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Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies

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BIOPIRACY AND BEYOND: A CONSIDERATION OF SOCIO-CULTURAL CONFLICTS WITH GLOBAL PATENT POLICIES

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This Article provides a fresh and multi-dimensioned approach to a long-standing claim of biopiracy patents made by developing countries and communities. The basic principles of patent law and policy are first established to provide a foundation from which to evaluate the claim that genetic resources and traditional knowledge from developing countries are being misappropriated in a variety of ways that are loosely referred to as biopiracy. The Article distinguishes rhetoric from reality in examining biopiracy allegations from the perspective of national patent laws, as well as international agreements. In addition, the Article explains the underlying conflicts, misconceptions, and historical biases that have predisposed some to biopiracy claims. Similarly, the Article presents a new perspective on how the present landscape of international agreements, as well as negotiation stances, has failed to lead to satisfactory resolution of biopiracy claims despite years of heated discussion within major international forums, including the World Trade Organization, the United Nations, and the Convention on Biological Diversity.

In addition to explaining the dynamics behind the current stalemate, this Article provides a template for moving forward. As a first step, the Article advocates that the piracy lingo be jettisoned and that substantive discussion instead focus on issues that have mutual appeal to all countries. Drawing upon past success of issue-framing in the context of the access to medicine debate, this Article proposes new foci that nations might universally agree on. For example, this Article suggests a novel linkage between biopiracy patents and more general problems within Western patent law to help focus on issues of interest to all nations. In addition the Article proposes a new internet-based process for promoting meaningful dialogue that will likely be more effective than current proposals because it avoids previous intransigent issues. This final proposal has broad application to many issues at the intersection of patent law and social policy, ranging from the proper scope of patentable subject matter, to the scope of exceptions from patent liability.

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INTRODUCTION

Piracy is a central theme running through the international discourse on patent rights. The concept was utilized as a rationale for including intellectual property rights within a global trade agreement; in particular, the United States asserted that it was losing millions of dollars a year because of global piracy of copyrighted and patented works.[1] One major response to these piracy claims was the creation of the World Trade Organization (WTO), along with the adoption of the landmark Trade-Related Agreement on Intellectual Property Rights (TRIPS), which established minimum levels of intellectual property standards for all member states.[2] However, these developments did not mark the end of global patent policy disputes or piracy rhetoric.

A decade after the creation of the WTO and minimum intellectual property rights, piracy continues to be a compelling theme, but the term is being used by parties with divergent interests. In particular, the United States and European "Western" countries[3] have enacted a series of bilateral and multilateral agreements based upon the premise that higher levels of protection are necessary to combat global piracy.[4] On the other hand, many developing

1. *See, e.g.*, 132 CONG. REC. 10, 291 (1986) (statement of Senator Wilson) ("In the area of intellectual property protection, plainly stated, criminals around the world are costing American companies billions of dollars by . . . expropriating patents and process patents, developed at great expense by U.S. companies, to make bootleg pharmaceuticals and chemicals."); BUS. SOFTWARE ALLIANCE, GLOBAL SOFTWARE PIRACY STUDY: TRENDS IN SOFTWARE PIRACY 4, 9 (2003); PRESIDENT'S COMM'N ON INDUS. COMPETITIVENESS, GLOBAL COMPETITION: THE NEW REALITY 52–53 (1985) (concluding that the strengthening of intellectual property rights via international implementation of an anti-counterfeiting code should be national policy). The United States' position was a result of organized efforts from major industries including pharmaceutical, entertainment and software companies. *See generally* SUSAN SELL, PRIVATE POWER, PUBLIC LAW 39–55 (2003).

2. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. 1143, 1197–1223 (1994) [hereinafter TRIPS, Marrakesh Agreement].

3. The term "Western" here refers to developed countries that predominantly favor patent rights, such as the United States, Japan, and the European Union member-states. In addition, it would be synonymous with references to countries of the "North" (primarily industrialized countries in the northern hemisphere) as opposed to countries of the "South" (economically poorer, but biologically richer countries primarily from the southern hemisphere).

4. *E.g.*, Office of the U.S. Trade Representative, The Work of the USTR-Intellectual Property (July 8, 2004), http://www.ustr.gov/Trade_Sectors/Intellectual_Property/The_Work_of_USTR_-_Intellectual_Property.html (noting that bilateral initiatives are one of the tools used by the USTR to combat "piracy" in other countries).

countries[5] have argued that these Western countries engage in their own piracy—"biopiracy"—by taking genetic resources and associated traditional knowledge[6] from biodiverse developing countries without permission,[7] then patenting related inventions, but failing to share any of the resulting commercial profits.[8] The process of obtaining private rights over products derived from third world resources or knowledge that is considered sacred or beyond private ownership is considered to be morally offensive to many citizens of developing countries, as well as those with sympathetic interests in other countries.[9] Moreover, many of these citizens view Western countries and companies with great suspicion since usurpation of resources harks back to colonial imperialism.[10]

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5. The term "developing countries" is used broadly here to also include indigenous groups and nongovernmental organizations with the same interest in protecting biodiversity. However, biopiracy is sometimes an issue only for indigenous populations within a country. *See* U.N. Conference on Trade and Development [UNCTAD] & the International Centre for Trade and Sustainable Development [ICTSD], *Protecting Traditional Knowledge and Folklore: A Review of Progress in Diplomacy and Policy Formulation*, at 17 (Oct. 2002) (*prepared by* Graham Dutfield), *available at* http://www.iucn.org/themes/pbia/themes/trade/training/Protecting%20TK%20and%20Folklore.pdf [hereinafter UNCTAD & ICTSD, *Protecting Traditional Knowledge and Folklore*] (noting that some countries, such as India, see the nation itself as a "victim of biopiracy," whereas for "New World countries" established by European settlers, the issue is localized to smaller communities outside of the mainstream culture).

6. Convention on Biological Diversity, art. 8(j), June 5, 1992, 1760 U.N.T.S. 79 [hereinafter CBD] (calling for the respect, preservation, and maintenance of the knowledge, innovations, and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity); WORLD INTELL. PROP. ORG. [WIPO], INTELLECTUAL PROPERTY NEEDS AND EXPECTATIONS OF TRADITIONAL KNOWLEDGE HOLDERS 25 (2000) (defining "traditional knowledge" broadly to include tradition-based innovation and creations transmitted orally between generations, typically unique to a given region and constantly evolving in response to a changing environment, including agricultural or scientific knowledge, medicinal knowledge). In addition, the term often refers to both scientific and literary works, although "traditional knowledge" will be used here only to refer to scientific knowledge. *Id.* Traditional knowledge is sometimes used synonymously with indigenous knowledge. *See, e.g.*, Padmashree Gehl Sampath, *Intellectual Property Rights on Traditional Medicinal Knowledge: A Process-Oriented Perspective*, 7 J. WORLD INTELL. PROP. 711, 714 (2004).

7. Some advocates of bioprospecting, including corporations that use these methods and academic researchers, assert that the process need not be exploitative. *See, e.g.*, SANTIAGO CARRIZOSA, *Introduction* to ACCESSING BIODIVERSITY AND SHARING THE BENEFITS: LESSONS FROM IMPLEMENTING THE CONVENTION ON BIOLOGICAL DIVERSITY 3, 4 (Santiago Carrizosa et al. eds., 2004) (noting that despite controversy concerning patenting genetic material and claims of biopiracy, bioprospecting can yield benefits to both developed countries, as well as those from biodiverse countries); WALTER V. REID ET AL., *A New Lease on Life*, *in* BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT 1, 1 (1993) ("[B]iodiversity prospecting [is] the exploration of biodiversity for commercially valuable genetic and biochemical resources.").

8. *See infra* Part I.

9. *See infra* Part I.A.

10. *See infra* Part II.A.3.

Developing countries are calling for immediate international resolution of the biopiracy problem through amendment of TRIPS as well as pending amendments to existing, or proposed international agreements.[11] The proposed amendments require patent grants to be conditioned upon compliance with the Convention on Biological Diversity (CBD).[12] Western countries concede that protecting genetic resources and traditional knowledge is important, but have opposed such efforts. Even though Western countries acknowledge that some allegations of biopiracy reflect improperly granted patents, they suggest that the present system adequately addresses such patents through existing correction mechanisms, such that amendments are unnecessary.[13]

Is biopiracy a real issue and if so, is it important? Developing countries believe that this is a real issue, as reflected by years of advocacy among multiple international forums, including the WTO, the CBD and the World Intellectual Property Organization (WIPO).[14] In addition, the issue has also attracted the attention of policy-makers, non-governmental organizations (NGOs)[15] and

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11. *See infra* Part II.

12. *See supra* notes 172–179 and accompanying text. Additionally, the United Nations' greater recognition of indigenous communities and their respective human rights, including rights to maintain their traditional culture and knowledge, also suggests that continued use of biological materials may be considered an affront to the human rights of indigenous peoples. U.N. Econ. & Soc. Council [ECOSOC], Sub-Comm. on Prevention of Discrimination & Prot. Of Minorities, Commission on Human Rights, *Draft United Nations Declaration on the Rights of Indigenous Peoples*, U.N. Doc. E/CN.4/Sub.2/1994/56 (Oct. 28, 1994) [hereinafter ECOSOC *Draft Declaration*].

13. *See infra* Part III.

14. *See infra* Parts I.B, II.B, III; *see also* Graham Dutfield, *Bioprospecting: Legitimate Research or 'Biopiracy?'*, SCI. & DEV. NETWORK POL'Y BRIEFS, at 1 (Oct. 2001, rev. Dec. 2002), *available at* http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&dossier=8&policy=40 (noting that "bioprospecting" is of recent vintage linguistically, but a "centuries-old" practice).

15. *See, e.g.*, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 82–104 (2002), *available at* http://www.iprcommission.org/graphic/documents/final_report.htm [hereinafter COMMISSION ON IPRs]; Robert Lettington & Kent Nnadozie, *A Review of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore at WIPO*, *in* TRADE-RELATED AGENDA, DEVELOPMENT AND EQUITY OCCASIONAL PAPERS, (No. 12, Dec. 2003) (providing background concerning the utility of genetic resources and traditional knowledge, including the possibility of misappropriation of resources, as well as international discussions of how to prevent such misappropriation under existing or proposed legal frameworks, as one of a series of papers from NGOs with an interest in aiding developing countries); Manuel Ruiz, *The International Debate on Traditional Knowledge as Prior Art in the Patent System: Issues and Options for Developing Countries*, *in* TRADE-RELATED AGENDA, DEVELOPMENT AND EQUITY OCCASIONAL PAPERS, (No. 9, Oct. 2002) (providing analysis of possible solutions to address biopiracy under patent law as part of a project for NGOs South Centre and the Center for International Environment Law). *See generally* WORLD WIDE FUND FOR NATURE AND THE CENTER FOR INT'L ENVTL. LAW, BIODIVERSITY AND INTELLECTUAL PROPERTY RIGHTS:

academics.[16] Western countries, on the other hand, typically dismiss claims as misunderstandings of patent rights and policies that operate to the benefit of all countries.[17] However, such a simplistic dismissal does not explain concerted efforts of Western countries in silencing discussion within international forums, including recent efforts to entirely exclude the issue from discussion in a pending global patent treaty.[18]

Biopiracy is indeed a very real problem for developing countries, although not one that they can address on their own.[19] For example, although the European Patent Office revoked a patent on a derivative of a neem tree in March 2005 in response to allegations of biopiracy, the final decision was only reached a decade after ini-

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REVIEWING INTELLECTUAL PROPERTY RIGHTS IN LIGHT OF THE OBJECTIVES OF THE CONVENTION ON BIOLOGICAL DIVERSITY (2001).

16. In addition to a plethora of articles discussing biopiracy, academic conferences have been devoted to biopiracy-related issues, such as the protection of traditional knowledge. *See, e.g.*, Symposium, *Traditional Knowledge, Intellectual Property, And Indigenous Culture*, 11 CARDOZO J. INT'L & COMP. L. 239 (2003); Symposium, *The Law and Policy of Protecting Folklore, Traditional Knowledge, and Genetic Resources*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 753 (2002); Conference, *Biodiversity and Biotechnology and the Protection of Traditional Knowledge* (Washington University in St. Louis, School of Law, Center for Interdisciplinary Studies, April 4–6 2003), http://law.wustl.edu/centeris/Confpapers/index.html.

17. *See infra* Part I.A.

18. *See infra* Part III.B.

19. The international discussion should speak for itself in terms of broad recognition of the problem of biopiracy. However, some have suggested that biopiracy is not a concern because pharmaceutical companies no longer engage in activities that result in biopiracy, or because so few drugs ever become commercialized there is no substantial compensation at issue and, hence, no need for discussion. *See, e.g.*, Susan Kling Finston, *The Relevance of Genetic Resources to the Pharmaceutical Industry*, 8 J. WORLD INTELL. PROP. 141, 143–44, 151 (2005) (suggesting that biopiracy assertions overstate the problem as well as the likelihood that a blockbuster drug could result from biodiverse resources and ultimately concluding that developing countries need *more* intellectual property rights to exploit the potential of natural products by analogizing to the United States' situation with Bayh-Dole, but without considering cultural and spiritual issues attendant to the biopiracy problem); Sally Satel, *Diminishing Biodiverse Returns*, TCS DAILY, Feb. 16, 2003, http://www.tcsdaily.com/article.aspx?id=021605I (noting that bioprospecting constitutes a "small and shrinking" percentage of the portfolio of major drug companies, with little prospect for eventual success). *But see* Carrizosa, *supra* note 7, at 3 (noting that although pharmaceutical companies such as Merck reduced their natural products discovery programs in 2002 and 2003, the economic value in genetic resources actually may have increased due to new technologies such as high-throughput screening, bioinformatics and genomics). Moreover, even if companies are no longer collecting natural products, it does not mean that they are not continuing to use products previously collected before there was a concern about impropriety and before CBD was effective. *See* CBD, *supra* note 6, at art. 15 (specifying that agreement only applies to material "acquired . . . in accordance with this Convention"); *see also* W. LESSER, SUSTAINABLE USE OF GENETIC RESOURCES UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY: EXPLORING ACCESS AND BENEFIT SHARING ISSUES 13–14 (1998) (noting that the national sovereignty aspect of CBD is presumed to apply only to activities occurring after the entry into force in December 1993).

tiation of the correction process.[20] Just two weeks after this decision, the European Patent Office (EPO) agreed to work towards thwarting biopiracy based upon traditional Indian medical knowledge through a new database to be provided by the Indian technology ministry under a non-disclosure agreement.[21]

Although the EPO action reflects some Western recognition of the need to address biopiracy allegations, it fails as a comprehensive solution. The EPO does not issue all patents and many of the patents alleged to result from biopiracy are issued by the United States.[22] Indeed, in the case of the neem tree patents, the decision to revoke the single EPO patent has no impact on the dozens of other related patents that continue in force in Europe, as well as a nearly identical patent that is considered valid in the United States because of differing patent laws.[23]

The biopiracy problem is an important issue for all countries because of its broader international implications. The conflict that exists between promoting patent rights versus protecting traditional knowledge challenges Western assumptions about the appropriateness of patents and also demonstrates the problems that arise based upon misunderstandings and disagreements about Western patent law. Such misunderstandings are not unique to biopiracy, and, as addressed in the final section of the Article, can be more effectively resolved. In addition, the biopiracy problem illustrates that the present landscape of international laws impedes resolution of the issue by promoting patent rights over other social and cultural norms, such as biodiversity and human rights. In particular, this Article argues that because TRIPS provides substantially more effective enforcement measures than those

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20. *See, e.g.*, LINDA BULLARD, RESEARCH FOUNDATION FOR SCIENCE, TECHNOLOGY, AND ECOLOGY, FREEING THE FREE TREE: A BRIEFING PAPER ON THE FIRST LEGAL DEFEAT OF A BIOPIRACY PATENT: THE NEEM CASE (2005), *available at* http://www.ifoam.org/press/press/pdfs/Briefing_Neem.pdf. This decision, essentially affirming a lower court's ruling in 2000, was made following a ten-year battle. For additional information on the earlier decision, see, e.g., U. Hellerer & K.S. Jarayaman, *Greens Persuade Europe to Revoke Patent on Neem Tree*, 405 NATURE 266, 266–67 (2000); Press Release, European Patent Office, "Neem tree oil" Case: European Patent No. 0436 257 Revoked (May 10, 2000), http://www.european-patent-office.org/news/pressrel/2000_05_11_e.htm.

21. *See, e.g.*, Gireesh Chandra Prasad, *EU to Protect India's Traditional Knowledge*, ECON. TIMES ONLINE, May 16, 2005, http://economictimes.indiatimes.com/articleshow/1111159.cms.

22. *See infra* Parts I.A, III.

23. *See infra* Part I.A. Every patent is presumed valid when issued. *See, e.g.*, 35 U.S.C. § 282 (2000). Moreover, even within each patent, individual claims (which define the patented invention) are considered independent of each other such that invalidity of any one claim does not impact other claims. As a broader analogy, resolution of the validity of a single patent only affects that patent and not related ones in the same way that claim preclusion only addresses the identical claim if relitigated. *Id.*

available to protect either CBD norms of biodiversity or international human rights, it de facto trumps other agreements and hence other social values. This is an important issue not only for biopiracy, but also for all international issues that may intersect with TRIPS. Similarly, this Article analyzes present proposals to amend TRIPS to address biopiracy. This analysis illustrates TRIPS's dominance in the international arena, as well as the present difficulties of challenging it.

Biopiracy allegations are also important because of what they reveal about the Western patent law upon which TRIPS is based. In particular, whereas there is already a rich discourse concerning the need to balance patent rights against public health, that argument is inherently different from balancing moral issues arising from biopiracy.[24] In the public health context, there is typically consensus that patents promote research on drugs that, in fact, provide direct health benefits.[25] Biopiracy patents, on the other hand, may be contrary to the desire of indigenous communities to keep certain information sacred.[26] Moreover, national sovereignty is implicated in biopiracy allegations in a manner different than the typical health care conflict. In particular, although most nations

24. In the context of access to medicine, there has been widespread criticism of the degree to which TRIPS impinges on domestic abilities to provide low cost medication. *See, e.g.*, Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO Health, Econ. & Drugs EDM Series No. 12, WHO/EDM/PAR/2002.3 (2002), *available at* http://whqlibdoc.who.int.hq/2002_edu.par_2002.3.pdf (discussing the impact of the Doha Public Health Declaration with particular emphasis on addressing the concerns of countries with insufficient capacity to utilize compulsory licensing as a mechanism for protecting public health); James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FLA. J. INT'L L. 261 (2002); Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27 (2002) (providing an overview of the changing perspective on access to medicine being adversely impacted by patented drugs); *see also* WHO, *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement*, Health, Econ. & Drugs DAP Series No. 7, WHO/DAP/98.9 Revised (1999) (providing an early overview of the implications of TRIPS on public health and access to drugs).

25. Of course, even if patents promote the development of drugs that benefit the general public, patents alone may not promote innovation to address diseases of third world countries, for which profits on patented drugs would be minimal. *See, e.g.*, ECOSOC, Comm'n on Human Rights, Sub-Comm'n on the Promotion and Protection of Human Rights, *The Impact of the Agreement on TRIPS on Human Rights*, at 12, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 2001) (noting that patent incentives inherently lead researchers "away from unprofitable diseases, such as those that predominantly affect people in poorer countries"); Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*, 2 PLOS BIOLOGY 147 (2004) (noting the low rate of patents and research in third world diseases and suggesting an alternative mechanism to promote innovation). In addition, there is also a similarity here between public health and biopiracy—in both instances a patent may provide a medical treatment, but in both instances, the patent incentive may only promote treatment for Western nations.

26. *See infra* Part I.A.

would prefer to decide their own balance of patent rights and exceptions in the interest of public health, the balance is just that—typically an acceptance that some patent rights are permissible and even desirable. However, in the biopiracy context, some believe that patent rights, regardless of limiting exceptions, are inherently irreconcilable with protecting genetic resources and traditional knowledge.[27]

Ultimately, this Article provides new templates for addressing both the immediate biopiracy problem, as well as the broader issue of balancing patent rights and social policy in Western countries. This Article rejects prior attempts to provide a single "magic bullet" to address biopiracy. As reflected in the protracted, yet unfruitful discussion of biopiracy, the problem is a complex one that is unlikely to be solved by a single solution. Moreover, prior proposals have failed, in part, for presenting biopiracy as a unique issue that had no easy analog to existing Western issues.[28]

This Article provides a multi-faceted approach to the nuanced biopiracy problem. As an initial step, the piracy lingo is jettisoned in favor of national sovereignty, which is a universally understood concept. In addition, this Article advocates that current biopiracy problems be considered concurrently with existing proposals to reform Western patent law and policy. These proposals provide a convenient vehicle to facilitate realistic consideration of patent law and policy. Moreover, such an approach can have a broad impact as Western patent laws have been used as a template for patent laws imposed on countries worldwide through TRIPS and other international agreements. This Article also provides a new method for addressing patent policy problems effective not only for biopiracy patents, but any controversial patents. These approaches are not intended to be exclusive of other proposals to address biopiracy.[29]

Part I of this Article begins with some historical background on the evolution of biopiracy as a concept, as well as the parallel negotiation and implementation of TRIPS and the CBD. Part II then

27. *See infra* Part II.A.

28. *See infra* Part III.

29. The proposal suggested in this Article is offered as *one* way to address this aspect of biopiracy without prejudicing additional solutions to protect traditional knowledge. In particular, proposals to protect traditional knowledge with sui generis protection, or new methods of access and benefit sharing, are beyond the scope of this Article. However, readers interested in specific and dramatic proposals addressing biopiracy will find plenty of pertinent documents. *See, e.g.*, Peter Drahos, *Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?*, 6 EUR. INTELL. PROP. REV. 245 (2000); Craig D. Jacoby & Charles Weiss, *Recognizing Property Rights in Traditional Biocultural Contributions*, 16 STAN. ENV. L.J. 74 (1997); Thomas J. Krumenacher, Note, *Protection for Indigenous People and Their Traditional Knowledge: Would a Registry System Reduce the Misappropriation of Traditional Knowledge?*, 8 MARQ. INTELL. PROP. L. REV. 143 (2004).

provides a detailed analysis of issues that underlie the present impasse. Part A explains the instrumentalist perspective of patent policy, as well as how that perspective clashes with protection of traditional knowledge and genetic resources of indigenous communities. Part B then gives an overview of the relevant international agreements relating to the biopiracy issue, focusing primarily on TRIPS and the CBD, with the ultimate goal of showing that TRIPS reinforces and elevates patent rights over social norms in competing international agreements that embrace and advocate protection of traditional knowledge, because of the ease of enforceability of the TRIPS provisions.

Part III focuses on the present proposals to amend TRIPS and presents fundamental flaws in their conception. In doing so, this Part illustrates that the dominance of TRIPS has negatively impacted resolution of biopiracy because its powerful enforcement provisions entice developing countries to propose amendments to TRIPS. A major problem is that TRIPS currently reflects the preferred norms of Western countries behind its creation, such that any proposed changes are likely to fail. In addition, in the unlikely situation of TRIPS amendments to address biopiracy, such amendments might nonetheless be futile because Western countries are utilizing other forums to negotiate increased levels of patent protection that might overshadow TRIPS.

Part IV provides specific strategies to promote productive discussion of the underlying issues behind the current biopiracy rhetoric and also provides a template for addressing the broader problem of socio-cultural conflicts with patent law and policies. Most importantly, this Part suggests abandoning the "piracy" term in favor of a focus on national and community sovereignty while refocusing patent law and policy on issues of overlapping concern between biopiracy allegations and the protection of traditional knowledge. For example, current controversies over whether certain patented inventions are unethical, such as those on gene patents, stem cells, and human cloning, raise similar issues to developing country claims of commodification of life forms. This Part concludes with an innovative method for addressing patent policies that should help to improve understanding and potentially effectuate necessary change.

I. BACKGROUND

A. Patent Law and Policy versus Genetic Resources and Traditional Knowledge

1. Patent Law and Policy—Patents serve an instrumental and utilitarian goal of fostering the development of new innovation.[30] As noted by the United States Supreme Court, the patent system reflects a "carefully crafted bargain" that encourages innovation and promotes increased knowledge by providing an incentive to risk time, research, and development costs.[31] The patent incentive exists because it provides exclusivity that may result in a commercial advantage in the marketplace. In particular, a patent provides its owner with the right to exclude others from making, using, selling, offering to sell, or importing the patented invention within the territory of the granting nation.[32] This exclusivity is considered essential to "stimulate ideas and the eventual development of further . . . advances."[33] In addition, the exclusivity is considered to encourage inventors to disclose inventions through the patent system, rather than maintain them as trade secrets in perpetuity. Inventions kept as trade secrets are less valuable to the public since patents are public documents that disclose the invention such that subsequent inventors can understand and build upon the innovation.

Although a patent provides a measure of exclusivity, that exclusivity is not absolute. A patent only provides its owner with the right

30. *See, e.g.*, Diamond v. Chakrabarty, 477 U.S. 303 (1980); Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990). In the United States, the instrumentalist purpose dates back to the Constitutional clause animating federal patent law, which provides Congress the right to *promote progress* by grants of limited exclusivity to inventors. *See* U.S. CONST. art. I, § 8, cl. 1 (providing that Congress may "promote the progress of science and useful arts").

31. *See, e.g.*, Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150 (1989) (noting that the federal patent system reflects a "carefully crafted bargain" that encourages innovation and promotes increased knowledge); *see also* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974) (noting that patents provide an incentive to risk time, research, and development, as well as a reward for disclosure of an invention).

32. *See, e.g.*, TRIPS, Marrakesh Agreement, *supra* note 2, at art. 28; 35 U.S.C. § 271(a) (2000).

33. *Bicron*, 416 U.S. at 481. *See also* Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1577–78 (Fed. Cir. 1983) (noting that the "the express purpose of the Constitution and Congress, to promote the progress of the useful arts, would be seriously undermined" without the right to exclude); Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983) (noting that the right to exclude is essential to patent rights since the Patent Act specifies that patents are a form of property and the right to exclude is the essence of property rights).

to *exclude* others from the patented invention; it is not an affirmative right to use the invention.[34] In particular, there may be regulations that prohibit or limit the use of the patented invention. A typical example exists in the area of patented drugs, which may not be sold in the commercial marketplace before approval by the Food and Drug Administration.[35] In addition, the exclusivity provided by a patent is limited to the territory in which the patent is granted. For example, a patent granted in the United States entitles its patent owner to exclude all others from making the patented invention in the United States, as well as from importing the patented invention into the United States.[36] However, a U.S. patent would not prevent someone from making the identical invention in Germany. On the other hand, if the patent owner had applied and been granted a similar patent in Germany, the patent owner would have such exclusionary rights in Germany.

A final important, but often misunderstood concept with respect to patents is that the right to exclude is bound not only by territorial restrictions, but also by the legal parameters of patents. In particular, a patent allows exclusion of others only from the "claimed invention," but not from all related subject matter. Claims are the technical "metes and bounds" that describe the legally enforceable boundaries of a patent against others.[37] Patents may more generally describe a subject matter, but not have any legal implications outside of the claims. For example, a patent with claims on a new method of baking a chocolate cake in a microwave oven would have no legal implications for traditional methods of cake-baking in conventional ovens. Moreover, claims are typically very detailed. In the hypothetical cake example, claims would typically specify temperature and time requirements, such that some cakes cooked in microwave ovens would not be legally excluded by the patent because of these important details. Although the cake example seems simple, the fundamental concepts about the scope of patent

34. *See* 35 U.S.C. § 271(a) (2000).

35. 21 U.S.C. § 355(a) (2000). Furthermore, as another example, the patent owner may actually need a license from another patent owner to use his invention. This typically occurs for owners of patents that improve on other patents—while the second patent may be commercially valuable in excluding others from the improvement, the owner of the patent on the more fundamental invention (sometimes referred to as a pioneering patent) may still have the right to exclude from a broader scope. *See generally* 35 U.S.C. § 271(a) (2000) (providing that a patent owner has the right to exclude anyone who infringes the patent during its term).

36. *See* 35 U.S.C. § 271(a) (2000).

37. *See* 35 U.S.C. § 112 (2000) (noting that patents must conclude with one or more claims describing the invention); *see also* 35 U.S.C. § 271(a) (2000) (noting that a patent owner has the right to exclude others from the patented invention).

claims are critical to evaluating statements (and misstatements) concerning patents that are based on traditional knowledge.

To obtain a patent, a formal application must be submitted to the country where the patent is desired and the invention, as well as the application, must satisfy certain requirements. First, the invention must constitute patentable subject matter.[38] Generally, laws of nature and products in their natural state, such as trees or rocks, are considered unpatentable discoveries.[39] In addition, the invention must be new, nonobvious, and useful.[40] The terms "new" and "nonobvious" have special meaning in patent law that do not necessarily reflect lay usage of the terms.[41] In addition, these terms do not have uniform definition in the global context. While some entities, such as the United States and EU, consider material isolated from living material, such as a derivative of a plant that does not naturally occur in nature, or an isolated portion of a gene to satisfy the definition of "new," developing countries predominantly object to such definitions.[42] In addition, in determining what is "new,"

38. *See, e.g.*, 35 U.S.C. § 101 (2000); Convention on the Grant of European Patents (European Patent Convention), art. 52, Oct. 5, 1973, 13 I.L.M. 268, 270, *available at* http://www.european-patent-office.org/legal/epc/ [hereinafter EPC]; *see also* TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27(1).

39. *See, e.g.*, Diamond v. Diehr, 450 U.S. 175, 185 (1981); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130–31 (1948). In addition, the Supreme Court has the opportunity to revisit and reaffirm this view in an upcoming case of *Metabolite*, for which it has granted certiorari. Metabolite Lab., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004), *cert. granted*, 126 S. Ct. 601 (2005).

40. *See, e.g.*, TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27(1).

41. For example, although lay persons often assume that something "obvious to try" is unpatentable, the United States has expressly rejected this on grounds that it unduly promotes hindsight speculation. Rather, the United States requires that there be some suggestion or motivation to combine two or more references for something to be obvious. *See, e.g.*, *In re* Oetiker, 977 F.2d 1443, 1447 (Fed. Cir. 1992). This has been questioned by academics and policy makers as imposing too high a standard for obviousness and thus allowing patents on sub par innovations. *See, e.g.*, Brief of Twenty-Four Intellectual Property Law Professors as Amici Curiae in Support of Petitioner, KSR Int'l Co. v. Teleflex, Inc., *petition for cert. filed* (U.S. May 12, 2005) (No. 04-1350), 2005 WL 1334163; Glynn S. Lunney, Jr., *E-Obviousness*, 7 MICH. TELECOMM. & TECH. L. REV. 363 (2000) (providing empirical evidence indicating a decrease in the Federal Circuit patent invalidations on grounds of obviousness and suggesting that the Federal Circuit test for obviousness is one of the causes); Press Release, The Progress and Freedom Found., High Court Must Address Patent Obviousness: Circuit Standard Flawed, PFF Fellows Argue in Brief (May 13, 2005), *available at* http://www.pff.org/news/news/2005/051305ksramicus.html. In addition, the U.S. Government also supports the request for certiorari. Brief for the United States as Amicus Curiae, KSR Int'l Co., *petition for cert. filed*, No. 04-1350 (U.S. May 25, 2006), 2006 WL 1455488.

42. Carlos M. Correa, *Patent Rights*, *in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 189, 198 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998); European Patent Office, *Guidelines for Examination in the European Patent Office*, Part C-IV, 2.3 (1994) (noting that if a substance found in nature is isolated, and the substance can

patent offices must compare an invention with the existing "prior art," which refers to what is previously known in the technical field of the invention. Because of differing national definitions of what constitutes prior art, the same invention may be granted or denied a patent in different countries.

2. Genetic Resources and Traditional Knowledge—Before discussing biopiracy patents, it is important to first understand the underlying resources that are alleged to have been "pirated." The relevant resources are typically from third world countries and consist of either genetic resources or traditional knowledge. The genetic resources often are plant-based and native to these biodiverse countries.[43] The traditional knowledge at issue is often traditional knowledge concerning natural resources, sometimes with a medicinal purpose. For example, traditional knowledge could involve the use of bark from a certain tree native to a third world country that cures certain wounds.

It is important to first clarify the scope of traditional knowledge to understand the objection to patents based upon such knowledge. Although there are a variety of definitions of traditional knowledge, at their core they all involve knowledge, innovation, and practices of indigenous and local communities that are transmitted orally between generations and are typically unique to a given geographic region.[44] In addition, unlike patents, which provide rights for a static invention, traditional knowledge is constantly evolving over generations and in response to a changing environment.[45] In particular, traditional knowledge is seen as part

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be characterized either by it structure, or the process by which it is obtained, it is 'new' and may be patentable).

43. Although there are some instances of human-based resources involved in biopiracy patents, such cases are not included within the scope of this paper because they raise different issues of informed consent, as well as ethical implications for research. However, additional information on that topic is available. *See, e.g.*, Annie O. Wu, Note, *Surpassing the Material: The Human Rights Implications of Informed Consent in Bioprospecting Cells Derived from Indigenous People Groups*, 78 WASH. U. L.Q. 979 (2000); Leonard H. Glantz et al., *Research in Developing Countries: Taking 'Benefit' Seriously*, HASTINGS CENTER REP., Nov.-Dec. 1998, at 38.

44. *See, e.g.*, WIPO, Intergovernmental Comm. on Intell. Prop. and Genetic Res., Traditional Knowledge and Folklore, *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore—An Overview*, Annex 3, at 3, 20–21, WIPO/GRTFK/IC/1/3 (Mar. 16, 2001) [hereinafter WIPO, *Matters Concerning Intellectual Property*] (noting that traditional knowledge does not seem to exist and that because of the "highly diverse and dynamic nature of traditional knowledge," it is difficult to develop a single and exclusive definition); Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT'L L. 233, 240–41 (2001) [hereinafter *TRIPS-RATK*] (noting different definitions).

45. *See, e.g.*, Council for Trade-Related Aspects of Intellectual Property Rights, Int'l Bureau of WIPO, *Intellectual Property and Genetic Resources—An Overview*, at 3, IP/C/W/218 (Oct. 18, 2000) ("[traditional knowledge] is being created every day, and it is evolving as a re-

and parcel of the holistic relationship that indigenous communities have with their environment. Such communities strongly value the development and preservation of their environment, including plant and agricultural resources.[46] The high value placed on environmental protection is often described as a result of a social and spiritual responsibility to respect all life forms based on the understanding that all parts of the natural world are infused with spirit.[47] For all the foregoing reasons, traditional communities typically foster discovery, development and preservation of the environment, as well as medical uses of plants through traditional knowledge. For example, traditional knowledge is considered responsible for helping communities develop diverse crops through knowledge and cultivation of their environment.[48]

In addition, unlike patents, which were created as a tool to promote innovation, traditional knowledge by definition coexists and evolves naturally within communities. Because the benefits of traditional knowledge inure to the entire community, it is not necessary to clearly identify an individual or group who should be "rewarded." This is an obvious contrast to Western patent rights.[49]

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sponse of individuals and communities to the challenges posed by their social and physical environment.").

46. As noted by Canadian anthropologist Martha Johnson, traditional knowledge is rooted in a social context that sees the world in terms of social and spiritual relations between all life forms and that all life forms are considered to be interdependent, with human life not superior to other elements. Martha Johnson, *Research on Traditional Environmental Knowledge: Its Development and Its Role*, *in* LORE: CAPTURING TRADITIONAL ENVIRONMENTAL KNOWLEDGE 3 (Martha Johnson ed., 1992).

47. *See, e.g.*, *id.*; Peter-Tobias Stoll & Anja von Hahn, *Indigenous Peoples, Indigenous Knowledge and Indigenous Resources in International Law*, *in* INDIGENOUS HERITAGE AND INTELLECTUAL PROPERTY: GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE 5, 15 (Silke von Lewinski ed., 2004) ("Indigenous peoples' profound relationship to land is not only based on the use of its natural resources, but is also a prerequisite for the spiritual and religious well-being of the group, and thus is central not only to their physical but also their cultural survival."). In addition, some have suggested that indigenous people regard their environment to be indistinguishable from their cultural heritage. *See, e.g.*, Russel Lawrence Barsh, *How do You Patent a Landscape? The Perils of Dichotomizing Cultural and Intellectual Property*, 8 INT'L J. CULT. PROP. 14 (1999).

48. *See, e.g.*, WIPO, *Matters Concerning Intellectual Property*, *supra* note 44, Annex 3 at 4; Dutfield, *TRIPS-RATK*, *supra* note 44, at 243 (noting that traditional knowledge and communities are "responsible for the discovery, development, and preservation of a tremendous range of medicinal plants, health-giving herbal formulations, and agricultural and forest products").

