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Correspondence

In Defense of Geographic Disparity

A response to Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679 (2003).

Craig Allen Nard†

One of the most controversial issues in international patent law relates to “biopiracy,” which concerns the exploitation of indigenous traditional knowledge by Western¹ firms without justly compensating the keepers of the knowledge.² A high-profile example is the neem tree controversy.³ The leaves and

† Professor of Law and Director, Center for Law, Technology, and the Arts, Case Western Reserve University School of Law. I am grateful to Olufunmilayo Arewa, Graham Dutfield, Christopher Heath, F. Scott Kieff, and Marco Ricolfi for their helpful comments.

1. The term “Western” is used here to refer to the developed world; however, in the context of traditional knowledge it is common to use the terms “North” and “South,” whereby the North represents the developed world.

2. Traditional knowledge is susceptible to multiple definitions. See Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT’L L. 233, 240–42 (2001) (discussing difficulty in defining traditional knowledge); see also *Intellectual Property Needs and Expectations of Traditional Knowledge Holders* 25–26, World Intellectual Property Organization (WIPO) (Apr. 2001), <http://www.wipo.org/globalissues/tk/ffm/report/final/pdf/part1.pdf> [hereinafter *Intellectual Property Needs*] (discussing the meaning of “traditional knowledge”). In this article, I am only concerned with technical or scientific knowledge. As with traditional knowledge, there is no accepted definition of “biopiracy.” *Integrating Intellectual Property Rights and Development Policy* 74, Commission on Intellectual Property Rights (Sept. 2002), http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf. To the extent meaning can be gleaned from examples, I am concerned with Western firms, who make a genuine inventive contribution, but, unfortunately, fail to (1) obtain the consent of the holders of traditional knowledge, and (2) equitably compensate the holders from rents earned from the commercial exploitation of the invention. See *infra* notes 53–56 and accompanying text.

3. The controversy has been well mined by commentators. See, e.g., VANDANA SHIVA, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE* 69–73 (1997); Emily Marden, *The Neem Tree Patent: International Conflict over*

bark of the neem tree, which is indigenous to India, have been used as natural pesticides and medicine by the people of India for years.⁴ In the early 1990s, a multinational company, W.R. Grace, obtained United States and European patents on pesticide products derived from the neem tree.⁵ One of the European patents was invalidated as lacking novelty,⁶ but the validity of the American patents remained intact.⁷ The central reason for this difference is that unlike European patent law, the United States patent code distinguishes between prior knowledge and use in foreign countries and prior knowledge and use in the United States.⁸ Specifically, American patent law does not recognize as prior art knowledge and use in a foreign country, such as that involved in the neem case.⁹

This geographic disparity in the American patent code has been the subject of much criticism,¹⁰ most recently by Professor Margo A. Bagley of Emory University School of Law.¹¹ In her well-written article, Professor Bagley contends that the geographic limitation of 35 U.S.C. § 102 is unconstitutional and bad policy.¹² I challenge those assertions. By advocating the

the Commodification of Life, 22 B.C. INT'L & COMP. L. REV. 279, 283–86 (1999).

4. SHIVA, *supra* note 3, at 69–73.

5. See, e.g., European Patent No. 0436 257 B1 (issued Sept. 14, 1994) (patenting a “[m]ethod for controlling fungi on plants by the aid of . . . neem oil”), <http://12.espacenet.com/espacenet/bnsviewer?CY=ep&LG=en&DB=EPD&PN=EP0436257&ID=EP+++0436257B1+I+>.

6. See 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. The invalidated European patent was specifically challenged by two Indian nongovernmental organizations. Alex Kriby, *U.S. Tree Patent Challenged*, BBC NEWS, May 5, 2000, at <http://news.bbc.co.uk/2/hi/science/nature/738002.stm>.

7. See, e.g., U.S. Patent No. 4,946,681 (issued Aug. 7, 1990) (“Method to Prepare an Improved Storage Stable Neem Seed Extract”); U.S. Patent No. 5,124,349 (issued June 23, 1992) (“Storage Stable Azadirachtin Formulation”).

8. See 35 U.S.C. § 102(a)–(b) (2000).

9. See *id.* Although foreign knowledge and use cannot be used as prior art, foreign inventive activity (i.e., conception and reduction to practice) can serve as proof of date of invention for purposes of obtaining patent rights. See 35 U.S.C. § 104 (2000).

10. See, e.g., Leanne M. Fecteau, *The Ayahuasca Patent Revocation: Raising Questions About Current U.S. Policy*, 21 B.C. THIRD WORLD L.J. 69 (2001); Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Tree Controversy*, 37 IDEA 371 (1997).

11. See Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679 (2003).

12. See *id.* at 679–91.

elimination of this geographic disparity and thereby allowing foreign knowledge and use to serve as prior art, Professor Bagley seeks to protect developing nations and indigenous peoples from Western countries' patent law regimes.¹³ In contrast, I argue for a proactive approach whereby patent rights serve not only to induce the commercialization of products derived from traditional knowledge, but also to compensate the keepers of traditional knowledge, while respecting the need to conserve the host country's biodiversity.¹⁴ Under this approach, the geographic disparity in American patent law is crucial.

