

“WILLFUL PATENT FILING”:
A CRIMINAL PROCEDURE PROTECTING
TRADITIONAL KNOWLEDGE

VINCENT M. SMOLCZYNSKI*

INTRODUCTION

There is a continual search for commercially valuable genetic and biological resources. Biological prospecting, or just “bioprospecting,” benefits the creation of new pharmaceuticals, cosmetics, biotechnology, and crop production.¹ Bioprospecting is an efficient means of obtaining biological information, leading to decreased research and development costs.² When this genetic and biological resource information is possessed by indigenous peoples in its naturally-occurring form, it is termed “traditional knowledge.” Demonstrating the value of bioprospecting in traditional knowledge, a study found that the base compounds in the majority of the top 150 plant-based pharmaceuticals correspond with traditional medicinal knowledge.³

Economic hardship and natural resource depletion can result when property rights are granted to bioprospectors, and more often occurs in the area from which the traditional knowledge was “harvested.” Two case studies illustrate the problems that occur when property rights in traditional knowledge are granted, the difficulties in combating the grant of these rights, and the inadequacy of the current procedures available as a remedy for the original holders of traditional knowledge. The first example involved a U.S. patentee who obtained a patent on a strain of a common field bean from Mexico. The second illustration comprised several patents issued in both the United States and European Union (E.U.) relating to the neem plant, an indigenous plant to India.

The “Enola bean” patent is one of the most discussed instances of a patent issued on a plant species developed from the traditional knowledge

* Candidate for Juris Doctor, Chicago-Kent College of Law, Spring 2010; Notes and Comments Editor, Chicago-Kent Law Review; B.A. Biological Sciences, University of Delaware, 2007.

1. Kerry ten Kate & Sarah A. Laird, *Bioprospecting Agreements and Benefit Sharing with Local Communities*, in POOR PEOPLE’S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 133, 144–45 (J. Michael Finger & Philip Schuler eds., 2004).

2. *See generally id.* at 134.

3. *See id.*

of an indigenous group.⁴ The U.S. patentee was a man named Larry Proctor who, in the mid-1990's, purchased a bag of beans from a Mexican market which he then planted and bred over several years.⁵ He noticed a particular strain of the bean that remained yellow through all four seasons.⁶ Claiming he developed a strain of the bean which did not change with regular seasonal variations and effects, Proctor filed for, and was granted, a U.S. patent (the '079 patent) on all beans and hybrids developed from his strain⁷ on April 13, 1999.⁸ He termed his "new" bean the "Enola bean" after his wife.⁹

After the '079 patent was granted, a request for reexamination¹⁰ was filed in December 2000.¹¹ Mexican farmers had been planting yellow bean varieties called Mayacoba beans, also known as Azufrado beans.¹² While the validity of the patent was reconsidered, Proctor actively sought to enforce his rights to exclude others from using or selling yellow beans.¹³ He filed suit against sixteen U.S. bean companies for infringement of the '079 patent,¹⁴ and also accused Mexican farmers of infringing his patent who were selling yellow beans in the United States.¹⁵ Proctor claimed royalties for six cents per pound of all yellow beans sold in the United States.¹⁶ As a result of his claims, imports of the Enola bean from Mexico to the United States dropped by ninety percent.¹⁷ Over 22,000 farmers in Mexico depend

4. See Philip Schuler, *Biopiracy and Commercialization of Ethnobotanical Knowledge*, in POOR PEOPLE'S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 159, 174-75 (J. Michael Finger & Philip Schuler eds., 2004); Olufunmilayo B. Arewa, *TRIPS and Traditional Knowledge: Local Communities, Local Knowledge, and Global Intellectual Property Frameworks*, 10 MARQ. INTELL. PROP. L. REV. 155, 175 (2006); Press Release, ETC Group, Hollow Victory: Enola Bean Patent Smashed at Last (Maybe), http://www.etcgroup.org/en/materials/publications.html?pub_id=683 (Apr. 29, 2008).

5. Press Release, International Center for Tropical Agriculture, *U.S. Patent Office Rejects Company's Patent Protection for Bean Commonly Grown by Latin American Farmers*, http://webapp.ciat.cgiar.org/newsroom/release_31.htm (last visited Feb 27, 2010).

6. *Id.*

7. *Id.*

8. Press Release, ETC Group, *supra* note 4.

9. Schuler, *supra* note 4, at 175.

10. A reexamination can be requested by members of the public to have the PTO reexamine the validity of a previously issued patent. See 35 U.S.C. § 302 (2010).

11. Schuler, *supra* note 4, at 175.

12. *Id.* at 174, n.30.

13. Press Release, International Center for Tropical Agriculture, *supra* note 5.

14. See Danielle Goldberg, *Jack and the Enola Bean*, Dec. 2003, <http://www1.american.edu/TED/enola-bean.htm> (last visited Apr. 28, 2010).

15. Press Release, ETC Group, *supra* note 4. Acts which constitute infringement are listed in 35 U.S.C. § 271. Importation of patented products is an act of infringement under 35 U.S.C. § 271(a).

16. Schuler, *supra* note 4, at 175.

17. Lorna Dwyer, *Biopiracy, Trade, and Sustainable Development*, 19 COLO. J. INT'L ENVTL. L. & POL'Y 219, 228-29 (2008).

on the bean's sale for their own subsistence.¹⁸

Proctor's patent was originally granted in 1999 despite a wealth of printed publications depicting the same strain of bean that Proctor claimed in his patent.¹⁹ For almost ten years Proctor reaped the benefits of his granted patent. During the reexamination procedure, the International Center for Tropical Agriculture (CIAT)²⁰ produced published evidence of six varieties of yellow beans that were identical to the '079 patent both in color and genetic markers.²¹ Armed with the additional information supplied by CIAT, the USPTO rejected the reexamined '079 patent for lack of novelty and obviousness on April 29, 2008, after almost half of the twenty-year patent term.²² Proctor subsequently appealed the USPTO's ruling to the Federal Circuit, but that court affirmed the rejection.²³ Currently, Proctor is pursuing two reissue applications based off of the '079 patent.²⁴

In contrast to the Enola bean patent in which revocation was ultimately successful, patents on the neem tree demonstrate the difficulties associated with invalidating a patent under the U.S. patent laws when the prior art is traditional knowledge. Indigenous communities will often not transcribe their practices into writing. Instead, the information is communally-held and passed down through generations, both by practicing the usage and through word of mouth.²⁵

Uses of the neem tree, a mahogany plant indigenous to India, take advantage of nearly every part of the tree, from its roots to its leaves.²⁶ Particular extracts from the tree possess medicinal qualities,²⁷ some of which have been described in Indian Sanskrit for over 2000 years.²⁸ Parts of the neem tree are also used as antiseptics; the extracted oil from the tree can be

18. *Id.* at 229.

19. Press Release, International Center for Tropical Agriculture, *supra* note 5.

20. The International Center for Tropical Agriculture mission is to reduce hunger and poverty in the tropical countries by improving agricultural research and natural resource management. International Center for Tropical Agriculture, *Mission, Vision, Values*, http://www.ciat.cgiar.org/AboutUs/Paginas/mision_vision_valores.aspx (last visited Apr. 8, 2010).

21. Press Release, International Center for Tropical Agriculture, *supra* note 5.

22. Press Release, ETC Group, *supra* note 4.

23. *In re Pod-Ners*, 337 Fed. Appx. 901, 903 (Fed. Cir. 2009) ("One of ordinary skill in the art seeking to reproduce (and hopefully improve) the yellow beans that Proctor brought back from Mexico would have done what he did: plant the beans, harvest the resulting plants for their seeds, planting the latter seeds, and repeat the process two more times.").

