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Biopiracy, Trade, and Sustainable Development

By Lorna Dwyer*

ABSTRACT

This article addresses the misappropriation of traditional knowledge by multinational corporations. It provides examples of biopiracy and evaluates the confrontations and arguments that have been raised between developing and developed countries regarding patent protection of traditional knowledge. Additionally, it briefly analyzes the divergent and conflicting approaches to the problem that international treaties and organizations have taken to date. Finally, the article proposes a number of strategies and recommends specific actions that developing countries should take to enhance protection of their traditional knowledge and indigenous cultures.

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I. INTRODUCTION

Imagine that a Brazilian scientist visits Wyoming. On his way to the mountains, he encounters a Cheyenne Shaman who joins him. The Shaman is particularly talkative that day, so they engage in an entertaining conversation. The Shaman tells the scientist the story of a very important and powerful plant. The Brazilian scientist learns that the Shaman is visiting the mountains to gather a plant that his tribe has nurtured for many generations and that they use to cure a very aggressive disease. The scientist feels curious and decides to visit that site. Once they arrive at the site, the scientist notices that the Shaman is performing a ritual ceremony, after which he picks up some plants. The Shaman explains later that this plant is sacred to the Cheyenne. The scientist takes a sample of the plant back to Brazil, and years later patents a medicine based on the plant compounds called "Visplantina" that cures HIV. Suppose that "Visplantina" has generated millions of dollars in profit for the Brazilian company and the scientist. Cheyenne tribal members complain to the U.S. government, arguing that they discovered the plant, they nurtured it for centuries, and they have used the plant in important religious ceremonies. The Brazilian pharmaceutical company argues that the plant is a product of nature, that it belongs to humanity and is a heritage of "mankind," and that the company spent ten years and millions of dollars in research to develop the drug.

Several questions arise from this hypothetical situation. Who is the owner of the plant? Does the United States have any right over it, or should the property rights be allocated to the Cheyenne people who cultivated it for centuries? Who has ownership rights over the medicine? Should the tribe benefit from the profits? Should the United States, under its trust obligation to the tribe, prevent other scientists from coming to the site and searching for other plants that may contain useful compounds?

These are obvious questions, and one would expect to find the answers easily through the use of local legal systems or international treaties. But the answers are in fact unclear. There is no global consensus over such fundamental issues as who owns plant genetic resources (PGRs) and what rights, if any, indigenous communities have when outsiders use their resources and traditional knowledge to develop profitable products. In fact, international treaties alternately conflict and overlap with each other on these issues. The jurisdiction of international organizations is also unclear.¹ The result is legal uncertainty, the

1. The World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), the Food and Agricultural Organization (FAO), and the United

likelihood of confrontation between developed and developing countries, and increasing resistance from developing countries and indigenous communities to share their traditional knowledge.

Only recently has traditional knowledge (TK) of PGRs and their medicinal and agricultural uses created social, economic, and legal issues.² “PGRs consist of seeds, plants, and plant parts useful in crop breeding and their medical value, which are explored for their genetic attributes.”³ PGRs can be “raw” or “worked,” where the latter are altered by human intervention.⁴ Before the development of biotechnology in the 1980s, the global community did not take into account the ethical and economic consequences of using indigenous knowledge.⁵ The impact of globalization on indigenous societies has many facets, but the focus of this article is one of economic concern.⁶ In 1995, the estimated market value of pharmaceutical derivatives from TK was \$43 billion; this represents almost thirteen percent of worldwide profits from pharmaceuticals.⁷ Developing countries use several expressions to refer to the appropriation of TK by industries of developed countries. “Biopiracy” is the term most commonly used⁸ when multinational corporations profit from the medicinal and agricultural uses of plants known to indigenous or native societies and fail to compensate those communities.⁹ Access to PGRs is an important issue because these resources fulfill many pharmaceutical and agricultural needs of the global community. As a result, many competing interests attempt to

Nations (UN) have adopted treaties on Plant Genetic Resources that conflict with each other, as explained *infra*, Part V.

2. Jonathan B. Warner, *Using Global Themes to Reframe the Bioprospecting Debate*, 13 IND. J. GLOBAL LEGAL STUD. 645, 647 (2006) (defining TK as “creation through a long period of time which has been passed down from generation to generation; new knowledge is integrated to the existing, as knowledge is improved; improvement and creation of knowledge is a group effort; and ownership of indigenous knowledge varies between indigenous peoples”).

3. Ronan Kennedy, *International Conflicts over Plant Genetic Resources: Future Developments?*, 20 TUL. ENVTL. L.J. 1, 2 (2006).

4. *Id.*

5. *See, e.g.*, David Dembo et al., *Biotechnology and the Third World: Some Social, Economic, Political and Legal Impacts and Concerns*, 11 RUTGERS COMPUTER & TECH. L.J. 431, 450 (1985).

6. Maggie Kohls, *Blackbeard or Albert Schweitzer: Reconciling Biopiracy*, 6 CHI.-KENT J. INTELL. PROP. 108, 111 (2007).

7. *Id.*

8. Warner, *supra* note 2, at 645 n.1 (noting that one scholar views “bioprospecting as a subclass of biopiracy” while another uses the terms interchangeably).

9. Richard Stallman, *Biopiracy or Bioprivateering?*, <http://www.stallman.org/articles/biopiracy.html> (last visited Apr. 22, 2008).

control the appropriation and use of PGRs; states, indigenous communities, and farming communities in developing countries usually compete with private multinational corporations and individuals from the developed world.¹⁰ Additionally, non-governmental organizations (NGOs) and international organizations sometimes intervene in defense of particular interests, groups, or communities.¹¹

International treaties and regulations reflect these competing interests. The World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS),¹² which was influenced by intensive lobbying from corporations,¹³ advocates for the expansion of intellectual property rights (IPRs). On the other hand, the United Nations Convention on Biological Diversity (CBD),¹⁴ signed at the United Nations Conference on Environment and Development (UNCED), and the International Treaty on Plant Genetic Resources for Food and Agriculture,¹⁵ negotiated at the Food and Agricultural Organization (FAO) Conference, advocate for the recognition of states' sovereignty over their PGRs and the defense of TK. The World Intellectual Property Organization (WIPO) has established an agenda that is friendlier to the interests of developing countries.¹⁶ Because of these somewhat conflicting forums and treaties, a unified legal system to protect PGRs and TK has yet to be established. The WIPO General Assembly, which met in September of 2007, extended the mandate of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) for two years. The Committee is expected to progress toward a shared international

10. Kennedy, *supra* note 3, at 3–4.

11. MICHAEL BROWN, WHO OWNS NATIVE CULTURE? 113 (Harvard University Press, 2004) (explaining the role of RAFI, a multinational NGO that opposes projects even bioprospecting oriented).

12. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 39, Apr. 15, 1994, 33 I.L.M. 81 [hereinafter TRIPS].

13. Warner, *supra* note 2, at 650–51.

14. Convention of Biological Diversity art. 2, June 5, 1992, 31 I.L.M. 822 [hereinafter CBD] (The CBD defines biotechnology as “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. . .”).

15. International Treaty on Plant Genetic Resources for Food and Agriculture, available at <ftp://ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf> [hereinafter Plant Genetic Resources].

16. WIPO, *Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions/Folklore*, <http://www.wipo.int/tk/en/> (last visited Apr. 22, 2008).

understanding of how best to protect TK and avoid misappropriation and misuse.¹⁷ Meanwhile, however, the practice of biopiracy seems to be expanding.

A major question is how to protect the rights and interests of indigenous communities and developing countries with regard to PGRs and TK. A more difficult question is how to do so while also protecting the environment, encouraging research and development, and enabling the production of new medicines and agricultural products. This article will first explore these issues by describing examples of biopiracy that provide insight into the overall problem. Second, it will consider the difficulties created by the use of IPRs to protect TK for the medicinal use of plants. Third, it will look briefly into the different international treaties that discuss these problems. Finally, it will analyze different proposals that offer new strategies for developing countries to implement in defense of their indigenous knowledge and resources.

II. BACKGROUND

During the 1960s, scientists became curious about the medicinal use of plants by indigenous people.¹⁸ Exotic plants became significant for their medicinal and agricultural uses. Richard Evans Schultes, a Harvard professor, spent years studying indigenous plants for these uses.¹⁹ Professor Schultes' research encouraged the development of ethnobotany²⁰ and stimulated the advance of biotechnology.²¹

During the 1970s and 1980s, ethnobotany became more important due to the accelerating rate at which tropical forests were being destroyed.²² The loss of tropical forests created awareness about the need to protect biodiversity in order to search for cures to diseases such as cancer and HIV/AIDS. The term "bioprospecting" refers to the work of some ethnobotanists who search the planet's remote regions, motivated mainly by the economic and social value of biodiversity, to find exotic

17. Press Release, WIPO, WIPO Member States Extend International Work on Protection of Traditional Knowledge, Genetic Resources and Folklore (Oct. 2, 2007), available at http://www.wipo.int/pressroom/en/articles/2007/article_0072.html.

18. BROWN, *supra* note 11, at 96.

19. *Id.*

20. *Id.*

21. CBD, *supra* note 14, art. 2 (defining biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use").

22. BROWN, *supra* note 11, at 97.

plants and animals “in hopes of finding new cures and new crops.”²³ The international patent system has reinforced the economic value of biodiversity by granting twenty-year monopolies to investors in pharmaceutical or agricultural products.²⁴

Bioprospecting has led to growing concern about the appropriation and use of PGRs to develop new pharmaceutical and agricultural products. In the 1980 case, *Diamond v. Chakrabarty*, the U.S. Supreme Court held that a genetically modified strain of bacteria created in a laboratory qualified for patent protection.²⁵ The decision suggested the possibility of broader biological patents. Some scholars opined that the bacteria in *Chakrabarty* were not an invention; rather, the scientists had merely shifted genes to stimulate a natural reaction and, therefore, did not “create” life.²⁶ Those scholars believed that the courts should not grant patents for that type of “mere discovery.”²⁷ Nevertheless, the United States has granted patents for plants and other forms of life on the grounds of “human intervention,”²⁸ and its patent system has expanded globally through the implementation of multilateral and bilateral treaties.²⁹

Some scholars argue that biopiracy is a non-issue,³⁰ and that biopiracy claims have been exaggerated or distorted.³¹ These scholars further suggest that the developing world’s aggressive defense of TK and PGRs discourages innovation³² and is not justified when weighed against the global benefit of publicizing an organism’s usefulness.³³ They claim

23. Kohls, *supra* note 6, at 108 (internal quotations omitted).

24. TRIPS, *supra* note 12, art. 33.

25. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

26. VANDANA SHIVA, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE* 20 (South End Press, 1997).

27. Dennis S. Karjala, *Biotech Patents and Indigenous People*, 7 MINN. J. L. SCI. & TECH. 483, 502-03 (2006) (internal quotations omitted).

