shiva notes that TRIPS was conceived and shaped by coalitions of U.S., Japanese and European corporations. See generally *id.*

⁶⁰ See generally Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

⁶¹ See Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255, 255–56 (1998); TRIPS Agreement, *supra* note 60; Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818, 837 (1992) [hereinafter Biodiversity Convention]; Convention on Biological Diversity, 3 DEP’T ST. DISPATCH 423 (June 1, 1992) [hereinafter DEP’T STATE DISPATCH]; John Passacantando, Commentary, *U.S. Insists on Loopholes for Toxics*, L.A. TIMES, Dec. 8, 2000, at B9.

⁶² TRIPS Agreement, *supra* note 60, pmbl.

In short, the agreement requires that signatory nations adopt intellectual property legislation that conforms to the treaty's provisions.⁶³

The provisions to which signatory nations must conform mirror the U.S. Patent Act's requirements of novelty, non-obviousness, and utility.⁶⁴ The agreement further states that a newly created World Trade Organization Council (WTO) for TRIPS will monitor compliance with TRIPS' terms and oversee disputes between Member States.⁶⁵ To date, the WTO's dispute resolution process has been successfully used to resolve patent enforcement problems before trade sanctions were imposed.⁶⁶ For instance, in 1997, both India and Pakistan had failed to comply with the requirement of enacting a system of intellectual property laws.⁶⁷ This is because each of these countries has until 2005 to pass patent legislation that conforms with TRIPS.⁶⁸

⁶³ See generally TRIPS Agreement, *supra* note 60. Prior to TRIPS, international treaties, such as the Paris Convention, Berne Convention, and Washington Treaty, did not set requirements for minimum levels of domestic intellectual property protection. See John E. Giust, *Noncompliance with TRIPS by Developed and Developing Countries: Is TRIPS Working?*, 8 *IND. INT'L & COMP. L. REV.* 69, 71 (1997). In contrast, TRIPS is replete with requirements for minimum levels of protection, thereby directly regulating intellectual property protection in each Member State. See *id.*

⁶⁴ See TRIPS Agreement, *supra* note 60, art. 27(1); Roht-Arriaza, *supra* note 6, at 953. Article 27(1) states: "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. . . ." TRIPS Agreement, *supra* note 60, art. 27(1). Some scholars have argued that the phrase "capable of industrial application" includes only innovations meant to be used in the industrial sector. See Roht-Arriaza, *supra* note 6, at 939. Equating the phrase to the U.S. requirement of "useful" allows for a broader interpretation. See *id.* However, as Roht-Arriaza points out, the very name of TRIPS—Trade-Related Intellectual Property Rights—illustrates the treaty's application to goods subject to international trade, excluding goods that are primarily used locally. See *id.*

⁶⁵ See Office of the U.S. Trade Representative, Executive Office of the President, The Uruguay Round Agreements Act, Statement of Administrative Action, Agreement on Trade-Related Aspects of Intellectual Property Rights, ¶ A.15, Sept. 27, 1994, available at 1994 WL 761796 [hereinafter Administrative Action].

⁶⁶ See *Violations of Intellectual Property Rights: How Do We Protect American Ingenuity?: Hearings Before the House Subcomm. on Int'l Econ. Pol'y and Trade of House Comm. on Int'l Relations*, 106th Cong. (1999) (statement of Ambassador Richard W. Fisher, Deputy U.S. Trade Representative), available at 1999 WL 27595601 [hereinafter Fisher]; see, e.g., World Trade Organization, *Pakistan-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Mar. 7, 1997, available at 1997 WL 371039 [hereinafter WTO].

⁶⁷ See Fisher, *supra* note 66; see also Sarma, *supra* note 11, at 133.

⁶⁸ See TRIPS Agreement, *supra* note 60, art. 65(4); Giust, *supra* note 63, at 91. Under article 65, a developing country has five years from the date that TRIPS went into effect (Jan. 1, 1995) to apply its provisions. TRIPS Agreement, *supra* note 60, art. 65(2). Additionally, to the extent that a developing country Member is obliged by the Agreement to extend product patent protection to areas of technology that were not formerly covered, it may delay the application of the provisions on product patents to such areas of technology for another five years. *Id.* art. 65(4).

In the interim, TRIPS requires these countries to set up "mailbox" systems for holding patent applications until passage of new legislation.⁶⁹ After these countries enact a permanent patent system that is in compliance with TRIPS requirements, the applications in the "mailbox" will receive priority dates as of the dates that they were originally submitted.⁷⁰ The failure of India and Pakistan to comply with TRIPS' "mailbox" requirement led the United States to file dispute resolution proceedings with the WTO against each country.⁷¹ The proceeding against Pakistan resulted in a settlement requiring Pakistan to pass an ordinance creating a "mailbox" system.⁷² The United States dropped its complaint when Pakistan complied with this requirement in 1997.⁷³ The case against India was resolved by the WTO Appellate Body, which upheld a panel ruling in favor of the United States.⁷⁴ As a result, the Indian government promulgated a temporary ordinance to meet its "mailbox" rule obligations.⁷⁵ In 1999, despite significant domestic opposition, India passed permanent legislation entitled the Patents (Amendment) Act, which updated India's patent system in order to cover pharmaceutical and agricultural chemical products.⁷⁶

⁶⁹ See *id.* art. 70(8)(a); Giust, *supra* note 63, at 91. Article 70(8)(a) of TRIPS reads:

Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligation under Article 27, that Member shall: (a) . . . provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed. . . .

TRIPS Agreement, *supra* note 60, art. 70(8)(a).

⁷⁰ See *id.* art. 70(8)(b).

⁷¹ See Fisher, *supra* note 66.

⁷² See WTO, *supra* note 66.

⁷³ See *id.*

⁷⁴ See Fisher, *supra* note 66.

⁷⁵ See *id.*; World Trade Organization, *Communication from the Permanent Mission of India, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Apr. 16, 1999, available at 1999 WL 231665.

⁷⁶ See Fisher, *supra* note 66. Prior to 1999, India's patent law did not protect agricultural, horticultural or medical products or processes. See Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507, 519-20, 524-25 (1996). India's weak patent protection and protectionist laws favored domestic manufacturers of pharmaceuticals. See *id.* at 519-20. For instance, Indian producers could copy the latest drugs from throughout the world and sell them in the domestic market. See *id.* These companies quickly gained in efficiency and became very competitive in the world market. See *id.*

The drawback to India's patent system was that Indian companies had no incentive to invest in research and development. See J.H. Reichman, *Compliance with the TRIPS Agree-*

In creating a system granting patents on agricultural and pharmaceutical products, India was complying with article 27 of TRIPS.⁷⁷ Article 27 states that signatory countries must protect property rights in genetic plant resources "either by patents or by an effective sui generis system or by any combination thereof."⁷⁸ However, many peo-

ment: Introduction to a Scholarly Debate, 29 VAND. J. TRANSNAT'L L. 363, 379 (1996). Proponents of TRIPS argue that expansion of India's patent system to cover pharmaceuticals will encourage domestic companies to invest in the research and development of drugs to combat diseases of local importance. *See id.* However, opponents of TRIPS point to the experience of Italy, since its introduction of strong patent protection for pharmaceutical products in 1978. *See* F.M. Scherer & Sandy Weisburst, *Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy*, 26 IIC 1009, 1023 (1995). Scherer and Weisburst concluded that "the legitimization of drug product patents in Italy did not induce a marked shift in Italian pharmaceutical manufacturers' strategic emphasis from emulating drugs developed elsewhere to developing innovative drugs." *Id.* Furthermore, research and development "expenditure growth . . . did not accelerate after the patent regime transition" and "the number and character of new product launches did not change significantly." *Id.* Given the results in Italy, Scherer and Weisburst doubt that "significantly increased new drug development efforts are likely in the nations required under the . . . [TRIPS Agreement] to offer drug product patents for the first time." *Id.* at 1024.

⁷⁷ *See* TRIPS Agreement, *supra* note 60, art. 27(3)(b).