24. See U.S. Patent App. No. 09/773,303; U.S. Patent App. No. 12/564,900.

25. See *supra* Section III.

26. Schuler, *supra* note 4, at 161.

27. *Id.*

28. Vandana Shiva, *The Neem Tree: A Case History of Biopiracy*, <http://www.twinside.org.sg/title/pir-ch.htm> (last visited Apr. 8, 2010).

found in products such as toothpaste and lamp fuel.²⁹

The patents in controversy cover the use of neem seeds as a fungicide.³⁰ Beginning in the mid-1980s, countries have issued over a dozen patents covering methods of extraction, the products of the extraction, and uses thereof. Certainly these patents do not cover the neem tree as it is found in nature and every country's patent law would prohibit the issuance of such a patent. Rather, such patents may cover the *method* for obtaining the extract, as well as the purified *product* obtained from the method.

U.S. patent 5,124,349 and European Union patent EP0436257 cover extracts from neem seeds for use as fungicide.³¹ Although both patents acknowledge that neem seeds have been used as a fungicide for years, both patents claim their process of obtaining the extract from the seeds provides the added advantage of an increased shelf life.³² The validity of these patents is the subject of a legal challenge headed by Vandana Shiva, Magda Aelvoet, and the International Federation of Organic Agriculture Movements (IFOAM).³³ As a result of IFOAM's involvement and the information of prior use it supplied, the European Patent Office (EPO) revoked the EP0436257 patent held by the U.S. Department of Agriculture and W.R. Grace.³⁴ It was the first patent revoked by the EPO due to claims that were based on traditional knowledge.³⁵ The revocation did not come without extensive effort and cost. The opposition and appeal procedures took over ten years, enlisted the services of multiple non-governmental organizations, and required great cost expenditure.³⁶ Further, increased demand for neem tree products has elevated the cost of neem from 300 rupees per ton to 8000 rupees per ton, an increase of over one hundred and seventy U.S. dollars per ton.³⁷ Despite the revocation by the EPO, the United States continues to

29. *Id.*

30. Schuler, *supra* note 4, at 161.

31. *Id.*

32. *Id.* at 162.

33. Press Release, International Federation of Organic Cultural Movements, *European Patent Office Upholds Decision to Revoke Neem Patent*, Mar. 8, 2005, http://www.ifoam.org/press/press/2005/neem_patent_victory.php. IFOAM is an international organization which participates in international negotiations at the UN, provides a market guarantee system for organic goods, and develops organic markets worldwide. *See, e.g.*, About the International Federation of Organic Agricultural Movements (IFOAM), http://www.ifoam.org/about_ifoam/index.html (last visited Apr. 28, 2010).

34. Fritz Dolder, *Traditional Knowledge and Patenting: The Experience of the Neemfungicide and the Hoodia Cases*, 26 BIOTECH. L. REP. 583, 583-87 (2007).

35. *Id.* at 583.

36. *Id.* at 583-87; Schuler, *supra* note 4, at 167 (reporting that CSIR spent Rs500,000 to overturn turmeric patent).

37. Schuler, *supra* note 4, at 165.

allow all patents on neem plant extracts to stand.³⁸ The United States Patent and Trademark Office (USPTO) found that, because the traditional uses cited were not supported by published, written documentation, such uses did not meet the requirements under U.S. patent laws to serve as prior art.³⁹ As will be discussed in more detail,⁴⁰ a U.S. patent is not invalid simply because it seeks to claim something already in public use outside of the U.S.⁴¹

This note examines the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement within the World Trade Organization and why the procedures currently in place are inadequate to protect the holders from the exploitation of their traditional knowledge. Section I examines what is meant by the term “traditional knowledge” and why its patenting may have detrimental consequences to the original holders of the knowledge. Section II discusses how and why patents on traditional knowledge are able to be obtained.⁴² Section III evaluates why the reexamination procedure for challenging the validity of an issued patent, as well as other proposed remedies for protecting traditional knowledge, are infeasible and inadequate to provide a remedy to the original holders of the information. Finally, section IV proposes that an amendment to TRIPS under Article 61 of the Agreement which would require member countries to implement a mandatory criminal procedure for those patentees found to have knowingly filed for a patent that would be invalid based upon the prior use of traditional knowledge. Additional suggestions for criminal sanctions and remedies are made with the primary goal of deterring the criminal conduct while also providing a realistic, achievable remedy for indigenous people.

I. TRADITIONAL KNOWLEDGE AND THE PROBLEMS ASSOCIATED WITH ITS PATENTING

The terminology “traditional knowledge” covers several subject matter areas each having one thing in common: they consist of information held communally by members of indigenous communities.⁴³ Despite its

38. Arewa, *supra* note 4, at 171.

39. Dorothy E. Schmidt, *Postcard from the Reality-Based Universe: “Wish You Were All Here!” A Meditation on the Relationship Between Science, Intellectual Property Law, and the Rights of Indigenous Populations in Plant Genetic Resources*, 38 ENVTL. L. 315, 332 (2008). *See infra* section II.

40. *See infra* Section III.

41. *See* 35 U.S.C. § 102(b) (2002) (Prior public uses must occur within the United States territory in order to serve as prior capable of invalidating a patent).

42. For the sake of convenience, when mentioning specific patent procedures the discussion will be confined within the context of United States patent law recognizing that certain procedures will differ even between signatories of the TRIPS Agreement.

43. *See* Daniel Gervais, *Traditional Knowledge & Intellectual Property: A TRIPS-Compatible*

colonial terminology, traditional knowledge is not static; it continually evolves and develops over time⁴⁴ and covers a wide range of biological and other cultural knowledge.⁴⁵

“Biopiracy” is the term used generally to describe the acquisition by industrially-developed entities of intellectual property rights, typically in the form of patents, over traditional biological knowledge originally held by indigenous peoples in biologically diverse regions of the world.⁴⁶ Examples of biological knowledge in which patent protection was sought include *hagen abyssinica*, ayahuasca, basmati rice, and turmeric.⁴⁷ Biopiracy is said to contribute to the ever widening disconnect between developed and developing countries with the material and monetary advantages derived from misappropriating this information contributing as such.⁴⁸ Beyond the monetary gap, indigenous people may also consider the use of their knowledge as offending non-commercial and spiritual values, illustrating the lack of consideration for those interests and values by the patentee.⁴⁹

The pejorative nature of the term “biopiracy” arises from the lack of compensation that is provided to the indigenous people that develop the traditional knowledge. Biopiracy has come to represent any number of acts, including the collection and use of traditional knowledge, as well as the unfair free-riding on such knowledge through use of the patent system.⁵⁰ Free-riding occurs when patentees reduce the research and development costs of new products by utilizing species the indigenous people have previously determined to be useful and effective, and then seek to patent a related process of purifying the medicinally-effective product, the product itself, or a process for using the product.

Large pharmaceutical companies are not actually trolling the tropical rainforests searching for commercially valuable traditional knowledge from indigenous populations. Most often, the knowledge is patented by “expatriate scientists and resident inventors with access to industrial country patent

Approach, 2005 MICH. ST. L. REV. 137, 140–41 (2005).

44. Krishna Ravi Srinivas, *Traditional Knowledge and Intellectual Property Rights: A Note on Issues, Some Solutions and Some Suggestions*, 3 ASIAN J. WTO & INT'L HEALTH L & POL'Y 81, 84 (2008).

45. Arewa, *supra* note 4, at 164.

46. Graham Dutfield, *What is Biopiracy?* International Expert Workshop on Access to Genetic Resources and Benefit Sharing, at 1 <http://www.canmexworkshop.com/documents/papers/1.3.pdf> (last visited Apr. 9, 2010).

47. Dwyer, *supra* note 17, at 230.

48. *See* Srinivas, *supra* note 44, at 88–90.

49. *See id.* at 86.

