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Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention

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ABSTRACT

After a brief overview of biodiversity prospecting, the authors review the historical context of biodiversity prospecting, including the common heritage doctrine, international patent law, and the Biodiversity Convention. The authors analyze the four major United States prospecting initiatives to date and identify their strengths and shortcomings. The authors then investigate two possible alternatives: (1) biological resource cartelization and (2) the development of a new type of biodiversity enterprise. The authors advocate the latter as a means of complying with the Biodiversity Convention.

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I. INTRODUCTION

In the three years since the signing of the United Nations Convention on Biological Diversity,[1] biodiversity prospecting[2] has been hailed as a possible means of furthering the conservation and development objectives of the Convention. The private sector, as well as the international development and conservation communities, has initiated numerous programs that attempt to support the Convention's objectives. For the developed countries of the North[3] to continue to have access to the developing world's biological diversity, the Convention calls for (i) active support for

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1. *Opened for signature*, June 5, 1992, 31 I.L.M. 818 (entered into force Dec. 29, 1993) [hereinafter Biodiversity Convention or Convention].

2. Biodiversity prospecting, or bioprospecting, is the intensive search for useful compounds from natural sources. For the purposes of this Article, it excludes the search for economically important genomes (the genes introduced from the wild into high-yield agricultural crops). Ignacio H. Chapela, Bioprospecting in the Information Age: Critical Analysis of Pharmaceutical Searches through Biodiversity 4 (April 13, 1994) (unpublished paper, on file with the author). Biodiversity prospecting has also been defined as "the search through biodiversity resources for active compounds for pharmaceutical development. . . ." Julie M. Feinsilver, *Biodiversity Prospecting: Prospects and Realities, in* PROSPECTS IN BIODIVERSITY PROSPECTING 21, 21 (A.H. Zakri ed., 1995).

3. Industrialized nations, long named "First World" or "developed" nations, are lately referred to as "the North." Underdeveloped nations, earlier called "Third World" nations, "developing" countries, or "LDCs" (Lesser Developed Countries), are lately referred to as "the South." This Article uses the labels interchangeably. *See* Roger D. Hanson, *North-South Policy: What's the Problem?*, FOREIGN AFF. 1104, 1104-05 (1980) (discussing the accuracy of North-South distinctions).

conservation efforts, (ii) equitable compensation to the source country[4] and its indigenous populations, (iii) technology transfer to the source country, and (iv) support for capacity-building within the source country.[5] With no consensus regarding how best to fulfill these objectives, the projects initiated in the past three years have varied in scope and effectiveness.

This paper describes recent experiences in biodiversity prospecting, examines the traditional roles of the North and South, and proposes how these roles may change to better fulfill the objectives of the Convention. Part II examines the rationale behind biodiversity prospecting. Part III looks at the legislative framework surrounding genetic resources, including (i) the Common Heritage Doctrine, (ii) patent laws, and (iii) the United Nations Convention on Biological Diversity. Part IV presents and critically analyzes four biodiversity prospecting projects: (i) the National Cancer Institute's Natural Products Program, which is funded by the U.S. government, (ii) the INBio-Merck[6] bilateral agreement for access to Costa Rica's biodiversity, funded by Merck and several foundations, (iii) the International Cooperative Biodiversity Groups, a NIH/USAID/NSF[7] funded initiative, and (iv) Shaman Pharmaceuticals, a venture capital and public market funded attempt to use indigenous knowledge from around the world to discover new drugs. Part V studies the possibility of cartelization of genetic resources by developing countries. Part VI describes a new bioprospecting initiative that may be better suited to fulfilling the objectives of the Biodiversity Convention. Finally, some general conclusions are drawn in Part VII.

II. BIODIVERSITY PROSPECTING

Dr. Norman Farnsworth, a renowned pharmacognacist, estimates that eighty percent of the world's population depends on botanical resources for their primary health care needs.[8] In contrast, the North is highly dependent upon pre-processed pharmaceutical compositions. Of those pharmaceuticals

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4. The term "source countries" refers to countries of the South that are sources of biological material for multinational pharmaceutical corporations based in countries of the North.

5. Biodiversity Convention, *supra* note 1, arts. 1, 8, 15, 16, 17, 19.

6. The National Biodiversity Institutes (INBio) and Merck & Co.

7. National Institutes of Health/U.S. Agency for International Development/National Science Foundation.

8. Norman R. Farnsworth, *How Can the Well Be Dry When It Is Filled with Water?*, 38(1) ECON. BOTANY 4, 6 (1984).

currently sold in the United States, it is estimated that up to twenty-five percent are either derived from or had their origins in plants.[9] For centuries, societies throughout the world have recognized the tremendous value of medicinal plants.

The process of identifying useful plants is thought to have evolved through trial and error.[10] Throughout the developing world, knowledge of a plant's usefulness has usually been empirical. The users could not identify the active compounds responsible for a specific pharmacological effect, but they did know that the plant had a specific beneficial effect.

Biodiversity prospecting, or natural products drug discovery (NPDD), as it is practiced today, is the search for bioactive compounds contained in natural sources such as plants, fungi, insects, microbes, and marine organisms. For several decades, it was believed that NPDD could be replaced by the synthetic creation of new compounds. In recent years, however, it has become clear that natural products remain a crucial starting point for drug discovery. Dr. Gordon Cragg, chief of the National Cancer Institute's Natural Products Branch, describes the relationship between rational drug design and natural product as follows: although a chemist can synthetically modify and improve a molecule, "no chemist can 'dream up' the complex bioactive molecules produced by nature."[11] This is essentially the rationale for biodiversity prospecting.

Today, the screening process used to evaluate a plant gathered from a source country generally requires about 500 grams of plant material. The sample undergoes an organic extraction using ethanol and then an aqueous (water) extraction. The extract is then presented to a progression of whole-cell, receptor, or enzyme tests to determine whether bioactivity exists. In whole-cell assays, bioactivity is determined by examining the types and rates of cells that the plant material kills. Those kill rates guide scientists in determining the material's usefulness and commercial viability. Extensive clinical trials in both live animals and humans are typically conducted before a drug is sold publicly. In the United States, drugs must undergo the Food and Drug Administration's lengthy approval process.

In light of the Biodiversity Convention, biodiversity prospecting has been touted, *inter alia*, as an incentive for conservation, the means for discovering the next AIDS or cancer cure, and a vehicle for sustainable economic development. While

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9. *Id.* at 6.

10. For a fascinating alternative theory, see WADE DAVIS, SHADOWS IN THE SUN 127-39 (1992).

11. Feinsilver, *supra* note 2, at 22.

there are clearly potential benefits to biodiversity prospecting, there are also potential dangers. Because almost all screening[12] facilities are located in the developed world,[13] the benefits (often in the form of royalties) from discoveries of novel bioactive compounds may never return to the source country. In addition, the identification of a valuable plant may create such a tremendous demand that expansive harvesting leads to extinction.

The Biodiversity Convention is a framework that may serve as a guide to future biodiversity prospectors so that the potential dangers inherent in the industry may be avoided. While Northern corporations involved in biodiversity prospecting activities seek adequate protection of their investments, indigenous groups and local communities in the South seek to protect their ways of life. The Convention is a document that can positively impact both of these divergent interests.

III. HISTORICAL CONTEXT

Throughout recent history, a variety of conceptual frameworks have been used to regulate the access and trade of genetic resources. This section examines the three most important of these frameworks: the common heritage doctrine, international patent law, and the United Nations Convention on Biological Diversity. This section describes these approaches in chronological order and highlights their respective strengths and shortcomings.

A. *Initial Assumption: Common Heritage Doctrine*

The common heritage doctrine proposes that plant genetic resources are the common heritage of humankind and therefore should be freely available to all. This idea dominated the global approach to genetic resources until very recently. At the 1983 International Undertaking on Plant Genetic Resources, developing countries still argued that "plant genetic resources are a heritage of humankind to be preserved, and to be freely available for use, for the benefit of present and future

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12. "Screening" refers to the testing of extracts or mixtures of synthetic compounds to determine if they contain certain bioactive compounds that may be purified and developed into pharmaceutical products.

13. Paul Gormley, *Compulsory Patent Licenses and Environmental Protection*, 7 TUL. ENVTL. L.J. 131, 137 (1993).

generations."[14] Although the International Undertaking was signed by developed countries, it was signed subject to reservations, which vitiated its essential purpose.[15]

It soon became clear the "common heritage" argument could be used to hurt developing countries' interests. Using the common heritage argument as its basis for access, a Northern pharmaceutical company created a tremendously lucrative drug from the rosy periwinkle, found in a highly threatened ecosystem in Madagascar.[16] None of the profits from the new drug, however, were returned to the source country where they could have helped to conserve the threatened ecosystem.[17]

Developing countries were quick to realize that common heritage language frequently protected the interests of developed nations over the interests of developing countries.[18] Recognizing all genetic lines as the common genetic heritage of humankind left developed nations in a superior financial and scientific position to take advantage of a large and easily accessible gene pool.[19] The industrialized North's treatment of source country resources often amounted to a new form of colonialism. Developing countries' resources were used to add value to developed economies without compensating developing countries.[20] Today, source countries

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14. *Report of the Conference of the FAO*, U.N. Food and Agriculture Organization, 22d Sess., U.N. Doc. C/83/Rep. (1983).

15. Michael D. Coughlin, Note, *Using the Merck-INBio Agreement to Clarify the Convention on Biological Diversity*, 31 COLUM. J. TRANSNAT'L L. 337, 348 (1993).

16. Shaya Kadidal, Note, *Plants, Poverty, and Pharmaceutical Patents*, 103 YALE L.J. 223, 223 (1993).

17. Steven M. Rubin & Standwood C. Fish, *Biodiversity Prospecting: Using Innovative Contractual Provisions to Foster Ethnobotanical Knowledge, Technology, and Conservation*, 5 COLO. J. INT'L L. & POL'Y 23, 27 (1994). It should be noted that other facets of the rosy periwinkle example are atypical of biodiversity prospecting. In fact, several facets of the rosy periwinkle make it a poor paradigm. First, it is a pan-tropical common weed. Second, it is neither rare nor endangered. Third, the ethnobotanical leads came from countries (Jamaica and the Philippines) other than the country in which the plant was collected (Madagascar). *See* A.B. Cunningham, Conservation, Knowledge and New Natural Products Development: Partnership or Piracy? 6 (June 1993) (unpublished paper, on file with the author).

18. *See* David R. Downes, *New Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology, and Intellectual Property in the Convention on Biological Diversity*, 4 TOURO J. TRANSNAT'L L. 1, 6 (1993) (briefly discussing the changed use of the common heritage argument).

19. Kadidal, *supra* note 16, at 229.

20. *See* Jose de Souza Silva, From Medicinal Plants to Natural Pharmaceuticals: the Commodification of Nature 3 (Apr. 1994) (unpublished paper, on file with the author) (referring to the "continuous interest of industrial capitalism in extending the reach of the commodity logic and private property into the resources of biodiversity").

reject the common heritage framework.[21] Thus, the challenge has been to formulate an alternate conceptualization of rights to biodiversity resources.

B. *Intellectual Property: International Patent Law*

Intellectual property can be loosely divided into five types: patents, trademarks, copyrights, breeder rights, and trade secrets. Some authors place much faith in the proposition that stronger and more pervasive protections of intellectual property rights will lead to improved environmental protection.[22] However, others note that, in the international context, biotechnology[23] firms do not want to share profits with developing countries and use intellectual property rights to protect their large profits from the efforts of developing countries to claim a portion of the benefits.[24]

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21. The politicized debate obscured the fact that developing countries have a common heritage argument in their favor. The Law of the Sea Convention negotiations involved disputes between the North and South over exploitation of manganese nodules located on the sea floor. *See* United Nations Convention on the Law of the Sea, Dec. 10, 1982, art. 136, U.N. Doc. A/CONF. 62/122, *reprinted in* 21 I.L.M. 1261 (1982) (containing the first appearance of the common heritage argument in international law). The South argued strongly that such nodules should not be exploited by the North for the North's sole economic gain because the manganese is the common heritage of mankind by virtue of its location on the sea floor. Only the North possessed the technology necessary to access the manganese. Even though developing countries were entitled to some benefit from the nodules, they could not realize the benefit because often they lacked the necessary technology. Developing countries sought to ensure that the manganese was conserved and that its ultimate benefits were shared. Today, the North possesses the technology to exploit genetic resources. Although tremendous genetic resources are located within developing countries' territory, developing countries cannot access those riches because they lack the requisite technological capacity. If they could access their own biodiversity resources, developing countries would be able to earn the necessary funds to improve their economies and preserve their environment. Such preservation is to the benefit of all nations. Therefore, developing countries can again argue that the common heritage doctrine requires restrictions on the North's access to a resource that can confer benefits on humankind as a whole.

22. *See* Michael A. Gollin, *Using Intellectual Property to Improve Environmental Protection*, 4 HARV. J. L. & TECH. 193, 194 (1991) (claiming that "increased reliance on intellectual property by environmental policy makers, regulators, and managers will improve environmental protection while stimulating beneficial economic and technical progress").

23. Biotechnology deals with "production of useful products by living micro-organisms and cell cultures." PHILIP W. GRUBB, PATENTS IN CHEMISTRY AND BIOTECHNOLOGY 150 (1986).