Professor Bagley asserts that the geographic distinction in § 102 is unconstitutional because it "allows the patenting of inventions in the public domain."¹⁵ According to Professor Bagley, the Framers of the Intellectual Property Clause (IP Clause), expressed in Article I, Section 8, Clause 8 of the United States Constitution, were skeptical of monopolies and "sought to avoid the granting of patents on 'old' information."¹⁶ Novelty is indeed the *sine qua non* of patent protection, but I believe Professor Bagley's conception of the "public domain" is too broad and does not fully take into account the utilitarian nature of American patent law.¹⁷ While it is true that the Framers drafted the IP Clause in the shadow of abusive monopolistic practices,¹⁸ the

13. *See id.*

14. *See infra* notes 40–71 and accompanying text.

15. Bagley, *supra* note 11, at 687.

16. *Id.* at 685.

17. The preamble of the IP Clause, "To promote the Progress of Science and useful Arts," is expressed in utilitarian terms. *See* U.S. CONST. art. I, § 8, cl. 8; Yochai Benkler, *Siren Songs and Amish Children: Autonomy, Information, and Law*, 76 N.Y.U. L. REV. 23, 59 (2001) (noting that "the basic ideological commitment of American intellectual property is actually heavily utilitarian, not Lockean or Hegelian"); Linda R. Cohen & Roger G. Noll, *Intellectual Property, Antitrust and the New Economy*, 62 U. PITT. L. REV. 453–61 (2001) (asserting that "the conceptual model underlying American intellectual property law is utilitarian: rights are granted for social objectives (advancing knowledge and producing useful products)"). Compare the philosophical influences of European intellectual property law, which is grounded in Kantian and Hegelian notions of personality, inalienability, and self-expression. Thomas F. Cotter, *Pragmatism, Economics, and the Droit Moral*, 76 N.C. L. REV. 1, 7 (1997) (noting that "European intellectual property law . . . derives in large part from a concept of property developed by Immanuel Kant and Georg Wilhelm Friedrich Hegel").

18. *See* *Graham v. John Deere Co.* 383 U.S. 1, 5 (1966) ("The [IP] clause is both a grant of power and a limitation. . . . It was written against the backdrop of the practices—eventually curtailed by the Statute of Monopolies—of the [English] Crown in granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public."); *see also* EDWARD

driving force behind the clause was the enhancement of public welfare.¹⁹ Section 102 of the patent code is consistent with utilitarianism because the geographic distinction provides an incentive to invest in and commercialize products derived from traditional knowledge—products that otherwise would most likely remain undeveloped or out of reach for a vast majority of potential beneficiaries.²⁰ Moreover, the wealth created from commercialization could, indeed should, be shared with the host country and keepers of the traditional knowledge.²¹ The prospect of a patent allows for wealth creation and access to products based on traditional knowledge in a manner that benefits many more people than would otherwise have benefited,²² and it is

WALTERSCHEID, TO PROMOTE THE PROGRESS OF THE USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION 1787–1836 39 (1998). According to one scholar,

it is precisely because the delegates were familiar with the Statute of Monopolies . . . that they were not about to give the Congress any general power to create monopolies. . . . If therefore they were to give power to Congress to secure exclusive rights for limited times to inventors in their discoveries, it was necessary to do so expressly.

Id.

19. As the Supreme Court stated in *Mazer v. Stein*, “The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in ‘Science and useful Arts.’” 347 U.S. 201, 219 (1954).

20. See generally WESLEY M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT), (Nat’l Bureau of Econ. Research, Working Paper No. 7552, 2000), <http://papers.nber.org/papers/w7552.v5.pdf> (showing empirical evidence indicating the importance of patent rights to the pharmaceutical industry); Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 831 (2002) (observing that patent incentives in the pharmaceutical industry are “critical”); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 289 n.1 (2003) (noting that “[v]arious empirical studies have underscored the critical role played by patents on end-stage pharmaceutical products”).

21. See *infra* notes 53–77; see also F. Scott Kieff, *Patents for Environmentalists*, 9 WASH. U. J.L. & POLY 307, 317–18 (2002) (discussing how the commercialization of products derived from biodiversity can, under a patent system, benefit the custodians of the biodiversity).

22. It is worth noting that a significant portion of pharmaceuticals are derived from plants. See Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255, 273 (1998) (“About one-quarter of all prescription drugs in the United States contain as their active ingredient a compound extracted or derived from plants.”); Thomas Eisner, *Chemical Prospecting: A Proposal for Action*, in ECOLOGY, ECONOMICS, ETHICS: THE BROKEN CIRCLE 198 (F.H. Bormann & S. Kellert eds., 1991) (“Drugs from nature make

this result the Framers sought to promote.²³

Professor Bagley makes several points relating to the policy ramifications of § 102's geographic distinction.²⁴ Citing the neem tree example, Professor Bagley states that "[i]f [W.R.] Grace patented the same invention in the United States, where § 102(b)'s geographical limitation would bar evidence of public use of the invention in India, European consumers could have competitive market access to an invention only available to U.S. consumers at monopoly pricing levels."²⁵ My initial response to this statement is: at least there is a product on the market. It is reasonable to assume that, absent a geographic distinction (i.e., absent patent rights), a pharmaceutical firm would not invest millions of dollars in commercialization efforts, thus depriving all consumers.²⁶ Moreover, exploiting the patent in the rich United States market²⁷ could lead to significant profits that would form part of a benefit-sharing arrangement.²⁸

Furthermore, Professor Bagley's market-differential scenario is unremarkable given the lack of uniformity among patent law regimes. The availability of a patent on any type of inventive contribution varies from country to country, depending on eligible subject matter or a particular reading of patentability requirements. Consider, for example, how American patent law treats biotechnology vis-à-vis European patent law. In 1998, the European Parliament, concerned about the competitive threat of a robust American biotech industry, issued a bio-

up a large fraction of our pharmaceutical arsenal. In the United States alone, upwards of one-quarter of all medical prescriptions involve formulations based on plant or microbial products or on derivatives or synthetic versions thereof.").