50. Dutfield, *supra* note 46, at 1.

offices.”⁵¹ Nevertheless, the impact remains the same. Half the world relies on traditional knowledge for their food supply.⁵² Natural resources and other biological products provide the world’s poor with eighty-five percent of their needs, including food, fuel, shelter, and medicine.⁵³ The source of these products is local.⁵⁴ Local communities and local ecosystems are continually evolving and the balance which has been established by their continuous interaction can be easily disrupted. Biological diversity is a result of the nexus between human interaction and local ecosystems; to not only preserve, but advance, future diversity, conditions must be maintained permitting those people who have nurtured the ecosystem to continue to do so.⁵⁵ If intellectual property rights disrupt the balance previously maintained, the consequences could be deleterious for both the ecosystem and the indigenous peoples who rely on it.

Beyond the direct impact that a patent may have upon the local indigenous communities lie the potential effects that overconsumption and alteration of diverse ecosystems may have in the future. Biodiversity is not static. The continuance of biodiversity is the result of dynamic interactions within an ecosystem—competition among plants, consumption by animals, natural disaster, and human interaction—which permit the environment to evolve.⁵⁶ Depleting one resource in an ecosystem modifies the balance of competitive power as related to the rest of the resources. Preserving the means by which we create biologically diverse resources must be an imperative concern because it is impossible to know what biodiversity we may need in the future.⁵⁷ For example, the genetic altering of food crops may increase agricultural production in the short term.⁵⁸ The availability of genetically modified seeds with increased production capabilities pressure indigenous communities to utilize those strains because of the increased production and fortitude of the crops. However, monocultural farming leaves crops susceptible to natural genetic modifications of parasites, such as the *E.Coli* strain O157:H7 that contaminated cow meat and then spinach crops,⁵⁹ that can have deleterious effects on a crop unable to resist a new

51. Schuler, *supra* note 4, at 168.

52. Rosemary J. Coombe, *The Recognition of Indigenous Peoples’ and Community Traditional Knowledge in International Law*, 14 ST. THOMAS L. REV. 275, 278 (2001).

53. *Id.*

54. *Id.*

55. *Id.* at 279.

56. *Id.*

57. *Id.* at 278–79.

58. *Id.* at 278.

59. MICHAEL POLLAN, *THE OMNIVORE’S DILEMMA: A NATURAL HISTORY OF FOUR MEALS* 82-83 (2006).

parasite.⁶⁰ Biological diversity and “survival of the fittest” evolution only prevails so long as the weak may be weeded out through traditional farming methods.⁶¹ And when almost 1.4 billion rural people require traditional biological knowledge just to eat, altering the delicate balance of human interactions within a local ecosystem can have far-reaching effects.⁶²

II. DIFFICULTY OF PROTECTING TRADITIONAL KNOWLEDGE UNDER CURRENT INTELLECTUAL PROPERTY SCHEMES.

Forums at the national, regional, and international levels have examined, and continue to address concerns over the protection of traditional knowledge.⁶³ There is debate over the proper venue for protecting traditional knowledge. The options include the national laws of those countries housing the information, the national laws of the countries patenting the information, or more generalized international directives aimed at creating a cohesive body of patent law.⁶⁴

Internationally, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) sets minimum standards that all signatory countries must implement within their national laws to protect intellectual property.⁶⁵ The Agreement also mandates enforcement measures including import/export obligations⁶⁶ and criminal sanctions.⁶⁷ The developing and less developed countries have an extended period by which time their laws must comply with TRIPS.⁶⁸ However, the overall level of regulation is the same and mandates apply equally to all countries; this imposes large costs upon countries that must start from scratch with intellectual property schemes not existing previously.⁶⁹

Despite the higher cost of implementation and compliance for developing countries, the structure of the Agreement and the nature of the forum persuaded developing countries to sign on due to expectations that costs

60. Coombe, *supra* note 52, at 278–79.

61. *See id.* at 279.

62. *Id.* at 278.

63. *See* Kate & Laird, *supra* note 1, at 137.

64. *See id.*; *see also* Hannu Wager, *Biodiversity, Traditional Knowledge, and Folklore: Work on Related IP Matters in the WTO*, 3 INTERCULTURAL HUM. RTS. L. REV. 215, 215–16 (2008).

65. Coenraad J. Visser, *Making Intellectual Property Laws Work for Traditional Knowledge*, in POOR PEOPLE'S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 207, 207–08 (J. Michael Finger & Philip Schuler eds., 2004).

66. Agreement on Trade-Related Aspects of Intellectual Property Rights pt. III § 4, Apr. 15, 1994, 33 I.L.M. 81 [*hereinafter* TRIPS Agreement].

67. *Id.* at art. 61.

68. Visser, *supra* note 67, at 208.

69. *Id.*

would be offset by increased international trade.⁷⁰ The WTO operates to advocate a global free trade market for the benefit of all parties involved in international trading.⁷¹ While free trade theoretically should produce a net benefit for all parties involved, competitive advantages and asymmetries in power can affect the negotiation and implementation of international agreements.⁷² The departure from these theoretical assumptions is readily apparent in the context of the negotiations behind the TRIPS. Specifically, the northern developed countries possess much greater control over the agenda in the WTO than the south and such imbalances of power can be seen in the resulting agreement.

For example, the TRIPS Agreement does not address issues pertaining to traditional knowledge while other forums have directly spoken on the topic. The World Intellectual Property Organization (WIPO) has taken note of possible problems with traditional knowledge and drafted proposals to ultimately deal with those issues.⁷³ However, because membership in WIPO is limited and dispute resolution is minimal, this forum has proven ineffective in enforcing the intellectual property issues it addresses.⁷⁴ The Convention on Biological Diversity (CBD) also addresses issues with traditional knowledge. The CBD is a legally binding international agreement which sets regulations on genetic resources and traditional knowledge.⁷⁵ The goal of the CBD is to “balance[] sovereignty and the authority of national governments to regulate access to their genetic resources with the obligation for them to facilitate access for environmentally sound purposes.”⁷⁶ While this seems a plausible goal, many countries, including the United States, are not signatories to the CBD and need not follow its provisions.⁷⁷ The CBD also suffers from rather weak mechanisms of enforcement.

The appropriate starting point for a full understanding of the contours of the traditional knowledge dialogue begins with a discussion of the re-

70. *Id.*

71. Arewa, *supra* note 4, at 158.

72. *Id.* at 158–59.

73. See generally World Intellectual Property Organization [WIPO], *Revised Provisions for the Protection of Traditional Knowledge: Policy Objectives and Core Principles*, WIPO/GRTKF/IC/9/5 available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_9/wipo_grtkf_ic_9_5.pdf (Jan. 9, 2006); see also WIPO, *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WO/GA/26/6 available at http://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_26/wo_ga_26_6.pdf (Aug. 25, 2000).

74. Yoshifumi Fukunaga, *Enforcing TRIPS: Challenges of Adjudicating Minimum Standards Agreements*, 23 BERKLEY TECH. L.J. 867, 871–73 (2008).

75. Kate & Laird, *supra* note 1, at 135.

76. *Id.*

77. Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79 [*hereinafter* Convention].

quirements for patentability under TRIPS. While all countries do not have the same view on patentable subject matter, signatories must at least meet the minimum requirements articulated in the TRIPS Agreement. For the purposes of illustration, this paper will highlight and define these broad requirements in terms of United States law.

Under TRIPS, all patents must possess industrial applicability, newness, and inventive step,⁷⁸ respectively referred to as utility, novelty, and non-obviousness in the United States.⁷⁹ The utility must be “specific” to the particular invention being patented, not just a general utility that all members of a certain inventive class possess.⁸⁰ Therefore, only those inventions which have real-world applicability can be patented.

Subject matter eligible for patent protection includes processes (methods), machines, manufactures, compositions of matter, or improvements thereon.⁸¹ However, certain other subject matter is excluded from patent protection, namely “laws of nature, natural phenomena, and abstract ideas.”⁸² The underlying theory prohibiting such patents states if rights were granted to laws of nature, natural phenomena, or abstract ideas, such patents would stifle downstream innovation since fundamental concepts like the theory of gravity or $E=MC^2$ would be unavailable to the public.⁸³ Except in rare cases the subject matter of the patent and the original use of the traditional knowledge are not in conflict.⁸⁴ This will be further developed in Section II(B) below.