24. *See* Gormley, *supra* note 13, at 156 (arguing that the benefits of intellectual property rights schemes are overstated). Moreover, Gormley argues that, for developing countries, an intellectual property rights system is often very

Patent law is the mechanism that presently attracts the most attention from benefit-sharing advocates. The Uruguay Round of GATT[25] is the most recent effort to formalize an international intellectual property law system capable of addressing biodiversity prospecting. The subject is highly controversial. Developing countries assert that intellectual property rights over biotechnology are a major obstacle to benefit-sharing and conservation.[26] Developed countries disagree; they assert that intellectual property rights protect fair rewards for innovation and increase the technological benefits of biodiversity by enhancing the commercial value of the genetic resources.[27]

The Uruguay Round of GATT lavished attention on the subject of Trade Related Intellectual Property and GATT's effort to require the creation of plant intellectual property rights in all member states. This effort created significant controversy among representatives of developing countries, nongovernmental organizations (NGOs), and environmental groups concerned with plant conservation.[28] The Uruguay Round's focus on biotechnology may potentially increase large corporations' access to third world resources.[29] GATT's effort to limit a nation's right to export its resources is of greatest benefit to multinational corporations that seek to ensure that world resources will remain cheap and readily accessible.[30]

Many developing countries are not parties to GATT and are therefore closed out of the GATT process. Those developing countries that are parties to GATT, however, generally oppose the GATT intellectual property approach to biotechnology. This long-standing disagreement within GATT over intellectual property issues is so severe that it is now contributing to diminished

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damaging and costly because it provides disparate protection to the inventions of the North, while underprotecting the inventions of the South. Gormley argues that the South can derive tangible benefits from the absence of intellectual property laws, specifically the absence of patent laws. *Id.*

25. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1. For a discussion of the General Agreement on Tariffs and Trade (GATT) as it relates to biodiversity issues, see *Uruguay Round of GATT Provides New Forum for Debating Germplasm Ownership Issues*, 6 DIVERSITY 39 (1990).

26. Downes, *supra* note 18, at 7.

27. *Id.*

28. Neil D. Hamilton, *Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources*, 28 TULSA L.J. 587, 590 (1993).

29. Michelle Syverson, Afterword, *GATT, the Environment, and the Third World*, 23 ENVTL. L. 715, 716 (1992).

30. *Id.* at 717.

confidence in the GATT multilateral free trade process as a whole.[31]

Patent law is a product of the legal systems of the North. As the system is currently structured, patent law does not allow a naturally occurring substance to be patented; this is the "product of nature exception."[32] However, where a substance, "previously unknown in its purified and isolated form," is refined so that the product can be distinguished in kind, and where it also demonstrates "unexpected properties," the refined substance is patentable.[33] The resulting United States patent endures for twenty years from date of filing,[34] although that period may be extended for pharmaceuticals, which often experience delays in the lengthy United States Food and Drug Administration approval process.[35] This is the avenue used by the preponderance of pharmaceutical corporations when creating and patenting a drug derived from natural products.

A popular critique of the patent system is that it is highly inequitable to give patent protection only to the companies that isolate and then purify or synthesize an existing natural compound.[36] Although it is argued by some that patent law's present refusal to protect compounds already existing in nature is one of the system's critical drawbacks,[37] this argument misses the point. The issue is not whether to lower the threshold for patentability to include products of nature, but whether there is a need to reconceptualize the entire idea of "inventiveness."[38]

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31. Kirsten Peterson, Recent Development, *Recent Intellectual Trends in Developing Countries*, 33 HARV. INT'L L.J. 277, 277-78 (1992).

32. *See* Gollin, *supra* note 22, at 198 (providing an overview of the present United States patent law system). The term "product of nature" is a term of art in United States patent law and should not be confused with "natural products," which are the materials from which pharmaceuticals are created.

33. Kadidal, *supra* note 16, at 238.

34. Uruguay Round Agreement Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994) (amending 35 U.S.C. § 154, among others, and changing the term of patent to 20 years from date of filing. The previous term had been 17 years from date of grant). This applies to all utility and plant patents filed on or after June 8, 1995. *Id.*

35. Gollin, *supra* note 22, at 210 n.92.

36. *See* Lester I. Yano, Note, *Protection of the Ethnobiological Knowledge of Indigenous Peoples*, 41 UCLA L. REV. 443, 458 (1993) (discussing intellectual property rights from the perspective of justice to indigenous peoples who preserve ethnobotanical knowledge).

37. Kadidal, *supra* note 16, at 225.

38. Edgar J. Asebey, Andes Pharmaceuticals, Inc.: A New Model for Biodiversity Prospecting 16 (Apr. 12, 1994) (unpublished paper, on file with the author) (discussing the concepts of patents, inventorship, and the indigenous knowledge chain-of-inventorship paradigm in biodiversity prospecting) [hereinafter Asebey, New Model]. *See also* Edgar J. Asebey, Indigenous

There is very significant disagreement between the North and South over biotechnology patents,[39] and intellectual property in developing countries is certainly a major source of contention between North and South.[40] International approaches to biotechnology regulation, including patent and other laws, diverge widely and any international harmonization will be difficult.[41] In fact, "increased use is being made of patents . . . to maintain a dominant role in the production and marketing of research results."[42]

Although some authors argue that developing countries will benefit from any strengthening of the international patent law system,[43] other scholars of the system conclude that it is economically unsound for developing countries to have a patent system if a large majority of patents are granted to foreigners.[44] Support for developing country participation in the international patent law regime hinges upon three assumptions. First, society needs more inventions than would be made if society lacked patent incentives. Second, the best incentive for creation of new inventions is the exclusivity provided by the patent system. Third, the granting of patents on inventions does actually lead to economic development.[45]

These three assumptions, however, are unwarranted.[46] In fact, the international patent law system is often deceptively harmful to developing countries, causing them to exchange real rights for rights that are mostly theoretical.[47] Thus, it appears that the international intellectual property system advances developing countries' interests only after developing countries

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Knowledge and Intellectual Property: Towards Equitable Compensation (Apr. 12, 1994) (unpublished paper, on file with the author) (discussing the patent system, indigenous knowledge, and compensation mechanisms).

39. *See* Gollin, *supra* note 22, at 215 (arguing that developing countries' weak protection of intellectual property rights cause less technology transfer from North to South). *But see* A. Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, 1987 DUKE L.J. 831 (arguing that developing countries stand to gain little from stronger internal intellectual property protections).

40. Peterson, *supra* note 31, at 277.

41. Gollin, *supra* note 22, at 217.

42. U.N. CENTRE ON TRANSNATIONAL CORPORATIONS, TRANSNATIONAL CORPORATIONS AND THE TRANSFER OF NEW AND EMERGING TECHNOLOGIES TO DEVELOPING COUNTRIES at 64, U.N. Doc. CS/CTC/98, U.N. Sales No. E.90.II.A.20 (1990).

43. *See, e.g.*, Kadidal, *supra* note 16; Downes, *supra* note 18; Gollin, *supra* note 22.

44. Oddi, *supra* note 39, at 832.

45. *Id.* at 837, 843.

46. *See id.* (meticulously disproving each of those assumptions).

47. *Id.* at 856.

acquire access to advanced technology, almost treating the acquisition of such technology as a pre-requisite for development of a patentable product.

The challenge is to accommodate the interests of both the North and South within the broader context of a political and economic debate of global proportions. If the answer to the biodiversity question lies in intellectual property, the answer will be long in coming. Because the needs of developing countries and concerns regarding "biopiracy" are pressing,[48] the search for solutions outside patent law continues.

C. *International Framework: The Biodiversity Convention*

In June of 1993, the United States signed the U.N. Convention on Biological Diversity. The previous summer, at the United Nations Conference on Environment and Development (UNCED)[49] in Rio de Janeiro, the United States was the only country that refused to sign the Convention.[50] Under the Bush Administration, the United States objected to certain economic and intellectual property provisions of the Convention.[51] It also opposed the requirement of compensation for the use of biological resources and transfer of biotechnology.[52] Because the Biodiversity Convention is not a self-executing treaty, the Convention does not acquire the force of law in the United States until the Senate ratifies it. If the Senate does ratify the Convention, the United States will participate in a global effort to protect biodiversity and will gain the opportunity to influence international policy on the subject. The potential consequences of not ratifying the Convention, discussed *infra*, are substantial.

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48. Frances Williams, *Bio-piracy Costs Third World $5.4bn a Year*, FIN. TIMES (London), Oct. 28, 1994, World Trade News, at 7. The term "biopiracy" refers to the North's use of genetic biodiversity resources without appropriate compensation.

49. Also known as the Earth Summit. At UNCED, the Convention was signed by 150 of the member states present. Walter V. Reid et al., *A New Lease on Life, in* BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT 1, 24 (Walter V. Reid et al. eds., 1993) [hereinafter BIODIVERSITY PROSPECTING].

50. *U.S. Objections to Biodiversity Treaty Based on Misreading of the Text, Study Says*, 15 Int'l Envt. Rep. (BNA) 704 (Nov. 4, 1992).

51. *Biotechnology: Industry Trade Groups Laud President Bush for Decision Not to Sign Biodiversity Treaty*, 16 Chemical Reg. Rep. (BNA) 571 (June 12, 1992).

52. Eugene Robinson & Michael Weisskopf, *'No' Leaves U.S. Isolated at Summit*, WASH. POST, June 6, 1992, at A1.

1. Key Provisions

The objectives of the Convention are summarized in its first article.[53] Technology transfer, conservation, sustainable use, and the equitable sharing of benefits are the explicit objectives of the Convention and are essential components of any bioprospecting effort. Article 8, *In-situ Conservation*, addresses the responsibilities that companies with access to the genetic resources of the South owe to the indigenous peoples within Southern countries.[54]

Article 16 is the main technology transfer reference in the Convention and, along with Article 19, was the basis of the United States initial objection to signing the Convention. Article 16 establishes a *quid pro quo* by linking the exchange of access to genetic resources with the transfer of technology to the developing world.[55] Thus, the Convention creates a two way exchange. The

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53. The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Biodiversity Convention, *supra* note 1, art. 1.

54. Each Contracting Party shall, as far as possible and as appropriate: (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations, and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

Id. art. 8.

55. (1) Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provision of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment . . . . (3) Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where

South gives access to genetic resources and the North provides compensation and technology transfer. Each is conditioned upon the other.

In the Convention, access to genetic resources is closely linked to equitable benefit-sharing. This arrangement permits developing countries to receive some benefits from the commercialization of their biological resources. Article 15 reinforces developing countries' sovereign control over their resources and emphasizes the mutuality of access agreements.[56] Article 19 explicitly states the developing world's expectation that, in exchange for access to its biodiversity, it will receive a fair and equitable portion of the benefits that the North derives from the use of the South's genetic resources.[57]

In summary, Articles 15 and 19 clearly announce that the developing world's biodiversity can no longer be used for free. Articles 15, 16, 17, and 19 establish the North-South exchange—access to the South's genetic resources will continue as long as relevant technologies and benefits are equitably shared

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necessary, through the provisions of Article 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

Id. art. 16.

56. (1) Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation . . . .

. . . .

(4) Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article . . . .

. . . .

(7) Each Contracting Party shall take legislative, administrative or appropriate policy measures, as appropriate, and in accordance with Article 16 and 19 and, where necessary, through the financial mechanisms established by Article 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Id. art. 15.

57. (2) Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

Id. art 19.

with the South. The challenge for all organizations involved in biodiversity prospecting initiatives with other countries' natural resources is to meet these new minimum requirements.

2. Inherent Conflicts

Numerous commentators note that the Biodiversity Convention suffers "from basic conceptual and drafting deficiencies,"[58] "memorializ[ing] rather than resolv[ing]" the deadlocks of the Convention's negotiation,[59] with an end result that has been deemed "impressively opaque."[60] Nonetheless, the Biodiversity Convention is a breakthrough. It is a visible admission by the international community that historically the North has exploited the South's resources without providing adequate compensation, usually with the source country's consent. The Convention is a crucial step in halting such uncompensated exploitation.[61] Additionally, the Convention can be regarded as a *quid pro quo* arrangement, under which the North exchanges technological and financial support to developing countries for access to biological resources.[62] Although international conventions were promulgated to deal with various aspects of species conservation in the period between the Stockholm Declaration and the signing of the Biodiversity Convention, each of those conventions was "fundamentally flawed in one respect or another."[63]

In its present form, the Convention contains serious defects, which could prevent it from adequately protecting biodiversity. In part, these defects are a natural result of the Convention's form itself. Conventions typically contain a statement of broad goals and procedures, but contain few, if any, substantive requirements.[64] Because international agreements require consensus among many nations, they "tend to reflect the lowest

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58. Melinda Chandler, *The Biodiversity Convention: Selected Issues of Interest to the International Lawyer*, 4 COLO. J. INT'L ENVTL. L. & POL'Y 141, 174 (1993).

59. Downes, *supra* note 18, at 9.

60. *The Earth Conference: Biodivisive*, ECONOMIST (United States), June 13, 1992, at 93, 94.

61. Biodiversity Convention, *supra* note 1, art. 3 (concerning a country's *sovereign* right over its biodiversity); *id.* art. 15(1) (concerning a country's authority to determine *access* to its genetic resources).

62. *Id.* arts. 15, 16, 17, 19.

63. *See* Coughlin, *supra* note 15, at 340.

64. *See generally* Pierre-Marie Dupuy, *Soft Law and the International Law of the Environment*, 12 MICH. J. INT'L L. 420 (1991).

common denominator" rather than the majority standard.[65] Each party must implement its own legislation in order to effectuate the goals of the Convention. These legislative initatives will eventually determine the strength or weakness of the Convention.