49. *See, e.g.*, Stoll & von Han, *supra* note 47, at 16 (noting that traditional knowledge is "generally not owned or monopolized by individual members of the indigenous group, but is a collective right that extends to the community as a whole"). Identifying a single source may be difficult since traditional knowledge by definition evolves over time and may be difficult to trace. *See, e.g.*, Johnson, *supra* note 46, at 3–4.

Entire communities often jointly share traditional knowledge.[50] There is often an important collective responsibility deriving either from a belief that traditional knowledge comes from an otherworldly source,[51] or a more general sense that each individual's "rights" are inextricably linked to collective responsibility in a manner distinct from Western property norms.[52] Moreover, because traditional knowledge is valued as part of community and spiritual norms, there is a naturally self-sustaining incentive to protect, promote, and continue to improve such knowledge. In addition, and perhaps most important, some indigenous groups would consider it improper to attribute authorship to an individual or even a group of people because of the close tie between traditional knowledge and prior ancestry.[53]

3. Biopiracy Patents?—Biopiracy allegations arise from patents that are based on, or in fact are identical to, genetic resources. Patents should not be permissible for genetic resources since by definition, patents do not cover naturally occurring material.[54] However, there is greater controversy concerning patents for materials derived from genetic resources through chemical isolation or genetic engineering processes. For example, although the neem tree, indigenous to India and considered sacred by Indian citizens, cannot be patented, there can be valid patents based upon the tree. They adequately satisfy the "new" requirement because they have qualities that do not exist in nature. For example, one patent

50. *See, e.g.*, Matthias Leistner, *Analysis of Different Areas of Indigenous Resources: Traditional Knowledge, in* INDIGENOUS HERITAGE AND INTELLECTUAL PROPERTY: GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE, *supra* note 47, at 49, 57. There is no single model of ownership of traditional knowledge—ownership may be determined based upon the predominant contribution of individual or collective contributions. In addition, shamans are sometimes considered individual creators, although their role as creator is often inextricably linked to their social function of the community, such that the word "owner" in a Western context is not entirely applicable. *See, e.g.*, WIPO, *Intellectual Property Needs and Expectations of Traditional Knowledge Holders*, WIPO Publication No. 768E (Apr. 2001); UNCTAD & ICTSD, *Protecting Traditional Knowledge Folklore*, *supra* note 5, at 15 (noting that over 10,000 individual inventions are documented by the India-based Honeybee Network).

51. *See, e.g.*, Michael Blakeney, *The Protection of Traditional Knowledge under Intellectual Property Law*, 22 EUR. INTELL. PROP. REV. 251, 252 (2000) (noting that traditional folklore may be attributed to the creator spirit). Similarly, traditional knowledge has been stated to reflect more than the efforts of either individual or collective efforts; rather, it has been described as "inextricably interwoven with historical, ethical and religious aspects that touch at the very identity of the respective indigenous group or local community." Leistner, *supra* note 50, at 56–57.

52. *See, e.g.*, Russel Lawrence Barsh, *Indigenous Peoples and the Idea of Individual Human Rights*, 10(2) NATIVE STUD. REV. 35 (1995).

53. *See* UNCTAD & ICTSD, *Protecting Traditional Knowledge and Folklore*, *supra* note 5, at 15.

54. *See supra* text accompanying notes 40–41.

that covers special storage properties the natural neem tree does not have is "new" under the patent law—because it contains features that do not exist in its natural state.[55]

Biopiracy allegations also arise from patents based upon, or identical to, traditional knowledge, such that it appears that the "new" requirement has been violated. For example, a patent was issued to two University scientists for a method of healing wounds using turmeric, an active ingredient based upon neem seed is distinct from the naturally occurring neem seed because it had a longer shelf life and stability compared to the natural seed,[56] even though the patent itself disclosed no information beyond the traditional knowledge that was known for centuries in India.[57] Patent proponents argue that this case proves the patent system works because it eventually corrected the error by canceling all the claims of the patent.[58] However, this only happened after a legal challenge by the Indian government that involved locating and translating thirty-two references from Sanskrit, Urdu, and Hindi to establish that the "invention" in the patent was not truly new.[59]

The turmeric example is also useful in highlighting an anomalous definition of what constitutes "new" under United States patent law. In particular, knowledge outside the United States is not considered relevant to determining patentability, unless documented in writing.[60] To the extent that a great deal of traditional

55. U.S. Patent No. 5,124,349 (filed Oct. 31, 1990).

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

57. In fact, the patent noted that "turmeric has long been used in India as a traditional medicine for the treatment of various sprains and inflammatory conditions." *Id.* at col.1 l.36–39. Nonetheless, the patent claimed to be a "[m]ethod of promoting healing [sic] of a wound by administering turmeric to a patient afflicted with the wound." *Id.* at [57].

58. *See, e.g.*, Communication from the United States, *Review of the Provisions of Article 27.3(b) Further Views of the United States*, ¶ 4, IP/C/W/209 (Oct. 3, 2000) (noting that in the turmeric case, the patent system "worked as it should" since the patent was eventually cancelled once relevant prior art was brought to the attention of the patent office).

59. The patent was cancelled during reexamination proceedings after the Indian Council of Scientific and Industrial Research (CSIR) formally requested a reexamination and submitted documentation to support its claims that what was disclosed in the patent was known in India. COMMISSION ON IPRS, *supra* note 15, at 76. After receiving this information, the USPTO decided that all the claims of the patent were invalid as anticipated and obvious. *Id.* This case is notable as the first time a United States patent was successfully challenged (i.e., revoked) on the basis of a challenge by a developing country asserting that the patent was based upon traditional knowledge.

60. 35 U.S.C. § 102(a) (2000). Some have criticized this rule as anachronistic in the global economy and even unconstitutional. Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitations on Prior Art in a Small World*, 87 MINN. L. REV. 679 (2003); Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy*, 37 IDEA 371 (1997). In addition, proposed legislation to amend the patent laws would potentially minimize this rule by including disclosures that are known through sources other than through printed publication and without geographical restriction. H.R. 2795, 109th Cong. (2005).

knowledge is oral in nature, the United States' rule may automatically exclude consideration of information that would show the invention is not truly "new" when considered in the entire global context. Accordingly, the turmeric patent would have been considered valid under United States' laws if no documentation had been found.

For patents that are based upon, but not identical to, either genetic resources or traditional knowledge, the issues are less clearly resolved under present patent law. Sometimes the problem is a misunderstanding of the scope of patent rights, or what the "new" and "nonobvious" standards require. In particular, sometimes indigenous communities or advocates on their behalf have argued that patents based upon traditional knowledge do not provide anything new, yet they do so without considering how "new" is defined under the relevant laws.

B. International Development of Biopiracy

The coinage of the term biopiracy coincides with a number of international developments, as well as protests against specific patents that were alleged to constitute biopiracy. The Rural Advancement Foundation (RAFI, now ETC Group), an environmental advocacy group[61] defines biopiracy as "the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions who seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge."[62] Technically, genetic resources cannot be patented as such; rather, only genetic resources that are *derived* from the natural products can be protected. Nonetheless, the definition of biopiracy resonated with an existing mistrust of big business and globalization.[63] A variety of definitions of biopiracy

61. The group has been referred to as Erosion, Technology and Concentration (ETC), as well as Rural Advancement Foundation International (RAFI). *See infra* note 125.

62. Keyword Definitions-ETC Group, http://www.etcgroup.org/key_defs.asp (on file with the University of Michigan Journal of Law Reform).

63. *See, e.g.*, Charles R. McMannis, *Fitting Traditional Knowledge Protection and Biopiracy Claims into the Existing Intellectual Property and Unfair Competition Framework, in* INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES 425, 427 (Burton Ong ed., 2004) (noting that mounting protests over biopiracy and globalization more generally represent a "visceral populist reaction" to seeming devaluation of biocultural contributions). Indeed, Vandana Shiva, an Indian activist, has authored several books and articles focused on the theme of biopiracy and Western misappropriation of resources. *See, e.g.*, VANDANA SHIVA ET AL., CORPORATE HIJACK OF BIODIVERSITY: HOW WTO-TRIPS RULES PROMOTE CORPORATE HIJACK OF PEOPLE'S BIODIVERSITY AND KNOWLEDGE (2002) [hereinafter SHIVA, CORPORATE HIJACK OF

have emerged, including: unauthorized use of biological material that results in a patent, unauthorized use of traditional knowledge concerning biological resources, and lack of benefit-sharing with those who provided resources.[64] Some groups consider patents based upon biological resources to constitute biopiracy either when the patent fails to meet present patent criteria, or because the patent criteria are considered unfair. The coinage of the term biopiracy also coincided with public protests against U.S. patents that appeared to fit this definition of biopiracy. For example, the existence of a patent relating to the Ayahuasca Vine was first uncovered in 1994 by an organization representing indigenous groups.[65] Similarly, although patents granted on variants of the neem tree were issued in the early nineties,[66] public outcries and subsequent legal challenges concerning improper misappropriation of what is considered a sacred tree in India did not begin until 1995.[67] The previously noted turmeric patent was similarly

BIODIVERSITY]; VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE (1997) [hereinafter SHIVA, BIOPIRACY: THE PLUNDER OF NATURE]; VANDANA SHIVA, MONOCULTURES OF THE MIND (1993).

64. *See* Dutfield, *supra* note 14, at 1 (noting that biopiracy refers to the "uncompensated commercial use of biological resources or associated traditional knowledge from developing countries, as well as the patenting by corporations of claimed inventions based on such resources or knowledge"); ETC Group, *From Global Enclosure to Self Enclosure: Ten Years After – A Critique of the CBD and the "Bonn Guidelines" on Access and Benefit Sharing (ABS)*, COMMUNIQUE, Jan.-Feb. 2004, at 2, http://www.etcgroup.org/article.asp?newsid=432 (stating biopiracy "refers to the privatization of genetic resources . . . from those people who hold, maintain, embody, develop, breed, or otherwise create, foster or nurture those resources," and that emphatically that "all bioprospecting unavoidably falls into the category of biopiracy").

65. *See, e.g.*, AmazonLink.org, The Ayahuasca Case: Vine of the Soul, www.amazonlink.org/biopiracy/ayahuasca.htm (on file with the University of Michigan Journal of Law Reform) (noting that the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) first learned of this patent in 1994 and subsequently instigated action to have the patent reexamined). A request for reexamination of this patent was filed in 1999, and the PTO cancelled all the claims of the patent during the same year. *See, e.g.*, Glen M. Wiser, Center for International Environmental Law, *PTO Rejection of the "Ayahuasca" Patent Claim: Background and Analysis* (Nov. 1999), http://www.ciel.org/Biodiversity/ptorejection.html. However, the PTO has since reversed its position as of 2001. Howard J. Locker, United States Dep't of Commerce Patent & Trademark Office, Notice of Intent to Issue Reexamination Certificate: Statement of Reasons for Patentability and/or Confirmation (Jan. 26, 2001), *available at* http://www.ciel.org/Publications/PTO_Examiner_Transcript.pdf.

66. *See, e.g.*, U.S. Patent No. 4,946,681 (filed June 26, 1989); U.S. Patent No. 5,124,349 (filed Oct. 31, 1990).

67. *See, e.g.*, Ulrike Hellerer & K.S. Jarayaman, *Greens Persuade Europe to Revoke Patent on Neem Tree*, 405 NATURE 266, 266 (2000) (noting that protests against the neem patents began in 1993 with legal opposition in 1995). The EPO canceled the neem patent in 2002, but because of differing patent standards, it remained valid in the U.S.. *See, e.g.*, Chakravarthi Raghaven, *Neem Patent Revoked by European Patent Office*, THIRD WORLD NETWORK, May 11, 2000, http://www.twnside.org.sg/title/revoked.htm (on file with the University of Michigan Journal of Law Reform); Press Release, European Patent Office, *supra* note 20.

challenged in the mid-nineties.[68] Other patents that have been embroiled in biopiracy allegations since then include a patent on Quinoa,[69] as well as the "Basmati Rice Patent,"[70] and more recently, the Enola Bean patent[71] and the so-called natural Viagra or Maca patent.[72] These examples are mentioned as illustrative of the biopiracy patent disputes, as well as the timing of these protests. This Article does not attempt to retread the voluminous history on such examples.[73] Rather, these specific patents are noted here because the timing of their protests coincide with important international agreements that are central to this Article.

Discussion of biopiracy patents are associated not only with these controversial cases, but also in conjunction with the signing of the 1992 CBD agreement, as well as the 1994 TRIPS agreement. The CBD provides an international framework for discussing protection of genetic resources and traditional knowledge, while the TRIPS agreement provides an international framework for what must be patented, without any mention of compliance with the CBD. One CBD objective is the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources . . . ."[74] CBD has a related goal of sharing benefits that arise from traditional knowledge, to the extent that such knowledge promotes the CBD goals of "conservation and sustainable use of biological diversity . . . ."[75] The TRIPS agreement, on the other hand, mandates

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

69. U.S. Patent No. 5,304,718 (filed Feb. 3, 1992).

70. U.S. Patent No. 5,663,484 (filed July 8, 1994).

71. U.S. Patent No. 5,894,079 (filed Nov. 15, 1996).

72. U.S. Patent No. 6,093,421 (filed Aug. 31, 1999); U.S. Patent No. 6,267,995 (filed Mar. 3, 1999); U.S. Patent No. 6,878,141 (filed June 28, 2000). The ETC reported protests of Maca patents in July 2002. *See* ETC Group, *Peruvian Farmers and Indigenous People Denounce Maca Patents*, GENOTYPE, July 3, 2002, http://www.etcgroup.org/documents/macafinal1.pdf. Also, a patent challenge was at least contemplated once pro-bono representation was secured. Alicia Upano, *D.C. Team Gets to the Root of the Problem*, LEGAL TIMES, Jan. 12, 2004, at 13.

73. However, for readers interested in greater discussion of the details of these biopiracy patents, *see* Leanne M. Fecteau, *The Ayahuasca Patent Revocation: Raising Questions about Current U.S. Patent Policy*, 21 B.C. THIRD WORLD L.J. 69 (2001) (providing details of the Vine patent controversy); Muriel Lightbourne, *Of Rice and Men: An Attempt to Assess the Basmati Affair*, 6 J. WORLD INTELL. PROP. 875 (2003) (providing a detailed discussion of the Basmati patent controversy); Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279 (1999) (providing a good discussion of commodification of life issues associated with neem tree patents); McMannis, *supra* note 63 (providing a good overview of controversial cases involving biopiracy, and analyzing which are not "true" problems according to Western patent law). *See also* Brendan I. Koerner, *Viagra Natural*, LEGAL AFFAIRS, Nov.-Dec. 2005, at 48 (describing the controversy surrounding the maca patent in Peru that has prompted greater Peruvian interest in countering biopiracy).

74. CBD, *supra* note 6, at art. 1.

75. *Id.* at art. 8(j).

that member states provide "minimum" standards of intellectual property protection, including patent rights, without any mention of whether such rights need be contingent on compliance with the CBD.[76]

The signing of these international agreements in conjunction with the issuance of controversial patents like those mentioned above has led to substantial discussion of whether CBD and TRIPS conflict, and whether patent laws—particularly under TRIPS—should be amended to address biopiracy. The issue was first discussed at a meeting of the Conference of Parties to the CBD—the highest decision-making body within the CBD.[77] Developing countries, beginning with Columbia in 1999,[78] have repeatedly proposed specific amendments to international patent law to mandate or at least suggest a linkage between patent validity and compliance with CBD norms.[79] Columbia's initial proposal generated immediate discussion, such that a new working group was formed under WIPO to further study of this issue.[80] Similarly, as a result of many

76. *See* TRIPS, Marrakesh Agreement, *supra* note 2, at art. 1.

77. *See, e.g.*, Conference of the Parties to the Convention on Biological Diversity and the Agreement on TRIPS, Third Meeting: Item 14 of the Provisional Agenda, Buenos Aires, Arg., Nov. 4–15, 1996, *Relationships and Synergies*, UNEP/CBD/COP/3/23 (Oct. 5, 1996). In addition, nongovernmental organizations also supported this issue. *See, e.g.*, Center for Int'l Envtl. Law, *Comments on Improving Identification of Prior Art: Recommendations on Traditional Knowledge Relating to Biological Diversity Submitted to the United States Patent and Trademark Office*, Aug. 2, 1999, http://www.ciel.org/Publications/IdentificationofPriorArt.pdf.

78. Columbia submitted a surprise proposal to condition patent grants on compliance with norms consonant with the CBD during a WIPO session concerning a draft patent law treaty that had until that point had been focused entirely on unifying procedural aspects of national patent laws. WIPO, Standing Committee on the Law of Patents, Third Session, Geneva, Switz., Sept 6–14, 1999, *Protection of Biological and Genetic Resources: Proposal by the Delegation of Columbia*, SCP/3/10 (Sept. 8, 1999) (suggesting that industrial property protection, such as patents, should "guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents . . . that relate to elements of that heritage shall be subject to their having been acquired legally"); UNCTAD & ICTSD, *Protecting Traditional Knowledge and Folklore*, *supra* note 5, at 4 ("The PLT was intended to harmonise certain patent procedures while steering clear of matters relating to substantive patent law.").

79. India suggested that patents based upon or essentially derived from traditional knowledge be excluded, or, that there at least be a mandatory disclosure of origin of biological resources, together with evidence of prior informed consent. Council for TRIPS, *Review of the Provisions of Article 27.3(b), Communication from India*, IP/C/W/161 (Nov. 3, 1999); General Council, *The Challenge of Integrating LDCs into the Multilateral Trading System: Coordinating Workship for Senior Advisors to Ministers of Trade in LDCs in Preparation for Third WTO Ministerial Conference, Communication from Bangladesh*, WT/GC/W/251 (July 13, 1999) (proposing that Article 27(3) be amended to state that patents must not be granted without prior consent of the country of origin and that patents "inconsistent" with Article 15 of the CBD should not be granted).

80. WIPO created a new Intergovernmental Committee in April 2000 to provide a platform for continued discussions of IP with respect to access of genetic resources, and benefit sharing for any commercial benefits arising from use of such resources. WIPO Gen.

proposals by developing countries that TRIPS needed to be amended to resolve an inherent conflict between it and the CBD,[81] the Doha Ministerial Declaration included an explicit directive that the TRIPS Council examine the relationship between TRIPS and CBD, including the protection of traditional knowledge.[82]

The United Nations and the World Health Organization (WHO) have also considered the biopiracy issue from a human rights perspective. For example, in August, 2000, the UN Subcommission on Human Rights issued a resolution that referred to an actual or potential conflict between intellectual property rights and human rights based in part on patents on the genetic material that leads to biopiracy; accordingly, the UN requested that the WTO take international human rights into account during its ongoing review of TRIPS.[83] Similarly, the WHO recommended traditional medical knowledge be protected from biopiracy, and that governments consider patent systems that not only protect traditional medicine from biopiracy, but also promote equitable benefit sharing.[84] In addition, the UN and WHO stated that human rights—including

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Assemb., Sept. 25–Oct. 3, 2000, *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, ¶ 13–14, WO/GA/26/6 (Aug. 25, 2000) (charging the committee with considering potential positive and negative roles of IPR with respect to genetic resources, as well as protection of folklore).

81. General Council, *Preparations for the 1999 Ministerial Conference: Implementation Issues to be Addressed before/at Seattle, Communication from Cuba, Dom. Rep., Egypt, El Sal., Hond., India, Indon., Malay., Nig., Pak., Sri Lanka, and Uganda*, WT/GC/354 (Oct. 11, 1999); General Council, *Preparations for the 1999 Ministerial Conference: Implementation Issues to be Addressed in the First Year of Negotations, Communication from Cuba, Dom. Rep., Egypt, El Sal., Hond., India, Indon., Malay., Nig., Pak., Sri Lanka and Uganda*, WT/GC/W/355 (Oct. 11, 1999); *see also* Council for TRIPS, *The Agreement Under Article 71.1: Proposal on Protection of the Intellectual Property Rights of the Traditional Knowledge of Local and Indigenous Communities, Communication from Cuba, Hond., Para., and Venez.*, IP/C/W/166 (Nov. 5, 1999) (requesting that negotiations "establish multilateral rules to accord effective moral and economic intellectual property rights to traditional knowledge, medicinal practices and expressions of folklore and take into account the social and collective nature of these rights" and suggesting the rules be incorporated into TRIPS by 2004, but failing to provide specific details to accomplish such a goal); Council for TRIPS, *Review of the Provisions of Article 27.3(b), Communication from India*, IP/C/W/161 (Nov. 3, 1999) (suggesting a more expansive amendment of Article 27(3)(b) to exclude all life forms from patentability).

82. World Trade Organization [WTO], Ministerial Declaration of 14 November 2001, ¶ 19, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Ministerial Declaration]. In addition, the declaration noted that the TRIPS Council should also examine any related developments. *Id.*

83. U.N. High Commissioner for Human Rights, Intell. Prop. and Human Rights: Sub-Comm'n on Human Rights Res., ¶ 8, 2000/7, E/CN.4/SUB.2/RES/2000/7 (Aug. 17, 2000); *see also* David Weissbrodt & Kell Schoff, *Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/07*, 5 MINN. INTELL. PROP. REV. 1, 3–26, 41–46 (2003) (providing historical context of the U.N. resolution).

84. WHO Traditional Medicine Workshop, Bangkok, Thailand, Dec. 6–8, 2000, Report of the Inter-regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, WHO/EDM/TRM/2001.1 (2000).

protection of the right to health and protection against biopiracy—should be given serious consideration in the implementation of TRIPS.[85]

Although international dialogues in established foras concerning patents based upon genetic resources and traditional knowledge have substantially increased since the initial allegations of biopiracy, there is little tangible progress towards resolution. Although developing countries have actively promoted discussions at the WTO and WIPO in recent years, their proposals to amend TRIPS and other international patent agreements have been largely forestalled for lack of agreement. In some instances, substantive discussion is curtailed on the grounds that another forum would be a more appropriate venue to address the issue. In addition, although the Conference of the Parties of the CBD has actively addressed biopiracy issues, the CBD only offers weak proscriptions because it is effectively powerless to effectuate proposed changes to patent laws.[86] In light of the seeming futility of these substantial efforts, the next section takes a closer look at the underlying tension between patent rights and traditional knowledge to help understand and move past the present stalemate in international discussions.

II. COMPLEXITIES OF COMMUNAL, NATIONAL AND INTERNATIONAL PERSPECTIVES ON BIOPIRACY

A. National and Communal Perspectives

This section analyzes the underlying reasons why biopiracy claims thus far have not achieved universal legitimacy. First, there is a major culture clash with respect to what—if anything—should be patentable, as well as disagreements concerning the proper scope of patent protection in lieu of other social policies. Second, the disagreements are exacerbated by misconceptions about the scope of patent rights. Moreover, allegations that biopiracy constitutes the newest form of Western imperialism may impede conciliation because the claim results in defensiveness.

1. Complex Conflicts

a. Can Patents Coexist with Protection of Traditional Knowledge?—A predominant Western view of patents based upon traditional

85. *See infra* Part II.B.1.
86. *See infra* Part II.B.

knowledge is that there is no conflict or cause for concern. First, to the extent that patents are based upon, rather than identical to, traditional knowledge, the patent is seen as providing a greater social good by creating commercial value from underutilized resources.[87] Second, patents are not seen as derogatory to traditional cultures since the patent does not prevent use of the original traditional knowledge and is not intended to be a statement about the value of such original knowledge.

Although the Western perspective adequately reflects the instrumentalist perspective of patents, it does so in a vacuum, divorced from the implications of such patents on the communities that provided the original traditional knowledge. Because traditional knowledge is part of a society's social fabric and is potentially sacred, the patent represents an improper incentive to commodify what traditional cultures have for years preserved and revered. In addition, some believe that patents based upon traditional knowledge may have a deleterious effect on the environment because while traditional knowledge aims to enhance the existing environment, the Western patent system does not.

An essential problem lies with the broader socio-cultural context in which patent rights versus traditional knowledge exists. Traditional knowledge exists and is perpetuated for the greater good of the community without any need to provide monetary reward or other compensation.[88] In contrast, patent rights function in a market context in which a patent provides its owner with a commercial advantage in the marketplace. A conflict arises because the "owners" of traditional knowledge may not want any part of a market economy. In particular, they may not be interested in trading in their traditional knowledge for a financial reward. As noted above, the creation and perpetuation of traditional knowledge has inherent value in a community-based economy that emphasizes sharing—without monetary rewards.[89] Rather, a society may place a high cultural importance on protecting the knowledge from those who cannot be trusted to appropriately protect its use. An excel-

87. *See, e.g.*, GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY 61–62 (2000) (describing the pro-patent position that local communities should not feel exploited because traditional knowledge alone would not be patentable and a patent does not technically prevent continued use of resources in their natural state); Craig Allen Nard, *In Defense of Geographic Disparity*, 88 MINN. L. REV. 222, 225 (2003) (suggesting that a patent based upon traditional knowledge could lead to significant profits if exploited in a rich market such as the United States).

88. *See supra* Part I.A.2.

89. *See* Stephen Gudeman, *Sketches, Qualms, and Other Thoughts on Intellectual Property Rights*, *in* VALUING LOCAL KNOWLEDGE: INDIGENOUS PEOPLE AND INTELLECTUAL PROPERTY RIGHTS 102, 103 (Stephen B. Brusch & Doreen Stabinsky eds., 1996).

lent example of a potential clash is presented by Professor Ghosh who hypothesizes that if a traditional knowledge holder has the cure for cancer, but does not wish for such knowledge to be marketed (through the use of a patent) because the knowledge should be used only for ritualistic purposes, there is a question of who should dictate use of the knowledge.[90] In other words, should the utilitarian premise of patent rights govern? This is especially a problem because of the cross-cultural issue: if Western countries elect to pursue a completely utilitarian regime of promoting innovation, should Western countries be allowed to impose this regime on other cultures who not only do not subscribe to this regime, but do not subscribe to the market economy in which this regime works?

Although some patent regimes may permit consideration of socio-cultural concerns in excluding some subject matter from patentability, the patent laws fail to address the particular cultural concerns inherent in the clash between traditional knowledge and patents. For example, some domestic patent laws provide that an invention may be excluded from patentability if it would be abhorrent to public morality.[91] However, the focus of such an inquiry is only on the society providing the patent—there is no place under present patent laws to consider the cultural offensiveness of subject matter to those outside the nation granting the patent, even if they are likely to be impacted. For example, in the United States, the potential morality of an invention is not a factor in the patentability calculus.[92] The lack of consideration of morality has been justified on the grounds that a patent is not an absolute license to use an invention; moral implications are arguably better left to

90. Shubha Ghosh, *Reflections on the Traditional Knowledge Debate*, 11 CARDOZO J. INT'L & COMP. L. 497, 508–09 (2003). Professor Ghosh further suggests that the problem is the inverse of the situation with access to AIDS medicine. In the public health context a company is reluctant to sell a patented drug for lower profit whereas, in the context of biopiracy and traditional knowledge, communities may not be willing to part with the knowledge for any price if market mechanisms and dissemination are perceived anathema to their culture. *Id.*

91. TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27(2); EPC, *supra* note 38, at art. 53(a).

92. *See, e.g.*, 35 U.S.C. §§ 101–03 (2000) (providing no provision for morality as a basis for denying patentability); Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366–67 (Fed. Cir. 1999); *Ex parte* Murphy, 200 U.S.P.Q. (BNA) 801, 802 (Bd. App. 1977). In addition, although Canada does not have any statutory authority for considering morality, it has recently denied a patent to a genetically engineered mouse purportedly on grounds of strict statutory construction, but for an invention that has raised morality concerns among patent offices worldwide. *See* Patent Act, R.S.C., ch. P 4 sec. 2 (1993) (Can.); Harvard Coll. v. Canada (Commissioner of Patents), File 28155, 2002 S.C.C. 76, paras. 152–58 (May 21, 2002), *available at* http://www.lexum.umontreal.ca/csc-scc/en/pub/2002/vol4/html/2002scr4_0045.html; *infra* note 415 (noting controversy surrounding same invention in Europe, where the laws expressly permit morality to be considered).

examination by agencies with greater expertise in regulating cultural norms.[93] However, this justification fails to consider the multicultural context of patents based on traditional knowledge. Regulatory agencies are only responsible for controlling behavior within their national borders. There is no corollary agency to regulate international behavior. The most analogous "institution" to an international regulatory body would be a creation of international agreements that provide for such regulation. In fact, the CBD may at first blush seem to be such an agreement since its objectives include not only the promotion of biodiversity, but also traditional knowledge.[94] However, as further explained later, the CBD has no effective enforcement abilities, such that it cannot actually function as an international regulatory agency.[95]

b. Conflict Created or Averted Through Compensation?—There is a Western world view that patents based upon traditional knowledge are in fact beneficial to the countries and communities that currently protest such patents. Based on the assumption that a patent provides an incentive to commercialize, some suggest that patents granted on traditional knowledge may yield monetary benefits for countries that are in undisputed need of greater economic re-

93. *See, e.g.*, Greenpeace U.K. v. Plant Genetic Systems N.V. (Opposition Div. EPO 1992), *reported in* 25 INT'L REV. INDUS. PROP. & COPYRIGHT L. 618, 620 (1993) (noting that "a patent does not confer a positive right to use an invention; exploitation of the patent is always subject to regulation by governmental agencies where appropriate," such that a patent should not be denied purely based on potential problems with commercial use); Case T-356/93-3.3.4, Plant Genetic Systems N.V. v. Greenpeace Ltd., 8 O.J. E.P.O. 557, 568–70 (Technical B. App. 1995) (noting that regulatory authorities are better equipped to assess potential hazards of exploiting technology and the grant of a patent alone is not cause for concern since a patent does not provide a license to exploit an invention); Transgenic Plant/Novartis II, 2000 O.J. E.P.O. 111, para. 3.9 (EPO Enlarged B. App. 1999) (noting that the patent office is not vested with considering economic impacts of a patent grant, such that they should not be relevant to determining the scope of patentability); *see also* Margaret Llewelyn, *The Legal Protection of Biotechnological Inventions: An Alternative Approach*, 19 EUR. INTELL. PROP. REP. 115, 122–23 (1997) (suggesting that morality in patent law is difficult to define such that it can be easily applied and suggesting that it might be more appropriate for morality to be considered by regulatory bodies "which would arguably be better for a for objectively deciding and enforcing concepts of morality"); Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1067–68 (1988) (arguing that "[t]he patent system normally is not the proper place to conduct technology assessment" since its purpose is the "simpler" goal of promoting science, such that potential social consequences should be dealt with in the regulatory context, rather than in patent law). Similarly, it is has been repeatedly noted that problems with commercial exploitation should not be decided by patent offices because such information would typically be unavailable during the course of patent examination due to the typical filing of applications long before commercial application. *Plant Genetic Systems, supra*, at 561, 624.

94. CBD, *supra* note 6, at art. 1.

95. *See infra* notes 206–208 and accompanying text.

sources.[96] This argument has been made despite the fact that patent owners often do not acknowledge use of traditional knowledge, let alone voluntarily provide compensation to originating communities.[97] An important note is that communities providing knowledge or information are not considered inventors of the patent, and thus would ordinarily have no legal entitlement to any profits resulting from a patent—even if they provided assistance in the broader search that led to the patented invention. Oftentimes, compensation is only negotiated after negative publicity. Moreover, some criticize the compensation arrangements as inadequate because royalty structures tend to provide only a miniscule percentage of profits which, of course, hinge on commercial success.[98]

Ultimately, monetary compensation is a Western solution that fails to acknowledge that traditional knowledge often transcends monetary value due to its sacred status. To many groups, sharing commercial proceeds is morally offensive because it necessitates acceptance of the very activity—patenting of sacred information—which they protest as improper.[99]

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96. *See, e.g.*, Nard, *supra* note 87, at 231 (noting that at least for pharmaceutical products developed based upon traditional knowledge, "the patenting and commercial exploitation . . . can bring much needed capital to these countries and their indigenous populations"). Similarly, some see the idea of protecting traditional knowledge as contrary to patent principles. *See, e.g.*, Ghosh, *supra* note 90, at 499 ("For those who see the issue through the lens of United States law, protecting neem or turmeric . . . seems to stray from the Constitutional mandate that intellectual property law should serve 'to promote the progress of science and the useful arts.' But, of course, this directive is largely isolated to the United States.").

97. *See, e.g.*, The Gaia Foundation, Genetic Resources Action International, *Biodiversity for Sale: Dismantling the Hype About Benefit Sharing*, GLOBAL TRADE AND BIODIVERSITY IN CONFLICT, Apr. 2000 [hereinafter *Biodiversity for Sale*].

98. *See id.* at 3 (referencing an example of a partnership agreement between Washington University, Monsanto, and the United States government to provide a twenty-five percent royalty which was understood by the Aguarana to mean twenty-five percent of the profits, but instead meant twenty-five percent of Washington University's one percent of Monsanto's Royalty, i.e. 0.25%). Some have advocated the sharing of the eventual commercial proceeds, or that patent rights are jointly owned, even if current law only provides rights to those who invent the *claimed* invention, and not to those who assisted in the broader search that led to the claimed invention. Indeed, some have suggested that the present definition of patent inventorship should be expanded to enable traditional communities to be included as inventors. *See, e.g.*, Michael J. Huft, *Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights*, 89 NW. U. L. REV. 1678 (1995). In addition, the same issue has arisen in the context of patents derived in part from genetic resources of Western patients. *See, e.g.*, Cynthia M. Ho, *Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship of Patent-Based Discoveries*, 2 HOUS. J. HEALTH L. & POL. 107, 132–50 (2002).

99. *See infra* note 109. The objection of traditional groups is akin to a moral right in their material, but in a very different sense than the narrowly defined moral rights that are linked to copyrighted subject matter. Drahos P., *Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Biocollecting Society the Answer?*, EUR. INTELL. PROP. REV. 2000, 22(6), 245–50. There has been a suggestion that an expanded definition of moral rights for patent law

Providing monetary compensation for something that previously was culturally shared creates additional complications. Some commentators have suggested that money deteriorates the structure of societies that traditionally protect indigenous culture.[100] In addition, to the extent that a genetic resource or traditional knowledge is located or known in multiple communities, there may be a 'race to the bottom' that enables Western companies to pay the lowest going rate among multiple communities that are willing to set aside cultural opposition for present profits.[101] This not only provides less economic value to communities, but also has been cited as contributing to animosity and reduced sharing of resources amongst communities.[102] In addition, even within a single community, there may be internal community strife since those that negotiate the benefit agreement need to reconcile such benefits with a community's fundamental opposition to any benefit-sharing.[103]

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could be helpful to traditional groups. *See, e.g.*, David R. Downes, *How Intellectual Property Could be a Tool to Protect Traditional Knowledge*, 25 COLUM. J. ENVTL. L. 253, 276 (2000) (noting that although moral rights have "received surprisingly little attention to date" in the context of protecting traditional knowledge, these rights are designed to protect non-market values, albeit in the context of copyrights, rather than in the context of patents); Ghosh, *supra* note 90, at n.10 (2003) (noting that moral rights, although typically used to refer to the rights of authors, could be considered to protect rights of all creators in that it "captures a recurrent problem of how much ownership and control any creator of intellectual property is allowed to have"). However, moral rights are not even universally accepted among Western countries. *See, e.g.*, TRIPS, Marrakesh Agreement, *supra* note 2, at art. 9(1); DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 124–26 (2d ed. 2003) (providing the history of the negotiations which resulted in the exclusion of moral rights from TRIPS). Given the tenuous reception of moral rights among Western countries, further expansion seems unlikely.

100. Thomas Greaves, *Tribal Rights*, *in* VALUING LOCAL KNOWLEDGE: INDIGENOUS PEOPLE AND INTELLECTUAL PROPERTY RIGHTS, *supra* note 89, at 29.

101. *See, e.g.*, *Biodiversity for Sale*, *supra* note 97, at 4 (noting that because there is potentially a large group of communities that have the same genetic resources or knowledge, benefit-sharing agreements could result in a "race to the bottom" that provides the bioprospector with the lowest price, but also excludes most of those with the same resource) (internal quotation marks omitted).