⁷⁸ *Id.* Art. 27(3)(b) reads:

Members may also exclude from patentability . . . plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

Id. The TRIPS Agreement does not define what is meant by an "effective sui generis system." *See id.* Yet, some commentators believe that this reference is intended to refer to a system modeled after the International Convention for the Protection of New Varieties of Plants (UPOV). *See* International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703 [hereinafter UPOV]; Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 111, 124 (1996) (stating that European nations adopted sui generis plant protection under UPOV rather than patent-based protection); J. Benjamin Bai, Comment, *Protecting Plant Varieties under TRIPS and NAFTA: Should Utility Patents be Available for Plants?*, 32 TEXAS INT'L L.J. 139, 140 (1997) (suggesting that the UPOV is a suitable system of protection on the international level). The UPOV sets minimum standards and assigns rights for both the finding and breeding of new plant species. Roht-Arriaza, *supra* note 6, at 941. Unlike patents, plant breeder rights allow the free use of a protected variety in order to breed and commercialize other new varieties. *Id.* Originally, the UPOV let farmers save seeds from season to season without paying royalties to the seed companies. *Id.* However, since its inception, the UPOV has been altered to give more protection to plant breeders and less to farmers. *Id.* In addition, like under a patent system, traditional farmers are not allowed protection for their innovative breeding work under UPOV. *Id.* To obtain UPOV protection, a plant must be: differentiated from existing plants through "precise recognition and description"; uniform or "sufficiently homogeneous"; and "stable in its essential characteristics." *Id.* (quoting UPOV, art. 4). While most developed states are parties to UPOV, practically no developing states have signed. *Id.*

ple in developing countries that have signed TRIPS are critical of assigning property rights in plant resources.⁷⁹ This requirement does not take into account the differing cultural perspectives of indigenous groups in member states regarding the commodification of biological resources.⁸⁰ In particular, it disregards the contributions of indigenous groups in discovering and nurturing the medicinal and agricultural uses of plants over the centuries.⁸¹

Historically, international law has allowed sovereign nations control over all persons and things within their territory, which means that lesser developed nations could act to protect the cultural knowledge of their people.⁸² However, these countries were economically pressured by developed countries to sign TRIPS, which prevents them from passing protectionist laws.⁸³ Many lesser developed nations succumbed to this pressure as a means of equalizing their economies with those of developed nations at the expense of their indigenous populations who consider their cultural knowledge as community, rather than private, property.⁸⁴

TRIPS has effectively resulted in continued exploitation of indigenous knowledge.⁸⁵ Some scholars have referred to this exploitation as a form of modern-day imperialism.⁸⁶ In this regard, article 27 of the TRIPS Agreement is in direct opposition to the goals of the Biodiversity Convention.⁸⁷

⁷⁹ See Sarma, *supra* note 11, at 113; *Indigenous Peoples' Seattle Declaration on the Occasion of the Third Ministerial Meeting of the World Trade Organization*, § 3(a), at http://www.nativeweb.org/manifestos/seattle_wto.html (Nov. 30-Dec. 3, 1999) [hereinafter *Seattle Declaration*].

⁸⁰ See Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 WAKE FOREST L. REV. 89, 122-23 (1993); Sarma, *supra* note 11, at 113.

⁸¹ See Roht-Arriaza, *supra* note 6, at 936; Sarma, *supra* note 11, at 113; see also Downes, *supra* note 14, at 277-78.

⁸² See Odek, *supra* note 10, at 168.

⁸³ See Sarma, *supra* note 11, at 109. TRIPS has been criticized for requiring developing countries to pass strong patent laws. See Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 52 (1998). Developing countries tend to regard patents as a means for developed countries "to maintain their head start in technology and deny a transfer of technology so that [the developing countries] can begin their own research and development industries." Bosselmann, *supra* note 78, at 127.

⁸⁴ See Sarma, *supra* note 11, at 109.

⁸⁵ See *id.* at 111-12, 118, 125.

⁸⁶ See, e.g., SHIVA, *supra* note 59; Marci A. Hamilton, *The TRIPS Agreement: Imperialistic, Outdated, and Overprotective*, 29 VAND. J. TRANSNAT'L L. 613, 613 (1996).

⁸⁷ See Biodiversity Convention, *supra* note 61, pmbli., art. 8(j); TRIPS Agreement, *supra* note 60, art. 27; Sarma, *supra* note 11, at 121.

2. The Biodiversity Convention

The United Nations Framework Convention on Biological Diversity, concluded in 1992 in Rio de Janeiro, endeavors to conserve the world's biological resources and to forward sustainable development.⁸⁸ Unlike TRIPS, the Biodiversity Convention recognizes and acknowledges the value of indigenous knowledge of regional biological resources.⁸⁹ Article 8(j) of the Convention states that respect and preservation should extend to "innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity"⁹⁰ In addition, article 9 of the Convention urges nations to include indigenous and local communities in the conservation and sustainable use of biological diversity.⁹¹ In so doing, the Biodiversity Convention recognizes, for the first time in an international treaty, the important role played by indigenous populations in the gathering and preservation of cultural knowledge regarding regional biodiversity.⁹²

Despite its laudable goals, the Biodiversity Convention has been criticized for investing in the governments of developing nations rather than in local communities, the sovereign right to control access to biodiversity located within their borders.⁹³ In these nations, the result has been a great incentive for prospecting agreements between governments and foreign researchers.⁹⁴ Prospecting agreements "provide a means by which the global community can turn local governments and peoples into biodiversity stakeholders, thus creating a viable economic alternative to competing ecologically destructive sources of income."⁹⁵ However, prospecting will not fulfill the goals of the Biodiversity Convention unless each agreement provides compensation to the indigenous and local groups who have preserved their

⁸⁸ See Biodiversity Convention, *supra* note 61, art. 1; McManis, *supra* note 61, at 255.

⁸⁹ See Biodiversity Convention, *supra* note 61, pmbl.

⁹⁰ *Id.* art. 8(j).

⁹¹ See *id.* art. 9. The Biodiversity Convention seeks to help indigenous people in lesser developed countries by recognizing their governments' sovereign rights over indigenous knowledge within their borders. See Steven M. Rubin & Stanwood W. Fish, *Biodiversity Prospecting: Using Innovative Contractual Provisions to Foster Ethnobiological Knowledge, Technology, and Conservation*, 5 COLO. J. INT'L ENVTL. L. & POL'Y 23, 34-36 (1994) (discussing Biodiversity Convention, articles 11, 15, 16 and 18 regarding importance of proper compensation to local people).

⁹² Roht-Arriaza, *supra* note 6, at 949.

⁹³ See *id.*

⁹⁴ See Rubin & Fish, *supra* note 91, at 35; Sarma, *supra* note 11, at 122.

⁹⁵ Rubin & Fish, *supra* note 91, at 32.

traditional knowledge.⁹⁶ Presently, the goal of the Biodiversity Convention to ensure that the contributions of indigenous populations are respected is thwarted in that the holders of traditional knowledge are still exploited.⁹⁷ The only difference is that the exploitation under the Biodiversity Convention is by their own governments.⁹⁸

Another roadblock to the success of the Biodiversity Convention is the failure of the United States to ratify it.⁹⁹ Since its inception, the United States has been critical of the Biodiversity Convention because it would impair American intellectual property rights.¹⁰⁰ The State Department voiced the United States' concerns about the Convention in 1992, stating that it focused on intellectual property rights "as a constraint to the transfer of technology rather than as a prerequisite."¹⁰¹

The Clinton Administration eventually signed the Biodiversity Convention in 1993, but only after considerable lobbying efforts by pharmaceutical and biotechnology firms.¹⁰² These firms had changed their position from opposition of the Biodiversity Convention to promotion of it, due to fear that continued opposition would exclude U.S. companies from opportunities to explore genetic resources in developing countries and preclude U.S. involvement in future negotiations interpreting the exact meaning of the Convention.¹⁰³ After signing the Biodiversity Convention, Clinton stated that future legislation ratifying the Convention would illustrate the White House's interpretation and would highlight the United States' concern that the Convention fails to protect intellectual property rights.¹⁰⁴ However, Congress never took up the issue of the Convention and has yet to ratify it.¹⁰⁵

⁹⁶ See *id.* at 35.

⁹⁷ See Biodiversity Convention, *supra* note 61, art. 8(j); Sarma, *supra* note 11, at 122-23.

⁹⁸ See Sarma, *supra* note 11, at 123.

⁹⁹ See McManis, *supra* note 61, at 257.

¹⁰⁰ See *id.* at 256. Shortly before the "Earth Summit" in Rio, President Bush expressed U.S. opposition to the Biodiversity Convention. See *id.* The United States interpreted the Biodiversity Convention as allowing countries to require technology transfer in exchange for access to genetic resources, and, therefore, found it unacceptable. See Amy E. Carroll, Comment, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2477-78 (1995).

¹⁰¹ DEP'T ST. DISPATCH, *supra* note 61.

¹⁰² See McManis, *supra* note 61, at 256.

¹⁰³ See *id.*

¹⁰⁴ See *id.* at 257.

¹⁰⁵ See *id.*

Despite the Biodiversity Convention's flaws, its underlying assumption that indigenous communities should share in the profits of inventions resulting from their traditional knowledge is a valid one.¹⁰⁶ The failure of the U.S. Congress to ratify the Biodiversity Convention is yet another way in which U.S. patent policy fails to acknowledge the value of indigenous cultural knowledge. The real life discriminatory effect of U.S. patent law and U.S. international patent policy is well illustrated by the controversy surrounding the ayahuasca patent.

II. THE AYAHUASCA PATENT

As described above, upon learning of Loren Miller's patent on ayahuasca, many indigenous tribes of South America organized to oppose the patent on the ground that the vine was a sacred religious symbol and a known medicinal herb.¹⁰⁷ This effort by the indigenous tribesmen and their attorneys proved very successful, and on November 3, 1999, the United States Patent and Trademark Office (PTO) ultimately rejected Miller's patent.¹⁰⁸ This section will describe in more detail the history of this patent and its eventual revocation.

