STATING THE OBVIOUS: PATENTS AND BIOLOGICAL MATERIAL

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It is important to protect the cultural and biological diversity of developing nations while attempting to strengthen their intellectual property systems. Many recent agreements and events have addressed developing countries and the expansion of the scope of patentable material. Developed nations generally assume that monopolistic protection for intellectual property will provide incentives for technological and economic progress. However, patenting biological substances, such as naturally occurring organisms and genetic material, is a moral and economic mistake for intellectual property systems, especially those in developing nations. This Note examines the relationship between the patenting of biological materials in the United States, current international intellectual property protection, and international human rights law. It then concludes that developing nations should take a cautious approach when implementing intellectual property rights in biological materials and should avoid depriving their citizens and research communities of access to this vital knowledge.

I. INTRODUCTION

The Northern Hemisphere nations of the international economic community have made an assumption that economic growth and stability in developing nations depends upon strengthening intellectual property regimes, which, in turn, will stimulate direct foreign investment and result in long-term economic progress. Establishing monopolistic protection for products of intellectual ingenuity will supposedly provide incentives for technological innovation and progress, which is presumed necessary for social and economic progress. These assumptions are most eagerly accepted by the proselytizers of private interests in intellectual property: large and politically influential transnational corporations who benefit most from a global strengthening of intellectual property rights. Although firmly entrenched in economic theory since the writings of Joseph Schumpeter,[1] this philosophy was initially challenged from both an economic and intellectual standpoint by economists and others in

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1. JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM, AND DEMOCRACY 88, 102-03 (1942).

"developing" European nations and the United States during the nineteenth century. Yet, these are the very same countries now considered the guardians of modern intellectual property interests.[2]

It is useful in our presently turbulent international and political climate to reexamine these assumptions to achieve a well-balanced solution to the economic dilemmas of developing nations, with an eye towards preserving their cultural and biological diversity. The patenting of biological and genetic material brings to the forefront the moral and economic issues instigated by the intellectual property push: Is it truly necessary, or even in the best interests of developing nations (or any nation, for that matter), to create private property interests in intellectual property where none were ever intended to exist? Does such a policy truly incentivize the technological progress that is ultimately beneficial to these nations, or is it merely the after-effect of erroneous judicial and patent office interpretations of intellectual property legislation in the United States? To what degree are these countries and individuals entitled to share in the benefits of the discoveries exploited through the patent system? It is most likely that the policy has been instigated and promoted by private parties interested in the commoditization of biological material. These parties appear academic on the surface, but in reality, their efforts are underwritten by privately funded research grants from biotechnology and pharmaceutical corporations, whose motives stem from profit interests.[3]

Ultimately, the question becomes whether developing nations will allow themselves to be enticed (or coerced) into believing that expanding the scope of patentable material at the price of their cultural and ethical beliefs, or biological integrity and diversity, is necessary in their quest to achieve modernization and economic prosperity. For many years, developing countries held out against pressure from the United States and pharmaceutical and software producers to negotiate the current Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Agreement. TRIPS was born out of the Uruguay round of the General Agreement on Tariffs and Trade ("GATT").[4] In response to threats of bilateral trade sanctions from the U.S. Trade Representative, these developing countries eventually agreed to come to the negotiating table.[5] It has been said that "[t]he TRIPS Agreement accomplishes, through the

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2. *See generally* Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century,* 10 J. ECON. HIST. 1 (1950); J. H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT'L L. 423, 441 (2000) (citing Eleanor M. Fox, *Trade, Competition, and Intellectual Property—TRIPS and Its Antitrust Counterparts*, 29 VAND. J. TRANSNAT'L L. 481, 490 (1996)).

3. *See* Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 50 (1998).

4. Michael P. Ryan, *The Function-Specific and Linkage-Bargain Diplomacy of International Intellectual Property Lawmaking,* 19 U. PA. J. INT'L ECON. L. 535, 563–64 (1998).

5. *Id.* at 564.

potential threat of economic ostracism, what could not be accomplished through negotiations independent of the international economic framework."[6]

The purpose of this paper is to examine the recent literature and events surrounding the patenting of biological material as it relates to the interests of developing nations, which strive to strengthen their economies while simultaneously preserving cultural and biological diversity and protecting fundamental human rights and ethics. This paper begins with a brief examination of the historical background of the intellectual property protection of biological materials and evaluates three treaties that address this endeavor: the TRIPS Agreement, which seeks to expand intellectual property rights; the United Nation's Committee on Biological Diversity ("CBD"), which seeks to control access and preserve biological diversity; and the Universal Declaration of Human Rights ("UDHR"), which puts forth the promotion and protection of fundamental human rights as its ultimate goal.

Biopiracy and bioprospecting will be discussed in relation to developing nations, as well as the incentives and disincentives for those countries to mimic the intellectual property system that currently exists in the United States. It is this author's opinion that patenting biological substances (that is, naturally occurring organisms and genetic material) is a mistake both morally and economically for any system of intellectual property and should be reanalyzed at all levels, particularly as it affects developing nations.