102. *See, e.g.*, Corinna Heineke & Franziska Wolff, *Access to Genetic Resources and the Sharing of Benefits: Private Rights or Shared Use for Biodiversity Conservation?*, 2 ENVTL. L. NETWORK INT'L. 26, 28 (2004) (noting that communities may become rivals because of commercial potential and therefore fail to freely exchange seeds, contrary to tradition, which would have long term negative impacts on food security); Shane Greene, *Indigenous People Incorporated? Culture as Politics, Culture as Property in Pharmaceutical Bioprospecting*, 45 CURRENT ANTHRO. 211 (2004) (noting that in Peru, an agreement led to conflicts between organizations representing different communities, as well as at the national level); Shane P. Mulligan, *For Whose Benefit? Limits to Sharing in the Bioprospecting 'Regime'*, 8 ENVTL. POLITICS 35 (1999).

103. *See, e.g.*, Mulligan, *supra* note 102, at 35 (noting that a benefit-sharing deal "contributed to animosities within an already divided tribe with regard to how to share benefits with those who oppose benefit-sharing" in the case of the Kani tribe of Kerala); B. Tobin, *Biodiversity Prospecting Contracts: The Search for Equitable Agreements*, *in* BIODIVERSITY AND TRADITIONAL KNOWLEDGE: EQUITABLE PARTNERSHIPS IN PRACTICE 287 (Sarah A. Laird ed.,

c. Communities v. Countries—The situation is further complicated by the fact that the holders of traditional knowledge are generally not the government and may in fact have diametrically opposed interests from governments who purport to speak on their behalf. In particular, although many communities contest that patents and associated monetary compensation are fundamentally inconsistent with the promotion of traditional knowledge, their countries may welcome patents on the presumption that profits will flow from such activity.[104]

Conflict may also arise between communities and a national government agency when a patent is based upon traditional knowledge known by the community. A recent example of this is a patent based upon the traditional knowledge concerning the ability of the Hoodia plant to block feelings of hunger. This discovery was brought to the attention of the South African Council for Scientific and Industrial Research (CSIR) by the San community. CSIR performed additional research over a period of nine years, patented the active components of the Hoodia plant and then licensed the patent to Phytopharm, which in turn licensed the patent to Pfizer.[105] The San did not know about the patent until a Phytopharm press release, leading the San to feel as if "someone had stolen the family silver."[106] There was also some initial discussion and division within the San community whether they should seek to share in benefits from the patent, or oppose the patent on moral grounds.[107] The community ultimately decided that moral principles were "too expensive."[108] Instead, the San attorney

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2002); WIPO and United Nations Environment Program [UNEP], *The Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Traditional Knowledge*, WIPO/PR/2004/399, (2004) (*prepared by* Anil K. Gupta), htpp://www.wipo.int/tk/en/publications1769_unep_tk.pdf (noting that there were divisions among a tribal community in India with respect to how traditional knowledge of a plant with anti-fatigue properties, Jeevani, should be used if commercialized).

104. *See, e.g.*, Michael R. Dove, *Center, Periphery and Biodiversity: A Paradox of Governance and a Developmental Challenge*, *in* VALUING LOCAL KNOWLEDGE: INDIGENOUS PEOPLE AND INTELLECTUAL PROPERTY RIGHTS, *supra* note 89, 41, at 56 (noting that developing countries that negotiate trade and intellectual property agreements may be representing the interests of the political elites, rather than the interests of indigenous groups).

105. Megan Lindow, *Reaping New Meds from Old Cures*, WIRED, Nov. 9, 2003, http://www.wired.com/news/medtech/0,1286,61090,00.html.

106. Lesley Stahl, *African Plant May Help Fight Fat*, CBS NEWS, Nov. 21, 2004, http://www.cbsnews.com/stories/2004/11/18/60minutes/main656458.shtml.

107. Rachel Wynberg, *Rhetoric, Realism and Benefit-Sharing: Use of Traditional Knowledge of Hoodia Species in the Development of an Appetite Suppressant*, 7 J. WORLD INTELL. PROP. 851, 859–60 (2004).

108. *Id.* at 870.

threatened to sue the CSIR for a share of proceeds.[109] A memorandum of understanding was eventually issued that acknowledges the San's prior rights to the natural Hoodia as an appetite suppressant, together with an agreement that promised royalties from any eventual commercial sales.[110] However, even though the agreement is hailed as a historic breakthrough in providing compensation to indigenous groups, it remains controversial because it excludes the possibility for other indigenous groups with prior knowledge about Hoodia from obtaining benefits.[111]

d. Compensation Complications—A further wrinkle in addressing biopiracy concerns is that even when parties are well-intentioned, actual compensation—assuming that this is a positive development to a given community—may remain a remote possibility. Indeed, in the case of the licensed CSIR patent benefit-sharing, victory became moot when Pfizer pulled out of its agreement with Phytopharm.[112] Similarly, a recently hailed "landmark agreement" between the University of California Berkeley and the Samoan government promises to share commercial profits equally with the Samoan people, who provided traditional knowledge leading to a patent on a promising anti-AIDS agent.[113] However, the agreement

109. In the wake of negative publicity, it was reported that the CSIR initially told its collaborators that the San were extinct, such that benefit-sharing was a non-issue. *See* Leon Marshall, *Africa's Bushmen May Get Rich from Diet-Drug Secret*, NAT'L GEOGRAPHIC NEWS, Apr. 16, 2003, http://news.nationalgeographic.com/news/2003/04/0416_030416_san1.html; *see also* Antony Barnett, *In Africa the Hoodia Cactus Keeps Men Alive. Now its Secret is 'Stolen' to Make Us Thin*, THE OBSERVER, June 17, 2001, (noting that the CSIR defended their actions on the grounds that they did not want to raise the San expectations with promises that could not be met and that their organization policy was to share resulting benefits with those who provide indigenous knowledge); Lindow, *supra* note 105 (noting that although the case sparked an "international scandal," CSIR always intended to recognize the San contribution).

110. *See* Stahl, *supra* note 106.

111. *See* Wynberg, *supra* note 107, at 861 (noting that other non-San groups also occupy the areas where Hoodia grows and probably share similar knowledge, such that they would seem entitled to claim similar benefits—either because of actual knowledge, or opportunistic behavior).

112. In 2003, Pfizer merged with Pharmacia and eliminated the group that was responsible for developing the drug based upon Hoodia, leaving Phytopharm free to license the patent to other parties. Press Release, Rphytopharm, Pfizer Returns Rights of P57 (July 30, 2003), *available at* http://www.phytopharm.com/press/rel%2080finalfinal.htm (on file with the University of Michigan Journal of Law Reform).

113. The agreement is considered notable both for its generous benefit-sharing provisions, as well as proper use of prior informed consent. *See* Memorandum of Understanding between the Gov't of Samoa and the Regents of the Univ. of Cal. Berkeley for Disposition of Future Revenue from Licensing of Prostratin Gene Sequences, an Anti-Viral Molecule (Aug. 13, 2004), http:// www.paclii.org/pits/treaty_database/2004/1.html (on file with the University of Michigan Journal of Law Reform); *see also* Press Release, Robert Sanders, Landmark Agreement Between Samoa and UC Berkeley Could Help Search for AIDS Cure (Sept. 29, 2004), http://www.berkeley.edu/news/media/releases/2004/09/29_samoa.shtml (on file with the University of Michigan Journal of Law Reform) (noting that Samoa's fifty

may face difficulties because of a preexisting patent.[114] In particular, the patent belongs to the National Cancer Institute, which exclusively licensed it to the AIDS Research Alliance (ARA) to develop Prostratin for use in HIV treatment.[115]

In addition, the Berkeley agreement does not address a variety of the previously discussed issues that often arise in connection with patents and benefit-sharing. For example, although it is true that some Samoan people assisted Western researchers in what ultimately resulted in a patented product, the native tree, the Mamala, grows throughout tropical forests in the South Pacific, such that it is possible that other indigenous communities may feel excluded.[116] To the extent that the Samoan story spreads to other communities, they may be less inclined to share knowledge with each other in the hopes that they can obtain their own exclusive benefit-sharing agreement with a Western organization. Accordingly, those who decry the incursion of benefit-sharing agreements as creating new conflicts between communities and decreasing the prior tradition of open sharing may see the Samoan agreement as a paradigm example.

2. Misconception and Miscommunication—The divergent perspectives concerning patent rights are further exacerbated by misconceptions and miscommunications. In particular, rhetoric concerning biopiracy is compounded by misunderstandings of patent rights and often leads to defensive denials of problems by Western nations and criticism of communities that fail to appreciate the Western patent system. This section provides a few illustrations to highlight the divergent perspectives, without

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percent share will be allocated between the national government, villages, and the families of the original healers that showed Western researcher Dr. Cox how to use the plant).

114. Samoan communities first disclosed information concerning use of the mamala tree to treat hepatitis, back pain, diarrhea and other ailments to Paul Alan Cox, who was doing an ethnobotanical study of traditional Samoan medicine. *See, e.g.*, Alex Lash, *Samoa Faces Patent Struggles*, DEAL, Oct. 28, 2004, *available at* http://forests.org/articles/print.asp?linkid=35911. The NCI initially screened the sample as a possible cancer treatment, but instead discovered it to be a useful antiviral drug, resulting in the issuing of a patent to NCI and Cox on Prostratin for use as anti-viral therapy in 1997. *See, e.g.*, Beverly Snell, *Ethnobotanical Research: Progress with Profit-Sharing Agreements Between Samoa and US Research Institutions*, E-DRUG, Jan. 2005 (on file with the University of Michigan Journal of Law Reform).

115. U.S. Patent No. 5,599,839 (filed Apr. 17, 1995). Even more confusing, the Samoan government had previously signed an agreement directly with the ARA that would give them twenty percent of the profits of any drug developed using Prostratin, although the terms were less generous than those of the Berkeley agreement. *See, e.g.*, Victoria Griffith, *Samoa to Get Percentage of AIDS Drug Profits*, FIN. TIMES, Dec. 13, 2001, at 7.

116. *See* Lash, *supra* note 114 (noting other indigenous locations of the Mamala tree).

attempting to provide an exhaustive portrayal of every instance where this unfortunate dynamic has occurred.

Part of the problem stems from misunderstandings of the scope of patent laws. Rhetoric regarding biopiracy is rife with statements that inaccurately describe the scope of patent rights. For example, Vanda Shiva, a well known activist against biopiracy, has described a patent as "an exclusive right, which gives the patent holder a monopoly to make, use, distribute and sell the patented product."[117] This misses the important subtlety that a patent is not an affirmative right to use the invention, but rather a right to exclude others from what is patented. Similarly, patents on compositions derived from the neem tree issued to multinational companies[118] provoked widespread protests from Indian farmers, scientists, and political activists.[119] Recall that the naturally occurring tree was not and could not be patented; the patents were granted because they covered a chemical composition not previously existing in nature that had the patentable quality of having a longer storage life achieved through human intervention.[120] Nonetheless, there was fear that the patent would prevent people from using the tree as naturally found in nature.[121] This fear seems unfounded to anyone with passing familiarity with Western patent laws because it is a fundamental tenet of such laws that products of nature are not patentable, although variations of those products that are created through human manipulation may be patentable.[122]

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117. SHIVA, CORPORATE HIJACK OF BIODIVERSITY, *supra* note 63, at 13–14.

118. The fact that the patent owner was a large corporation, W.R. Grace, did not seem to diminish the perception that the patents were a new type of western imperialism that granted more rights to those who already had access to financial resources.

119. *E.g.*, Vandana Shiva, *The Neem Tree: A Case History of Biopiracy*, THIRD WORLD NETWORK, http://twnside.org.sg/title/pir-ch.htm (on file with the University of Michigan Journal of Law Reform) (describing protests during the GATT Uruguay Round that arose in part from concerns by farmers "incensed at what they regard[ed] as intellectual piracy" because the patents were based upon centuries of indigenous experimentation as well as Indian scientific research); Press Release, Background Paper on the Neem Patent Challenge, www.ifoam.org/press/neem_back.html (noting that a delegation of Indian farmers and scientists are bringing 500,000 signatures of Indian citizens to Munich, Germany, to protest neem patents, as well as a broad range of organizations supporting the patent challenge).

120. U.S. Patent No. 5,124,349 (filed Oct. 31, 1990).

121. *See* SHIVA, CORPORATE HIJACK OF BIODIVERSITY, *supra* note 63, at 13–14; *see also* Anil Gupta, *Patents on Neem—Will it Deprive Indian Farmers of the Right to use it?*, 15 BIOTECHNOLOGY L. REP. 6, 6–15 (1996) (suggesting that there is widespread confusion about the implication of the neem patent on use of the natural product); Marden, *supra* note 73, at 290 (noting that there was a common misperception that the patented neem extract "somehow confers a property right on the original entity itself").

122. *See* Diamond v. Chakrabarty, 477 U.S. 303, 309 (1980) ("The laws of nature, physical phenomena, and abstract ideas have been held not patentable."); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("patents cannot issue for the discovery of the

However, some related concerns should give greater pause. Some of those who protested the neem-related patents contended that the neem tree is sacred and should not be unjustly commodified by multinational companies. Although the tree itself was not commodified, the patents did impact the availability of natural neem because multi-national companies set up factories to make products based upon neem and the price of natural neem seed rose, threatening its availability to local consumers.[123] As noted by Vanda Shiva, "If such monopolies are granted to corporations . . . Indian cultures will over time be denied the free use of seeds, medicinal plants and indigenous knowledge. Every day items like . . . Neem . . . will go beyond our reach for food and medicine."[124]

Misstatements are most detrimental when broadly advocated, thereby further inflaming and ingraining anti-patent inclinations. For example, in one case, the nongovernmental organization RAFI[125] transmitted an electronic press release broadcasting the headline "Indigenous Person From Papua New Guinea Claimed in U.S. Government Patent."[126] The text of the press release continued in the same doomsday tone to declare that "the United States Government has issued itself a patent on a foreign citizen" who it claimed "ceased to own his genetic material."[127] To anyone familiar with patent laws and principles, the statement that a human could be patented is flat wrong since a human would not satisfy the novelty requirement as something that is naturally occurring and thus not "new." Moreover, since patents only provide a right to exclude others from the patented invention, any invention based upon a person would never bar the person from using his own genetic

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phenomena of nature"); *see also* Lab. Corp. v. Metabolite Labs., 370 F.3d 1354 (Fed. Cir. 2004), *cert. granted*, 126 S. Ct. 601 (2005) (*mem.*) (considering on certiorari whether a method patent can claim observation of a scientific phenomena as one step in achieving a tangible result).

123. *E.g.*, Shiva, *Neem Tree Case History*, supra note 119; SHIVA, CORPORATE HIJACK OF BIODIVERSITY, *supra* note 63, at 13–14.

124. SHIVA, CORPORATE HIJACK OF BIODIVERSITY, *supra* note 63, at 14.

125. RAFI stands for the Rural Advancement Foundation International, and is now known as the Action Group on Erosion, Technology and Concentration [ETC Group]. ETC Group, About Us, http://www.etcgroup.org/about.asp (last visited Jan. 1, 2006) (on file with the University of Michigan Journal of Law Reform). The focus of the group is the "conservation and sustainable advancement of cultural and ecological diversity and human rights," at the global and regional level, with a focus on the impact of technologies on disadvantaged societies. *Id.*

126. *See, e.g.*, Gary Taube, *Scientists Attacked for 'Patenting' Pacific Tribe*, 270 SCIENCE 1112 (1995).

127. *Id.*

material.[128] However, perhaps the most striking and ironic aspect of the press release is that the accused researchers had already agreed to provide the tribe with royalties from any commercial benefits, in contrast to the cases of biopiracy that RAFI traditionally rallies against.[129] In addition, the press release suggested that this was the beginning of a dangerous path towards patenting all life forms, with the clear implication—at least under a misperception of the patent system—that people would be owned by untrustworthy patent owners. The press release seems to suggest that patents can result in a type of pseudo-slavery.[130]

In reality, the scope of the patent was much narrower than the press release suggested. Rather than patenting an indigenous person, the patent only covers a cell line initially derived from the indigenous person.[131]

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128. *See generally* TRIPS, Marrakesh Agreement, *supra* note 2, at art. 28 (providing the right to exclude others from patented invention); 35 U.S.C. § 271(a) (2000) (providing the right to exclude from patented invention).

129. Taube, *supra* note 126, at 1112. The scientists responding to the charges observed that "[t]here is a certain hysterical quality to all of this which smacks of a Frankenstein-like fear of molecular biology." *Id.* Indeed, one sub-issue to the biopiracy debates might be an underlying public suspicion of molecular biology and/or a presumption that such technology can only be used for harm.

130. Ironically, although Western governments have criticized developing countries for misunderstanding patent law, similar concerns about patents on humans have percolated within the very societies that grant such patents. *E.g.*, Howard Florey Inst. v. Fraktion der Grünen im Europäischen Parlament, 6 O.J. E.P.O. 388, 397–98 (Opposition Div. 1995). Moreover, in an express acknowledgement of such concern, the U.S. Patent & Trademark Office [USPTO] issued a statement in the early days of genetically modified animals to clarify that patents on humans would be denied as unconstitutional. *See* Animals—Patentability, 1077 OFFICIAL GAZETTE PAT. & TRADEMARK OFFICE 24 (April 7, 1987) (stating that a patent claiming an exclusive property right in a human being would be "prohibited by the Constitution"). The Constitutional basis referred to by the USPTO is generally presumed to also be the prohibition against slavery. *See, e.g.*, Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 502 (2003) (noting that the PTO statement apparently refers to the Thirteenth Amendment prohibition against slavery); *cf.* Rachel E. Fishman: *Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?*, 15 AM. J. L. & MED. 461, 462 (1989) (noting that although the USPTO did not refer to any specific provision of the Constitution, the Thirteenth Amendment against slavery might have been the reference, although a misplaced one). Moreover, the academic community has ridiculed the USPTO for even issuing such a statement when it is clear under patent law that a human being *per se* would not be patentable as an unmodified product of nature. *See, e.g.*, Dan L. Burk, *Patenting Transgenic Human Embryos: A Non-Use Cost Perspective*, 30 HOUS. L. REV. 1597, 1654–55 (1993); Fishman, *supra* at 474–75. However, there is sufficient confusion that some student notes have argued to the contrary. *See, e.g.*, Esther Slater McDonald, Note, *Patenting Human Life And The Rebirth Of The Thirteenth Amendment*, 78 NOTRE DAME L. REV. 1359, 1383 (2003) (stating that the USPTO is correct that the Thirteenth Amendment would prohibit the patenting of a human embryo because the "*prohibition* of slavery would supercede the Patent Clause's *allowance* of patents").

131. U.S. Patent No. 5,397,696 (filed Aug. 12, 1991).

3. Patent "Imperialism"—The irreconcilable policies that underlie patent protection versus promotion of traditional rights have led to accusations of patent "imperialism." To the extent that the term imperialism is bandied about in conjunction with biopiracy rhetoric and misstatements concerning patent law, divergent perspectives may become further entrenched. This section explains the two main contexts in which the imperialism charge has been used. First, the very existence of systems that permit patents to issue based upon traditional knowledge is said to constitute a new type of imperialism over indigenous cultures.[132] Second, the TRIPS agreement is considered imperialistic to the extent that it forces countries opposed to patent rights to nonetheless acknowledge and adopt these systems.[133]

The patent imperialism claims are best understood against the historical backdrop of Western colonialism. In particular, there is a strong sensitivity to prior history of Western territorial expansion over lands that were seen as unowned, or at least occupied only by "native" or primitive peoples, and thus free for conquest by Western countries.[134] During the colonial era, indigenous groups found themselves forced out of their homes by Western claims of ownership over territory they had previously regarded as owned by none, except some higher spiritual order.[135] In the current twenty-first century, indigenous societies fear a reprisal of the same situation where their cultural and sacred knowledge is appropriated and they are excluded from use.[136] The Western notion of individual

132. E.g., Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy*, 37 IDEA 371 (1997); Marden, *supra* note 73, at 280 (suggesting that the "uncompensated 'harvesting' of biological resources from developing states can be seen as an insidious new form of colonialism, since multinational companies reap huge benefits while none of the profits flow back to the states providing the resources"); Laurie Anne White, *Interdisciplinary Perspectives: Indigenous Peoples, Intellectual Property and the New Imperial Science*, 23 OKLA. CITY U. L. REV. 211 (1998).

133. *See, e.g.*, Marci Hamilton, *The TRIPS Agreement: Imperialistic, Outdated and Overprotective*, 29 VAND. J. TRANSNAT'L L. 613 (1996); A. Samuel Oddi, *TRIPS—Natural Rights and a 'Polite Form of Economic Imperialism,'* 29 VAND. J. TRANSNAT'L L. 415 (1996); Lakshmi Sarma, *Biopiracy: Twentieth Century Imperialism in the Form of International Agreements*, 13 TEMPLE INT'L & COMP. L.J. 107 (1999).

134. *E.g.*, Johnson v. M'Intosh, 21 U.S. 543 (1823) (finding that the federal government, rather than the Native Americans, had title to the land based upon the "right" to conquer and occupy).

135. ECOSOC, *Draft Declaration*, *supra* note 12, Annex I (noting a historical concern that indigenous peoples "have been deprived of their human rights and fundamental freedoms ... [because of] colonization and dispossession of their lands, territories, and resources").

136. *See, e.g.*, BIOPIRACY: THE PLUNDER OF NATURE, *supra* note 63, at 2–3 ("Columbus set a precedent when he treated the license to conquer non-European peoples as a natural right of European men .... These Eurocentric notions of property and piracy are the bases

ownership of property was and remains anathema to notions of community ownership as well as a communal relationship between societies and their environment.[137]

The Western conquest analogy is not entirely identical to the extent that the actual land and raw materials of indigenous material are not being technically claimed by Western nations. Rather, the raw materials are being utilized as starting material to develop subsequent innovations that did not previously exist. According to Western patent norms, there is nothing illegitimate about creating patentable inventions based on natural materials. However, this process assumes that natural biological materials are "free" (or in the public domain) for use in this way in a manner that bears some resemblance to the prior colonialism assumption that land was free to be taken and improved upon. Just as land was considered sacred during the colonial era, natural resources are often considered sacred today, such that use of such resources would be considered immoral.[138]

In addition, patent rights are seen as a tool that promotes and elevates Western norms in a manner that necessarily fails to acknowledge the value of traditional communities. Some have suggested that Western notions of property and public domain simultaneously trivialize the contributions of indigenous peoples while enabling such contributions to be appropriated under Western notions of patent rights.[139] In particular, the Western property view that considers all things either privately owned, or in the public domain and free for use by anyone, is inconsistent with the

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on which the IPR laws of the GATT and World Trade Organization (WTO) have been framed.").

137. *See e.g.*, Keith Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection*, 6 IND. J. GLOBAL LEGAL STUD. 11, 46 (1998) [hereinafter Aoki, *Neocolonialism*] (noting that there is a "serious question" concerning whether the individualized Western notion of property is appropriate "when discussing things like agricultural practices, cell lines, seed plasm and oral narratives that 'belong' to communities rather than individuals").

138. *See supra* notes 135–137 and accompanying text.

139. *See, e.g.*, Ruth Gana, *The Myth of Development, the Progress of Rights: Human Rights to Intellectual Property and Development*, 18 LAW & POL'Y 315, 339, 341 (1996) [hereinafter Gana, *The Myth of Development*]; Michael J. Huft, *Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights*, 89 NW. U. L. REV. 1678 (1995); James O. Odek, *Biopiracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. INTELL. PROP. L. 141 (1994); Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH. J. INT'L L. 919, 929 (1996); *see also* Chidi Oguamanam, *Localizing Intellectual Property in the Globalization Epoch: The Integration of Indigenous Knowledge*, 11 IND. J. GLOBAL LEGAL STUD. 135, 146 (2004) (suggesting that the patent regime is "designed to recognize, legitimize and consequently empower Western scientific narrative" without giving due regard to "cultural accounts of science outside the Western paradigm").

principles of many traditional communities that see some things as not owned by anyone.[140] Accordingly, patent rights are particularly suspect as a means to further consolidate Western resources—at the cost of developing nations. As described by Professor Keith Aoki, "Invaluable biological cultural resources [are] flowing out of the countries of the South as 'raw materials' into the developed nations of the North where they are magically transformed in the laboratories of pharmaceutical and agricultural corporations into protected intellectual properties."[141]

The TRIPS agreement can be seen as the ultimate act of imperialism to the extent that it forces countries opposed to patents to nonetheless tolerate and grant patents within their own countries. Not only do many indigenous communities oppose patent rights, but also the scope of patentable subject matter under TRIPS. In particular, many communities object to patent rights over any type of life forms, regardless of the amount of human intervention involved.[142] This objection reflects their philosophy that life is sacred. However, their philosophies are inherently irreconcilable with the mandatory language under TRIPS that plant and animal varieties *must* be granted protection.[143]

The negotiation of TRIPS is also considered an act of imperialism to the extent that it was conceived by Western countries and imposed upon developing countries that are widely acknowledged to have had no negotiation power. In particular, just as dominant Western nations previously "conquered" land without regard for the rights and interests of indigenous populations, so too TRIPS was imposed upon countries with less political power.[144] In addition, just as Western colonial conquerors claimed that they were improving the lifestyle of natives (or savages), so too TRIPS was presented as beneficial to developing countries based on the

140. *See, e.g.*, Michael Blakeney, *Bioprospecting and the Protection of Traditional Medical Knowledge of Indigenous Peoples: An Australian Perspective*, 19 EUR. INTELL. PROP. REV. 298, 300 (1997) (noting that indigenous people may view traditional knowledge in terms of community and individual responsibility, rather than in terms of property rights).

141. Aoki, *Neocolonialism*, *supra* note 137, at 49.

142. *E.g.*, WTO Secretariat, *Review of the Provisions of Article 27.3(b), Summary of Issues Raised and Points Made*, 2–3, IP/C/W/369 (Aug. 8, 1992); GERVAIS, *supra* note 99, at 228–29.

143. TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27(3).

144. *See, e.g.*, Aoki, *Neocolonialism*, *supra* note 137, at 20 ("Third World countries might be thought of as being coerced into joining GATT, which literally said to Third World countries: If you want to export your goods . . . you must protect the intellectual properties of other nations."). In particular, because TRIPS was part of the new WTO world order, opting out of the system was not an option. *See, e.g.*, Gana, *The Myth of Development*, *supra* note 139, at 335 (noting that "the forces of globalization are so strong that it would be impossible, if not self-destructive, for any country to attempt to isolate itself from the international economic system").

premise that patents spur innovation.[145] Not only has TRIPS not resulted in spurring innovation or foreign direct investment in these countries, but the premise is questionable for pre-industrialized countries, given that most nations that presently thrive on patent protection only adopted such protection at a later period in their industrialization. For example, the United States Office of Technology Assessment has noted that "[w]hen the United States was still a relatively young and developing country, for example, it refused to respect international intellectual property rights on the grounds that it was freely entitled to foreign works to further its social and economic development."[146] Similarly, the UK Commission on studying Intellectual Property Rights concluded that "[d]eveloping countries should not be deprived of the flexibility to design their IP systems that industrialized countries enjoyed in earlier stages of their own development."[147]

B. International Architecture: The Role of International Agreements

This section describes the relevant international framework for evaluating the relationship between TRIPS and biopiracy. The dominant international agreements—TRIPS and the CBD—are first described, together with relevant human rights norms. Then,

145. *See, e.g.*, Michael Lehmann, *TRIPs, the Berne Convention, and Legal Hybrids*, 94 COLUM. L. REV. 2621, 2622–23 (1994); *see also* Gana, *The Myth of Development*, *supra* note 139, at 331–32 (describing long-term "promise of development" as a justification for modern arguments demanding higher levels of intellectual property protection by developing countries).

146. U.S. OFFICE OF TECHNOLOGY ASSESSMENT, INTELLECTUAL PROPERTY RIGHTS IN AN AGE OF ELECTRONICS INFORMATION 228 (1986); *see also* James Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 9 DUKE L. & TECH. REV. 1, 3 ("[C]ountries that now preach the virtues of expansive minimum levels of intellectual property protection, did not themselves follow that path to industrial development."). *See generally* Gana, *The Myth of Development*, *supra* note 139, *passim* (arguing that the modern regime of international intellectual property protection fails to protect developing countries).

147. COMMISSION ON IPRS, *supra* note 15, at 8; *see also* Carlos M. Correa & Sisule F. Musungu, *The WIPO Patent Agenda: The Risks for Developing Countries*, *in* TRADE-RELATED AGENDA, DEVELOPMENT AND EQUITY WORKING PAPERS, 23, 198–200 (No. 12, Nov. 2002) (noting that industrialized countries had varying evolutions of their patent systems that enabled them to take into account the competitive strength of their industries); NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY 12 (Stephen A. Merrill et al. eds., 2004) [hereinafter NAT'L RESEARCH COUNCIL] (noting that the report does not attempt to address less developed countries with the implication that countries at different levels of economic development should be entitled to different patent standards and also acknowledging that determining such standards is an "enormously complex" issue).

this section illustrates how TRIPS not only fails to promote CBD's objectives, but also dominates over all international agreements and norms in a manner that is inconsistent with its status as an international trade agreement.

1. Relevant International Agreements: TRIPS, CBD, UN

a. TRIPS—TRIPS requires that patents be available for all "inventions" in all fields of technology—subject to a few exceptions that are later discussed—if they comply with the other requirements of TRIPS.[148] For all inventions, patents must be granted if the inventions meet the technical requirements of being "new, involve an inventive step, and are capable of industrial application," or are new, nonobvious, and useful,[149] and the patent application adequately discloses the invention sufficiently for a person of similar technical skill to carry out the invention.[150] Both the technical requirements of the invention and the patent application are not further defined in TRIPS, but are understood to be identical to Western patent laws.[151] Importantly, the lack of an explicit definition of what constitutes "new" allows member states to self-define these terms. For Western countries that already used such terms in their patent laws, TRIPS permits continued use of the same standards.[152]

148. *See* TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27(1). The term "invention" is not defined in TRIPS, leading to some possible flexibility for countries to exclude undesired subject matter claiming it is not adequately an invention. Although Western countries tend to adopt a very broad definition of invention—considering it satisfied if a substance in nature is isolated or purified—TRIPS does not require member states to follow such standards. *See, e.g.*, Correa, *Patent Rights*, *supra* note 42, at 198.

149. TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27(1); *id.* n.5 ("For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively.").

150. *Id.* at art. 29.

151. *Compare* TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27 *with* EPC, *supra* note 38, at art. 52(1) *and* Patent Act, 35 U.S.C. §§ 102–103 (2000); *Compare* TRIPS, Marrakesh Agreement, *supra* note 2, at art. 29(1) *with* Patent Act, 35 U.S.C. § 112 (2000). In addition, the policy may also be consistent with the objectives in TRIPS, as noted in Article 7, which provides that "intellectual property rights should contribute to the promotion of technological innovation" since full disclosure of an invention is necessary to contribute to dissemination of such innovation. *See* TRIPS, Marrakesh Agreement, *supra* note 2, at art. 7; GERVAIS, *supra* note 99, at 239.

152. For example, in Europe, an invention is only considered new based on a test of "absolute novelty"; in other words, if an invention was previously known anywhere in the world, whether in oral or written form, it is no longer new and must be denied a patent. *See* EPC, *supra* note 38, at art. 52(4). In contrast, the United States has a narrower definition of new, sometimes referred to as "relative novelty;" under the United States rules, an invention may be deemed new, and thus patentable even if it is known in another country—so long as the knowledge is not documented in any fixed writing. 35 U.S.C. § 102(a) (2000).

There are several possible exceptions available to member states to the general rule that patent protection be available for all inventions. Members may, but need not, exclude methods of medical diagnosis and treatment for humans and animals.[153] In addition, they may exclude plants and animals, "other than micro-organisms," from patentability, although "plant varieties [must be protected] either by patents or by an effective *sui generis* system."[154] In addition, TRIPS Article 27(2) permits members to exclude an invention if a member believes that commercial exploitation of such invention must be precluded to protect "*ordre public* or morality."[155]

Although TRIPS mandates compliance with certain patent rules, the framework of TRIPS provides some leeway for national discretion.[156] In particular, nations are free to provide more intellectual property protection.[157] For example, although TRIPS permits nations to exclude some subject matter from patentabilty, such as medical procedures, nations may still permit such subject matter to be patented because TRIPS merely provides a minimum level of patentability that member countries may exceed. In addition, although TRIPS primarily regulates the substantive standards of patentability, it also provides some guidelines, as well as discretion for procedural requirements associated with patentability. In particular, TRIPS Article 62(1) provides that members "may require . . . compliance with reasonable procedures and formalities" as a condition for patent rights.[158]

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153. TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27(3)(a) (noting that members may exclude "diagnostic, therapeutic and surgical methods for the treatment of humans or animals").

154. *Id.* at art. 27(3)(b). Notably, TRIPS required this provision to be reviewed four years after the agreement because of controversy over the terms of this provision at the time of its enactment. *See* GERVAIS, *supra* note 99, at 227–28.

155. TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27(2). However, an invention cannot be excluded "merely because the exploitation is prohibited by . . . law." *Id.* Rather, the focus is on whether commercialization of the invention—legal or not—would contravene *ordre public* and morality. Although this provision has yet to be interpreted by a WTO panel, it specifies that *ordre public* or morality may include "to protect human, animal or plant life or health or to avoid serious prejudice to the environment." *Id.*

156. *Id.* at art. 27(3)(a) (providing that members may exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals").

157. *Id.* at art. 1(1).

158. *Id.* at art. 62(1). The term "reasonable procedure or formality" is not defined in TRIPS, but the one WTO panel to opine on this issue suggested that it must be "tied to valid reasons required to ensure a proper examination." Panel Report, *Canada—Term of Patent Protection*, 6.115, WT/DS170/R (May 5, 2000) *aff'd*, WT/DS170/AB/R (Sept. 18, 2000), *available at* http://docsonline.wto.org/gen_search.asp?searchmode=simple (search for document number 00-1965) [hereinafter *Canada Patent Term*].

b. CBD—CBD governs access and use of genetic resources and traditional knowledge. In particular, the CBD is a departure from the prior perspective that the products of nature belonged to the "common heritage of mankind," and were thus free for taking without any regulation.[159]

The CBD states that member countries should "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity . . . ."[160] In addition, the CBD further provides that members should "encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."[161] However, there are some notable caveats to what, at first glance, appears to be an advancement of the interests of indigenous culture. In particular, the entire clause is couched in very vague language—each member is obliged "as far as possible and as appropriate" to take such measures, and even then, the measures are "[s]ubject to its national legislation."[162]

Subsequent meetings of the CBD Council of Parties have set forth additional guidelines to promote the CBD provisions concerning the protection of traditional knowledge. In particular, the CBD issued the Bonn Guidelines on Access to Genetic Resources (Bonn Guidelines) in 2002, which explicitly note that they are intended "to provide [p]arties and stakeholders with a . . . framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits."[163] Although the Bonn Guidelines are

159. *See, e.g.*, Report of the Conference of the Food and Agriculture Organization, 1983, *International Undertaking on Plant Genetic Resources for Food and Agriculture*, art. 1, U.N. Doc. C/83/Rep (stating the "universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction") (emphasis omitted); WIPO, *Matters Concerning Intellectual Property*, *supra* note 44, at para. 33; *see also* Zakir Thomas, *Common Heritage to Common Concern: Preserving a Heritage and Sharing Knowledge*, 8 J. WORLD. INTELL. PROP. L. 241, 246–50 (2005) (tracing evolution from plant resources as common heritage of all to biodiversity conservation as common concern, including the implications for nations to recover financially from bioprospecting activities of pharmaceutical companies).

160. CBD, *supra* note 6, at art. 8(j).

161. *Id.*

162. *Id.*

163. Secretariat of the Convention on Biological Diversity, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, ¶ 11(b), U.N. Doc. UNEP/CBD/COP.6/20 (May 27, 2002) [hereinafter Bonn Guidelines]. The Bonn Guidelines provide objectives beyond those specified in the CBD while simultaneously noting that they are intended to be merely a "useful first step in an evolutionary process in the implementation of relevant provisions" of the CBD for access to genetic resources and benefit-sharing. Conference of the Parties to the Convention on Biological Diversity, Feb. 9–20, 2004 Report of the Open-Ended Inter-Sessional Meeting on the Multi-Year Programme of Work of the Conference of the Parties up to 2010, ¶ 6, U.N. Doc.

merely advisory to member states, they attempt to nonetheless provide a template for national laws and policies that would effectuate CBD goals with respect to three main areas.[164] First, the Bonn Guidelines suggest that prior informed consent should be sought from the providing country[165] prior to accessing genetic resources or traditional knowledge.[166] Second, the Bonn Guidelines suggest that for any invention that concerns or makes use of a genetic resource or traditional knowledge in its development, a related patent application should disclose the country of origin.[167] This suggestion is noted to assist in tracking "compliance with prior informed consent" and the "mutually agreed terms on which access [to those resources] was granted."[168] Finally, the Guidelines suggest that countries should "[e]nsure the fair and equitable sharing of benefits . . . arising from the commercialization or other use of genetic resources,"[169] and provide specific examples of monetary and non-monetary benefits that might be provided.[170]

c. International Human Rights—UN Declarations—International human rights provide an additional basis for recognizing and protecting traditional knowledge. The pertinent human rights include rights recognized in the Charter of the United Nations, the Universal Declaration of Human Rights, and international human rights laws. For example, indigenous peoples have a right to full enjoyment of all human rights and freedoms, including the right to cultural sovereignty, which in their case may include a right to control traditional knowledge relating to biodiversity, medicine and agriculture.[171]

Multiple UN resolutions, reports, and statements consider biopiracy as one of several human rights issues that conflict with TRIPS.