A. Issuance of the Patent

In 1974, a tribe in Ecuador gave Loren Miller samples of a local ayahuasca vine.¹⁰⁹ In return for the plants, Miller claims to have built a school for the tribe's people.¹¹⁰ Upon returning to the United States, Miller cultivated the plant in Hawaii and developed a stable variety that was eligible for a patent.¹¹¹ He then formed a small company, International Plant Medicine, to investigate whether the plant had any useful purpose.¹¹²

In 1986, Miller obtained a plant patent on his ayahuasca, which he called "Da Vine."¹¹³ In his patent application, he stated merely that he had originally obtained the ayahuasca from a "domestic garden in the Amazon rain-forest of South America."¹¹⁴ He claimed that Da Vine

¹⁰⁶ See Roht-Arriaza, *supra* note 6, at 949.

¹⁰⁷ See Wiser, *supra* note 1, § 2.

¹⁰⁸ See *id.* § 5.

¹⁰⁹ See Pollack, *supra* note 15, at C4.

¹¹⁰ See *id.*

¹¹¹ See *id.*

¹¹² See *id.* Mr. Miller has said that the effort to find a distributable medicinal use for ayahuasca was unsuccessful and he has no plans to study it further. See *id.*

¹¹³ See U.S. Plant Patent No. 5751 (issued June 17, 1986); Wiser, *supra* note 1, § 2.

¹¹⁴ U.S. Plant Patent No. 5751 (issued June 17, 1986); see Wiser, *supra* note 1, § 2.

represented a new and unique variety of ayahuasca distinct from other forms primarily because of the color of its flower petals.¹¹⁵

In 1994, the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) discovered that Miller had obtained a patent on ayahuasca.¹¹⁶ Perplexed at the idea of an outsider “discovering” a plant that had been used by their ancestors since ancient times, some tribes in Ecuador reacted in a hostile fashion.¹¹⁷ One coalition actually issued a threat of bodily harm to Miller should he ever return to the Amazon Basin.¹¹⁸ This threat, in turn, led the United States to cancel all aid to the indigenous tribal group.¹¹⁹ COICA also learned that Miller intended to build a pharmaceutical laboratory in Ecuador to process ayahuasca.¹²⁰ This discovery prompted fear among COICA members that a bilateral intellectual property reciprocity agreement being forged between the United States and Ecuador would force indigenous peoples to recognize Miller’s proprietary rights over a plant which they viewed as sacred.¹²¹

B. PTO Re-Examination of the Ayahuasca Patent

COICA and the Amazon Coalition both decided that the best way to assert tribal rights to their cultural knowledge and their sacred plant was to object formally to Miller’s patent.¹²² The tribal organizations set out to use the U.S. patent law as a tool in their fight.¹²³ They began working with attorneys at the Center for International Environmental Law (CIEL) to prepare a Request for Re-examination of the patent.¹²⁴

Attorneys from CIEL filed the Request for Reexamination of the ayahuasca patent on March 30, 1999.¹²⁵ In their Request, they argued

¹¹⁵ See U.S. Plant Patent No. 5751 (issued June 17, 1986).

¹¹⁶ See Wisner, *supra* note 1, § 2.

¹¹⁷ See Lambrecht, *supra* note 7, at A5.

¹¹⁸ See *id.* The indigenous tribes declared Mr. Miller an “enemy of indigenous peoples” and stated that if Miller or his associates returned to the Amazon, tribes “will not be responsible for the consequences to their physical safety.” See *id.* (quoting COICA).

¹¹⁹ See *id.* The U.S.-based Inter-American Foundation stopped all aid to COICA in 1998, after allotting more than \$500,000 in recent years. See *id.*

¹²⁰ See Wisner, *supra* note 1, § 2.

¹²¹ See *id.* To the tribes, the ayahuasca vine has a similar religious significance to the Christian cross. See *id.* § 1.

¹²² See *id.* § 3.

¹²³ See *id.*

¹²⁴ See *id.*

¹²⁵ See Wisner, *supra* note 1, § 3; see also DURHAM, *supra* note 6, at 38 (explaining that re-examination allows the Patent Office to reconsider and reject previously issued patents in

that prior art revealed that Da Vine was not, in fact, distinct or new, thus failing the Patent Act's requirement of novelty.¹²⁶ Miller's patent application described ayahuasca as it was already illustrated in scientific literature and known by indigenous Amazonian peoples.¹²⁷ The CIEL attorneys further argued that the Da Vine patent violated the Plant Patent Act because the vine is "found in an uncultivated state."¹²⁸ Lastly, the attorneys charged that the patent on ayahuasca violated the Patent Act's utility requirement because issuing a patent on a plant that is sacred to indigenous peoples violates notions of public policy and morality.¹²⁹

On May 28, 1999, based on the fact that Da Vine was identical to other specimens of ayahuasca found in U.S. herbarium collections, the PTO granted the Reexamination Request.¹³⁰ In November 1999, after reviewing the facts, the PTO ordered the rejection of Miller's patent on the narrow ground that the same plant had been described in herbarium sheets in Chicago's Field Museum over a year prior to Miller's application.¹³¹

By revoking the ayahuasca patent on these narrow grounds, the PTO failed to address the more significant issues of whether the prior use by indigenous tribes or the fact that the plant was a sacred religious symbol precluded issuance of the patent.¹³² In the absence of any attempt by Congress or the U.S. PTO to address the issues raised by the ayahuasca patent, many developing nations have enacted laws making it more difficult for researchers from developed nations to study indigenous plants and animals for possible medicinal value.¹³³

light of newly uncovered prior art). While the public is normally barred from patent prosecutions, anyone can request a reexamination, "... including a licensee, an accused infringer, a government agency or someone who simply likes to meddle. All that is necessary to begin is knowledge of a prior patent or printed publication that casts doubt on the validity of some or all of the patent claims." DURHAM, *supra* note 6, at 38-39 (footnotes omitted).

¹²⁶ See Wisner, *supra* note 1, § 3; see also 35 U.S.C. § 102 (1994).

¹²⁷ See Wisner, *supra* note 1, § 3.

¹²⁸ See 35 U.S.C. § 161; Wisner, *supra* note 1, § 3; see also DURHAM, *supra* note 6, at 177 (explaining that a patent cannot issue for the discovery of a plant in the wild).

¹²⁹ See Wisner, *supra* note 1, § 3.

¹³⁰ See *id.* § 4.

¹³¹ See CTR. FOR INT'L ENVTL. LAW & COALITION FOR AMAZONIAN PEOPLES & THEIR ENV'T, U.S. PATENT OFFICE ADMITS ERROR, REJECTS PATENT CLAIM ON SACRED "AYAHUASCA" PLANT 2, at http://ciel.org/Ayahuasca_RejectionPR.html (Nov. 4, 1999). This is the first time that herbarium sheets have been used to bar someone from obtaining a plant patent. See Wisner, *supra* note 1, § 5(B).

¹³² See Shiva, *supra* note 10; Wisner, *supra* note 1, § 5(A).

¹³³ See Pollack, *supra* note 15, at A1, C4.

In particular, the ayahuasca patent controversy has led Ecuador to reject a proposed bilateral intellectual property rights agreement with the United States.¹³⁴ Ecuador was likely on its way to signing the agreement prior to this controversy.¹³⁵ As the ayahuasca controversy demonstrates, U.S. patent policy (and policies of other developed nations) inevitably leads to international conflict and protectionist response from developing nations. As a result, the resources of developing nations are often effectively cut off from the world, to the detriment of nations on both sides of the dispute. In order to effectively prevent similar reaction from developing nations in the future, the time is ripe to re-evaluate and reform U.S. patent policy.

III. SUGGESTIONS FOR REFORM OF U.S. PATENT LAWS

In order to avoid the ill effects of biopiracy that are demonstrated by the ayahuasca controversy, the United States should reform its patent policy in three distinct ways. First, the PTO should give greater consideration to the morality component of the utility requirement when deliberating an invention's patentability.¹³⁶ For instance, Loren Miller's patent should have been refused on the basis that it was immoral to grant a property right in a religious symbol.¹³⁷ Second, the United States should recognize foreign prior use as a prior art under the Patent Act's novelty requirement.¹³⁸ Such recognition would prevent biopirates like Loren Miller from claiming an exclusive patent right over plants which have been used by indigenous populations for centuries.¹³⁹ Furthermore, recognizing prior foreign use would likely help to convince underdeveloped nations to stop restricting researcher access to their diverse ecosystems.¹⁴⁰ Finally, the United States and other signatory nations should reject TRIPS, as it presently reads, in favor of a reformed treaty which provides a more

¹³⁴ See CIEL, *supra* note 6, § IV(D).

¹³⁵ See *id.*

¹³⁶ See *id.*

¹³⁷ See *id.*

¹³⁸ See Kadidal, *supra* note 19, at 402-03.

¹³⁹ CIEL, *supra* note 6, § III; see also Kadidal, *supra* note 19, at 396-97, 400-01.