The Convention requires that countries gathering genetic resources must do so on "mutually agreed terms" by obtaining "prior informed consent."[66] At first glance, this provision appears to further developing countries' interests. The mutually agreed terms requirement, however, is inconsistent throughout the text and is subject to wide interpretation.[67]

The Convention also requires buyers and source countries to arrange "fair sharing" of the benefits they derive from the genetic resources.[68] This provision appears to ensure compensation for developing countries, but provides no guidance on the criteria for fairness and does not address the issue of disparate bargaining power. The combined effect of Articles 15 and 19, however, is to vest in developing countries the right to exclude nationals of foreign territories from access to biological organisms in their territory.[69]

Because the Biodiversity Convention never uses the phrase "common heritage of mankind" to describe biodiversity resources, the Convention appears to reject the argument, which initially formed the basis of exploitation efforts of developed nations.[70] The Convention, however, does not choose to treat genetic resources as a form of property like all other natural resources, which are subject to tangible property rights.[71] Although the North's common heritage argument arguably failed in the Convention, the North was able to prevent developing countries from asserting full sovereign control over their resources.[72] However, local legislation within developing countries enables the South to retain a great degree of control over genetic resources.

When the United States initially refused to sign the Biodiversity Convention, it did so in part because of pressure from the United States pharmaceutical and biotechnology

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65. Peter H. Sand, *International Cooperation: The Environmental Experience, in* PRESERVING THE GLOBAL ENVIRONMENT: THE CHALLENGE OF SHARED LEADERSHIP 236, 240 (Jessica T. Mathews ed., 1991).

66. Biodiversity Convention, *supra* note 1, arts. 15(4), 15(5).

67. *See, e.g.*, Chandler, *supra* note 58, at 164.

68. Biodiversity Convention, *supra* note 1, art. 15(7).

69. Coughlin, *supra* note 15, at 363.

70. Kadidal, *supra* note 16, at 231.

71. *See generally id.* (arguing that intellectual property rights in genetic resources should be created).

72. Downes, *supra* note 18, at 10.

industries.[73] Representatives of these industries claimed that the terms of Article 16[74] would lead to compulsory licensing of United States biotechnology.[75] In fact, these clauses most likely will not lead to compulsory licensing as initially claimed. After the pro-Convention Clinton Administration came into office, the same groups that had opposed the Convention recommended its signing, announcing that "on closer reading" they had determined there was little danger of compulsory licensing.[76] The United States, still concerned over compulsory licensing, is drafting an Interpretive Statement to protect United States-based companies against the possible development of compulsory licensing. Ultimately, the United States did sign the Convention,[77] but the Senate has yet to ratify it.[78]

Failure to ratify the treaty and to support the Convention and the international consensus it represents is already beginning to have repercussions for United States business interests. For example, when the United States initially refused to sign the Biodiversity Convention in 1992, Venezuela stopped signing new agreements for scientific collaboration with United States companies that wished to study genetic resources.[79] In addition, in the spring of 1995, India threatened to block United States access to its medicinal plants and other biological materials from the Third World unless the United States ratifies the Convention before the end of the summer of 1995.[80] Numerous other countries are waiting in the wings, ready to follow India's lead.[81]

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73. Robinson & Weisskopf, *supra* note 52, at A1.

74. Biodiversity Convention, *supra* note 1, art. 16(4) ("Each contracting party shall take . . . measures . . . with the aim that the private sector facilitates access to joint development and transfer of technology . . . for the benefit of both governmental institutions and the private sector of developing countries.").

75. *Biodiversity Treaty Risks Interfering with Patent Protections, Official Says*, 9 Int'l Trade Rep. (BNA) 1071, 1072 (June 17, 1992).

76. *U.S. Objections to Biodiversity Treaty Based on Misreading of the Text, Study Says*, *supra* note 50, at 705.

77. *U.S. Reverses Bush's Rejection of Environmental Pact*, L.A. TIMES, June 5, 1993, at A20.

78. Sanjoy Hazarika, *India Presses United States to Pass Biotic Treaty*, N.Y. TIMES, Apr. 23, 1995, § 1, at 13.

79. *U.S. Objections to Biodiversity Treaty Based on Misreading of the Text, Study Says*, *supra* note 50, at 705.

80. Hazarika, *supra* note 78.

81. "The mega-biodiverse countries of Latin America, South, and South-east Asia are waiting for India to take the lead . . . . If we do not have progress this summer then we will meet to map out a joint strategy on the transfer of genetic material."

. . . .

The Indian position . . . has support from major countries with diverse biological resources like Brazil, Indonesia and Malaysia. . . .

Id.

Thus, even if the Convention is not yet customary international law in a technical sense, it is clear that on a practical level the Convention is quickly becoming the benchmark of international behavior. It now appears developing countries will demand that future biodiversity prospecting efforts be conducted in compliance with the letter and spirit of the Biodiversity Convention.

IV. U.S.-BASED BIOPROSPECTING INITIATIVES

In 1985, it was estimated that the world market for both prescription and over-the-counter drugs based on plants was about $43 billion.[82] As of 1993, twenty-one pharmaceutical, biotechnology, and institutional organizations were actively involved in biodiversity prospecting.[83] This section analyzes the four prominent biodiversity prospecting initiatives in light of the legal, financial, and political frameworks in which they have evolved.

A. *Moving Away From Common Heritage: the National Cancer Institute*

The National Cancer Institute (NCI) first began to study natural products as a potential source of anti-cancer agents in 1955, making it one of the oldest bioprospecting programs in existence. At that time, most investigators subscribed to the common heritage doctrine, which proposes that plant genetic resources are the heritage of humankind and therefore should be freely available to all. This permitted the NCI to freely collect plants and other natural products from dozens of countries by merely paying collectors for their services.

As source countries became more aware of the potential value locked in their biodiversity, a movement emerged that rejected the common heritage doctrine and replaced it with the doctrine of sovereignty. This movement culminated in the 1992 Biodiversity Convention. As noted above, the Convention announces the sovereign rights of States over their natural resources, a clear repudiation of the common heritage doctrine.

The NCI has been sensitive to the changing international approaches to biodiversity access. While it began its acquisition

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82. Reid et al., *supra* note 49, at 7-12.
83. *Id.* at 8-13.

program forty years ago, relying on the common heritage doctrine, today the NCI is one of the leaders in implementing the mandates of the Biodiversity Convention. This is especially notable since the United States has not yet ratified the Convention. Currently, no United States company or governmental body is legally obligated to comply with the Convention and they can choose to ignore any or all of its terms. Thus, while the NCI is an excellent example of voluntary compliance with parts of the Convention, there is little pressure or support for the NCI's full compliance.

1. History

In 1955, NCI established its Cancer Center Chemotherapy National Service Center (CCNSC).[84] The mission of the CCNSC was to obtain and screen materials in the United States for chemotheraputic activity and to develop active agents showing promise for treating cancer. A large number of active agents were isolated and characterized through this program. By 1980, the NCI screened over 180,000 microbial extracts, leading to the discovery of such clinically useful agents as doxorubicin, mitomycin C, bleomycin, and mithramycin.[85]

During the same period, a collaborative drug discovery program between the NCI and the United States Department of Agriculture resulted in the collection and screening of over 35,000 plant samples, mainly from temperate regions of the world. The collection led to over 114,000 extracts, yielding numerous clinically active agents including, taxol from *Taxus brevifolia*, semisynthetic derivatives of camptothecin from *Camptotheca acuminata*, and homoharringtonine from *Cephalotaxus harringtonia*. The program also led to the following commercially available plant-derived anti-cancer agents: vinblastine and vincristine (the Vinca alkaloids from the rosy periwinkle, *Catharanthys roseus*), and etoposide and teniposide (semisynthetic derivatives of epipodophyllotoxin, which is an epimer of podophyllotoxin from *Podophyllum peltatum* and *P. emodii*).[86]

In the mid-1970s, the NCI began screening marine organisms as potential sources of antitumor agents. By 1981, the NCI

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84. Gordon M. Cragg et al., Drug Discovery and Development at the U.S. National Cancer Institute: International Collaboration in the Search for New Drugs from Natural Sources 1-2 (1993) (unpublished manuscript, available from the Natural Products Branch, National Cancer Institute, Frederick Cancer Research & Development Center, Building 1052, Room 109, P.O. Box B, Frederick, MD, 21702-1201).

85. *Id.* at 2.

86. *Id.*

screened over 16,000 extracts derived from 561 species. The screening led to two marine-derived agents, didemnin B and bryostatin 1, which are advancing to clinical trials.[87] In the early 1980s, the NCI Natural Products Program was discontinued because it was concluded that only a few novel (and therefore patentable) active leads were being isolated from natural sources. The major objection to the program was that it had yielded few agents effective against the resistant solid tumor disease types. It is now widely recognized, however, that this apparent failure was caused by the limitations of the *in vivo* primary mouse leukemia screen that was being used, rather than by a deficiency in the natural substances being tested.[88]

Beginning in 1985, the NCI adopted a new *in vivo* screening strategy involving the use of sixty solid tumor cell lines. Concurrently, a new natural products acquisition, extraction, and isolation project was implemented. In 1987, the program was extended to screen for agents for the treatment of AIDS. Today, the mechanism for acquisition of natural products no longer involves the United States Department of Agriculture. Instead, the NCI awards collection contracts. Multi-year contracts were awarded in 1986 to the Missouri Botanical Garden (MBG), the New York Botanical Garden (NYBG), and the University of Illinois at Chicago (UIC).[89] Under the terms of the contract, the MBG collects natural products throughout Africa and Madagascar, the NYBG collects natural products in over ten South American countries, and the UIC collects in at least twenty Southeast Asian countries.[90] Additionally, marine organisms have been collected from Australia, New Zealand, Papua New Guinea, the Philippines, Thailand, and Antarctica through other contractors.[91]

2. Letter of Collection

The NCI's Letter of Collection (LOC)[92] is the legal instrument the NCI uses to gain access to other countries' genetic resources. Over the past four years, the LOC has evolved to include many of

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87. *Id.*

88. *Id.*

89. The UIC program is assisted by the Arnold Arboretum at Harvard University and by the Bishop Museum in Honolulu.

90. Asebey, New Model, *supra* note 38, at 4.

91. *Id.*

92. Letter of Collection: Agreement Between Source Country and Developmental Therapeutics Program, Division of Cancer Treatment, National Cancer Institute (formerly known as the Letter of Intent (LOI)) (Apr. 21, 1995) [hereinafter LOC] (on file with the author).

the terms used in the Biodiversity Convention, attracting the attention of several organizations interested in developing adequate legal mechanisms for access to the South's biodiversity. This is commendable because, as noted above, the United States Senate still has not ratified the Biodiversity Convention, and accordingly, the NCI has no mandate to fully comply with the terms of the Convention.

The LOC has two major components. One component is the role of the Developmental Therapeutics Program (DTP), the Division of Cancer Treatment (DCT), and the NCI in the collaboration (Role of NCI);[93] the other is the role of the source country government or source country organization(s) in the collaboration (Role of the SCG).[94] The latter announces that "permission of the traditional healer or community will be sought before publication of their [sic] information, and proper acknowledgement will be made of their [sic] contribution."[95] This section is consistent with the clause of the Biodiversity Convention stating that each contracting party shall "preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles."[96]

Furthermore, Section Four of the Role of NCI states that the NCI "agrees to invite a senior technician or scientist designated by [the source country] to work in the laboratories of DTP/NCI . . . using technology which would be useful in furthering work under this agreement."[97] This is consistent with Article 12 of the Convention, which calls for the establishment of scientific and educational programs that can lead to the sustainable use of biodiversity.[98]

As discussed previously, Article 16 of the Convention sets the guidelines governing access to and transfer of technology from the North and South. The LOC's Section Five of the Role of NCI states the NCI's commitment to technology transfer: "The DTP/NCI will make a sincere effort to transfer any knowledge, expertise, and technology developed during such collaboration in the discovery and development process to [the source country]."[99]

Section One of the Role of NCI announces that the NCI will provide the results from its bioassays to the country of origin of the biological material being tested. This conforms to the Convention's requirement in Article 17 (1) and (2) regarding the

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93. *Id.* at 1.
94. *Id.* at 4.
95. *Id.* at 4.
96. Biodiversity Convention, *supra* note 1, art. 8(j).
97. LOC, *supra* note 92, at 2.
98. Biodiversity Convention, *supra* note 1, art. 12.
99. LOC, *supra* note 92, at 2.

exchange of information. Section Five of the Role of NCI announces that, where a promising agent from a plant collection in a source country is isolated, "further development of the agent will be undertaken by DTP/NCI in collaboration with [the source country]. . . ."[100] This provision conforms with the Biodiversity Convention's Article 18 (1) and (2), the "Technical and Scientific Cooperation Guidelines."

Finally, Section Eight of the Role of NCI provides that, if a promising agent is isolated from a plant collected in a source country and it is eventually licensed to a pharmaceutical company, the NCI "will require the successful licensee to negotiate and enter into agreement(s) with the Source Country Government . . . agency(ies) or Source Country Organization(s) as appropriate."[101] To some extent, this LOC section is consistent with Article 19 (2) of the Biodiversity Convention, which calls for equitable treatment of the benefits arising from biotechnologies based upon genetic resources provided by source countries.[102]

Through the use of the LOC, as it is currently written, the NCI clearly has moved away from the common heritage doctrine. But without ratification of the Convention by the United States, there is no mandate to completely adhere to the Convention. This is problematic because there are several important areas of the Convention that are not fully satisfied by the LOC.

Perhaps the most important of these areas is the sharing, on an equitable basis, of the benefits resulting from discoveries derived from genetic resources. While Section Eight of the Role of NCI indicates that the NCI will require any pharmaceutical company licensing technology to negotiate and come to an agreement with the source country,[103] it does not provide any guarantees that this agreement will be equitable. The NCI's ability to offer compensation to source countries is limited because the NCI is a branch of the Department of Health and Human Services, a United States government agency. Therefore, the NCI must conform to federal regulations regarding the licensing of federally-funded technology. The net effect is that the NCI cannot enter into deals with source countries for the sharing of future royalties. The source country must wait until a pharmaceutical company licenses an NCI technology that is based upon the source country's natural product.