II. HISTORICAL BACKGROUND

It is widely accepted that some forms of intellectual property rights originated in Venice during the fifteenth century,[7] followed by the Statute of Monopolies in England in 1623, and further codified in the patent laws of France and the United States in the late eighteenth century.[8] However, during the nineteenth century, several scholars began to question whether laws favorable to inventors actually benefited technological and commercial progress at all.[9] Unsurprisingly, those stakeholders who stood to receive the greatest private economic benefits from strong patent law protection were its most ardent supporters.[10]

Those in favor of abolishing patent laws were generally free-trade economists who reasoned that such laws actually "hinder[ed] rather than further[ed] the progress of invention; that they hamper[ed] the prompt general utilization of useful inventions; that on balance they cause[d]

6. Ruth L. Gana, *The Myth of Development, The Progress of Rights: Human Rights to Intellectual Property and Development*, 18 LAW & POL'Y 315, 334 (1996).

7. Machlup & Penrose, *supra* note 2, at 2.

8. *Id.* at 2–3.

9. *Id*. at 4.

10. *Id*.

more harm than benefit to the inventors themselves and, [were] thus, a highly deceptive form of compensation. . . ."[11] However, the tide eventually turned in favor of patent protection, due in part to a concerted propaganda campaign and to the efforts of inventors and industrialists following unfavorable economic conditions in Europe during the late nineteenth century.[12]

Economists and scholars have offered several philosophical rationales for patent protection. One rationale argues that intellectual property rights stem from the "natural rights" of private property found in ideas and their resulting inventions.[13] However, opponents of this philosophy view this description as a mere ruse for the introduction of a form of privilege, rather than a protection of any right occurring naturally to mankind.[14]

Another argument simplistically focuses on the moral rights of the inventor to the reward of the fruits of his or her labor.[15] Again, opponents of protection have argued that if one truly is the first to invent, he or she would naturally enjoy a period of time free from competition to recoup the initial investment of time and energy associated with the invention and to continue to profit from its commercialization ahead of any competitors.[16] Such a position was dubbed the "head-start" theory of profits.[17]

A more pro-patent rationale was expressed by Abraham Lincoln, the only U.S. president to hold a patent,[18] who commented that "the patent system . . . added the fuel of interest to the fire of genius. . . ."[19] This eloquent articulation summarized the sentiment behind the theory that the patent system is a method of rightly rewarding inventors with a prize for the expression of their creative energies.[20] The danger, according to many, is that without protection of private property interests in knowledge, and the resulting profits, there will be no creation of new knowledge.[21] However, much of the explosion of scientific information and resultant innovation during the nineteenth century had its genesis outside of the profit-making motive of its participants. In fact,

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11. *Id.* at n.8.
12. *Id*. at 5–6.
13. *Id*. at 15.
14. *Id*. at 16.
15. *Id*. at 17.
16. *Id*. at 18.
17. *Id*.
18. Smithsonian Institution Press, Legacies, Patent Model and Application Submitted by Abraham Lincoln, "Method of Buoying Vessels over Shoals," 1849, *at* http://smithsonianlegacies.si.edu/objectdescription.cfm?ID=130 (last visited Nov. 19, 2003).
19. Machlup & Penrose, *supra* note 2, at n.81 (quoting Abraham Lincoln, "Discoveries, Inventions, and Improvements," lecture (1859), *in* COMPLETE WORKS OF ABRAHAM LINCOLN 113 (Tandy-Thomas eds., 1905)).
20. *See id*. at 22.
21. R. Blackhurst, TRIPS Article 27.3(b): The Case Against Patenting of Life Forms and Living Processes, 18 (Mar. 23, 2001) (paper presented at the Graduate Institute of International Studies, Geneva, Conference in International Trade Policy: Theory and Practice).

"[t]he rewards and penalties of scientific activity were less monetary than intellectual—a combination of approval or disapproval by one's peers and the satisfaction of success in a highly intellectual and deeply respected form of puzzle-solving activity."[22]

III. THE U.S. EXPERIENCE

The patenting of biological materials in the United States is a relatively recent phenomenon. The U.S. Patent Act clearly limits patentability to "any *new* and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. . . ."[23] The generally accepted tenets of patentability are newness, usefulness, and non-obviousness. Prior to 1980, these were interpreted by the lower courts to exclude living matter from patentability.[24] However, in the seminal case of *Diamond v. Chakrabarty*,[25] the Supreme Court revolutionized patent law by answering a "narrow" question of statutory interpretation. In that case, the Court construed 35 U.S.C. § 101 to mean that Congress intended for patent laws to be interpreted expansively; hence, biotechnology rightly fit within the Patent Act's boundaries of "any," "manufacture," or "composition of matter."[26] The result was the patentability of human-made microorganisms, regardless of the source of the original material.[27] With this Pandora's box opened, the entrepreneurial curiosity of corporations was piqued—millions (and now billions) of dollars were invested in biotechnological research by corporations hoping to gain a stake in the relatively unregulated area of so-called "life patents."[28]

This expansion of the scope of patentability was confirmed in the issuance of a Patent and Trade Office ("PTO") notice on April 7, 1987. The notice restated a phrase from the Congressional Committee Reports on the re-codification of patent laws in 1952[29] which stated that "any*thing* under the sun that is made by man" is properly patentable, including "non-naturally occurring non-human multi-cellular living organisms, including animals . . . within the scope of 35 U.S.C. 101. . . ."[30]

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22. NATHAN ROSENBERG & L.E. BIRDZELL, JR., HOW THE WEST GREW RICH 255 (1986).

23. 35 U.S.C. § 101 (2002) (emphasis added).

24. David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture,* 27 CASE W. RES. J. OF INT'L L. 83, 95 (1995).

25. 447 U.S. 303 (1980).

26. *Id*. at 307.