¹⁴⁰ See CIEL, *supra* note 6, § III. Although adding foreign prior use as prior art reference would reduce the number of biotechnology patents issued, this decrease in the available monetary compensation for developers could be offset by setting up licensing agreements with indigenous communities wherein the corporate developer shares with the community that supplied the traditional knowledge any royalties from successful drugs or agricultural products. See Laurie Goering, *Brazil Wants Cut of Biotech Firms' Jungle Plunder*, CHI. TRIB., Apr. 6, 1999, at 1.

equitable distribution of the rights over, and benefits deriving from, the world's biodiversity.¹⁴¹ To that end, the United States should support an effort to integrate some of the goals of the 1992 Rio Biodiversity Convention into the TRIPS agreement.¹⁴²

A. *Enforcing the Morality Component of the U.S. Patent Act*

1. Genesis and Rebirth of the Patent Act's Morality Component

There is sufficient ground in the development of the utility requirement to expand its morality component to include things like religious symbols.¹⁴³ The history of the morality component of the utility requirement can be traced to an 1817 Massachusetts case authored by Justice Joseph Story.¹⁴⁴ In that case, *Lowell v. Lewis*, the court found that an invention relating to the construction of water pumps satisfied the utility requirement of the Patent Act.¹⁴⁵ The court reached its decision by concluding, "[a]ll that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral."¹⁴⁶ Thus, from its inception, the utility requirement drew its meaning, in part, from a reliance on morality.¹⁴⁷

Following the *Lowell* decision, other courts in the nineteenth and early twentieth centuries generally struck down patents on the basis of immorality in two types of cases.¹⁴⁸ First, courts struck down inven-

¹⁴¹ See *Item 8: The Relationship Between the TRIPS Agreement and the Convention on Biodiversity*, ¶¶ 13–18, WTO Doc. WT/CTE/W/65 (Sept. 29, 1997) (communication from India) [hereinafter *India Paper*]; Shiva, *supra* note 10.

¹⁴² See *India Paper*, *supra* note 141, ¶¶ 13–18; *Seattle Declaration*, *supra* note 79, § 3(d); Shiva, *supra* note 10; see also CUTS CTR. FOR INT'L TRADE ECON. & ENV'T, BRIEFING PAPER, TRIPS AND BIODIVERSITY, at <http://Cuts-India.org/trade-susdevl.htm> (1999) [hereinafter CUTS].

¹⁴³ See *Wiser*, *supra* note 1, § 3; *CIEL*, *supra* note 6, § IV(D). See generally *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft, m.b.H.*, 945 F.2d 1546 (Fed. Cir. 1991); *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8568); U.S. Patent and Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans, Media Advisory 98–6, at <http://www.uspto.gov/web/offices/com/speeches/98-06.htm> (Apr. 1, 1998) [hereinafter PTO, Media Advisory].

¹⁴⁴ See *Lowell*, 15 F. Cas. at 1019.

¹⁴⁵ See *id.*

¹⁴⁶ *Id.*

¹⁴⁷ See *id.*

¹⁴⁸ See Robert Patrick Merges, *Intellectual Property in Higher Life Forms: The Patent System & Controversial Technologies*, 47 MD. L. REV. 1051, 1062–66 (1988); Brett G. Alten, Note, *Left to One's Devices: Congress Limits Patents on Medical Procedures*, 8 FORDHAM INTELL. PROP. ME-

tions used to defraud buyers.¹⁴⁹ Second, courts denied patents for items useful for gambling or similarly immoral activity.¹⁵⁰

Since early in the twentieth century, federal courts have stopped applying the moral utility doctrine to reject patent applications.¹⁵¹ Many scholars argue that this is based on the fact that moral norms can change over the course of only a few years and that the PTO is not institutionally equipped to make moral judgments.¹⁵² Rather, it is argued, the PTO should limit itself to deciding issues of novelty.¹⁵³ Since the middle of this century, the courts have done just that.¹⁵⁴

However, with the recent explosion of the biotechnology industry and the moral questions this explosion has raised, the moral utility doctrine is experiencing a re-birth, both in the United States and abroad.¹⁵⁵ In particular, the PTO has recently issued an advisory citing *Lowell* and the moral utility doctrine, as did the federal circuit court in *Tol-O-Matic, Inc. v. Proma Product-Und Marketing Gesellschaft, m.b.H.*¹⁵⁶ Additionally, the European Union has used a form of the moral utility doctrine as a means of rejecting immoral or destructive patents.¹⁵⁷ Finally, article 27(2) of the TRIPS Agreement allows for the barring of

DIA & ENT. L.J. 837, 845–46 (1998); Thomas A. Magnani, Note, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 451 (1999).

¹⁴⁹ See, e.g., *Rickard v. Du Bon*, 103 F. 868, 868, 873 (2d Cir. 1900) (holding that process for artificially producing spots on tobacco leaves used to wrap cigars, such that leaves resembled those used to wrap high-quality cigars, was unpatentable for lack of utility); see *Merges*, *supra* note 148, at 1062; Magnani, *supra* note 148, at 451.

¹⁵⁰ See *Alten*, *supra* note 148, at 845; Magnani, *supra* note 148, at 451.

¹⁵¹ See DONALD CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 4.03, at 4–17 to 4–24.1 (1999) (reviewing relevant case law); *Alten*, *supra* note 148, at 846.

¹⁵² See CHISUM, *supra* note 151, at 4–17; *Merges*, *supra* note 148, at 1062–66.

¹⁵³ See *Carrie F. Walter*, Note, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025, 1026 (1998); see also CHISUM, *supra* note 151, at 4–17; *Merges*, *supra* note 148, at 1062, 1067–68, 1075.

¹⁵⁴ See, e.g., *Chicago Patent v. Genco*, 124 F.2d 725, 726, 728 (7th Cir. 1941) (holding that pinball is different from gambling in order to uphold a patent on pinball machine); *Whistler Corp. v. Autotronics, Inc.*, 14 U.S.P.Q.2d 1885, 1886 (N.D. Tex. 1988) (upholding patent on radar detector despite claims that its sole purpose was to circumvent police attempts to enforce speed limit); *Ex parte Murphy*, 200 U.S.P.Q. 801, 802, 803 (P.T.O. Bd. App. 1977) (upholding patent on slot machine); see *Alten*, *supra* note 148, at 846–47.

¹⁵⁵ See Magnani, *supra* note 148, at 453.

¹⁵⁶ See *Rick Weiss*, *US Ruling Aids Opponent of Patents for Life Forms*, WASH. POST, June 17, 1999, at A2 [hereinafter *Weiss*, *US Ruling*]. See generally *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft, m.b.H.*, 945 F.2d 1546, 1552–53 (Fed. Cir. 1991); PTO, *Media Advisory*, *supra* note 143.

¹⁵⁷ See Council Directive 98/44/EC, art. 6, 1998 O.J. (L 213) 13 [hereinafter *Council Directive*]; Magnani, *supra* note 148, at 453.

patent protection if “commercial exploitation” of an invention would harm public policy or morality.¹⁵⁸

2. The Revived Morality Component in Action: Recent Decisions and Legislation

a. *Human-Animal Chimera*

One instance of the recent revival of the morality component of the U.S. Patent Act’s utility requirement involved a proposed patent on a human animal chimera.¹⁵⁹ A human animal chimera is a genetically engineered creature composed of some human and some animal cells.¹⁶⁰ In December of 1997, Dr. Stuart Newman, a cellular biologist at New York Medical College, and Jeremy Rifkin, a biotechnology activist opposed to the patenting of life forms, applied for a patent on the production of human-animal chimeras that could be up to fifty percent human.¹⁶¹ The co-applicants hoped either to forestall other scientists from creating human-animal chimeras for the twenty-year term of a patent or that the PTO would reject the patent due to the moral questions such a creature would raise.¹⁶²

As it turned out, the PTO quickly issued an advisory opinion to the media stating that it would likely reject the patent.¹⁶³ In particular, the PTO stated that it would not “issue a patent for an invention of incredible or specious utility or for inventions whose utilization is not adequately disclosed in the application.”¹⁶⁴ While this sentence, taken alone, merely illustrates the PTO’s intention to question the proposed utility of the invention, the advisory went on to state that, “the courts have interpreted the utility requirement to exclude inventions deemed to be ‘injurious to the wellbeing, good policy, or good morals

¹⁵⁸ See TRIPS Agreement, *supra* note 60, art. 27(2).

¹⁵⁹ See generally Magnani, *supra* note 148; Weiss, *US Ruling*, *supra* note 156, at A2; PTO, Media Advisory, *supra* note 143.

¹⁶⁰ See Magnani, *supra* note 148, at 445. In ancient Greek mythology, a chimera was a fire-spewing monster with the head of a lion, body of a goat, and tail of a snake. See WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 389 (ed. 1986). Recently, advances in biotechnology have resulted in permutations of species called chimera. See Magnani, *supra* note 148, at 443. Some suggested future uses for such inventions are using them as subjects of research and as organ donors. See *id.* at 456. It is theorized that humans would be less likely to reject organs from an animal with some human characteristics. See *id.*

¹⁶¹ See Magnani, *supra* note 148, at 443; Rick Weiss, *Patent Sought on Making of Part-Human Creatures*, WASH. POST, Apr. 2, 1998, at A12 [hereinafter Weiss, *Patent Sought*].

¹⁶² See Magnani, *supra* note 148, at 443; Weiss, *Patent Sought*, *supra* note 161, at A12.

¹⁶³ See PTO, Media Advisory, *supra* note 143.