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100. *Id.*
101. *Id.*
102. Biodiversity Convention, *supra* note 1, art. 19 (2).
103. LOC, *supra* note 92, at 3.

There is no reason to assume that a developing country's government or institution will be able to bargain on equal footing with the licensee, which most likely is a multinational pharmaceutical company. Furthermore, the customary secrecy surrounding actual royalty rates paid to source countries increases the possibility of an inequitable agreement. Both of these problems are present in the other initiatives discussed *infra.* Finally, the licensee has little incentive to work out a supply contract with the source country if the bioactive compound of interest has already been synthesized in the laboratory. Thus, taking the NCI out of the compensation negotiations does not necessarily lead to the equitable distribution of benefits.

Treatment of indigenous knowledge is another area in which the LOC falls short of the Convention. While the Convention calls for the parties to preserve and maintain knowledge, innovation, and practices of indigenous and local communities, it also requires the equitable sharing of benefits arising from their utilization.[104] While Section Two of the Role of SCG announces that the NCI will ask permission of an indigenous healer before publishing information obtained from her and will properly acknowledge her when that information is published,[105] there are no provisions in the LOC to guarantee an equitable sharing of financial benefits arising from that knowledge. Perhaps this stems from the incorrect assumption that national governments represent the interests of indigenous people. This is necessarily not the case in the developing world where indigenous peoples' interests are often at odds with those of their countries' governments. Although the indigenous knowledge of medicinal plants may rise to the level of an "intellectual contribution," (the standard for inventorship in the United States),[106] the LOC contains no provisions to ensure that these contributions are properly compensated.

Despite these shortcomings, the NCI's LOC remains an influential legal instrument, which continues to move away from the common heritage doctrine and closer to the objectives of the Biodiversity Convention. Analysis of the NCI's LOC provides a lucid comparison with the goals of the Biodiversity Convention. Unlike the LOC, the contractual terms of other bioprospecting initiatives have generally been kept secret. Therefore, a similarly rigorous textual analysis of the following sections of this Article cannot be undertaken.

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104. Biodiversity Convention, *supra* note 1, art. 8 (j).
105. LOC, *supra* note 92, at 5.
106. Asebey, New Model, *supra* note 38, at 16.

B. *Bilateral Contracts: INBio-Merck Agreement*

The INBio-Merck Agreement was created by Merck & Co., a corporation based in New Jersey, and the National Biodiversity Institute (INBio), a Costa-Rican nonprofit organization created by decree of the Costa Rican government.[107] When it was signed on September 20, 1991, it was hailed as the wave of the future.[108] The mere existence of a bilateral plant collection agreement is a recent positive development.[109] In the past, pharmaceutical companies have either collected samples themselves or through a private collector. In both cases, pharmaceutical companies traditionally did not request permission for the right of access or provide remuneration for the use and commercialization of such resources.[110]

The terms of the Merck agreement, like those of other bilateral agreements, are largely confidential and therefore difficult to analyze.[111] It is known that Merck paid an initial $1 million prospecting fee, promised to transfer some technology, train some scientists, and pay an unspecified royalty from future profits if an INBio extract yields a commercially viable product.[112] In return, Merck received INBio's research services, genetic material location services, genetic material screening services,

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107. Although some authors identify INBio as a governmental entity, *see* Coughlin, *supra* note 15, at 356 (saying that an agreement "was struck between the United States pharmaceutical firm, Merck and *the government of Costa Rica*" [italics added]), it is not a governmental entity. *See* Cooperative Agreement Between the Ministry of Natural Resources, Energy, and Mines (Costa Rica) and the Association, National Biological Diversity [Instituto Nacional de Biodiversidad] (INBio), May 11, 1992 (available from INBio, Apdo. 22-3100 Santo Domingo, Heredia, Costa Rica [hereinafter MIRENEM-INBio Agreement] (creating INBio as a nonprofit association).

108. "[I]t is the prototype of an international system for 'chemical prospecting' in wild areas throughout the world, and returning to countries of origin a share of any profits from . . . substances derived from natural resources." Charles Petit, *New Effort to Save Tropical Rain Forests: Pact on Natural "Chemical Prospecting,"* S. F. CHRON., Sept. 21, 1991, at A15.

109. Rubin & Fish, *supra* note 17, at 28.

110. *Id.*

111. *Summary of Terms, Collaboration Agreement, INBio-Merck & Co., Inc.* (press release by INBio detailing the contract's provisions) (available from INBio, Apdo. 22-3100 Santo Domingo, Heredia, Costa Rica) [hereinafter INBio-Merck Agreement].

112. This rate is believed to be 1-3%. INBio stated that "the royalty rate falls into the range of royalty rates which is typical for agreements of this kind." *Summary of Terms, Collaboration Agreement, INBio-Merck & Co., Inc.*, *supra* note 105. This range is known to be 1-5%. Sarah A. Laird, *Contracts for Biodiversity Prospecting, in* BIODIVERSITY PROSPECTING, *supra* note 48, at 99, 111.

and the exclusive right to patent an undisclosed number of products developed under the agreement.[113]

Arguably, the INBio-Merck agreement's greatest value to developing countries is its tacit recognition that the North accepts developing countries' claims to compensation and realizes that compensation should be given for both the use of genetic material as well as the search for such material.[114] The agreement, however, raises significant concerns for developing countries.

One major concern is the amount of the royalty INBio will receive for the sale of genetic resources. Because the terms of the agreement were not publicized, it is unclear whether Costa Rica is being fairly compensated. Unconfirmed reports place the royalty to INBio from new Merck products at one to three percent.[115] The typical royalty range for undeveloped drug products is one to five percent,[116] and the one to three percent rate may be seen as appropriate because the costs of collection and extraction (the services INBio provides to Merck) are roughly equal to one to three percent of the total drug discovery cost.

Some claim that, if Costa Rica is undercompensated by the terms of the Merck agreement, it is Costa Rica's natural resource—the knowledge of the structure of drug compounds—that is being undervalued.[117] Indeed, the agreement does not value Costa Rica's plant and genetic resources *per se*, but rather compensates Costa Rica for the investment INBio makes into the processing of those resources. Theoretically, the conservation goals of the Biodiversity Convention would be better served if developing countries' property rights were broad enough to extract full economic rents from those who benefit from its

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113. INBio-Merck Agreement, *supra* note 111.

114. Hamilton, *supra* note 28, at 628.

115. *Pharmaceutical Companies Go "Chemical Prospecting" for New Medicine*, PHARMACEUTICAL BUS. NEWS, Aug. 21, 1992, at *4 *available in* Westlaw, PTS-NEWS Database. Current industry practice suggests that 3% is the most accurate figure. Feinsilver, *supra* note 2, at 29. Some reports place the royalty rate as high as 51%-60%. *See* Hamilton, *supra* note 28, at 629 (citing Christopher Joyner, *Prospectors for Tropical Medicines*, NEW SCIENTIST, Oct. 19, 1991, at 38). However, the figure is unrealistic and probably results from confusion of the terms in the INBio-Merck Agreement and the MIRENEM-INBio Agreement. Under the terms of the latter, when INBio receives money from Merck at the undisclosed compensation rate (roughly 1-3%), INBio must turn over at least 50% of those funds and 10% of the INBio budget for certain research projects to the Costa Rica National Parks Fund which MIRENEM administers. *See* MIRENEM-INBio Agreement, *supra* note 107, clauses 4 and 5. Thus, the 50-60% figure represents INBio's obligations to MIRENEM, not Merck's obligations to INBio.

116. Laird, *supra* note 106, at 112.

117. Kadidal, *supra* note 16, at 234.

genetic resources.[118] Practically, however, this argument does little to advance the interests of Costa Rica or other developing countries.

The services that INBio provides to Merck are of limited scientific scope. INBio contracted to supply Merck roughly 2000 natural products extracts for screening, yet Merck's annual through-put[119] is far greater. Merck's screening equipment requires at least 5,000 samples per week to operate efficiently,[120] and it is not uncommon for United States pharmaceutical companies such as Merck to have a weekly through-put of 10,000 samples.[121] Thus, INBio supplies Merck with less than one week's work over a period of two years. Even the value of the technology transferred through the agreement is small. Merck agreed to transfer the technology needed to produce the extracts destined for its research and development laboratories in the United States. The technology's market value of only $130,000 is limited in light of Merck's total research and development budget.[122]

The INBio-Merck contract's significance is also defined in terms of the benefits to Costa Rica's natural resources. It is true that ten percent of INBio's initial revenue and fifty percent of its profits from any drug developed through Merck will be donated to Costa Rica's National Park system.[123] What receives little attention, however, is that such donations are not the result of Merck's or INBio's disinterested generosity. The ten percent and fifty percent nations are required by the Costa Rican governmental decree that created INBio in 1992.[124] Moreover, the fifty percent donation represents only fifty percent of the one to three percent of profits that Merck has agreed to repatriate to INBio.

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118. *Id.* *See also* Yano, *supra* note 36, at 467-68 (discussing rent dissipation theory in the context of compensating ethnobotanical knowledge and defining rent as the "difference between what society would pay for an innovation and its actual cost of development") (quoting Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 308 (1992)).

119. "Through-put" refers to the number of samples that a laboratory can screen for bioactivity in any given period.

120. Feinsilver, *supra* note 2, at 29.

121. Chapela, *supra* note 2, at 16.

122. Telephone Interview with Nicole Bruno, Public Affairs Department, Merck & Co., quoting the 1994 Annual Report which puts Merck's annual research and development expenses at $1,230,600,00 (Sept. 27, 1995).

123. Ana Sittenfeld & Renata Villers, *Exploring and Preserving Biodiversity in the Tropics: the Costa Rican Case*, 4 CURR. OPINION IN BIOTECHNOLOGY 280, 283 (1993).

124. INBio-Merck Agreement, *supra* note 111, cls. 4, 5.

One author concisely highlights the inherent defect of the Biodiversity Convention, the Merck agreement, and probably all future substantive bilateral contracts: "[T]he Merck-Costa Rica deal . . . provides for the transfer of some very valuable technology without going beyond what the owner of that technology, Merck, would tolerate."[125] Here is the developing countries' central challenge: It will never be in the interest of multinational pharmaceutical corporations to transfer the technology developing countries most want and need, because the multinational corporations have tremendous incentive to protect their market share.[126] Certainly, INBio's provision of one week's worth of samples is unlikely to persuade Merck to transfer the technology or know-how Costa Rica would need to become an independent pharmaceutical producer and viable competitor.

The agreement's main value for both INBio and Merck is probably public relations rather than actual genetic discovery.[127] Aside from any drug development through the INBio agreement, the extensive, free, and favorable publicity given to Merck has already caused Merck to recoup its investment in the agreement.[128] In fact, Merck renewed its contract with INBio despite the lack of any significant scientific leads during the first contract. Such continued good public relations must certainly be welcome in light of the pharmaceutical company bashing that accompanied recent debates over United States health care reform.[129] Indeed, the publicity surrounding the INBio-Merck agreement was called "the best public relations investment of the [pharmaceutical] industry in recent times."[130]

Within Costa Rica, INBio's success is measured not by "products" in the traditional sense, but in terms of the massive

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125. Coughlin, *supra* note 15, at 359.

126. The Biodiversity Convention fails to address or resolve this potent disincentive. One author's comment on a domestic United States law could just as easily have been made about the Biodiversity Convention: "This law wishfully presumes capital 'A' Altruism among these . . . actors not because it will happen but because it is a necessary assumption to make the law work." William H. Rodgers Jr., *Where Environmental Law and Biology Meet: Of Panda's Thumbs, Statutory Sleepers, and Effective Law*, 65 U. COLO. L. REV. 25, 74 (1993).

127. Secrecy surrounding the terms of the agreement probably furthers the goal of good publicity for Merck. Secrecy focuses attention on what is known, that INBio will donate 50% of its royalties to Costa Rica's National Parks, rather than on what is not known, that INBio's royalty rate is probably only 3% at most.

128. Karen A. Goldman, Note, *Compensation for Use of Biological Resources Under the Convention on Biological Diversity: Compatibility of Conservation Measures and Competitiveness of the Biotechnology Industry*, 25 LAW & POL'Y INT'L BUS. 695, 720 n. 148 (1994).

129. Feinsilver, *supra* note 2, at 45-46.

130. Chapela, *supra* note 2, at 11.

international media profile it acquired.[131] The extreme novelty of the agreement, which generated such media attention, may be responsible for the subsequent lack of similar agreements.[132] Given that bilateral contracts are now no longer a novel feature of the international landscape, other source countries following in the wake of the INBio-Merck agreement will not be able to capitalize on the same level of media attention.

Finally, unlike other developing countries, Costa Rica is optimally positioned to attract foreign interest in its biodiversity. Costa Rica possesses a high level of scientific and business management expertise, as well as a profound commitment to environmental conservation.[133] It is one of the richest biological regions in the world, containing nearly four percent of all the world's terrestrial species and at least half a million species.[134] Costa Rica also has a particularly favorable socio-political climate, having enjoyed democracy for over a century. Today, the country's indices of health, education, and literacy are comparable to those of major industrial nations.[135] Moreover, INBio's operations do not focus solely upon biodiversity prospecting. INBio has four distinct divisions: biodiversity inventory, biodiversity information management, biodiversity information dissemination, and biodiversity prospecting.[136] The Merck contract relates solely to the latter division. Finally, the protected areas from which INBio collects natural products for its biodiversity prospecting operations are areas devoid of indigenous people. By choosing to collect only in these areas, INBio has avoided the contentious issues surrounding the use and adequate compensation of indigenous knowledge. This choice makes the INBio model even less applicable to countries with large indigenous populations.