28. Marina L. Whelan, *What, If Any, Are the Ethical Obligations of the U.S. Patent Office? A Closer Look at the Biological Sampling of Indigenous Groups*, 14 DUKE L. & TECH. REV. 1, ¶3 (2006) (stating that by “2000, the USPTO had issued over 6,000 patents on full-length genes isolated from living organisms and were considering over 20,000 gene-related patent applications”) (internal quotations omitted).

29. JOSEPH E. STIGLITZ, *MAKING GLOBALIZATION WORK* 116–17 (W.W. Norton & Co. 2006).

30. Jim Chen, *There’s No Such Thing as Biopiracy . . . and It’s a Good Thing Too*, 37 MCGEORGE L. REV. 1, 5 (2006).

31. *Id.* at 6.

32. See Keith Aoki, *Distributive and Syncretic Motives in Intellectual Property Law (with Special Reference to Coercion, Agency, and Development)*, 40 U.C. DAVIS L. REV. 717, 734 (2007).

33. Kohls, *supra* note 6, at 112.

that developing countries can protect their domestic PGRs by issuing environmental laws³⁴ and denying patents covering naturally occurring substances or medicinal TK.³⁵ Additionally, they note that ethnobiological knowledge is a public good,³⁶ that the cost of transforming a single compound into a marketable drug requires an average development investment of \$300–\$500 million, and that the time period between plant collection and marketing of a drug often exceeds ten years.³⁷ They also assert that researchers often find different uses than the ones suggested by the local community.³⁸ Finally, it is important to note that the FDA approved only twenty percent of proposed new drugs in 2005³⁹ and that profits from any particular research and development effort are not guaranteed.⁴⁰

Pharmaceutical developers defend their property claims over PGRs by producing evidence of “human intervention” through the use of technology.⁴¹ Patent offices typically overlook any prior custody and use of those resources by indigenous communities.⁴² This is a dangerous oversight, however, because the indigenous knowledge of plants actually plays an important role in the discovery of new pharmaceutical products. If a native shares his knowledge of the traditional uses for certain plants, a pharmaceutical company’s search for TK is vastly simplified.⁴³

The western concept of intellectual property law is based on individual invention and private property. This concept does not respond adequately to the new challenges raised by the advances in biotechnology and their application to biodiversity and indigenous knowledge regarding PGRs.

34. Karjala, *supra* note 27, at 490.

35. *Id.* at 493.

36. Margaret Chon, *Intellectual Property and the Development Divide*, 27 *CARDOZO L. REV.* 2821, 2883 (2006) (noting that the UN Secretary General lists “[c]oncerted management of knowledge, including worldwide respect for intellectual property rights” as one of ten public goods of particular importance).

37. BROWN, *supra* note 11, at 110.

38. *See* Chen, *supra* note 30, at 5, 19.

39. Kohls, *supra* note 6, at 111.

40. *Id.*

41. BROWN, *supra* note 11, at 126.

42. Whelan, *supra* note 28, ¶20.

43. BROWN, *supra* note 11, at 126.

III. ILLUSTRATIVE EXAMPLES OF BIOPIRACY

A. Rosy Periwinkle (Catharanthus Roses)

Scientists from developed nations engineered the cancer-fighting medicines vinblastine and vincristine from the rosy periwinkle plant, found in Madagascar.⁴⁴ Vinblastine has increased the chance of surviving childhood leukemia⁴⁵ and is used to treat Hodgkins' disease.⁴⁶ The U.S. pharmaceutical company Eli Lilly has patented and generated huge profits from Vincristine⁴⁷ despite the fact that none of the financial benefits have gone to Madagascar or to the indigenous group that first made use of the plant.⁴⁸

The difficulty with this situation is that the pharmaceutical industry took rosy periwinkle out of Madagascar and used it in ways other than initially suggested by the indigenous people.⁴⁹ This example illustrates the difficulties inherent in the protection of TK and biodiversity, especially when the final pharmaceutical use differs from the use suggested by indigenous communities.

B. The Neem Tree (Azadirachta Indica)

The Neem tree grows in India,⁵⁰ where villagers are very familiar with its medicinal properties and call it the "curer of all ailments."⁵¹ In 1995, the U.S. Department of Agriculture and a pharmaceutical research firm patented a technique to extract an antifungal agent from the tree.⁵²

44. Olufunmilayo B. Arewa, *TRIPS and Traditional Knowledge: Local Communities, Local Knowledge, and Global Intellectual Property Frameworks*, 10 MARQ. INTELL. PROP. L. REV. 155, 173 (2006) (noting that rosy periwinkle was used to treat leukemia and Hodgkin's disease).

45. See *Pharmacology of Vinblastine, Vincristine, Vindesine, and Vinorelbine*, (BioTech Resources, 1996), available at <http://biotech.icmb.utexas.edu/botany/vvv.html>.

46. *Id.*

47. See CTA, *Biopiracy and Law of the Jungle*, Dec. 28, 2004, <http://knowledge.cta.int/en/content/view/full/868> (last visited Apr. 22, 2008).

48. Arewa, *supra* note 44, at 173 n.108.

49. *Id.*

50. David R. Downes, *How Intellectual Property Could be a Tool to Protect Traditional Knowledge*, in INTERNATIONAL TRADE AND SUSTAINABLE DEVELOPMENT 372, 388 (Kevin P. Gallagher & Jacob Werksman, eds. Earthscan Publications Ltd., 2002).

51. See Herbal Extracts Plus, *Neem Leaf*, <http://www.herbaextractsplus.com/neem-leaf.cfm> (last visited April 22, 2008).

52. See Joris Kocken & Gerda Van Roozendaal, *The Neem Tree Debate*,

The tree became a symbol of India's TK and its resistance to biopiracy.⁵³ U.S. timber importer Robert Larson brought the tree into the United States, received a patent, and commercialized a pesticide from Neem extract called Margosan-O.⁵⁴ He later sold the patent to W.R. Grace & Co., a multinational chemical corporation.⁵⁵ Other American and Japanese companies also obtained patents for various products derived from the Neem tree, including toothpaste, one of the native, traditional uses of the plant.⁵⁶ The Indian government took legal action and the pesticide patent was overturned in 2005.⁵⁷ The main reason for the patent's failure was that the patented product lacked an "inventive step."⁵⁸ Although the Indian people knew a great deal about the medicinal uses of the Neem tree, the pharmaceutical industry argued that the traditional medicinal uses of the tree did not constitute "prior art"⁵⁹ because those findings were not published in an academic journal or in any other form.⁶⁰ When patent holders formulated this argument, Indian people for the first time became aware of the importance of managing information and recording TK.⁶¹ Since that time, the government of India

BIOTECHNOLOGY AND DEVELOPMENT MONITOR, March 2007, available at <http://www.biotech-monitor.nl/3004.htm>.

53. See Patricia H. Werhane & Kristi Severance, *W. R. Grace & Co. and the Neemix Patent (B)*, Social Science Research Network, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=596987 (scroll down and click on link to download).

54. See *Neem a Tree for Solving Global Problems*, app.A (Bostid, ed., 1992), available at http://www.appropedia.org/index.php?title=Neem_A_Tree_for_Solving_Global_Problem_s_15&printable=yes.

55. Patricia H. Werhane & Kristi Severance, *W.R. Grace & Co. and the Neemix Patent (A)*, Social Science Research Network, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=908425 (scroll down and click on link to download).

56. See *id.*

57. See Press Release, International Federation of Organic Agriculture Movements (IFOAM), European Patent Office Upholds Decision to Revoke Neem Patent (March 8, 2005), available at http://www.ifoam.org/press/press/2005/neem_patent_victory.php.

58. See *id.*

59. Prior art is "a legal term referring to previous knowledge about a particular subject matter; it has to be not obvious from the 'prior art' to someone possessing ordinary skill in the art at the time the invention was made." See *W. R. Grace & Co. and the Neemix Patent (B)*, *supra* note 53.

60. See Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279 (1999).

61. See Kohls, *supra* note 6, at 130.

has been translating and publishing ancient manuscripts and medicinal knowledge to protect its TK.⁶²

This is a very important issue because “prior art” is essential to determining “novelty,” which is necessary to obtain a patent.⁶³ If patent claimants use information that has been disclosed previously, the novelty requirement is not met. The problem for indigenous people is that certain patent laws, including U.S. patent laws, do not include unpublished works or oral disclosures⁶⁴—the most common means of communicating TK—within the scope of “prior art.”⁶⁵ Even if TK is widespread among indigenous communities, patent officers in the developed world will not find it, because they limit their searches locally;⁶⁶ even if they look more widely, in many instances local people will not receive credit for “prior art,” because they have not documented their TK in published works.

C. *The Enola Bean*

Larry Proctor, an American executive in the agricultural industry, traveled to Mexico on vacation and bought a bag of different varieties of beans that he found interesting because of their yellow color.⁶⁷ Upon his return to the United States, Proctor began a selective breeding program, and two years later he received a patent for one of the beans, which he named the Enola bean.⁶⁸ Proctor’s company, POD-NERS LLC, admitted that its Enola bean was a descendent from a traditional Mexican bean called Mayacoba.⁶⁹ The company argued, however, that its bean had a “better” yellow color and consistency than the Mayacoba.⁷⁰ Proctor aggressively defended his patent by suing other companies that grow the bean and by asking for royalties on imports from Mexico.⁷¹ Proctor’s appropriation seriously impacted Mexican farmers: export sales dropped

62. *Id.*

63. 35 U.S.C. § 102(a) (2002).