A. Prior Art

The references used to prove that an invention is ineligible for patent protection are called “prior art.” Each subsection of section 102 articulates what qualifies as prior art for purposes of proving anticipation (lack of novelty.)⁸⁵ The same references can also be used to prove non-obviousness. The statutory provisions guiding what prior art is relevant possess a strong bias against invalidating a U.S. patent because of activity abroad. Such a

78. TRIPS Agreement, *supra* note 68, at pt. II § 5.

79. 35 U.S.C. §§ 101-103.

80. *See, e.g., In Re Fisher*, 421 F.3d. 1365, 1370 (Fed. Cir. 2005).

81. 35 U.S.C. § 101 (2006).

82. *Lab. Corp. of America Holdings v. Metabolite Labs, Inc.*, 548 U.S. 124, 126 (2006) quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

83. *Id.* at 126-27.

84. *See* U.S. Patent No. 5,401,504 (filed Mar. 28, 1995) (Use of Turmeric in Wound Healing); Schuler, *supra* note 4, at 166-67.

85. Compare 35 U.S.C. § 102(a) (“printed publication[s] in this or a foreign country”) with 35 U.S.C. § 102(b) (“printed publication[s] in this or a foreign country [and] public uses or on sale in this country”).

bias can be explained by the desire to promote U.S. businesses and industries.⁸⁶

Under 35 U.S.C. § 102(a), a patent is invalid if “the invention was known or used by others *in this country*, or patented or described in a printed publication *in this or a foreign country*, before the invention thereof by the applicant for patent.”⁸⁷ Whereas prior “knowledge” or “use” of the invention in the United States sufficiently bars patentability, identical knowledge or use in a foreign country does not. Only foreign activity resulting in the issuance of a patent or printed publication can invalidate a patent in the United States.⁸⁸ In fact, even knowledge that is held in the United States but originated overseas is not relevant prior art.⁸⁹

Under 35 U.S.C. § 102(b), a patent is valid 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.”⁹⁰ Like § 102(a), only printed publications or patents in foreign countries can invalidate a patent under § 102(b).

Similarly under § 102(g)(2), a patent is invalid if “before such person’s invention thereof, the invention was made *in this country* by another inventor who had not abandoned, suppressed, or concealed it.”⁹¹ Again, inventive activity occurring outside the U.S. is insufficient to show a lack of novelty even though the same invention was already in existence.

Finally, under § 102(e) a patent is invalid if (1) a previous patent application was filed for in the United States before the date of invention or (2) a United States Patent was granted prior to the date of invention.⁹² However, even if an international patent application is filed in the United States and is granted as under § 102(e)(2), the patent still must be published in English in order to qualify as relevant prior art. While this may not pose any serious burden on outside applications because of the dominant use of the English language, it still demonstrates the unwillingness of the U.S. patent scheme to appreciate foreign inventive activity.

The very nature of traditional knowledge makes it extremely difficult to invalidate a U.S. patent. The knowledge is typically communicated

86. Murray Lee Eiland, *Patenting Traditional Medicine*, 89 J. PAT. & TRADEMARK OFF. SOC’Y 45, 48 (2007).

87. 35 U.S.C. § 102(a) (emphasis added).

88. *Id.*

89. *See* Westinghouse Mach. Co., v. Gen. Elec. Co., 207 F. 75, 77–78 (2d Cir. 1913).

90. 35 U.S.C. § 102(b) (emphasis added).

91. *Id.* § 102(g) (emphasis added).

92. *Id.* § 102(e).

orally, and therefore lacks the requisite publishing required under § 102(a). And although the subject matter may have been known or in public use prior to the application for the patent, prior uses can only be invalidating under § 102(a) and § 102(b) if they occur within the United States. “It seems particularly ironic that the requirement of publication is not imposed on domestic prior art in a highly literate society but publication is demanded from peoples whose knowledge has been orally transmitted.”⁹³ Finally, if an applicant for a patent claims the exact same subject matter as the traditional knowledge, a prior invention cannot act as prior art when created outside the country.⁹⁴

B. Novelty and Non-Obviousness

An invention must possess novelty and non-obviousness to be eligible for patent protection.⁹⁵ An invention that is not novel is anticipated. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”⁹⁶ Novelty is not a subjective consideration; inventors are presumed aware of any and all prior art regardless of actual awareness.⁹⁷ So long as the prior art is reasonably accessible it is capable of invalidating an application for patent.⁹⁸

An invention is also ineligible for patent protection if it would have been obvious to create the invention in light of what has come before it.⁹⁹ The non-obviousness requirement prohibits the grant of a patent, despite the fact that the invention is not identically disclosed in the prior art, “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.”¹⁰⁰ Therefore, obviousness is adjudged from the perspective of a person having ordinary skill in the particular field of technology.

There are several key differences between the two analyses. Lack of novelty must be proven by a single prior art reference containing the identical invention. The prior art need not claim the same invention; it is suffi-

93. Coombe, *supra* note 52, at 283.

94. 35 U.S.C. § 102(g)(2).

95. *See* 35 U.S.C. §§ 102–103.

96. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

97. *See, e.g.*, 35 U.S.C. § 102(a).

98. *Bruckelmyer v. Ground Heaters, Inc.*, 453 F.3d 1352, 1354 (Fed. Cir. 2006).

99. 35 U.S.C. § 103(a).

100. *Id.*

cient just that the invention be disclosed in some respect. In comparison, an invention may be obvious in light of one or more prior art references.¹⁰¹ If the person having ordinary skill in the field of technology would be motivated to combine multiple prior art references, or the prior art references teach that individual to combine the prior inventions, the combination of prior art references is obvious if such combination produces the expected result.¹⁰² If the combination of prior art references produces an unexpected result, then the invention is non-obvious.¹⁰³

When considering relevant prior art, novelty is assessed without regard to the particular inventor or a “reasonable person” who might be aware of the prior art. Patentees are presumed to be aware of all prior art references. Therefore, ignorance of a prior invention or publication is not a defense to lack of novelty. Obviousness is assessed from the point of view a person having ordinary skill in the particular field of art. An invention is obvious if, in light of the information such a person would possess, they would find it obvious.

Applying these standards used to evaluate the novelty and obviousness of an invention, it is evident that some of the patents on traditional knowledge will not be invalidated as lacking novelty or non-obviousness.¹⁰⁴ For example, a plant, as found in nature, is unpatentable subject matter because it is naturally occurring and lacks any human input. However, there are three ways to obtain patent protection over living things: purify a naturally occurring substance found within the organism, develop a new use for the living thing (extracted or original), or genetically alter the species.¹⁰⁵ Purification of naturally occurring substances enable the inventor to obtain a patent covering the purified substance under the subject matter of § 101, a “composition of matter.”¹⁰⁶ A patent may also be sought on the process/method of extraction, under a § 101 method patent.¹⁰⁷ Thus, while patenting the naturally-occurring plant is prohibited, the active substances, processes for obtaining such substances, and methods for uses thereof, may be within the purview of current patent laws.

101. MANUAL OF PATENT EXAMINING PROCEDURE § 1504.03(II)(A) (8th ed., rev. 6 2007) (“A rejection under 35 U.S.C. 103(a) would be appropriate if a designer of ordinary skill would have been motivated to modify a primary reference by deleting features thereof or by interchanging with or adding features from pertinent secondary references.”).

102. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007).

103. *Id.* at 416–18.

104. The utility of an invention based upon traditional knowledge is usually not an avenue pursued to invalidate a patent because the very reason the original holders and patentees find such knowledge valuable is because it is useful.

105. Schmidt, *supra* note 39, at 340.

106. 35 U.S.C. § 101.