27. *See* 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, 984 (2000).

28. *See id*.

29. *See Chakrabarty*, 447 U.S. at 309.

30. Scalise & Nugent, *supra* note 24, at 99 (emphasis added).

Later, in *Moore v. Regents of the University of California,*[31] the highly influential California Supreme Court determined that medical patients possessed no property interest in the cell-lines derived from their own cells, which were initially a naturally-occurring substance that formed the basis for scientific advances.[32] To have granted such an interest would allegedly impede the progress of research by requiring remuneration by biotech actors (physicians, research institutions, and private corporations) to the "owners" of human cells. Thus, expropriating (or perhaps condemning) them for "academic research" was the court's solution, resulting in richer rewards for researchers and their funding sources.[33]

Ironically, the *Moore* court held that such a property interest in the cell-lines extracted and reproduced from patients does belong to those researchers that expend the "*inventive effort*" to grow such human tissues and cells in cultures, and that the interest can be preserved in the form of patent protection.[34] The California court reiterated that "[f]ederal law permits the patenting of organisms that represent the product of 'human ingenuity,' but not naturally occurring organisms."[35] Its myopia, however, has done an injustice to the subjects of human research.

Combined with the decision in *Chakrabarty*, the ironic result has been to reward a select few individuals and corporations for their efforts while generally threatening the progress and diversity of research by artificially restricting access to biological materials.[36] In the process, the human subjects of such research are stripped of all control or benefit from the discoveries associated with their unique genetic material. A prime example of this profound result deals with the research on the gene for Canavan disease.

Canavan disease is caused by a mutated copy of the aspartoacylase gene on chromosome seventeen.[37] The disease mostly affects Jews of Ashkenazi (Eastern and Central European) descent; approximately one out of every forty people in this group is a carrier for the disease.[38] When two parents who are carriers bear a child, there is a 25 percent chance that the child will have the disease, a 50 percent chance that the child is a

31. 793 P.2d 479 (Cal. 1990).

32. *Id*. at 489.

33. *Id*. at 494. It is interesting to note that this decision appears to be contradicted by the United States Supreme Court's interpretation of the right to procreation and other related interests in the human body.

34. *Id*. at 493 (emphasis in original).

35. *Id*. at 492.

36. *See* Peter Gorner, *Breast Cancer Triggers Found; Scientists Isolate Stem Cells That Produce Tumors*, CHI. TRIB., Feb. 25, 2003, at 1.

37. Geraldine A. Collier, *Lawsuit Challenges Gene Patent*, WORCESTER TELEGRAM & GAZETTE, Dec. 11, 2000, *available at* http://www.canavanfoundation.org/news/12-00_lawsuitgenepatient.php.

38. *Id*.

carrier, and a 25 percent chance that neither the disease nor carrier status will occur.[39]

Canavan disease is typically characterized by abnormal development of a child's brain due to a deficiency of the enzyme aspartoacylase that leads to a destruction of the myelin sheaths that protect brain cells.[40] The disease manifests itself by three to five months of age and eventually results in severe muscular atrophy (floppiness), spasticity, inability to speak, and blindness. The average life expectancy for those afflicted by the Canavan gene is only into the teens.[41]

In 1987, the Greenberg family of Homewood, Illinois, suffered the tragedy of having two children born with Canavan disease.[42] Their response was to seek out Dr. Reuben Matalon, then a scientist with the University of Illinois at Chicago, to assist them in their search for the Canavan gene. Dr. Matalon began a registry of Canavan victims, and many families in that registry were enlisted to submit blood and tissue samples, as well as significant financial contributions, in an effort to isolate the source of the mutation so that a widely available genetic test could be developed to give parents the option of preventing the syndrome from affecting their children. In 1993, Dr. Matalon finally discovered the gene responsible for Canavan disease but, by then, he had transferred to the University of Miami Children's Research Hospital ("MCH"). As a result of Dr. Matalon's discovery, and unbeknownst to the families, MCH obtained a patent on the isolated gene in 1997 (U.S. Patent No. 5,679,635).

Because MCH subsequently restricted access to the test and drove up its cost by licensing it only to a limited number of laboratories, several of the parents, joined by the Canavan Foundation, the National Tay-Sachs and Allied Diseases Association, and Dor Yeshorim, an organization founded to prevent recessive genetic diseases, filed a federal lawsuit. Their complaint alleged: 1) lack of informed consent; 2) breach of fiduciary duty; 3) unjust enrichment; 4) fraudulent concealment; 5) conversion; and 6) misappropriation of trade secrets, and it asked for a permanent injunction to restrain MCH from enforcing its patent rights, as well as for damages in the form of all royalties received on the licensing of the technology in addition to the financial contributions the plaintiffs made to the research efforts.[43] The court, *sua sponte*, transferred the action to the Southern District of Florida on July 8, 2002, for reasons related to a lack of jurisdiction over MCH.[44] The issues in this case are similar to those in *Moore*, and it will be interesting to see

39. *Id*.

40. American Medical Association, *Gene Patent Leads to Legal Action*, *at* http://www.ama-assn.org/ama/pub/category/3358.html (Oct. 30, 2000).

41. *Id*.

42. Greenberg v. Miami Children's Hosp., 208 F. Supp. 2d 918 (N.D. Ill. 2002).

43. *Id*. at 922.