23. See *supra* notes 17–20 and accompanying text.

24. See Bagley, *supra* note 11, at 688–91.

25. *Id.* at 688.

26. See *infra* notes 45–51 and accompanying text.

27. In 2002, more than half (53.4%) of the pharmaceutical industry's revenues were from sales in the United States. PATENTED MEDICINE PRICES REVIEW BOARD ANNUAL REPORT 19 (2002), <http://www.pmprb.com/CMFiles/ar2002e21LEF-6252003-6142.pdf>. Germany accounted for 6.2%; France, 5.3%; the United Kingdom, 3.9%; and Italy, 3.7%. *Id.* See generally Jean O. Lanjouw, *A New Global Patent Regime for Diseases: U.S. and International Legal Issues*, 16 HARV. J.L. & TECH. 85, 102–03 (2002) (proposing a patent enforcement mechanism that would "maintain research incentives . . . limited to diseases with markets that are concentrated in the rich countries").

28. See *infra* notes 53–71 and accompanying text. It is for this reason that other wealthy markets for pharmaceuticals (e.g., Europe and Japan) should amend their patent laws and adopt a prior art geographic distinction.

technology directive codifying patent protection for biotech-related inventions.²⁹ The directive was over ten years in the making and has been adopted by only a minority of E.U. member states, despite a deadline of July 30, 2000.³⁰ One of the principal points of contention among several countries³¹ and political parties³² in adopting the directive continues to be the patenting of DNA sequences, which is stridently opposed on grounds of public morality.³³ This intra-E.U. discordance over biotech patents highlights an important distinction between the American and European patent systems. Like its counter-

29. See Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, art. 3, 1998 O.J. (L 213) 13, 18 [hereinafter Directive].

30. *Patents: EC Faults Members for Not Implementing Directive for Legal Protections of Inventions*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA) (Jan. 29, 2003) [hereinafter *EC Faults Members*].

31. The Netherlands, which unsuccessfully brought legal action against the E.U. Parliament to annul the Directive, and France are the two most prominent opponents. See 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, 1657 (2001). Even though the French government was not a party to the Dutch lawsuit, "French officials [were] especially vigorous in their efforts to circumscribe the patenting of human DNA sequences. French President Jacques Chirac [] stressed the need to prevent any possibility of patenting the discovery of a gene, except for its therapeutic or diagnostic applications." *Id.* (citations omitted) (internal quotation marks omitted).

32. Environmentalists have been particularly vociferous in their opposition to the European Parliament Directive. *EC Faults Members*, *supra* note 30.

33. In an attempt to address this concern, Article 6(1) of the Directive states that inventions are "unpatentable where their commercial exploitation would be contrary to *ordre public* or morality." See Directive, *supra* note 29, art. 6(1) at 18. This section mirrors Article 53(a) of the European Patent Convention, which excludes from patent protection "inventions the publication or exploitation of which would be contrary to *ordre public* or morality." European Patent Convention, Oct. 5, 1973, art. 53(a), 1065 U.N.T.S. 255, 272. For an excellent discussion of the public morality requirement in the context of biotechnology, see Marco Ricolfi, *Biotechnology, Patents and Epistemic Approaches*, J. BIOLAW & BUS., Bio-Ethix™ Special Supplement, at 77 (2002). The public mortality argument against patenting DNA sequences is all but a whisper in American law circles. See, e.g., Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J.L. & POL'Y 247, 249 (2000). As noted by Cynthia Ho,

Although courts once relied on "moral utility" to deny patent protection for inventions used solely for gambling or fraud, no court has relied on this doctrine since the PTO Board of Appeals held that an invention used solely for gambling could be patentable in the 1977 decision of *Ex parte Murphy*.

Id. (citing *Ex parte Murphy*, 200 U.S.P.Q. (BNA) 801 (Bd. Pat. App. & Int. 1977)).

part in the United States, the European Patent Office (EPO) has issued patents on human DNA.³⁴ Contrary to the American system, however, a patent granted by the EPO matures into individual national patents (as designated by the applicant), which are governed by their respective national laws.³⁵ There is no such thing as a European patent that is valid throughout the entire E.U.³⁶ Member states, which often have divergent interpretations of the European Patent Convention, retain jurisdiction over issues of infringement and scope of patent protection,³⁷ thus increasing the likelihood of disparate enforcement.³⁸ Therefore, while great strides have been made toward patent harmonization within the E.U. and throughout the world, uniformity among nations remains unrealized.³⁹

Professor Bagley also notes that the United States condemns the pirating of American intellectual property by trading partners, yet the geographic disparity in § 102(b) “facilitates the ‘pirating’ of unpatented, unpublished, traditional knowledge.”⁴⁰ I agree that the United States has been willing to

34. For a hyperlink to a list of the worldwide applications for patents of human gene sequences, see Guardian Unlimited, *Patent Applications: Full List*, (Nov. 15, 2000), at <http://www.guardian.co.uk/genes/article/0,2763,397503,00.html>.