107. Schmidt, *supra* note 39, at 327.

Patents can be issued on “food crops.”¹⁰⁸ By crossbreeding plant species or genetically modifying the plants, an inventor creates a new strain of food crops which are eligible for patent protection because that particular strain is not produced in a natural environment.¹⁰⁹ This was the means by which Larry Proctor obtained a patent on his Enola bean. Even a valid patent issued for a genetically-altered strain in the country of origin (where the indigenous communities reside) does not prohibit use of the naturally-occurring strain.¹¹⁰ Therefore, traditional knowledge holders can never be prohibited from using the natural resources they have been using even if patents have been granted based upon their traditional knowledge. However, if the indigenous farmers are using a genetically-altered strain, their use constitutes patent infringement, regardless of intent or knowledge, because infringement is a strict liability offense.¹¹¹

III. INADEQUACY OF REEXAMINATION AND OTHER SUGGESTED SOLUTIONS AS A REMEDY FOR MISAPPROPRIATION OF TRADITIONAL KNOWLEDGE.

Once a patent has issued, the patentee obtains the right to exclude others from “make[ing], us[ing], offer[ing] to sell, or sell[ing] any patented invention, within the United States or import[ing] into the United States.”¹¹² The right bestowed on the patentee is a product of national law and only extends to the borders of the nation in which the patent was granted. A U.S. patentee with a patent on a process for obtaining an extract from neem could not prevent a person from utilizing the same method in India without a patent in India. However, though the right to exclude may only extend within that particular country, the effects of patenting and commercialization of traditional knowledge can extend far beyond the territorial limits of the country.¹¹³ Many plant species are indigenous to one area of the world. If a patentee obtains a patent in the United States involving the use of the species, his “right to exclude others from making, using, offering for sale, or selling the invention” allows the patentee to market and exploit his product in the United States. Increased demand and increased consumption in the U.S. may decrease the availability and increase the price of the resource within the indigenous country. As discussed previ-

108. *Id.* at 326.

109. *Id.* at 327.

110. *Id.* at 331.

111. *In re Seagate Tech.*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc) (“patent infringement is a strict liability offense . . .”).

112. 35 U.S.C. § 271(a).

113. *See, e.g.,* Schmidt, *supra* note 39, at 333.

ously, *supra* Section II, the economic impact may also couple with environmental concerns as well. Because of the potentially far-reaching effects, cohesive traditional knowledge protection must be obtained.

There are two different manners in which the original holders of traditional knowledge can be protected. The two goals are not mutually exclusive. “Positive protection” provides benefits to the communities holding traditional knowledge by awarding them the profits from the commercialization of their knowledge.¹¹⁴ “Defensive protection” schemes grant to the traditional knowledge holders an intellectual property right which the holders can enforce against others attempting to use their knowledge.¹¹⁵

The reexamination procedures are an example of a defensive-like protection mechanism. A reexamination procedure is a process whereby a third party can request that a granted patent or claim in a patent be reconsidered by the examiner to determine if it indeed is eligible for patent protection.¹¹⁶ Reexaminations can be initiated by any member of the public and can take two forms: *ex parte*¹¹⁷ and *inter parte*.¹¹⁸ During an *ex parte* proceeding, once the member of the public requests a reexamination they no longer participate in the proceeding, leaving the remainder of the process to be conducted between the patentee and the government.¹¹⁹ A person who files a request for an *inter parte* proceeding continues to participate throughout the process.¹²⁰

According to USPTO’s Performance and Accountability Report for the Fiscal Year 2008, 680 *ex parte* requests for reexaminations were filed, a number which has continued to rise from the 2004 figure of 441 requests filed.¹²¹ The number of *inter parte* requests filed in 2008 was 168.¹²² Most requests are granted¹²³ and there is a high likelihood¹²⁴ that the patentee

114. Visser, *supra* note 67, at 212.

115. Srinivas, *supra* note 44, at 87.

116. 35 U.S.C. § 301, 302.

117. *Id.* §§ 301–07.

118. *Id.* §§ 311–18.

119. *Id.* § 305.

120. *Id.* §§ 314(b)(2), 315(b).

121. USPTO, *Performance and Accountability Report for Fiscal Year 2008*, Table 13A: Ex Parte Reexamination, http://www.uspto.gov/web/offices/com/annual/2008/oai_05_wlt_13a.html (last visited Apr. 10, 2010).

122. USPTO, *Performance and Accountability Report for Fiscal Year 2008*, Table 13B: Inter Parties Reexamination, http://www.uspto.gov/web/offices/com/annual/2008/oai_05_wlt_13b.html (last visited Apr. 10, 2010).

123. Of 666 determinations on *ex parte* requests, 626 were granted. USPTO, *supra* note 123. Of 150 determinations on requests for *inter parties* proceedings, 142 were granted. USPTO, *supra* note 124.

124. Robert Saltzberg & Mehran Arjomand, *Reexaminations Increase in Popularity*, INTELL. PROP. Q. NEWSL. Sept. 2007, <http://www.mofo.com/news/updates/files/12748.html> (last visited Apr. 10, 2010) (approximately seventy-five percent likelihood in *ex parte* requests).

will amend at least one of the claims in the patent. In twenty-six percent of the ex parte requests, all the claims were confirmed; however, in only ten percent of the requests was the entire patent thrown out during ex parte proceedings.¹²⁵

Thus, while statistically reexamination may appear to be a viable option, the typical medium in which traditional knowledge is held and the requirements for reexamination procedures make success unlikely. Initiation of a reexamination requires a question of patentability based on a printed prior art reference.¹²⁶ There is no possibility of a reexamination based upon prior public use or knowledge. Even if such use were allowed to initiate a proceeding it would be unhelpful to traditional knowledge holders; U.S. patent laws limit prior art to public uses within the United States.¹²⁷ Finally, reexamination can be costly. Parties would need to hire an attorney admitted to practice before the U.S. Patent and Trademark Office, which can require financial resources unavailable to traditional knowledge holders without outside assistance. For example, the South African Council for Scientific and Industrial Research (CSIR) spent approximately \$11,000 (Rs 500,000) to overturn a patent granted on the use of turmeric.¹²⁸

The patents issued on traditional knowledge demonstrate that the “USPTO makes little effort to verify the prior art”¹²⁹ which leads to the issuance of patents like Proctor’s original Enola bean patent that never should have been granted in the first place. Reexamination is an after-the-fact means of protecting traditional knowledge requiring a granted patent before a request can be filed and procedures initiated. Other options for protecting traditional knowledge have been advocated which seek to prevent the exploitation of traditional knowledge before the patent’s issuance. Such suggestions include: disclosure of origin obligations, contractual arrangements, compensatory liability regimes, and possible sui generis systems of intellectual property rights.

A. Disclosure of Origin

Disclosure of origin requires all patents making use of traditional knowledge to disclose in the application the location from where the tradi-

125. *Id.*

126. *See* 35 U.S.C. §§ 301, 311.

127. *Id.* § 102(a)–(b).

128. Schuler, *supra* note 4, at 167.

129. *Id.* at 168.

tional knowledge was derived.¹³⁰ The requirement to disclose is triggered by even the most minimal use of traditional knowledge and is said to increase transparency in the patent system.¹³¹ Furthermore, the requirement would provide developing countries with a means to monitor developed countries to ensure their compliance with the CBD.¹³²

However, a disclosure of origin obligation may still provide inadequate protection of traditional knowledge and the rights of the holders of traditional knowledge. First, it is difficult to discern when a patent is based upon traditional knowledge.¹³³ Thus, monitoring compliance with the obligation would only be feasible when the “piracy” is blatantly obvious,¹³⁴ a small hurdle around which patentees can draft claims. More importantly, disclosure of origin standing alone provides no remedy to traditional knowledge holders.¹³⁵ Individuals seeking to patent an invention derived from traditional knowledge are free to obtain those patents so long as they comply with the disclosure obligations. The proposed solution falls short in that it fails to compensate traditional knowledge holders for the patentee’s use beyond mere acknowledgement of the origin of the information.