44. *Id*. at 928-29.

how the federal court interprets the rights of research subjects and non-profit fundraising organizations to share in the benefits of the resulting discoveries. Such an example may prove instructive to other countries seeking to develop equitable intellectual property regimes.

IV. CURRENT INTERNATIONAL INTELLECTUAL PROPERTY PROTECTION AND BIOLOGICAL MATERIAL

Recently, after a decade of intense debate, the countries of the European Union extended patents to biological materials,[45] primarily through the 1998 enactment of Directive 98/44/EC, the Legal Protection of Biotechnological Inventions.[46] The Directive accedes to biotechnology industry supporters' demands to expand the scope of patentable subject matter, yet it also recognizes the hesitation on the part of E.U. member nations to grant the European Patent Office ("EPO") carte blanche in this area by adding the ability to consider moral issues when making patent determinations.[47] Although such safeguards placated concerns of the Green Party and others long enough to achieve passage of the 1998 Directive, the safeguards have thus far been interpreted quite narrowly during the prosecution of biotechnological patents.[48]

The TRIPS Agreement of 1994[49] is the latest and arguably most effective attempt by developed nations to protect the interests of individuals in their supposedly unique creations by establishing minimum standards for intellectual property rights ("IPR") protection. Additionally, it creates incentives (or disincentives) for protection of IPR, and provides enforcement mechanisms and dispute settlement procedures for member nations to provide for the protection of IPR.[50]

The rationale behind such a system is that adequate international IPR protection creates incentives for technological development in all nations.[51] Somewhat predictably, the principal proponent of TRIPS was the United States, joined by Japan and the European Community, [52] in response to a (then) more than $60 billion annual loss due to patent

45. Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L L. 1, 10 (2001).

46. *Id*. at 1.

47. *Id*. at 2.

48. *Id*. at 41 (stating that of the four patents that have been opposed on morality grounds, none had been denied a patent as of the writing of this Note).

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

50. Evelyn Su, *The Winners and the Losers: The Agreement on Trade-Related Aspects of Intellectual Property Rights and Its Effects on Developing Countries*, 23 HOUS. J. INT'L L. 169, 186–89 (2000).

51. Gary W. Smith, *Intellectual Property Rights, Developing Countries, and TRIPS: An Overview of Issues for Consideration during the Millennium Round of Multilateral Trade Negotiations,* 2 J. WORLD INTELL. PROP. 6 (Nov. 1999).

52. *Id*.

violations in developing nations.[53] Intellectual property is now considered to be the largest export of the United States.[54]

TRIPS was eventually ratified during the 1994 Uruguay Round of the GATT, which also created the World Trade Organization ("WTO").[55] The ostensible purpose of TRIPS is to "reduce distortions and impediments to international trade, [ ] tak[e] into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."[56] The agreement is applicable to all nations that are members of the WTO.

WTO member nations are required to implement the TRIPS Agreement's minimum standards for intellectual property protection (which include aspects of both the Paris Convention (1967)[57] and the Berne Convention (1971)[58]), within a one-year period. The TRIPS Agreement outlines enforcement mechanisms for ensuring compliance, including the use of trade sanctions (such as raising tariffs on imports) by a member nation should another member fail to implement the TRIPS Agreement's minimum standards.[59] As for positive incentives, TRIPS offers the potential for an attractive liberalization of trade in textiles, apparel, and agricultural products for member nations.[60]

Developing nations are afforded a somewhat more generous time frame. They are allowed a further implementation delay of four years from the date of application to the WTO and an additional five years to extend patent protection to technologies that were not presently patentable on the date of application.[61] For "least-developed" country members, the deadline for implementation is extended to ten years from the date of application or beyond.[62] The general objectives for TRIPS are listed in Article 7, which provides:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and

53. Scalise & Nugent, *supra* note 24, at 114.

54. Richard A. Posner, *The Law & Economics of Intellectual Property*, DAEDALUS, Spring 2002, at 5.

55. TRIPS Agreement, *supra* note 49.

56. *Id.* at pmbl.

57. Paris Convention for the Protection of Industrial Property, July 14, 1967, *available at* http://www.jurisnotes.com.res/industrialproperty.htm.

58. Berne Convention for the Protection of Literary and Artistic Works, July 24, 1971, as amended Sept. 28, 1979, *available at* http://www.wipo.int/clea/docs/en/wo/wo001en.htm.

59. Office of the United States Trade Representative, Executive Office of the President, Statement as to How the Uruguay Round Agreements Achieve Congressional Negotiating Objectives (Sept. 27, 1994), *available at* 1994 WL 761805.

60. Blackhurst, *supra* note 21, at 5.

61. TRIPS Agreement, *supra* note 49, at art. 65(1)–(4).

62. *Id*. at art. 66(1).