UNEP/CBD/COP/7/5 (May 27, 2002). The Guidelines explicitly contemplate further consideration of the issues raised by the Working Group on Access and Benefit-Sharing and that this group will further advise the Conference on the Parties. *Id.* ¶ 8.

164. The Bonn Guidelines are not binding on members of the CBD, although parties and governments are invited "to use the Guidelines" for national laws and policies. Bonn Guidelines, *supra* note 163, ¶ 4, at 262.

165. *Id.* ¶ 28.

166. *See id.* ¶ 16(d) (noting that member nations with "users of genetic resources under their jurisdiction *should* take appropriate legal, administrative, or policy measures, *as appropriate,* to support compliance with prior informed consent") (emphasis added); *see also id.* ¶ 16(b)(1); *id.* ¶ 16(b)(ix). In addition, the Bonn Guidelines provide specific principles and procedures for such a system. *Id.* ¶¶ 26, 36.

167. *Id.* ¶ 16(d)(ii) (suggesting that countries consider "[m]easures to encourage the disclosure of the country of origin" in applications for intellectual property rights).

168. *Id.* ¶ 16(d).

169. *Id.* ¶ 16(b)(ix).

170. *Id.* at app. II.

171. *See, e.g.*, ECOSOC *Draft Declaration, supra* note 12, at arts. 1, 29.

For example, Resolution 2000/07 specifically mentions biopiracy and community control over genetic and natural resources as a conflict that exists between implementation of TRIPS and realization of human rights norms.[172] Although the resolution "affirms" the existence of human rights over intellectual property, it clarifies that such patent rights are "subject to limitations in the public interest,"[173] such that human rights obligations should be given "primacy" over competing economic policies and agreements.[174] The 2001 Report of the High Commissioner similarly mentioned a need to protect traditional medical knowledge from biopiracy.[175] The Report is consistent with Resolution 2000/07 with respect to its view that intellectual property rights must be considered in context with human rights norms. For example, the Report advocated a "human rights approach" to intellectual property rights, which would necessitate that such rights be conceptualized as "more akin to a privilege."[176] Such language suggests that the stated rights under TRIPS should be taken as privileges that must be considered in the context of human rights, even though human rights are not expressly noted in TRIPS. In particular, the Report states that human rights "are inalienable and universal," such that they should transcend state-granted rights.[177] Once again, this suggests that rights under TRIPS, which are state-granted rather than inalienable should, where appropriate, bow to the more universal human rights. Moreover, the Report supports the World Health Organization's report recommending "ways and means" to protect

172. U.N. High Comm'r for Human Rights, U.N. Sub-Comm'n on the Protection of Human Rights, 52d Sess., *Intellectual Property Rights and Human Rights, Res. 2000/07*, pmbl., U.N. Doc. E/CN.4/Sub.2/RES/2007 ("[A]ctual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights in relation to . . . 'bio-piracy' and the reduction of communities' control over their own genetic and natural resources and cultural values."). The declaration also notes that the CBD "echoes the International Covenant on Economic, Social and Cultural Rights on the right to self-determination and on the balance of rights and duties inherent in the protection of intellectual property rights." *Id.*

173. *Id.* ¶ 1.

174. *Id.* ¶ 3. The resolution declares that implementation of TRIPS fails to reflect "all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self-determination." *Id.* ¶ 2. *See also* ECOSOC, Comm. on Econ., Soc. and Cultural Rights, *Substantive Issues Arising in the Implementation of the International Covenant of Economic, Social and Cultural Rights, Human Rights and Intellectual Property*, ¶¶ 8, 16, U.N. Doc. E/C.12/2001/15 (Dec. 14, 2001) ("States . . . must give particular attention . . . to the adequate protection of the human rights of . . . indigenous peoples . . . . National sovereignty over wealth and resources is an important prerequisite for the effective promotion and protection of human rights.").

175. ECOSOC, *The Impact of the Agreement, supra* note 25, at 65, (citing *Report of the Interregional Workshop, supra* note 84, at 35).

176. *Id.* ¶ 14.

177. *Id.* ¶ 14.

"traditional medicine knowledge from biopiracy," including "the adaptation of IP systems so that they fully take into account the cultural and other rights of indigenous and local communities."[178] With specific reference to the tension between TRIPS and the CBD, the Report suggests that these tensions "could require amendments, adaptations and additions to IP systems," although the Report stops short of articulating such change, beyond its broader exhortation of construing intellectual property rights in conjunction with human rights.[179]

In addition, there is a United Nations Draft Declaration on the Rights of Indigenous Peoples that, while not yet ratified,[180] provides further support for the protection of indigenous communities from competing intellectual property rights based upon human rights principles.[181] The Draft declares that such peoples have the "right to . . . control, develop and protect their sciences . . . including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora . . . ."[182] The Draft may attempt to consider such control of science to be an intellectual property right, since the same Article declares that indigenous peoples are entitled to recognition of "full ownership, control and protection of their cultural and intellectual property."[183] However, if intellectual property is intended to be defined as knowledge of properties of biological material alone, that would be contrary to Western definitions of intellectual property that typically consider discovery of natural properties as outside the scope of protection.[184]

178. *Id.* ¶ 65.

179. *Id.* ¶ 26.

180. Although the draft has not yet become a UN General Assembly resolution or declaration, which would open it up for ratification, it has nonetheless been a starting point for continued discussions among the United Nations Organization. *See, e.g.*, ECOSOC, Res. 1995/32, 52nd plen. mtg., U.N. Doc. E/Res/1995/32 (July 25, 1995); ECOSOC, Res. 2000/22, 45th plen. mtg., U.N. Doc. E/Res/2000/22 (July 28, 2000); ECOSOC, Permanent Forum on Indigenous Issues, 2nd Sess., *Outcomes Achieved in Response to the First Session of the Forum*, U.N. Doc. E/C.19/2004/3 (Mar. 17, 2003) (providing overview of developments and recommendations at the first forum); G.A. Res. 57/191, U.N. Doc. A/Res/57/191 (Jan. 23, 2003) (noting the forum's review of all existing mechanisms within the UN concerning indigenous issues and providing recommendations on how to streamline activities and promote effectiveness).

181. ECOSOC, *Draft Declaration*, *supra* note 12, Annex I (noting there is an "urgent need to respect and promote the inherent rights and characteristics of indigenous peoples, especially their rights to their lands, territories and resources, which derive from their political, economic and social structures and from their cultures, spiritual traditions, histories and philosophies").

182. *Id.* at art. 29.

183. *Id.*

184. *See, e.g.*, Lawrence Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence*, 5 MINN. INTELL. PROP. REV. 47, 54 (2003) (noting that the Draft defines "protectable subject matter more broadly than existing intellectual property" rights). However, some

Even if the attempt to broaden the definition of intellectual property to encompass traditional knowledge is not successful, the Draft reinforces CBD concepts, such as the fact that informed consent, and even restitution, be provided if "cultural, intellectual, religious and spiritual property" is "taken without their free and informed consent or in violation of their laws, traditions and customs."[185] The definition of "cultural, intellectual, religious and spiritual property" is unclear, but could conceivably embody some of the issues of prior biopiracy cases, such as when a derivative of the sacred neem tree was patented.

2. Conflict or Coexistence: TRIPS and CBD—There are two primary issues of conflict that have been identified regarding TRIPS and the CBD.[186] First, TRIPS is alleged to be complicit in biopiracy for its failure to define patent requirements in a way that would limit patents based on traditional knowledge of other countries. Second, TRIPS has been criticized for failing to promote the CBD goals of benefit-sharing and informed consent because such issues are not included as requirements to patent protection. Although there has been substantial discussion of whether these two agreements technically conflict,[187] this section primarily outlines the

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scholars have suggested that indigenous knowledge be protected under existing or proposed regimes of intellectual property. *See, e.g.*, David R. Downes, *How Intellectual Property Could be a Tool to Protect Traditional Knowledge*, 25 COLUM. J. ENV. L. 253 (2000); Michael Halewood, *Indigenous and Local Knowledge in International Law: A Preface to Sui Generis Intellectual Property Protection*, 44 MCGILL L.J. 953 (1999); Surinder Kaur Verma, *Protecting Traditional Knowledge: Is a Sui Generis System an Answer?*, 7 J. WORLD INTELL. PROP. 765, 767 (2004).

185. ECOSOC, *Draft Declaration*, *supra* note 12, at art. 12.

186. In addition, there is a third issue that is sometimes raised in discussions of conflict between TRIPS and the CBD, but which does not directly address a conflict between the two agreements; in particular, there is an argument that there is an inherent tension in philosophies concerning whether "life" may be owned. This is not discussed in detail here, but is addressed in the context of proposed strategies for addressing biopiracy. *See infra* Part IV.

187. *See, e.g.*, Council for Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity: Summary of Issues Raised and Points Made*, IP/C/W/368 (Aug. 8, 2002) (providing overview of positions made by different parties prior to August, 2002); CATHERINE MONAGLE & AIMEE T. GONZALES, CTR. FOR INT'L ENVTL. LAW & WORLD WIDE FUND FOR NATURE INT'L, BIODIVERSITY & INTELLECTUAL PROPERTY RIGHTS: REVIEWING INTELLECTUAL PROPERTY RIGHTS IN LIGHT OF THE OBJECTIVES OF THE CONVENTION ON BIOLOGICAL DIVERSITY (2001), http://www.ciel.org/publications/tripsmay01.pdf (discussing requirements under both the CBD and TRIPS, as well as the issues of whether TRIPS negatively impacts CBD objectives); The Gaia Foundation, *Genetic Resources Action Int'l, TRIPS versus CBD: Conflicts Between the WTO Regime of Intellectual Property Rights and Sustainable Biodiversity Management*, GLOBAL TRADE AND BIODIVERSITY IN CONFLICT, Apr. 1998, at 7–11 (arguing that TRIPS threatens the implementation of CBD and suggesting measures to address the "contradiction" between the agreements). Western countries have primarily asserted that there is no conflict. *See, e.g.*, Commission on Intellectual and Industrial Property, Policy Statement: TRIPS and the Biodiversity Convention: What Conflict? (June 28, 1999), http://ww.iccwbo.org/home/statements_rules/statements/1999trips_and_bio_convention.asp

arguments because the structural dominance of TRIPS, as discussed in the next section, plays a more critical role.

a. Patent Requirement—TRIPS's lack of definition for the term "new" is alleged to promote a preexisting problem of biopiracy. Specifically, United States patent law presently considers inventions to be new and patentable without regard to what is known outside the United States—if such information is not documented in writing.[188] To the extent that there is preexisting indigenous knowledge, this knowledge is by its nature typically oral, such that it would be excluded from consideration by the United States. United States law is different from most Western countries and is often seen as responsible for some of the most egregious cases of biopiracy.[189] For example, although a patent on a method of controlling fungi on plants using extracted neem oil was recently revoked in Europe based upon evidence that the fungicidal effect of neem seed extracts has been known for centuries in India,[190] such evidence would not preclude the existence of a United States patent because the United States does not consider public use in countries beyond itself as relevant prior art unless such use is documented in writing.[191]

b. CBD "requirement" (benefit-sharing and informed consent)—TRIPS is also alleged to promote biopiracy to the extent that it enables patenting of genetic material without ensuring that CBD provisions are respected. In particular, there is concern that TRIPS provisions do not mandate obtaining prior informed consent or practicing benefit-sharing.[192] These CBD goals, as recently affirmed and fur-

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(stating policy of the International Chamber of Commerce that CBD and TRIPS are equally binding, but no amendments to TRIPS are necessary because of lack of conflict, and in the alternative, that TRIPS should control as the later in time agreement pursuant to interpretation under the Vienna Convention); Communication from the European Communities and Their Member States, *Review of Article 27.3(B) of the TRIPS Agreement, and the Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore*, IP/C/W/383 (Oct. 17, 2002) (noting that there is no legal conflict between TRIPS and the CBD, and recognizing openness to continued discussion).

188. 35 U.S.C. § 102 (2000).

189. *See, e.g.*, McMannis, *supra* note 63, at 450. However, the issue of TRIPS complicity in condoning the United States laws may become a moot point since this law may need to be revised for both domestic and international concerns. *See infra* Part IV.B.

190. *See supra* notes 20–23 and accompanying text (describing recent revocation of neem patent; *see also* European Patent Spec. 0,436,257,B1 (filed Dec. 20, 1990).

191. *See supra* Part I.A.

192. *See, e.g.*, Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting, Held in the Centre William Rappard on 21 and 22 Sept. 2000*, ¶ 144, IP/C/M/28 (Nov. 23, 2000); Communication from Brazil, *Review of Article 27.3(b)*, ¶ 21, IP/C/W/228 (Nov. 24, 2000) (noting that conflicts may arise between TRIPS and CBD to the extent that patents may exist over naturally occurring resources, in violation of the CBD); *Communication from India*, ¶°4, IP/C/W/196 (July 12, 2000) ("It is widely agreed that the TRIPS

ther clarified in the Bonn Guidelines, are not embodied in TRIPS. Accordingly, some countries have advocated that TRIPS should be amended to mandate that patents inconsistent with CBD Article 15—which relates to access and benefit-sharing—not be granted.[193] These countries argue that countering specific instances of biopiracy patents by utilizing revocation procedures is cost-prohibitive, such that an international requirement under TRIPS is needed.[194] These requirements have been suggested as useful in ensuring that resources are appropriately accessed if patent applicants know that they must not only be under an ethical obligation to seek prior informed consent of the community from which the resource was obtained, but also so indicate on their patent applications. Moreover, both proposals for reconciling TRIPS and the CBD are suggested as helpful in ensuring that resources are appropriately shared with communities that helped in the path towards a patentable invention.

Western countries have countered that patent requirements have no bearing on whether countries have national laws barring improper access or on the extent to which such laws are adequately enforced. For example, as noted by the European Union, because the goal of intellectual property rights is not the regulation of genetic resources, a patent office should not be required to act as a de facto "enforcement agency for a third country's legislation on access to genetic resources."[195] Inclusion of these requirements in patent applications has been suggested as an incomplete solution since those who currently seek patents, which are public documents, might instead protect their inventions through trade secrets, which by definition, are kept secret from the public.[196] In

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Agreement is incompatible with the Convention on Bio-Diversity."); *Communication from India*, ¶¶ 13–16, IP/C/W/195 (July 12, 2000) (expressing concern about the need to reconcile contradictions between CBD and TRIPS).

193. *See, e.g.*, Communication from Bangladesh, *The Challenge of Integrating LDCs into the Multilateral Trading System*, ¶ 39, GC/W/251 (July 13, 1999); IP/C/W/196, *supra* note 192, ¶ 4 (asserting that the first priority is to "incorporate a provision that patents inconsistent with Article 15 of the CBD must not be granted").

194. *See, e.g.*, Communication from Brazil et al., *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, ¶¶ 10–12, IP/C/W/356 (June 24, 2002) (suggesting that TRIPS must be amended to mandate disclosure of origin of biological resources or traditional knowledge, as well as informed consent and evidence benefit-sharing because developing countries do not have the resources to attack patents individually); Submission by India, *Protection of Biodiversity and Traditional Knowledge—The Indian Experience*, ¶¶ 8–11, WT/CTE/W/156 (July 14, 2000).

195. Communication from the European Communities and Their Member States, *Review of the Provisions of Article 27.3(b) of the TRIPS Agreement*, ¶°21, IP/C/W/254 (June 13, 2001).

196. Communication from the United States, *Review of the Provisions of Article 27.3(b)*, at 6, IP/C/W/162 (Oct. 29, 1999).

addition, to the extent that some inventors would continue to file patent applications, such a requirement would be administratively unwieldy for patent offices,[197] and would adversely impact inventors, small businesses, and developing countries because of necessary increased costs. Western countries have thus suggested that a better approach would be to use contracts, in addition to developing databases of traditional knowledge to facilitate the discovery and documentation of such knowledge for patent examiners.[198] Even some developing countries are amenable to creation of databases, although they typically do not consider this a complete solution.[199]

c. De facto domination of TRIPS—A related problem is that the structure of TRIPS, including the unique WTO enforcement provisions under the Dispute Settlement Understanding that governs all WTO agreements, results in the dominance of TRIPS provisions over competing international agreements, without rising to the level of a clear conflict of treaties under international law. First, this section will establish that the obligations stated under TRIPS are clearly delineated in comparison to other international agreements that are alleged to conflict with TRIPS. Second—and some would say more importantly—the TRIPS obligations carry extreme

197. *See, e.g., id.*; IP/C/W/209, *supra* note 58, at 6 (suggesting that disclosure of origin would be "a legal and administrative nightmare for all involved" without necessarily ensuring the benefit-sharing desired). Other countries have countered that the requirement would be no more burdensome than existing patent requirements. *See, e.g.*, Submission by Brazil et al., *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, ¶¶ 12–13, IP/C/W/403 (June 24, 2003) (arguing that because the patent applicant would be in the best position of knowing where resources were derived from, a disclosure requirement would not be an undue onus on the applicant); IP/C/W/228, *supra* note 192, ¶ 27 (noting that because there would probably be few applications suspected of violating biodiversity provisions, administrative burden would be minimal); IP/C/W/356, *supra* note 194, ¶ 13 (asserting that the suggested requirements would be no more burdensome than existing requirements and would have the benefit of creating predictability).

198. *See, e.g.*, Communication by the United States, *Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, ¶¶ 31–32, IP/C/W/449 (June 10, 2005); Communication by the United States, *Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, ¶¶ 7, 29, IP/C/W/434 (Nov. 26, 2004); Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting, Held in the Centre William Rappard from 18 to 22 June 2001*, ¶ 137, IP/C/M/32 (Aug. 23, 2001); IP/C/W/209 supra note 58, ¶ 6; *see also* Communication from Switzerland, *Review of Article 27.3(b): The View of Switzerland*, ¶¶ 16–19, IP/C/W/284 (June 15, 2001) (proposing an international database of traditional knowledge related to genetic resources to enhance the patent process).

199. *See, e.g.*, IP/C/W/228, *supra* note 192; Submission by India, *Protection of Biodiversity and Traditional Knowledge-The Indian Experience*, ¶¶ 16–23, IP/C/W/198 (July 14, 2000). However, there is concern about whether the databases themselves could potentially facilitate piracy. *See, e.g.*, IP/C/M/32, *supra* note 198, ¶ 136; IP/C/W/228, *supra* note 192, ¶ 41; IP/C/W/198, *supra*, ¶ 17.

weight because failure to comply with TRIPS can result in trade sanctions through the effective dispute resolution proceedings that are tied to TRIPS/WTO.[200] Each of these issues will be addressed in more detail below.

With respect to the competing international agreement related to the biopiracy problem, the obligations stated under TRIPS are more clearly defined. Unlike TRIPS, the CBD tends to state broad aspirations, rather than specific obligations.[201] For example, the CBD only states that sharing of commercial benefits from the use of genetic resources is an "aim," not a firm requirement.[202] Although the CBD states this aim "shall be upon mutually agreed terms,"[203] the multitude of biopiracy claims suggest that arriving at such terms is not readily achieved based on the CBD alone. Even the more specific Bonn Guidelines are couched in caveats, such as parties should be "encouraged," and "to the extent practicable." In addition, the CBD does not create affirmative rights, so much as suggestions that member states pursue certain actions. For example, although the CBD is often noted as declaring that nations have sovereign rights over their resources, the actual language does not create an affirmative right. Rather, it *recognizes* a state's sovereign right to its natural resources.[204] Similarly, although Article 1 of the CBD is often invoked against claims of biopiracy, this provision only states the objectives of the CBD, but not any actual internationally enforceable right.[205]

Even the few CBD provisions that are stated in more affirmative language have relatively little impact compared to the TRIPS provisions, which are backed by stronger enforcement provisions. TRIPS is ultimately enforceable under the WTO Dispute Settlement Proceedings, which is uniformly regarded as one of the most

200. Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M 1125 (1994) [hereinafter DSU]; *see also id.* art. 23; *id.* at app. 1 (noting TRIPS as one of the agreements covered by the DSU).

201. Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 29 (2004) [hereinafter Helfer, *Regime Shifting*]; Marc Pallemaerts, *International Environmental Law in the Age of Sustainable Development: A Critical View of the UNCED Process*, 15 J.L. & COM., 623, 660–61 (1996).

202. CBD, *supra* note 6, at art. 15(7); *see also id.* at art. 8 (providing that member countries "shall, as far as possible and as appropriate . . . *encourage* the equitable sharing of the benefits" with regard to traditional knowledge) (emphasis added).

203. *Id.* at art. 15(7).

204. CBD, *supra* note 6, at art. 15(7).

205. *See id.* at art. 1 ("The objectives of this Convention, to be pursued in accordance with its relevant provisions, are . . . the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources . . . .").

effective means of enforcing international law.[206] This stands in marked contrast to the CBD system which permits, but does not mandate, a system for resolving disputes that arise under the agreement.[207] Even if the parties willingly submit to the voluntary CBD system, there is no means to enforce any final decision.[208]

UN resolutions are even less specific than the aspirational statements in the CBD. The draft declaration on rights of indigenous communities exemplifies lofty language that lacks enforceability. One clause states that indigenous peoples have the "right to maintain and strengthen their distinctive spiritual and material relationship with . . . resources which they have traditionally owned or otherwise occupied or used."[209] For example, although the UN has recently taken an active role in alleging that TRIPS undermines the realization of human rights, UN reports and resolutions primarily advocate that human rights should be given "primacy" with respect to interpretation of TRIPS's requirements, but without defining what "primacy" means, or how to effectuate this goal.[210] Similarly, recognized UN rights have no simple mechanism of enforcement.[211]

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206. *TRIPS*, Marrakesh Agreement, *supra* note 2, at art. 64; Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275 (1997); Laurence R. Helfer, *Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments*, FAO LEGAL PAPERS ONLINE #31, July 2002, at 20–21, http://www.fao.org/legal/prs-oL/Lpo31-2.pdf. The DSU provides that if countries fail to comply with WTO decisions, they may suffer trade sanctions. DSU, *supra* note 200, at art. 22 (describing procedures for compensation and suspension of concessions if a member fails to comply with a WTO panel ruling).

207. CBD, *supra* note 6, at art. 27(3). Member states are directed to "seek solution by negotiation" if there is a dispute concerning the interpretation or application of the CBD. *Id.* at art. 27(1). There are no guidelines provided for how such negotiations should be conducted. If they fail, the parties are to jointly seek mediation by a third party, but the CBD does not itself specify any rules for how the mediation shall be conducted. *Id.* at art. 27(2). Finally, if mediation is unsuccessful, parties may seek either arbitration or litigation with the International Court of Justice. *Id.* at art. 27(3).

208. *See, e.g.*, Chantal Thomas, *Should the World Trade Organization Incorporate Labor and Environmental Standards?*, 61 WASH. & LEE L. REV. 347, 356 (2004).

209. ECOSOC, *Draft Declaration*, *supra* note 12, at art. 25; *see also id.* at art. 24 ("Indigenous peoples have the right to their traditional medicines and health practices, including the right to the protection of vital medicinal plants, animals and minerals."). To the extent that some patents have issued on agricultural resources that are traditionally used by indigenous communities, perhaps this clause would be violated. On the other hand, it is also possible that indigenous peoples can maintain their spiritual and material relationship with resources when a derivative of such resources is patented, since a patent does not have any bearing on the use or ownership of the original resource.

210. *See supra* Part II.B.1.

211. *See, e.g.*, Erica-Irene Daes, *Intellectual Property and Indigenous Peoples*, 95 AM. SOC'Y INT'L L. PROC. 143, 148 (2001) (noting that the UN system "still lacks any meaningful enforcement machinery short of a military intervention, which is plainly a matter of last resort"). *See generally* FERENCZ, ENFORCING INTERNATIONAL LAW: A WAY TO WORLD PEACE: A DOCUMENTARY HISTORY AND ANALYSIS (1983) (noting that human rights under the Univer-

Since each international regime provides its own rights and enforcement, the regime with the strongest enforcement ability—TRIPS—will effectively dominate other international norms, although the agreement itself does not explicitly suggest such a result. In particular, although conflicts with other international norms could be raised in a proceeding under the WTO, this would at most result in consideration of TRIPS *in light of* other norms. Moreover, it may be particularly difficult for an alleged conflict between TRIPS and another international norm to even be addressed in an official WTO dispute proceeding.

There is no specific mechanism, apart from the all-purpose dispute settlement proceedings or limited action of the WTO TRIPS Council, to consider the extent to which TRIPS conflicts with, or even nullifies, other international norms. The Dispute Settlement Understanding (DSU) requirements, in turn, require a violation of TRIPS's requirements (or other WTO requirements not at issue here).[212] However, because there is no official requirement that TRIPS not impinge on other international treaties, arguable conflicts would not generate anything analogous to a legal cause of action, leaving those who believe agreements to be inconsistent, or even irreconcilable, without a remedy under TRIPS. At most, a perceived conflict between TRIPS and other treaty norms may arise as a defense for failure to fully implement TRIPS requirements. However, treaty conflicts are narrowly interpreted[213] and WTO

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sal Declaration of Human Rights have been notoriously difficult to enforce). In particular, the only UN organ that has authority to issue immediately binding directives is the Security Council, but its stated purpose of preserving peace does not seem to implicate biopiracy conflicts, or the rights of indigenous peoples. Similarly, although the Commission on Human Rights was established to deal with Human Rights violations that might cover the rights discussed here, the Commission notably has no power to make binding decisions. Jeremy A. Rabkin, *The Politics Of The Geneva Conventions: Disturbing Background to the ICC Debate*, 44 VA. J. INT'L L. 169, 171–72 (2003). Moreover, to the extent that human rights involved with biopiracy are only in draft resolution, they stand even less chance of being enforced.

212. DSU, *supra* note 200, at art. 23 (providing grounds for nullification or impairment).

213. Technically, the official bodies that interpret TRIPS—the WTO panels and the Appellate Body—are to apply the "customary rules of interpretation of public international law," which in turn utilize the Vienna Convention on the Law of Treaties, which presumes treaties relating to the same subject matter are compatible. *See* Vienna Convention on the Law of Treaties, *Opened for Signature* May 23, 1969, U.N. Doc. A/Conf. 39/27, 1155 U.N.T.S. 321 (1980). In addition, customary interpretations of conflicts view conflicts very narrowly, such that there is no technical conflict if both treaty provisions can possibly be complied with, even if not maximally fostered. Indeed, some scholars have noted that it is difficult to imagine that there would be a true conflict found between TRIPS and another international agreement. *E.g.*, Helfer, *Regime Shifting*, *supra* note 201, at 29. In addition, theoretically, there should be no conflict between TRIPS and other international agreements because most agreements state that members should not enter into conflicting agreements. *See* Universal Declaration of Human Rights, G.A. Res. 217A, at art. 30, U.N. GAOR, 3d Sess., 1st plen.

jurisprudence thus far shows little likelihood of being receptive to claims that a failure to implement TRIPS is excusable to avoid a conflict with other treaty commitments.[214] International law scholar Professor Lawrence Helfer has suggested that other international agreements could be considered soft law to interpret TRIPS, although he admits that WTO jurists have yet to address this issue directly.[215]

Moreover, legal arguments concerning such conflicts are unlikely to even reach resolution by dispute settlement panels to the extent that the United States continues to use the threat of unilateral trade sanctions to "resolve" disputes before they are even considered by a formal WTO panel. In particular, the U.S. has continued to utilize a domestic trade act referred to as "Special 301," which enables it to identify countries that provide inadequate protection for intellectual property rights.[216] Ultimately, a country that is listed under this procedure, on either a "Watch list" or a "Priority Watch List," may suffer unilateral U.S. trade sanctions if no changes are made to address the U.S. concern.[217] These sanctions are exclusive of any sanction that would be provided pursuant to the WTO Dispute Settlement proceedings. The United States has used this procedure to force countries to comply with TRIPS requirements before they are technically required to do so (because of phase-in periods), and to mandate requirements that are left ambiguous in TRIPS. For example, the United States imposed trade sanctions on Argentina before a WTO panel was ever created

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mtg., U.N. Doc. A/810 (Dec. 12, 1948); CBD, *supra* note 6, at art. 22(1); TRIPS, Marrakesh Agreement, *supra* note 2, at art. 1(1).

214. In particular, the WTO panel reports suggest that a treaty conflict only exists where compliance with one treaty rule necessarily compels violation of another. *See* Appellate Body Report, *Guatemala-Anti-Dumping Investigation Regarding Portland Cement from Mexico*, ¶ 61, WT/DS60/AB/R (Nov. 2, 1998); Panel Report, *Indonesia-Certain Measures Affecting the Automobile Industry*, § 5.356, WT/DS54/R (July 2, 1998); *see also* Helfer, *Regime Shifting*, *supra* note 201, at 76 ("WTO jurists are likely to reject claims that violating TRIPs is necessary to avoid a conflict with other treaty commitments."). Moreover, given that the CBD norms are not strict requirements, it would seem difficult for TRIPS requirements to compel complete violation of them.

215. Helfer, *Regime Shifting*, *supra* note 201, at 77–79.

216. Omnibus Trade and Competitiveness Act of 1988, 19 U.S.C. §§ 2901–06 (2000).

217. Trade Act of 1974, 19 U.S.C. § 2411(c) (2000). Beyond the threat of trade sanctions, the United States has also sometimes tied (or threatened to tie) foreign aid to the level of intellectual property protection. *See, e.g.*, Andean Trade Preference Act, 19 U.S.C. §§ 3201–06 (2000); United States-Caribbean Basin Trade Partnership Act, 19 U.S.C. §§ 2701–07 (2000). *See also* Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105–277, 112 Stat. 2681–153 (1998) (*amending* 42 U.S.C. 7671c by adding subsecs. (d)(5), (d)(6), (e)(3), and (h)) (suspending economic assistance to South Africa in retaliation for South Africa's defense of its compulsory licensing law against attack by pharmaceutical companies contending that it was not consistent with TRIPS).

and indeed, the USTR asserted to the WTO that the countries had resolved their dispute.[218] Although a developing country may hope for a favorable resolution at the WTO, this would still not immunize the country from the trade sanctions pursuant to Special 301. Indeed, the threat of being listed on a "watch list" has prompted countries into action, including signing bilateral agreements, or modifying their laws prior to complying with purported interpretations of TRIPS.[219] In light of this dynamic, developing countries are likely hesitant to rely on defenses they believe are legitimate since they may face the wrath of the U.S. before a formal adjudication at the WTO.[220]

The de facto dominance of TRIPS over other international agreements and norms is implicitly understood, even if not condoned, by developing countries who have focused on the WTO/TRIPS structure since 1999 as a method of addressing their concerns.[221] In particular, some developing countries utilized a preexisting framework for reconsidering one article of TRIPS

218. *See* Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement, *Argentina-Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*, WT/DS171/3, WT/DS196/4 (June 20, 2002); Request for Consultations by the United States, *Argentina-Certain Measures on the Protection of Patents and Test Data*, WT/DS196/1 (June 6, 2000); Request for Consultations by the United States, *Argentina-Patent Protection of Pharmaceuticals and Test Data Protection For Agricultural Chemicals*, WT/DS/171/1, (May 10, 1999). *See also* Hernan L. Bentolila, *Lessons from the United States Trade Policies to Convert a "Pirate": The Case of Pharmaceutical Patents in Argentina*, 5 YALE J. L. & TECH. 57 (2002–03), *available at* http://research.yale.edu/lawmeme/yjolt/files/20022003 Issue/Bentolila.pdf. (discussing unilateral actions taken by the United States to force Argentina to adopt patent protection beyond what was required under TRIPS).

219. *See, e.g.*, Office of the United States Trade Representative, The Work of USTR—Intellectual Property, http://www.ustr.gov/Trade_Sectors/Intellectual_Property/The_Work_of_USTR_-_Intellectual_Property.html (last visited March 6, 2006). *See generally* SELL, *supra* note 1.

220. Indeed, this was one reason that developing countries sought the Doha Public Health Declaration to clarify that they could utilize compulsory licensing for public health crises, such as the AIDS epidemics. *See* Proposal by the African Group, et al., ¶ 10, WT/GC/W/450 (Oct. 4, 2001).

221. The de facto dominance raises issues beyond the present focus of reconciling patent rights and competing rights under the CBD and human rights norms. In particular, to the extent that TRIPS obligations are considered to have been negotiated as an international contract, the de facto dominance challenges the presumption that the end result is one that was properly bargained for. *See generally* Peter M. Gerhart, *Why Lawmaking for Global Intellectual Property is Unbalanced*, 22 EUR. INTELL. PROP. REV. 309 (2000) (suggesting that TRIPS can be conceived as either a contract that exchanged acceptance of TRIPS for market access and limits on the use of unilateral threats by industrial countries, or as a complete result of coercion by the United States). There is widespread scholarship documenting the resistance of developing countries to adopting TRIPS—even before it became the de facto dominant international agreement. *See, e.g.*, Abdulqawi A. Yusuf, *TRIPs: Background, Principles and General Provisions*, *in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 3, 8–10 (Carlos M. Correa & A. A. Yusuf eds., 1998) (describing genesis of TRIPS as initiated by developed countries).

subject to explicit review, Article 27(3), to raise the issue of TRIPS's dominance over the CBD, although as initially contemplated, the review probably did not include this issue. Even though initial proposals were met with resistance from Western countries, with responses ranging from the inappropriateness of addressing biopiracy as beyond the proper scope of review to comments on the impracticability of the proposals,[222] developing countries continued to press their proposals. At the Doha Round in 2001, the Ministerial Declaration explicitly recognized this issue and charged the Council of TRIPS, the organizational body (open to all WTO members) responsible for administering TRIPS,[223] "to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity" with respect to "the protection of traditional knowledge and folklore . . ."[224] This charge expressly noted that the perspective of developing countries, the "development dimension," should be considered.[225] The TRIPS Council has yet to act on this, but developing countries have continued to press their agenda with further communications that provide more details concerning proposals to alleviate the biopiracy problem.[226] Unfortunately, present proposals by developing countries have a number of issues that prevent their global acceptance, as further explained in the next section.

222. *See, e.g.*, Communication from United States, *Review of the Provisions of Article 27.3(b)*, IP/C/W/162 (October 29, 1999).

223. TRIPS, Marrakesh Agreement, *supra* note 2, at art. 68.

224. Doha Ministerial Declaration, *supra* note 82, ¶ 19. "In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension." *Id.*

225. *Id.*

226. In an attempt to further assist the process, several countries provided a checklist of issues to help facilitate a "more focused, structured and result oriented discussions." Submission by Brazil et al., *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD): Checklist of Issues*, at 1, IP/C/W/420 (March 2, 2004). Developing countries have continued to make proposals, as well as rebut objections of other countries. *See, e.g.*, Submission from India et al., *The Relationship Between the TRIPS agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge—Elements of the Obligation to Disclose Evidence of Benefit-sharing Under the Relevant National Regime*, IP/C/W/442 (March 18, 2005); Submission by Brazil et al., *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge—Technical Observations on U.S. Submission, IP/C/W/449*, IP/C/W/459 (Nov. 18, 2005).

III. THE FALLACY OF PRESENT INTERNATIONAL PROPOSALS

Although the dominance of TRIPS over competing international agreements and norms has made it an obvious focal point for discussion as well as proposed solutions,[227] there is a need to seriously evaluate whether TRIPS can, in fact, deliver. This section analyzes present proposals to amend TRIPS with an eye towards the feasibility of such proposals. In addition, because discussion has moved beyond the WTO/TRIPS forum, this section also considers the implications of the forum-shifting discussion on the resolution of the tension between patent rights and traditional knowledge.

