Cardozo Journal of International and Comparative Law
Summer 2003

**Symposium**
**Traditional Knowledge, Intellectual Property, and Indigenous Culture**
**Articles**

# ***547** INTELLECTUAL PROPERTY, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE PROTECTION: THINKING GLOBALLY, ACTING LOCALLY [FNa1]

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One of the great questions of our time is how to promote global economic development, while simultaneously preserving local biological and cultural diversity. Nowhere is the tension between these two seemingly conflicting goals more vividly illustrated than in the fractious debates surrounding two international agreements that were hammered out in the last decade of the twentieth century. In the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), [FN1] which is one of a bundle of agreements concluded in 1994 as a result of the Uruguay Round of Multilateral Trade Negotiations, and is now administered by the World Trade Organization (WTO), members of the predecessor ***548** General Agreement on Tariffs and Trade (GATT) organization sought to strengthen international intellectual property protection in the developing world in order to promote world trade and stimulate economic development. In the United Nations Framework **Convention** on **Biological Diversity** (CBD), [FN2] which was concluded at the 1992 "Earth Summit" in Rio de Janeiro, and has now been ratified by more than 175 countries, [FN3] the United Nations Program on the Environment sought international support for the conservation, sustainable use, and guaranteed access to genetic resources in the developing world, in return for a fair and equitable share of the benefits arising out of the utilization of those resources.

As has been noted in more detail elsewhere, the international debates surrounding TRIPS and the CBD seemed to expose a series of fault-lines dividing the technology-rich industrialized countries located primarily in the temperate zone of the Northern Hemisphere, and the biodiversity-rich developing countries located primarily in the tropics and Southern Hemisphere. [FN4] For example, the United States initially refused to sign (and still has not ratified) the CBD, complaining that it would impair American intellectual property rights, and that it conceives intellectual property rights "as a constraint to the transfer of technology rather than as a prerequisite." [FN5] Meanwhile, farmers in India reacted strongly to the successful conclusion of the TRIPS negotiations, mounting increasingly violent political demonstrations to complain, in particular, about the requirement in Article 27 of TRIPS that patent protection is to be extended to pharmaceutical and agricultural chemical ***549** products and microbiological products and processes, and that plant varieties are to be protected by patents or an effective sui generis system of protection or any combination of the two. [FN6] The demonstrators argued for collective, not individual control over seeds and plants. [FN7] They echoed widespread concerns in the developing world over "gene piracy," whereby researchers and agricultural and pharmaceutical companies from industrialized countries obtain patents on inventions based on genetic resources and traditional knowledge from the developing world, while the developing world is saddled with the cost of preserving biodiversity and yet deprived of the opportunity to share in its benefits. [FN8]

Not surprisingly, the first TRIPS dispute to make its way completely through the new WTO dispute settlement process was brought by the United States and the European Union against India. The specific complaint was that India had failed to fulfill its obligations under TRIPS to adopt "mailbox" procedures and "exclusive marketing rights" governing pharmaceutical and agricultural chemical products during the transitional period for implementing the TRIPS Agreement, but the dispute exemplifies the larger conflicts between the technology-rich North and the biodiversity-rich South. [FN9]

***550** Notwithstanding these North-South conflicts, a more cooperative vision of the interface between biotechnology and biodiversity has gradually begun to emerge, recasting the relationship between TRIPS and the CBD, and the larger relationship between biotechnology and biodiversity, as one of interdependence rather than

fundamental conflict. [FN10] Embodied in the concept and practice of biodiversity research and "bioprospecting," [FN11] the threefold goal is to promote human health, economic development and conservation of biodiversity. These three tasks are both urgent and highly interdependent, as pharmaceutical and agricultural product discovery is a "high-risk science" that depends on the existence of and ready access to biodiversity. [FN12] However, many developing countries are currently making unsustainable use of their natural resources. ***551** Accordingly, it is estimated that .25% of the world's biodiversity is lost to extinction each year due to tropical deforestation alone, at which rate up to 10% of the world's species will be extinct within 25 years. [FN13] Easing the pressures that contribute to this rapid rate of extinction will require the rapid development of environmentally sound food and agricultural technologies. Yet, these technologies likewise depend both on high-risk science and on the preservation of and access to biodiversity.