> in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[63]

The TRIPS Agreement also requires patents to be available for "any inventions, whether products or processes . . . provided that they are new, involve an inventive step, and are capable of industrial application."[64] However, member nations are granted exceptions to this requirement and "may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. . . ."[65] In an effort to secure the support of developing nations,[66] TRIPS also provides certain concessions, allowing member nations to optionally exclude "plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."[67] Furthermore, "members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[68]

In addition, governments of WTO members or their authorized agents may make other uses of patented subject matter—sometimes without the authorization of the right holder. However, the freedom to do so exists only so long as the provider has made an attempt to obtain permission from the patent owner, offered reasonable commercial terms, and experienced no success in such efforts within a reasonable period of time.[69] In the case of a national emergency or extreme urgency, the member nation may waive such requirements in order to effectuate public, non-commercial use so long as the right holder is notified within a reasonable time period and adequate remuneration is made under the circumstances.[70]

The debate regarding the effects of TRIPS on developing nations centers on whether it truly promotes their ultimate economic interests by encouraging direct foreign investment, or whether it "simultaneously narrows the developing countries' access to technology, discouraging the rapid diffusion of new technology needed for economic growth."[71] Developing countries have argued that the economic prosperity of

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63. *Id*. at art. 7.
64. *Id*. at art. 27(1).
65. *Id*. at art. 27(2).
66. Scalise & Nugent, *supra* note 24, at 115.
67. TRIPS Agreement, *supra* note 49, at art. 27(3)(b). However, plant varieties must be protected by a form of *sui generis* intellectual property protection. *Id*.
68. *Id*. at art. 30.
69. *Id*. at art. 31(b).
70. *Id*. at art. 31 (b), (h).
71. Su, *supra* note 50, at 171.

Northern Hemisphere countries, particularly the United States, Japan, and Great Britain, has come partly at the expense of developing nations, and these wealthier countries therefore owe access to technological resources in order to spur development in the impoverished nations.[72]

Although these under-developed nations have the perception of entitlement to technological resources, they appear to be moving toward greater protection in the area of IPR.[73] A recent study indicates that increased IPR protection can actually work to the detriment of the poorest, least-developed nations by exposing them to the effects of monopolization, resulting in detrimental effects on trade terms.[74] However, for those countries considered to possess middle-income economies and the potential to capitalize on imitations, strengthening IPR appears to have a positive effect on trade volume and direct foreign investment.[75] Research suggests that the transitional costs associated with strengthened IPR have a strong negative effect on employment, which may be further magnified depending upon the level of economic development.[76]

An intuitive argument against overly restrictive IPR is found in Michael Heller's "Tragedy of the Anticommons,"[77] the antithesis to Garrett Hardin's "Tragedy of the Commons."[78] Heller's point is that when independent parties possess too much power to exclude others, there is a resulting under-utilization of particular resources, [79] which is particularly true in the case of technologies requiring numerous components that may be held by many patent owners. Such under-utilization might occur in the patenting of biological material, resulting in impediments to further research similar to those warned against in *Moore v. Regents of the University of California.*[80]

Others believe that it might be useful to delineate a zone of "intellectual public trust" to encompass those areas of knowledge that are too important to public progress to be hampered by issues of private domain ownership.[81] A way of implementing such a "zone" might be to institute a higher bar to patentability in developing nations than

72. *Id*. at 200.

73. *Id*. at 192.

74. Keith E. Maskus, *Intellectual Property Challenges for Developing Countries: An Economic Perspective*, 2001 U. ILL. L. REV. 457, 464 (2001).

75. *Id.* at 464, 466.

76. *See id*. at 468.

77. *See* Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 622 (1998); *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

78. Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243 (1968) (illustrating the paradox that occurs when too many people obtain access to a resource because it is freely available, resulting in over-utilization and exhaustion of the resource in the process).

79. Heller, *supra* note 77, at 677.

80. 793 P.2d at 504.

81. *See* 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, 44 (1998).

presently exists in developed nations.[82] By narrowing the judicial interpretation of the requirements of patentability (new, useful, and non-obvious), these countries may well position themselves to attract more research and development activities while keeping important innovations in the biological sciences within the public domain.[83] Such a strategy would be consistent with the views of developing nations that the sharing of knowledge is the most efficient path to innovation.[84]

Additionally, there is little evidence that anyone besides big corporations actually benefits from increased patent protection. For example, those large multinational firms with greatest access to the United States' Trade Representative "keep on pressing for ever higher levels of intellectual property protection, regardless of the costs, and few have bothered to ask the small and medium-sized firms that actually drive the U.S. economy whether they would benefit or suffer from such proposals."[85] Additionally, any patent system is only beneficial if patentees can afford to enforce their rights; otherwise, there may be no real protection whatsoever afforded by patents.[86]

It seems quite obvious that developing countries and least-developed countries would require many years of economic "ramp up" time before the newly found benefits of patent protection could be realized. Interestingly, evidence shows that small organizations, at least in the United Kingdom, place little emphasis on the importance of the information gained through the patent system as a source for their innovations.[87] Much of the interaction these smaller firms have with their patent system revolves around employing patent attorneys to conduct regular patent searches in order to keep track of competition and to steer them away from possible infringement issues.[88] The point is that these firms innovate even without relying on information disseminated by the patent system.[89] Where they do have interaction with the system, most of their resources are spent merely trying to satisfy the demands of the system itself, without reaping any significant corresponding benefits.[90]

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82. Lee Petherbridge, *Intelligent TRIPS Implementation: A Strategy for Countries on the Cusp of Development*, 22 U. PA. J. INT'L ECON. L. 1029, 1059 (2001).

83. *Id*. at 1048-56.

84. *See* Lakshimi Sarma, *Biopiracy: Twentieth Century Imperialism in the Form of International Agreements*, 13 TEMP. INT'L & COMP. L.J. 107, 108–09 (1999).

85. Reichman, *supra* note 2, at 456.

86. Stuart Macdonald, Exploring the Hidden Costs of Patents, Notes of an Address Before the Quaker House, Geneva (May 16, 2001), at 6, *available at* http://www.geneva.quno.info/pdf/OP4.pdf.