A. Present Proposals to Amend TRIPS

Developing countries have been primarily proposing two specific amendments to the patent requirements under TRIPS in order to address the perceived biopiracy problem.[228] The proposals would make patent rights contingent on compliance with new requirements designed to ensure that CBD goals are satisfied.[229] An

227. *See, e.g.*, Joint Communication from the African Group, *Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement*, at 2, IP/C/W/404 (June 26, 2003) ("any protection of genetic resources and traditional knowledge will not be effective unless and until international mechanisms are found and established within the framework of the TRIPS Agreement.").

228. Most recently, a group of developing countries have suggested that evidence of benefit-sharing be demonstrated in patent applications. Submission from Bolivia, et al., *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge—Elements of the Obligation to Disclose Evidence of Benefit-Sharing Under the Relevant National Regime*, IP/C/W/442 (Mar. 18, 2005). This is the third major issue from the previously issued March 2004 checklist of topics for consideration by the WTO/TRIPS Council. *Id.* at 1.

229. *See, e.g.*, IP/C/W/403, *supra* note 197, at 1 (June 24, 2003); IP/C/W/356, *supra* note 194, at 5. Developing countries have suggested that applications not be processed if either requirement is not satisfied. Submission from Bolivia, et al., *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge-Elements of the Obligation to Disclose Evidence of Prior Informed Consent Under the Relevant National Regime*, at 4, IP/C/W/438 (Dec. 10, 2004). In addition, they have suggested patent-based, as well as criminal and administrative penalties if noncompliance is not discovered until after patent issuance. Submission from Brazil et al., *Elements of the Obligation To Disclose the Source and Country of Origin of Biological Resources and/or Traditional Knowledge Use in an Invention*, at 4, IP/C/W/429/Rev.1 (Sept. 27, 2004). For example, patent-based penalties include revocation of the patent or narrowed claims if the patent does not meet the standard requirement of novelty. *Id.* In addition, they have suggested full or partial transfer of rights if the disclosure would have shown that another person or community should have been an inventor. *Id.*

initial requirement is that patent applications that use or are based upon genetic resources or traditional knowledge disclose the source, as well as the country of origin of such resources.[230] A second requirement is that the patent application include evidence of prior informed consent of any materials used from another country and satisfaction of the CBD mandate that access to genetic resources be subject to the prior informed consent of the contracting party providing such resources.[231] The disclosure of origin requirement is suggested as potentially helpful in addressing biopiracy by providing information relevant to prior art while the prior informed consent is seen as facilitating compliance with the CBD.[232] In particular, in some biopiracy cases, prior art was not known to patent examiners until an issued patent was challenged by developing countries; the disclosure of origin is intended to alert patent examiners to the fact that there may be relevant prior art in the noted country.[233] Accordingly, the proposed requirement is suggested to be an improvement over the existing system whereby patents are issued if the patent examiner is not informed of prior art during the examination.[234] Similarly, the informed consent requirement is suggested as mandatory to avoid prior problems with patents issuing based upon the unauthorized use of resources.

Although neither proposed requirement is new to discussion in either the WTO forum or in the broader international community, there is nonetheless notable opposition to the substance of the requirements. There has been a long-standing and substantial discussion about whether a mandatory versus permissive requirement to disclose the country of origin of applications, and a requirement of informed consent, would be compatible with TRIPS obligations.[235] In addition, even assuming the requirements

230. *See, e.g., id.* Some developing countries believe that this requirement would be a "prime candidate to move the discussion forward" as well as an area in which there was a possibility for "convergence of views." *Id.* at 1–2.

231. *See, e.g.*, IP/C/W/438, *supra* note 229.

232. *Id.* at 2.

233. *E.g.*, IP/C/W/429/Rev.1, *supra* note 229.

234. *Id.* at 2. Moreover, it is noted to be similarly useful for challenges to issued patents. *Id.*

235. For example, some have suggested that because TRIPS is a minimum standard agreement, no additional requirements may be imposed. *See, e.g.*, WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Report*, n.236, WIPO/GRTKF/IC/3/17 (June 21, 2002) (noting that the United States believed that a requirement establishing a "substantive requirement of patentability" would be incompatible with TRIPS); NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 153 (2003) (noting that conditions having nothing to do with assessing patentability requirement are probably TRIPS inconsistent); Graham Dutfield, *Sharing the*

were TRIPS compliant, Western countries have also objected to the proposed requirements because they are not sufficiently linked to the claimed subject matter to be relevant to patentability. For example, the disclosure is proposed to be required not only where the genetic resources or traditional knowledge are part of the claimed invention, but also if they were *used* during the process of development, or "facilitate" the development of the invention.[236] Western countries maintain—despite protests from developing countries—that the proposals are unworkable because they are perceived as creating an undue administrative burden on patent offices.[237] Moreover, Western countries suggest that other approaches would be better suited than the proposed amendments. In particular, Western countries suggest contracts for benefit-sharing, as well as an increase in the use of traditional knowledge databases to reduce the possibility of patents being improperly granted.[238] Developing countries have repeatedly rejected such

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Benefits of Biodiversity: Is there a Role for the Patent System?, 5 J. WORLD INTELL. PROP. 899, 921 (2002) (suggesting that it may not be TRIPS compatible to require disclosure of source, although description of the relevant traditional knowledge would likely be compatible); Daniel Gervais, *Traditional Knowledge and Intellectual Property: A TRIPS-Compatible Approach*, 2005 MICH. ST. L. REV. 137, 160–65 (2005) [hereinafter Gervais, *A TRIPS-Compatible Approach*] (suggesting a Doha-type declaration to avoid some of the mentioned TRIPS-compatibility problems); Cynthia Ho, *Disclosure of Origin and Prior Informed Consent for Applications of Intellectual Property Rights Based on Genetic Resources: A Technical Study of Implementation Issues*, ¶¶ 3.1.10–3.1.32, UNEP/CBD/WG-ABS/2/INF/2 (Sept. 29, 2003) (*prepared for* the Convention on Biological Diversity), *available at* http://www.biodiv.org/doc/meetings/abs/abswg-02/information/abswg-02-inf-02-en.pdf [hereinafter Ho, *Disclosure of Origin*] (suggesting that some variations would have TRIPS compliance problems); Jens Schovsbo, *The Disclosure of the Origin of Components of Biotechnological Inventions in Relation to the Implementation of the Convention on Biological Diversity, prepared for the Norway Ministry of Foreign Affairs*, ¶¶ 3.3.1–3.3.3 (2000), *available at* http://odin.dep.no/ud/norsk/tema/handelspolitikk/032121-220011/dok-bu.html (concluding that mandating disclosure of origin as a requirement would be impermissible with TRIPS Article 27, but that a permissive requirement could be consistent with TRIPS Article 29); Memorandum from Joshua Sarnoff to Stephen Price (June 23, 2004), *available at* http://www.piipa.org/DOO_Memo.doc (arguing that a requirement would be TRIPS compatible). While it is possible that a voluntary requirement would be consistent, that is not the type of requirement favored by developing countries. In addition, there is another argument that compliance with TRIPS is possible if the requirements were construed not as requirements of patentability under TRIPS Articles 27–29, but, rather, as procedural requirements necessary to obtain patents under TRIPS Article 62.1. *See* Schovsbo, *supra*, ¶ 3.3.2; Ho, *supra*, ¶¶ 3.1.15–3.1.23.

236. *See, e.g.*, IP/C/W/429/Rev.1, *supra* note 229, at 3. In addition, the disclosure is also considered relevant if the resources are "necessary" either as background to development of the invention, or a "prerequisite for the development of the invention." *Id.*

237. *See, e.g.*, IP/C/W/449, *supra* note 198, ¶¶ 36–38 (suggesting that developing countries have not mitigated the concern that the proposed requirements would be unduly burdensome).

238. *See, e.g.*, *supra* note 198. *See generally* Communication from the United States, *Views of the United States on the Relationship Between the Convention on Biological Diversity and the TRIPS Agreement*, IP/C/W/257 (June 13, 2001).

alternatives as inadequate because of the lack of uniformity and enforceability associated with any solution beyond TRIPS.[239] Moreover, developing countries suggest that while contracts and databases may be useful adjuncts to their proposed amendments to TRIPS, they are incomplete solutions.[240]

1. Bleak Prospects for any amendment to TRIPS—Even if the substantive objections to the proposals could be overcome, effectuating amendments within the WTO in general, and for combating biopiracy in particular, are highly unlikely. First, for TRIPS to be changed, there must be substantial agreement by member states since two thirds of member states must generally agree.[241] In addition, politics may stall action by the WTO Council and before member states formally adopt an amendment; for example, in the single instance where the WTO Council adopted an amendment, the action took place on the eve of a WTO ministerial meeting and after years of negotiations.[242] There is also the political reality implicated by the dominance of the TRIPS agreement. In particular, because the TRIPS provisions largely reflect the existing laws, as well as interests of Western countries, such countries have no incentive to alter them.[243] Unlike prior attempts to achieve in-

239. *See, e.g.*, IP/C/W/404, *supra* note 227, at 2 (noting that contracts and databases can only be supplementary aids to an explicit obligation within the TRIPS agreement); IP/C/W/403, *supra* note 197, at 5.

240. *See, e.g.*, IP/C/W/403, *supra* note 197, at 5 (noting that databases alone are an incomplete solution because documentation is an ongoing and costly process that will inevitably fail to completely document the "vast breadth and depth" of traditional knowledge in each relevant country and that contracts are also ineffective because of vastly unequal bargaining strengths). Developing countries also have reservations about using a database to document traditional knowledge because it might put sacred knowledge into the public domain that is currently only known to a small number of people. A widely available database is feared to potentially result in greater use of traditional knowledge, which would be contrary to their desires. IP/C/W/403, *supra* note 197, at 5. Even if patent examiners all had access to the database and could verify whether inventions were based upon traditional knowledge, because of the difference of opinion between developing and Western countries with respect to whether inventions *based upon* traditional knowledge are properly patentable, a database might only increase the number of patents considered inappropriate to developing countries.

241. Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 33 I.L.M. 1125, 1149, at art. X(1) (1994); *see also* Gervais, *A TRIPS-Compatible Approach*, *supra* note 235, at 139 (noting that while TRIPS may be vulnerable to criticism, the prospect of actual amendment is slim and likely to take years to negotiate—let alone one that would satisfy "every need and concern of holders of traditional knowledge").

242. *See* WTO, *Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the DOHA Declaration on the TRIPS Agreement and Public Health*, IP/C/41 (Dec. 6, 2005); Tove Gerhardsen, *WTO Strikes Agreement on TRIPS and Public Health on Eve of Ministerial*, INTELL. PROP. WATCH, June 12, 2005, http://www.ip-watch.org/weblog/index.php?p=168&res=1024&print=0.

243. This is particularly true because WTO panels have primarily taken a very literal reading of TRIPS, resulting in affirmation of strong patent rights. *See, e.g.*, Jacques Werner,

ternational agreement on intellectual property rights, it is widely noted that TRIPS could not have been concluded but for the ability to leverage other parts of the WTO in a "package deal."[244] Now that negotiations on the WTO as well as side agreements such as TRIPS are concluded, developing countries are left with no bargaining power to uproot the status quo.

The dim prospects for an amendment are underscored by the single amendment adopted by the WTO Council after years of protracted discussion that remains to be ratified by member countries. The pending amendment involves an exception to one of the current procedural requirements under TRIPS Article 31 regarding compulsory licensing. Under Article 31, a government may grant a third party the right to make, use, or sell the patented invention without permission from the patent owner, as an exception to the typical patent rights.[245] Often, this enables a country to promote generic production of patented drugs. To prevent the exception from entirely swallowing the typical patent right, there are several procedural requirements specified,[246] one of which includes a requirement that the use be predominantly domestic.[247] For example, the domestic use restriction would prevent India, which has adequate manufacturing capacity, from producing inexpensive

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The TRIPS Agreement under the Scrutiny of the WTO Dispute Settlement System: The Case of Patent Protection for Pharmaceutical and Agricultural Chemical Products in India, 1 J. WORLD INTELL. PROP. RIGHTS 309 (1998) (noting a very strict textual approach of the parties). *But see* Ghosh, *Traditional Knowledge Debate*, *supra* note 90, at 502 (suggesting that literal reading of TRIPS language could enable interpretation of other provisions of TRIPS that provide flexibility, including the possible creation of a sui generis or other regime to protect traditional knowledge).

244. *See, e.g.*, CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES 11 (2000) (noting that developing countries believed that by signing onto WTO and TRIPS, they could avoid unilateral actions by developed countries); Gervais, *A TRIPS-Compatible Approach*, *supra* note 235, at 161 (noting that TRIPS was a "package deal"). *See also* JAYSHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 11–47 (2001) (providing a detailed discussion of the negotiation of TRIPS and emphasizing the importance of the uniform position of the North versus the relatively divided position of Southern countries); Gana, *The Myth of Development*, *supra* note 139, at 334 ("[T]he TRIPS Agreement accomplishes, through the potential threat of economic ostracism, what could not be accomplished through negotiations independent of the international economic framework.").

245. TRIPS, Marrakesh Agreement, *supra* note 2, at art. 31. *See also id.* at art. 29 (providing a right to exclude others from making, using, selling, offering to sell, or importing the patented invention).

246. For example, compulsory license must be negotiated for a specific use, reasonable compensation must be provided, and the license must be limited in time. *See id.* at arts. 31(c), 31(f), 31(h). In addition, in case of emergencies, the patent owner must first be contacted to try to negotiate a voluntary license. *Id.* at art. 31(b). Even if this is not possible, the patent owner is to be contacted as soon as possible about the license. *Id.*

247. *Id.* at art. 31(f) ("[A]ny such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.").

antiretroviral drugs for export to other countries. Moreover, countries such as those in sub-Saharan Africa could not effectively utilize the compulsory licensing provision because although they could legally authorize a third party to make the patented compound without consent of the patent owner, they have no domestic company with adequate manufacturing capacity to take advantage of such authorization. Most parties agreed that TRIPS did not intend for sub-Saharan Africa to be deprived of AIDS drugs because of their lack of domestic manufacturing capacity; rather, the prevailing belief was that the negotiators of TRIPS did not contemplate such a situation. Accordingly, after the problem surfaced and public opinion turned against such a clearly inequitable law, member states at the Doha Ministerial Conference unanimously agreed in 2001 that the WTO Council should expeditiously work towards a solution, as stated in the Doha Public Health Declaration.[248] The WTO Council first provided a solution in 2003, in the form of a waiver of some of the requirements of TRIPS article 31, to be effective until transformed into an official amendment of TRIPS, but because of continued opposition by some countries, adoption of the amendment by the WTO Council was stalled until December 2005, and will nonetheless not become effective until official ratification by member states, with a hopeful target date of December 2007—long after the initially targeted date of 2004.[249]

The broader context of the Doha Public Health Declaration shows not only the difficulties of effectuating amendment, or even clarification of TRIPS terms, but also the importance of issue-framing. Developing countries had long been concerned about maintaining adequate flexibility to address domestic issues under TRIPS.[250] In the months immediately prior to the Doha Public

248. WTO, *Ministerial Declaration on the TRIPS Agreement and Public Health*, ¶ 6, WT/MIN/(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha Public Health Declaration].

249. *See* General Council Decision of 30 August 2003, *Implementation of Paragraph 6 of the DOHA Declaration on the TRIPS Agreement and Public Health*, ¶ 11, WT/L/540 (Sept. 2 2003) ("This decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member"). Moreover, the Decision explicitly contemplated that an amendment be adopted during 2004. *See id.*

250. Developing countries believed that the policy statements in Articles 7 and 8 would more broadly enable them to foster their own social policy concerns. *See, e.g.*, Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, ¶ 5.17, WT/DS114/R (Mar. 17, 2000) [hereinafter Canada—Generic Drugs] (noting Columbia's assertion that the preamble to TRIPS indicates that WTO members must respect national legislation "designed to achieve a public policy objective"); IP/C/W/195, *supra* note 192, ¶¶ 3, 8, 14–16 (suggesting that the preamble of TRIPS, as well as Articles 7 and 8 are relevant to requiring TRIPS be amended to require disclosure of the country of origin for inventions based upon biological materials); *see also* Jerome Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement*, 29 INT'L LAWYER 2 (1995) (suggesting that

Health Declaration, developing countries expressed particular concern that because of pressure from Western countries, they would not be able to utilize some of the built-in TRIPS flexibilities, such as compulsory licensing of patented drugs to address national AIDS epidemics.[251] Despite global acknowledgement of a serious health crisis, there was not a general consensus concerning the role of patents or TRIPS. Patent proponents initially suggested that other issues, such as inadequate health care infrastructure, were primarily to blame.[252] However, an increasingly successful public campaign by NGOs, as well as the WHO and the UN, helped to frame the issue as a matter concerning the right to health.[253] Such framing made the issue difficult to deny.

Nonetheless, effective issue-framing alone may not be enough to create the impetus for change. For example, although access to life-saving antiretroviral drugs seemed a compelling issue, this was not the sole cause of consensus behind the Doha Public Health Declaration. Rather, Western countries that had previously been resistant to acknowledging a problem were able to view the situation in a different light after facing their own potential national health care crises. In particular, the United States and Canada had a different perspective about the need for nations to utilize compulsory licensing in the case of national emergencies when they were confronted with potential anthrax crises if stockpiles of the patented antibiotic Cipro could not be secured.[254] Although TRIPS

Articles 7 and 8 could provide developing countries with "a considerable degree of domestic control over intellectual property policies").

251. Indeed, the draft declaration that developing countries proposed prior to the Ministerial conference suggested that members

> shall, within or beyond the framework of the WTO, refrain from imposing or threatening to impose sanctions and refrain from employing the grant of incentives or other benefits in a manner which could curtail the ability of developing and least-developed country Members to avail themselves of every possible policy option to protect and promote public health.

WT/GC/W/450, *supra* note 220, ¶ 10. In addition, the draft preamble specifically alluded to unilateral action by Western countries. *See id.*, pmbl. ("*[A]cknowledging* the vulnerability of developing and least-developed country Members to the imposition or the threat of sanctions and to the prospect of being deprived of incentives or other benefits, including those imposed or offered, as the case may be, *beyond the framework of the WTO.*") (emphasis added).

252. *See, e.g.*, Amir Attarran & Lee Gillespie-White, *Do Patents on Antiretrovirals Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886, 1890–91 (Oct. 17, 2001).

253. *See, e.g.*, SELL, *supra* note 1, at 52, 146–50.

254. *See, e.g.*, Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT'L & COMP. L. REV. 613, 624–25 (2004) (noting that negotiations "took a sharp turn in the wake of the anthrax scare in the United States" such that the "prospects for a pro-public health TRIPS accord soared," resulting in unanimous approval of the Doha declaration);

permits such action in the event of a "national emergency," the prior Western position was that sub-Saharan Africa and other countries with AIDS epidemics did not face a sufficient emergency that would enable them to avoid initial negotiations. The United States and Canada were accused of hypocrisy for precluding other nations from utilizing compulsory licensing in the face of epidemics that threatened to decimate entire populations while giving no thought to use of the same measure when a handful of North American citizens were at risk.[255] The Doha Public Health Declaration was concluded in the wake of this international ridicule.

Beyond the utility of fortuitous circumstances and hypocrisy, a broader lesson is that an important component of modifying Western mindsets is framing the problem in a manner that is analogous to Western problems to secure Western sympathies. Until Western nations faced their own health crises, they readily dismissed the concerns of other nations in favor of the familiar mantra by Western drug companies that strong patent rights are essential to promoting innovation. The ability to challenge a perspective that is inclined towards the pharmaceutical industry may prove particularly challenging in the case of biopiracy allegations since the conflict between patent rights and the protection of traditional knowledge involves the valuation of spiritual and cultural values—values that have no value in Western countries, or at least not within current patent frameworks—above commercialization and promotion of innovation. This is an important challenge for fram-

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Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 42–43 (2002) (noting that the anthrax scare, threatened shortage of Cipro, and the effectiveness of developing countries, in conjunction with an active international NGO movement helped to make the Doha Declaration possible); *see also* Dan Ackman, *A New Deal on Cipro*, FORBES, Oct. 24, 2001, http://www.forbes.com/2001/10/24/1024topnews_print.html (noting that Canada initially issued a compulsory license for Cipro, but later negotiated an agreement with the patent holder); Emma Young, *US Accused of Double Standards on Drug Patents*, NEW SCIENTIST, Nov. 2, 2001, http://www.newscientist.com/article.ns?id=dn1512 (noting a number of contributing factors to the United States' shift in position, including that India and Brazil threatened to block further WTO trade talks without concessions on access to medicine, that the French trade secretary accused the U.S. of double standards, and that even some U.S. senators suggested that the government should permit compulsory licensing of the Cipro patent, in direct contravention to the U.S. position for other countries).

255. *See, e.g.*, Paul Blustein, *Drug Patent Dispute Poses Trade Threat; Generics Fight Could Derail WTO Accord*, WASH. POST, Oct. 26, 2001, at E1 (noting the global implications of the Cipro patent fight, including WTO negotiations scheduled to take place at Doha); Sarah Bosely, *Drug Dealing*, GUARDIAN, Oct. 24, 2001, at 2, http://www.guardian.co.uk/Archive/Article/0,4273,4283652,00.html (comparing the two anthrax deaths to the thousands of daily deaths in Africa from HIV in context of U.S. hypocrisy in enforcing patents in developing countries, such as Thailand and South Africa); Geoff Dyer & Adrian Michaels, *A Bitter Pill for the Drug Makers*, FIN. TIMES, Oct. 23, 2001, at 27 (noting a double standard between U.S. action concerning Cipro versus action against South Africa and Brazil).

ing realistic solutions to address biopiracy, as is later discussed in more detail. However, before considering new approaches, it is helpful to first understand how poor and incomplete issue-framing is hampering the present proposals to amend TRIPS. This is helpful to not only understand the current stalemate in negotiations, but also important in considering realistic ways forward.

2. Past Problems with Issue Framing—The present proposals to amend TRIPS, as well as the related communications explaining such proposals, illustrate the difficulties of issue framing within the context of TRIPS. This section shows how the developing country proposals to amend TRIPS are insufficiently analogous to Western problems to elicit Western support. Some of the efforts at first glance seem to invoke Western values, but ultimately display a lack of understanding as they advocate solutions that are inconsistent with intransigent Western beliefs about the scope of patent law, or are inconsistent with TRIPS.

The suggestion to require patent applicants to disclose the origin of an invention based on prior art needs is a close, but ultimately incomplete framing of the biopiracy problem within Western values. Developing countries have suggested that a mandatory disclosure of an invention's origin is necessary to ensure all relevant prior art is available to patent examiners.[256] Prior art[257] is a fundamental concept in Western patent law since patents are only to be granted if no prior art exists for the same invention.[258] However, while the proposal appropriately used this important patent term, its explanation did not illustrate how it would improve prior art. In particular, rather than focus on prior art that would invalidate patents in all countries, developing countries noted that the origin of an invention would be helpful in determining whether an invention should be unpatentable as contrary to "*ordre public* or morality."[259] Although possibly true, the ambiguous TRIPS exception

256. IP/C/W/429/Rev.1, *supra* note 229, ¶¶°3–6. In addition, it is suggested that such information would continue to be useful after the issuance of a patent for challenges to patents, as well as infringement cases.

257. As defined by WIPO, "prior art is generally understood to constitute the body of knowledge which was available to the public before the filing date" of a patent application. WIPO Standing Committee on the Law of Patents, *Suggestions for the Further Development of International Patent Law*, ¶¶ 11–13, WIPO Doc. SCP/4/2 (Sept. 25, 2000).

258. *Id.* ¶ 11 (noting that "[i]dentifying the relevant prior art is one of the cornerstones of patent examination" because it determines whether an invention satisfies the novelty and inventive step requirement and continues to be relevant after the grant of the patent with respect to its validity).

259. *See, e.g.* IP/C/W/429/Rev.1, *supra* note 229, ¶ 13 (suggesting that disclosure of source would be useful in determining whether claimed inventions are excluded under paragraphs 2 and 3 of TRIPS Article 27). Similarly, the suggestion that the existing TRIPS exception to patentable subject matter based upon *ordre public* and morality is "meaningless,"

that permits, but does not require countries to decline to patent inventions that are contrary to "ordre public or morality" is one that is merely an *option* and not all countries need to have such an exclusion in their laws.[260] Because it is only optional, the proposal of developing countries may be of little utility for Western countries that do not have such an exclusion from patentability. Moreover, an issue with morality is not relevant to prior art.

Accordingly, it is perhaps not surprising that Western countries have countered that the proposal merely provides information largely irrelevant to prior art.[261]

Similarly, framing the proposed disclosures as similar to existing Western patent disclosure requirements ultimately fails because the proposals are not sufficiently identical to be embraced by the existing structure. In particular, developing countries have suggested that the proposed amendments should be adopted because "disclosure requirements of various types are already an accepted norm in international patent law practice."[262] Indeed, TRIPS does require that an application adequately describe an invention to others of similar skill and also explicitly allows for certain other types of disclosures.[263] On the other hand, none of the listed disclosure requirements under TRIPS required Western countries to modify their laws. In addition, TRIPS expressly contemplated different disclosure obligations amongst member states. For example, TRIPS expressly notes that disclosure of the best mode of carrying out an invention known to the applicant may be required by national law, but TRIPS does not mandate such a requirement.[264]

The attempt to frame this as similar to other disclosures may overlook the important fact that all of the other noted disclosures

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without explicit clarification that the objectionable subject matter may be excluded, is not only likely to be dismissed, but also considered an incomplete understanding of patent law. *See* IP/C/W/404, *supra* note 227, at 2.

260. TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27(2). In addition, even assuming the proposal had cited the patent provisions that must be adopted by all countries, such as the requirement that an invention be new, the proposal is still incomplete in its failure to consider varying definitions of what constitutes "new" or even what constitutes prior art. Notably, the origin of an invention would not necessarily be relevant to prior art in the United States because the United States does not consider undocumented knowledge outside its borders to constitute prior art. *See, e.g.*, 35 U.S.C. § 102(a)–(b) (2000).

261. *See, e.g.*, IP/C/W/434, *supra* note 198, ¶ 13; IP/C/W/449, *supra* note 198, ¶ 30.

262. IP/C/W/429/Rev.1, *supra* note 229, ¶ 5. In addition, it is broadly noted that "there are a number of other disclosure requirements including disclosure of best mode." *Id.* ¶ 9. In the same breadth, it is also noted that there are a number of members that require disclosure of source and country of origin of biological resources and/or traditional knowledge. *Id.* What is unstated is that these members do not include any of the current opponents to including a mandatory requirement.

263. *See* TRIPS, Marrakesh Agreement, *supra* note 2, at art. 29.

264. *See id.*

under TRIPS—either required or permitted—are directly related to patentability. In contrast, several aspects of the proposed disclosure requirements would not be immediately relevant to patentability, although they might assist with benefit-sharing of subsequent commercial resources if a patent were granted.

Some attempts to frame the biopiracy issue might fail immediately because they directly contradict deeply held Western beliefs concerning the appropriate realm of patent law by suggesting that TRIPS should accommodate and promote social norms outside the patent system. For example, some countries have asserted that that the patent requirements under TRIPS result in misappropriation of their genetic resources or traditional knowledge.[265] However, there is a strong difference of opinion with regard to whether patent law (and TRIPS) should be responsible for regulating other issues. Developing countries strongly believe that TRIPS should assist in the promotion of CBD norms; in particular, they have asserted that protection of genetic resources and traditional knowledge should be acknowledged as a matter of equity to enable preserving "the invaluable heritage of humankind that biological diversity and traditional knowledge constitute."[266] Western countries, on the other hand, are accustomed to patent laws operating exclusive of regulatory measures, such as measures to protect health and safety or the environment.[267] For example, the United States has noted that "[p]atent law was not designed to regulate or enforce misconduct issues, such as misappropriation of traditional knowledge or genetic resources, but to promote the progress of the useful arts."[268] Accordingly, attempts to rely on basic principles of "equity" in intellectual property law to address biopiracy[269] fail

265. For example, one communication/proposal stated that "the TRIPS Agreement . . . has not provided adequate and equitable means to prevent patents mainly in developed Members that have amounted to and resulted in the misappropriation of genetic resources and traditional knowledge mainly from developing Members." IP/C/W/404, *supra* note 227, at 2. *See also* IP/C/W/420, *supra* note 226, at 1 (noting that a solution under TRIPS is required to prevent misappropriation and support CBD objectives).

266. IP/C/W/404, *supra* note 227, at 1–2 (suggesting that member states should be entitled to honor their public policy goals of food security, nutrition, and elimination of poverty, with the implication that mandating protection of plant varieties would be contrary to such goals).

267. IP/C/W/434, *supra* note 198, ¶ 25. However, none of the cited regulatory schemes involve a situation where a patent is considered to commodify something sacred.

268. *Id.*

269. Developing countries cite Article 7 as suggesting that intellectual property rights should promote "all sections of society." In particular, the argument is that because of equity, granting patents tainted by biopiracy should be improper. IP/C/W/438, *supra* note 229, ¶ 5. A closely related argument to general equity under intellectual property laws is that the proposed new requirements would be analogous to the established patent law doctrine of inequitable conduct. IP/C/W/403, *supra* note 197, at 4. Although disclosure of origin of

because Western countries easily retort that TRIPS is intended to primarily address patent requirements and that the current patent rules reflect a "delicately balanced patent system" that already takes into account social policy.[270] For example, Western countries repeatedly note that statements in TRIPS Article 8 concerning the consideration of social policies beyond patent law is qualified by the caveat that such social policy measures are only permissible "provided that such measures are *consistent* with the provisions of the Agreement."[271] Moreover, broader statements in proposals that stress the potential for the proposed disclosures to enhance the credibility of the patent system by "contributing to the realization of the stated principles and objectives of TRIPS"[272] are similarly rejected by those who believe the present system is already credible.

In addition, some proposals may be doomed because they raise issues beyond biopiracy that resurrect intransigent issues of prior disagreement between developing and Western countries. For example, one communication that attempted to explain a proposal to amend TRIPS simultaneously criticized patents on "life forms" as unethical, such that they should be precluded from patentability.[273] The criticism is a reference to TRIPS Article 27(3)(b), which

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biological resources is not presently a requirement, some proposals suggest that a corollary of such a requirement would be that failure to comply would have the same consequence, i.e. revocation or unenforceability of a patent. Although disclosure of origin of biological resources is not presently a requirement, some proposals suggest that a corollary of such a requirement would be that failure to comply could result in revocation or unenforceability of a patent. *See* WIPO Intergovernmental Committee On Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore, *Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge*, ¶¶ 149–50, WIPO/GRTKF/IC/5/10 (May 2, 2003) (providing a range of potential consequences, including refusal to grant an application, as well as subsequent invalidation of a patent). Moreover, reliance on the inequitable conduct doctrine itself may be shaky in light of the recent suggestion that the doctrine is overbroad and should potentially be abandoned. *See* NAT'L RESEARCH COUNCIL, *supra* note 147, at 121–23 (proposing elimination of inequitable conduct defense as one possible method of reducing patent litigation costs).

270. IP/C/W/434, *supra* note 198, ¶ 3.

271. *See, e.g.*, Assafa Endeshaw, *The Paradox of Intellectual Property Lawmaking in the New Millennium: Universal Templates as Terms of Surrender for Non-industrial Nations; Piracy as an Offshoot*, 10 CARDOZO J. INT'L & COMP. L. 47, 63 (2002) (suggesting that it would be naïve to think that the language in Article 8 could be interpreted in favor of non-industrialized countries when the enactment of TRIPS itself was forced upon them).

272. IP/C/W/438, *supra* note 229, ¶ 6; *see also* IP/C/W/429/Rev.1, *supra* note 229, at 3 (noting that existing patent laws on disclosure are broadly intended to ensure the quality of patents, as well as to ensure transparency, such that these same goals would be enhanced by an obligation to disclose the source).

273. *See* IP/C/W/404, *supra* note 227, at 2 (noting that because "[p]atents on life forms are unethical," and "contrary to the moral and cultural norms of many societies in Members of the WTO," TRIPS should prohibit them). Moreover, this issue may have been particularly inflammatory because it suggests that the present exception within TRIPS to exclude patents that violate morality is "meaningless" unless patents on life forms are prohibited. *Id.*

requires that animals beyond micro-organisms be patentable.[274] There are a significant number of developing countries who maintain that patents on "life" are inappropriate. However, this is an uphill battle against an existing TRIPS provision that requires the contrary. The issue of whether higher life forms should be patentable was a contentious issue at the time TRIPS was negotiated, such that negotiators of TRIPS agreed to review the provision four years after TRIPS was concluded as a means to reach sufficient consensus.[275] The provision has been reviewed since then but the divide between Western and developing countries has only grown—Western countries want to eliminate exclusions from patentability while developing countries want to scale back the existing provisions.[276] Accordingly, language that resurrects this contentious issue is likely to resurrect conflict, rather than consensus.

B. Competing Forums and Focus

The possibility of implementing change within the TRIPS/WTO forum seems increasingly remote if the dominant players can—and are—moving to other forums to enact ever-increasing standards of intellectual property. In particular, although countries continue to discuss the issue of inappropriate access to genetic resources and traditional knowledge within the WTO, those arguments form an incomplete picture in light of other international negotiations and agreements. First, the US, EU, and to a lesser extent Japan, have been quietly enacting bilateral and multilateral trade agreements that mandate standards of patent protection beyond TRIPS in what are called "TRIPS-plus" agreements.[277] Moreover, the draft Substantive Patent Law Treaty (SPLT), which is currently being discussed

274. TRIPS, Marrakesh Agreement, supra note 2, at art. 27(3)(b).

275. *See, e.g.*, TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27(3)(b).

276. *See, e.g.*, GERVAIS, *supra* note 99, at 227–32. Indeed, the discussions concerning the review of Article 27(3)(b) have been described as "among the 'most controversial' in the work of the TRIPS Council." *Id.*

277. FTAs negotiated by the United States are available at the Office of the United States Trade Representative [USTR] Homepage, http://www.ustr.gov. *See also* GRAIN, TRIPS plus Bilateral Agreements, http://www.grain.org/brl/?typeid=15 (on file with the University of Michigan Journal of Law Reform) (providing an alphabetical list of TRIPS-plus agreements). In addition to trade agreements, bilateral investment agreements have also been enacted that condition trade on the level of intellectual property protection. *See, e.g.*, CARLOS M. CORREA, GRAIN, BILATERAL INVESTMENT AGREEMENTS: AGENTS OF NEW GLOBAL STANDARDS FOR THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS? (2004), http://www.grain.org/briefings_files/correa-bits-august-2004.pdf.

under the auspices of WIPO, is a TRIPS-plus agreement with broader reach than any of the prior free trade agreements because it is aimed at establishing uniform patent standards for a much broader scope of countries than any of the prior free trade agreements.[278]

Developing countries have tried to utilize the draft SPLT negotiation as an opportunity to initiate discussions and specific proposals to address biopiracy. For example, Article 2 of the draft, entitled "General Principles and Exceptions," states that "[n]othing in this Treaty . . . shall limit the freedom of a Contracting Party to take any action it deems necessary for the preservation of essential security interests or to comply with international obligations, including those relating to the protection of genetic resources, biological diversities, traditional knowledge and the environment."[279] Similarly, Articles 13 and 14 include language that explicitly supports an enhanced disclosure requirement under national patent law; "A contracting party may also *require compliance with the applicable law on* public health, nutrition, ethics in scientific research, environment, *access to genetic resources, protection of traditional knowledge* and other areas of public interest in sectors of vital importance for their social, economic and technological development."[280]

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278. See *e.g.*, WIPO Standing Committee on the Law of Patents, *Study on the Interface between the SPLT, the PLT and the PCT*, ¶ 13, WIPO Doc. SCP/6/5 (Sept. 24, 2001); WIPO Standing Committee on the Law of Patents, *Draft Substantive Patent Law Treaty*, arts. 3–14, WIPO Doc. SCP/9/2 (Mar. 3, 2003). *See also* GRAIN, *WIPO Moves Toward 'World' Patent System* (July 2002), http://www.grain.org/briefings_files/wipo-patent-2002-en.pdf (noting that if successful, the SPLT "could make . . . TRIPS . . . obsolete" to the extent that TRIPS only provides the minimum, whereas the SPLT "will spell out the top and the bottom line"); Carlos M. Correa & Sisule F. Musungu, *The WIPO Patent Agenda: The Risks for Developing Countries* (South Centre Trade-Related Agenda, Development and Equity Working Papers, Paper No. 12, 2002), *available at* http://www.southcentre.org/publications/wipopatent/wipopatent.pdf.