Emblematic of the growing awareness of the interdependence of biotechnology and biodiversity, the Fourth WTO Ministerial Conference, held in Doha, Qatar, in November, 2001, issued the widely publicized "Doha Declaration." [FN14] The Doha Declaration included a statement that not only stressed the importance of implementing the TRIPS Agreement in a manner supportive of public health, by promoting access to existing medicines and research and development of new medicines, but also specifically instructed the WTO TRIPS Council to examine the relationship between the TRIPS Agreement and the CBD. [FN15] The TRIPS Council is to give particular attention to the protection of traditional knowledge and folklore, and take into account the stated objective of TRIPS to contribute to the promotion of technological innovation and transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, and in a manner conducive to social and economic welfare. [FN16] On March 5-7, 2002, the WTO TRIPS Council began work on the list of issues that were assigned to it at the Doha Ministerial Conference. [FN17]

The WTO is not the only international organization focusing on the intersection of biotechnology, biodiversity and the protection of traditional knowledge. The WTO will in fact be working with at least three other international organizations as the TRIPS ***552** Council implements the Doha Declaration. [FN18] Almost a decade before the CBD was opened for signature in 1992, the United Nations Food and Agricultural Organization (FAO) adopted the International Undertaking on Plant Genetic Resources for Food and Agriculture (International Undertaking). [FN19] One hundred and thirteen countries now adhere to the International Undertaking, which is designed as an instrument to promote international harmony regarding access to plant genetic resources for food and agriculture. [FN20] After years of negotiations to harmonize the International Undertaking with the CBD and transform it into a legally binding instrument the FAO adopted in November 2001, the International Treaty on Plant Genetic Resources for Food and Agriculture, which will become effective upon ratification by at least forty states. [FN21]

Meanwhile, the Conference of the Parties for the CBD has established a working group and developed an agenda for implementation of Article 8(j) of the CBD, which in principle obligates member countries to: respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity; 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. [FN22] Likewise, the World Intellectual Property Organization (WIPO), the specialized U.N. agency responsible for the promotion of intellectual property, has established an Inter-governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, which is to facilitate discussion of intellectual property issues that arise in the context of access to genetic resources and benefit-sharing, protection of traditional ***553** knowledge, innovations and creativity, and protection of expressions of folklore. [FN23]

The foregoing international initiatives represent the current "global thinking" that will be the subject of Part I of this Article. To illustrate how this global thinking has been and can be acted upon locally, Part II of this Article will describe the International Cooperative Biodiversity Groups (ICBG) Program funded by the U.S. Government through the National Institutes of Health, the National Science Foundation, and the Department of Agriculture. [FN24] The ICBG has provided support for a variety of multi-disciplinary international partnerships among research institutions, companies, communities and non-governmental organizations in twelve developing countries, the United States and the United Kingdom to address a complex set of research, development and conservation efforts. [FN25]

In particular, Part II will focus on the ICBG-Peru Project which was organized as a partnership of five

organizations, including three universities (one of which is the author's home institution, Washington University in St. Louis), a corporate partner, and a confederation of indigenous organizations. [FN26] This project represents a milestone in the evolution of intellectual property and associated contractual protection for traditional knowledge and genetic resources for two interrelated reasons. First, the ICBG-Peru project produced a know-how license, in which the corporate partner recognized the traditional plant knowledge of the Aguaruna peoples of Peru as valuable know- how for disclosure of which annual licensing fees would be paid. Second, the project has more recently produced a provisional patent application which discloses a compound discovered by means of the disclosure of this know-how and later found to inhibit the protozoan responsible for the most serious types of malaria. This patent application not only identifies the Aguaruna people of north-central Peru as having provided plants, plant parts and preparations used by them to treat malarial symptoms, and acknowledges the specific know-how provided by three ***554** individuals, but also names the confederation of indigenous peoples along with the three collaborating universities as assignees (i.e. co-owners) of the patent application. [FN27] These two interrelated outgrowths of the IGBG-Peru Project represent an important local illustration of the current global thinking about how international intellectual property and associated contractual protection might be used to protect traditional knowledge.