35. See GRAEME B. DINWOODIE ET AL., *INTERNATIONAL INTELLECTUAL PROPERTY LAW AND POLICY* 994, 996, 1009 (2001).

36. *Id.*

37. See European Patent Convention, *supra* note 33, arts. 64, 138, 1065 U.N.T.S. at 295–96; see also Friedrich-Karl Beier, *The European Patent System*, in *THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM* 462, 464 (Frederick Abbott et al. eds., 1999)

38. An oft-cited example of disparate enforcement is the “Epilady” patent litigation in the United Kingdom, Germany, and the Netherlands. For a history of the litigation, see Sanford T. Colb, *The Epilady Hair Remover Litigation*, in *GLOBAL INTELLECTUAL PROPERTY SERIES 1993: SUCCESSFUL MULTI-COUNTRY PATENT LEGISLATION STRATEGIES* 107 (Practicing Law Institute ed., 1993).

39. A recent example of divergent patentability requirements is the Canadian Supreme Court case involving Harvard University’s onco-mouse. See *Commissioner of Patents v. President and Fellows of Harvard College*, [2002] D.L.R. (4th) 577. This transgenic mammal has been patented in several countries, but the Supreme Court of Canada refused to extend patent protection because a higher life form, in the Court’s opinion, is not a “composition of matter” or “article of manufacture” under Section 2 of the Canadian Patent Act. See *id.* at 578, 580; see also Patent Act, R.S.C., ch. P-4, § 4 (1970) (Can.). Interestingly, the Canadian Supreme Court refused to follow the lead of the famous American case, *Diamond v. Chakrabarty* and its well-known language: “Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’” 447 U.S. 333, 309 (1980) (citation omitted).

40. Bagley, *supra* note 11, at 688–89.

“push and prod developing countries into accepting intellectual property rules,”⁴¹ and that Western firms should compensate keepers of traditional knowledge.⁴² As Professor Bagley notes, however, traditional knowledge is unpublished⁴³ and, I would suggest, underutilized. The virtue of a patent is its ability to “smoke out” this knowledge and to provide an inducement for firms to develop products derived therefrom—products that otherwise may not be realized. I am not suggesting that patent rights can solve all suboptimal innovation patterns across all industries, and I am sympathetic to concerns prompted by recent proprietary trends in intellectual property law. My focus here is only on pharmaceuticals, an industry that relies heavily on patent rights.⁴⁴

In addition, Professor Bagley argues that the geographic distinction no longer makes sense because information is generally more accessible today than it was in 1836, when the distinction found its way into the patent law.⁴⁵ Though the assumed rationale for the geographic limitation may be anachronistic,⁴⁶ doing away with it (and therefore the prospect of patent rights) would obstruct wealth creation. Professor Bagley suggests, however, that even if the geographic distinction is removed, pharmaceutical firms “can still deliver new drugs based on traditional knowledge” as long as the drugs are novel and nonobvious.⁴⁷ Perhaps, but I am not as sanguine as she. First, the pharmaceutical company brings something to the table by way of testing and refining products—endeavors that are quite costly and not necessarily lacking in inventive contribution. Second, and more directly responsive, establishing and documenting the precise prior art parameters of traditional knowledge, preserved mainly in oral histories, is a difficult un-

41. PETER DRAHOS & JOHN BRAITHWAITE, *INFORMATION FEUDALISM* 100 (2002) (discussing United States' use of “Special” 301 and the amendment to Section 182 of the Trade Act of 1974, codified at 19 U.S.C. § 2242 (2000)).

42. See *infra* notes 53–71 and accompanying text.

43. See Bagley, *supra* note 11, at 688–89.

44. See *supra* note 22. This article does not address the important issue of drug access in the developing world such as that which played out in South Africa a few years ago. Rather, I am concerned with patent law's incentive dynamic as it relates to traditional knowledge and notions of benefit sharing.

45. Bagley, *supra* note 11, at 712–24.

46. For a historical discussion of the geographic distinction in § 102, see Donald S. Chisum, *Foreign Activity: Its Effect on Patentability Under United States Law*, 11 INT'L REV. INDUS. PROP. & COPYRIGHT L. 26, 33–42 (1980).

47. Bagley, *supra* note 11, at 719.

dertaking.⁴⁸ Blurred prior art boundaries lead to uncertainty, which is undesirable in a property rights regime. Third, information is a classic public good,⁴⁹ and, as a general matter, accessibility without exclusivity leads to serious inefficiency concerns.⁵⁰ The aforementioned uncertainties brought about by a

48. As Graham Baines states:

An investigator of traditional knowledge faces a daunting challenge, and many difficulties. Irrespective of "scientific objectivity", differences of perception, values and language between those who hold traditional knowledge and those who wish to document it and apply it are significant. Unless investigators of traditional knowledge make more effort to understand these differences and to develop effective investigative methods then, at best, incomplete revelations of traditional knowledge will result. At worst, the information obtained will prove misleading.

Graham B.K. Baines, *Conclusion: Issues in the Application of Traditional Knowledge to Environmental Science*, in *TRADITIONAL ECOLOGICAL KNOWLEDGE: A COLLECTION OF ESSAYS* 67, 68 (Robert E. Johannes ed., 1989).