279. WIPO Standing Committee on the Law of Patents, *Draft Substantive Patent Law Treaty*, art. 2(2), WIPO Doc. SCP/10/2 (Sept. 30, 2003); *see also id.* at art. 2(3) (noting that "[n]othing in this Treaty . . . shall limit the freedom of a Contracting Party to protect public health, nutrition and the environment or to take any action it deems necessary to promote the public interest in sectors of vital importance to its socio-economic, scientific and technological development"). This language was first proposed for inclusion in 2002 by the Dominican Republic and Brazil to ensure sovereign rights to achieve policy goals, "including those whose purpose is the protection of traditional knowledge and genetic resources against unlawful appropriation and biopiracy." WIPO Standing Committee on the Law of Patents, *Proposals by the Delegations of the Dominican Republic and Brazil Concerning Articles 2, 13, and 14 of the Draft Substantive Patent Law Treaty*, Annex I, p. 2, WIPO Doc. SCP/8/5 (Nov. 5, 2002).

280. WIPO Doc. SCP/9/2, *supra* note 278, at arts. 13(2), 14(2) (grounds for refusal or invalidation of a patent). This language was proposed in 2002 to ensure national flexibility. WIPO Doc. SCP/8/5, *supra* note 279, at Annex 1, p. 2.

The suggested SPLT language proposes fairly modest changes to the international landscape. In particular, the language in Article 2 only refers to a particular country's ability to take action to protect its *own* interests, but does not impose any requirements on other members.[281] In addition, the language in Articles 13–14, while stating more detail, is still only a permissive requirement for member states to adopt if they so choose.[282] A permissive requirement is generally believed to be less useful for addressing biopiracy problems.[283]

Despite the lack of legal force behind such proposals, there has still been substantial opposition. Actual substantive discussion of these proposals was tabled from the moment the language was introduced. In particular, the initial draft that included the new language bracketed the text and added a critical footnote at each juncture that stated: "The SCP agreed . . . to include this paragraph . . . but to postpone substantive discussions on this provision."[284] However, in the most current draft, an anticipated date of discussion was eliminated entirely; instead, the footnote merely indicates that substantive discussions have been postponed.[285] In addition, the draft only relates to optional imposition of provisions *outside* the patent system, as clarified by other provisions that explicitly state that "[n]o contracting party may require compliance with any requirement relating to the examination of an application or the grant of a patent on a claimed invention different from or additional to the requirements provided . . . ."[286] In other words, unlike the TRIPS agreements, parties cannot deviate from the patentability requirements such that developing countries could be precluded from modifying their own patent laws to require the disclosures that they are proposing.

Moreover, there have been increasing hurdles to actual discussion of the merits of the developing countries' proposals. In particular, in April 2004, the three dominant countries that issue

281. *Id.* at art. 2. In addition, as seen in the context of the WTO, statements in preambles and general principles are often discounted by other countries as irrelevant to interpretation of treaty requirements.

282. *Id.* at arts. 13–14.

283. Dutfield, *Sharing the Benefits of Biodiversity*, *supra* note 235, at 921 (noting that a mandatory disclosure would be most useful, although expressing concern that it be considered a procedural requirement under TRIPS to ensure compatibility); Cynthia Ho, *Disclosure of Origin*, *supra* note 235, at 17–23 (analyzing TRIPS compatibility problems with a mandatory disclosure requirement).

284. WIPO Doc. SCP/9/2, *supra* note 278, at art. 2, n. 1.

285. *See* WIPO Doc. SCP/10/2, *supra* note 279, at art. 2(2), n.1.

286. *Id.* at art. 13(3); *see also id.* at art. 14(2) (stating that "[n]o Contracting Party may require compliance with any requirement with respect to the grounds for invalidation or revocation of the patented claim or patent additional to or different from those provided").

patents—the United States, Japan, and the European Patent Office—proposed that the upcoming May 2004 meeting on the SPLT should be refocused on a narrower "first package" of issues using a "pragmatic approach aimed at [an] early and realistic result" that would likely "lead to near-term agreement."[287] In particular, the proposal aimed to focus on prior art to the exclusion of the developing countries' proposed language to address protection of traditional knowledge and genetic resources. The stated impetus for this proposal was that "several provisions" in the draft treaty "have been extremely controversial and of a high political sensitivity," such that they consume much of the debate and "hampered the desired progress."[288] In addition, in an attempt to preempt criticism of this approach, the proposal was touted to "improve patent quality and address concerns regarding protection of traditional knowledge," while at the same time setting aside initially "certain contentious issues."[289]

The next meeting of the Standing Committee on the Law of Patents did initially follow the proposed "first package" of issues proposed by the Western countries, although no agreement was reached during the meeting.[290] Western countries noted that they were receptive to discussing the traditional knowledge issue—but that it was not necessary and possibly even improper to discuss within the SPLT context.[291] For example, Japan stressed that recent changes to the Patent Cooperation Treaty (PCT) had alleviated the need for further consideration of this issue[292] and Ireland, speaking

287. WIPO Standing Committee on the Law of Patents, *Proposal from the United States of America, Japan and the European Patent Office Regarding the Substantive Patent Law Treaty*, at 1–2, WIPO Doc. SCP/10/9 (Apr. 22, 2004). *See generally* WIPO Standing Committee on the Law of Patents, *Information on Certain Recent Developments in Relation to the Draft Substantive Patent Law Treaty (SPLT)*, WIPO Doc. SCP/10/8 (Mar. 10, 2004) (noting discussions and proposals for streamlined approach to SPLT issues).

288. WIPO Doc. SCP/10/9, *supra* note 287, at 1.

289. *Id.* at 2.

290. WIPO Standing Committee on the Law of Patents, *Summary By the Chair*, ¶ 45, WIPO Doc. SCP/10/10 (May 14, 2004). According to the summary of the Chair of the Committee, a number of delegations expressed support for the proposal, but others opposed the proposal, "emphasizing the need to consider . . . the interrelationship of those provisions . . . such as the disclosure of the origin of genetic resources and traditional knowledge, public health, patentability criteria and the general exceptions." *Id.* ¶ 7.

291. The Ireland delegation noted that the EU member states have previously noted a willingness "to engage in a positive manner" to reach agreement in discussions on genetic resources and traditional knowledge, but opposed discussing these issues within the SPLT. WIPO Standing Committee on the Law of Patents, *Report*, ¶ 42, WIPO Doc. SCP/10/11 (June 1, 2005) [Hereinafter WIPO, *Report*].

292. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 9 I.L.M. 978. Japan suggested that the object of harmonization should be to "lower costs" for obtaining broad patent protection and that traditional knowledge concerns have "been recently improved"

on behalf of the EU noted that the draft SPLT was simply "not the appropriate context" to consider issues that had the ability to prevent consensus and were "not directly linked to substantive patent law."[293] Developing countries, on the other hand, primarily opposed the proposal[294] and voiced varying degrees of concern about eliminating discussion of protecting genetic resources and traditional knowledge.[295] Egypt and India expressed concern about harmonizing patent standards without simultaneously considering grounds for refusing patent applications based upon protection of genetic resources.[296] In particular, conclusion of an initial package of topics was suggested as necessarily precluding subsequent consideration of the protection of genetic resources and traditional knowledge.[297] The unstated implication is that once Western countries attain the desired patent standards, developing countries are left with no bargaining power to force consideration of the

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under the PCT by incorporating periodicals that relate to such knowledge. WIPO, *Report*, *supra* note 291, ¶¶ 17–18.

293. *Id.* ¶ 42.

294. China stated that it did not oppose a narrowing of scope in principle, but expressed hope that WIPO would take an active and productive role in creating a legal framework for protecting traditional knowledge and genetic resources. In addition, China expressed support for including these provisions within discussion. SCP/10/11 Prov.2, *supra* note 291, at 6; *see also id.* at 8 (noting that India was amenable to a more limited focus *provided* that it included topics of particular interest to developing countries, such as disclosure and other issues connected with genetic resources, traditional knowledge, and folklore).

295. Some countries opposed limiting the scope of discussion, but did not have extensive comments. For example, the South African delegation preferred continuing with the broader framework of the draft SPLT, but that even if there was a reduce scope, it should nonetheless include discussion of traditional knowledge and genetic resources. *Id.* ¶ 40. Similarly, the Delegation of Algeria was opposed to limiting the scope and explicitly noted that doing so would fail to "take account the interests of all concerned in the intellectual property system, including those relating to the protection of genetic resources and traditional knowledge." *Id.* ¶ 31. Other countries were also opposed to limiting the discussion, but not expressly because of traditional knowledge of genetic resource issues. For example, Argentina noted that there was not broad consensus regarding the initial discussion of a draft SPLT on behalf of developing countries to begin with, such that it preferred more comprehensive discussion in the hopes of permitting a balance between patent owners and society. *Id.* ¶ 32. In addition, public health and the general balance of patent owners versus users was noted by a number of representatives. *See, e.g., id.* ¶ 28 (noting that India preferred that the term "users" be broadly construed).

296. *See* WIPO, Standing Comm. on the Law of Patents, 10th Sess., Geneva, May 10 to 14, 2004, *Draft Report*, ¶¶ 26, 28, WIPO Doc. SCP/10/11 Prov. (June 14, 2004) (stating that "it was not possible to harmonize the conditions for novelty and inventive step without taking account of certain general exceptions as grounds for the refusal of an application, in particular provisions for the protection of genetic resources and traditional knowledge"). Similarly, the Russian Federation delegation opposed restricting the scope of discussion because it perceived that many issues were interrelated, without specifically addressing the issue of genetic resources or traditional knowledge. *Id.* ¶ 27.

297. *Id.* ¶ 28.

biopiracy issue.[298] The lack of bargaining power is reminiscent of the problems that developing countries face within the WTO, where their attempts to secure amendments to TRIPS have met with great resistance from primarily Western countries that have no need to modify TRIPS since the existing provisions reflect the interests of Western nations that initiated the negotiation of TRIPS.

Despite continued discussions within both the WTO and WIPO forums, developing countries have not made substantive progress. Developing countries continue to promote proposed amendments to TRIPS that would make patent rights contingent on satisfying CBD norms.[299] However, Western countries continue to oppose an amendment to TRIPS.[300] Similarly, no progress has been made within WIPO discussions on the issue of reconciling TRIPS and the CBD.[301] Accordingly, looking beyond the existing forums of discussion is required.

IV. TOWARDS A TEMPLATE FOR ADDRESSING SOCIO-CULTURAL CONCERNS

This Part provides a multi-faceted approach towards dealing with not only biopiracy problem, but also broader conflicts be-

298. Moreover, some countries, such as Brazil, discussed traditional knowledge within a broader argument concerning the need to consider the rights of users. Brazil noted that because an international treaty was a matter of public, rather than private interest, consideration of the impact of intellectual property rights on users was important, including a broad interpretation of users such that it would protect traditional knowledge and genetic resources. *Id.* ¶ 29.

299. *See generally* IP/C/W/442, *supra* note 228, *passim* (providing detailed description of proposed requirement of evidence of benefit-sharing); Communication from Peru, Article 27.3(b), *Relationship Between the TRIPS Agreement and the CDB, and the Protection of Traditional Knowledge and Folklore, passim*, IP/C/W/447 (Nov. 7, 2005) (supporting TRIPS amendment and providing additional information concerning recent activity in Peru, as well as Andean countries to combat biopiracy); IP/C/W/459, *supra* note 226, *passim* (providing detailed description of proposed requirement of evidence of benefit-sharing).

300. *See, e.g.*, IP/C/W/449, *supra* note 198, at 3–8 (arguing that the proposed amendment is ill-conceived because it would not completely address the articulated problem and that national solutions would be more appropriate). *See generally* Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity: Summary of Issues Raised and Points Made*, IP/C/W/368/Rev. 1 (Feb. 8, 2006) (providing a detailed description of proposed amendment, as well as opposition).

301. *See, e.g., WIPO Genetic Resources, Traditional Knowledge Panel Seeks to Continue Unchanged*, IP-WATCH, July 2005, at 7. *See generally* Communication from United States, *Article 27.3(b), Relationship Between the TRIPS Agreement and the CDB, and the Protection of Traditional Knowledge and Folklore*, IP/C/W/469 (March 13, 2006) (repeating U.S. position that there is no conflict between TRIPS and the CBD, and that the proposed disclosure requirements are an inappropriate solution to achieve objectives outside the patent system).

tween patent law and socio-cultural concerns. First, this Part proposes an alternative framing of the problem around issues of sovereignty, rather than piracy, in hopes of reducing alienation and miscommunication. In addition, what has previously been considered the biopiracy problem of developing countries is reconceptualized as a problem for Western countries to set the stage for reform of global patent laws. Finally, this Part suggests a new method that can adequately deal with a broad range of conflicts arising in patent law, ranging from the biopiracy issues of developing countries, to the frontiers of human cloning.

A. Issue-Framing

The first step towards achieving consensus is to eliminate some of the current dialogue that is impeding substantive communication. This section examines the problems of the piracy label and suggests that it be discarded as an initial step. In addition, this section provides an alternative approach for framing the perceived conflict between patents and traditional knowledge.

1. Biopiracy Issue-Framing—Close, but Not Compelling—The term biopiracy itself can be considered as an initial approach to frame the problem in the Western language of piracy. After all, the piracy concept was highly effective when used by pharmaceutical companies to lobby the United States to accord greater protection for intangible, yet highly valued domestic products.[302] On the other hand, the piracy term has not had the same power in effectuating the interests of developing countries. As discussed earlier, developing countries and their sympathizers have repeatedly characterized the actions and laws of Western governments and corporations as pirating their natural resources and traditional knowledge, most typically by using the label of biopiracy. However, the typical Western reaction is that what is taken—natural resources and information—fails to rise to the level of intellectual property and thus cannot be pirated in the Western sense.[303]

Ironically, the reverse argument was successfully used to lobby the U.S. government to pursue increased international intellectual property laws. Although there is technically no intellectual property infringement in a country that does not have intellectual property laws—for one cannot break a law that does not exist—industry

302. *See supra* note 1 and accompanying text.

303. *See, e.g., supra* Parts I.A, II.A.2.

advocates nonetheless successfully claimed that piracy of intellectual property rights *was* occurring and depriving the U.S. of its just profits.[304] In other words, the piracy argument underlying enactment of TRIPS ignored the strict legal parameters of intellectual property laws.[305]

Understanding why biopiracy claims have been ineffective is important for considering future issue-framing. Although the arguments are analogous, there are important distinctions with respect to structural incentives and power relationships. For example, the U.S. lobbying was backed by intellectual property attorneys as well as economists who alleged that their argument was essential to bolster the national economy.[306] In contrast, accepting the argument of developing countries would have a *negative* implication for Western economy and trade flow.[307] Those who most care about preventing biopiracy are indigenous communities, who by definition are small groups that are often marginalized. These groups are hardly in the position to develop strong lobbying within their national governments, let alone lobby other nations with interests that are likely not similarly aligned. In addition, whereas the piracy argument advanced by corporate interests portrayed the United States as a victim of unsavory activities of other nations, the biopiracy argument implies that the United States and other Western countries are the predators. No one is likely to embrace being por-

304. *See* SELL, *supra* note 1, at 50–51. *See generally* Oddi, *supra* note 133, at 433 (noting that from a strict legal perspective, if a country does not have a patent system, there can be no piracy, or even patent infringement).

305. In particular, unless an international agreement dictates otherwise (i.e., the situation prior to TRIPS), each nation may choose to enact—or not to enact—intellectual property laws in accordance with national priorities. Technically, when a nation elects not to adopt any intellectual property laws, there are no "rights" that can be pirated because the nation has opted not to provide any such rights. However, there is one theory of intellectual property rights that transcends national boundaries, in particular, if such rights are conceived of as reflecting the natural rights of inventors and authors, rather than an instrumental perspective that grants rights for the purpose of promoting social welfare. *See generally* Oddi, *supra* note 133. Indeed, this was the underlying theory behind the successful adoption of the United States negotiating position that resulted in the new global norms of international intellectual property protection. *See, e.g.*, SELL, *supra* note 1, at 44–51.

306. *Id.*

307. As noted by one commentator,

> In a 1986 U.S. Department of Commerce survey, U.S. companies claimed they lost $23.8 billion yearly due to inadequate or ineffective protection of intellectual property . . . . [However] if the contributions of Third World peasants and tribespeople are taken into account, the roles are dramatically reversed: the United States would owe Third World countries $302 million in agriculture royalties and $5.1 billion for pharmaceuticals.

SHIVA, BIOPIRACY: THE PLUNDER OF NATURE, *supra* note 63, at 56.

trayed as a predator. Moreover, this is particularly true with respect to the United States—or at least those corporate entities—that have already co-opted the piracy argument to portray themselves as in need of protection.

Accordingly, attempts by developing countries to use the same piracy lingo for a problem that is contrary to the interests of those who first co-opted the phrase are unlikely to yield success. Rather, a new framework is necessary. The failure of the biopiracy characterization suggests a need to reframe the issue in a way that is familiar to currently opposing parties without directly challenging ingrained Western perceptions.

2. National Sovereignty—This section suggests that developing countries focus on advocating their interest and right to protect national sovereignty as a theme that might be accessible to Western countries. Although international agreements by definition require nations to surrender some aspect of sovereignty, national sovereignty continues to be an issue of concern and discussion even after such agreements are adopted. For example, although TRIPS was signed more than ten years ago, discussion has been continuous concerning the appropriate balance between global rules and national sovereignty under TRIPS,[308] as well as other agreements governed by the WTO.[309] In addition, intellectual property rights remain creations of national law, regardless of globalization trends,

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308. *See, e.g.*, Olivier Cattaneo, *The Interpretation of the TRIPS Agreement: Considerations for the WTO Panels and Appellate Body*, 3 J. WORLD INTELL. PROP. RTS. 627 (2000) (suggesting that balancing national sovereignty and interpretation of TRIPS may be challenging); Ruth L. Gana, *Prospects for Developing Countries Under the TRIPS* Agreement, 29 VAND. J. TRANSNAT'L L. 735 (1996) (providing an early critical view of TRIPS as unduly subordinating the needs of developing countries in the area of flexibility of intellectual property protection in return for arguable benefits in the areas of textiles and agriculture); James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Epidemic*, 14 FLA. J. INT'L L. 261, 322 (2002) (arguing that TRIPS reduced the sovereignty rights of countries to select an intellectual property regime most appropriate for national priorities); Robert Howse, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times*, 3 J. WORLD INTELL. PROP. RTS., 493 (2000).

309. *See, e.g.*, Steve Charnovitz, *Supervision of Health and Biosafety Regulation by World Trade Rules*, 13 TULANE ENVTL. L.J. 271 (2000); Steve Charnovitz, *Environment and Health Under WTO Dispute Settlement*, 32 INT'L LAW. 901, 912–16 (1998) (noting potential WTO constraints on domestic health policy under the SPS agreement); Sara Dillon, *Fuji Kodak, the WTO and the Death of Domestic Political Constituencies*, 8 MINN. J. GLOBAL TRADE 197 (1999) (suggesting that the Fuji-Kodak dispute is symbolic of social and cultural concerns being subservient to WTO legalism); Andrew Green, *Climate Change, Regulatory Policy And The WTO How Constraining Are Trade Rules?*, 8 J. INT'L ECON. L. 143 (2005) (discussing some flexibility in domestic regulatory policy under the WTO, but also some constraints on domestic policy); Edward T. Hayes, *A Comparative Analysis of the Regulation of State and Provincial Governments in NAFTA and GATT/WTO*, 5 CHI. J. INT'L L. 605 (2005); Youngjin Jung & Ellen Jooyeon Kang, *Toward an Ideal WTO Safeguards Regime—Lessons from U.S.-Steel*, 38 INT'L. LAW. 919 (2004) (discussing whether the escape clause under GATT provides sufficient flexibility to address national domestic crises).

such that national sovereignty is an issue of continuing importance to all countries. Even as Western countries try to impinge on the national sovereignty of others, Western countries are adamant about preserving their own sovereign interests.

Although the issue of national sovereignty may often have different implications for developing versus Western countries, there is one area where consensus has been reached—the need for nations to balance patent rights against domestic public health needs. Patent norms that limit the ability of nations to address public health crises are a universal issue—as acknowledged in the Doha Public Health Declaration, which was a uniform declaration by all member states at the Doha round in support of the need to respect public health in the context of TRIPS.[310] In addition, this issue was also recognized in WTO disputes among Western countries, focusing on Canada's right to limit patent rights in the interest of promoting greater access to generic medicine.[311] Granted, there may be more dissension on the precise balance between patent norms and public health needs. However, there exists at least a starting point for discussion. All nations recognize national sovereignty and invoking this issue does not pose an immediate threat to the interests of other nations. In addition, a focus on sovereignty is a natural fit for indigenous communities that are already claiming sovereignty in the human rights context.[312]

There are some notable instances where national sovereignty interests in promoting public health ultimately triumphed over competing calls for stronger patent rights associated with TRIPS. For example, Brazil successfully countered an AIDS epidemic with compulsory licensing of drugs, while being aggressively pursued by the United States for noncompliance with TRIPS.[313] The TRIPS is-

310. *See* Doha Public Health Declaration, *supra* note 248, at pmbl.

311. *See id.* (affirming importance of public health); Canada Generics, *supra* note 250, *passim* (discussing whether Canada's exception to patent infringement constituted a "limited exception" permissible under TRIPS); *see also* Panel Report, *Canada Patent Term*, *supra* note 158, at ¶¶ 6.52–6.54, 6.83–6.89. (discussing the interpretation of patent term requirements under TRIPS that inherently implicates the balance between patent rights and public health since the patent term dictates the time of exclusivity when lower-cost generic equivalents cannot yet be sold); Press Release, Canadian Drug Manufacturers Association, Pharmacy Bills Stay High Thanks to WTO Ruling on Patent Extensions: Canadians Delayed Access to Lower Cost Generic Drugs (Mar. 7, 2000) (on file with the University of Michigan Journal of Law Reform) (reporting on WTO panel ruling, including a forecasted $200 million in costs to consumers in prescription fees because of a delay into entry of lower-cost generic drugs).

312. *See supra* Part II.B.

313. *See, e.g.*, Lawrence O. Gostin, *The Global Reach Of HIV/Aids: Science, Politics, Economics, and Research*, 17 EMORY INT'L L. REV. 1, 36–37 (2003); Jose Marcos Nogueira Viana, *IP Rights, the WTO and Public Health*, 17 CONN. J. INT'L L. 311, 311–13 (2002); *see also* Abbott, *The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WIDENER L.

sue eventually subsided in the wake of public opinion that applauded Brazil's success.[314] A similar situation occurred in South Africa when the United States government, as well as pharmaceutical companies, initially challenged the sale of generic retroviral drugs.[315] While a technical argument could be made that the South African law did not fully comply with the TRIPS requirements on compulsory licensing, the legal issue was overwhelmed by angry protests, as well as negative publicity. Bowing to public pressure, the companies dropped the case[316] and the United States' position changed as well, as reflected by an executive order providing that the "United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country . . . that regulates HIV/AIDS pharmaceuticals or medical technologies."[317]

Western countries have stated that they understand the importance of national sovereignty in the context of balancing intellectual property rights and other social concerns, although their actions have not always matched their rhetoric. For example, Western nations have asserted that TRIPS contains adequate flexibility for nation states to consider issues of domestic priority.[318]

SYMP. J. 71, 75 (2001) (noting that the U.S. has alleged TRIPS violations even where use was authorized under Article 31 for health emergencies).

314. *See, e.g.*, Stephen Buckley, *U.S., Brazil Clash Over AIDS Drugs, 'Model' Treatment Program Seen at Risk in Dispute on Patents and Pricing*, THE WASH. POST, Feb. 6, 2001, at A1; Chakravarthi Raghavan, *U.S. Beats a (Tactical) Retreat over Brazil's Patent Law*, THIRD WORLD NETWORK, June 25, 2001, http://www.twnside.org.sg/title/tactical.htm (on file with the University of Michigan Journal of Law Reform).

315. *See, e.g.*, James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727, 768 (2001) (noting that U.S. put South Africa on the watch-list under super 301 of the Trade Act, which could ultimately lead to retaliatory trade action after South Africa enacted the compulsory licensing law); Carla Power et al., *Paying for AIDS*, NEWSWEEK INT'L, Mar. 19, 2001, at 16–17 (noting that a conglomerate of forty-one major drug companies sued the South African government in the South African courts to block the 1997 Medicines Act).

316. *See, e.g., Drug Firms Drop AIDS Case*, BBC NEWSLINE, Apr. 19, 2001, http://news.bbc.co.uk/1/low/world/Africa/1284633.stm (noting that the case was dropped to "[secure] a quiet exit from [a] case that left them mired in bad publicity").

317. Exec. Order No. 13,155, 65 Fed. Reg. 30,521 (May 10, 2000). In addition to negative publicity, politics may have played a role. At the time, then Vice President Gore was known to have accepted money from pharmaceutical companies that promoted strong patent rights. An AIDS advocacy group, ACT UP, utilized this information to disrupt his presidential campaign with banners that stated "Gore's Greed Kills." *See, e.g.*, Kathy Chanault, *Will the AIDS Plague Change US Trade Policy?*, BUS. WK., Sept. 13, 1999, at 58 (noting that the U.S. decided not to pursue a WTO complaint after AIDS activities threatened to make this an issue in Gore's campaign). According to one source, the effect was immediate in withdrawing objections to the South African law during the same week that Gore announced his intent to run for president. SELL, *supra* note 1, at 152.

318. *See, e.g., Canada-Term of Patent Protection*, WT/DS170/R, *supra* note 158.

However, such assertions are belied by the Western imposed TRIPS-plus agreements that eliminate the flexibility of TRIPS by setting absolute standards for developing countries.[319] Currently, the duality that exists between asserting that TRIPS has flexibilities, and negotiations for agreements that eliminate those flexibilities, has been an issue primarily noticed (and criticized) by NGOs and academics.[320] However, to the extent that this issue is publicized further, there could be the potential for change. In particular, just as the medicine access debate reached beyond the offices of trade representatives into the popular press, greater transparency of the biopiracy issue might provide sufficient leverage to change international negotiating stances.

Past history has shown that hypocrisy can be a component of fostering change. For example, returning once again to the anthrax/Cipro "crisis" that the United States faced, the United States abruptly modified its position towards compulsory licensing under TRIPS as a result of widespread public ridicule regarding the apparent hypocrisy in its stance.[321] However, this "about-face," in response to public criticism does not reflect a complete enlightenment on the part of government officials. For example, although the United States participated in the uniform adoption of the Doha Public Health Declaration, it subsequently contested the

319. *See infra* notes 326–327 and accompanying text (concerning elimination of TRIPS flexibilities in TRIPS-plus agreements).

320. *See, e.g.*, GRAIN, TRIPS-PLUS MUST STOP: THE EUROPEAN UNION CAUGHT IN BLATANT CONTRADICTIONS 3 (March 2003), http://www.grain.org/briefings_files/trips-plus-eu-2003-en.pdf; CARLOS M. CORREA, GRAIN, BILATERAL INVESTMENT AGREEMENTS: AGENTS OF NEW GLOBAL STANDARDS FOR THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS? 4 (Aug. 2004), http://www.grain.org/briefings_files/correa-bits-august-2004.pdf (providing study of implications of both free trade agreements and bilateral investment treaties under commission of GRAIN and noting that arguments for minimizing TRIPS flexibilities through bilateral dealings are prompted by business interests); OXFAM INT'L, OXFAM BRIEFING NOTE: UNDERMINING ACCESS TO MEDICINES: COMPARISON OF FIVE US FTAS 2 (June, 2004), http://www.oxfam.org.uk/what_we_do/issues/health/downloads/undermining_access_ftas.pdf; DAVID VIVAS-EUGUI, TRIPS ISSUE PAPERS 1: REGIONAL AND BILATERAL AGREEMENTS AND A TRIPS-PLUS WORLD: THE FREE TRADE AREA OF THE AMERICAS (FTAA) 13–16 (2003), *available at* http://www.geneva.quno.info/pdf/FTAA%20(A4).pdf. *See generally* Peter Drahos, *BITS and BIPS—Bilateralism in Intellectual Property*, 4 J. WORLD INTELL. PROP. 791 (2001); Ruth L. Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 OTTAWA L. & TECH. J. 125 (2003–04).

321. *See, e.g.*, *Patent abuse*, FIN. TIMES, Oct. 22, 2001 (noting that "Western governments are guilty of double standards" in comparison of the 11 confirmed cases of anthrax infection versus the 25 million people faced with dying of AIDS in Africa for lack of medical treatment); *see also supra* notes 254–255 and accompanying text (discussing hypocrisy in context of Doha negotiations).

scope of certain provisions, arguing that they should be more narrowly interpreted.[322]

3. TRIPS-Plus—The ongoing negotiations of TRIPS-plus agreements present an opportunity to highlight a serious incursion on the national sovereignty of developing countries. Although developing countries can be conceived of as willingly entering into these agreements, it is well established that developing countries have enormous pressure and incentive to cooperate with countries that have not only lucrative export markets, but also power to control their credit.[323] As one commentator noted, "the ruling elites of most non-industrialized countries act swiftly to rush to accept and put into law every demand and whim of these industrialized countries. The evidence is so overwhelming that to cite examples would be superfluous."[324] Indeed, the conclusion of TRIPS is widely acknowledged to have only been accomplished because developing countries wanted the market access that the WTO offered, even though they did not subscribe to the rules under TRIPS.[325]

The new and pending agreements present greater problems to national sovereignty because they impose rules that provide less flexibility than TRIPS. In particular, agreements that mandate developing countries to provide patents without any exclusions from patentability are more restrictive than TRIPS because TRIPS at least provides nations with the possibility of excluding patents on

322. *See* Doha Ministerial Declaration, *supra* note 82, ¶ 5(a). For example, although the declaration specifically notes certain diseases as illustrative of national epidemics that would justify use of compulsory licensing, the United States has subsequently suggested that these are the *only* instances where compulsory licensing may be adequate—in complete contradiction of the explicit text. *See, e.g.* MARY MORAN, MÉDICINS SANS FRONTIERES, RENEGING ON DOHA (May 2003), http://www.cptech.org/ip/wto/p6/msf052003.pdf; *Deadlock over Scope of Diseases Threatens to Kill Solution*, CPTECH, Nov. 27, 2002, http://www.cptech.org/ip/wto/p6/ngos11272002.html; *TRIPS Consultations on Implementing Doha Recessed*, THIRD WORLD NETWORK, Nov. 29, 2002, http://www.twnside.org.sg/title/5246a.htm (on file with the University of Michigan Journal of Law Reform); Brook K. Baker, Doha Redux—U.S. Enters New Phase of Bad Faith Bargaining (July 2, 2003), http://www.cptech.o rg/ip/wto/p6/hgap07022003.html.

323. *See* Frederick Abbott, *The Cycle of Action and Reaction: Latest Developments and Trends in IP and Health*, ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, Bellagio, Oct. 12–16, 2004, at 7, *available at* http://www.iprsonline.org/unctadictsd/bellagio/docs/Abbott_Bellagio3rev1.pdf (noting that despite limitations inherent in FTAs with the United States, developing countries continue to enter into these on the belief that the overall agreements are beneficial, with compromise in some areas, such as pharmaceutical protection as necessary for broader gains); Endeshaw, *supra* note 270, at 64 (noting that fear of access to "lucrative markets" in the United States and Europe or the threat of withdrawal of credit from international institutions are a major force behind the move towards adopting FTAs).

324. Endeshaw, *supra* note 271, at 64.

325. *See supra* note 144 and accompanying text.

inventions that are contrary to morality.[326] Although this clause has never been definitively interpreted under TRIPS, it is important to developing countries who have invoked the provision as a reason that Western countries should be concerned about biopiracy patents.[327]

Moreover, to the extent that some countries such as India and South Africa have enacted patent laws that bar patents for inventions which fail to disclose the origin of materials used in the invention in an attempt to limit biopiracy patents within their own countries, new bilateral or international agreements may preclude such efforts.[328] This may be considered a serious incursion of national sovereignty when considered in the context of existing vehement protests against Western countries that allegedly grant biopiracy patents based upon their own standards.[329] Essentially, if developing countries are prohibited from tailoring their patent laws to prevent patents issuing within their own countries based upon biopiracy, they will be forced to accept an even greater evil than what they have been lobbying against. In particular, while developing countries have argued that Western patents based upon indigenous materials are immoral, they would most certainly be opposed to laws that would force them to condone such practice within their own countries.

Sovereign interests in dictating the appropriate balance between patent rights and public health is a major issue in bilateral TRIPS-plus agreements. Prior agreements negotiated by the United States have already been criticized for having an undue impact on public health of developing countries.[330] Even the recently concluded

326. *See* TRIPS, Marrakesh Agreement, *supra* note 2, at art. 27, ¶ 2.

327. *See generally* WTO, Index of Dispute Issues, http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#bkmk87 (last visited Mar. 8, 2006) (providing no dispute based on TRIPS Article 27(2)). However, some commentators have nonetheless opined on the scope of this provision. *See, e.g.*, M. Bruce Harper, *TRIPS Article 27.2: An Argument for Caution*, 21 WM. & MARY ENVTL. L. & POL'Y REV. 381 (1997); INT'L CTR. FOR TRADE AND SUSTAINABLE DEV. AND U.N. CONFERENCE ON TRADE AND DEV., ICTSD-UNCTAD CAPACITY BUILDING PROJECT ON IPRS: RESOURCE BOOK ON TRIPS AND DEVELOPMENT 375–76 (Feb, 2005), *available at* http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm.

328. *E.g.*, Patent Act, § 25 (2002) (India) (providing additional grounds for revocation, including the fact that an applicant did not disclose or wrongly disclosed the geographical origin of biological material used in the invention); Decision 486: Common Intellectual Property Regime, Community of Andean Nations, art. 26, Sept. 14, 2000 (unofficial translation), *available at* http://www.comunidadandina.org/INGLES/normativa/D486e.htm (providing that patent applications must include documentation of an agreement on access to genetic resources or traditional knowledge).

329. *See supra* note 134 and accompanying text.

330. *See generally* MSF, ACCESS TO MEDICINES AT RISK ACROSS THE GLOBE: WHAT TO WATCH OUT FOR IN FREE TRADE AGREEMENTS WITH THE UNITED STATES (2004); OXFAM

agreement between the United States and Australia—the first such agreement between Western countries—raised concern about access to health issues.[331] In fact, the impact of the new patent requirements on Australia's government-subsidized drug program was a potential deal-breaker.[332] In addition, the impact of FTAs on public health will likely arise again since the United States Trade Representatives have stated that they consider each free trade agreement to be a template to use for subsequent agreements—a "one size fits all" standard that seems completely at odds with addressing a variety of national sovereignty issues.[333]

ITN'L, UNDERMINING ACCESS TO MEDICINES: COMPARISON OF FIVE U.S. FTAS (2004); Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*, Quaker United Nations Office (QUNO) Occasional Paper 14, Apr. 2004, *available at* http://www.geneva.quno.info/pdf/OP14Abbottfinal.pdf.

331. *See, e.g.*, Peter Drahos et al., *The FTA and the PBS: A Submission to the Senate Select Committee on the US-Australia Free Trade Agreement* (2004), *available at* http://www.drs.org.au/articles/2004/FTA/Doc/drahos%20et%20al%20senatesub.htm; Medicines Sans Frontieres, International Implications of the Free Trade Agreement between Australia and the United States, http://www.msf.org.au/docs/reports/us_aust_fta.pdf (providing overview of AUSFTA provisions that are considered to have negative health implications not only for Australia, but also for other bilateral agreements entered into by the United States); Letter from Pieta-Rae Laut, Executive Director, Public Health Association of Australia, to Australian Parliament (May 25, 2004), *available at* http://www.phaa.net.au/Advocacy_Issues/pbs.htm (expressing concern about implication of AUSFTA on Australia's drug pricing system); Submission of Richard Denniss & Clive Hamilton, The Austl Inst., to the Senate Select Committee on the Free Trade Agreement Between Australia and the United States of America, *available at* http://www.aph.gov.au/Senate/committee/freetrade_ctte/submissions/sub171.pdf; *see also* Free Trade Agreement, arts. 17.9–.10, U.S.-Austl., May 18, 2004, *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/asset_upload_file148_5168.pdf.