## I. Thinking Globally

### A. The FAO--From "Common Heritage" to Equitable Benefit-Sharing

The evolution in the thinking of the FAO, from its 1983 International Undertaking to its recently promulgated International Treaty on Plant Genetic Resources for Food and Agriculture, illustrates the development in global thinking over the past two decades about how best to preserve genetic and cultural diversity, while promoting economic development. The 1983 International Undertaking stated that it was based on the "universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction." [FN28] By 1989, however, a resolution of the FAO, entitled "Agreed Interpretation of the International Undertaking" and included as Annex I of the Undertaking, [FN29] recognized that some countries had not adhered to the Undertaking or had adhered with reservation because of possible conflict with their obligations under the International Union for the Protection of New Varieties of Plants (UPOV), while other countries had not adhered or adhered with reservation because of conflict with existing national regulations. [FN30] Apparently, the industrialized world feared that the Undertaking would undercut the recognition of intellectual property rights for plant breeders, while the developing world feared that the Undertaking would merely legitimate gene piracy.

***555** While reiterating that plant genetic resources "are a common heritage of mankind to be preserved, and to be freely available for use, for the benefit of present and future generations," [FN31] the 1989 resolution recognized the need to balance the rights of plant breeders (formal innovators) and farmers (informal innovators). The resolution thus explicitly stated that plant breeders' rights were not incompatible with the Undertaking; that the best way to implement the concept of farmers' rights (which was the subject of a separate resolution attached as Annex II to the Undertaking) [FN32] was to ensure the conservation, management and use of plant genetic resources for the benefit of present and future generations of farmers, through the International Fund for Plant Genetic Resources (already established by the FAO); and that the term "free access," as used in the Undertaking, does not mean free of charge. [FN33] By 1991, apparently in anticipation of the promulgation of the Convention on Biological Diversity, a further FAO resolution (attached as Annex III to the 1983 Undertaking), while reiterating the "common heritage of mankind" principle, endorsed the point that nations have sovereign rights over their plant genetic resources. [FN34]

The new International Treaty on Plant Genetic Resources for Food and Agriculture abandons the "common heritage of mankind" language altogether. Instead, it states that the objectives of the Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security. [FN35] The Treaty recognizes that these objectives will be achieved by closely linking the Treaty to the FAO and the CBD. [FN36] Reflecting that linkage, Part II of the Treaty spells out the obligations of member countries to promote the exploration, conservation and sustainable use of plant genetic resources. Part III elaborates on the concept of farmers' rights, explicitly recognizing the need to protect traditional knowledge relevant to plant genetic ***556** resources for food and agriculture and to promote the equitable sharing of benefits and participation in national decision making on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture. Parts IV and V of the Treaty lay out an elaborate multilateral system of access and benefit-

sharing and supporting components for same. [FN37] In so doing, the Treaty echoes each of the main themes of the Convention on Biological Diversity.