¹⁶⁴ *Id.*

of society.’”¹⁶⁵ This language is quoted directly from Justice Story’s opinion in *Lowell*.¹⁶⁶ By citing the moral utility doctrine illustrated in *Lowell*, the PTO intimated that it would consider the morality of patenting a life form.¹⁶⁷ This indication was contrary to earlier federal court decisions that upheld patents on transgenic animals including animals with human genes or organs.¹⁶⁸

In relying on *Lowell*, the PTO was following the recent example of the U.S. Circuit Court of Appeals.¹⁶⁹ In *Tol-O-Matic v. Proma Produkt-Und Marketing Gesellschaft*, a 1991 decision, the court upheld a patent on a rodless piston-cylinder.¹⁷⁰ In arriving at its opinion, the court noted that 35 U.S.C. § 101 has “been interpreted to exclude inventions deemed to be immoral.”¹⁷¹ Although neither party argued that the rodless piston-cylinder was immoral, the court went on to cite the *Lowell* opinion extensively in upholding the patent.¹⁷² It has been suggested that the willingness of the Federal Circuit to cite to such a controversial doctrine in a setting where the morality argument was not even raised indicates that the courts may be preparing to invoke the doctrine with greater frequency in the future.¹⁷³

Ultimately, the PTO did reject the human-animal chimera patent in June of 1999, in part because the invention “embraces” a human being and is, therefore, unpatentable on the longstanding policy of the PTO that human beings are not patentable.¹⁷⁴ However, the PTO

¹⁶⁵ *Id.* (quoting Judge Story as quoted in *Tol-O-Matic, Inc. v. Proma Produkt-und Marketing Gesellschaft m.b.H.*, 945 F.2d at 1546, 1552–53 (Fed. Cir. 1991)).

¹⁶⁶ See *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568); PTO, Media Advisory, *supra* note 143.

¹⁶⁷ See PTO, Media Advisory, *supra* note 143.

¹⁶⁸ See *id.* See generally *Ex parte Allen*, 2 U.S.P.Q.2d 1425, 1427 (Bd. Pat. App. & Interferences 1987) (rejecting claim that genetically engineered oysters were naturally occurring subject matter but rejecting the patent on obviousness); Transgenic Non-Human Mammals, U.S. Patent No. 4,736,866 (issued Apr. 12, 1988) (patent for mouse injected with human hormones) [hereinafter Harvard Mouse Patent].

¹⁶⁹ See *Tol-O-Matic*, 945 F.2d at 1552–53; PTO, Media Advisory, *supra* note 143.

¹⁷⁰ *Tol-O-Matic*, 945 F.2d at 1547.

¹⁷¹ See *id.* at 1552.

¹⁷² See *id.* at 1552–53; *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8568); Magnani, *supra* note 148, at 453.

¹⁷³ See Magnani, *supra* note 148, at 453 (new type of cylinder would not be considered immoral, so there was no reason to bring in the moral utility argument). *But see* Juicy Whip, Inc. v. Orange Ban, Inc., 185 F.3d 1364, 1365–66 (Fed. Cir. 1999) (stating moral utility doctrine has not been broadly applied by courts in recent years and upholding patent despite fact that invention was designed to deceive customers by imitating another product).

¹⁷⁴ See Weiss, *US Ruling*, *supra* note 156, at A2 (quoting PTO opinion); PTO, Media Advisory, *supra* note 143.

did not say in the holding why other animals injected with human genetic material do not embrace a human being.¹⁷⁵ Thus, the holding that a being that is fifty percent human is too human to be patentable appears to be, in part, a rejection of a patent based on moral questionability.¹⁷⁶

Dr. Newman and Mr. Rifkin, the human-animal chimera patent applicants, have already filed an appeal of the PTO decision rejecting their patent, in hopes that the case will eventually reach the Supreme Court for a long-awaited limitation of the holding of *Diamond v. Chakrobarty*, which upheld a patent on a genetically-altered bacterium.¹⁷⁷ It was that case that led to the inevitable patents of genetically-engineered animals.¹⁷⁸ The United States courts and the PTO have reopened the door for using the moral utility doctrine to reject immoral patents.¹⁷⁹ This positive step could make patents like the one on ayahuasca less likely to be upheld.¹⁸⁰

b. *The European Union's Use of Morality Determinations to Bar Patents*

In addition to the progress made in the United States in resurrecting the moral utility doctrine, the European Union has employed a similar doctrine.¹⁸¹ In July 1998, the European Parliament and the Council of the European Union issued a directive expressly allowing patents on genetically engineered plant and animal species, but forbidding biotechnological applications that "would be contrary to ordre public or morality."¹⁸²

The term "ordre public" derives from French law and is similar to the notion of public policy.¹⁸³ However, "ordre public" encompasses a few separate and distinct ideas that are not covered by the Anglo-

¹⁷⁵ See Weiss, *US Ruling*, *supra* note 156, at A2.

¹⁷⁶ See *id.*; PTO, Media Advisory, *supra* note 143.

¹⁷⁷ See *Diamond v. Chakrobarty*, 447 U.S. 303, 309 (1980); Weiss, *US Ruling*, *supra* note 156, at A2.

¹⁷⁸ See *Diamond*, 447 U.S. at 309; *Ex parte Allen*, 2 U.S.P.Q.2d 1425, 1428 (Bd. Pat. App. & Interf. 1987); Harvard Mouse Patent, *supra* note 168.

¹⁷⁹ See *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H.*, 945 F.2d at 1546, 1552-53 (Fed. Cir. 1991); PTO, Media Advisory, *supra* note 143.

¹⁸⁰ See CIEL, *supra* note 6, § IV(D). The attorneys at CIEL argue that a case by case analysis of the morality of patent applications is not feasible. See *id.* Rather, they suggest that the PTO should develop new procedures and principles that would aid it in setting guidelines for the patenting of living things. See *id.*

¹⁸¹ See Council Directive, *supra* note 157, art. 6; see also Magnani, *supra* note 148, at 453.

¹⁸² See Council Directive, *supra* note 157, arts. 3, 6.

¹⁸³ Timothy G. Ackerman, Comment, *Dis'ordre'ly Loopholes: TRIPS Patent Protection, GATT and the ECJ*, 32 TEX. INT'L L.J. 489, 495 (1997).

American doctrine of public policy.¹⁸⁴ First, according to the doctrine of *ordre public*, judges have some discretion to bar enforcement of contracts which they find to offend public order.¹⁸⁵ Second, there are statutory requirements within the *ordre public* which limit private contracts.¹⁸⁶ Finally, the notion of *ordre public* can be used to bar application of a foreign law which would normally apply, on the basis that the foreign law "would sanction conduct that offends against the forum's concept of fundamental norms."¹⁸⁷

In 1998, the European Parliament and the Council of the European Union issued a directive on the legal protection of biotechnological inventions.¹⁸⁸ Included in the directive was an article making unpatentable inventions whose "commercial exploitation would be contrary to *ordre public* or morality."¹⁸⁹ That article lists human cloning, commercialization of human embryos, and modifying the genetic makeup of animals in ways likely to cause them suffering without any apparent benefit as examples of inventions which would be rejected on the basis of offending morality or being contrary to *ordre public*.¹⁹⁰

At this point, it is unclear whether Europe's new patent laws will have any effect on U.S. domestic policy.¹⁹¹ However, this is an area in which the United States has been lagging behind in legislation.¹⁹² Therefore, it is very possible that Congress and the National Bioethics Advisory Commission (NBAC) could look to Europe in formulating U.S. policy.¹⁹³ But, regardless of Europe's effect on U.S. domestic policy regarding biotechnology, its provision against granting patents on

¹⁸⁴ See *id.*

¹⁸⁵ See CIVIL CODE [C. CIV], arts. 1131, 1133 (Fr.); DENNIS LLOYD, PUBLIC POLICY 6 (1953); Ackerman, *supra* note 183, at 495.

¹⁸⁶ See CIVIL CODE [C. CIV], art. 6 (Fr.); Ackerman, *supra* note 183, at 495. Article 6 of the Civil Code reads, "One may not derogate by private agreements from laws which involve public policy and morality." CIVIL CODE [C. CIV], art. 6 (Fr.).

¹⁸⁷ See Ackerman, *supra* note 183, at 495 (quoting M. Forde, *The "Ordre Public" Exception and Adjudicative Jurisdiction Conventions*, 29 INT'L & COMP. L.Q. 259, 259-60 (1981)).

¹⁸⁸ See generally Council Directive, *supra* note 157.

¹⁸⁹ See *id.* art. 6.

¹⁹⁰ See *id.*

¹⁹¹ See Magnani, *supra* note 148, at 454.