B. Contractual Agreements

Contracts can be negotiated between indigenous communities and patentees providing benefits to both parties. These agreements are typically called “benefit sharing agreements” or “biodiversity prospecting agreements.”¹³⁶ The companies benefit because they gain access to genetic resources and traditional knowledge. Demand for this access is fairly high due to downstream usage in drug discovery efforts and other biotechnology.¹³⁷ The indigenous communities, in return, may request monetary and non-monetary benefits.¹³⁸ Monetary benefits include access fees or upfront payments, as well as royalties and milestone payments if the resulting product is commercially successful.¹³⁹ Non-monetary benefits include access to scientific research and resources, education, and training.¹⁴⁰

130. Srinivas, *supra* note 44, at 91 n.46.

131. *Id.* at 92–95.

132. *Id.* at 92.

133. *Id.* at 91–92.

134. *Id.* at 96.

135. *Id.*

136. Kate & Laird, *supra* note 1, at 133, 147.

137. *See id.* at 144–46.

138. *See id.* at 151–52.

139. *Id.*

140. *Id.* at 151–52.

An example of a successful benefit sharing agreement is illustrated in the use of a compound called P57 derived from the Hoodia plant.¹⁴¹ The San bushman from the Kalahari desert have been using the Hoodia plant for thousands of years to prevent thirst and hunger.¹⁴² The CSIR began studying the uses of the Hoodia plant without signing an agreement with the San people.¹⁴³ The CSIR isolated a compound, P57, which it patented and licensed to Pfizer to use as an appetite suppressant.¹⁴⁴ Because the CBD recognized the San as legitimate stakeholders in the revenue, the San were able to negotiate with the CSIR to receive royalties and milestone payments.¹⁴⁵

These benefit sharing agreements are promising in that they benefit both parties in the short and long term, both monetarily and non-monetarily. However, one problem in relying on parties to make these agreements is that the traditional knowledge is commonly used and publicly available.¹⁴⁶ If patentees do not need to personally access the information from the indigenous people themselves, the bargaining power of the community is greatly diminished. Further, these agreements are still the product of national law and rely on those laws as a means to negotiate and enforce the agreements.¹⁴⁷ A prerequisite to beneficial agreements between parties requires that the laws of the nations must empower local communities to ensure fair agreements are made.

C. *Compensatory Liability Regime*

Under a model compensatory liability regime (CLR), traditional knowledge cannot be patented.¹⁴⁸ Traditional knowledge is treated as “technical know-how” which prevents any party from obtaining a patent and thereby the power to exclude others.¹⁴⁹ Instead, the information is placed in a “semi-common pool” of knowledge where the original holders receive compensation for their contribution to the pool but cannot restrict second-comers from using their contribution.¹⁵⁰ Second-comers can then make use of the original holder’s contribution to develop innovations them-

141. *Id.* at 146–47.

142. *Id.* at 146.

143. *Id.*

144. *Id.*

145. *Id.* at 146–47.

146. *Id.* at 156.

147. *Id.* at 155.

148. Srinivas, *supra* note 44, at 98.

149. *Id.*

150. *Id.* at 99.

selves. Because traditional knowledge holders receive compensation the free rider problem is thereby eliminated.¹⁵¹

However, the communally-shared nature of traditional knowledge makes it difficult to discern who should receive the compensation. Furthermore, quantifying the value that the addition of the traditional knowledge made to the overall patented invention would prove difficult. Presumably the value would derive from the commercial value of the traditional knowledge standing alone but, as discussed previously, some holders emphasize spiritual and non-commercial values in their knowledge which are incapable of being quantified.

D. Sui Generis System

Recognizing that current intellectual property schemes provide inadequate protection should indigenous peoples seek intellectual property protection themselves, proposals for a system which specifically protects traditional knowledge have been suggested. Countries like India, the Philippines, and Peru have already developed and passed *sui generis* systems protecting their own traditional knowledge.¹⁵² *Sui generis* systems seek to remedy problems with traditional intellectual property regimes and “accommodate the specificities *and* interests of [traditional knowledge] holders.”¹⁵³ For example, Peru’s objectives in establishing the country’s *sui generis* system were:

- (a) To promote respect for and the protection, preservation, wider application and development of the collective knowledge of indigenous peoples;
- (b) To promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge;
- (c) To promote the use of the knowledge for the benefit of the indigenous peoples and mankind in general;
- (d) To ensure that the use of the knowledge takes place with the prior informed consent of the indigenous peoples;
- (e) To promote the strengthening and development of the potential of the indigenous peoples and of the machinery traditionally used by them to share and distribute collectively generated benefits under the terms of this regime;
- (f) To avoid situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions.¹⁵⁴

Problems with implementation of a *sui generis* system are numerous.

151. *Id.*

152. *Id.* at 104.

153. *Id.*

154. Law N° 27811 of August 10, 2002, El Peruano, art. 5 (Peru).

One issue is compatibility with TRIPS.¹⁵⁵ Signatories to TRIPS must implement laws “consistent with the provisions of [the] Agreement.”¹⁵⁶ Incorporating provisions from the CBD, the agreement specifically addressing traditional knowledge concerns, may prove difficult due to the silence of TRIPS on the issue.¹⁵⁷ Further, the numerous different objectives that a sui generis system would seek to accommodate may prove difficult to implement. There exist many commercial, cultural, and spiritual objectives which must be considered. These objectives span across customary law and intellectual property regimes and finding an appropriate balance between those interests may prove difficult, especially in an international forum.

IV. TRIPS CRIMINAL SANCTIONS

The TRIPS Agreement has proven the most effective avenue for implementing internationally binding obligations regarding intellectual property law. The structure and voting practices in the WTO, as compared to the UN/WIPO, allow “package deal” negotiating.¹⁵⁸ Developing countries can agree to compromises benefiting developed countries in return for their desired increased standards protecting traditional knowledge.¹⁵⁹ Although arriving at a consensus within the WTO can prove difficult to negotiate, an amendment to the TRIPS Agreement implementing a criminal sanction shifts the current doctrine toward an *ex ante* scheme which effectively deters misappropriation of traditional knowledge.

Articles 41 through 61 of the TRIPS Agreement enumerate the enforcement obligations of member countries.¹⁶⁰ Articles 41 to 49 list the civil and administrative procedures and remedies and Articles 51 through 60 relate to border measure requirements.¹⁶¹ Article 61 is the sole article containing requirements for criminal procedures that signatories to the Agreement must implement.¹⁶² Article 61 provides that:

Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corre-

155. Srinivas, *supra* note 44, at 105.

156. TRIPS Agreement, *supra* note 68, at pt. I art. 8.

157. Srinivas, *supra* note 44 at 105.

158. *See, e.g.*, Fukunaga, *supra* note 76, at 874–75.

159. *See, e.g., id.*

160. TRIPS Agreement, *supra* note 68, at pt. III §§ 1-2.

161. *Id.* at pt. III § 4.

162. *Id.* at pt. III § 5.

sponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed willfully and on a commercial scale.¹⁶³

While specifically providing for criminal procedures with regards to trademark and copyright infringement, the Article makes no mention of a mandatory criminal procedure for any violation of a member country's patent laws. However, looking to the drafting history of Article 61 demonstrates that such a law is not far-fetched. In fact, Article 61 was debated back and forth during negotiations with one of the original drafts containing language that provided for criminal procedures in cases of willful "infringements on a commercial scale of intellectual property rights concerned by this agreement."¹⁶⁴ Such language would have applied to patent infringers. Indeed, certain participants made clear that they wanted to provide criminal measures for any and all intellectual property infringement, regardless of willfulness.¹⁶⁵ The proposed language ultimately included a mens rea requirement of "willful" action along with the language "on a commercial scale." This was introduced to limit the application and deter what have been referred to as "professional infringers," not simply innocent infringers.¹⁶⁶ The drafting history of Article 61 demonstrates the particular issues that should also be considered when contemplating a scheme to remedy the failed protection of traditional knowledge. And although TRIPS ultimately eliminated any mention of criminal sanctions for patent infringement, TRIPS sets only minimal standards with which countries must comply.