There is indeed a movement afoot to document traditional knowledge. See, e.g., The World Bank Group's Indigenous Knowledge Program, at <http://www.worldbank.org/afr/ik/index.htm> (last visited Oct. 17, 2003). The goals of this movement, however, must be defined. According to the World Bank, the "ultimate objective" of its internet-based indigenous knowledge program "is to help mainstream indigenous/traditional knowledge into the activities of development partners and to optimize the benefits of development assistance, especially to the poor." *Id.* If the goal is to create patent-destroying prior art, then this movement seems to be misguided for reasons discussed in this article. It makes sense, however, if the goal is to provide for a centralized database of traditional knowledge with an eye towards commercial exploitation. One must be careful, however, not to disclose too much, lest prior art be created. As Professor Coenraad Visser noted, "If you want to exploit the traditional knowledge by means of compilation or a transfer technology agreement, then it is in your interest to disclose as little as possible in the agreement." Coenraad Visser, Panel Remarks at Fordham Law School Symposium on Global Intellectual Property Rights, in *The Law and Policy of Protecting Folklore, Traditional Knowledge, and Genetic Resources*, 12 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 753, 768 (2002). He goes on to suggest that the "solution . . . seems to be to tag . . . [s]o you would list in the database only the items that are available for the transfer of technology." *Id.*

49. Public goods have two characteristics. They are nonrival (i.e., inexhaustible) and nonexclusive. A good is nonrival if consumption by one person does not leave any less of the good to be consumed by others. A good is nonexclusive if people cannot be excluded from consuming it. In addition to information, other public goods include national defense, television signals, and police protection.

50. See OFFICE OF TECH. ASSESSMENT, 102D CONG., FINDING A BALANCE: COMPUTER SOFTWARE, INTELLECTUAL PROPERTY AND THE CHALLENGE OF TECHNOLOGICAL CHANGE 185 (1992). According to a report by the Office of Technology Assessment,

Individuals have an incentive not to pay for the good, or to undervalue it, in hopes of getting access as "free riders." The inability to exclude free riders distorts market signals and is thought to result in

change to § 102 would weaken the prospect of a strong property right. As a result, in the pharmaceutical industry, private ordering and benefit sharing would suffer because traditional knowledge will not be optimally commercialized.⁵¹

While it is true that this argument can apply to domestic knowledge (i.e., knowledge within the United States), it is not my intent to read the knowledge and use provisions out of the patent code. Rather, I believe there is something special about traditional knowledge in developing countries. Specifically, the patenting and commercial exploitation of products based on their traditional knowledge can bring much-needed capital to these countries and their indigenous populations.⁵²

Professor Bagley and I are on common ground when she argues that indigenous peoples deserve to be compensated for the commercial exploitation of their traditional knowledge.⁵³ This concern is important; however, the problem here is not the availability of patent protection but rather the lack of an adequate compensatory mechanism for developing nations and indigenous peoples.⁵⁴ Safeguards must be put in place so as to prevent "biopiracy" similar to the Hoodia cactus incident.⁵⁵ The

inefficient allocation of resources to nonexclusive goods and underproduction of them, relative to socially optimal quantities.

Id. For a more detailed discussion of public goods and the market failures associated with them, see ROBERT COOTER & THOMAS ULEN, LAW AND ECONOMICS, 33-38, 107-10, 120-22, 167-72 (2004).

51. For a discussion of a commercialization-based patent system supported by a strong property right, see F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697 (2001); see also Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977); Giles S. Rich, *The Relation Between Patent Practices and the Anti-Monopoly Laws* (pts. 1-5), 24 J. PAT. OFF. SOC'Y 85, 159, 241, 328, 422 (1942).

52. Even if traditional knowledge were properly catalogued and thus rendered prior art under the current version of § 102, we may nonetheless want to treat this prior art as nonpatent defeating. That is, if our goal is to provide incentives to commercialize products derived from traditional knowledge and enhance benefit-sharing opportunities, it may be desirable to have a developing nation prior art exception. This proposal may also help address the "how much to disclose" problem associated with documentation efforts discussed by Professor Visser. See *supra* note 48.

53. See Bagley, *supra* note 11, at 689 (noting the lack of equitable compensation for use of traditional knowledge).

54. See Dutfield, *supra* note 2, at 273 (asserting "that the exploitation of traditional peoples and communities, including holders of [traditional knowledge], is fundamentally due to a widespread failure to respect their basic rights").

55. In 1996, the Council for Scientific and Industrial Research (CSIR) in

availability of patent protection must be accompanied by a compensatory structure and mutual consent so that the keepers of traditional knowledge will be equitably compensated, the sovereignty of the host nation respected, and its biodiversity conserved.

One way to accomplish these goals is through a contractual arrangement and a notification provision⁵⁶ that are consistent with the aims of patent law and biodiversity conservation. To this end, it is preferable, as Professor Marco Ricolfi has argued, to amend the domestic patent laws of developed countries to

South Africa isolated and patented the active hunger-suppressing component, P57, of the Hoodia cactus. See Ginger Thompson, *Bushmen Squeeze Money from a Humble Cactus*, N.Y. TIMES, Apr. 1, 2003, at A4. The patent was subsequently licensed to the British firm Phytopharm, who in turn licensed the patent to Pfizer for \$21 million in payments. See Antony Barnett, *In Africa the Hoodia Cactus Keeps Men Alive. Now Its Secret Is 'Stolen' to Make Us Thin*, THE OBSERVER, June 17, 2001, <http://education.guardian.co.uk/print/0,3858,4205467-102275,00.html>. The San people, who have known about the hunger-suppressant qualities of the Hoodia cactus for thousands of years, were not told of the commercialization of the patented product and did not receive any remuneration from the sales thereof. *Id.* In fact, the Pfizer spokesman thought the San people were extinct. *Id.* After an international uproar, CSIR entered into an agreement with the San people recognizing their traditional knowledge and paying them six percent of the royalties made from sales of the patented product. *Id.*

56. A full discussion of the notification requirement is beyond the scope of this article. Such a requirement, however, could resemble the proposal made by the Colombian delegation at the World Intellectual Property Organization's Third Session of the Standing Committee on the Law of Patents. See *Protection of Biological and Genetic Resources*, WIPO, WIPO Doc. SCP/3/10 (Sept. 8, 1999), http://www.wipo.org/scp/en/documents/session_3/pdf/scp3_10.pdf. The proposal stated:

Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.