¹⁹² See *id.*

¹⁹³ See *id.*; see also Walter, *supra* note 153, at 1045. The NBAC was formed on October 3, 1995 by executive order of President Clinton. See Walter, *supra* note 153, at 1026, 1045. Up to that point, the U.S. was one of few industrialized nations without a commission to examine bioethics. See *id.* at 1045. President Clinton stated that one of the primary tasks of the NBAC was to review the proprietary and social effects of issuing patents on genes. See *id.*

inventions which are contrary to "ordre public or morality" has already been included in the TRIPS agreement.¹⁹⁴

c. *Article 27(2) of the TRIPS Agreement*

Finally, like the European Union and the United States, TRIPS has placed greater emphasis on morality.¹⁹⁵ The Agreement on Trade-Related Aspects of Intellectual Property, in article 27(2), provides that states may exclude an invention from patent protection if prevention of "commercial exploitation" of that invention in their territory is "necessary" in order to "protect *ordre public* or morality."¹⁹⁶ This provision allows that if prevention of "commercial exploitation" of an invention is "necessary" to protect "the *ordre public* or morality," and if exclusion of the invention from patentability is the only way to prevent its commercial exploitation, then the state may bar the patent.¹⁹⁷ Thus, under article 27(2), states may only exclude an invention from patentability on the basis of *ordre public* where granting a patent would result in commercial exploitation of the invention, and that such commercialization would offend the state's concept of fundamental norms.¹⁹⁸

The inclusion of this clause in the TRIPS Agreement has led to some speculation that it creates a loophole in the requirement that Member States create adequate systems for protecting intellectual property rights.¹⁹⁹ Some scholars argue that this clause could especially hinder the goal that Member States protect technology.²⁰⁰ However, the application of the clause by Member States is limited in that patent protection can only be denied if preventing commercial exploitation of an invention is necessary to protect *ordre public* or morality.²⁰¹

¹⁹⁴ See TRIPS Agreement, *supra* note 60, art. 27(2).

¹⁹⁵ See *id.*

¹⁹⁶ *Id.*

¹⁹⁷ See Ackerman, *supra* note 183, at 496.

¹⁹⁸ See Forde, *supra* note 187, at 261 (discussing treaties that help determine what law will be used in a transnational dispute and the exceptions provided in that law); Ackerman, *supra* note 183, at 496.

¹⁹⁹ See Ackerman, *supra* note 183, at 496-97.

²⁰⁰ See *id.*

²⁰¹ See TRIPS Agreement, *supra* note 60, art. 27(2); Ackerman, *supra* note 183, at 492. It is useful to look to prior GATT decisions concerning the definition of the word necessary in order to appreciate the limited scope of this exception. See Ackerman, *supra* note 183, at 506-07.

By allowing Member States to exclude patent protection on certain inventions for public policy reasons, article 27(2) of the TRIPS Agreement is in line with the morality component of the utility requirement of the U.S. Patent Act.²⁰² The inclusion of morality considerations in determining an invention's patentability, therefore, comports with both domestic law and an international treaty.²⁰³ Therefore, by applying a morality test in determining whether a patent should issue, U.S. courts and the U.S. PTO would be applying the Patent Act correctly and would not be violating the TRIPS Agreement.²⁰⁴

B. Foreign Prior Use

In addition to expanding the application of the morality component, the United States should also reconsider the exclusion of foreign prior use as a bar to granting a patent.²⁰⁵ In particular, under the novelty requirement of the Patent Act, the United States should recognize foreign prior use in the form of traditional knowledge as a prior art reference.²⁰⁶

1. Recognizing Traditional Knowledge as Prior Art Is Consistent with the Mission of U.S. Intellectual Property Law

In recognizing cultural knowledge as a prior art reference the U.S. Patent Act would remain consistent with its underlying purpose of granting property rights in new and useful inventions.²⁰⁷ In the United States, intellectual property law has its basis in the U.S. Constitution, which states that "[t]he Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."²⁰⁸ The award of patents for inventions is one means of fulfilling the mission of promoting the progress

²⁰² See 35 U.S.C. § 101 (1994); TRIPS Agreement, *supra* note 60, art. 27(2); *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H.*, 945 F.2d 1546, 1552-53; *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568).

²⁰³ See TRIPS Agreement, *supra* note 60, art. 27(2); *Tol-O-Matic*, 945 F.2d at 1552-53; *Lowell*, 15 F.Cas. at 1019.

²⁰⁴ See TRIPS Agreement, *supra* note 60, art. 27(2); *Tol-O-Matic*, 945 F.2d at 1553; *Lowell*, 15 F. Cas. at 1019.

²⁰⁵ See Chisum, *supra* note 19, at 37; Kadidal, *supra* note 19, at 371, 396-97; *see also* Shiva, *supra* note 10.

²⁰⁶ Kadidal, *supra* note 19, at 371, 396-97; Shiva, *supra* note 10.

²⁰⁷ See Kadidal, *supra* note 19, at 371, 396-97; CIEL, *supra* note 6, intro.

²⁰⁸ U.S. CONST., art. 1 § 8, cl. 8.

of science and useful arts.²⁰⁹ However, financially rewarding inventors by granting exclusive patent rights is only one means of progressing science and the useful arts, it is not an end in itself.²¹⁰ Another important means of promoting innovation is by way of the patent application and publication process itself.²¹¹ Patent applications disclose to the public the basis for inventions.²¹² By acknowledging the prior art used, inventors can at once recognize their predecessors and provide a complete view of the inventive process relied upon by future inventors.²¹³ Such acknowledgment is just given that indigenous people often facilitate the ability of transnational corporations to access these substances by helping a corporations' researchers to identify the natural sources of various compounds.²¹⁴

The Center for International Environmental Law, whose attorneys successfully challenged the ayahuasca patent on behalf of COICA, argues that the disclosure of traditional knowledge that forms part of the prior art promotes the progress of science and the useful arts in two ways.²¹⁵ First, it would recognize the holders of cultural knowledge of local biological resources, providing incentive for continued use and maintenance of indigenous knowledge systems.²¹⁶ Such an incentive could work to slow the rapid loss of traditional knowledge due to cultural assimilation and the destruction of local biological resources.²¹⁷ Second, by encouraging the maintenance of traditional knowledge systems through positive incentives, a reformed U.S. Patent Act would induce knowledge holders to continue the traditional practices which have helped to maintain high levels of biodiversity in their regions over many centuries.²¹⁸

2. The Exclusion of Foreign Prior Use as a Prior Art Is Outdated and Should Be Eliminated from the Patent Act

Given that the foreign prior use exclusion comes out of a nineteenth century legislation, the United States should reconsider the

²⁰⁹ See CIEL, *supra* note 6, § I.

²¹⁰ See *id.*

²¹¹ See *id.*

²¹² See *id.*

²¹³ See *id.*

²¹⁴ See Roht-Arriaza, *supra* note 6, at 926–28; Sarma, *supra* note 11, at 113.

²¹⁵ See CIEL, *supra* note 6, § I.

²¹⁶ See *id.*

²¹⁷ See *id.*

²¹⁸ See *id.*

continued utility of its application in the modern world.²¹⁹ Exclusion of foreign prior use as a prior art first appeared in U.S. law in the Patent Act of 1836.²²⁰ The 1836 Act required that prior knowledge, use or invention by others be "in this country" in order to bar issuance of a patent.²²¹ This exclusion of foreign prior knowledge, use or invention as a prior art remains in the Patent Act today.²²² Thus, while foreign patents and printed publications are considered prior art and preclude subsequent patent of the same invention in the United States, the existence of foreign traditional knowledge, which is rarely printed, does not preclude issuance of a U.S. patent.²²³ As illustrated by the ayahuasca patent, the exclusion of prior foreign use as a prior art makes it difficult for a foreign litigant to defeat a plant patent.²²⁴

The exclusion of foreign prior knowledge, use or invention as a prior art has been under attack for at least thirty years.²²⁵ The President's Commission on the Patent System's 1966 Report to the U.S. Congress recommended that § 102's geographical distinction be abolished so that foreign knowledge, use and sale would be included as prior art.²²⁶ As scholars have argued, enacting this recommendation

²¹⁹ See Chisum, *supra* note 19, at 37; Kadidal, *supra* note 19, at 387, 397; see also Shiva, *supra* note 10.

²²⁰ See Act of July 4, 1836, ch. 357, 5 Stat. 117, 119 (current version at 35 U.S.C. § 102(b) (1994)) [hereinafter 1836 Act]; Chisum, *supra* note 19, at 36; Kadidal, *supra* note 19, at 385.

²²¹ 1836 Act, ch. 357, *supra* note 220, §§ 7, 15. Congressional rationale of the exclusion did not appear "in the report accompanying the 1836 Act or in the subsequent codifications." Chisum, *supra* note 19, at 36. Chisum speculates that the change may have been in response to a contemporaneous Supreme Court decision which "invalidated a patent because of use of the invention in England and France with the inventor's consent prior to his filing an application in the United States." *Id.* (citing *Shaw v. Cooper*; 32 U.S. (7 Pet.) 292 (1833)). Chisum further speculates that the evidentiary difficulties in proving foreign use were influential to Congress's decision. See *id.* In addition, in 1836, one major goal of the patent system was to disclose foreign inventions to the American public which would probably have remained secret absent granting of a U.S. patent. See Kadidal, *supra* note 19, at 386.

²²² See 35 U.S.C. § 102(a), 102(g).

²²³ See *id.*

²²⁴ See Kadidal, *supra* note 19, at 387. "Biodiversity often leaves little in the way of a patent record because it tends to occur in countries where its products, or improvements thereon, are unpatentable." *Id.*

²²⁵ See *id.* at 395.