87. *See id*. at 5–6.

88. *Id.* at 5.

89. *See id*. at 6–7.

90. *See id*. at 15–16.

V. INTELLECTUAL PROPERTY PROTECTION, BIODIVERSITY, AND HUMAN RIGHTS

A. The Convention on Biological Diversity

The United Nations 1992 Convention on Biological Diversity ("CBD") is another agreement that is closely related to the debate surrounding the questions of patenting life forms and biopiracy in developing nations.[91] The CBD recognizes the global threat to biological diversity posed by the widespread exploitation of the natural resources of the world's most biologically rich nations, which also tend to be the developing nations of the world. Such nations are therefore ill-equipped to protect themselves from the biocolonial behavior of huge transnational corporations. The solution agreed upon by many, as is evidenced by the CBD, is to thwart such behavior by granting state sovereignty over biological resources[92]

In its preamble, the CBD recognizes that "economic and social development and poverty eradication are the first and overriding principles of developing countries,"[93] and it recommends the equitable distribution of benefits arising from the exploitation of biological resources and indigenous knowledge from member nations.[94] The primary tool for achieving these objectives is by access to genetic resources through agreements based upon informed consent of the relevant parties.[95] A glaring shortcoming of the CBD is its specific exclusion of humans and human genetic resources, a huge source of patentable material for pharmaceutical concerns.[96]

Thus far, the CBD has been ratified by 130 nations—the United States is still one of the non-ratifying countries, primarily because of its objection to the benefit-sharing provisions of the agreement.[97] There is some discord among the objectives of the CBD and TRIPS, particularly with respect to the interests associated with the strengthening of patent rights for biological organisms and those requiring a sharing of benefits from biological prospecting activities that result in the commercialization of patented products, particularly pharmaceuticals.

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91. Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818, *available at* http://www.biodiv.org/doc/legal/cbd-en.pdf.

92. *Id.*

93. *Id*. at pmbl.

94. *Id*. at art. 1.

95. *See id*. at art. 15.

96. Cindy Hamilton, *The Human Genome Diversity Project and the New Biological Imperialism*, 41 SANTA CLARA L. REV. 619, 636 (2001).

97. *See id.* Rosemary J. Coombe, *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity*, 6 IND. J. GLOBAL LEGAL STUD. 59, 71–72 (1998).

The CBD appears to cause a dilemma for developing nations. In order to effectuate the CBD's purpose, nations must accede to the interests of bioprospecting corporations in other nations that protect life patents (for example, the United States), although in theory, they receive some economic and environmental benefit. At the same time, however, these countries seem to struggle with the notion of patenting life forms from a moral standpoint—a potentially hypocritical exercise, given that they are potentially benefiting from such policies in other nations.

One of the most controversial areas of the IPR discussion concerning the CBD centers around the activities of prospectors for biological materials in developing nations, which account for the largest percentage of the world's biodiversity. One leading example of such "bioprospecting" is the Ayahuasca Patent Case.[98] In 1999, the Center for International Environmental Law ("CIEL") successfully challenged U.S. Plant Patent Number 5,751 on the "ayahuasca" vine, which is native to the Amazonian rainforest and is used in sacred religious and healing ceremonies.[99]

The narrow rejection by the PTO was based on the fact that publications had described the plant before the filing of the patent application.[100] The patentee, Loren Miller, claimed that his variety of the plant, dubbed Da Vine, was distinct from other forms because of its distinct petal color.[101] The PTO found that the specimen matched specimen sheets pre-existing in the Field Museum of Chicago's Herbarium.[102] However, CIEL argued that such a patent on a living, naturally occurring organism should never have been considered in the first instance.[103]

On January 26, 2001, the PTO rescinded its decision on the Ayahuasca patent, acquiescing to Miller's repeated extensions and new arguments that his species differed from those in the Chicago Field Museum in terms of leaf shape and size.[104] Through a series of erroneous procedural and substantive decisions, the patent was then reinstated.[105] This is but one example of circumventing the spirit of the "newness" prerequisite in U.S. patent law, while also completely ignoring its

98. Center for International Environmental Law, The Ayahuasca Patent Case, *at* http://www.ciel.org/Biodiversity/ayahuascapatentcase.html (last updated Feb. 5, 2002).

99. Press Release, Center for International Environmental Law, U.S. Patent Office Admits Error, Rejects Patent Claim on Sacred "Ayahuasca" Plant (Nov. 4, 1999), *at* http://www.ciel.org/Biodiversity/AyahuascaRejectionPR.html.

100. *Id.*

101. GLEN M. WISER, CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW, PTO REJECTION OF THE "AYAHUASCA" PATENT CLAIM, *at* http://www.ciel.org/Biodiversity/ptorejection.html (Nov. 1999).

102. *Id*.

103. *Id.*

104. GLEN M. WISER, CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW, PTO U.S. PATENT AND TRADEMARK OFFICE REINSTATES AYAHUASCA PATENT: FLAWED DECISION DECLARES OPEN SEASON ON RESOURCES OF INDIGENOUS PEOPLES 1–2 (2001), *available at* http://www.ciel.org/Publications/PTODecisionAnalysis.pdf.

105. *Id*. at 12.