B. The CBD and Traditional Knowledge Protection

Article 1 of the Convention on Biological Diversity (CBD) states that its three objectives are: 1) the conservation of biological diversity; 2) the sustainable use of its components; and 3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources through such means as (a) appropriate access to genetic resources, (b) appropriate transfer of relevant technologies, and (c) appropriate funding. [FN38] Articles 6-14 of the CBD set forth various measures for promoting the conservation and sustainable use of biodiversity (the first and second objectives of the CBD), including specific measures for promoting in-situ and ex-situ conservation. [FN39] Among the measures listed in Article 8 for promoting in-situ conservation is the requirement contained in Article 8(j), which in principle obligates member countries to: 1) respect, preserve, and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity; 2) promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices; and 3) encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices. [FN40]

***557** To that end, the CBD Conference of the Parties (COP) established a Working Group to address the implementation of Article 8(j). [FN41] The Working Group held its first meeting in Seville, Spain, in March 2000, and based on its recommendations, the COP adopted a Programme of Work on the implementation of Article 8(j), consisting of seven elements and seventeen specific tasks, which are, in turn, divided into two phases for implementation, according to the priority given to the specific task. [FN42] Phase one of the Programme of Work will focus on specific tasks for implementing the first, fourth, sixth and seventh elements of the Programme. [FN43] The first element is to develop participatory mechanisms for indigenous and local communities; the fourth is to develop mechanisms for the equitable sharing of benefits; the sixth is to develop monitoring mechanisms; and the seventh is to review existing national and international intellectual property instruments that may have implications for the protection of traditional knowledge. [FN44] The Working group was due to hold a second meeting in Montreal, Canada, in February of 2002. [FN45]

The COP also emphasized that further work is required to develop a common appreciation of the relationship between intellectual property rights, the WTO TRIPS Agreement, and the CBD. [FN46] To that end, the COP has invited both WIPO and WTO to explore the relationship between the TRIPS Agreement and the CBD. [FN47]

C. The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

At its Twenty-Sixth Session, held in Geneva from September 26th to October 3rd, 2000, the WIPO General Assembly established an Intergovernmental Committee on Intellectual Property ***558** and Genetic Resources, Traditional Knowledge and Folklore. [FN48] The Intergovernmental Committee met twice in 2001 and was scheduled to meet a third time in June 2002. [FN49] To facilitate the work of the Committee, the WIPO Secretariat has prepared a number of documents elaborating upon specific tasks to be taken up by the Committee.

For the Committee's first meeting, the Secretariat prepared a document, providing an overview of the topics for the Committee to discuss, including specific tasks that the Committee might wish to consider with respect to intellectual property issues relating to genetic resources access and benefit- sharing, and the protection of traditional knowledge, innovations and creativity. [FN50] For the Committee's second and third meetings, the Secretariat prepared a number of follow-up documents on specific tasks, about which there was consensus at the Committee's first meeting. [FN51]

The first task the Committee will take up is the development of "guide contractual practices" and model intellectual property clauses for contractual agreements on providing for access to genetic resources and benefit-sharing. [FN52] The second set of tasks the Committee will address deals with the protection of traditional knowledge and its status as prior art in existing patent systems. [FN53] A third, more controversial set of tasks, which lacks any consensus as

yet, relates to the development of appropriate national and international patent measures, including a requirement that applicants for biotechnology patents disclose the origin of relevant genetic resources and provide evidence of prior informed consent by such providers, thereby facilitating access to genetic resources and benefit-sharing. [FN54]

***559** 1. Contractual Agreements for Access to Genetic Resources and Benefit-Sharing

As the WIPO overview document recognizes, contractual agreements are the most common legal mechanism for regulating access to genetic resources and benefit- sharing. [FN55] These agreements are said to govern the transfer of genetic materials for a variety of purposes, including ex-situ conservation in gene banks, research and development, commercial exploitation, or a combination thereof, and have become collectively known as "Material Transfer Agreements" (MTAs). [FN56] The overview document notes that while several international instruments, including the FAO International Code of Conduct for Plant Germplasm Collection and Transfer (1993), regulate the transfer of genetic resources, the intellectual property provisions of MTAs have become a source of controversy and confusion, and the international fora in which these clauses are discussed may not have the expertise to develop technically accurate clauses that balance public policy objectives with private interests of stakeholders. [FN57]