In summary, the INBio-Merck agreement is not a viable model for most developing countries to use in their attempts to derive significant income from biodiversity prospecting. For INBio, biodiversity prospecting has meant locating, identifying, extracting, and selling natural products. While this is a laborious task, it is still roughly equal to only one to three percent of the value-adding necessary to get a natural products-based

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131. *Id.* at 9.

132. *Id.*

133. Feinsilver, *supra* note 2, at 30-32, 46 (listing the qualities that enhance INBio's bargaining position *vis à vis* other potential source countries and institutions).

134. Sittenfeld & Villers, *supra* note 122, at 281.

135. *Id.*

136 INBio-Merck Agreement, *supra* note 111.

pharmaceutical to market. If developing nations seek to promote conservation and sustainable economic development through responsible biodiversity use, they will have to provide more than 3% of the value-adding to their biodiversity products.

C. *Multilateral Contracts: ICBGs*

The International Cooperative Biodiversity Groups (ICBGs) are five consortia composed of United States academics, pharmaceutical companies, and various developing world counterparts. The groups are funded by the National Institutes of Health, the National Science Foundation, and the Agency for International Development. Each ICBG receives between $400,000 and $475,000 annually for a period of five years beginning in 1994.[137] The stated purpose of the ICBGs is that each group "will collaborate on projects which address biodiversity conservation and the promotion of sustained economic activity through drug discovery from natural products."[138]

The typical ICBG project involves a multinational pharmaceutical corporation, a nongovernmental organization, a United States university, and a source country collaborating institute. Collections and extractions, as well as some preliminary screening in some cases, are performed in the source country. The majority, if not all, of the screenings are performed in the United States in the laboratories of the pharmaceutical corporation.[139]

At a 1994 conference on biodiversity, biotechnology, and sustainable development held in Costa Rica,[140] Dr. Ignacio Chapela, who referred to the ICBGs as a "visionary conception,"[141] raised several troubling questions about the program. First, several of the ICBGs greatly limit the potential use of their industrial partners' capacity when they choose to collect plants using ethnobotanical leads. While it is estimated

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137. Francesca T. Griffo, *Chemical Prospecting: An Overview of the International Cooperative Biodiversity Groups Program*, *in* EMERGING CONNECTIONS: BIODIVERSITY, BIOTECHNOLOGY, AND SUSTAINABLE DEVELOPMENT IN HEALTH AND AGRICULTURE (Julie Feinsilver ed., forthcoming 1995).

138. Chapela, *supra* note 2, at 15-16 (quoting press release from the U.S. Agency for International Development, U.S. National Institutes of Health, and U.S. National Science Foundation (Dec. 7, 1993)).

139. Asebey, New Model, *supra* note 38, at 3-16.

140. Pan American Health Organization-Inter American Institute for Cooperation in Agriculture (PAHO-IICA) Symposium on Biodiversity, Biotechnology, and Sustainable Development, in San Jose, Costa Rica (Apr. 12-14, 1994).

141. Chapela, *supra* note 2, at 16

that about 20,000 medicinal plants in the world have been identified through ethnobotany,[142] the multinational pharmaceutical corporations involved in the ICBGs have high through-put screening programs that can test up to 10,000 samples per week.[143] Chapela believes this discrepancy exists because the priorities of the academic partners in the groups take precedence over those of the industrial partners.[144]

Second, it is notable that Bristol-Myers-Squibb is the industrial partner in three of the five ICBGs. It is also notable that companies with long traditions in natural products drug discovery are missing from the ICBGs. Chapela reported that this may be attributable to a less than rigorous selection criteria for industrial partners.[145] Third, because the ICBGs focus upon academic research, the ICBGs generally do not require all partners to commit to conservation of local biodiversity and equitable distribution of profits from drug discovery. Chapela noted that, during the first public announcement of the ICBGs, the pharmaceutical partners were absent.[146]

While all of Dr. Chapela's observations are valuable, the third is the most significant. All of the agreements between the pharmaceutical companies and the source country collaborators contain undisclosed royalty payment agreements. As in the INBio-Merck agreement, the royalty rates are considered confidential business information. This makes monitoring of the fairness of these deals nearly impossible. As long as there is no disclosure, there will be little accountability and plenty of deniability.

Because of the nondisclosure of royalty rates, it remains an open question whether the proper arrangements are in place to ensure the equitable sharing of benefits with the source country. In November 1994, the Rural Advancement Foundation International (RAFI) published the royalty terms contained in one of the ICBG contracts.[147] The terms published were the royalty payment agreement negotiated by the Monsanto Corporation and Washington University for the ICBG project that will study Peruvian medicinal plants. According to the agreement, the royalty payments would be "based on a sliding scale, ranging from

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142. *Id.*
143. *Id.*
144. *Id.*
145. *Id.*
146. *Id.*
147. *Bioprospecting/Biopiracy and Indigenous Peoples*, RAFI COMMUNIQUE (Rural Advancement Found. Int'l, Ontario, Can.) Nov. 1994, at 7.

1% to 0.2% of [the] net sales of a licensed product."[148] Monsanto would pay one percent only if (1) "the licensed product incorporates a [p]lant [e]xtract, isolated or synthetic natural product or analog or isomer thereof present in such [p]lant [e]xtract, and (2) [the product] is sold for the same use as the historical use by the [i]ndigenous [p]eople [who use] the plant from which the . . . [e]xtract was obtained."[149] "Up to one-half of that [0.2%-1%] royalty payment must first be used to reimburse individual ICBG member institutions for any reasonable direct costs for research, development and invention management."[150] Additionally, the RAFI report states that, under the terms of the Monsanto-Washington University agreement, indigenous peoples may not receive any royalties at all "in the event that the biological activity of an active agent was in the public domain or was known or otherwise available to [Monsanto]. . . ."[151]

If this agreement is representative of the types of deals the pharmaceutical companies made with their source country counterparts, the ICBGs have not gone very far in creating an equitable sharing of benefits resulting from the use of the developing world's biodiversity. On the other hand, because most of the "value-adding" (i.e., screening, structural elucidation, and clinical trials) is being performed and funded by the pharmaceutical company, it may be quite equitable that they receive ninety-nine percent of the potential royalties.

Thus appears the fundamental problem in all of the programs this section has analyzed: ninety-nine percent of the value-adding in biodiversity prospecting projects is still being performed outside the source country, primarily in the United States. Until this arrangement changes, it will be difficult if not impossible to justify more than one or two percent royalty rates for source countries. Only when advanced screening technology, know-how, and financial support for these activities are transferred to a source country will it be possible to justify a greater royalty rate for developing source countries.

D. *Private Sector Bioprospecting: Shaman Pharmaceuticals*

In 1989, Shaman Pharmaceuticals, Inc. (Shaman) was founded with the goal of developing pharmaceuticals using

148. *Id.*
149. *Id.*
150. *Id.* (quoting the License Option Agreement between G.D. Searle & Co. and Washington University for Peruvian Plant Extract Collection).
151. *Id.* at 6 (quoting the License Option Agreement between G.D. Searle & Co. and Washington University for Peruvian Plant Extract Collection).

ethnobotanical knowledge.[152] Shaman screens plants known to be used by native peoples in at least three geographically distinct regions.[153] Its approach is based upon the premise that working with traditional healers is a more efficient method of identifying useful drugs than the industry practice of random screenings.[154] Shaman's exclusive interest in ethnobotanical-based drug discovery has garnered tremendous positive press attention.[155] The company also has created a nonprofit organization, the Healing Forest Conservancy, to channel future profits back into source countries.[156] However, until a Shaman product generates profits for the company, the Healing Forest Conservancy is limited in the benefits that it can return to the indigenous peoples of source countries.[157] Even without realizing profits, Shaman claims to expend approximately twenty percent of its plant prospecting budget to assist the native communities that share their ethnobotanical information.[158]

Lisa Conte, Shaman's president, formerly worked for a venture capital firm and holds advanced degrees in both physiology/pharmacology and business.[159] Shaman has undergone two rounds of venture capital-raising and sports an impressive array of investors.[160] Despite the daunting risks inherent in the drug discovery business, its initial stock offerings were very successful and raised great hopes.[161] Although Shaman is currently funding clinical trials for two of its leads, Eli

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152. "Ethnobotany" is most simply defined as the study of how indigenous people use plants. *See* CHRISTINE FRANQUEMONT ET AL., THE ETHNOBOTANY OF CHINCHERO, AN ANDEAN COMMUNITY IN SOUTHERN PERU 1 (1990).

153. Gary Stix, *Back to Roots: Drug Companies Forage for New Treatments, Plant-Derived Pharmaceuticals*, SCI. AM., Jan. 1993, at 142.

154. William K. Stevens, *Scientists and Shamans Seek Cures in Plants*, MIAMI HERALD, Feb. 2, 1992, at 7C.

155. *See infra* notes 156-61, 166, 169-70, 173, 176 a sample of the intensive press coverage.

156. Thomas A. Carr, *Rain Forest Entrepreneurs: Cashing in on Conservation*, ENVIRONMENT, Sept. 1993, at 12.

157. Katy Moran, Director of Healing Forest Conservancy, Comments at the Biodiversity and Human Health Seminar in Washington, D.C., Smithsonian Seminar Series (Apr. 3-4, 1995).

158. Thomas M. Burton, *Magic Bullets: Drug Company Looks to "Witch Doctors" to Conjure Products*, WALL ST. J., July 7, 1994, at A1.

159. *Pharmaceutical Companies Go "Chemical Prospecting" for New Medicines*, supra note 115, at *3.

160. Shaman's investors include Technology Funding, Salomon Brothers, Odyssey Fund, Calvert Social Venture Partners, and Capital Health Venture Partners. *Id.* at *4.

161. Shaman's initial offering generated $3 million. Anne Newman, *Shaman's IPO Success Sets Example for Biotech Firms*, WALL ST. J., Jan. 28, 1993, at B2.

Lilly, Shaman's pharmaceutical-industry partner, chose not to renew its research contract with Shaman when it expired in October 1994.[162]

The very nature of venture capital financing is to create tremendous pressure for short term profits to compensate the venture capital investors for the unusually high degree of risk they undertake. Because the degree of risk is so high, investors typically expect a return of 1000% to 5000% on their initial investment.[163] A broad rule of thumb is that venture capitalists will not invest in a company unless they foresee the possibility of receiving at least ten times the amount of their initial investment within the first five years, and they seek even greater returns in early stage companies that require five to seven years to develop.[164] Moreover, because the risk to venture capital investors is so great, they also expect the total sales of the business to be very high.[165] Thus, the message to investors is clear: "There's no sense taking a long shot unless it pays off big if you win. Second, cut your losses; identify losers early, and if you can't fix the problem . . . throw no good money after bad."[166] The high stakes cut-and-run philosophy that underpins venture capital enterprises is the reason the Lilly withdrawal was interpreted by Wall Street as a vote of no-confidence in Shaman's ethnobotanical approach,[167] and caused a precipitous decline in the value of Shaman's stock.[168]

In the aftermath of its stock decline, Shaman acknowledged that it was reassessing and reprioritizing its research programs.[169] It also undertook significant internal restructuring

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162. Shaman's clinical trials are being conducted on Provir, an oral drug to treat respiratory viral infections, and Virend, a topical anti-viral drug to treat herpes. *Conclusion of Antifungal Research Alliance, Eli Lilly and Co. and Shaman Pharmaceuticals,* BUSINESSWIRE, Oct. 12, 1994 *available in* Westlaw, Database Int-News.

163. CHRISTINE AMMER & DEAN S. AMMER, DICTIONARY OF BUS. & ECON., 406 (1984) (defining "risk capital" and "venture capital").

164. Jane Koloski Morris, *Venture Capital I: Industry Structure and Investment Strategy in* 2 CAPITAL RAISING & FIN. STRUCTURE 361 (Robert Lawrence Kuhn ed. 1990).

165. Frederick R. Adler, *Venture Capital II: What Venture Capitalists Look For in* 2 CAPITAL RAISING & FIN. STRUCTURE 378 (Robert Lawrence Kuhn ed. 1990). Venture capitalists typically will not invest in a company unless it can be expected to have sales of 50 million within five years and yield ten times, the initial investment within seven years. *Id.*

166. RICHARD A. BREALEY & STEWART C. MYERS, PRINCIPLES OF CORP. FIN. 341-42 (4th ed. 1991).

167. *Shaman Says Lilly Ends Alliance; Stock Tumbles,* WALL ST. J., Oct. 13, 1994, at B7.

168 Feinsilver, *supra* note 2, at 48.

169. John Eckhouse, *Eli Lilly Ends Investment in Shaman,* S.F. CHRON., Oct. 13, 1994, at D1.

and apparently changed its focus from one of ethnobotanical collection to *in vivo* whole animal model testing.[170] Laying off forty percent of its staff, Shaman drastically altered key areas of its corporate structure, downsized its anti-infectives program, eliminated anti-fungal screening efforts, and cut back on anti-viral screening.[171] Although this restructuring may make the company more sound, it also means that the Shaman model can no longer act as a guide for countries of the South that seek to use biodiversity prospecting as a way to assist their economic development and preserve their environment.