²²⁶ See Chisum, *supra* note 19, at 37; Kadidal, *supra* note 19, at 395-96 (both citing PRESIDENT'S COMMISSION ON THE PATENT SYSTEM, TO PROMOTE THE PROGRESS OF THE . . . USEFUL ARTS IN AN AGE OF EXPLODING TECHNOLOGY 6 (1966)) [hereinafter PRESIDENT'S COMMISSION]. Chisum notes that the Commission's report "failed to induce any legislative action," despite its strong advocacy of a universal conception of prior art. Chisum, *supra* note 19, at 37.

would improve global patent protection in three distinct ways.²²⁷ First, it would prevent the PTO from granting U.S. patents on inventions which would be unpatentable abroad because of long use or sale there.²²⁸ Second, eliminating § 102's geographical distinction would further conform U.S. patent law with current European patent laws, thus promoting acceptance of a common definition of prior art.²²⁹ And third, it would lead to the establishment of international scientific data banks, eliminating one of the barriers to the useful exchange of search results among national patent offices around the world.²³⁰

The final and strongest reason to eliminate § 102's geographical distinction is that, due to increased international communications, travel and trade, the distinction has become unnecessary.²³¹ Today, the ease and frequency of researcher access to foreign indigenous knowledge point to the falseness of the foreign prior use distinctions.²³² The ayahuasca case illustrates this idea well. As discussed above, Loren Miller traveled to Ecuador where indigenous people gave him samples of ayahuasca, a vine which they had been using for religious and healing purposes for generations.²³³ Because he obtained this information outside of the United States, his subsequent patent application was not required to contain any acknowledgment of the traditional knowledge supplied by the indigenous tribespeople.²³⁴ Due to the increased ease of traveling to other countries and the frequency with which researchers go to developing nations to find specimens of plants used in traditional medicine, information gathered in foreign countries, whether previously published or not, should be credited as prior art under the Patent Act.²³⁵

²²⁷ See Chisum, *supra* note 19, at 37; Kadidal, *supra* note 19, at 395-96 (both citing PRESIDENT'S COMMISSION, *supra* note 226, at 6).

²²⁸ See Chisum, *supra* note 19, at 37; Kadidal, *supra* note 19, at 395-96 (both citing PRESIDENT'S COMMISSION, *supra* note 226, at 6).

²²⁹ See Chisum, *supra* note 19, at 37; Kadidal, *supra* note 19, at 395-96 (both citing PRESIDENT'S COMMISSION, *supra* note 226, at 6).

²³⁰ See Chisum, *supra* note 19, at 37; Kadidal, *supra* note 19, at 395-96 (both citing PRESIDENT'S COMMISSION, *supra* note 226, at 6).

²³¹ See Kadidal, *supra* note 19, at 397 (citing PRESIDENT'S COMMISSION, *supra* note 226, at 6).

²³² See *id.* (citing CHISUM, *supra* note 152, § 3.05(5) n.13).

²³³ See Pollack, *supra* note 15, at C4; Wisner, *supra* note 1, § 1.

²³⁴ See 35 U.S.C. § 102 (1994); Wisner, *supra* note 1, § 2.

²³⁵ See Kadidal, *supra* note 19, at 397; Shiva, *supra* note 10.

C. Reconciling the TRIPS Agreement with the Biodiversity Convention

Finally, working to reconcile TRIPS with the goals of the Biodiversity Convention could help to promote a more equal sharing of profits from products developed from indigenous sources of knowledge.²³⁶ As discussed above, article 27 of the TRIPS Agreement requires Member States to protect property rights in microorganisms, non-biological and microbiological processes, and plants by either a patent system or a sui generis system.²³⁷ In contrast, article 3 of the Biodiversity Convention recognizes that “[s]tates have . . . the sovereign right to exploit their own resources pursuant to their own environmental policies”²³⁸ Despite the differing requirements of the two treaties regarding intellectual property protection, it is possible to reconcile the goals of both.²³⁹

The purpose of the TRIPS Agreement is to reduce distortions and impediments to international trade by protecting intellectual property rights on a global level.²⁴⁰ Whereas, the ultimate purpose of the Biodiversity Convention is to prevent the depletion of the Earth’s biodiversity and ensure the equitable sharing of the benefits arising out of the use of genetic resources.²⁴¹ To this end, the Convention recognizes that sovereign nations have the autonomy to enact protective measures to conserve their biodiversity.²⁴² It further provides that nations can protect both the indigenous knowledge of their people and the biological resources within their borders.²⁴³ Finally, in contrast to TRIPS, the Biodiversity Convention recognizes that knowledge deserving of intellectual property protection can be held by communities, not just private individuals.²⁴⁴ As India has argued to the WTO,

²³⁶ See Roht-Arriaza, *supra* note 6, at 936–37, 948–49, 965; Sarma, *supra* note 11, at 135–36; see also Shiva, *supra* note 10.

²³⁷ TRIPS Agreement, *supra* note 60, art. 27(3)(b).

²³⁸ Biodiversity Convention, *supra* note 61, art. 3.

²³⁹ See *India Paper*, *supra* note 141, ¶ 5; Tejera, *supra* note 10, at 983; see also Shiva, *supra* note 10.

²⁴⁰ See TRIPS Agreement, *supra* note 60, pmbl.

²⁴¹ See Biodiversity Convention, *supra* note 61, arts. 1, 8(j).

²⁴² See *id.* art. 3.

²⁴³ See *id.* arts. 8(c), 8(j).

²⁴⁴ See *id.* art. 8(j); SHIVA, *supra* note 59, at 122; Tejera, *supra* note 10, at 984. Article 8(j) states that application and promotion of the knowledge should be made “with the approval and involvement of the holders of such knowledge.” Biodiversity Convention, *supra* note 61, art. 8(j).

the TRIPS Agreement should be reviewed with an eye to recognizing these points of the Biodiversity Convention.²⁴⁵

First, the WTO should review TRIPS' failure to require that biotechnology patent applications disclose the geographical source of the biological resources and the indigenous knowledge used in the inventive process.²⁴⁶ Presently, TRIPS requires only that the inventor disclose his invention such that a person skilled in the art could utilize it.²⁴⁷ In this way, TRIPS' disclosure requirements are similar to the patent laws of developed countries, which were, for the most part, written with an eye to mechanical and chemical patents.²⁴⁸ TRIPS should be amended to recognize that biotechnological inventions require additional disclosure requirements.²⁴⁹ By including in article 29 a requirement that biotechnological patent applicants disclose the biological source and the indigenous knowledge utilized in the invention, the WTO would take a step toward reconciling TRIPS with the goals of the Biodiversity Convention.²⁵⁰ Such a disclosure to the public would give countries the opportunity to review patent applications and file any claims before the patent is granted.²⁵¹

Second, the TRIPS Agreement should be amended to recognize that biological resources and indigenous knowledge are often inseparable.²⁵² To this end, TRIPS should oblige inventors to share the benefits derived from inventions with the communities from whence the biological resources and indigenous knowledge came.²⁵³ This could be accomplished through the use of Material Transfer Agreements where the inventor is using biological resources from a developing country and a Transfer of Information Agreement where the invention is based on indigenous knowledge.²⁵⁴ Thus, recognition of both biological resources gathered and indigenous knowledge used would allow for compensation of the holders of such resources and knowledge.²⁵⁵

²⁴⁵ See *India Paper*, *supra* note 141, ¶¶ 13–18; Tejera, *supra* note 10, at 984; see also CUTS, *supra* note 142; Shiva, *supra* note 10.

²⁴⁶ See *India Paper*, *supra* note 141, ¶ 13; Downes, *supra* note 14, at 274–75.

²⁴⁷ See *India Paper*, *supra* note 141, ¶ 13; TRIPS Agreement, *supra* note 60, art. 29(1).

²⁴⁸ See *India Paper*, *supra* note 141, ¶ 13.

²⁴⁹ See *id.*

²⁵⁰ See Biodiversity Convention, *supra* note 61, art. 15; *India Paper*, *supra* note 141, ¶ 13; see also Downes, *supra* note 14, at 274–75.

²⁵¹ See *India Paper*, *supra* note 141, ¶ 13.

²⁵² See Tejera, *supra* note 10, at 985; see also *Seattle Declaration*, *supra* note 142, § 3(f).

²⁵³ See *India Paper*, *supra* note 141, ¶ 15.

²⁵⁴ See *id.*

²⁵⁵ See *India Paper*, *supra* note 141, ¶ 15; Tejera, *supra* note 10, at 985.