To that end, the WIPO Secretariat has produced a follow-up document entitled "Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit-Sharing." [FN58] This document describes the most important categories of public policy frameworks which are relevant to contractual agreements for access and benefit-sharing. [FN59] It provides a sampling of contractual provisions governing the scope of the contract, the respective intellectual property rights and obligations of the provider and recipient of genetic materials, and other standard clauses governing such matters as dispute resolution, the term and termination of the contract, entry into force, and cancellation. [FN60] Finally, the document articulates certain operational principles for the development of guide contractual clauses. [FN61] On the agenda for discussion at the Intergovernmental Committee's third meeting in June 2002 was yet another WIPO document suggesting a possible format for a database of contractual ***560** practices and clauses relating to intellectual property, access to genetic resources and benefit-sharing. [FN62]

2. Traditional Knowledge Protection--Categories of Intellectual Property Issues

The WIPO overview document identifies two member-country concerns about traditional knowledge protection: 1) the availability of intellectual property protection for traditional knowledge holders, and 2) the acquisition by parties other than traditional knowledge holders of intellectual property rights over traditional knowledge-based creations and innovations. [FN63] The document goes on to identify four specific categories of intellectual property issues growing out of these two concerns.

The first category involves terminological and conceptual issues. [FN64] While Annex 3 of the document provides definitions of relevant terms used in international discussions of traditional knowledge, the document concludes that exclusive definitions may not be possible or necessary to delimit the scope of the subject matter for which protection is sought. [FN65] It notes that existing international intellectual property agreements, such as the Berne Convention for the Protection of Literary and Artistic Works, merely provide a non-exhaustive enumeration of protected subject matter. [FN66] The document identifies four conceptual issues that need to be addressed, namely: 1) agreement on the principles and objectives of traditional knowledge protection; 2) understanding the interface between the formal intellectual property system and customary legal systems which apply to traditional knowledge in local and indigenous communities; 3) developing methodologies to deal with the collectivity of creation, innovation and ownership in certain traditional knowledge systems; and 4) developing means for ***561** dealing with legal and administrative problems created by "regional [i.e., transnational] traditional knowledge." [FN67]

The second category of issues concerns the availability, scope and use of existing intellectual property protection and the development of new, sui generis forms of intellectual property protection for traditional knowledge. [FN68] The WIPO overview document summarizes the existing forms of intellectual property protection currently available for traditional knowledge. It also describes various efforts to develop sui generis protection for elements of traditional knowledge not covered by existing intellectual property systems, and notes that new intellectual property standards could be accommodated within the broad concept of "intellectual property" in the WIPO Convention, which provides that "intellectual property" shall include both existing forms of intellectual property rights "and all

other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields." [FN69]

***562** The third category of issues concerns the legal criteria for the definition of "prior art," i.e., the entire body of knowledge available to the public before a given filing or priority date for any patent, utility model, or industrial design. [FN70] The WIPO overview document suggests that member states may consider revising existing criteria and developing new criteria to allow for effective integration of traditional knowledge documentation into searchable prior art. [FN71] To that end, the WIPO Secretariat produced a follow-up document, entitled "Progress Report on the Status of Traditional Knowledge as Prior Art." [FN72] This document suggests a number of practical ways to respond to the current inability of patent examiners to discover relevant traditional knowledge already in the public domain as prior art. Possibilities include: compiling and prioritizing an inventory of existing traditional knowledge-related periodicals that document traditional knowledge data, with a view to a possible recommendation for integration into the minimum documentation list under the Patent Cooperation Treaty and into guidelines for search and examination of patent applications; and, creating an electronic exchange of public domain traditional knowledge documentation data through online databases and digital libraries. [FN73] On the agenda for discussion at the Intergovernmental Committee's third meeting in June 2002 were additional WIPO documents inventorying traditional knowledge-related periodicals and databases and reviewing existing intellectual property protection and elements of a potential sui generis system of protection for traditional knowledge. [FN74]