Id. Consent could be subsumed within the duty to disclose all information material to patentability under 37 C.F.R. § 1.56. See 37 C.F.R. § 1.56(a) (2002) (detailing the duty to disclose material information regarding patentability). A failure to obtain consent or fraudulently obtained consent can be sanctioned by a finding of inequitable conduct. See Nuno Pires de Carvalho, *Requiring Disclosure of the Origins of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U. J.L. & POL'Y 371, 396-401 (2000) (describing the use of equitable doctrines by U.S. courts and arguing that disclosure of consent be required for the enforcement of patent rights); see also Willem Pretorius, *TRIPS and Developing Countries: How Level Is the Playing Field?*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT 183, 187-88 (Peter Drahos & Ruth Mayne eds., 2002) (arguing that TRIPS should require a patent applicant to prove it obtained explicit consent).

require lawful acquisition of genetic resources and an equitable compensatory arrangement based on the commercial exploitation of these resources.⁵⁷ A less satisfactory, though workable, approach is to encourage the formation of voluntary contractual relationships between the keepers of traditional knowledge and those who desire it. A prominent example is the bioprospecting agreement⁵⁸ entered into between the Instituto Nacional de

57. See Ricolfi, *supra* note 33, at 85. According to Professor Ricolfi, “a missing link is bound to remain unless appropriate cooperation by recipient states is not . . . put in place.” *Id.* In addition to domestic action, many countries, organizations, and scholars have argued that TRIPS, which does not address protection of traditional knowledge, should be amended to reflect the need for equitable compensation and consent, thereby aligning TRIPS more closely with the Convention on Biodiversity (CBD)—an “international legal framework that has sought to encourage the formation of mutually beneficial relationships between providers and users of genetic resources based on a concept of bilateral agreement,” Michael I. Jeffrey Q.C., *Bioprospecting: Access to Genetic Resources and Benefit-Sharing Under the Convention on Biodiversity and the Bonn Guidelines*, 6 SING. J. INT’L & COMP. L. 747, 749 (2002). See, e.g., *id.* at 773; Kamal Puri, *Biodiversity and Protection of Traditional Knowledge*, in PRINCIPLES OF PATENT LAW 82, 84–85 (Chisum et al. eds., 2001); cf. Convention on Biological Diversity, arts. 8(j), 16, 31 I.L.M. 818 (entered into force Dec. 29, 1993) (describing the guidelines for conserving and transferring traditional knowledge via equitable contractual arrangement). For instance, Kenya, on behalf of the African group, proposed a footnote be added to Article 27.3(b) of TRIPS to provide for “the protection of the innovations of indigenous and local farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources.” *Review of the Provisions of Article 27.3(b)* ¶ 13(i), Council for Trade-Related Aspects of Intellectual Property Rights, WTO Doc. IP/C/W163 (Nov. 8, 1999), <http://docsonline.wto.org/ddfdocuments/t/IP/C/W163.doc>. The WTO, in its recent Doha Ministerial Declaration, instructed the Council for TRIPS to “examine . . . the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore.” *Ministerial Declaration* ¶ 19, Ministerial Conf., 4th Sess., WTO Doc. WT/MIN(01)/DEC/1 (Nov. 20, 2001), <http://docsonline.wto.org/DDFDocuments/t/WT/min01/DEC1.doc> (adopted Nov. 14, 1999). Oxfam has recommended that the “TRIPS regime should be harmonised with the Convention on Biodiversity.” Oxfam, *Cut the Cost—Patent Injustice: How World Trade Rules Threaten the Health of Poor People* at 36 (Feb. 2001), http://www.oxfam.org.uk/what_we_do/issues/health/downloads/patentinjustice.pdf; see also Pretorius, *supra* note 56, at 187–88 (asserting that “TRIPS should . . . contain a requirement that the enforcement of patent rights should be subject to the disclosure, at the time of registration, of the country of origin of biological materials and/or traditional knowledge”). The United States, however, has resisted amendments to TRIPS relating to traditional knowledge, prompting commentators such as Professor Graham Dutfield to remark, “It seems highly unlikely that a new framework to protect [traditional knowledge] will be inserted into TRIPS anytime soon.” Dutfield, *supra* note 2, at 273.

58. I use this term only to refer to a mutually beneficial contract between

Biodiveridad (INBio),⁵⁹ a private, nonprofit, Costa Rican organization, and Merck, the U.S. pharmaceutical company.⁶⁰ The terms of the Merck agreement are confidential, but it is known that Merck paid INBio \$1.35 million in return for 10,000 samples of flora, soil, and insects collected by INBio and for information about how these samples have been traditionally used.⁶¹ Merck is also obligated to pay INBio royalties on future sales of products developed from the samples,⁶² which are invested, in part, in conservation efforts.⁶³