Finally, the WTO should amend TRIPS such that it would recognize the intellectual property rights of both individuals and communities.²⁵⁶ To this end, the WTO should evaluate implementing a system wherein traditional knowledge and contemporary innovations of indigenous communities could be protected under a system of intellectual property rights.²⁵⁷ The ability to patent such knowledge and innovation would provide a concrete means by which to achieve the benefit-sharing objective of the Biodiversity Convention.²⁵⁸ However, under current patent regimes, recognizing an indigenous community's right to patent its cultural knowledge would prove difficult as most patent systems only award patents to individuals.²⁵⁹ One alternative to patenting traditional knowledge would be a system of geographical indications for products derived from traditional knowledge.²⁶⁰

TRIPS currently allows protection of geographic indications which it defines as "indications which identify a good as originating in the territory of a [WTO] Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin."²⁶¹ Geographical indications differ from patents in that their main purpose is not to reward innovation.²⁶² Rather, they reward good will and reputation cultivated over many years by a group of producers.²⁶³ In addition, geographic indications are particularly well-suited to protecting traditional knowledge because they are communally based, as opposed to patents which reward individual effort and innovation.²⁶⁴ Geographic indicators are based upon collective traditions and decision-making and they protect and reward traditions while allowing for evolution.²⁶⁵

²⁵⁶ See Tejera, *supra* note 10, at 985; Shiva, *supra* note 10.

²⁵⁷ See *India Paper*, *supra* note 141, ¶ 16.

²⁵⁸ See Biodiversity Convention, *supra* note 61, art. 1; *India Paper*, *supra* note 141, ¶ 16.

²⁵⁹ See Downes, *supra* note 14, at 268–69.

²⁶⁰ See *id.*

²⁶¹ See TRIPS Agreement, *supra* note 60, art. 22. The most well-known example of a system of geographic indications is France's system of protecting its locally produced food and wine. See Downes, *supra* note 14, at 269–70. Such products are considered valuable because of a combination of environmental factors and cultural factors, including the "traditional, collectively maintained techniques for production." *Id.*

²⁶² See Downes, *supra* note 14, at 271.

²⁶³ See *id.*

²⁶⁴ See *id.* at 272.

²⁶⁵ See *id.* at 269.

As TRIPS now reads, it does not extend either patent or geographic indication protection to the traditional knowledge of indigenous groups.²⁶⁶ Amending TRIPS to allow for such protection of common intellectual property could preserve the integrity of indigenous cultural knowledge, thereby allowing the survival of indigenous communities.²⁶⁷ Such an amendment would therefore bring TRIPS closer to being reconciled with the goals of the Biodiversity Convention.²⁶⁸

CONCLUSION

Shortly after the PTO issued its decision to overturn Loren Miller's patent on ayahuasca, Mr. Miller declined to say whether he would appeal the PTO decision.²⁶⁹ He did, however, express that he could not comprehend what all of the fuss was about.²⁷⁰ He stated, "If this patent was causing any harm to the indigenous people I would have canceled it myself."²⁷¹ Miller went on to say, "I don't care about the patent. It's worthless. It's useless, it's just sitting in a drawer."²⁷² In his failure to comprehend the viewpoint of the indigenous tribes regarding ayahuasca, Miller personifies the U.S. perspective toward intellectual property rights in biological resources.

First, like most U.S. courts, Miller fails to recognize the moral harm in creating a property right in a sacred plant.²⁷³ Although courts have historically construed the Patent Act's utility requirement to enjoin the issuance of patents that offend morality, the PTO and modern courts have largely failed to bar issuance of such patents.²⁷⁴ However, a few recent decisions in the biotechnology field have signaled a possible end to judicial reticence in this area.²⁷⁵ These indications, coupled with international legislation that recognizes morality exceptions to patent rights, has opened the door to a revival of the moral utility doctrine, which could provide a powerful argument for the

²⁶⁶ See TRIPS Agreement, *supra* note 60, arts. 15, 24, 27.

²⁶⁷ See Shiva, *supra* note 10.

²⁶⁸ See Biodiversity Convention, *supra* note 61, art. 1; Shiva, *supra* note 10.

²⁶⁹ Brenda Salburg, *Farmers, Indigenous Folk Fight Patenting of Plants: An Ecuadorian Vine Is a Symbol for What Critics Call Theft of Culture*, NAT'L L.J., Dec. 13, 1999, at col. 4.

²⁷⁰ See *id.*

²⁷¹ *Id.* (quoting Loren Miller).

²⁷² *Id.* (quoting Loren Miller).

²⁷³ See Alten, *supra* note 148, at 846-47.

²⁷⁴ See Alten, *supra* note 148, at 846-47; Magnani, *supra* note 148, at 451.

²⁷⁵ See *Tol-O-Matic, Inc. v. Proma Produkt-Und Gesellschaft m.b.H.*, 945 F.2d 1546, 1552-53 (Fed. Cir. 1991); PTO, *Media Advisory*, *supra* note 143.

barring of biological patents that are morally offensive to indigenous communities in developing countries.²⁷⁶ The United States should resolve to consider morality when determining whether a patent application passes the utility requirement.

Second, Miller's disregard for the value of indigenous use and knowledge of ayahuasca reflects the U.S. Patent Act's exclusion of prior foreign use as prior art.²⁷⁷ The U.S. patent system rewards exclusive property rights to individuals who create new, non-obvious and useful inventions.²⁷⁸ The Patent Act does not recognize foreign, indigenous use as prior art, nor does it recognize collective intellectual property rights in the form of indigenous communities' traditional knowledge of local biological resources.²⁷⁹ Thus, the United States' narrow definition of intellectual property rights not only precludes indigenous communities from reaping a share of the benefits of their traditional knowledge, but it encourages the appropriation of this knowledge by rewarding individuals who isolate useful chemical compounds from plants used by indigenous people.²⁸⁰ The United States should recognize the collective traditional knowledge and use of indigenous communities as prior art.²⁸¹ Such an amendment to the Patent Act could improve U.S. relations with developing countries, encouraging them to allow researchers more open access to their biodiversity.²⁸²

Finally, through the TRIPS Agreement, the United States is ensuring that its intellectual property regime will become the universal norm.²⁸³ Over 130 countries have already signed TRIPS, thus promising to enact patent systems or sui generis systems that meet its requirements regarding the protection of individual property interests in plant resources.²⁸⁴ Like U.S. patent law, TRIPS only recognizes individual patent rights.²⁸⁵

²⁷⁶ See *Tol-O-Matic*, 945 F.2d at 1552-53; Council Directive, *supra* note 157, art. 6; PTO, Media Advisory, *supra* note 142.

²⁷⁷ 35 U.S.C. § 102 (1994).

²⁷⁸ 35 U.S.C. §§ 101-103.

²⁷⁹ See *id.*; Sarma, *supra* note 11, at 129-30.

²⁸⁰ See 35 U.S.C. §§ 101-103; Roht-Arriaza, *supra* note 6, at 936-37, 938-39.

²⁸¹ See Chisum, *supra* note 19, at 37; Kadidal, *supra* note 19, at 397; Shiva, *supra* note 10.

²⁸² See Pollack, *supra* note 15, at C4.

²⁸³ See TRIPS Agreement, *supra* note 60, art. 27.

²⁸⁴ See *id.*; *Membership of the World Trade Organization, Revision*, WTO Doc. WT/INF/6/Rev.7, available at <http://www.wto.org> (Mar. 21, 2000).

²⁸⁵ See TRIPS Agreement, *supra* note 60, pmbl; see also SHIVA, *supra* note 59, at 122.

As scholar, Vandana Shiva argues, the globalization of Western intellectual property rights will inevitably diminish the world's biodiversity because Western intellectual property regimes place no value on the communal knowledge of indigenous societies.²⁸⁶ Shiva points out that it is the lifestyle of these indigenous groups that has sustained and nurtured their countries' biodiversity.²⁸⁷ TRIPS-compliant patent laws will lead to the monopolization of the world's biological resources and knowledge, shutting out the indigenous communities who sustain that biodiversity.²⁸⁸

Only by recognizing indigenous rights in their communal knowledge and biological resources will TRIPS ensure that the world's biodiversity is sustained. To this end, the United States should work to reconcile TRIPS with the Biodiversity Convention, which recognizes communal property rights.²⁸⁹ The ayahuasca patent controversy well illustrates the diverging views of developed and developing countries regarding patents on biological products. Although, standing alone, Miller's patent may seem harmless, it brought out fierce emotion from the indigenous people who felt that their very culture was being stolen.²⁹⁰ Such a reaction is not unique to the ayahuasca case, as evidenced by the reaction of indigenous communities to their countries' compliance with TRIPS.²⁹¹ The United States needs to change its domestic and international patent policies in order to address the claims of indigenous people to their biodiversity and traditional knowledge.

²⁸⁶ See SHIVA, *supra* note 59, at 120–21.

²⁸⁷ See *id.* at 66, 123–24.

²⁸⁸ See *id.* at 68.

²⁸⁹ See Biodiversity Convention, *supra* note 61, pmbi., art. 8(j).

²⁹⁰ See, e.g., Lambrecht, *supra* note 7, at A5.

²⁹¹ See, e.g., SHIVA, *supra* note 59, at 125–26 (discussing the anti-GATT movement led by Indian farmers); Valerie Taliman, *Native Peoples Protest WTO: Activists Fear Threats to Sovereignty*, INDIAN COUNTRY TODAY, at <http://www.alphacdc.com/ien/intellectualproperty.html> (Dec. 1999) (discussing indigenous groups' involvement in the protests at the WTO meeting in Seattle); *India: An Anti-National, Anti-People Law*, THE HINDU, Jan. 19, 1998, available at 1998 WL 7698418.