The fourth and final category of issues relates to the enforcement of rights in traditional knowledge. [FN75] The WIPO overview document***563** notes that the most urgent need in this regard is to reduce transaction costs for enforcement of those rights, as the current enforcement mechanisms are prohibitively expensive and complicated. [FN76] The document specifically notes that the few Legal Aid organizations that exist to represent traditional knowledge holders have difficulty raising funds for intellectual property cases and suggests possible institutional structures for a coordinated enforcement of rights in traditional knowledge. [FN77]

3. Other National and International Patent Measures Regulating and Facilitating Access to Genetic Resources and Benefit-Sharing

A final set of tasks identified in the WIPO overview document, but not yet acted upon by the Intergovernmental Committee, concerns various national and international patent measures to regulate and facilitate access to genetic resources and benefit-sharing. [FN78] In this regard, the document notes that a Panel of Experts on Access and Benefit-Sharing convened by the CBD identified two intellectual property issues: first, the use of intellectual property rights as a mechanism "to support, in user countries, prior informed consent requirements in provider countries;" and second, the recording of interests in inventions that arise from access to or use of genetic resources. [FN79]

The WIPO overview document also notes that proposals to establish a requirement that patent documents disclose the origin of genetic resources used in the development of inventions have been articulated in many multilateral forums, including the WTO, the CBD, the United Nations Conference on Trade and Development (UNCTAD), and WIPO, and poses a number of questions for further discussion. [FN80] These include the following: Would the requirement also apply when the invention concerns synthesized substances isolated or derived from active compounds of an accessed genetic resource and, if so, what should be meant by "derived" ? Would the requirement apply to genetic resources accessed from multilateral systems for facilitated access to genetic resources, ***564** which may be established in the agricultural sector? What would be the consequences of non-compliance with the requirement - fines, invalidation or revocation of the patent? While the document makes no effort to answer these questions, it does note that existing standards on the availability, scope and use of patents, such as those set out in TRIPS Articles 27, 29, 32, and 62 may afford some guidance. [FN81]

Although the WIPO and the WTO have yet to address these issues, a recent article by a current WIPO (and former WTO) official, Dr. Nuno Pires de Carvalho, explores the third issue in some detail. [FN82] In this article, Dr. Carvalho concludes that, although requiring disclosure of origin and evidence of prior informed consent as a condition for obtaining patent protection would be inconsistent with current TRIPS standards, [FN83] such a requirement could be made a condition for enforcement of patent rights, utilizing well established equitable doctrines of unclean hands and fraudulent procurement. [FN84] As a practical matter, non-compliance with such requirements will most likely be discovered only after a patent issues and enforcement is sought. By addressing non-compliance at the enforcement rather than the application stage of the patent ***565** process, both patent tribunals and

challengers will be able to concentrate on scrutinizing compliance with disclosure and informed consent requirements as they apply to the minority of issued patents that have sufficient economic value to warrant enforcement. [FN85] This approach would also leave open to legislatures and tribunals the remedial option of requiring an equitable sharing of the benefits as a condition of enforcing a patent against an infringer, or for that matter, as a condition for enforcing an associated patent license.

In sum, this represents the current global thinking about intellectual property, genetic resources, and traditional knowledge protection. The remainder of this Article will focus on how the foregoing global thinking might be acted upon locally.