332. *See, e.g.*, Elizabeth Becker & Robert Pear, *Drug Dispute Snags US-Australia Pact*, N.Y. TIMES, Nov. 15, 2004, at W1; Ian Heath, Examining the Impact of the Australia-United States Free Trade Agreement (AUSFTA) on Intellectual Property, Keynote Address at Recent Developments in Protecting and Commercializing Intellectual Property 5 (Aug. 10, 2004), http://www.ipaustralia.gov.au/pdfs/news/ausfta.pdf. In addition, there was broader disapproval for negotiation of this agreement under fast-track legislation. *See, e.g.*, 151 CONG. REC. S1498–99 (daily ed. Feb. 16, 2005) (statement of Sen. Kennedy) (criticizing the Bush Administration's use of Trade Promotion Authority in a manner inconsistent with the Doha Declaration).

333. As explained by the Acting Director of the USPTO

> the US has developed models or prototypes of the kind of bilateral treaties it wishes to have with other countries. Once a model treaty is ratified by the Senate, U.S. trade negotiators know that if they stick to its terms in other negotiations there is a good chance the treaties flowing from these negotiations will also be approved.

Pirates of the 21st Century: the Curse of the Black market: Hearing Before the Sen. Subcomm. On Oversight of Gov'tal Mgmt., the Fed. Workforce & the Dist. of Columbia, 108th Cong. (April 20, 2004) (statement of Jon W. Dudas, Acting Under Secretary of Commerce for Intellectual Property & Acting Director of the USPTO).

Although a focus on national sovereignty of indigenous communities may be a natural tool in addressing the encroachment of TRIPS-plus agreements, relying on sovereignty alone to address biopiracy is unlikely to be a successful strategy. Although nations acknowledge the importance of national sovereignty, the continuing negotiations of bilateral agreements that limit such sovereignty suggest that acknowledgement alone will not result in desired action. This is especially true since many TRIPS-plus FTAs have been negotiated since the Doha Public Health Declaration, which purported to acknowledge national sovereignty in addressing public health needs. Moreover, sovereignty may be complicated in the context of biopiracy because sovereign nations may have differing interests from the indigenous groups that oppose biopiracy.[334] Accordingly, although sovereignty is a preferable focus over piracy, it is not a complete solution.

B. Questioning Western Patent Law, Policy and Politics

This Part moves beyond issue-framing to address fundamental patent law and policy issues that lie at the heart of the biopiracy problem. In particular, this Part provides a new mechanism to work with the existing Western patent system to address biopiracy as well as other current complaints of the Western system. As noted in the discussion of current proposals to amend TRIPS, a major flaw of proposed patent solutions to date has been an attempt to impose solutions that would address biopiracy without adequate consideration of the intransigence of those in favor of the existing patent laws. Although there will continue to be strong proponents of the patent system, there are specific areas that present an opportunity for dialogue and potential change. To the extent that some of these areas share commonality with the problems underlying biopiracy, a re-examination of Western patent law may offer a "win-win" solution.

1. Reconsidering the Premise of TRIPS-Plus and Uniform Patent Law—This section questions whether the underlying goal behind the proliferation of TRIPS-plus agreements to raise global patent rights[335] to the level of Western countries is appropriate in light of

334. *See supra* Part II.A.1.

335. Although this section focuses on patent rights, other intellectual property rights incorporated in TRIPS-plus agreements have also been questioned. For example, many have suggested that the present copyright system does not adequately balance incentives to innovate with other societal needs. There has been substantial discussion concerning the

increasing domestic discussion in Western countries concerning the appropriate balance between patents and public policy.[336] In addition, this section highlights the questionable premise of such agreements, as a first step towards breaking the momentum towards TRIPS-plus agreements. This is important to the issue of biopiracy since, as previously noted, many TRIPS plus agreements further exacerbate existing biopiracy concerns. In particular, this section highlights some major areas of concern that have been raised concerning the impact of Western patent laws.

2. Western Patent Problems

a. Patent Rights versus Public Health—Balancing patent rights against access to medicine is not merely a third world concern; rather it is a major problem for Western countries that tend to promote strong patent rights, yet are facing increasing difficulties in providing access to medicine. In recent history, pharmaceutical

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appropriate level of copyright protection in light of new technology, for example, in the case of file-sharing. *See, e.g.*, MGM Studios, Inc., v. Grokster, Ltd., 125 S. Ct. 2764 (2005); MGM Studios, Inc. v. Grokster, Ltd., 380 F.3d 1154, *passim* (9th Cir. 2004); *In re* Aimster Copyright Litigation, 334 F.3d 643, *passim* (7th Cir. 2003); A&M Records, Inc. v. Napster, Inc., 239 F.3d 1004, *passim* (9th Cir. 2001); *see also* U.S. Copyright Office, Supreme Court Rules in MGM v. Grokster, http://www.copyright.gov/docs/mgm/ (last visited Mar. 8, 2006) (providing links to legal briefs in the Grokster case); Emily Bazelon, *Grok Around the Clock: Share Those MP3s Now—The Supreme Court may try to stop you soon*, SLATE, Mar. 29, 2005, *http://slate.msn.com/id/2115919/*. Recent expansion of copyright protection has also been criticized. *See, e.g.*, Jacqueline Lipton, *The Law of Unintended Consequences: The Digital Millennium Copyright Act and Interoperability*, 62 WASH. & LEE L. REV. 487 (2005). In addition, after Congress extended the copyright term for all existing and future works another twenty years, there was criticism of the legislation as unsupported and even unconstitutional. *See, e.g.*, Brief for Intellectual Property Law Professors as Amici Curiae Supporting Petitioners, Eldred v. Ashcroft, 537 U.S. 186 (2003) (No. 01-618); Stan J. Liebowitz & Stephen Margolis, *Seventeen Famous Economists Weigh in on Copyright: The Role of Theory, Empirics, and Network Effects*, 18 HARV. J.L. & TECH. 435, 438–57 (2005); Robert P. Merges & Glenn H. Reynolds, *The Proper Scope of the Copyright and Patent Power*, 37 HARV. J. ON LEGIS. 45 (2000).

336. One topic in recent United States discussions is the issuance of permanent injunctions, which by statute are to consider competing equity concerns, but have mostly issued as a de facto matter following strong direction from the Federal Circuit, such that a change to the current law is proposed in pending legislation and also subject to review by the United States Supreme Court. *See* Ebay v. Mercexchange, 401 F.3d 1323 (Fed. Cir. 2004); Patent Reform Legislation, H.R. 2795, 109th Cong. (1st Sess. 2005) (minimizing proposals for injunctive relief in the original H.R. 2795 proposal). Other commentators have also questioned or criticized the TRIPS-plus trend, although primarily in the context of protecting public health, rather than addressing biopiracy. *See, e.g.*, Carlos M. Correa, *Internationalization of the Patent System and New Technologies* (Mar. 2002) (revised version of a paper submitted to the Conf. on the Int'l Patent System, WIPO, Geneva, March 25 to 27, 2002), http://www.wipo.int/patent/agenda/en/meetings/2002/presentations/correa.pdf (noting that "it does not seem advisable, at least from the perspective of developing countries, to promote the further international harmonization of a system that has gone far beyond its essential function: to foster and reward genuine inventiveness"); *supra* note 331 and accompanying text (criticizing FTA with Australia for having potential negative impacts on health care).

companies and their lobbyists have successfully argued that strong patents rights are essential to providing incentives to create important advances in technology, as well as to subsidize research that does not result in marketable products.[337] However, there is a growing global sentiment that patented drugs and medical tests unduly increase costs because the right to exclude others legally permits owners to charge higher prices, such that patients are precluded from accessing needed medical care.[338] In the United States, this sentiment is reflected by proposed legislation to create exceptions to patent infringement claims for medical tests involving gene patents,[339] as well as allowing importation of patented drugs.[340] As an example, a number of Western countries, including Canada, Belgium, and the Netherlands, took action to challenge Myriad Technologies' patented gene for detecting breast cancer, out of concern that enforcement of this patent would cause serious hardship on accessibility of health care.[341] Most recently, and of particular interest for the TRIPS-plus trend is Australia's concern

337. *See, e.g.*, SELL, supra note 1, at 43–48; Robert Weissman, *A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1088–89 (1996).

338. *See, e.g.*, MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT (2004) (suggesting, among other things, that patents increase costs by encouraging firms to engage in competitive and wasteful use of resources in attempts to find "blockbuster" drugs that are highly marketable and profitable); NAT'L INST. FOR HEALTH CARE MGMT., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION: A RESEARCH REPORT BY THE NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT RESEARCH AND EDUCATIONAL FOUNDATION (2002), *available at* http://www.nihcm.org/innovations.pdf; ORG. FOR ECON. CO-OPERATION AND DEV., GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES: EVIDENCE AND POLICIES (2002), *available at* http://www.oecd.org/dataoecd/42/21/2491084.pdf; Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. HEALTH L. & POL'Y. J. 65 (2002).

339. Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2d Sess. 2002) (proposing to amend the patent act to exempt medical practitioners utilizing genetic diagnostic tests from patent infringement remedies); 148 CONG. REC. E353, E354 (daily ed. Mar. 14, 2002) (introduction of The Genomic Research and Diagnostic Accessibility Act of 2002, HR 3967, and The Genomic Science and Technology Innovation Act of 2002, HR 3966, by Hon. Lynn N. Rivers). In addition, although this bill has not been reintroduced in Congress, a similar issue has attracted legislative and policy attention in Japan. *See, e.g.*, INDUSTRIAL STRUCTURE COUNCIL, APPLICATION OF METHODS RELATED TO MEDICAL ACTIVITY TO THE PATENT LAW (2003), *available at* http://www.jpo.go.jp/shiryou_e/toushin_e/shingikai_e/appli_med_pl.htm.

340. *See, e.g.*, Safe Importation of Medical Products and Other Rx Therapies Act of 2005, H.R. 753, 109th Cong. (2005); Safe Importation of Medical Products and Other Rx Therapies Act of 2005, S. 184, 109th Cong. (2005).

341. Press Release, Institut Curie, European-wide Opposition Against the Breast Cancer Patents (Sept. 26, 2002) (expressing concern that if the Myriad patent covering breast cancer predisposition and other similar gene patents were not eliminated, or at least narrowed, it would negatively influence health care because of the financial strain).

about the health implications of the recently negotiated USFTA that reflects the strongest global patent rights.[342] Interestingly, there was brief concern that the patent provisions might impede the ability of the United States to enact legislation permitting the importation of patented drugs into the United States to partially address a growing concern about access to affordable drugs. When the proposed legislation failed to garner enough support to pass, the issue faded. However, it nonetheless reflects a partial realization that ever-increasing patent rights may clash with public health needs, even for Western countries.

b. Promoting or Impeding Research—There are also serious concerns raised regarding the impact of patent rights on research and innovation. The process of scientific discovery generally involves cumulative development from past research; indeed, many believe that the progress of scientific research would be fostered if research were less encumbered by patent rights.[343] When patents are introduced into the field of scientific discovery, subsequent development may be stymied. Although the potential of patents to impede research has always been a theoretical issue, it has become a growing reality as a result of changes in the culture of academic research, and what is patented. In particular, more scientists, including those from universities, are patenting results of research, rather than providing them to the public domain for free use by all.[344] In addition, the type of technology patented is increasingly more fundamental, such that patents may have the potential to preclude, or at least impede subsequent research on commercial products.[345] An increase in patents on research tools, such as gene sequences, that are necessary for subsequent research on methods of medical treatment, diagnosis or drugs, have been particularly problematic since the research tools are often far "upstream" of the end commercial products, such that the path towards research and commercialization is littered with preexisting patents.[346] A

342. *See supra* notes 331–332 and accompanying text.

343. *See, e.g.*, Clarissa Long, *Proprietary Rights and Why Initial Allocations Matter*, 49 EMORY L.J. 823 (2000); HUGO Intell. Prop. Comm. Statement on Patenting of DNA Sequences: In Particular Response to the European Biotechnology Directive (April 2000), http://www.gene.ucl.ac.uk/hugo/patent2000.html.

344. *See, e.g.*, Sheldon Krimsky, *The Profit of Scientific Discovery and its Normative Implication*, 75 CHI.-KENT L. REV. 15 (1999).

345. *See, e.g.*, THE ROYAL SOCIETY, KEEPING SCIENCE OPEN: THE EFFECTS OF INTELLECTUAL PROPERTY POLICY ON THE CONDUCT OF SCIENCE ¶¶ 3.21–23 (2003) *available at* http://www.royalsoc.ac.uk/displaypagedoc.asp?id=11403; NAT'L RESEARCH COUNCIL, *supra* note 147, at 25–27.

346. *See, e.g.*, NAT'L RESEARCH COUNCIL, *supra* note 147, at 70–75 (highlighting instances where patented research tools precluded access). Although access issues continue to be problematic, the U.S. Supreme Court recently opened the door slightly in *Merck KGaA v.*

patent owner may refuse to license use to others, or the fee to license use may be cost-prohibitive. In addition, as more research tools are patented, there is a serious logistical problem of negotiating amidst a thicket of preexisting patents to conduct research—even assuming that the cost of using each patent can be overcome.[347] Access by subsequent researchers is particularly an issue if initial pioneering patents are very broad.

There are additional troubling issues for Western patent law beyond patented research tools. Patents on business methods are stated to over-reward behavior that needed no patent incentive and create problems for subsequent businesses as well as research. In addition, for all subject matter, there is always a concern regarding the scope of enforcement of patent rights. Until recently, most researchers in academic and other non-profit settings assumed that they were immune from patent infringement suits.[348] However, the Federal Circuit has ruled otherwise.[349] In addition, although the Federal Circuit ruling is only applicable to United States patents, the broader issue of how strong patent rights can be reconciled with enabling researchers with the ability to build upon past innovation is a current issue for all Western countries.

All of the foregoing issues are contributing to an atmosphere that is increasingly questioning what used to be unquestionable Western patent law doctrine. Some scientists who are particularly concerned about the impact of patents on subsequent research are taking affirmative steps to opt-out of the patent system and pre-

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Integra Lifesciences I, Ltd., 125 S. Ct. 2372, 2381–84 (2005), in a 9–0 vacation of the Federal Circuit opinion, rejecting prior narrow readings of a limited statutory exception to infringement for some types of clinical testing under 35 U.S.C. § 271(e)(1).

347. The problem is particularly acute with respect to biomedical and gene-based patents. *See, e.g.*, Lori B. Andrews, *supra* note 338, at 79–81 (discussing gene patents as impediments to research); Rebecca S. Eisenberg, *Genetics and the Law: Patenting the Human Genome*, 39 EMORY L.J. 721, 725–29 (1990); Michael Heller and Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–701 (1998); Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735 (2000) (proposing alternative mechanism to patents to alleviate research impediment problem that currently exists with gene patents); Jordan Paradise et al., *Patents on Human Genes: An Analysis of Scope and Claims*, 307 SCIENCE 1566, 1566–67 (2005).

348. *See, e.g.*, NAT'L RESEARCH COUNCIL, *supra* note 147, at 23 (noting that "[u]ntil very recently it was widely believed that purely research uses of patent inventions were shielded from infringement liability by an experimental use exception").

349. Madey v. Duke, 307 F.3d 1351, 1362 (Fed. Cir. 2002). In addition, even before the *Madey* decision, there was already concern about the scope of experimental use. *See generally* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Maureen O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000) (proposing that patent law create an exception to infringement analogous to the existing fair use provision that limits liability to copyright infringement).

preemptively publish their research results immediately, to create prior art that precludes others from obtaining patents on such research.[350] Although this is not yet a widespread phenomenon, its very existence indicates concern among the scientific community about the potential for patents to stifle research; it is a strategy that has attracted the attention of academic commentary as well.[351] In addition, some have advocated open-source models, even within the traditionally patent-dominated area of biotechnology, to ensure that researchers have adequate access to necessary tools.[352]

c. Patents on Questionable Subject Matter—Although the scope of patentable subject matter has been expanding on both domestic[353] and international levels,[354] such expansion is not uniformly embraced. There is increasing concern about whether some types of subject matter should be unpatentable. For example, the

350. This is an extension of some celebrated instances. For example, the human genome research group led by Craig Venter patented all the isolated sequences they discovered while a competing group, financed by the federal government, published all of their research in the public domain to promote accessibility. *See* Rebecca S. Eisenberg, *Intellectual Property at the Public-Private Divide: The Case of Large-Scale cDNA Sequencing*, 3 U. CHI. L. SCH. ROUNDTABLE 557 (1996).

351. *See, e.g.*, Alexander K. Haas, *The Wellcome Trust's Disclosures of Gene Sequence Data into the Public Domain & the Potential for Proprietary Rights in the Human Genome*, 16 BERK. TECH. L.J. 145, 145 (2001); Gideon Parchomovsky, *Publish or Perish*, 98 MICH. L. REV. 926, 926–27 (2000); The SNP Consortium, http://snp.cshl.org/about/ (last visited Mar. 9, 2006) (describing project to make genetic sequences available to the public without patent restrictions).

352. *See, e.g.*, Arti Rai, *Open and Collaborative Research: A New Model for Biomedicine*, *in* INTELLECTUAL PROPERTY RIGHTS IN FRONTIER INDUSTRIES: SOFTWARE AND BIOTECH (Robert Hahn ed., forthcoming 2005), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=574863; Kenneth N. Cukier, *Open Source Biotech: Can a Non-proprietary Approach to Intellectual Property Work in the Life Sciences?*, ACUMEN J. LIFE SCI., Sept-Oct. 2003 (providing an overview of current problems with patents for life sciences, as well as description on some early open source activities); Carina Dennis, *Biologists Launch Open-source Movement*, 431 NATURE 494 (Sept. 30, 2004); Andrew Pollack, *Open Source Practices for Biotechnology*, N.Y. TIMES, Feb. 10, 2005, at C8; *see also* UNCTAD/ICTSD Regional Dialogue on Intellectual Property Rights (IPRs), Innovation and Sustainable Development, Nov. 8–10, 2004, *Meeting Report*, at 7, *available at* http://www.iprsonline.org/unctadictsd/dialogue/docs/Report_2004-11-8.pdf (noting that meeting participants suggested consideration of an open source model as an alternative to patent protection). An alternative option that has been proposed is to develop patent pools along the lines of what already exists for copyrighted songs, whereby one organization can handle all the licensing of individual songs. *See, e.g.*, JEANNE CLARK ET AL., PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 8 (Dec. 5, 2000), *available at* www.uspto.gov/web/offices/oac/daoo/opla/patpoolcover.html (noting that patent pools could address blocking patents in biotechnology).

353. Domestic expansion of patentable subject matter in recent years includes the area of internet business method patents, as well as computer software.

354. The scope of patentable subject matter may be broadened in some TRIPS-plus agreements by either eliminating TRIPS exceptions to patentable subject matter or by mandating that the "highest international standards" be adopted. This may require adoption of the prevailing standard, including the broad scope of patentability under United States law. *See supra* notes 326–327 and accompanying text (describing TRIPS-plus agreements).

Canadian Supreme Court, in a 5–4 opinion, refused to follow the United States, the EU, and Japan in patenting a genetically modified mouse.[355] In addition, although the U.S. Supreme Court upheld the patentability of plants, some amicus briefs urged the Court to rule otherwise on grounds of public policy, arguing that patent rights undermined farmers' interests and ultimately public health.[356]

With technical advances in cloning and human embryonic stem cells, there is increasing public discomfort with patents on products of such research, which has prompted calls for modifying patent laws to prohibit patents on immoral inventions. An early example lies in the history of the EU Directive for Protecting Biotechnological Inventions, passed only after incorporation of language that addressed ethical considerations, including the exclusion of specific types of controversial subject matter such as embryo cloning methods.[357] Even in the United States, which has expressly rejected consideration of moral implications for more than twenty years,[358] there are renewed discussions of whether the patent system is inappropriately encouraging immoral inventions, such that moral implications should be reinstated as a reason to bar patentability.[359] In addition, there have been attempts to legislatively limit the scope of patentability.[360]

d. Uniform Patent Laws are Questionable—TRIPS-plus agreements are also questionable to the extent that they promote uniform

355. Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45. *See also* Dan Burk, *Reflections in a Darkling Glass: A Comparative Contemplation of the Harvard College Decision*, 39 CAN. BUS. L.J. 219 (2004) (suggesting that the Canadian decision may provide an interesting experiment in patent policy because of its divergent approach from United States interpretation of the same express patent language). Although the decision is based on a narrow statutory interpretation, it nonetheless reflects some hesitancy even among Western countries concerning the scope of patent rights.

356. J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001); Brief for Malla Pollack and Other Law Professors as Amici Curiae Supporting Reversal, J.E.M. AG Supply, 534 U.S. 124 (2001) (No. 99-1996).

357. *See infra* Part IV.B.2 (discussing genesis of EU Biotechnology Directive and differences among member countries with respect to ethical aspects of patentability).

358. Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366–67 (Fed. Cir. 1999).

359. *See* Bagley, *Patent First, Ask Questions Later*, *supra* note 130; Benjamin Enerson, *Note, Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685 (2004) (opposing resurrection of the moral utility doctrine).

360. In particular, Sen. Brownback had proposed an amendment to a terrorism bill that aimed to narrow the scope of patentable subject matter. Unpatentability of Human Organisms, S.A. 3843, 107th Cong., 148 CONG. REC. S5556 (daily ed. June 13, 2002). Although the direct proposal failed, when it was redrafted to limit funding to the PTO for issuance of similar patents, it passed. Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3 (2003) (purporting to disallow the PTO from using government funds to "issue patents on claims directed to or encompassing a human organism").

rules for all countries.[361] First, there is an equity argument to the extent that countries that currently advocate uniformly strong levels of patent protection actually benefited from relatively [lax] patent rights to accommodate national interests at a time of economic development—a benefit that subsequent countries no longer have under TRIPS and TRIPS-plus agreements.[362] There are additional problems with uniform rules for all countries. Uniformity tends to result in rules that are incapable of adapting to changing circumstances of individual countries, as well as to changing technology. The typical development of law often benefits from cross-fertilization of ideas from diverse systems. Indeed, the premise of comparative patent law has traditionally been to gain wisdom from the experiences of different nations.[363] As noted by the United Nations Committee on Economic Social and Cultural Rights, "international rules concerning intellectual property should not necessarily be uniform if this might lead to forms of intellectual property protection inappropriate for development goals."[364] Rather, the Committee recommended the adoption of "special and differential treatment" for developing countries, as have others who have examined the implications of imposing Western-style patent rules on developing countries.[365]

Smaller-scale experiments with uniform patent laws have provided mixed results. For example, the United States successfully created more uniformity in the validity of patents when it created the Federal Circuit as the exclusive appellate court to hear patent appeals.[366] However, in the two decades since its creation, there has

361. Although TRIPS-plus agreements need not be identical, the approach of the United States Trade Representatives in using each FTA as a template for subsequent negotiations suggests a trend towards uniformity.

362. *See supra* notes 145–146 and accompanying text (noting this as part of an argument for why TRIPS is an act of Western imperialism).

363. *See, e.g.*, Kara Belew, *Stem Cell Division: Abortion Law and its Influence on the Adoption of Radically Different Embryonic Stem Cell Legislation in the United States, the United Kingdom, and Germany*, 39 TEX. INT'L L.J. 479 (2004); Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair Use Exemption*, 76 N.Y.U. L. REV. 1623 (2001); Horacio Rangel-Ortiz, *Comparative Law Alleviates Biotech Uncertainty: When Providing Much-Needed Clarification on the Patentability of Biotechnological Inventions, the Mexican Patent Office Considered How Other Countries Had Dealt with the Issue*, MANAGING INTELL. PROP., June 1, 2005, at 79 (noting that the Mexican Patent Office had recently proposed guidelines for patenting biotechnology after meeting with EPO and WIPO representatives to gain wisdom from comparative perspectives).

364. U.N. Doc. E/C.12/2001/15, *supra* note 174, at 15.

365. *Id.*

366. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982) (effective Oct. 1, 1982). For more extensive discussion of the creation of the Federal Circuit, as well as an evaluation of its performance, see Rochelle Cooper Dreyfus, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 8–22 (1989); Paul M. Janicke, *To Be or*

been increasing concern that the Federal Circuit has been creating uniform law that overly protects patent rights. One problem is the fundamental structure of a single appellate court; by definition this system lacks the countervailing balance that typically occurs when there are other circuit courts to hear similar issues and potentially develop other approaches. In addition, because the Federal Circuit is the exclusive appellate court, there are no circuit splits that typically lead to resolution of contentious issues by the United States Supreme Court.[367] This systemic anomaly has been noted as one possible contributing factor to a host of problems at the Federal Circuit, including an overly sympathetic stance to patent proponents that fails to promote a proper balance between patent incentives and public interests.[368]

e. Moving Forward: A Moratorium?—These issues may seem to suggest that a moratorium on development of further international patent norms, or at least TRIPS-plus standards would be appropriate. Indeed, NGOS have already been urging for a cessation of TRIPS-plus standards in bilateral agreements.[369] There is precedent for considering and utilizing a moratorium during times of legal uncertainty. In the TRIPS agreement itself, there was an initial moratorium imposed on non-violation complaints[370] which

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Not to Be: The Long Gestation of the US Court of Appeals for the Federal Circuit, 69 ANTITRUST L.J. 645 (2002).

367. *See generally* NAT'L RESEARCH COUNCIL, *supra* note 147, at 86 (noting that the Federal Circuit "is in most instances the final arbiter of patent law"); Mark Janis, *Patent Law in the Age of the Invisible Supreme Court*, 2001 U. ILL. L. REV. 387 (noting that the Federal Circuit is effectively the court of last resort for patents since historically, the U.S. Supreme court rarely reviews Federal Circuit cases). Interestingly, recent Supreme Court jurisprudence has slightly widened the opportunity for greater regional circuit participation in *some* patent cases. *See, e.g.*, Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc., 535 U.S. 826, 834 (2002); Elizabeth Rogers, *The Phoenix Precedents: The Unexpected Rebirth of Regional Circuit Jurisdiction over Patent Appeals and the Need for a Considered Congressional Response*, 16 HARV. J.L. & TECH. 411, 437–72 (2003).

368. *See, e.g.*, Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1075, 1110 (2003) (noting that the Federal Circuit, unlike other generalist courts hears cases predominantly from patent attorneys who are less likely to make sweeping legal and policy arguments). In addition, the Federal Circuit may have "insular tendencies" that also create problems. *See* NAT'L RESEARCH COUNCIL, *supra* note 147, at 86.

369. *See* OXFAM INT'L, *supra* note 320, at 3.

370. TRIPS, Marrakesh Agreement, *supra* note 2, at art. 64.2 (declaring moratorium until January, 2000). *See also* Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275 (1997). In addition, there were calls to extend the moratorium. *See, e.g.*, Frederick M Abbott, *Nullification or Impairment Causes of Action under the TRIPS Agreement and the Fifth Ministerial Conference: A Warning and a Reminder*, Quaker United Nations Office Occasional Paper 11, Jul. 2003, *available at* www.quno.org/geneva/pdf/economic/Occasional/Non-violation.pdf; HAOCHEN SUN, TRIPS AND NON-VIOLATION COMPLAINTS: FROM A PUBLIC

continues to exist following recent calls to extend the moratorium.[371] Similarly, there were proposals to implement a moratorium on dispute settlement actions to ensure access to low cost generic versions of AZT drugs.[372]

However, a moratorium on regional agreements is politically unlikely, if not impossible. The USTR has a strong mandate to continue to negotiate and implement trade agreements with ever-stronger terms for intellectual property laws.[373] Moreover, even countries that stand to lose in these agreements are nonetheless eager to sign them for believed trade benefits, no matter how illusory.[374] In addition, even if a moratorium could be negotiated, it would not abolish the many existing bilateral agreements. Although a moratorium has intuitive appeal to developing countries, only a less radical approach will have any likelihood of adoption. Accordingly, the next section considers realistic ways forward.

3. Reconsidering "Fundamental" Patent Law and Policy—This section advocates a critical review of fundamental issues of Western patent law and policy that share some commonality with issues underlying biopiracy disputes.[375] This review goes beyond issue-framing, it inherently couches concerns from a Western perspective which, as prior history shows, increases the opportunity for change. The timing of this review may be particularly well suited for addressing biopiracy because there is an existing

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HEALTH PERSPECTIVE (Nov. 2002), http://www.cid.harvard.edu/cidtrade/Papers/Sun-TRIPS.pdf.

371. *See, e.g.*, Tove Gerhardsen, *Non-Violation Complaint Moratorium Extended in Latest Hong Kong Draft*, INTELL. PROP. WATCH, Dec. 18, 2005, http://www.ip-watch.org/weblog/index.php?p=184&res=1024&print=0.

372. *See, e.g.*, Joint Communication from the African Group, *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/351 (June 24, 2002) (suggesting that there should be moratorium on disputes against members that take measures to address national health concerns in countries with inadequate manufacturing capacity); Second Communication from the United States, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/358 (July 9, 2002) (suggesting that the most expeditious solution would be either a moratorium on dispute settlement, or a waiver of the Article 31(f) requirement that compulsory licensing be predominantly for domestic use).

373. *See, e.g.*, Trade Act of 2002, Pub. L. No. 107-210, §°2102(b)(4)(a)(i)(II), 116 Stat. 933, 995–96 (codified at 19 U.S.C. §°3802(b)(4)(a)(i)(II) (2004)) (noting that a primary objective of the United States regarding trade-related intellectual property rights is to ensure that "provisions of any multilateral or bilateral trade agreement . . . entered into by the United States reflect a standard of protection similar to that found in United States law").

374. *See supra* notes 323–324 and accompanying text.

375. There are additional issues of current concern among Western patent law that could potentially also be considered alongside traditional knowledge concerns. For example, there is a strong concern that patents are impeding adequate access to health. This could be an area of emphasis with respect to the indirect impact of patenting traditional knowledge on the health and sustainability of developing countries.

concern among Western countries that present patent laws and policies are in need of reconsideration.[376] Biopiracy, as well as current issues arising in Western countries, raises questions about the appropriate balance between promoting scientific invention and competing social and cultural priorities.[377]

a. Patents and Morality/Ethics—One ethical issue at the intersection of patents and biotechnology is whether patents unduly commodify life. This is not an entirely new issue, but is gaining broader discussion as patents come increasingly closer to people's conceptions about the building blocks of life. In the early nineties, patient John Moore wanted to claim patent or property rights in technology derived from his diseased spleen, but the majority of the California court that heard his case declined to find any such interest and sided with providing patent rights solely to the doctor in the interest of promoting the biotechnology industry.[378] However, Judge Mosk noted in his dissent that because society acknowledges the importance of protecting the human body as "the physical and temporal expression of the unique human persona," there are prohibitions against indirect abuse of the body

376. Western countries are involved in serious reflection of patent law and policy, as reflected in the recent promulgation of many governmental and non-governmental reports. *See generally* AUSTL. ADVISORY COUNCIL ON INTELL. PROP., PATENTS AND EXPERIMENTAL USE ISSUES PAPER (Feb. 2004), *available at* http://www.acip.gov.au/library/patentsexpuse.PDF (providing a comparative analysis of experimental use, with proposed policies for Australia); W.R. CORNISH ET AL., INTELLECTUAL PROPERTY RIGHTS (IPRS) AND GENETICS: A STUDY INTO THE IMPACT AND MANAGEMENT OF INTELLECTUAL PROPERTY RIGHTS WITHIN THE HEALTHCARE SECTOR (July 2003), *available at* http://www.phgu.org.uk/about_phgu/resources/word/s-ipr1.doc; FED. TRADE COMM., TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf; NAT'L RESEARCH COUNCIL, *supra* note 147, at 41; NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA (2002), *available at* http://www.nuffieldbioethics.org/go/ourwork/patentingdna/introduction; THE ROYAL SOCIETY, KEEPING SCIENCE OPEN: THE EFFECTS OF INTELLECTUAL PROPERTY POLICY ON THE CONDUCT OF SCIENCE (2003), *available at* http://www.royalsoc.ac.uk/displaypagedoc.asp?id=11403; Background Study for the European Commission within the Framework of the Expert Group on Biotechnological Inventions, *Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evaluation*, (2004) (*prepared by* Sven J.R. Bostyn), *available at* http://www.ivir.nl/publications/bostyn/patentingdna.pdf.

377. The role of patents in promoting innovation more generally could be further studied since there is little evidence to support the claims of Western nations that strong patent rights will promote the local economy, or increase the amount of foreign direct investment. *See generally* KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY (2000); WTO and WHO Secretariats, *WTO Agreements & Public Health: A Joint Study by the WHO and the WTO Secretariat* (2002), *available at* http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf; WIPO, *WIPO Patent Agenda: Options for Development of the International Patent System*, at 24, WIPO Doc. A/37/6 (Aug. 19, 2002). However, unlike the issues proposed, directly challenging the ability of patents to promote innovation may face substantial opposition.

378. Moore v. Regents of Univ. of Cal., 793 P.2d 479, 494 (Cal. 1990).

through economic exploitation for the sole benefit of another.[379] He suggested that this issue "haunts the laboratories and boardrooms of today's biotechnological research-industrial complex."[380] In a concurring opinion, Judge Arrabian suggested that for scientists to claim the right to appropriate and exploit a patient's tissue for profit without compensation to the patient, would be to improperly treat the human body as a commodity.[381] More recently, the Nuffield Council evaluated the ethics of patenting DNA on behalf of the British Royal Society and found that there is an "anxiety about what might be termed 'private appropriation of the genetic commons.'"[382] The Nuffield Council found that "human DNA sequences hold a special status as our common heritage" and thus, there is an ethical concern over patenting such subject matter.[383]

The issue of commodification of life has special pertinence to biopiracy patents. In particular, although the underlying technology that is patented may be different, the argument is essentially the same—patents on some types of inventions devalue important social issues. For Western countries, the current issue is whether gene patents and stem cell patents unduly commodify human life, based upon the belief that such material has special status as common heritage. For indigenous communities, patents based upon their sacred resources and traditions are considered to defile the sanctity of their culture.[384]

There is a parallel discourse concerning the commodification of life between Western and developing countries. The counterargument that is made in both instances is that opposition to such patents is overstated because a patent does not constitute private ownership in life itself, such that the fears are overstated.[385] In particular, Western countries note that because a patent right is one of

379. *Id.* at 515 (Mosk, J., dissenting).

380. *Id.*

381. *See, e.g., Moore*, 793 P.2d at 497 (Arabian, J., concurring) (noting that the request of plaintiff to recognize and enforce a right to sell his body tissue for profit would be tantamount to equating human tissue as "equal with the basest commercial commodity").

382. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 376, at 5.

383. *Id. See generally* Barbara Knoppers, *Status, Sale and Patenting of Human Genetic Material: An International Survey*, 22 NATURE GENETICS 23 (1999); David B. Resnik, *Patents on Human-Animal Chimeras and Threats to Human Dignity*, 3 AM. J. BIOETHICS 35 (2003) (noting that patents on DNA threaten human dignity because it contributes to a trend towards complete commodification of human beings); Melissa Sturges, Note, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 AM. U. INT'L L. REV. 219 (1997).

384. In addition, indigenous communities have also opposed patents on living matter, such as plant resources; patents are seen as leading to commercialization, which is seen as threatening the relationship that communities have with protecting their environment.

385. *See supra* notes 257–261 and accompanying text.

exclusion, it does not give control over life itself. For example, a patent on a method of creating an oil-eating bacteria provides its owner with the right to exclude all others from creating such bacteria, but is not an unrestricted right in the bacteria itself. Laws outside the patent realm can—and often do—restrict the ability of patent owners to make or use what they have patented.[386] The implication is that since there is no technical control over living matter, commodification is a non-issue. In addressing opposition to perceived immoral patents, proponents of the patent system typically refer to the effectiveness of the patent system in promoting science and technology. For example, in addressing the concerns of developing countries with respect to biopiracy patents, the United States has stated that "[t]he patent system has been and continues to be a highly effective tool for technological and economic development."[387] Similarly, the United States has asserted that "[i]t is no accident that countries with strong patent systems, where exclusions from patentabilty are few, are also countries with strong private industries covering the broad range of technology, providing jobs and contributing to the creation of capital that can be invested further."[388] However, even if strong patent rights promote economic status—which itself is a questionable proposition—this ignores the extent to which other values might be prioritized over absolute wealth, such as cultural norms concerning the sanctity of life.

The proper role of ethics in patent law has historically been an issue for sovereign consideration. However, in an increasingly global economy, ranging from the creation of the EU to bilateral and multilateral agreements, the role of ethics may need to similarly be considered on a more global basis. This is particularly true since while the grant and enforcement of patents technically remains limited to national boundaries, there is no limit to where the underlying patented technology may be derived. In particular, whereas patentable subject matter limits may have previously been able to reflect cultural perspectives on the appropriate limits of what should be patentable, this is impossible if there are multiple cultures involved.