"nonobvious" requirement to capitalize on the biodiversity of developing nations.[106]

Other examples of bioprospecting and biopiracy are well-documented. Such instances range from the patenting of the Indian neem tree, to the patenting of basmati and jasmine rice, all of which are indigenous to developing nations, but patented by U.S. companies. Another more egregious example is the genetic sampling and testing of indigenous populations in developing countries.[107] These groups consist of communities of individuals who share customs, knowledge, and geographic territory, and who are relatively isolated from the dominant national society in which they reside.[108]

For example, the sampling of human cells from women in the Guayami Indian community in Panama who had contracted hairy-cell leukemia resulted in the isolation of, and application for, a U.S. patent on a cell line cultivated from their blood.[109] It also resulted in an uproar in the international community and the immediate withdrawal of the patent application by its Centers for Disease Control ("CDC") "inventor."[110] Such discoveries and genetic sampling (formerly without informed consent) are common among bioprospectors seeking to capitalize on the availability of relatively pure strains of genetic material from indigenous populations.[111]

In some cases, the fact that biological patents are unavailable in developing nations only acts to their detriment. Such was the case with the African Soapberry, used for centuries as a natural insecticide and fish intoxicant.[112] Dr. Akilu Lemma, an Ethiopian researcher, reported to the English Tropical Products Institute that this plant was toxic to certain water snails that carried the disease dilharzia.[113] Soon thereafter, the Institute patented an extraction process that resulted in a molluscicide that killed zebra mussels, which were a bane to North American waterways.[114] Because of the lack of available patent protection (and possibly naiveté of prior publication), however, Dr. Lemma received absolutely no benefit from his discovery.[115] It is wholly conceivable that if patent protection is not awarded in these countries, more cases of individual researchers losing the benefits of their discoveries will occur.

106. *Id*.
107. Hamilton, *supra* note 96, at 622; Wu, *supra* note 27, at 983.
108. Wu, *supra* note 27, at 983.
109. Aoki, *supra* note 81, at 53; Hamilton, *supra* note 96, at 627.
110. Hamilton, *supra* note 96, at 627.
111. *Id.* at 619–21.
112. Aoki, *supra* note 81, at 52.
113. *Id.*
114. *Id*.
115. *Id.*

B. The Universal Declaration of Human Rights

Closely related to the CBD is the Universal Declaration of Human Rights ("UDHR"),[116] which seeks to embody current international norms on human rights.[117] Originally drafted as a proclamation rather than a treaty, and therefore not legally binding, the UDHR has since become "customary international law" and is enforceable upon all nations.[118] Accordingly, third parties that participate in biotechnology patenting, such as transnational corporations in the United States, are accountable to member countries that have jurisdiction over them.[119]

Article 25.1 of the UDHR recognizes the basic human right to food, thereby possibly conflicting with the TRIPS requirement that plant forms be protected by patents. The argument is that this requirement results in higher seed costs for farmers in developing nations, who, through centuries of refinement, have actually bred the plants themselves.[120] Additionally, Article 25.1 recognizes the right to "security in the event of . . . sickness. . . ."[121] This also appears to conflict with the patenting of pharmaceuticals, particularly those derived from indigenous biological matter—both plant and human—that are obtained from the developing nations and resold at market prices reflecting the value of the patent's monopoly. Finally, in Article 27, the UDHR protects the right of "everyone . . . to share in scientific advancement and its benefits" while preserving the rights of "author[s]" to their "scientific . . . production."[122] Interestingly, there are no "authors" of scientific advancements that are based solely on the artificial copying of substances found in nature, despite the fact that this is exactly upon what many biotechnological patents are based.[123]

Examples of indirect violations of the UDHR are readily available in the international community. As a direct result of biopiracy, the firm RiceTec, whose trade slogan happens to be "more rice, less land, lower cost,"[124] has patented both basmati rice, which is indigenous to India, and jasmine rice, which developed over centuries in Thailand. The firm's own promotional literature proudly admits to using the Asian methods of

116. *Universal Declaration of Human Rights*, G.A. Res. 217A (III), U.N. GAOR, 3d Sess., Resolutions at 71, U.N. Doc. A/1810 (1948) [hereinafter UDHR], *reprinted in* 43 AM. JUR. INT'L L. SUPP. 127 (1949).

117. *See* Coombe, *supra* note 97.

118. BETH ANDRUS, AMNESTY INTERNATIONAL-USA LEGAL SUPPORT NETWORK, THE UNIVERSAL DECLARATION OF HUMAN RIGHTS 1948-1988: HUMAN RIGHTS, THE UNITED NATIONS AND AMNESTY INTERNATIONAL 1, 5 & n.20 (1988) (citing the Montreal Statement of the Assembly for Human Rights 2 (1968).

119. Coombe, *supra* note 97, at 69–70.

120. *See* Blackhurst, *supra* note 21, at 7. *See also* Aoki, *supra* note 81, at 46–48.

121. UDHR, *supra* note 116, at art. 25(1).

122. *Id*. at art. 27.

123. *See* Mario Biagioli, *The Instability of Authorship: Credit and Responsibility in Contemporary Biomedicine*, 12 FASEB J. 3 (1998), *available at* http://www.fasebj.org/cgi/reprint/12/1/3.pdf.