a developing nation and either a private concern (e.g., a pharmaceutical company) or a developed nation. Sometimes these agreements are referred to as "Material Transfer Agreements" (MTAs). See generally Secretariat, *Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Generic Resources and Benefit Sharing* 6, WIPO Intergovernmental Comm. on Intell. Prop. and Genetic Resources, Traditional Knowledge and Folklore 2d Sess., WIPO Doc. WIPO/GRTKF/IC/2/3 (Sept. 10, 2001) [hereinafter *WIPO Operational Principles*] (explaining the usage of the term "MTA"), http://www.wipo.int/eng/meetings/2001/igc/pdf/grtkfic2_3.pdf. A properly drafted bioprospecting agreement should be consistent with the goals of the Convention on Biological Diversity (CBD). See *supra* note 57; see also *WIPO Operational Principles, supra*, at 19 (providing information on extant contractual practices and related intellectual property clauses for access to and benefit-sharing of genetic resources). According to Charles McManis, a "consensus is developing among scientists, world bodies, anthropologists, and conservationists, that the best way for developing countries to capture the benefits of biodiversity is through a system of intellectual property, environmental, and contractual protection designed to harmonize the goals of development and conservation by building an international framework for sustainable biodiversity prospecting." McManis, *supra* note 22, at 270.

59. INBio states that it is an "institution leader in the search and popularization of the knowledge about biodiversity and its sustainable uses" and its mission is to "[p]romote a new awareness of the value of biodiversity, and thereby achieve its conservation and use to improve the quality of life." Instituto Nacional de Biodiveridad, at <http://www.inbio.ac.cr/en/default.html> (last visited Oct. 17, 2003).

60. See Christopher Joyce, *Prospectors for Tropical Medicines*, NEW SCIENTIST, Oct. 19, 1991, at 36, 36-39 (describing the Merck/INBio agreement). INBio also has numerous contractual arrangements with other private companies and academic institutions. See, e.g., Agreements with Academia, Instituto Nacional de Biodiversidad, at <http://www.inbio.ac.cr/en/pdb/academicos.htm> (last visited Oct. 17, 2003) (listing INBio's academic agreements); Agreements with the Industrial Sector, Instituto Nacional de Biodiversidad, at <http://www.inbio.ac.cr/en/pdb/comerciales.htm> (last visited Oct. 17, 2003) (listing INBio's industrial agreements).

61. See Frank J. Penna & Coenraad J. Visser, *Cultural Industries and Intellectual Property Rights*, in DEVELOPMENT, TRADE, AND THE WTO: A HANDBOOK 390, 397 (Bernard Hoekman et al. eds., 2002).

62. *Id.*

63. See Bioprospecting Agreements, Instituto Nacional de Biodiversidad, at <http://www.inbio.ac.cr/en/pdb/acuerdos.htm> (last visited Oct. 17, 2003). INBio describes their bioprospecting agreements as follows:

The seed for this type of contractual agreement was planted by the idea of “chemical prospecting,” which Thomas Eisner, who coined the phrase, defined as an “exploratory process by which new, useful natural products are discovered.”⁶⁴ Eisner advocated that developing nations, because of their geographic proximity to and interest in conserving their biodiversity, could act as screening laboratories that would, in a non-invasive manner, search natural products for chemical and biological activities and isolate the active components of these products.⁶⁵ According to Eisner:

The inevitable follow-up to the discovery of chemical uses of selected organisms would be the establishment of working linkages with universities and industries—initially, perhaps, mostly in developed nations—that would undertake the characterization and synthesis of the active chemicals uncovered. At that stage, proprietary arrangements could be made to insure that profits derived from the eventual commercialization of the new chemicals revert in fair measure to the nations that did the screening.⁶⁶

Each agreement has its corresponding work plan and research budget that establishes a 10% donation to the Ministerio del Ambiente y Energía (MINAE) (Ministry of the Environment and Energy), which helps cover direct biodiversity conservation costs. Furthermore, it contributes to increasing services, species identification, sample collection and preparation, collection records, information management, training, management

. . . .

In prospecting, the processes are executed in conjunction with research centers, universities, and national and international companies. This network of associations makes state-of-the-art technologies available and provides the opportunity to rapidly and efficiently train Costa Rican scientists as well as laboratory and field personnel. At the same time, this type of collaboration generates financial resources that are used to fund the country’s conservation activities, and also other research projects oriented towards satisfying the demands of users who contribute to the country’s sustainable development.

Id.

64. Eisner, *supra* note 22, at 196.

65. *See id.* at 200–01.

66. *Id.* at 201; *see also* Bioprospecting Agreements, Instituto Nacional de Biodiversidad, at <http://www.inbio.ac.cr/en/pdb/acuerdos.htm> (last visited Oct. 17, 2003). Other prominent examples of bioprospecting arrangements include efforts made by the National Cancer Institute (NCI). *See generally* Edgar J. Asebey & Jill D. Kempenaar, *Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention*, 28 VAND. J. TRANSNAT’L L. 703, 719–24 (1995) (detailing the efforts of the NCI). The NCI has awarded millions of dollars to nonprofit organizations to engage in research in biodiversity-rich countries in Central and South America, Asia, and Africa. *Id.* Although under the contracts the NCI will own any resulting patent rights, the developing country will receive royalty payments, a representative from that country will be listed as a codiscoverer, and the NCI will offer technical training to local personnel. *Id.*

The nature and nuances of bioprospecting agreements are complex and variable,⁶⁷ and they are not without problems.⁶⁸ Particularly troubling issues include asymmetrical bargaining power, domestic technology-transfer management (e.g., the ability to screen and organize traditional knowledge and representative legitimacy at the bargaining table), and internal institutional concerns (e.g., the establishment of a legal framework or comparable structure that recognizes and properly assigns ownership interests in traditional knowledge; determines who should collect, manage, and equitably distribute royalties; and monitors such to assure probity in the collection and distribution).⁶⁹

The NCI's "Letter of Collection" states:

While investigating the potential of natural products in drug discovery and development, NCI wishes to promote conservation of biological diversity, and recognizes the need to compensate source country organizations and peoples in the event of commercialization of a drug developed from an organism collected within their borders. . . . The NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to the [appropriate Source Country Institution] in [Source Country] as the agent appointed by the [Source Country Government or Source Country Organization], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology.