In addition to injunctive relief and awards of damages, several countries have criminalized patent infringement including Japan, the United Kingdom, Germany and France. Under Article 196 of the Japanese Patent Act the infringement of a patent or an exclusive license is subject to criminal sanctions.¹⁶⁷ Sanctions include imprisonment up to five years and fines up to five million yen, or approximately \$50,000.¹⁶⁸ In fact, no private right of action is available to the patentee in Japan because of the characterization of tort law as criminal in nature, thereby placing exclusive control over

163. *Id.*

164. DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 234 (1998).

165. *Id.*

166. *Id.* at n.28.

167. TOKKYOHŌ [Patent Act], Law No. 121 of 1959, art. 196 (Japan).

168. *Id.*

the trial with the Japanese government.¹⁶⁹ In the United Kingdom, the U.K. Patents Act provides criminal penalties for the falsification of register,¹⁷⁰ an unauthorized claim of patent rights,¹⁷¹ an unauthorized claim that a patent has been applied for,¹⁷² and misuse of the title "Patent Office."¹⁷³ Violations of any of these sanctions can result in a fine and possible imprisonment for the falsification of register.¹⁷⁴ In Germany, any individual who, without consent, "makes or offers, puts on the market, uses or imports or stocks for these purposes a product which is the subject matter of a patent" shall be subject to a fine or imprisonment not exceeding three years.¹⁷⁵ However, unlike the Japanese system which places exclusive control over the prosecution of patent infringers in the hands of the government, such offenses are only prosecuted in Germany on the basis of a complaint or if the authorities feel prosecution would best serve the public interest.¹⁷⁶ Finally, in France, criminal procedures are available for exceptional cases of patent infringement. For example, when patent infringement prejudices the national defense, imprisonment up to five years may be appropriate.¹⁷⁷ The knowing infringement of another's patent rights may carry a two year prison term and up to 1,000,000 franc fine.¹⁷⁸

While these systems may increasingly deter potential patent *infringers*, Article 61 specifically states that member countries may "provide for criminal procedures and penalties to be applied in other cases of *infringement*."¹⁷⁹ Unfortunately, traditional knowledge holders typically do not obtain intellectual property rights (indeed, TRIPS recognizes only personal property rights, not communal property rights)¹⁸⁰ in their traditional knowledge so another's (mis)use of it cannot constitute "infringement" per se. Therefore, an addition to the TRIPS Agreement should be made under Article 61 implementing a mandatory criminal procedure, the initiation of which does not require "infringement of intellectual property rights" based on traditional knowledge but rather just an "infringement of traditional

169. Larry Coury, *C'Est What? Saisie! A Comparison of Patent Infringement Remedies Among the G7 Economic Nations*, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1101, 1145-46 (2003).

170. Patents Act, 1977, c. 37, § 109 (Eng.).

171. *Id.* § 110.

172. *Id.* § 111.

173. *Id.* § 112.

174. *Id.* § 109.

175. Patentgesetz [Patent Act], Dec. 7, 1990 RGBI. II, at § 142(1) (F.R.G.).

176. *Id.* § 142(4).

177. Law No. 92-597 of July 1, 1992, Journal Officiel de la Republique Francaise [J.O.] [Official Gazette of France], Feb. 8, 1994, L. 615-13.

178. *Id.* at 615-14.

179. TRIPS Agreement, *supra* at 68, at pt. III § 5 art. 61.

180. Visser, *supra* note 67, at 209-10.

knowledge.”

A. Proposal

The shortcomings of the current intellectual property regimes, as well as the proposed solutions discussed supra, demonstrate that there are six main objectives that must be addressed when protecting traditional knowledge. These are: 1) coherent application across nations; 2) *ex ante* application; 3) economic feasibility; 4) adequate deterrence; 5) not easily circumvented; and 6) ability of indigenous people to grant consent and thereby obtain compensation for their knowledge.

Under this new amendment, the criminal procedures would be mandatory for all signatories of the TRIPS Agreement. This would ensure a consistent, harmonized body of law across all countries, both developed and developing. To achieve this standardization, traditional knowledge must be uniformly defined. Looking to the CBD, Article 8(j) refers to traditional knowledge as “knowledge, innovations and practices of indigenous and local communities.”¹⁸¹ To ensure further uniformity, the same activities undertaken by the traditional knowledge holders must be sufficient to initiate the criminal procedure across countries. For example, whereas some countries, like the United States, do not consider foreign prior use invalidating prior art, others do consider such uses. Traditional knowledge is typically transmitted orally from generation to generation and is held collectively. Therefore, to achieve the maximum level of protection of traditional knowledge, all foreign prior uses should be considered sufficient to initiate the procedure. This prevents companies from end-running the patent system by filing in countries like the United States to avoid the prior art. And although the amendment does not implement the same structures as the CBD, a further benefit of implementing this amendment would be to advance the integration of the CBD into the TRIPS Agreement given the similarity in language.¹⁸²

Further, traditional knowledge must be protected from exploitation *ex ante*, that is, before the patent is granted. Otherwise, the time and resources necessary to challenge the patent, either during reexamination or litigation, are infeasible remedies for those most directly affected by the exploitation of traditional knowledge. Likewise, the procedure must be economically feasible for indigenous people to participate. A criminal procedure places the cost of litigation on the government. However, traditional knowledge

181. Convention, *supra* note 79, at art. 8(j).

182. There has been discussion over whether the TRIPS Agreement and the CBD can be harmonized. See Kate & Laird, *supra* note 1, at 137.

holders should be given the opportunity to actively participate in the procedure if they elect to, providing evidence of publications and prior use, or other resources needed to charge and convict the defendant.

This can be achieved by providing traditional knowledge holders the ability to initiate the criminal prosecution much like filing a request for reexamination. This serves both the traditional knowledge holders' interests and the public interest. First, holders will possess both commercial and non-commercial interests in the knowledge. Commercial interests include the higher cost of a product resulting from the increased demand due to its commercialization, the value lost from their own sales of the products, or any other monetary value lost. Non-commercial interests might include the sustainability of the ecosystem from which the product is obtained, as well as the spiritual and cultural significance some communities attribute to the particular biological product.¹⁸³ Traditional knowledge holders should be able to protect both areas of interest.

Second, this procedure also promotes the dissemination of information. "Facilitated access" is encouraged by the CBD.¹⁸⁴ In order that a prosecutor can show that a patent applicant filed with knowledge of the traditional knowledge, it is in the indigenous community's best interests to disclose their use. An international database containing all traditional knowledge might be established, the contours of which lie outside the scope of this article. Countries such as China and India are already establishing databases containing their indigenous communities' traditional knowledge.¹⁸⁵ While the overall onus of the work in a criminal procedure will be placed on the national governments, which will undeniably lead to policing issues, countries rich with traditional knowledge can assist by disseminating their communities' traditional knowledge.

This proposed system would mimic the criminal procedures proposed in a recent directive passed by the European Union. The directive allows intellectual property right holders whose rights have been violated to assist in the investigations for prosecution.¹⁸⁶ While acknowledging that it may be difficult to ascertain who the true holders of a particular piece of tradi-

183. For example, the ayahuasca plant is a South American vine used in Amazonian Indian rituals. When a patent was granted to a U.S. citizen on a new strain of the plant, the tribe objected because it gave rights to a sacred plant used in religious ceremonies. Schuler, *supra* note 4, at 170.

184. Kate & Laird, *supra* note 1, at 133.

185. Press Release, European Patent Office, *Protecting Traditional Knowledge: India Opens Online Database to EPO Examiners*, <http://www.epo.org/topics/news/2009/20090211.html> (Feb. 11, 2009).