64. *Id.*

65. *Id.* See Manuel Ruiz, *The International debate on Traditional Knowledge as Prior art in the Patent System: Issues and Options for Developing Countries*, Center for International Environmental Law, Oct. 2002, available at http://www.ciel.org/Publications/PriorArt_ManuelRuiz_Oct02.pdf.

66. Murray Lee Eiland, *Patenting Traditional Medicine* 89, J. PAT. & TRADEMARK OFF. SOC’Y 45, 63 (2007).

67. Kohls, *supra* note 6, at 115.

68. *Id.*

69. See Danielle Goldberg, *Jack and the Enola Bean*, Dec. 2003, <http://www.american.edu/TED/enola-bean.htm> (last visited Apr. 22, 2008).

70. *Id.*

71. *Id.*

over ninety percent,⁷² causing severe economic damage to more than 22,000 farmers in northern Mexico who depended on sales from this bean.⁷³

Proctor claimed that the “new” characteristic of his Enola bean was its color.⁷⁴ Questions remained, however, as to whether Proctor’s Enola bean was patentable (i.e., whether he had changed the plant in a way that created a “new” variety).⁷⁵ Scientific studies concluded that “probability calculations of matching the specific Enola fingerprint showed that the most likely origin of Enola is by direct selection within pre-existing yellow-bean cultivars from Mexico, most probably ‘Azufrado Peruano 87.’”⁷⁶ Experts thus have recognized that Proctor’s Enola bean is identical to the Mexican bean.⁷⁷

Armed with the expert studies, Action Aid,⁷⁸ an NGO, protested the U.S. patent⁷⁹ for Proctor’s Enola bean.⁸⁰ The Colombia-based International Center for Tropical Agriculture (CIAT), with support from FAO,⁸¹ also challenged the patent in 2000.⁸² In May 2008, the United States Patent and Trademark Office (USPTO) rejected all of the patent claims for Enola bean.⁸³ Despite the NGO victory, Proctor and his

72. Kohls, *supra* note 6, at 116.

73. See ETC Group, *Enola Bean Patent Challenge*, http://www.etcgroup.org/en/materials/publications.html?pub_id=286 (last visited Apr. 22, 2008).

74. See Goldberg, *supra* note 69.

75. *Id.*

76. See L. Pallotini et al., *Plant Genetic Resources, The Genetic Anatomy of a Patented Yellow Bean*, *CROP SCI.* 44:968–77 (2004), available at <http://crop.scijournals.org/cgi/content/abstract/44/3/968> (2004).

77. See ETC Group, Action Group on Erosion, *What Ever Happened to the Enola Bean Action Challenge?*, available at <http://www.etcgroup.org/upload/publication/41/01/genotypeenola05.pdf>

78. See Action Aid, *About Us*, <http://www.actionaid.org/main.aspx?PageID=2> (last visited Feb. 15, 2008).

79. U.S. Patent No. 5,894,079 (issued Apr. 13, 1999).

80. See text of Proctor patent at United States Patent and Trademark Office website, <http://patft.uspto.gov/patft/index.html> (follow Quick Link Search link under Issued Patents Section and conduct search for “bean” and “enola”) (last visited Feb. 19, 2008).

81. International Center for Tropical Agriculture (CIAT), www.ciat.cgiar.org/ (last visited Apr. 23, 2008) (NGO based in Colombia).

82. Goldberg, *supra* note 69.

83. See Press Release, CIAT, US Patent Office Rejects US Company’s Patent Protection for Bean Commonly Grown by Latin American Farmers (May 2008), available at http://www.ciat.cgiar.org/newsroom/release_31.htm.

company profited from the patent for more than seven years prior to the challenge; one-third of the twenty-year patent term.⁸⁴

D. Other Examples

Other examples of biopiracy include: (1) the commercialization of *Hagen abyssinica* products as a treatment for cancer after Ethiopians had used the plant for centuries;⁸⁵ (2) the use of the ayahuasca plant from the Amazonian rainforest, for which a patent was granted to an American scientist but later rescinded by the PTO, in response to action taken by 400 indigenous groups;⁸⁶ (3) the proposed patenting of basmati rice and a later finding that the term is a generic one;⁸⁷ (4) the revocation of a patent for using Indian turmeric for wound healing;⁸⁸ and (5) the aborted patenting of Bolivian quinoa by two American researchers.⁸⁹ These are just a few examples of the multiple reported biopiracy claims; there are many others.⁹⁰

A recent report presented at a meeting of the Convention of Biological Diversity (CBD) denounced thirty-six examples of medicines, cosmetics, and agricultural products that originated in African countries but had resulted in products patented without the consent of, or benefit to, the countries of origin.⁹¹ The African Center of Biosafety took only one month to identify these cases.⁹² Developing countries, therefore, can expect that with a more detailed analysis on current patents, there will be more cases reported. India conducted a study of the USPTO, the United Kingdom Patent Office (UKPO), and the European Patent Office (EPO) databanks in 2000 and found 4,896 references to medical plants, eighty percent of which originated in India.⁹³ By 2003, the number of patents

84. *Id.*

85. Kohls, *supra* note 6, at 114.

86. Arewa, *supra* note 44, at 175-76.

87. *Id.* at 172.

88. *Id.*

89. *Id.* at 176.

90. BROWN, *supra* note 11, at 106.

91. Chee Yoke Heong, *Africa Suffers 36 Cases of Biopiracy*, PUBLIC AGENDA, Mar. 31, 2006, http://www.ghanaweb.com/public_agenda/article.php?ID=5062 (last visited June 6, 2008) (reporting a study sponsored by the U.S.-based Edmonds Institute and the African Center of Biosafety. See JAY MCGOWN, OUT OF AFRICA: MYSTERIES OF ACCESS AND BENEFIT SHARING (2006), available at <http://www.edmonds-institute.org/outofafrica.pdf>).

92. *Id.*

93. See WIPO, *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO GRTKF/IC/8/15 PROV, July 30,

based upon TK had risen to 15,000.⁹⁴ A study based on a random selection of these patents showed that forty-nine percent were based on TK.⁹⁵

Additionally, crop-breeders and agro-biotech corporations in developing countries have obtained IPRs by exploiting PGRs within the public domain and those collected by the Consultative Group of International Agricultural Research (CGIAR)⁹⁶ ex situ seed banks.⁹⁷ This practice raises concerns about food security, the accessibility and adequacy of food, and the exclusion of natural and original suppliers.⁹⁸ Even more, it affects traditional farming practices in indigenous communities, makes communities dependent on industrialized countries for most of their food,⁹⁹ threatens the world's biodiversity¹⁰⁰, and raises the possibility that modification will lead to the loss of original genetic information.¹⁰¹

In summary, it cannot be disputed that biopiracy practices are advancing in a way that cause great concern over public health and food security in the developing world.

IV. PATENT PROTECTION AND TRADITIONAL KNOWLEDGE

Patents are designed to stimulate innovation by granting exclusive property rights to the inventor of a novel product. In essence, patents create monopolies. The duration of a new patent generally is twenty years from the date on which the application for the patent is filed.¹⁰² The USPTO expresses the concept very clearly: "The right conferred by the patent grant is: 'the right to exclude others from making, using,

8 Session Geneva, June 6-10, 2005.

94. *Id.*

95. *Id.*

96. CGIAR is a strategic alliance of countries, international organizations and private foundations that works with national agricultural research systems. Consultative Group on International Agricultural Research, *CGIAR Home*, <http://www.cgiar.org/> (last visited Feb. 16, 2008).

97. Chidi Oguamanam, *Intellectual Property Rights in Plant Genetic Resources Farmer's Rights and Food Security of Indigenous and Local Communities*, 11 DRAKE J. AGRIC. L. 273, 278 (2006).

98. *Id.* at 277.

99. *Id.* at 303.

100. *See id.*

101. Warner, *supra* note 2, at 652.

102. TRIPS, *supra* note 12, art. 28.

offering for sale, or selling' the invention in the United States or 'importing' the invention into the United States."¹⁰³ The patent and the corresponding monopoly are recognized internationally and are included in the TRIPS, the governing WTO international intellectual property agreement.¹⁰⁴

Once a patent is granted, its holder can exclude others from exploitation of the product. In the case of pharmaceutical and agricultural products, this means that even indigenous communities that have contributed to the invention by providing the plant and suggesting its medical use could be, and actually have been, excluded from any benefit. In some cases, patents have gone so far as to prevent an indigenous community access to the final, commercialized products that were derived from their TK.¹⁰⁵

Patent protection has increased mainly as a result of pressure from developed countries within the WTO.¹⁰⁶ Additionally, the United States has consistently expanded not only patenting but other forms of IPRs by entering into bilateral or regional agreements with developing and less developed countries.¹⁰⁷

Within the TRIPS model, patents are conceived as "private rights,"¹⁰⁸ and TK is viewed as part of the global commons.¹⁰⁹ Therefore, by definition, the model excludes TK because it develops and evolves within the community rather than from individual efforts. Vandana Shiva has criticized the concept of IPRs in TRIPS that "excludes all kinds of knowledge, ideas, or innovations that take place in the 'intellectual commons'—in villages among farmers, in forests among tribe people."¹¹⁰

The purpose of IPRs is to encourage innovation, but concerns exist regarding poverty in developing countries and the need to adopt a more

103. USPTO, General Information Concerning Patents, <http://www.uspto.gov/web/offices/pac/doc/general/index.html#patent> (last revised Jan. 2008).

104. TRIPS, *supra* note 12, art. 39.

105. Warner, *supra* note 2, at 651–52.

106. See generally SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW, THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (2003).

107. Examples include recent agreements with Colombia, Peru, Panama, Morocco, Singapore and CAFTA which include TRIPS-plus provisions that enhance greatly patent holders' rights. These agreements are available at the Office of the United States Trade Representative (USTR), *Trade Agreements Home*, <http://www.ustr.gov/> (last visited June 6, 2008).