The Shaman experience is significant because it represents one corporation's attempt to use biodiversity prospecting to help the inhabitants of Southern source countries. Shaman's failure to meet expectations for its success is a powerful illustration of the limitations of United States biotechnology firms. Such firms are generally small, heavily reliant on venture capital, and characterized more by ideas and promises than by actual product output.[172] Despite the Shaman founders' good intentions of benefiting Southern source countries, the very nature of the biotech industry requires that the overarching goal must always be short-term profit.

Section Four of this Article traced the evolution of biodiversity prospecting mechanisms and highlighted the challenges that confront any effort to create a workable North-South biodiversity prospecting arrangement. The National Cancer Institute, through its Letters of Collection, led the charge away from the common heritage doctrine approach and toward the objectives of the Biodiversity Convention. But without the United States ratification of the Biodiversity Convention, it is difficult for the

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170. Feinsilver, *supra* note 2, at 41. The usual testing steps are: (1) preliminary screening to determine general bioactivity; (2) advanced screening to determine selective bioactivity; (3) fractionation and structural elucidation of the bioactive molecule; (4) *in vivo* whole animal model testing; and (5) *in vivo* human testing. When initial chemical screenings (Steps 1, 2, and 3) suggest that a given substance will be effective in people, the substance is then tested on nonhuman animals (Step 4). If the substance appears to be effective in these other animals without being unduly harmful, the substance is then tested on humans (Step 5). Shaman's new approach takes the *in vivo* animal testing step, which is usually Step 4, and uses it as the preliminary screen (Steps 1 and 2). Shaman believes this method will permit it to efficiently obtain information on both the substance's bioactivity (usually found in the first two steps) and its oral bioavailability and toxicity (usually determined in the *in vivo* animal testing stage). *See Shaman Inverts Its Drug Development Model*, BIOCENTURY PART II B1 (The Bernstein Report on Bio Business) Nov. 14, 1994.

171. *Id.*

172. Chapela, *supra* note 2, at 13-14.

NCI to go much farther in fulfilling all the objectives of the Convention.

The ICBG Program is the first multi-party bioprospecting initiative that attempts to incorporate all the major objectives of the Biodiversity Convention. It opens the way to comprehensive implementation of the Convention. The major deficiency of the program appears to be its inability to arrange for equitable benefit-sharing between its corporate participants in the North and its source country participants in the South. Still, it represents a new standard of compliance to the Biodiversity Convention.

The landmark INBio-Merck agreement established an important precedent: Northern companies seeking access to the South's genetic resources will need to pay for that access. The agreement is an important step forward in compliance with the objectives of the Biodiversity Convention. Unfortunately, the INBio scenario is not readily reproducible in other parts of the developing world, thus limiting its utility. Post-Convention bilateral contracts such as the INBio-Merck agreement may lack substance. If they are substantive, multinational pharmaceutical companies' overweening bargaining power may render each individual source country unable to negotiate on an equal footing. Such inequity causes the agreement to be disproportionately beneficial to the pharmaceutical company and to undervalue the developing country's biodiversity.

Venture-capital funded Shaman Pharmaceuticals showed the private sector that there is money to be made in natural products-based drug discovery. Shaman's effort focused interest not only on natural products, but also upon indigenous peoples' knowledge of the use of medicinal plants. With Shaman's recent shift away from ethnobotanically-driven drug discovery, even the best-intentioned biotechnology company is unlikely to repatriate a substantial portion of its profits. The very nature of venture-capital financing subordinates corporate altruism to bottom-line profits.

The common thread in all of the initiatives discussed above is an unequal distribution of value-adding activities. Most of the significant value-adding is performed in the United States. This causes the majority of profits to be returned to the developed country entity. The owners of the biotechnology that developing countries need are the same corporate interests that profit from the South's low level of technology. In summary, the biodiversity initiatives implemented thus far are the product of the North's institutions and, not surprisingly, primarily serve to further the interests of the North rather than the interests of the South. If the South is to realize significant benefits from its biodiversity, the challenges described above must be overcome.

V. POTENTIAL ALTERNATIVE: RESTRICTION OF SUPPLY

When the United States initially refused to sign the Biodiversity Convention in 1992, Venezuela retaliated by refusing to sign any new scientific collaboration agreements with United States corporations for the study of genetic resources.[173] Such retaliation was hardly a surprise to the global community as international environmental organizations at the Rio de Janeiro summit had predicted such action.[174] Venezuela's move was by no means the sole act of an international renegade. Since the Convention was opened for signature, many source countries established or made more stringent, "regulations on the collection and export of biological resources in an effort to both control and capture some of the [attendant] economic benefits."[175] In essence, Venezuela chose to treat the Biodiversity Convention as an international benchmark for the conduct of corporations wishing to undertake genetic exploration within its borders, denying access to countries that refused to accede to the voluntary code of conduct.[176]

Ultimately, the United States did sign the Biodiversity Convention, and the incident received only passing attention. This seemingly small confrontation is extremely important, however, because it sets crucial precedent for similar actions in the future.[177] The significance of the action is underscored by the actor that chose to boycott United States investors: Venezuela, a member of the Organization of Petroleum Exporting Countries (OPEC).

Developing countries may seek to increase their revenue from biodiversity prospecting by increasing the market value of their genetic resources through supply restrictions and coercive imposition of favorable conditions. In its least threatening form, this could be accomplished with the voluntary cooperation of multinational pharmaceutical corporations through creation of codes of conduct. In the alternative, developing countries may

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173. *U.S. Objections to Biodiversity Treaty Based on Misreading of the Text, Study Says*, supra note 50, at 705.

174. Gormley, *supra* note 13, at 161.

175. Feinsilver, *supra* note 2, at 22.

176. The threat was not taken lightly. One expert observed that, "Non-governmental organizations, governments, universities, and private corporations will lose out when countries [restrict] access to their genetic material to only those who signed the [C]onvention." *Leak of Reilly Cable on Biodiversity Treaty Said to Eliminate Possibility of U.S. Signature*, 23 Envtl. Rep. (BNA) 646 (June 12, 1992) (quoting Russell Mittermeier, President of Conservation International).

177. *See* Hazarika, *supra* note 78 and accompanying text.

seek to create higher market value for their genetic materials by developing one or more genetic resource cartels. Cartelization and the rise of codes of conduct are not mutually exclusive mechanisms. They may overlap, follow one another in progression, or act as two extreme points on a continuum. In either case, they are a response to the enduring features of prior approaches: the absence of an inherent market value in genetic material, developing countries' lack of individual bargaining power, and the absence of value-adding processes within source countries.

The historical discussion above illustrated the reality that multinational corporations of the North do not value biodiversity and genetic materials *per se*; the countries of the South are compensated, if at all, based upon the value added to their resources by refinement.[178] This is an unsurprising result given the North's historically easy access to the South's genetic materials. As with all natural resources, the laws of supply and demand are applicable to the cost of biological resources. When demand remains constant but supply is restricted, the price of a good will increase. This basic law of supply and demand can be harnessed by the South to achieve its goals of increased revenue, technology transfer, economic development, and improved environmental protection. Several authors refer in passing to the possibility of collective action to reduce supply in several contexts related to biodiversity,[179] but none seriously examine the possibility of concerted action by the South as a mechanism through which the South can attain its goals.

Collective action by the South will fall along a continuum from a series of isolated unilateral standards to a broad-scale cartel that drastically restricts Northern corporations' access to genetic resources. One scenario, voluntary multilateral regional

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178. Chapela, *supra* note 2, at 4.

179. *See* Yano, *supra* note 36, at 486 (concluding that "[t]he most viable alternative [to patent law for solving the narrow problem of compensation for ethnobotanical knowledge] is the formation of monopoly contracts that would serve the same function as patent protection"); Hamilton, *supra* note 28, at 645 (noting that "[o]ne direct result of contract production and industrialization [in genetically-engineered agricultural production] may be the need for farmers to consider collective action in negotiating fair contracts"); Kadidal, *supra* note 16, at 235 ("[a] collective national property scheme involving risk-spreading among several [developing countries] could accomplish the same goals [as patent protection.]"); Coughlin, *supra* note 15, at 370 n.134 ("It might be possible for developing countries party to the Convention to bring pressure by collectively denying the biotechnology firms of the offending nation access to their genetic resources. One might, however, question the viability and force of such a maneuver. Its effectiveness might be especially curtailed if the biotechnology firms in question already have access to sufficient genetic material under bilateral agreements such as [Merck-INBio].").

coordination, analogous to the U.N. Codes of Conduct,[180] falls in the middle of the spectrum, and probably represents the most likely possibility.[181] A number of countries with gene-rich resources might confer and formulate an agreement among themselves. Such an agreement would require genetic prospectors to satisfy a series of specific conditions in exchange for the right to collect or examine genetic samples. In the absence of significant technology transfer, one of the conditions would almost certainly be a royalty rate much higher than the customary one to three percent and an up-front payment for access to the resource. Such a condition would meet developing countries' needs for increased revenue. Other likely conditions include requiring the multinational corporation to locate permanent research and development facilities within the source country, conduct extensive scientific training of local personnel, and transfer significant quantities of technology to the source country. These conditions would meet the developing countries' needs for economic development and acquisition of scientific know-how and hardware.

Myriad contractual issues ranging from access to and use of ethnobotanical knowledge to technology to conservation[182] could be addressed in such a code. The result might be boilerplate contractual language for use in bilateral agreements, or perhaps a document to which multinational pharmaceutical corporations would have to formally agree in order to gain access to any of the signatory nations' resources. The agreement could be as broad or as detailed as political realities would allow; it would be dictated by what the source countries thought they could realistically extract from potential prospectors and by the number of

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180. *See infra* note 184.

181. Personal communication with Fernando Casas Castaneda, National Coordinator of Proyecto Biopacifico, a United Nations Development Program (U.N.D.P.) and Global Environmental Facility sponsored biodiversity project in Colombia (July 1, 1995). Such efforts are currently underway in the Andean Pact countries.

182. Numerous contractual issues could be addressed by a multilateral agreement. *See* Rubin & Fish, *supra* note 17 (discussing the following contractual clauses in the context of bilateral biodiversity prospecting agreements: rights in inventorship, ownership of inventions, licensing, protection of intellectual property of local plant users and indigenous peoples, and state of the art methods for reasonably limiting the exclusivity commercial partners may seek, thereby maximizing both present and future value of the resources. Compensation mechanisms discussed include concession fees, extended fees, royalties, technology transfers, and opportunities for source countries to participate in research and development, opportunities for source countries to provide sustainable future supplies of commercial quantities of raw and improved material.).

signatories and strength of the coalition. If a sufficient number of nations signed a multilateral genetic prospecting code, multinational corporations' access could be so restricted as to force them to comply with the conditions of the accord. In a worst-case scenario, all gene-rich developing countries might flatly deny multinational corporations access to genetic resources unless multinational corporations complied with source countries' terms. Given that the worst-case scenario would require unprecedented cohesive multilateral action, however, such an extreme result seems unlikely.

Industries, such as pharmaceutical manufacturers, that were opposed to the Biodiversity Convention maintain that compensation to developing countries should be negotiated contractually between the parties rather than by international agreement or national legislation, which the Convention requires on some issues.[183] A code of conduct instigated by developing countries can be seen as falling within the purview of contractual negotiations, albeit collective negotiations confined only by the South's economic realities. Market factors will limit the compensation that developing countries can realistically demand.[184] At the same time, however, collective action will prevent nations of the South from being individually disadvantaged when they enter bilateral negotiations with multinational corporations.[185]

Taken to the extreme, restricting supply to create valuation of plant resources *per se* could result in a genetic resource cartel—a new OPEC. Aggressive multilateral cooperation among the biodiversity rich nations of the developing world could potentially starve the North of biological resources. Such cartelization would likely start among countries who find they have little to lose by cutting off the North's access. Countries that were promised only a three percent royalty of sales, which may not materialize for decades, might be willing to sign a multilateral accord that offers the hope of realistic compensation.

There is already international precedent for multilateral agreements that impose limitations on multinational corporations' behavior. Although never completed, the U.N. Model Code of Conduct for Transnational Corporations gives an illuminating glimpse at the demands the South has made on Northern

183. Goldman, *supra* note 127, at 724 n.167.

184. *Id.* at 724.

185. In the case of the Merck-INBio negotiation, Merck's annual research and development budget was as much as Costa Rica's annual income ($1 billion). Leslie Roberts, *Chemical Prospecting: Hope for Vanishing Ecosystems?*, SCIENCE, May 22, 1992, at 1142.

multinational corporations for almost two decades.[186] Moreover, Northern multinational corporations outside the pharmaceutical

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186. For example, the Section entitled "General Principles of Behavior of Transnational Corporations" provides:

(A) Observance of local laws.

(1) Every Member state has the right to prescribe the conditions under which transnational corporations operate within its national jurisdiction, subject to international law and to the international agreements to which it has subscribed.

(2) Each entity of a transnational corporation is subject to the laws of the country within which it conducts its operations.

(B) Adherence to economic goals and development objectives.

(1) Transnational corporations are subject to the national policies, objectives and priorities for development of the host country and shall contribute positively to carry them out.

(2) Transnational corporations shall supply to the government of the host country pertinent information about their activities in order to assure that these activities are in accord with the national policies, objectives and priorities of development of that country.

(3) Transnational corporations shall put special emphasis on the need of the least developed countries for the establishment of production facilities involving a maximum utilization of local human resources, the output of which meets identified material and social requirements, thus assuring a convergence between local resource use and needs as well as offering adequate employment opportunities.

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Chapter III. Economic and Commercial Issues.

A. Ownership and Control.

(1) Member states shall have the right to permanent sovereignty over their natural wealth, and resources shall be used in the interests of their national development.