National Cancer Institute, Letter of Collection, ¶¶ 1-2 (obtained from correspondence with Dr. Gordon Cragg, National Products Branch, NCI) (on file with the author). The NCI's "Memorandum of Understanding" uses virtually identical language. *See id.* Two commentators have called the NCI "one of the leaders in implementing the mandates of the Biodiversity Convention." Asebey & Kempenaar, *supra*, at 720.

67. For a discussion of the principles and operation of contractual arrangements relating to traditional knowledge, see *WIPO Operational Principles*, *supra* note 58, at 18-22.

68. The agreement between INBio and Merck has been criticized by a variety of authors. *See, e.g.*, Asebey & Kempenaar, *supra* note 66, at 726-30; Neil D. Hamilton, *Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources*, 28 TULSA L.J. 587, 627-29 (1993); Shayana Kadidal, *Plants, Poverty, and Pharmaceutical Patents*, 103 YALE L.J. 223, 234-35 (1993); Kirsten Peterson, *Recent Intellectual Property Trends in Developing Countries*, 33 HARV. INT'L L.J. 277, 288-89 (1992). *See generally* Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 111, 141-45 (1996) (criticizing the current system of preserving biodiversity).

69. *See generally* HERNANDO DE SOTO, *THE MYSTERY OF CAPITAL: WHY CAPITALISM TRIUMPHS IN THE WEST AND FAILS EVERYWHERE ELSE* (2000) (discussing the institutional problems in the developing world associated with managing capital and recognizing property rights); HERNANDO DE SOTO, *THE OTHER PATH: THE ECONOMIC ANSWER TO TERRORISM* (1989) (same). A partial solution to these concerns is to create a nonprofit organization as a centralized

Nonetheless, these contractual arrangements are a positive development. They reflect an implicit concession that developing nations should be compensated for their traditional knowledge and that developed countries have a vested interest in biodiversity conservation. Bioprospecting agreements also create wealth for keepers of the traditional knowledge and developing nations, wealth that can be invested in, among other things, research and development, health care, conservation, or general infrastructure.⁷⁰ Moreover, developing nations and indigenous peoples do not incur the often prohibitively high cost of obtaining and enforcing patent rights.⁷¹ Lastly, and perhaps most importantly, bioprospecting agreements will yield the commercialization of medicines that will benefit many more lives than would be the case absent a meeting of the minds.

While there is a tendency to adopt a paternalistic attitude when discussing patent rights and the developing world, and while Western notions of property rights frequently differ from those of indigenous peoples,⁷² it is worth noting the results of an extensive empirical study conducted by the World Intellectual Property Organization (WIPO).⁷³ In 1998 and 1999, WIPO conducted nine fact-finding missions in twenty-eight countries to discern the "IP needs and expectations of TK [traditional knowledge] holders."⁷⁴ These missions resulted in several interesting findings; most notably, WIPO found that "[d]espite criticism of IP laws . . . by certain informants, many others expressed interest in exploring further the actual and potential role of the IP system in TK protection,"⁷⁵ and informants also

coordinating entity. But as Professor Visser has experienced from his work in Venezuela, the indigenous tribes have concerns about the creation of a corporate entity. See Visser, *supra* note 48, at 769–70. He states that the tribal elders "see the corporation as supplanting the traditional authority structure in the tribes." *Id.* at 770.

70. See *supra* notes 58–63 and accompanying text.

71. See Penna & Visser, *supra* note 61, at 397 (asserting that a "basic problem" with holders of traditional knowledge obtaining patents themselves "is that a patent protects active ingredients that have been isolated and tested" and "[s]uch isolation and testing may cost hundreds of millions of dollars and are out of reach for most developing countries, let alone their indigenous peoples").

72. See, e.g., Kamal Puri, *Cultural Ownership and Intellectual Property Rights Post-Mabo: Putting Ideas Into Action*, 9 INTELL. PROP. J. 293, 307–09 (1995) (arguing that Aboriginal communities and Western ideas of copyright differ).

73. See generally *Intellectual Property Needs*, *supra* note 2.

74. See *id.* at 17.

75. *Id.* at 223.

expressed the desire to facilitate a “dialogue and contact between TK holders, the private sector, governments, [non-governmental organizations], and other stakeholders to assist in developing modalities for cooperation between them, at community, national, regional and international levels.”⁷⁶ As the Indigenous Peoples Secretariat submitted, the WIPO report “could focus on the fact that [the] commodification [of traditional knowledge] . . . does not per se work to the detriment of the rights of traditional knowledge holders, but, under appropriate conditions to be further investigated and defined, can in fact work to their benefit.”⁷⁷

Further investigation of the virtues and problems of patent rights in the developing world is in order, but given the promise of contractually marrying proprietary rights with traditional knowledge, cautious optimism is also in order. And while Professor Bagley provides an important alternative, I believe that a proactive use of patent law compares favorably to a system that seeks to render patent protection unavailable for products derived from traditional knowledge.

76. *Id.* at 218.

77. *Id.*