108. TRIPS, *supra* note 12, at Preamble.

109. SHIVA, *supra* note 26, at 10.

110. *Id.*

development-oriented, equitable policy.¹¹¹ There is no equal access to knowledge in the global community. To enjoy the economic and social benefits of their indigenous TK, developing countries must increase their accessibility to knowledge. Existing imbalances in scientific and technological capacities have resulted in weakened IPRs in the third world.¹¹²

The countries that benefit most from IPRs belong to the developed world; primarily the United States, member states of the European Union, and Japan.¹¹³ Even though many raw materials with medicinal uses originate in the developing world, profits from the commercialization of new products are granted to the industries in the developed world that perform research on those raw materials.¹¹⁴ In 1995, the worldwide market value of TK-generated pharmaceuticals was estimated at \$43 billion.¹¹⁵ This sum amply demonstrates why the potential of benefit sharing or the shared distribution of profits can be significant.¹¹⁶ IPR treaties try to make sure that developing countries pay for access to knowledge, even when they contributed to the invention by providing TK.¹¹⁷

The recognition of knowledge created in developed countries and the failure to acknowledge developing countries' indigenous knowledge explains why the problem is often framed as a North-South confrontation.¹¹⁸ The developed world is interested in higher levels of IPRs, while the developing world is interested in the protection of PGRs and TK, or at least in the guarantee of benefit sharing. Developing countries question the benefits attributed to IPRs because they experience disadvantages when IPRs are strengthened. These disadvantages include administrative and enforcement costs,¹¹⁹ opportunity costs of additional domestic research and development that is lost through the payment of royalties, price increases that impair the

111. STIGLITZ, *supra* note 29, at 118.

112. Arewa, *supra* note 44, at 170.

113. *Id.* at 166.

114. Eiland, *supra* note 66, at 46 (stating that in 1982, 50% of prescriptions in the United States originated from drugs that were derived from natural substances).

115. *Id.*

116. Kennedy, *supra* note 3, at 4.

117. Lauren Loew, *Creative Industries in Developing Countries and Intellectual Property Protection*, 9 VAND. J. ENT. & TECH. L. 171, 177 (2006).

118. Eiland, *supra* note 66, at 47.

119. See Loew, *supra* note 117, at 186 (estimating that Egypt has a \$1 million annual cost of compliance with IP laws, and Bangladesh has \$1.1 million cost; whereas the World Bank estimates costs of \$1.5 million to \$2 million to upgrade the IP laws of a developing country).

process of technological diffusion, and economic and social costs of displacement piracy.¹²⁰ Even more, there is no proven relationship between increasing IPRs and attracting foreign direct investment in developing countries.¹²¹

Concern also exists over the inability of IPRs to stimulate innovation because IPRs protect patent holders from competition and create exclusive rights.¹²² They also slow research innovations based on other innovations, and impede the dissemination and application of knowledge.¹²³ Additionally, developing countries have complained about the inequitable and inefficient global system of research funding and the lack of research funding for diseases that affect their own populations.¹²⁴

Cultural issues exist in this realm as well, because in traditional communities the acts of sharing knowledge and exchanging ideas are indispensable for creativity.¹²⁵ Indigenous communities believe that some natural resources, including plants, are sacred and often use those resources in religious ceremonies.¹²⁶ For these reasons and others, developing countries advocate for sovereign rights over their PGRs.¹²⁷

Michael Trebilcock has argued that “[t]he economic argument for the protection of intellectual property rights only makes sense if the welfare gain from the added incentive to innovation is greater than the reduction of the benefit from competition.”¹²⁸ Intellectual property discussions at the WTO and in other fora implicate fundamental questions of sustainable development and human rights. Developing nations need to realize that IPR discussions are directly tied to concerns about equal access to medicine and food in developing countries.¹²⁹

120. Carlos Primo Braga, *The Developing Country Case for and Against Intellectual Property Protection*, in PAUL GOLDSTEIN, INTERNATIONAL INTELLECTUAL PROPERTY 64–80 (2001).

121. See Loew, *supra* note 117, at 187.

122. STIGLITZ, *supra* note 29, at 109–10.

123. *Id.*

124. See Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 252 (2004).

125. SHIVA, *supra* note 26, at 15.

126. Eiland, *supra* note 66, at 68. (This is the case of the “yage” or “Ayahuasca,” a plant use by indigenous people in the Amazonian Basin that plays an important role in sacred traditions, and was subject to a patent application which was later canceled due to the reexamination petition filed by the Center of International Environmental Law (CIEL). The patent was later reinstated.)

127. Oguamanam, *supra* note 99, at 299–300.

128. MICHAEL J. TREBILCOCK & ROBERT HOWSE, THE REGULATION OF INTERNATIONAL TRADE, 398–399 (3d ed. 2005).

129. See Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal*

V. THE INTERNATIONAL PROTECTION OF TRADITIONAL KNOWLEDGE

The main international organizations involved with the regulation of IPRs regarding TK and PGRs are: the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), and the United Nations Food and Agricultural Organization (FAO). Over the years the international community has developed several international agreements governing IPRs, but these agreements respond only to the main interests represented at the time of their enactment. The agreements, therefore, do not constitute a consistent or coherent body of law that efficiently or effectively protects the IPRs of TK and PGRs. For instance, while the Union for the Protection of Plant Varieties (UPOV) and TRIPS consider TK as part of the commons and seek to strengthen private IPRs, the CBD recognizes national sovereignty over PGRs and seeks to strengthen the distribution of profits gained by TK based patents.¹³⁰ This section will discuss some of the competing frameworks and treaties meant to govern international IPR issues.

A. The Geneva-Based International Union for the Protection of Plant Varieties (UPOV)

American interest in the extension of IPRs were first piqued due to the perceived need to protect agro-biotech and plant breeding.¹³¹ The International Convention for the Protection of New Varieties of Plants¹³² was adopted in Paris in 1961 by a group of mainly industrialized countries that sought a multilateral framework to advance private ownership of PGRs¹³³ and was revised in 1972, 1978, and 1991. UPOV¹³⁴ was the result of a joint effort of mainly industrialized

Options Under TRIPS and the Case of Brazil, 6 YALE HUM. RTS. & DEV. L.J. 103 (2003).

130. See generally, Kue-jung Ni, *The Incorporation of the CBD Mandate on Access and Benefit-Sharing into TRIPS Regime: An Appraisal of the Appeal of Developing Countries with Rich Genetic Resources*, 1 ASIAN J. WTO & INT'L HEALTH POL'Y. 433 (2006).

131. Oguamanam, *supra* note 97, at 279.

132. Kennedy, *supra* note 3, at 20.

133. Oguamanam, *supra* note 97, at 280.

134. See generally UPOV, *UPOV – Welcome to the International Union for the Protection of New Varieties of Plants*, http://www.upov.int/index_en.html (last visited June 6, 2008).

countries to structure private ownership of PGRs.¹³⁵ It introduced an international regime of Plant Breeders Rights (PBRs) to assure proprietary control over PGRs, and it continues to seek the expansion and consolidation of IPRs regarding PGRs.¹³⁶ UPOV's mission is "[t]o provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society."¹³⁷

B. The UN Convention on Biological Diversity (CBD)

The UN Convention on Biological Diversity was signed at the UN Conference on Environment and Development (UNCED) during the 1992 Rio de Janeiro Earth Summit.¹³⁸ The CBD is an environmental convention meant to develop measures for the use and protection of TK related to the conservation and sustainable use of biodiversity.¹³⁹ To date, the Convention has been signed by 168 countries.¹⁴⁰ The United States is not a party to the Convention.¹⁴¹

The CBD embraces the general principle that states have national sovereignty over genetic resources;¹⁴² it therefore tries to facilitate sustainable use of biodiversity and disperse bioprospecting profits to developing countries.¹⁴³ The Convention establishes three main goals: (1) the conservation of biological diversity, (2) the sustainable use of biodiversity components, and (3) the fair and equitable sharing of the benefits derived from the use of PGRs.¹⁴⁴ The Conference of the Parties (COP) is the CBD's governing body. It has adopted guidelines called "Access to Genetic Resources and Benefit Sharing"¹⁴⁵ in accordance

135. Oguamanam, *supra* note 97, at 279–80.

136. *Id.* at 280.

137. UPOV, *supra* note 134.

138. CBD, *supra* note 14.

139. See Aphrodite Smagadi, *Analysis of the Objectives of the Convention on Biological Diversity: Their Interrelation and Implementation Guidance for Access and Benefit Sharing*, 31 COLUM. J. ENVTL. L. 243, 264 (2006).

140. CBD, *List of Parties*, <http://www.biodiv.org/world/parties.asp> (last visited Jan. 14, 2008).

141. *Id.*

142. CBD, *supra* note 14, at art. 3 ("States have . . . the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.").

143. Kennedy, *supra* note 3, at 21.

144. CBD, *supra* note 14, at Preamble.

145. CBD, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable

with the principles of the Convention that seeks: the mutual sharing of research and development; the transfer of biotechnology; the exchange of information, research, and training; and technical and scientific cooperation.¹⁴⁶ Article 8(j) establishes that the Contracting Party shall “respect, preserve and maintain knowledge, and innovations and practices of indigenous and local communities....”¹⁴⁷

The main weakness of the CBD is its lack of enforceability and the absence of rules governing liability.¹⁴⁸ Another criticism focuses on inconsistencies regarding informed consent. In particular, the CBDs lack of precision in defining which activities require prior consent, what information must be provided, and which entity is obliged to provide the information presents compliance ambiguity.¹⁴⁹ A further shortfall exists because the CBD is a conservation treaty and, therefore, does not govern national IPR systems.

One significant accomplishment of the CBD has been the development of the Bonn Guidelines, which suggest more appropriate and concrete measures to defend TK than other treaties and call for implementation of access and benefit-sharing agreements.¹⁵⁰ Certain countries adopted these guidelines by incorporating them into domestic laws.¹⁵¹ The Parties to the Convention which met during March 20–31, 2007, in Curitiba, Brazil, set a 2010 target to negotiate an international, legally-binding regime on access and benefit sharing (ABS).¹⁵² The CBD approach clearly conflicts with TRIPS and UPOV, most notably because the CBD recognizes national sovereignty over PGRs, while TRIPS promotes private ownership of PGRs.

Sharing of the Benefits Arising out of their Utilization Apr. 7–19, 2002, <http://cbd.int/decisions/?m=cop-06&d=24> (last visited June 6, 2008).

146. CBD, *supra* note 14, at arts. 1, 12, 16, 19.

147. *Id.* at art. 8J.