Even amongst Western countries, there may be important differences of opinion regarding the appropriate scope of patentability. This was readily seen in the discussions concerning

386. *See, e.g.*, IP/C/W/209, *supra* note 58, at 4 (noting that a patent owners have a right to exclude others, but that the patent owner does not have any affirmative rights, such that a patent would not give control over the human source that originated the gene).

387. IP/C/W/434, *supra* note 267, ¶ 33.

388. IP/C/W/209, *supra* note 58, at 4.

the need for an EU Biotechnology Directive. The original 1997 proposal attempted to mirror US law to increase the competitiveness of the EU biotechnology industry.[389] However, this proposal was rejected because of inadequate consideration of ethical issues.[390] Some of the member states, including the Netherlands, Belgium and Italy were opposed to the proposal because of a general opposition to the patenting of plants and animals.[391] In an interesting parallel to the current discussion on biopiracy, there was a suggestion to include in the text of the EU Biotechnology Directive some language to require patents to state the geographical place of origin of the invention, as well as evidence that the material was used in accordance with access regulations—two of the very proposals that developing countries have been urging be adopted via TRIPS amendments.[392] In addition, even after the Directive was passed, member states continued to protest the directive, including filing a formal challenge with the European Court of Justice. One argument was that the Directive would unduly deprive member states of their right to utilize TRIPS Article 27(3)(b) to exclude certain plants and animals from patentability. The European Court of Justice expressly rejected Netherlands's claim that the Directive contradicted the CBD. Indeed, echoing the prior discussion of the CBD's subordination to other international agreements, the court noted that the CBD "is more in the nature of a framework agreement" that merely "proposes a series of approaches which Contracting Parties . . . are to adopt, in many cases only as far as possible and as appropriate." The scope of the Convention is rather wide; the suggested measures are rather varied and in most cases couched in general terms.[393] Moreover, the Court of Justice echoed the position currently taken by Western countries with respect to biopiracy:

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389. *Commission Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions*, at 6, COM (1988) 496 final (Oct. 17, 1988) [hereinafter *EU Biotech Directive*]. *See also Communication from the Commission to the Council, Biotechnology in the Community*, at 34, COM (1983) 672 final (Oct. 3, 1983) (noting the necessity of taking actions "for the promotion of competitiveness in modern biotechnology" in Europe).

390. *Decision on the Joint Text Approved by the Conciliation Committee for a European Parliament and Council Directive on the Legal Protection for Biotechnological Inventions*, 1995 O.J. (C 68) 26; Joseph Straus, *Patenting Human Genes in Europe—Past Developments and Prospects for the Future*, 26 IIC 920, 942–46 (1995).

391. *See, e.g.*, Sigrid Sterckx, *Some Ethically Problematic Aspects of the Proposal for a Directive on the Legal Protection of Biotechnological Inventions*, 1998 EUR. INTELL. PROP. REV. 123, 125, 127 (1998).

392. *EU Biotech Directive*, *supra* note 389, ¶ 16 ("whereas the free and informed consent of the person from whose body material is taken is required in order for an application to be made for a patent in respect of the use of that material.").

393. Case C-377/78, Netherlands v. Parliament and Council, 2001 E.C.R. 1-7079, ¶ 179.

> [I]t is not for patent legislation to provide for broader matters such as monitoring the source of biological material in respect of which patent protection is sought. The Directive does not—nor can it—affect the ability of developing countries to establish controls over their genetic resources in order to prevent the unregulated plundering of such resources.[394]

Although the Court of Justice opinion speaks in definitive language, member states have not all uniformly transformed the EU Directive into national law.[395]

In addition, although there is no place under current laws for a consideration of implications on other countries, patent laws have been known to evolve over time. Sometimes patent laws have changed in response to calls by industry groups to strengthen patent rights.[396] However, patent laws have also changed in response to public policy concern. For example, the USPTO twice modified its guidelines for patent examination to accommodate public concerns about unduly lax patenting of gene patents that were feared to put the future of genetic development in the hands of a few individuals who had not adequately discovered or described all aspects of the isolated gene sequences.[397] Also, national courts and legislatures have often made modifications to law to better balance proprietary patent rights with needs to access medicine. In particular, many nations have an exception to patent infringement to enable manufacturers of generic drugs to produce enough of the patented product during the patent term to obtain regulatory approval, thus expediting the availability of lower cost generic drugs once the patent expires.[398]

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394. *Id.*, ¶ 181.

395. Interestingly, some member states continued to believe that national laws implementing the EU Directive should include some aspect of the watered-down preamble relating to the need for informed consent. *See, e.g.*, Deryck Beyleveld, *Why Recital 26 of the EC Directive on the Legal Protection of Biotechnological Inventions Should be Implemented in National Law*, INTELL. PROP. Q., Issue 1, 2000, at 1. Indeed, Belgium has proposed changing its law to nullify patents that fail to comply with disclosure of origin. *See, e.g.*, Geertrui van Overwalle, *Belgium Goes its Own Way on Biodiversity and Patents*, 24 EUR. INTELL. PROP. REV. 233, 234 (2002) (noting proposal, but suggesting application problems).

396. This is the case in the United States, where federal law has been designed to make patentability in the area of biotechnology easier. *See* 35 U.S.C. § 103(b) (2000). Similarly, amendments to create "extraterritorial infringement" under United States patent laws were also a result of efforts of the biotechnology industry to ensure that their research was not pirated abroad. *See* 35 U.S.C. § 271(g) (2000).

397. *See, e.g.*, Utility Examination Guidelines, 66 Fed. Reg. 1092, 1097–99 (Jan. 5, 2001); Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001).

398. *See, e.g.*, 35 U.S.C. § 271(e)(1) (2000) (providing exception from patentability for generic drug manufacturers to prepare data for submission to FDA); Law No. 24.766, Dec.

While the role of morality in patent law may seem highly analogous to present objections concerning biopiracy patents, the morality issue may be the most difficult to address because of historic problems of reaching consensus on this thorny question. Discussion of the proper place of morality in patent law is important, but not a recommended short-term strategy for addressing biopiracy problems. Indeed, this strategy has already been utilized by developing countries to no avail. However, there are other issues with Western patent law that share commonalities with biopiracy that could bring more immediate resolution to the biopiracy problems, as will be discussed in the next section.

b. Western Patent Problems as Templates for Addressing Problems of Biopiracy—This section considers a panoply of issues that can serve as templates to address various aspects of biopiracy-related concerns. Because these issues are already under consideration by Western countries, there is no uphill battle in convincing such countries of the importance of the issues. While this approach does not offer the simplicity of a single amendment to TRIPS, it may provide the more important advantage of actual success. Some of these issues have in fact been raised by developing countries in conjunction with allegations of biopiracy. However, they tended to be noted in conjunction with more inflammatory statements that challenged ingrained Western patent law principles, such that they were likely not given serious consideration.[399] Accordingly, this section highlights current issues that may provide some success with the goal that they be the primary focus of advocacy, rather than biopiracy alone.

c. Inadequately Inventive?—One current issue is whether Western patent systems currently grant patents inappropriately for what are inferior inventions. There are actually two sub-issues, both of which may have relevance for addressing biopiracy. First, there are serious concerns about whether existing patent rules are rigorously applied by patent offices. More specifically, there is an issue with regard to the standard for patenting isolated or modified genes

30, 1996, art. 8, B.O. 18/12/96 (Arg.); Patent Act, R.S.C., ch. P-4, 55.2(2) (1985) (Can.); Bundesgerichtshof [BGH] [Federal Court of Justice] "Clinical Trials II," *Klinische Versuche II*, April 17, 1997, 1998 R.P.C. 424 (F.R.G.) (providing, under a decision by the German Federal Court of Justice, an exception from patentability for tests carried out with view of obtaining data for marketing approval); *see also* 35 U.S.C. § 287(c) (2000) (creating immunity for medical doctors from infringing certain patented medical procedures); *Clinical Trials III (Decision of the Supreme Court 1999)*, *in* 30 INT'L REV. INDUS. PROP. & COPYRIGHT L. 448, 448–49 (1999) (providing interpretation of Japanese patent law to create exemption from patent infringement for clinical trials conducted to obtain government approval for generic products).

399. *See supra* part III.A.

that may have special relevance for patents based upon genetic resources or traditional knowledge of developing countries.

The quality of patent examinations has been a systemic concern for all inventions. In particular, the USPTO has been a target of criticism, both because of its process of rewarding patent examiners based upon the number of applications examined, as well as for issuance of invalid inventions.[400] In recent years, the USPTO was subject to particular criticism for issuance of internet business method patents that were not truly novel.[401] In response, the USPTO added an additional layer of examination, established additional technical training for examiners of business method patents, and also began to compile a database to help address a deficit in the documented prior art for software and business methods, which were traditionally not patented or published.[402] However, the USPTO continues to be the subject of criticism; recent reports by the Federal Trade Commission and National Research Council have continued to suggest that the USPTO is not adequately applying the standards of novelty and nonobviousness.[403] As noted by the NRC, the existing internal quality review by the USPTO "does not inspire confidence."[404]

In addition, the definition of what constitutes a sufficiently novel chemical compound to be patentable under Western law is also of current concern. The United States has long held that isolated and purified genes and gene sequences are sufficiently analogous to chemicals, such that they should be considered patentable.[405] Other Western countries have generally followed suit in embracing patent laws that mirror the US, although such action may be more a function of a desire to capture the commercial proceeds that emanate from the profitable biotechnology industry in the U.S.,

400. *See, e.g.*, NAT'L RESEARCH COUNCIL, *supra* note 147, at 47. In addition, some have suggested that the USPTO is subject to special workload pressures as the technology in patent applications has become increasingly complex, yet the number of patent examiners has actually been reduced by twenty percent in recent years. *Id.* at 51.

401. Amazon.com's "one-click" method of shopping on the internet is one example.

402. *See* U.S. Patent & Trademark Office, Business Methods Patent Initiative; An Action Plan (2000), http://www.uspto.gov/web/offices/com/sol/actionplan.html; U.S. Patent & Trademark Office, Patent Quality Improvement: Expansion of the Second-Pair-of-Eyes Review, http://www.uspto.gov/web/offices/com/strat21/action/q3p17a.htm (last modified April 4, 2003); Press Release, U.S. Patent & Trademark Office, Under Secretary of Commerce for Intellectual Property Dickinson Unveils New Initiative Focusing on Business Method Patents (March 30, 2000), *available at* http://www.uspto.gov/web/offices/com/speeches/00-22.htm.

403. *See, e.g.*, NAT'L RESEARCH COUNCIL, *supra* note 147, at 47 (noting that "there is no lack of examples of issued patents that appear dubious on their face").

404. *Id.* at 50.

405. *See, e.g.*, Funk Bros. Seeds v. Kalo Inoculant, 333 U.S. 127 (1948).

than a principled consideration of the social implications of such patents.[406] However, some are beginning to question this policy as the implications of gene patents are becoming more obvious. In particular, many have noted that gene patents are impeding access to genetic testing, as well as subsequent research. Accordingly, there are renewed calls to reconsider the long-standing approach to patented genes and gene sequences.[407] This reconsideration could be opportune for addressing the biopiracy problem to the extent that some patents are genetically engineered equivalents of plants that are known through traditional knowledge to have medicinal value.

Gene patents discovered with the assistance of nonscientists are a special subset of gene patents that raise an additional issue beyond those applicable to all gene patents. In particular, only the scientist who isolates the genetic material is considered the inventor of such patents. However, the fact that traditional communities or Western patients provide instrumental assistance in expediting the process is another reason to question the inventive contribution that leads to such patents. Developing countries have alleged that patent rights are inequitable when communities provide substantial input for the patented invention, yet are excluded from any resulting patent bounty. Similarly, Western patients who contribute biological material to facilitate and expedite the process of finding medical treatments are affronted by resulting patents that may impede their access to discovered medical treatments because of the patent cost, as well as the fact that others are profiting from their generosity.[408] In both instances, a group of individuals is willing to share their knowledge and resources—until they realize that those resources are being used to create patents that may then have a negative implication on them. In the context of biopiracy, the negative result is often the patent itself because it is seen as a per se violation of cultural traditions. In the case of patient contributions, the negative result may be a violation of fiduciary

406. Council Directive 98/44/EC of the European Parliament and of the Council on 6 July on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13.

407. Some have suggested that with technological advances in DNA sequencing, the process of isolating a gene is no longer inventive, even if the resulting product technically does not exist in nature. *See, e.g.*, NUFFIELD COUNCIL ON BIOETHICS, *supra* note 376, at 3.30; John H. Barton, *Rational Limits on Genomic Patents*, 18 NATURE BIOTECH 805, 805 (2000) (noting that although discovery of DNA sequences used to be a laborious task, automatic sequencing devices available today should make the process lack adequate inventive step for patentability); Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707 (2004) (reevaluating United States patent law regarding the patentability of DNA and ultimately concluding that gene patents should not be patentable).

408. *See generally* Cynthia M. Ho, *supra* note 98 (providing discussion of a gap between patient preceptions and patent law, as well as possible avenues to address the gap).

responsibility, as well as an unexpected lack of access to the medical test or treatment that the patient helped to produce since the patent owner has the right to exclude all others from the patented invention.

Another important issue to biopiracy is a potential modification to the United States' definition of prior art, which could help prevent the issuance of what are currently considered valid patents. As previously noted, to determine whether an invention is adequately new, and thus deserving of patent protection, the United States considers any printed document published anywhere in the world, but does not afford equal status to oral information. There is not a groundswell of support at present to modify this rule, although some academics have advocated eliminating the distinction as anachronistic and even unconstitutional.[409] In addition, while one recent Congressional proposal that attempts to address a number of patent reforms modifies this rule, it is not clear whether this proposal will become law.[410] Similarly, at the international level, the current SPLT, being negotiated under the auspices of the World Intellectual Property Organization (WIPO), notably would impose a uniform definition of novelty that would replace the United States' rule with one that would consider knowledge known anywhere in the world—whether oral or written—to be relevant prior art.[411]

C. A New Proposal for addressing Socio-Cultural Conflicts

This section proposes a new method of promoting patent policy by first gathering information that will not immediately threaten the interests of patent owners. As previously noted, patent proponents are highly sensitive and opposed to any changes to the scope of patent rights.[412] This method leaves untouched present patent rights, such that patent proponents are less likely to find it objectionable. Nonetheless, this section provides a method for public commentary and direct dialogue with patent owners that should help foster better patent policy.

409. *See supra* note 60 (referencing arguments for changing the definition of prior art in 35 U.S.C. § 102(a)). In addition, the NRC also recommended eliminating this distinction, albeit for reasons of international harmonization. *See* NAT'L RESEARCH COUNCIL, *supra* note 147, at 127 (noting that "in the interest of arriving at a uniform definition of prior art, the United States should remove its limitation on non-published prior art").

410. *See* The Patent Reform Act of 2005, H.R. 2795, 109th Cong. (1st Sess. 2005).

411. *See supra* Part III.B (describing SPLT definition of prior art).

412. *See, e.g., supra* Part III.A.

The envisioned system would provide for internet-based commentary that is hyperlinked to patents. The comments would not appear on the face of the patent itself because they are not a part of the patented invention. However, the comments would be hyperlinked to the first page of each patent. Since most patent offices are publishing patents, and even patent applications on the internet, a web link on the face of the patent to a separate site with commentary should be technologically feasible.[413] The patent owner would also be permitted to directly respond to comments, which would be similarly hyperlinked to the actual patent. In particular, because objections to patents sometimes stem from misunderstanding the underlying science, as well as a misunderstanding of patent rights, providing patent owners with the ability to clarify issues would be in the best interests of all.

This proposal avoids problems with incorporating morality considerations directly in patent laws, which although a frequent proposal to address ethical conundrums in patent law, has its own host of problems. Current systems that allow considerations of morality within patent laws have been criticized on a number of grounds. A major objection is that patent examiners typically are unqualified to make assessments of whether a patent is adequately immoral to be denied patentability since such examiners are hired for their technical, rather than ethical expertise. There is also the potential for inconsistency in application of the morality rule because of the inherent ambiguity in determining whether an invention is sufficiently problematic to deny patentability—whether by someone trained in science or ethics. Moreover, although some existing patent systems enable third parties to raise objections based upon morality, the result is typically that the issuance of a patent is delayed, but the third parties are unsatisfied with the process. The systems nonetheless are subject to intense criticism from these parties.[414] This proposal, on the other hand,

413. *See, e.g.*, 35 U.S.C. § 12(b)(1)(A) (2000) (noting that U.S. patent applications will generally be published "promptly" after a period of eighteen months from the earliest filing date unless an applicant requests an earlier date, or an exception to publication applies); Japanese Patent Law, Law No. 121 of Apr. 13, 1959, art. 64(1), *as last amended by* Law No. 220 of Dec. 22, 1999 (publication "one year and six months from the filing date"); EPC, *supra* note 38, at art. 93 (noting that European patent application shall be published "as soon as possible after the expiry of a period of eighteen months" from the date of filing or of priority); PCT, *supra* note 292, at art. 21(2) (noting that in general, the application will be published "promptly after the expiration of 18 months from the priority date of the application"). *See also* Japan Patent Office, Trilateral Patent Website, http://www.jpo.go.jp/index.htm (providing for the ability to search U.S., Japanese, and EPC patents).

414. For example, under the European system that enabled consideration of morality issues, the examination of a patent application on the Harvard "Onco-mouse," a mouse that was genetically predisposed to develop cancer, was subject to over a dozen formal

provides dialogue while avoiding the problems that have traditionally arisen under patent systems that consider morality.

In addition, while this proposal enables discussion of moral implications, it would not raise strong political challenges against modifying patent rights in the United States. In fact, it is possible that patent proponents may embrace this system because it provides an opportunity for patent owners to present an affirmative case for their inventions. Moreover, adoption of this system, rather than a whole-sale change to patent laws, could enable patent proponents to assert that they were sympathetic to concerns raised about both biopiracy and immoral patents, without directly threatening their immediate economic interests.

Beyond side-stepping problems associated with past approaches, the present proposal provides new benefits. For example, this proposal *would* provide for transparency of public opinion concerning the implications of the patent, and would enable an indirect impact on the potential commercialization since the comments would be publicly available.[415] Such a system would add an important layer of public transparency about the patent process that could play an important role in development of patent law and policy. For example, such an accessible system could facilitate investigative reporting and discussion by bloggers. In addition, the system could impact ultimate commercialization of inventions by providing additional information that might not otherwise be available. For example, prior to entering into licensing and/or commercialization agreements, a company could consult the comments for a gauge of public perception and opposition. Moreover, the increased transparency and dialogue could assist policy makers and legislators who would be able to consult the comments when concerns arise regarding whether the patent system should be modified. This could be particularly helpful in evaluating the United States patent system—devoid of explicit consideration of morality—because there is concern that legislators lack complete

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oppositions by individuals and organizations, and several levels of review before the patent was granted. *See* Oncomouse/HARVARD O.J. E.P.O. 1989, 451; T19/90 Oncomouse/HARVARD O.J. E.P.O. 1990, 476; Oncomouse/HARVARD O.J. E.P.O 1992, 588. *See also* Press Release, European Patent Office, Public Oral Proceedings in the Appeal Case T315/03 Relating to the "Oncomouse/Harvard" patent EP 0169672 (July 2, 2004), http://www.european-patent-office.org/news/pressrel/2004_07_02_e.htm.

415. A contrary argument is that the opposition systems of some countries, such as Europe, already allow for objections, but that the process has typically nonetheless resulted in a patent. *See* DAVID A. KEVLES, A HISTORY OF PATENTING LIFE IN THE UNITED STATES WITH COMPARATIVE ATTENTION TO EUROPE AND CANADA 58–60 (2002) (noting that despite substantial dissent, there were duplicative arguments made and the same eventual result as under the United States patent system).

information concerning what is patented, such that law makers are unaware of morality issues concerning patents.[416]

Public opinion can shape commercialization of patented products, as well as patent policy. For example, Monsanto disavowed intent to commercialize genetically modified plants designed to produce no reproducible seeds because of public protest over what was dubbed "terminator technology."[417] In addition, although not a patent issue, public opinion has impacted the commercialization of genetically modified food. Similarly, although Myriad Technology, the company awarded patents on breast cancer marker genes, aggressively sought to promote expensive licenses world-wide, it faced major opposition from the Canadian provinces as well as European nations.[418] This proposal provides for broader access and input than present patent systems that enable direct challenges based upon lack of morality. In contrast to current legal systems that require specific legal challenges to individual patents, the present proposal would reduce costs because no legal action is required. Cost is an important issue that has been cited by

416. Bagley, *Patent First, Ask Questions Later*, *supra* note 130, at 502.

417. *See, e.g.*, David R. Nicholson, *Agricultural Biotechnology And Genetically-Modified Foods: Will The Developing World Bite?*, 8 VA. J.L. & TECH. 12–13 (2003). The United States, in particular, which had an interest in the patent, undertook efforts to block negative appraisals of the technology. Although UPOV initially reported that this technology presented "considerable disadvantages for society," it ultimately omitted this characterization after repeated pressure from the United States. ETC Group, *US Government Forces UPOV to Abandon Terminator Critique*, April 17, 2003, http://www.etcgroup.org/article.asp?newsid=393.

418. *See, e.g.*, Press Release, Institut Curie, Against Myriad Genetics' Monopoly on Tests for Predisposition to Breast and Ovarian Cancer Associated with the BRCA1 Gene (Sept 26, 2002); Jurdan Paradise, *European Opposition to Exclusive Control over Predictive Breast Cancer Testing and the Inherent Implications for US Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 134–39, 147–50 (2004) (providing overview of objections to BRCA patents, including policy issues). *See also* ONTARIO MINISTRY OF HEALTH AND LONG-TERM CARE, GENETICS, TESTING AND GENE PATENTING: CHARTING NEW TERRITORY IN HEALTHCARE 40–43 (2002); AMERICAN MEDICAL ASSOCIATION, REPORT 9 OF THE COUNCIL ON SCIENTIFIC AFFAIRS: PATENTING OF GENES AND THEIR MUTATIONS (2000), http://www.ama-assn.org/ama/pub/category/13570.html (providing overview of policy issues relating to gene patents and recommending that gene patents be granted only when credible utility is established and that measures be taken to ensure access to health care). Although the Myriad patents have been very high-profile, gene patents in general have been considered a major patent policy problem. *See, e.g.*, M.K. CHO, PREPARING FOR THE MILLENIUM: LABORATORY MEDICINE IN THE 21ST CENTURY 47–58 (2d ed. 1998) (noting that twenty-five percent of genetic testing laboratories surveyed had not been able to offer a test due to patent issues and that fifty percent did not develop new tests because of patent issues); John Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577 (2002) (noting that thirty percent of laboratories stopped developing tests based upon the hemochromatosis gene due to threats of patent litigation); American College of Medical Genetics, Position Statement on Gene Patents and Accessibility of Gene Testing (Aug. 2, 1999), http://www.acmg.net/resources/policies/pol-015.asp.

developing countries in the context of biopiracy.[419] The removal of a cost barrier could result in a broader range of constituencies who could participate in discussions.[420] There would still be a cost in finding problematic patents, but the cost would be less than a full legal challenge. In addition, it is possible that greater transparency of the problem may lead to new organizations with funding and momentum to spearhead legislative challenges. For example, in the copyright context, the Electronic Frontier Foundation was initiated with the purpose of challenging laws that unduly restrict public access.[421]

A system that works with the existing patent framework offers systematic advantages that are presently lacking. For example, although concerned citizens may write editorials, or even web site articles about patents they view as improper, such avenues are likely to be read and considered only by similarly interested parties, rather than broadly considered by those responsible for patent policy such as those in Congress and the court systems. In addition, the lack of a formal system may ultimately doom their continued existence and utility. One example is the former website "bountyquest.com," which enabled interested parties to post a "reward" on the website to anyone who could help find "prior art" to defeat the noted patent that the web site considered to be improper. Although initially hailed as a great innovation and tool to attack improper patents, it is now defunct.[422]

The present proposal would likely encourage a broader consideration of policy issues than current formal or informal systems. With respect to informal systems, such as bountyquest.com, there is no encouragement of participation from the patent owner and indeed, the premise of the website is to attack the patent owner by finding prior art to invalidate the patent. However, such a system provides little assistance to objections against patents that are not

419. *See, e.g.*, IP/C/W/403, *supra* note 197, at 2 (noting that challenging individual patents "may not be economically feasible for many aggrieved countries," especially in light of prior art rules that make legal challenges "formidable and cumbersome").

420. For example, under the European patent system that considers lack of morality as a basis for denying a patent, all of the published cases involving third party challenges include Greenpeace. This may make the challenges more easily dismissed as solely representing the views of a narrow segment of society.

421. *See* Electronic Frontiers Foundation, Mission Statement, http://www.eff.org/mission.php (last visited Mar. 7, 2006).

422. *See, e.g.*, Michael J Felton, *A Call for Bounty Hunters*, MODERN DRUG DISCOVERY, Mar. 2001, at 57–58 (noting that BountyQuest was "born out of necessity" to address shortcomings of the U.S. patent system); Posting from Tim O'Reilly to Richard K. Belew, http://www.oreilly.com/pub/a/oreilly/ask_tim/2003/bountyquest_1003.html (Oct. 2003) (noting that although BountyQuest "seemed like a great idea," it was not able to translate it into a successful business model).

grounded in existing patent laws, but are nonetheless important from a policy perspective; namely, objections to moral implications of patenting traditional knowledge, as well as new technology. In addition, present informal systems do not promote broader understanding of the scope of patent rights. Although editorials for and against patents may provide some limited exchange of views, they typically involve a delay in time. Moreover, because there is no official venue, there is no incentive to encourage broad participation by patent owners. Past experience shows that formal systems for objection through patent offices may stymie serious discussion of issues that are not present considerations under patent law. For example, in the case of the "Vine" patent, there was a reexamination of the patent in the United States. Although the Center for International Environmental Law (CIEL) raised objections to the patent on the basis of moral utility, the patent office did not address this issue.[423] Technically, CIEL's comments inappropriately fail to distinguish between utility and plant patents, for which there are different patentability requirements, while simultaneously invoking trademark registration standards, for which the requirements are vastly different than those for either type of patents.[424] Nonetheless, if there were a broader forum for airing the problem, CIEL, or another party more familiar with patent laws could have argued that the moral utility doctrine *should* be considered for plant patents. In addition, beyond enhancing arguments, the Vine patent illustration is particularly notable because although the case raised issues concerning immorality of patents based upon biopiracy, the limited public access to the proceedings effectively kept this argument hidden from public view, thus postponing public discussion of this issue.

For example, if this proposal had existed at the dawn of allegations of biopiracy, it could have helped to rewrite the current history. Organizations that have been vigilant about publicizing biopiracy patents, such as ETC/RAFI, could have provided comments linked to the specific patents. Although this would not likely have diffused their public campaigns, it would have offered a more organized attempt to diffuse some issues of misunderstanding. In

423. *See* David R. Downes & Glenn Wiser, Center for International Environmental Law, *Detailed Statement in Support of Request for Reexamination of U.S. Plant Patent No. Plant 5,751* 24 (Mar. 30, 1999) (suggesting that patent right "offends religious and moral sensibilities to an extent that is inconsistent with the concept of utility that underpins United States patent law").

424. *See id.* at 24–28. *See also* 35 U.S.C. §§ 101–03 (2000) (providing requirements for utility patents); 15 U.S.C. § 1052 (2000) (providing types of trademarks that cannot be federally registered).

particular, rather than wait for academic commentators to discuss a claim's merits or lack thereof, patent owners could directly address misconceptions in a rebuttal format. For example, in response to the misperception that the neem tree itself was patented such that it could not continue to be used, an explanation linked to the actual patent might be more effective than articles that state the same assertion but are only read by academics. In addition, although owners of U.S. patents would likely dismiss assertions of commodifying a sacred symbol in their responses, there could have been a direct and immediate dialogue about whether U.S. patents *should* consider morality issues within its patent laws. Moreover, an open forum could have been readily joined in by NGOs, academics, and anyone with an interest in patent policy. For example, some of the biopiracy allegations have appeared at a time when the U.S. was considering application of a bar to federal registrations of trademarks that are unduly disparaging of other groups—Indian groups in particular.[425] Although the scenario is different in the sense that trademark laws have an existing basis for denying patents based on disparagement, there are patent laws in other countries that deny patents for morality-based concerns, which are at a minimum, analogous to disparagement. There could have been an interesting synergy of discussion by like-minded groups about the perception of misappropriation of cultural identities. Intellectual property academics could have also participated in the dialogue in a more effective manner than attempts to diffuse rhetoric, on both sides, years after the rhetoric has crystallized into a mindset.

Although this proposal is conceptualized within the context of gathering information to address patents based on unauthorized access to resources, the method can be readily transposed to other areas where patent law and policy are in need of consideration. For example, the negative impacts of specific patents on health care, scientific research, or any other social policy concern could poten-

425. The PTO requested comments on whether trademarks should be prohibited for any federally recognized Indian tribe since many insignia have religious symbols, such that their use in commerce is considered sacrilegious. *See* Official Insignia of Native American Tribes; Statutorily Required Study, 64 Fed. Reg. 29,841 (June 3, 1999); Official Insignia of Native American Tribes; Statutorily Required Study, 63 Fed. Reg. 71,619 (Dec. 29, 1998). *See also* 152 CONG. REC. S8927 (statement of Senator Bingaman) (proposing that federally recognized Indian tribe insignia be excluded from registration); Justin Blankenship, *The Cancellation of Redskins as a Disparaging Trademark: IS Federal Trademark Law an Appropriate Solution for Words that Offend?*, 72 U. COLO. L. REV. 415 (2001); Gavin Clarkson, *Racial Imagery and Native Americans: A First Look at the Empirical Evidence Behind the Indian Mascot Controversy*, 11 CARDOZO J. INT'L & COMP. L. 393 (2003); Rachel Clark Hughey, *The Impact of* Pro-Football, Inc. v. Harjo *on Trademark Protection of Other Marks*, 14 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 327 (2004).

tially be vetted through this proposal. To some extent, the need for transparency and greater information is less urgent concerning the intersection of patent and health law because the issue has already been subject to years of discussion at the WTO, and among the popular press. However, the ability to provide public comments to specific patents could still have an impact that potentially enhances prior discussions. In addition, there are other areas of patent law that could be addressed through this system. For example, with software and with business method patents, there remains concern as to whether the patent system is working effectively.[426]

The present proposal is admittedly embryonic with respect to its precise format. However, hopefully the above outlined issues show sufficient promise to engage further discussion and potential adoption. Because this Article is focused on addressing the biopiracy problem from multiple angles, significant details about the present proposals are beyond its scope. However, a few logistical concerns are nonetheless outlined for completeness.

One practical issue is what organization(s) are responsible for linking comments to the specific patents. This could be a logical role for WIPO, which already helps to streamline international filings of patent applications.[427] Moreover, WIPO is a well-funded organization that would potentially have adequate infrastructure to sustain such a role.[428] On the other hand, to the extent that WIPO sees its mission as protecting the rights of patent owners, this may present a conflict of interest.[429] Given the current state of technology, a small group of individuals could probably craft a method for public input via a website that would then be of minimal cost to maintain. To the extent that people and organizations have a vested interest in the outcome of the system, perhaps the process

426. *See, e.g.*, Robert P. Merges, *As Many as Six Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577 (1999); Tobias Buck, *IT Groups Win EU Ruling on Patents*, FIN. TIMES, June 20, 2005, at 9; Josh Lerner, *Where Does State Street Lead? A First Look at Finance Patents, 1971–2000* 29 (Nat'l Bureau of Econ. Research, Working Paper No. 7918, 2000); Press Release, Gov't of Pol., Pol. Does Not Support Current Proposal for EU Software Patent Directive (Nov. 17, 2004), *available at* http://swpat.ffii.org/news/04/cons1117/index.en.html. *But see* John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 BERKELEY TECH. L.J. 987 (2003); Jeffrey R. Kuester & Lawrence E. Thompson, *Risks Associated with Restricting Business Method and E-Commerce Patents*, 17 GA. ST. U. L. REV. 657 (2001).

427. In particular, WIPO is the organization that coordinates filings under the Patent Convention Treaty.

428. *See, e.g.*, WIPO, ANNUAL REPORT 2003 26 (2003), *available at* http://www.wipo.int/freepublications/en/general/441/wipo_pub_441_2003.pdf (noting that nearly 90 percent of WIPO's total income in 2003 came from filing fees for, and fees associated with, its arbitration services).

429. Convention Establishing the World Intellectual Property Organization, art. 3(i), Jul. 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3.

and product could be jointly funded by a diverse group of stakeholders. For example, religious groups that fundamentally oppose patents on living matter may have an interest in funding the process, as might advocates of biotechnology patents who want to ensure fair representation of their interests. If a wide spectrum of stakeholders contributed, the financial burden would be minimized for each party, while bias would be kept at a relative minimum because of competing interests.

In addition, actual implementation of the system would necessitate considering limits on the system to stem potential misuse, or even abuse.[430] Typical penalties for procedural abuses could be imposed, including charging fees for frivolous postings.[431] Other techniques might include a word limit for each posting, or a requirement that each comment include contact information and organizational affiliation, such that there is increased accountability. The word limit could stem some manifestos against technologies while the organizational affiliation information could provide a means to limit over-use by specific organizations that contest all patents of a certain class. Perhaps there could also be a limit to one opposition per organization, per patent, to prevent each member of an organization from filing a separate commentary.

CONCLUSION

Biopiracy has been, and remains, a major concern to developing countries. The looming question is how to adequately address these concerns while giving proper credence to the claims of patent proponents, that Western patent rights must be respected to promote innovation that ultimately benefits all societies. As this Article shows, biopiracy is a multi-faceted problem involving not only countries with polar interests, but intra-country conflict as well. However, biopiracy remains of sufficient interest to developing countries such that they have continued to raise this issue in the international arena despite rejections by Western countries in multiple forums. Notably, developing countries are raising biopi-

430. A recent example outside of the patent setting lies in the attempt by the Los Angeles Times to introduce an interactive editorial page. The site only existed for a matter of days before it had to be removed because of posting of obscene pictures. *See, e.g.*, Katharine Q. Seelye, *Hands on Readers: Why Newspapers are Betting on Audience Participation*, N.Y. TIMES, July 4, 2005, at C1, C4.

431. *See, e.g.*, FED. R. CIV. P. 11.

racy claims with increasing frequency that at least approaches, if not exceeds their interest in challenging patent rights that impinge on public health, which would seem a more immediate problem.

In addition, although some have suggested that the claims from developing countries for increased benefit-sharing are not worth pursuing because many inputs fail to result in actual commercial success, the fundamental allegations of biopiracy raise serious issues of broader concern to Western patent law and policy. In particular, once the rhetoric of biopiracy is stripped away, there is an important challenge at the heart of these claims that should have resonance for all societies—namely, what the appropriate balance is between promoting innovation versus other public policy goals. Developing countries and indigenous groups may prioritize the protection and preservation of cultural heritage as the most important public policy goal that competes with patent rights. However, Western countries also have competing public policy goals that include access to medicine and adequate access to technology to enable cumulative research and innovation. Ironically, the TRIPS-plus agreements that Western countries are increasingly pursuing may not serve the interests of any countries because of increased restraints on the ability of countries to prioritize how to balance domestic policy concerns against patent rights.

Biopiracy may not be a simple problem to solve, but perhaps that is because the solution requires discussion of more issues than are typically considered. Rather than highlight the anomaly in use of traditional knowledge for patented inventions, highlighting the similarity of this problem to existing issues in Western patent law and policy may be more readily accepted and may potentially lead to important reconsiderations of how to better effectuate patent policy for all. In particular, although Western countries repeat the mantra that patents are important to promote innovation, questioning whether patent law actually does so is important to ensuring that patent law is serving its goal. Although developing countries may not embrace the same instrumental purpose of patent law, it may nonetheless be in their interest for Western patent law to be evaluated to the extent they share similar problems with contemporary Western challenges.

Tackling biopiracy together with Western patent policy concerns is a tall order. However, this Article provides not only templates to developing countries and their advocates that should lead to more productive discussions, but also a method for addressing broader issues of socio-cultural conflict with patent law. There is definite unanimity that patent law needs to address socio-cultural issues

and the increasing globalization of society. Actual international patent agreements have only heightened the importance of this issue. The proposal offered in this Article provides an important avenue for beginning to address such problems in a manner that will not raise the ire of patent owners concerned about changes that would impact their interests and investments. In addition, it enables discussion to extend beyond those who are more financially capable and hopefully will help inform all sectors of society in evaluating the continual balance of patent rights with competing socio-cultural policy.