124. RiceTec, Hybrid Rice Seed, *at* http://www.ricetec.com/hybrid.htm (last visited Mar. 1, 2003).

hybridization to cultivate its brand-name *Texmati*® and *Jasmati*® rice varieties:

> The technology for producing hybrid rice was developed in China over 25 years ago. Rice in China is grown under a very small-scale, labor-intensive system of nursery beds and hand transplanting. Using traditional breeding methods, RiceTec's research and development group has worked for the past decade to adapt Chinese hybrid technology to meet the complex needs of the large-scale, highly mechanized US rice producer.[125]

As would be expected, the reaction of farmers in both India and Thailand to RiceTec's "invention" was extreme.[126] It has been noted that the Asian regions produce over 90 percent of the world's supply of rice, accounting for up to half of Asian farm incomes, and 80 percent of the daily calories of these countries' populations.[127] The actions of the top transnational patent holders on rice are designed to increase the dependency of Asian farmers on the "new" pesticide-dependent hybrids, while correspondingly increasing the price of these commodities, which further detriment their already-impoverished end consumers.[128] It is apparent that these actions ultimately frustrate the UDHR's goal of protecting the rights of all people to share in the advancements of science, and particularly the most basic necessity: food for survival.

VI. RECENT DEVELOPMENTS

A November 2001, WTO meeting in Doha, Qatar, primarily addressed the issue of compulsory licensing of pharmaceuticals in the face of the AIDS epidemic plaguing many of the least-developed countries. The result was the Declaration on the TRIPS Agreement and Public Health.[129] The agreement recognizes that protection of intellectual property interests is directly related to the production of new medicines. However, it also acknowledges the corresponding price increases that such protective measures effectuate.[130] Consequently, the Declaration reiterates and clarifies the right of member nations to utilize the provisions of the TRIPS agreement that allow for the ability to grant compulsory licenses when a member-nation determines, of its own accord, that a national health emergency exists.[131]

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125. *Id*. (emphasis in original).

126. GENETIC RESOURCES ACTION INTERNATIONAL, BIOPIRACY, TRIPS, AND THE PATENTING OF ASIA'S RICE BOWL (1998), *at* http://www.grain.org/publications/rice-en-p.htm.

127. *Id*.

128. *See id*. *See also* GENETIC RESOURCES ACTION INTERNATIONAL, STATEMENT OF PEOPLE'S MOVEMENTS AND NGOS ACROSS ASIA: NO PATENTS ON RICE! NO PATENTS ON LIFE! (2001), *available at* http://www.grain.org/publications/rice-no-patents-en.cfm.

129. World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/Dec/2 P4 (Nov. 14, 2001) [hereinafter WTO Declaration], *available at* http://www.wto.org.english/thewto_e/minist_e/mindecl_trips_e.pdf.

130. *Id*. at ¶ 3.

131. *Id*. at ¶ 5(b), (c).

The Declaration also addresses the issue of the incapacity of the least-developed WTO members to make effective use of the compulsory licensing provisions of the TRIPS agreement due to their lack of manufacturing capacity for pharmaceuticals.[132] Presumably, these countries—in the form of the "African Group," along with several countries in Asia and Latin America—were seeking permission to import drugs from developing countries in order to meet the public health needs of their citizens in the form of parallel imports.[133] They were met at the conference by strong opposition from the United States, Switzerland, and others who have developed vested interests in the comparative advantages of pharmaceutical trade.[134] However, the least-developed countries did receive permission to extend their implementations of patent rights for pharmaceuticals until 2016.[135]

A fascinating development in the area of patenting higher life forms occurred recently in a case decided by the Canadian Supreme Court on December 5, 2002. The court in *Commissioner of Patents v. President and Fellows of Harvard College*[136] held that Section 40 of the Canadian Patent Act did not encompass higher life forms, such as the transgenic "Harvard Mouse," which had previously been granted patent protection in the United States. As a matter of statutory construction, the *Harvard College* Court refused to construe the words "manufacture" and "composition of matter," as used in the Act, to indicate that the Canadian Parliament meant to include higher life forms within the meaning of "invention."[137] However, the Court did agree that the protection of "lower" forms of biological material was included in the definition of patentable subject matter. It appears that at least one nation is moving much more cautiously (and prudently) in the area of life patents.

VII. CONCLUSION

As far as the implementation of intellectual property rights in biological materials is concerned, this Note argues that the United States should have been more cautious in permitting patent rights for organisms and gene fragments attributable to naturally occurring sources. Congress should give serious consideration to limiting the patentability of vital upstream biological information, and at the very least, provide clear guidance on the issue of benefit-sharing with research subjects. Given

132. *Id*. at ¶ 6.

133. Chakravarthi Ragavan, *U.S., Swiss Take Hard-Line on TRIPS, Public Health and Doha*, SUNS SOUTH-NORTH DEV. MONITOR, July 30, 2001, at 4946, *available at* http://www.sunsonline.org/results.php.

134. *Id*.

135. WTO Declaration, *supra* note 129, at ¶ 7.

136. Harvard College v. Canada (Commissioner of Patents), [2002] SCC 76, 2002 Can. Sup. Ct. LEXIS 86, at *1 (Dec. 5, 2002).

137. *Id*. at *5.

this opinion, it seems equally obvious that developing and least-developed nations should not make the mistake of depriving their own citizens and research communities of access to such vital knowledge with low transactional costs.

There appears to be disagreement among economists about the degree to which innovation is encouraged or stifled by increased patent protection. Economic issues aside then, it seems prudent to err on the side of caution where the restriction of access and underutilization of information may result in the perpetuation of hardship and suffering for the world's poorest inhabitants. Perhaps someone will develop a highly useful process for stuffing genies back into bottles. Of course, they'll patent it, and none of us will likely be able to afford to pay the price to license the technology.