148. Daniel Rettig, *In Search of Pirate's Treasure: The Control and Ownership of Genetic Resources in the Mesoamerican Barrier Reef System*, 37 U. MIAMI INTER-AM. L. REV. 261, 279 (2006).

149. *Id.* at 282–83.

150. Ni, *supra* note 130, at 453 (discussing the disclosure of Traditional Knowledge requirement).

151. *Id.* at 436.

152. Ahmed Djoghlaif, Exec. Sec'y of the CBD, Statement at the Opening Meeting on Cities and Biodiversity: Achieving the 2010 Biodiversity Target (Mar. 26, 2007), available at <http://www.biodiv.org/doc/speech/2007/sp-2007-03-26-mayors-e.pdf>.

C. The WTO Agreement on Trade Related Aspects on Intellectual Property

The WTO Agreement on Trade Related Aspects on Intellectual Property (TRIPS) was adopted in 1994. Its objective is to standardize IPRs and to grant extended protections to IPR holders. Pharmaceutical¹⁵³ and entertainment industries¹⁵⁴ lobbied to obtain patent regulations under TRIPS that favor their respective interests.

TRIPS exemplifies the asymmetry in negotiations between developed and developing countries.¹⁵⁵ The WTO has been criticized for supporting bioprospectors and for its lack of power to protect traditional knowledge.¹⁵⁶ Inequities in the text of the TRIPS agreement grew out of a global trading system with inherent "power asymmetries,"¹⁵⁷ and developing countries' concessions were not compensated with advantages in other areas of the negotiations.¹⁵⁸ The United States has moved away from using a model of multilateral trade agreements and toward a system of bilateral trade agreements (BITs). This places the United States in a much stronger negotiating position, which widens the asymmetry between developed and developing countries.¹⁵⁹ The United States pressured the TRIPS negotiations by using trade mechanisms such as Section 301, which basically constitutes a unilateral method of punishing countries that do not follow U.S. trade policies.¹⁶⁰ Therefore, TRIPS represented the victory of U.S. and European industries over developing countries.¹⁶¹

Since 1994, TRIPS has received much criticism, especially for its lack of regulations to protect TK and biodiversity. TRIPS has been accused of being the new arm of neo-colonialism¹⁶² because it embraces a Western notion of property where IPRs are framed as private individual rights, ignoring TK and biodiversity. This "monoculture" of knowledge

153. STIGLITZ, *supra* note 29, at 116.

154. *Id.*

155. Rahul Rajkumar, *The Central American Free Trade Agreement: an End Run Around the Doha Declaration on TRIPS and Public Health*, 15 ALB. L.J. SCI. & TECH. 433, 449–54 (2005).

156. Warner, *supra* note 2, at 657.

157. Arewa, *supra* note 44, at 158.

158. *See* SELL, *supra* note 106, at 109.

159. Mark B. Baker, *No Country Left Behind: The Exporting of U.S. Legal Norms Under the Guise of Economic Integration*, 19 EMORY INT'L L. REV. 1322, 1330 (2005).

160. RALPH FOLSOM, INTERNATIONAL BUSINESS TRANSACTION 889 (West Group ed., 2006).

161. STIGLITZ, *supra* note 29, at 105.

162. SHIVA, *supra* note 26, at 3.

is based on a restrictive concept of innovation weighted in favor of transnational corporations and against citizens of the third world.¹⁶³ The TRIPS IPR system does not recognize collective creativity and therefore has not included protection for TK or communal knowledge.¹⁶⁴ Developing countries initially resisted TRIPS IPRs,¹⁶⁵ but finally accepted the agreement because of the threat of U.S. sanctions under Section 301 and pressure from industry.¹⁶⁶

One important unresolved issue concerns how to define what is patentable. Under existing U.S. patent law, the subject matter that can be patented “include[s] practically everything that is made by man and the processes for making the products.”¹⁶⁷ This definition includes plants.¹⁶⁸ Therefore, in the United States, it is possible to patent naturally-occurring chemicals if their structures have not been published before.¹⁶⁹

Internationally, there is no consensus on whether plants are patentable. TRIPS Article 27(3)(b) states:

Members may also exclude from patentability... (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological 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. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.¹⁷⁰

To date, WTO parties have not reached an agreement on this new provision.

Current debate focuses on how the TRIPS Agreement relates to the CBD, which recognizes national sovereignty over PGRs as it pertains to

163. See Warner, *supra* note 2, at 657.

164. SHIVA, *supra* note 26, at 10–15.

165. Ni, *supra* note 130, at 442

166. *Id.* at 442

167. USPTO, *General Information Concerning Patents*, <http://www.uspto.gov/web/offices/pac/doc/general/index.html#patent> (last revised Jan. 2008).

168. *Id.* (stating that a plant is patentable when a person has “invented or discovered and asexually reproduced any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state. . . . Asexually propagated plants are those that are reproduced by means other than from seeds, such as by the rooting of cuttings, by layering, budding, grafting, inarching, etc.”).

169. Eiland, *supra* note 66, at 54.

170. TRIPS, *supra* note 12, at art. 27.

protecting indigenous knowledge.¹⁷¹ Some scholars believe that the life patenting exception under Article 27.3(b) should be maintained in order to explore ways to use IPRs to enhance benefits for TK holders.¹⁷² These scholars believe that governments may want to slow innovation until they can better control it and ensure that it is not abused through anti-competition forces.¹⁷³

New bilateral agreements between the United States and other countries has lifted the exclusion of plants and animals from patentability: “[A] party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available consistent with paragraph 1.”¹⁷⁴ Since the 2001 Doha Declaration,¹⁷⁵ a group of developing countries, among them Brazil and India, have sought to amend TRIPS.¹⁷⁶ These countries wish to impose an obligation on IPR applicants to disclose the country of origin of any PGRs and TK used in their inventions and to provide evidence that they received “prior informed consent” and evidence of “fair and equitable” benefit sharing.¹⁷⁷ This approach would be effective because it would bind all parties to the WTO and offer better protection for the developing world. TRIPS, unlike the CBD, does include enforcement and dispute settlement mechanisms.

The European Union agrees with the obligation to disclose, but suggests that the consequences for not meeting the requirement should be addressed outside of patent law.¹⁷⁸ Switzerland also agrees with the disclosure obligation but believes it should occur within WIPO.¹⁷⁹ The United States, on the other hand, opposes a binding international system

171. Ni, *supra* note 130, at 444.

172. Downes, *supra* note 50, at 379–80.

173. *Id.*

174. See Article 16.9.2 US Peru Trade Promotion Agreement, available at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Final_Texts/asset_upload_file392_9546.pdf.

175. World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

176. See WTO, *TRIPS: Reviews, Article 27.3(b), and Related Issues*, http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm (last visited Jan. 14, 2008) (other countries include Colombia, Peru, Bolivia, Cuba, Dominican Republic and the African Group).

177. Ni, *supra* note 130, at 446 (further discussing the disclosure of the traditional knowledge requirement).

178. See Doha Declaration, *supra* note 175.

179. Ni, *supra* note 130, at 446 (further discussing the disclosure of Traditional Knowledge requirements).

that would embrace the objectives of the CBD, including the disclosure obligation, and proposes instead the use of national legislation and contractual arrangements based on local legislation.¹⁸⁰

An additional concern is that U.S. patent laws have adopted a flexible concept of “novelty” that effectively excludes TK as “prior art” because it has not been used in the United States nor has it been described in a printed publication. The relevant statute, 35 U.S.C. § 102, states:

an invention cannot be patented if: ‘(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent,’ or ‘(b) 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 application for patent in the United States . . .’,¹⁸¹

Therefore, TK originating in a foreign country is no bar to obtaining a patent in the United States, unless the TK related information has previously appeared in a printed publication. This paradigm favors U.S. industry to the detriment of indigenous cultures in other nations and makes it hard for developing countries to succeed in claims against unjust patents within the United States.¹⁸²

The result of the WTO negotiations will dramatically impact the future of TK and PGRs. Some believe that discussions over global standards should be taken out of the WTO and put back into WIPO.¹⁸³ Meanwhile, developing countries should refrain from entering into bilateral agreements that allow for the patentability of naturally occurring plant life.

180. Doha Declaration, *supra* note 175.

181. See USPTO, *Novelty and Other Conditions for Obtaining a Patent*, <http://www.uspto.gov/web/offices/pac/doc/general/novelty.htm> (last visited Jan. 14, 2008).

182. Eiland, *supra* note 66, at 57, 63.

183. STIGLITZ, *supra* note 29, at 128.

D. The Food and Agricultural Organization (FAO) Commission on Genetic Resources for Food and Agriculture (CGRFA) and the International Treaty on Plant Genetic Resources for Food and Agriculture

The FAO Commission is the principal forum for international IPRs over PGRs.¹⁸⁴ The Commission's mission is:

to ensure the conservation and sustainable utilization of genetic resources for food and agriculture, as well the fair and equitable sharing of benefits derived from their use, for present and future generations. The Commission aims to reach international consensus on areas of global interest, through negotiations.¹⁸⁵

After seven years of negotiations, the FAO Conference adopted, through Resolution 3/2001, the International Treaty on Plant Genetic Resources for Food and Agriculture¹⁸⁶ (ITPGRFA) in November 2001.¹⁸⁷ This legally-binding treaty covers all PGRs relevant to food and agriculture. It is in harmony with the CBD because it seeks recognition of farmers' rights and the sharing of benefits arising for the use of PGRs and TK.¹⁸⁸ The United States has signed but not ratified ITPGRFA. This treaty is the result of the initiative of developing countries—mainly Mexico—and some NGOs.¹⁸⁹ It states:

[A]ffirming that the past, present and future contributions of farmers in all regions of the world, particularly those in centers of origin and diversity, in conserving, improving and making available these resources, is the basis of Farmer's Rights."¹⁹⁰

The treaty additionally advocates for fair and equitable sharing of the benefits derived from the use of PGRs for food and agriculture, which are considered fundamental to the realization of farmers' rights.¹⁹¹ However, ITPGRFA conflicts with the UPOV, which seeks an international regime of plant-breeders' rights to assure proprietary control over PGRs.