(2) Transnational corporations shall be subject to the exercise by the host country of permanent sovereignty over all its wealth, natural resources, and economic activities.

B. Terms of admission and operation.

(1) Prior authorization by the competent national authorities may be required for all inward foreign direct investment or acquisition of existing undertakings by transnational corporations.

(2) Each Member state may reserve sectors of economic activity for national, public or private enterprise and has the right to determine whether the participation of mixed enterprises in these sectors shall be admitted.

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H. Transfer of Technology.

(1) Transnational corporations shall endeavor to ensure that their activities fit satisfactorily into the scientific and technological policies and plans of the host country, and contribute to the development of its national scientific and technological capabilities, including, as far as

industry regularly develop their own codes of conduct. The codes are usually specific to a given industry and are association-based, applying both within the United States and, to some extent, internationally.[187] Such codes are often environmental, but address more visibly pressing concerns, such as hazardous materials. Private codes are proliferating throughout the developed world, creating a universe of voluntary commitments to better environmental practices by multinational corporations.[188]

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appropriate, the establishment and improvement of the host country's capacity to innovate.

(2) Transnational corporations shall to the fullest extent practicable, adopt, in the course of their business activities, practices which permit the rapid diffusion of technologies with due regard to the protection of industrial and intellectual property rights.

(3) Transnational corporations shall, when granted licenses for the use of property rights, or when otherwise transfering technology, consider that developing countries regard transfer of technology as an indispensable means for promoting and accelerating their economic development and shall do so on reasonable terms and conditions.

(4) Transnational corporations shall take all practicable measures for creating an environment conducive to the strengthening of the technological capacity of countries, including encouraging universities and other research and training institutes to create special technological programs for the nationals of the host country, expanding their own respective research and development activities which can be of benefit to the host country and supporting the establishment of a network of research and development institutions such as the United Nations University.

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K. Environmental protection.

(1) The protection, preservation, and enhancement of the environment is the responsibility of all countries. All Member states shall endeavor to establish their own environmental and developmental policies in conformity with such responsibility. All Member states have the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other countries or of areas beyond the limits of national jurisdiction. All countries should cooperate in evolving international norms and regulations in the field of the environment.

(2) Transnational corporations shall give due consideration to the aims and priorities of host countries regarding the protection, preservation, and enhancement of the environment.

MODEL CODE OF CONDUCT FOR TRANSNATIONAL CORPORATIONS (Draft 1977) (World Peace Through Law Center).

See also Informal Proposals to Resolve Differences, U.N. CHRON., May 1983, at 65 (discussing negotiations on the Model Code); Robert Grosse, *Codes of Conduct for Multinational Enterprises*, 16 J. WORLD TRADE L. 414, 419-26 (comparing the provisions of nine existing model codes on multinational corporations).

187. See Michael S. Baram, *Multinational Corporations, Private Codes, and Technology Transfer for Sustainable Development*, 24 ENVTL. L. 33, 55 (1994).

188. *Id.* at 54.

Significantly, however, even the most conscientious corporations almost never adhere to their codes of conduct in relations with developing countries.[189]

Domestic regulatory policy within the United States is also moving toward voluntary compliance. The system is being redesigned to stimulate voluntary corporate initiatives and to reward or punish companies on the basis of the policies and management practices they adopt.[190] Taken in the aggregate, there appears to be a pervasive movement toward constructing mechanisms that induce multinational corporations to comply voluntarily with environmental requirements.

The most well-known precedent relevant to this discussion is, of course, the creation of the OPEC oil cartel and its control on global oil supplies in the early 1970s. In the OPEC context, access to a natural resource took on the political cast of a battle between countries of the North and South, as oil exporting nations sought to demonstrate and solidify a fundamental political recognition of their national sovereignty.[191]

Individual nations are already beginning to coordinate restricted access to their genetic resources. The Venezuelan and Indian position discussed previously are not the only examples of movements which threaten to tighten the supply of genetic resources. The presidents of Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama signed a nonbinding resolution that encouraged the passage of internal laws to regulate the extraction of medicinal plants and other biogenetic substances.[192] The next logical step is for them to create an enforcement mechanism which will make such pro-restriction resolutions binding.

A cartel effort would be built upon the platform of shared perceptions that underpins the label "South," which when properly used, refers to an observable process in international politics.[193] The "bloc diplomatic behavior" exhibited by nations of the South, especially when they are represented by the Group of

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189. *See id.* at 54-55 (discussing different types of multinational corporations and the voluntary codes of conduct they have adopted).

190. *Id.* at 51.

191. *See* Joseph Stanislaw & Daniel Yergin, *Oil: Reopening the Door*, 72 FOREIGN AFF. 81, 82-84 (Sept./Oct. 1993) (reexamining the early 1970's oil crisis and its underlying causes).

192. *Central American Presidents Resolve to Pass Laws Restricting Use of Resources*, 15 Int'l Envt. Rep. (BNA) 397, 397 (June 11, 1992).

193. Hanson, *supra* note 3, at 1105-06.

77 (the Nonaligned Movement),[194] is underpinned by several fundamental shared perceptions: (1) Status quo institutional structures (particularly GATT and the International Monetary Fund) and attendant political and economic processes are deeply biased against developing countries; (2) the North has constructed a system of international impediments to the South's economic growth; and (3) Southern nations share the goal of achieving higher levels of political influence and economic welfare in international relations.[195]

If the ties which bind the South into a cohesive political entity are not strong enough to support a unitary cartel effort, then cartelization may occur along regional lines drawn for other purposes. In South America, for example, the nations of the Andean Common Market[196] have cooperated with each other in creating a draft framework for access to genetic resources.[197] Similarly, the nations that participated in the Contadora[198] process of the mid-1980s could be expected to become an early focal point for collective efforts to reduce the North's access to biological resources. However, multinational pharmaceutical corporations will prefer to keep their options open and acquire genetic samples from numerous geographic locations, institutions, and collection agencies.[199] If too many regional cartels develop, their effectiveness will be compromised. Thus, various cartels can be expected to coordinate with one another for maximum effectiveness.

The potential financial benefits of cartelization are not without some risk. One risk of cartelization is that the Northern multinational corporations might play a long waiting-game, gambling that the South's immediate financial needs are so pressing that individual nations will break the united front in order to fulfill their needs for revenue. This is especially likely

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194. *See* Jonathan I. Charney, *Entry Into Force of the 1982 Convention on the Law of the Sea*, 35 VA. J. INT'L L. 381, 400 n.104 (1995). The Group of 77 (the nonaligned states) now consists of over 122 developed countries. David L. Larson, *Deep Seabed Mining: Definition of the Problem*, 17 Ocean Dev. & Int'l L, No. 4, 271, 272 (1986). *See also* Resolutions of the Conference of Heads of States or Government of the Nonaligned Countries, 7th Session (Luanda, 1985).

195. *Id.* at 1105-08.

196. *See* Grosse, *supra* note 185, at 419-26 (comparing the provisions of nine existing model codes on multinational corporations and discussing the Andean Common Market's efforts to control the actions of multinational corporations operating within their borders).

197. Personal communication with Fernando Casas Casteneda, *supra* note 180.

198. *See generally* Tom J. Farer, *Contadora: The Hidden Agenda*, 59 FOREIGN POL'Y 59 (Summer 1985) (discussing the Contadora's process in the context of Central American politics in the 1980s).

199. Feinsilver, *supra* note 2, at 43.

with the growing prominence of a combinatorial chemistry,[200] which is capable of producing millions of compounds in a short time for testing in high-throughput screening systems. This, undoubtedly, will reduce the demand for natural products as the starting materials for drug discovery screening.[201] Such a strategy would cut off a large portion of the cartel members' revenue from biodiversity prospecting for several years.

A second risk is that the governments of the North might play political hardball on economic issues of greater importance to the South, such as loan rescheduling and various other forms of trade treatment. These risks seem unlikely, however, because the United States cherishes its position as the global biotechnology leader, and United States companies desire the South's resources at least as much as source countries wish to allow the access.[202]

The history of OPEC amply demonstrates a third risk: factionalization within the cartel itself. Bilateral disagreements within a large cartel may be a never-ending threat to the harmony of the group and its ability to remain cohesive for the greater benefit of all involved. This fact suggests that a series of smaller regional cartels would be more likely to achieve the South's objectives than one large cartel. Multinational corporations could certainly attempt to manipulate internal tensions in an effort to weaken the cartel's control of accessible genetic resources by playing one member off another.

A fourth risk is that the North might attempt to sanction Southern cartel members for restricting access to their resources in violation of the Biodiversity Convention.[203] However, if the North fails to honor its Convention duty to provide technology transfer, technical and scientific cooperation, and financial resources,[204] the South will be able to justifiably evade its Convention obligation to provide access. The Convention

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200. Combinatorial chemistry refers to the synthetic production of millions of peptides from a block set of 20 standard amino acids using recombinant systems such as bacteriophage.

201. Personal communication with Gordon M. Cragg, Ph.D., Chief, Natural Products Branch, National Cancer Institute (Aug. 17, 1995). Dr. Cragg presents the widely held counterargument that while combinatorial chemistry has the power to very quickly create millions of analogues to a set of starting materials, it lacks nature's ingenuity for creating true diversity.

202. Coughlin, *supra* note 15, at 370.

203. Article 15 (2) states: "Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention." Biodiversity Convention, *supra* note 1, art. 15(2).

204. *Id.* arts. 16, 18, 20 respectively.

recognizes that developing countries' duty to provide access is conditioned upon ample support from developed countries.[205]

It is not clear from the Convention to what degree the South could restrict access and still be in compliance. The interpretation of "access" may ultimately be quite loose. The majority of signatories are nations of the South and, as they ratify the Convention, their enabling domestic legislation will almost certainly adopt a broad interpretation of their powers to provide and restrict access. The Convention frequently uses the phrases "mutually agreeable terms" and "subject to mutual agreement" when discussing access,[206] and this could provide an escape clause for cartel members. Presently, Northern corporations can argue that their bilateral contracts with developing countries constitute "mutually agreed terms" despite the multinational corporations' strong bargaining power. Conversely, the phrase "mutually agreed terms" could be construed to allow the nations of the South to drive an extremely hard bargain with the North by threatening restricted access to genetic resources. A final risk is that attempts to control the flow of biological materials could result in black market smuggling of raw genetic materials; a market and infrastructure already exists.

Some commentators feel that the Biodiversity Convention is too vague to have any real adverse impact on the North's goal of preserving intellectual property rights.[207] If the Convention is so weak as not to harm the North, it may also be too vague to help the South achieve its goals of increased benefit sharing and technology transfer. Moreover, the Convention was the product of agreement among governments, not institutions. It is institutions, such as multinational corporations, which hold much of the money, knowledge, and technology that developing countries need. There is significant risk that the South's disillusionment with the North's economic and political tactics will continue to grow. If enough Southern countries become sufficiently frustrated with a continued lack of compensation and technology transfer, cartelization cannot be ruled out. Cartelization is a readily available mechanism that offers the South a measure of control and self-determination currently absent from its dealings with the North. Because the South currently receives so few benefits from status quo biodiversity prospecting agreements, countries of the South have little to lose, and much to gain, by cooperating to restrict the North's access to genetic resources.

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205. Chapela, *supra* note 2, at 13-14.
206. *See, e.g.*, arts. 15(4) and (7), 16(2) and (3), 18(5), 19(2).
207. Coughlin, *supra* note 15, at 354 n.81.

VI. NECESSARY ALTERNATIVES: NEW ENTERPRISES AND CONVENTION COMPLIANCE

The primary goal of the Biodiversity Convention is to engage the world community in activities that will preserve, or at least not further destroy, the world's biological wealth.[208] Not surprisingly, most of the destruction of biological diversity is occurring in the developing world. The reason is that in the developing world there are often few economically viable alternatives to destructive uses of biodiversity. If a peasant in the Colombian Amazon is given the opportunity to make a living in an "environmentally friendly" manner, he will no longer have the need to fell trees to feed his family.

Biodiversity prospecting is potentially one of these "environmentally friendly" alternatives. It is theorized that local communities (e.g., peasants or indigenous persons) in developing countries could engage in the collection and preliminary identification of useful plants for a biodiversity prospecting project. This is already being done on a small scale through INBio's parataxonomist program.[209] But parataxomonists alone will not save the world's disappearing biodiversity, and the limitations of the INBio model have already been discussed *supra*. In countries with rich endowments of biological diversity, such as Brazil, Colombia, Indonesia, and Bolivia, economic alternatives to destructive uses of biodiversity must be created.

Today, developing countries with rich biological endowments are almost universally considered "biodiversity providers." A company or institution desirous of a developing country's biodiversity can simply pay collectors or source country institutions a fee for providing them with natural products.[210] Although this is slowly changing, some view this type of payment as "equitable compensation." But, as with parataxonomists, collection fees alone will not save the world's biodiversity.

Unfortunately, all four biodiversity prospecting initiatives described in Part IV essentially limit a developing country's participation to playing the role of a "biodiversity provider." In all four models, the major value-adding activities are performed outside the source country. These activities include fractionation, screening, structural elucidation, advanced *in vitro* studies, and *in*

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208. Biodiversity Convention, *supra* note 1, art. 1.

209. *See* Daniel H. Janzen et al., *The Role of Parataxonomists, Inventory Managers, and Taxanomists in Costa Rica's National Biodiversity Inventory*, *in* BIODIVERSITY PROSPECTING, *supra* note 49, at 223.