186. Press Release, European Parliament, *Intellectual Property Rights: Criminal Sanctions to Fight Piracy and Counterfeiting*, <http://www.europarl.europa.eu/sides/getDoc.do?language=EN&type=IM-PRESS&reference=20070319IPR04284> (Mar. 20, 2007).

tional knowledge are, the concern cannot outweigh the overall benefit of preventing the misappropriation of traditional knowledge. In fact, all potential schemes to compensate and protect traditional knowledge holders would have similar difficulties since traditional knowledge by its very nature is continually evolving and is communicated orally within a community. A modest procedure could be implemented in which the individual or group who filed the request for prosecution would have to furnish proof they do in fact possess an interest, monetary or non-monetary, in the subject matter of the patent or application.

Criminal sanctions also remedy the problem of inadequate deterrence. Under current intellectual property laws, the only consequence if a patent application is declared invalid based on prior art is denial of the patent. And as discussed earlier, this can be easily end-run. Prior uses occurring outside the United States, for example, do not invalidate a patent. And filing for a patent on a process or method of using the traditional knowledge product eliminates the subject matter invalidity. By requiring that the definition of prior art include both domestic and foreign prior uses and instituting a criminal procedure when a patent is invalid because of the prior art, individuals seeking patents will be more hesitant to file for a patent when there is the possibility that it is found invalid based on traditional knowledge. Further, the indigenous communities would have greater access to the legal system and may be able to police applications filed or patents granted with assistance from organizations like IFOAM.

The drafts and negotiations of Article 61 indicate that criminal sanctions were intended to deter "professional infringers."¹⁸⁷ To remain in line with this understanding, the proposed amendment should require knowledge of indigenous community's interest in the traditional knowledge before criminal procedures can be initiated. The scienter requirement ensures that the innocent filing of a patent will not turn into a strict liability offense subjecting the patent applicant to criminal sanctions.

Further, permitting holders of traditional knowledge to consent provides benefits to both parties. First, allowing the holders of traditional knowledge to grant consent recognizes a pseudo-right, based on the labor theory of property rights, in their own knowledge. Essentially, traditional knowledge holders would be given the opportunity to license their information without having to obtain a property right in the knowledge in the first place. This comports with the CBD which recognizes original traditional knowledge holders as legitimate stakeholders in intellectual property rights granted on their knowledge while also eliminating the costs, time and need

187. See GERVAIS, *supra* note 167, at n.28.

for patent prosecution.¹⁸⁸

Second, the consent clause makes that information available to the public. While one goal of the amendment is to prohibit the exploitation of traditional knowledge to the original holders' detriment, the public may be better served when the progress of science or humanity is promoted by the disclosure of such knowledge. Therefore, the ability to give consent satisfies both goals in implementing a new property regime; it provides protection to traditional knowledge while permitting the original holders of that knowledge to benefit from its value.

The amendment to the TRIPS Agreement should contain the following language:

Member countries shall provide for criminal procedures and penalties to be applied in cases where a patent is knowingly obtained, or an application for patent is knowingly filed, without consent, and the subject matter of the patent or application would be ineligible for patent protection under Article 27 due to prior awareness or use of traditional knowledge. "Traditional knowledge" shall be defined as any knowledge, innovations and practices of indigenous and local communities involving biological diversity or genetic resources. Criminal procedures may be initiated by the member country's prosecuting authorities or by the filing of a request by a third party, located within or outside the member country's borders, who can demonstrate a monetary or non-monetary interest in the subject matter of the patent.

The amendment would apply in the following manner. Consider the Enola bean patent discussed *supra*, but without the publications discussing the prior use of the Mayacoba bean. Proctor files for a patent on his genetically-modified strain of bean, knowing that it is the same strain of bean he bought in a bag from Mexico. When the application is filed in the United States, the USPTO examines the validity of the patent in light of the prior art under 35 U.S.C. § 102 as well as considering prior uses of traditional knowledge. Agriculture and farming techniques by the Mexican farmers would fall under the definition of "traditional knowledge" as a practice of a local community involving biological diversity. The Mexican farmers can request that criminal prosecution be initiated if they become aware of Proctor's patent application, since they can demonstrate a monetary interest in their bean. They can also assist the prosecution by providing background information about their prior public use. Once the request is filed, Proctor's pending application would be suspended until it was determined whether Proctor was guilty under the new criminal statute. While it is fairly evident that Proctor's patent lacked any novelty over the prior use, other cases in which traditional knowledge is used to develop "method" or "use" patents

188. Convention, *supra* note 79.

may be more difficult to prove lack of novelty or non-obviousness.

B. Remedies

Fines and imprisonment would be proper sanctions for a violation of the proposed amendment. Further if the crime is caught prior to granting of the patent, the application should be denied; if the crime is not caught until after a patent is granted, the patent should be revoked. These sanctions might provide adequate deterrence to those individuals contemplating such acts.

However, restitution to the victims of the crime should also be considered, not simply deterrence of the filing. Violation of the amendment could require mandatory benefit sharing agreements be entered into by the parties. The mandatory benefit sharing agreements give traditional knowledge holders significant leverage to extract desired benefits. Under a pure benefit sharing regime (without possible criminal sanctions), patentees have little incentive to give in to negotiations with indigenous communities. However, if failure to coordinate an agreement will result in criminal sanctions, the traditional knowledge holders have greater leverage to negotiate for more favorable terms. The traditional knowledge holders could agree to permit the patentee to obtain a patent in return for royalties and milestone payments. They might also negotiate a system in which the returns to the community are in access to research facilities and scientific testing to investigate communal genetic trends and diseases.

Should the holder feel that the use of their knowledge would offend spiritual and religious values, as with the Ayahuasca plant,¹⁸⁹ their increased bargaining power would permit them to refuse to negotiate an agreement. However, a procedural mechanism must be put in place within the WTO or CBD which requires the dissemination and use of the knowledge when the potential benefits of commercializing that knowledge significantly outweigh the non-monetary significance placed on that knowledge by the original holders.

The possible benefits of an agreement must also be weighed against the value of the resource in its natural environment. Refusing to come to an agreement could result in over-consumption of the resource since the information would be available to the public and many people could make use of the natural resource without an exclusionary property right. Coming to an agreement with the potential patentee might also result in overuse if the licensee is able to create a large enough demand for the product. Of

189. See, e.g., Schuler, *supra* note 4, at 169–70.

course, within negotiations of the agreement the original holders might limit the level of consumption of the resource in order to maintain the vitality of their ecosystems. Whatever decision is ultimately made about the utilization of the traditional knowledge, the most important consideration is that the traditional knowledge holders themselves are one of the parties who have a voice in the decision.

CONCLUSION

The traditional knowledge issue presents a difficult problem of balancing normative and economic/public considerations when determining what level of protection, if any, is appropriate for the subject matter. On one hand is the recognition and protection deserved by those groups who are responsible for developing, testing, and determining the value of the traditional knowledge. While their contribution is undeniably great, a complete ban of all intellectual property rights that appear to use traditional knowledge runs counter to every intellectual property right scheme. Enabling such people to “hoard” their information would stifle innovation that might potentially benefit a large number of the population.

As the north-south divide becomes ever more apparent the member states of TRIPS must be cognizant of the interests of countries that may not be similarly situated. That recognition should be reflected in the articles that are implemented into the Agreement. Traditional knowledge is the backbone of a large percentage of the world population’s livelihood and must be protected to ensure that its continued use is available to those who have been using it for ages. The current regulatory schemes and procedures for protecting traditional knowledge are ineffective in certain respects that mandate the implementation of a new procedure. Traditional knowledge holders must be able to take an active role in the procedure without shouldering the burden of combating those who seek to obtain patents. Once traditional knowledge is protected from foreign intellectual property rights and the original holders of the knowledge benefit from its commercialization, the misappropriation of traditional knowledge will be minimized and the gap between developing and developed countries narrowed.