184. Oguamanam, *supra* note 97, at 283.

185. FAO, *About the Commission on Genetic Resources*, <http://www.fao.org/ag/cgrfa/> (last visited Jan. 14, 2008).

186. Plant Genetic Resources, *supra* note 15.

187. *Id.*

188. See ITPGRFA, *Home Page*, <http://www.planttreaty.org/> (last visited June 6, 2008).

189. Kennedy, *supra* note 3, at 25.

190. Plant Genetic Resources, *supra* note 15, at Preamble.

191. *Id.*

Consequently, several countries have expressed reservations about implementation.¹⁹²

E. The World Intellectual Property Organization (WIPO) and the Fight Against Biopiracy

WIPO was established in 1967 to promote the protection of IPRs throughout the world.¹⁹³ It administers various international IPR treaties, assists members in drafting legislation, and promotes harmonization.¹⁹⁴ WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in 2000.¹⁹⁵ The IGC addresses issues of biopiracy from a worldwide perspective. The organization focuses on demands of developing nations for TK protection and preservation. It offers a flexible new forum to address potential solutions. In 2004, WIPO adopted a Development Agenda (Agenda) that the United States strongly opposed.¹⁹⁶ Developing countries proposed the Agenda to ensure that IPRs are used to advance development.¹⁹⁷ WIPO considers biopiracy not only a trade abuse but also a threat to biodiversity.¹⁹⁸ WIPO members believe that the IGC Committee could play a useful role in developing appropriate international legal instruments to fight biopiracy and the misappropriation of TK and folklore.¹⁹⁹ Furthermore, the Committee has been an important forum to analyze case studies, hold regional discussions, and propose solutions in order to reach international consensus in developing IPR systems that can effectively protect PGRs and TK.²⁰⁰ Developing countries have called for more productive action toward formal protection of TK, seeking the establishment of a binding treaty and the inclusion of a general obligation to disclose origin and TK in patent systems.²⁰¹

192. See FAO, Fact Sheet No. 8: History of the Treaty, ftp://ftp.fao.org/ag/agp/planttreaty/factsheets/fs08_en.pdf (last visited April 9, 2008).

193. WIPO, *What is WIPO?*, http://www.wipo.int/about-wipo/en/what_is_wipo.html (last visited Feb. 15, 2008).

194. See WIPO, *Substantive Patent Law Harmonization*, <http://www.wipo.int/patent-law/en/harmonization.htm> (last visited June 6, 2008).

195. *Id.*

196. Kennedy, *supra* note 3, at 17.

197. Madhavi Sunder, *IP³*, 59 STAN. L. REV. 257, 310 (2006).

198. *Id.*

199. See Kennedy, *supra* note 3, at 16–17.

200. See Kohls, *supra* note 6, at 122.

201. WIPO, *Intergovernmental Committee*, <http://www.wipo.int/tk/en/igc/> (last visited Feb. 15, 2008).

In the Committee's Tenth Session, held in Geneva from November 30 through December 8, 2006, the Committee requested its Secretariat to prepare for future consideration:

- (i) a document listing options for continuing or further work, including work in the areas of the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources; the interface between the patent system and genetic resources; and the intellectual property aspects of access and benefit-sharing contracts; and (ii) a factual update of international developments relevant to the genetic resources agenda item.²⁰²

As of the Committee's Twelfth Session, held in Geneva in February 2008, the Committee was still seeking measures to extend TK protection, including: disclosure of the use of TK before patent authorities; the consideration of legal and ethical aspects in the patent systems; the legal responsibility for patent authorities; the recognition of cultural differences among the countries' TK; and the use of customary tools. The Committee also encourages WIPO members to use patent laws to protect TK and create strategies to avoid undisclosed appropriation of TK. Additionally, it recognizes the need to take steps to improve patent procedures, increase cooperation between patent offices, and encourage the publication of indigenous knowledge.²⁰³

F. Summary

Consideration of these various international treaties leads to the conclusion that international recognition of IPRs relating to PGRs has led to a complex regime under which varying treaties conflict and governing institutions compete for jurisdiction in different areas.²⁰⁴ Each agreement typically reflects the interests of one particular group. Inconsistencies among the treaties encourage forum shopping and negatively impact both the protection of TK and research and development related to PGRs. These inconsistencies further reflect a lack of consensus over fundamental issues such as benefit and profit sharing from the use of PGRs, the protection of TK, and the democratization of decisionmaking

202. WIPO IGC Tenth Session, Nov. 30–Dec. 8, 2006, *Decisions of the Tenth Session of the Committee*, ¶ 9, U.N. Doc WIPO/GRTKF/IC/10/DECISIONS (Dec. 6, 2008), available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=7141.

203. See generally WIPO IGC Twelfth Session, Feb. 25–29, 2008, *Decisions of the Twelfth Session of the Committee*, U.N. Doc WIPO/GRTKF/IC/12/7 (Feb. 12, 2008), available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=92093.

204. See Oguamanam, *supra* note 97, at 278–286.

on a national and international level. Even among developing countries these issues are remain unresolved.

Uncertain or conflicting regulations and interests do not favor humanity. The continued failure to reach agreement delays needed research to develop products and technology that would surely benefit the global population. Regardless of its ultimate form, a solution to the IPR disagreement must focus on the development of improved food and medicine production for the entirety of humanity.

VI. PROPOSED SOLUTIONS

A. The Precautionary Approach

1. The Disclosure of Information, Prior Consent, and Benefit-Sharing

One solution offered by the CBD and WIPO is a “checklist” approach toward monitoring compliance with guidelines established by the respective organizations.²⁰⁵ The checklist would focus on CBD provisions relating to the disclosure of information on the human source, country of origin, and detailed nature of TK used in an invention. Evidence of obtaining informed consent for the use of TK and proof of compliance with benefit sharing under relevant national rules²⁰⁶ would also be disclosed pursuant to the checklist.²⁰⁷

This approach would require developing countries to play an active role in gathering and publishing their TK. By doing so, these countries would also gather evidence that could be useful in later reexamination procedures to prove “prior art.” India is already implementing some of these practices and provides an important example of the effectiveness of managing TK information for the purpose of defending TK rights.²⁰⁸ In 2004, South Africa adopted a policy on indigenous knowledge systems

205. See Ni, *supra* note 130, at 435 n.9. Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, at 262, available at <http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf>.

206. See Kohls, *supra* note 6, at 132.

207. Ni, *supra* note 130, at 436 n.10. See Sabrina Safrin, *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life*, 98 AM. J. INT’L L. 641, 649 n.56 (2004).

208. Kohls, *supra* note 6, at 130.

that recognizes TK's economic value and its role in globalization.²⁰⁹ In tandem to the policy, South Africa also crafted legislation to protect biodiversity.²¹⁰ Some countries have appealed to WIPO to establish a database on PGRs, TK, and folklore for the benefit of less-developed countries (LDCs).²¹¹ The final goal is the development of a universal database system.²¹² In the interim, the developed world should grant benefit-sharing in recognition of past information disclosures by developing countries. Without benefit sharing, indigenous communities will be discouraged from sharing their knowledge.

The universal database would serve as a filter for unjust patents since disclosure of information contained in the system would constitute an admission of prior art for purposes of protecting against future patent claims by third parties. At the same time, this approach would strengthen the patents that are granted and create more certainty about patent rights, thereby reducing litigation costs. Additionally, it would enable the preservation and documentation of TK, the loss of which is an ongoing concern as indigenous people rapidly integrate into modern societies.

The problem with the database approach is that it requires the cooperation of the developed world. The United States and Japanese governmental positions are that the introduction of a TK disclosure requirement is irrelevant to patentability criteria and would be ineffective in preventing patent abuses.²¹³ Despite governmental positions, the universal database approach will undoubtedly face strong lobbying opposition from the developed world's industries for similar reasons.²¹⁴

During past WIPO meetings, India and other developing countries have supported the idea of a mandatory disclosure of TK in the patent application process.²¹⁵ The European Union supports disclosure

209. See generally *The Indigenous Learning Company, South Africa*, <http://www.indigenouslearning.com/news/articles/south-africa> (last visited Jan 8, 2008).

210. *Id.*

211. Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, June 6–10, 2005, *Second Draft Report*, WIPO/GRTK F/IC/8/15 (Oct. 5, 2005), available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_8/wipo_grtkf_ic_8_15_prov_2.pdf.

212. *Id.*

213. Ni, *supra* note 130, at 453.

214. Arewa, *supra* note 44, at 166.

215. See STEVE SUPPAN, INSTITUTE FOR AGRICULTURE AND TRADE POLICY, AMENDING WTO INTELLECTUAL PROPERTY RULES TO PREVENT BIO-PIRACY AND IMPROVE PATENT QUALITY (July 2006), available at <http://www.tradeobservatory.org/library.cfm?refid=88376> [hereinafter PATENT QUALITY].

requirements, but not under the WTO.²¹⁶ Japan has rejected this proposal²¹⁷ and many developed countries, mostly supported by the United States, consider that disclosure will not be useful in preventing biopiracy.²¹⁸ India and Brazil are also pushing for a uniform examination application that includes prior informed consent from indigenous communities when TK is used.²¹⁹ The Conference of the Parties (COP) of the Convention of Biological Diversities (CBD) invited WIPO to examine issues regarding the disclosure of TK in the examination process and benefit sharing on PGRs.²²⁰

The Committee insists on creating binding documents for the patent examination process.²²¹ In addition to the obligation to disclose the origin of TK, some have proposed that patent applicants should provide proof of prior informed consent²²² and benefit-sharing guarantees.²²³ In order to fully implement this proposal, countries would need to introduce IP laws regarding prior informed consent and benefits sharing. Additionally, the proposal requires clarification of the terms “traditional knowledge” and “indigenous communities.”²²⁴

As explained above, even though developing countries have widely supported these ideas, developed countries, including the United States and Japan, have opposed the disclosure of origin and prior consent requirements and argued that including the requirements in the patent system is not an appropriate way to achieve the desired goals.²²⁵ In sum, there is no international consensus on these issues—and there probably never will be.

216. *Id.*

217. See WIPO, Japan (Dec. 17, 2004), <http://www.wipo.int/tk/en/genetic/proposals/japan.pdf> (last visited June 6, 2008).