210. Asebey, New Model, *supra* note 38, at 4.

vivo studies. Consequently, it will be difficult for developing countries to receive more than 0.2-3%[211] in royalties. With this low level of return, a developing country's initiatives to preserve biodiversity will almost certainly be unable to compete economically with the lucrative, but more destructive, alternatives already available. These alternatives include fulfilling consumer demand for precious wood, meat, and soybeans.[212]

If the objectives of the Biodiversity Convention are to be fulfilled, the signatories of the developed North must begin to view their counterparts in the developing South not simply as cheap providers of genetic resources, but as partners in a global effort to use biodiversity responsibly. In essence, this is the Biodiversity Convention's mandate. Until developing countries can capture a meaningful amount of the benefits from their biodiversity, biodiversity prospecting will not be linked to conservation or sustainable development in any meaningful way. Until a developing country can economically benefit from its biodiversity, there will be no significant incentive to protect it from destruction.

The first step in assuring that a developing country can capture more of its biodiversity's value is to transfer appropriate technologies, including fractionation technology, screening technology, and know-how. This can be accomplished by coordinating the activities of source countries' nongovernmental organizations, scientific institutions, and local and indigenous communities. By actively engaging source country entities in more of the value-adding steps[213] of biodiversity prospecting, a greater share of the benefits can be justifiably returned to the source country. Although transferring technology implies that developed world pharmaceutical interests would eventually need to share royalties with their developing world partners, it is a small price to pay for preserving the world's rich sources of biological diversity. Such a true partnership approach can assure industrial interests continued access to biodiversity while simultaneously creating an economic incentive for the preservation of biodiversity.

As previously discussed, the underlying problem of biodiversity prospecting is the problem of valuation of genetic resources. Cartelization attempts to address the valuation problem by forcing a front-end increase in the value of natural

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211. These figures are the composite of 0.2%-1% from the RAFI report and the estimated 1-3% of the INBio-Merck agreement, discussed *supra* notes 112 and 115 and accompanying text.

212. WORLD RESOURCES INSTITUTE ET AL., GLOBAL BIODIVERSITY STRATEGY 1 (1992).

213. Examples of value-adding steps include advanced screening, structural elucidation of compounds, and clinical development.

products before they are screened for bioactivity. The necessary alternative to the valuation problem is to change the amount of value-adding performed in developing countries. At present, developing source countries are in a dilemma because they are short of funds. They seek to develop the in-country scientific and technological capacity that will yield profits, yet such capacity-building requires a significant financial expenditure. At base, drug discovery hinges on exportable biological information and human resources,[214] and development of both of these requires an initial capital investment. In the wake of the Biodiversity Convention, it may now be possible for developing countries to break out of the old cycle with the appearance of a different kind of biodiversity prospecting enterprise.

To date, the existing players on the biodiversity prospecting scene have seldom pursued goals that are compatible with those of the developing source countries.[215] So long as the North pursues its goals through these entities, the goals of source countries will remain unsatisfied. Each of these initiatives adds compliance with the Convention as a gloss upon the goals it was already pursuing. The solution is to create a new type of biodiversity enterprise which will make compliance with the goals of the Biodiversity Convention a guiding principle. This guiding principle will then lead enterprises to cross-institutional collaboration, technology transfer, creation of original knowledge, and flow of capital back to the source country.[216] It also will lead to direct contact between industry and indigenous communities (suggested by the Shaman experience), direct and active

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214. Chapela, *supra* note 2, at 2.

215. Source countries seek to generate revenue, develop a form of valuation that provides a workable basis for policy decisions, and build their scientific and technological capacity. Indigenous communities within the source countries have slightly different yet compatible goals: They seek to ensure their survival and to balance the overlapping goals of conservation and economic development. In contrast, multinational pharmaceutical companies, biotech companies, academic organizations, and nongovernmental organizations (NGOs) hold goals of their own, which are incompatible with the source country's needs. Pharmaceutical companies, seek to increase their profits and, as a result, to increase their shareholders' wealth. Venture capitalists, the traditional supports of biotechnology companies, seek short-term profits. Organizations run by the international academic community seek scientific progress and the advancement of pure knowledge. NGOs' goals vary widely, but tend to be purely technical. *Id.* at 37, tbl. 1.

216. Chapela, *supra* note 2, at 7. These desirable traits are inferred from the case study of a Mexican corporation, Syntex, that achieved unprecedented success in the development of a new drug in the 1960s, despite the tremendous advantages of existing multinational pharmaceutical corporations. *Id.*

involvement of the source country government (suggested by the INBio experience), and feedback from the market.[217]

These new biodiversity enterprises will require strong support from source country governments in securing capital, ensuring a favorable or even preferential domestic regulatory environment, facilitating passage through layers of domestic bureaucracy, protecting against possible predatory behavior of multinational pharmaceutical companies, and generally creating an overall atmosphere conducive to the needs of a new biodiversity prospecting industry. [218] Moreover, new biodiversity enterprises will need the support of an unusual combination of financing mechanisms, both public and private.[219] The enterprises may turn to any number of nonprofit organizations for grants or even distributions of United States foreign aid,[220] and also to large foreign firms with environmental interests or major environmental organizations that keep a low profile.[221] The new enterprises will also be able to apply to the funding mechanisms created by the Biodiversity Convention itself.[222] Finally, the United Nations and

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217. *Id.*

218. Feinsilver, *supra* note 2, at 49. Bioprospecting works best as part of a broader plan for economic development and environmental preservation (sustainable development). High-level governmental support is greatly desirable, preferably a high-level official at the ministerial level to formulate policy, oversee programs, and create mutually reinforcing institutional arrangements. *Id.*

219. As discussed in the section on Shaman Pharmaceuticals, *supra* Part IV.D., United States venture capital is not a viable funding source for the new biodiversity enterprises.

220. Some nonprofit organizations that may support such initiatives include: the Mott Foundation, the MacArthur Foundation, the Rockefeller Foundation, the Pew Charitable Trusts, and the Institute for Sustainable Communities. United States foreign aid is channeled through many nongovernmental sources, including the American Bar Association's Central and East European Law Initiative.

221. *See* Feinsilver, *supra* note 2, at 52 (referring in passing to such evolving funding sources).

222. Biodiversity Convention, *supra* note 1, arts. 20, 21. The Convention requires, *inter alia*, that:

> Each Contracting Party undertakes to provide, in accordance with its capabilities, financial support and incentives . . . . The developed country Parties shall provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfill the obligations of this Convention and to benefit from its provisions. . . . Other Parties . . . may voluntarily assume the obligations of the developed country Parties . . . . Contributions from other countries and sources on a voluntary basis would also be encouraged. . . . Developed country Parties may also provide . . . financial resources related to the implementation of this Convention through bilateral, regional and other multilateral channels.

Id.

World Bank may create additional financial resources that are conditioned upon demonstrable compliance with the Biodiversity Convention.

While capital is being raised, the new enterprises should build ties to the indigenous communities where natural products collections will be conducted[223] and develop working relationships with source country organizations that possess useful knowledge and resources. The latter type of contact may ultimately result in a partnership with a private entity inside the source country. Because the in-country partners would have an equity stake in the joint venture, their assumption of some risk and responsibility will lead to greater opportunities for technology transfer and to a greater share of the profits for the source country.[224]

Once the new biodiversity prospecting enterprise is operational, the source country will realize increasing benefits. Local citizens will need to conduct daily operations, thus resulting in income to the community and increased scientific literacy. As additional scientists are attracted to the enterprise, the source country's scientific and technological capacity will grow. As the enterprise expands, it will purchase high-tech equipment and continue to build local capacity. Biotechnology development uses standardized technologies that can be used in a wide variety of research, agricultural, and industrial applications.[225] Thus, citizens trained to use instruments or procedures in a pharmaceutical context will also be able to work with them in another sector of the country's economy, thereby increasing the source country's technological capability. The biodiversity enterprise will help prepare the source country's scientific workforce for the challenges of the 21st century.[226] In addition, the enterprise will generate revenue for the source country and contribute to the protection of the environment.

Under the Biodiversity Convention, countries are required to inventory their biodiversity.[227] At a minimum, the new biodiversity enterprises could develop reliable, high quality collection and extraction capabilities. These tasks are not highly

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223. Some communities have already been approached by Shaman, INBio, the National Cancer Institute, and participants in the International Cooperative Biodiversity Groups. A start-up enterprise will be able to follow their example in this area.

224. Feinsilver, *supra* note 2, at 44-45.

225. *Id.* at 51.

226. *Id.*

227. Biodiversity Convention, *supra* note 1, art. 7.

sophisticated, yet training and considerable care are necessary.[228] In an effort to control their genetic resources, build scientific capacity, and create value-added biodiversity, some source countries recently banned collection by traditional intermediaries, such as botanical gardens.[229] Some of these countries are already working to develop scientific institutions capable of collection and extraction, and later possibly initial screening.[230]

Even if the biodiversity enterprise continues to remain essentially an intermediary between collectors and multinational pharmaceutical companies and does not progress beyond collection, labeling, and elementary chemical analysis, the enterprise will still create significant benefits for the source country. The country's genetic resources and samples will no longer be merely a "black box," waiting to be opened by multinational pharmaceutical companies. Instead, the source country will be able to deliver an organism or extract with informed knowledge about its real chemical potential.[231]

If the new biodiversity prospecting enterprise moves beyond the function of channeling genetic materials to multinational pharmaceutical corporations, it must develop and profit from a new drug. Drug discovery is high risk. In the United States, only one of every 80,000 to 250,000 substances screened reaches the drug market.[232] However, the chances for lucrative operations may be markedly better in the developing world because Northern multinational pharmaceutical companies confine themselves to a narrow section of the pharmaceutical market: the search for big-ticket treatments for the ailments that are of most concern to developed nations.[233] They generally ignore the diseases indigenous to developing source countries and do not create screens that would identify natural products to treat those local diseases.[234] There is a particularly urgent need to screen natural products for a wide range of tropical infectious and chronic diseases.[235]

Plant-derived pharmaceuticals developed in a source country and marketed to other developing countries face a much less restrictive regulatory environment than those developed in the

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228. Feinsilver, *supra* note 2, at 52.
229. *Id.* at 24.
230. *Id.*
231. Chapela, *supra* note 2, at 26.
232. Feinsilver, *supra* note 2, at 33-34.
233. Cancer and AIDS are two of the most visible "big ticket" undertakings. They are high-risk, involve a large market, and offer potentially enormous profits.
234. Feinsilver, *supra* note 2, at 51-52.
235. *Id.* at 49.

United States.[236] Less regulation means that drugs can be brought to market faster and generate revenue earlier. Thus, the new biodiversity enterprise could produce scientifically validated and standardized herbal remedies to meet the primary health care needs of the developing world, as well as some European countries in which these phytopharmaceuticals and herbal remedies are common.[237] Such advancements would occur within the confines of a market niche not challenged by multinational pharmaceutical companies. Simultaneously, the new enterprise could compete more directly with multinational pharmaceutical companies in seeking to find a cure for the diseases of the developed world. In either case, because more value-adding would occur inside the developing country, a larger share of profits could remain in the source country. If a new enterprise is highly successful, it may be in danger of being "vertically integrated" into a pre-existing multinational pharmaceutical company.[238] Vertical integration causes profits to be retained by the parent multinational company, which in turn exports profits out of the source country. Strong collaboration between the new enterprises and the source countries in which they operate is necessary in order to combat vertical integration.

In the future, groups of new enterprises may also attempt to cooperate with one another. Various developing countries have complementary assets that could synergize if national interests were subordinated to regional considerations.[239] Development of scientific capacity is not beyond the reach of many developing countries and could be done in either federal or multinational research and development consortia.[240] Regional coordination efforts might complement each other and lead to regional competitiveness in the global market.[241] In the absence of positive incentives, opportunities and human resources will continue to be drained out of developing countries and will flow toward established industry in the North.[242]

In summary, technology transfer performed in the context of a Convention-driven bioprospecting company offers developing countries the chance to increase their revenue and technological

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236. *Id.* at 48.
237. *Id.* at 49.
238. *See* Chapela, *supra* note 2, at 6-8 (describing how this fate befell an earlier Mexican start-up company, which developed a treatment for hormonal imbalances in the 1940s from a Mexican tuber, *dioscorea mexicana*).
239. *Id.* at 23.
240. Feinsilver, *supra* note 2, at 51.
241. Chapela, *supra* note 2, at 2.
242. *Id.* at 23.

basis by creating the capacity to perform value-adding processes.[243] Rather than increasing revenue at the front end of the bioprospecting process by raising the cost of raw genetic material to developers through supply restrictions, the Convention-driven enterprises will train source country citizens and retain a greater portion of profits within the source country. The net result will be the linkage between conservation and sustainable development through the creation of an economically sustainable biodiversity-based industry, which is an effective alternative to destructive uses of biodiversity.

VII. CONCLUSION

This Article examined the development of North-South biodiversity prospecting and critiqued the major initiatives that were undertaken in response to the Convention on Biological Diversity. This Article concludes that existing models do not meet the goals of the Convention. The future of United States biodiversity prospecting may depend upon whether the United States ratifies the Biodiversity Convention. If it does not ratify, the South can be expected to restrict the United States access to the South's genetic resources. Whether or not the United States ratifies the Convention, a new type of business enterprise may develop that uses compliance with the Biodiversity Convention as a guiding corporate principle. Such an enterprise would be the first mechanism to comply with both the spirit and substance of the Biodiversity Convention.

243. For an example of the "Convention-driven bioprospecting enterprise" see Feinsilver, *supra* note 2, at 43-45, 48 (contrasting Washington D.C.-based Andes Pharmaceuticals, Inc. and other bioprospecting initiatives) and Asebey, *supra* note 38, generally (describing the mission of Andes Pharmaceuticals, Inc. in relation to the Biodiversity Convention).