218. See PATENT QUALITY, *supra* note 215.

219. Ni, *supra* note 132, at 446.

220. See WIPO, *Examination of Issues Regarding the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications*, available at

http://www.wipo.int/edocs/mdocs/tk/en/wipo_ip_gr_05/wipo_ip_gr_05_3.pdf

221. *Id.*

222. Downes, *supra* note 50, at 384.

223. See WIPO, *ad hoc* Intergovernmental Meeting on Genetic Resource and Disclosure Requirements, available at http://www.wipo.int/meetings/en/html.jsp?url=http://www.wipo.int/edocs/mdocs/tk/en/wipo_ip_gr_05/wipo_ip_gr_05_3.doc.

224. *Id.* at 385.

225. See INSTITUTE FOR AGRICULTURE AND TRADE POLICY, *supra* note 215.

2. Watchdog Groups

The experience of the African Centre of Biosafety, which detected thirty-six likely cases of biopiracy after a single month of investigating patents granted in the developed world,²²⁶ provides a good example for developing countries. Watchdog groups that trigger alerts to developing countries that may be affected by a patent can be an effective and inexpensive mechanism for developing countries to pursue. Most of the industries involved in biopiracy cases have obtained their patents in American, European, or Japanese patent offices.²²⁷ Cooperative efforts between NGOs and developing countries' governments may be very effective in the fight against biopiracy. Eventually these groups could investigate all patents that have already been granted in order to assess prior undocumented TK abuse.

Regional organizations could also play an important role. For example, the environmental authorities of Andean countries established the Andean Genetic Resources Committee (AGRC) in order to define a coherent regional strategy for dealing with the international community's use of genetic resources and ensure equitable benefit-sharing for their countries' populations.²²⁸ The Andean Environmental Agenda seeks to strengthen the capacities of member countries with respect to environmental and sustainable development issues.²²⁹ The AGRC also promotes action to protect TK in compliance with Andean Community Decision 391.²³⁰ Decision 391 regulates access to genetic resources of the member countries and seeks to:

- a) Establish the conditions for just and equitable participation in the benefits of the access;
- b) Lay the foundations for the recognition and valuation of the genetic resources and their by-products and of their associated intangible components, especially when native, Afro-American or local communities are involved;

226. *Id.* at 15.

227. *Ni, supra* note 130, at 436.

228. *See* Comunidad Andina, *CAN Firma Convenio Para Apoyar Lucha Contra la Biopirateria*, <http://www.comunidadandina.org/prensa/notas/np9-8-05.htm> (last visited April 12, 2008) [hereinafter *CAN*].

229. *See* Comunidad Andina, *Andean Environmental Agenda*, <http://www.comunidadandina.org/ingles/biodiversity.htm> (last visited Jan. 14, 2008).

230. For a translated version, see Lewis & Clark Law School, *International Environmental Law Project: Andean Pact*, <http://www.lclark.edu/org/ielp/andeaneng.html> (last visited June 6, 2008).

- c) Promote conservation of the biological diversity and the sustainable use of the biological resources that contain genetic resources;
- d) Promote the consolidation and development of scientific, technological and technical capacities at the local, national and sub-regional levels; and
- e) Strengthen the negotiating capacity of the Member Countries.²³¹

At the state level, some countries are taking action to prevent misappropriation of TK and PGRs.²³² As an example, Peru recently created the National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples (National Anti-Biopiracy Commission) and charged it with the task of identifying and following-up on patent applications derived from Peruvian biological resources.²³³

B. A Sui Generis System of Intellectual Property Protection for Traditional Knowledge and PGRs

At both national and international levels it is important to create a new legal IP system that recognizes and protects TK. On a national level, some countries, such as Peru, Panama, New Zealand, and the Philippines, have adopted *sui generis* systems to protect TK.²³⁴ On the international level, it is clear that TRIPS has failed to grant protection to TK because the IP system remains grounded on cultural concepts that do

231. Comunidad Andina, *Decision 391, Common Regime on Access to Genetic Resources*, art. 2, available at <http://www.comunidadandina.org/ingles/normativa/D391e.htm>.

232. WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Comparative Summary of Existing National Sui Generis Measures and Laws for the Protection of Traditional Knowledge*, July 7–15, 2003, WIPO/GRTK F/IC/5/INF/4, available at www.wipo.int/documents/en/meetings/2003/igc/doc/grtkf_ic_5_inf_4.doc.

233. See, WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Combating Biopiracy-The Peruvian Experience* (July 9, 2007), available at http://www.wipo.int/meetings/en/html.jsp?url=http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkic_11/wipo_grtkf_ic_11_13.doc.

234. See Anne Haira, *Calls for Sui Generis Protection of Traditional Knowledge*, Feb. 2, 2007, http://www.kensingtonswan.com/print/Publications/Maori%20Law/Traditional_Maori_knowledge_sui_generis.htm (last visited Apr. 22, 2008).

not respond to the concepts of TK in indigenous communities. Some legal proposals, such as geographical indications or trade secret protection standards, give hope for the eventual protection of TK.²³⁵ Any new approach, however, should not accommodate traditional forms of IP law, but instead, expressly recognize the value of communities that have protected and transmitted useful knowledge. Furthermore, the system should allow those communities to directly profit from their TK.²³⁶ The ideal IP system would be a hybrid property regime that allows access to TK and PGRs for research, but is committed to the idea of economic benefit sharing. If the global community fails to shape this concept in the near future, it is likely that research and development will slow down because of direct opposition from developing nations' governments and NGOs.

Some have proposed a "limited common property" scheme (LCP) that has characteristics to protect TK holders while also encouraging TK use: it would be communal for the insiders but would allow private exploitation outside of the community.²³⁷ LCP is defined as "property held as a commons, among the members of the groups, but exclusively vis-a-vis the outside world."²³⁸ The purpose of these collective IPRs will be to recognize the diversity of IPRs, including collective rights. Borrowing from Vandana Shiva's ideas, the new concept will be "biodemocracy": a *sui generis* system that maintains the exchange of knowledge in third-world farming communities and recognizes that knowledge and production systems of biological organisms have equal validity.²³⁹ Others have proposed joint ownership schemes,²⁴⁰ but it is unclear how this solution will solve the problem of identifying the proper level of TK co-ownership: is it the village, the individual tribesman, or a whole community? Furthermore, these proposals lack a discussion as to what entity will legally represent the co-owner. What is clear is that states have to develop systems to deal with these questions. To solve the representation problem, some have proposed the creation of a trust regime,²⁴¹ whereby governments or NGOs would enter into negotiations with companies on behalf of TK holders.²⁴²

235. Eiland, *supra* note 66, at 72–75.

236. Downes, *supra* note 50, at 373.

237. BROWN, *supra* note 11, at 239 n.12.

238. Carol M. Rose, *The Several Futures of Property: Of Cyberspace and Folk Tales Emission Trades and Ecosystems*, 83 MINN. L. REV. 129, 132 (1998).

239. SHIVA, *supra* note 26, at 80–81.

240. Kohls, *supra* note 6, at 122.

241. *Id.* at 125.

242. *Id.*

In any event, new IP laws governing TK should consider differential treatment of patents in order to encourage research and development efforts that address tropical diseases and developing country epidemics. They should also address the question of what constitutes an “indigenous” community and how to ensure an adequate representation of indigenous community interests during the benefit sharing negotiations. In the past, these important issues blocked the success of the U.S.-led International Cooperative Biodiversity Groups (ICBG) program initiative, a partnership between U.S. and host-country scientists and drug companies that was meant to identify commercially-exploitable TK resources in Africa and Latin America.²⁴³ The program partially failed because of difficulties with properly identifying indigenous communities and their representatives.²⁴⁴ Another important issue will be determining criteria by which to establish royalty amounts. Regardless, new IP laws governing TK will need to be established in an internationally binding treaty.

A general lack of consensus among countries remains an obstacle in treaty development. In general, developing countries have emphasized the need for the IGC Committee to accelerate its work to establish an internationally binding instrument for the protection of PGRs, TK, and folklore.²⁴⁵ On the other hand, the United States has expressed opposition to this codification, arguing that a single universal document cannot provide comprehensive protection in a manner that suits national priorities, legal and cultural environments, and the myriad needs of diverse traditional communities.²⁴⁶ If the past indicates future agreement, it remains unlikely that consensus between developed and developing countries will be reached in the near future.

C. The Harmonization and Coordination of Treaties and Different Forums

It is important to create synergy between the different forums and processes that are dealing with the biopiracy problem. A single instrument will not be effective unless it is part of an integrated solution and designed to be implemented by combined international bodies and states. The conflict between different treaties and the lack of coordination between competing forums only leads to confusion and

243. BROWN, *supra* note 11, at 121.

244. *Id.*

245. See PATENT QUALITY, *supra* note 215.

246. *Id.*

lessens the possibility of strengthened protection for TK and PGRs. The renegotiation of TRIPS Article 27, which governs IP derived from living resources, is not only crucial because the WTO is the most powerful trade organization in the world, but also because TRIPS includes enforcement mechanisms. The developing world needs to reach consensus on the main issues in order to enhance its bargaining power with the developed world. WIPO is a good forum to reach consensus, but it will first need to solve existing bureaucratic problems and further accelerate the process.

Hope that progress will be achieved was evidenced during WIPO's Eleventh Meeting, held July 3–12, 2007. There, the discussion focused on three issues: (1) defensive protection of genetic resources; (2) disclosure requirements in patent applications for information related to genetic resources used in the claimed invention; and (3) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources.²⁴⁷ To date, however, no concrete, beneficial measures have resulted from the WIPO meetings.

D. The Participation of Indigenous Communities in the Formulation of International Intellectual Property Policies

The international community must ensure that indigenous communities, those most directly affected by the misappropriation of PGR and TK, are represented in the various world forums. Inclusion of the communities must emphasize: capacity-building; consultation; and the promotion of regional, national and local dialogue to be managed and directed in close collaboration with indigenous peoples and local communities. The participation of indigenous people in the formulation of international policies, however, does raise some concerns. Certainly, there is some difficulty in achieving a geographical balance and sufficient diversity in any form of representation. Additionally, some mechanism needs to be devised in order to assure that international negotiation participants are truly representative of all indigenous community interests.

In October 2005, the Member States of WIPO created a voluntary Fund for Accredited Local and Indigenous Communities to facilitate the participation of indigenous communities in the work of the Intergovernmental Committee on Intellectual Property and Genetic

247. See WIPO, *Brief Summary of the Working Documents for the Eleventh Session of the IGC*, <http://www.wipo.int/tk/en/igc/igc11-docsummary.html> (last visited June 6, 2008).

Resources, Traditional Knowledge and Folklore (IGC).²⁴⁸ However, concerns remain as to the lack of wider participation by these communities.²⁴⁹ Other concerns relate to the administration of patent derived funds, the selection of financial support “eligibility” criteria, and the proper implementation of mechanisms to ensure dissemination of knowledge and information within indigenous communities.²⁵⁰

E. Self-Defense Mechanisms

Self-defense is always the best defense. Local governments should use their police and regulatory powers to prevent and control the misappropriation of TK. Individual nations should use their domestic immigration, intellectual property, criminal, and other laws as important tools for self-defense. Defense should be proactive and not reactive. Once a local community loses control of its TK and PGRs, the damage may be inevitable and the potential benefits unrealizable. Consequently, the precautionary approach is the most desirable option.

Enactment of IP legislation that seeks to defend TK and PGRs is sorely needed. A recent WIPO survey asked forty-seven countries if they had enacted legislation to protect TK, and most responded they had not.²⁵¹ Some developing countries, including Costa Rica, Panama, and Nigeria,²⁵² are enacting regulations on the utilization of PGRs that seek to achieve equitable PGR benefit sharing, sustainable PGR conservation, and prior informed consent requirements.²⁵³ In 2001 Brazil enacted a similar law, but was persuaded to modify it in 2005 because researchers criticized that it had a chilling effect on research and development.²⁵⁴

In addition to protective legislation, governments in developing countries should generate revenue to contribute to technical and legal counseling for indigenous communities and to fund projects in defense of TK. They should also make greater efforts to enhance communication and improve their relationship with their indigenous communities.

248. *Id.*

249. WIPO, *NGO Participation*, <http://www.wipo.int/tk/en/ngoparticipation/> (last visited April 22, 2008).

250. WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Participation of Indigenous and Local Communities*, Nov. 1–5, 2004 (July 15, 2004), available at http://www.wipo.int/meetings/en/html.jsp?url=http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_12.doc.

251. Eiland, *supra* note 66, at 50.

252. Kohls, *supra* note 6, at 123.

253. See Haira, *supra* note 234.

254. Kohls, *supra* note 6, at 124.

Perhaps, most importantly, however, local TK research and management efforts are best suited to address existing TK shortcomings: first, to acknowledge the content, extension, and potential economic uses of TK; second, to correctly address the protection of PGRs and prevent their extinction; and finally, to document TK and establish it as a “prior art” developed by indigenous communities. As explained above, some countries have already taken steps in that direction. In Colombia, for instance, the Botanic Garden Jose Celestino Mutis,²⁵⁵ named after the Spanish botanist who in colonial times dedicated his life to the “Botanic Expedition of the New World,” could be used for these purposes. This institution could provide a leadership example by reassuming the mission to create a databank of known and recently discovered plants, as reported by indigenous communities. It could demonstrate that local databases could be compared to and integrated into international databases and create a means for patent examiners to identify what is novel in reference to TK.²⁵⁶ Efforts to create an international database were recently pursued by WIPO, however, the global pharmaceutical industry opposed the effort, and argued that it would discourage research and development.²⁵⁷ Local efforts could strengthen the case for the WIPO database, assist in its content development, and provide a counterforce to industry opposition.

Developing countries should additionally focus on improving their negotiation skills with multinational pharmaceutical companies that seek the discovery of new PGRs. Some countries have been successful in improving their bargaining power and negotiating more favorable deals.²⁵⁸ For instance, in 2004 the Samoan government signed an agreement with the University of California to equally share the profits from a potential anti-HIV drug called “Prostratin,” derived from the bark of the Samoan mamala tree.²⁵⁹ Paul Alan Cox, Director of the Institute for Ethnobotany at the National Tropical Botanical Garden in Hawaii, stated, “This may be the first time that indigenous people have extended their national sovereignty over a gene sequence.”²⁶⁰ Developing countries should take heart and follow the Samoan example.

255. See Jardin Botánico - Jose Celestino Mutis, *Un Viaje al País de las Maravillas*, <http://www.jbb.gov.co/web/home.php?pag=section&id=5#> (last visited June 6, 2008).

256. Eliand, *supra* note 50, at 65.

257. *Id.* at 65–66.

258. *Id.* at 70.

259. Press Release, Robert Sanders, University of California–Berkeley, Landmark Agreement Between Samoa and UC Berkeley Could Help Search for AIDS Cure (Sept. 29, 2004), *available at* http://www.berkeley.edu/news/media/releases/2004/09/29_samoa.shtml.

260. *Id.*

Another example of successful negotiation involved the Costa Rican government, which entered into an agreement with Merck & Co., wherein the multinational company agreed to provide financial support, share profits, and build research facilities in return for TK.²⁶¹ From these examples it is clear that developing countries must establish unambiguous rules regarding representation of indigenous communities in order to negotiate successfully.

F. The Correctional Approach and the Reexamination Process

As discussed above, some countries have managed to fight biopiracy through the legal reexamination process. Despite some success, this method has proven to be both cumbersome and expensive. The Enola bean case is a good example of how unjust patents can still create yearly profits for patent holders as a function of overly complicated and grindingly bureaucratic reexamination processes.²⁶² The case also shows the potentially negative impacts of such patent monopolies on the global community. Despite these problems, India examined the USPTO, UKPO, and EPO databanks and has reported some patents apparently based on TK.²⁶³ Developing countries should focus on these actions to detect misappropriations and push for the establishment of expedited procedures to reexamine patents and find unjust patent holders liable for illegally gained profits. It is likely that as countries become more experienced in detecting TK based infringements, they will also develop internal mechanisms to more efficiently handle and correct biopiracy through their reexamination processes.

VII. CONCLUSION

The concept of IPRs adopted by international society was firmly established in TRIPS and has expanded through bilateral agreements. This concept is based on the understanding of IPRs as “private rights,” which by nature are “individualist and exclusionary.” Over the course of hundreds or thousands of years, indigenous communities have developed and orally transmitted knowledge to successive generations for the free use and benefit of all of their members. Because TK is, at its essence,

261. Kohls, *supra* note 6, at 128 n.201.

262. See etcgroup.org, *Whatever Happened to the Enola Bean Patent Challenge*, Dec. 21, 2005, <http://www.etcgroup.org/upload/publication/41/01/genotypeenola05.pdf> (last visited June 6, 2008).

263. Eiland, *supra* note 66, at 65.

“communal,” a *sui generis* approach is perhaps most compatible with its inherent characteristics and history.

The multitude of conflicting international treaties reflects the divergent interests of the developed and developing world in regard to TK. The WTO, UPOV, and developed countries advocate for the expansion of IPRs on PGRs and oppose the establishment of a unified IPR system that significantly protects the interests of TK holders. They also oppose the amendment of TRIPS to include a patent applicant's obligation to disclose TK or to guarantee benefit sharing with indigenous communities. In contrast, the UN, WIPO, and developing countries are more concerned with the recognition of sovereignty over PGRs and the establishment of an international system to protect traditional knowledge. However, unlike TRIPS, neither the WIPO nor CBD establish enforcement mechanisms. Consequently, TRIPS has imposed a globally dominant IP system that completely neglects TK concerns.

These divergent, overlapping, and conflicting international rules only create confusion and generate uncertainty that favors the position of developed countries' industries. However, developing states are beginning to organize in order to defend their PGRs and TK assets. The developing world needs to reach consensus surrounding basic issues such as the exceptions to patentability, the nature of TK based intellectual property, the appropriate means of representing indigenous communities, the best method of instituting benefit sharing, the right level of indigenous community participation in the formulation of international policies, and many related issues. If developing countries succeed in forming a coherent group, they will have better bargaining power in renegotiating TRIPS Article 27 and entering into IP negotiations with the developed world. In the interim, developing countries should refrain from entering into bilateral agreements or concluding negotiations within the WTO until they reach consensus among themselves and establish clear goals to be achieved in multilateral negotiations.

Incidental to consensus is the need for harmonization of domestic legal systems. Equilibrium between developed and developing countries is essential. The developing world should grant access to PGRs in order to encourage research and development for purposes of financial benefit sharing, sustainable development, and rapid technology transfer. Once the developing world reaches agreement, the risk of concerted opposition to existing TK policies will increase and developed countries will likely compromise. All parties will surely realize that negotiation failures will only endanger research, technological development, and ultimately, humanity. Harmonization is ultimately necessary to achieve food security, insure human health, and guarantee sustainable development. Unfortunately, harmonization remains elusive because of the reluctance

of the United States, Japan, and other developed countries to embrace these TK ideas.

Due to the lack of an effective international system to protect TK and PGRs, the developing world needs to adopt a self-defense approach. This approach contemplates an active role for developing countries in the defense of their PGRs and TK. It requires countries to develop practices to modify their internal laws and regulations and to exercise more governmental control at both the state and local levels. Developing countries' efforts should focus on gathering and managing information regarding their own PGRs and TK. In addition, developing countries should strengthen communications between governmental organizations and indigenous communities. They should improve their negotiation skills to deal with multinational industries and enact regulations to protect PGRs. They should also define the modes of legal representation for their indigenous communities. The self-defense approach should be further complimented by a correctional strategy. To support the correctional approach, developing countries should encourage a network of watchdog groups to permanently review all patents granted in the USPTO, UKPO, or EPO and alert the developing countries of any possible TK transgressions.

Finally, developing countries have a fundamental responsibility to guarantee the survival and individual human rights of indigenous communities. These countries, supported by the world community, have the opportunity to correct for the long-standing neglect, displacement, and unnecessary deaths of indigenous peoples.²⁶⁴ Until developing countries stand up together in uncompromising defense of their indigenous cultures, any arguments to protect PGRs and TK lack credibility and are destined to remain ineffective in the international arena.

264. See Press Release, UN Economic and Social Council, Indigenous Face Poverty-Even Extinction at Hands of Indifferent Governments, Profit Hungry Nations, United Nations Forum Told (May 18, 2007), available at <http://www.un.org/News/Press/docs/2007/hr4921.doc.htm>.