## II. Acting Locally

### A. The International Cooperative Biodiversity Groups Program

An illustration of how the foregoing global thinking can be acted upon locally is found in the International Cooperative Biodiversity Groups ("ICBG") Program. [FN86] As a comprehensive report on the Program notes, the philosophy and basic operating principles of the ICBG Program were originally developed at a 1991 international workshop on drug development, biodiversity ***566** conservation and economic growth. [FN87] The following year, the National Institutes of Health, the National Science Foundation, and the U.S. Agency for International Development (which was later replaced by the Department of Agriculture) requested proposals to establish multidisciplinary projects addressing drug developments, biodiversity conservation, and economic growth. [FN88] According to the terms of the request, proposals were required to address each of these objectives, to include substantial and novel efforts in natural products drug discovery, biological inventory, research capacity-building, and benefit-sharing, and to include at least one associate program within each ICBG project based in and led by a developing country organization. [FN89] After an initial round of funding for five ICBG projects, the funding organizations in 1997 asked a panel of experts to evaluate the progress and utility of the program. [FN90] The panel strongly endorsed the concept of the program, and made a number of specific improvement proposals, including broadening the research to include agricultural research, that led to a second cycle of five-year funding awards for three of the initial projects and three new ones, one of which subsequently became embroiled in controversy and was eventually terminated. [FN91]

The eight projects exhibit certain commonalities, but are more notable for their diversity of approaches, to say nothing of their degree of success. All of the projects involved at least some work with terrestrial plants (largely from tropical forests), all have conducted research in multiple disease areas simultaneously, most have involved an ethno-medical component in their field efforts, and most include collaboration with at least one industrial partner that finances its own research and development activities. [FN92] Together, ***567** they have involved researchers from over 35 organizations in 12 countries on four continents, and the eight group leaders have included three chemists, a physician, an ecologist, an anthropologist, a plant taxonomist, and an ethnobotanist. [FN93] One project, the University of Arizona-Latin America ICBG, is working entirely in arid and semi-arid areas. [FN94] Another, the Cornell University-Costa Rica ICBG, focused primarily on insects and other arthropods. [FN95] Two projects (the Cornell-Costa Rica ICBG and the Smithsonian-Panama ICBG) focused their fieldwork primarily on ecological cues regarding chemistry. [FN96] The Suriname ICBG sought to compare the success rate of ethnobotanical and random collection strategies, [FN97] while the ICBG-Peru project relied primarily on ethnobotanical prescreening. [FN98] One project, the Walter Reed Army Institute of Research-West and Central Africa ICBG, involved no industrial partner, as the project focused on parasitic diseases of little interest to the pharmaceutical industry. [FN99]

Together, the groups have collected over 11,000 samples from some 5800 species of plants, 550 species of insects and 500 species of fungi. [FN100] At least 260 compounds of interest have been isolated in the first six years of the projects, of which approximately 50 are novel, and 25 are considered active leads. [FN101] While compounds have been studied in animals in at least six therapeutic areas, none ***568** have reached clinical trials. [FN102] Over 1400 persons have received formal training through the program and 90% represent developing country participants, 80 of whom have been enrolled in long-term degree programs, the remainder having participated in short-term training efforts, such as workshops or laboratory experience. [FN103] The governments of a number of the developing countries involved (i.e., Mexico, Argentina, Chile, Peru, and Suriname) have used the ICBG projects as a testing ground for their developing policies on access and benefit sharing. [FN104]

The comprehensive report on the projects states that the single most important contribution of the ICBG projects has been in providing important models for governments and other organizations for collaborative research that support the objectives of the CBD. [FN105] From the experience gained thus far, the report draws the following additional conclusions: 1) While business and legal issues are unavoidable, bioprospecting is essentially a research effort and succeeds best when treated as such; 2) there is no single, "one size fits all" model for bioprospecting, and inflexible access regulations may simply wind up hurting the interests of both producers and users of genetic materials; [FN106] and 3) a diversity of benefits may be available through such collaborations, but monetary benefits from any single project are unpredictable, as drug discovery is an inherently high-risk (low-probability) form of research. [FN107] With respect to traditional knowledge, the report concludes that while ethnomedical information is of interest to both academic and industrial scientists, it is difficult to integrate ethnomedical knowledge into the large-scale high-throughput systems commonly used ***569** by the industrial partners, and traditional knowledge may thus be more useful in academic environments and government laboratories and to companies with flexible research systems that can be customized to take advantage of traditional knowledge. [FN108]

The report also notes that in the current legal and commercial environment, patent protection for natural product derivatives is basic to the development of most pharmaceutical and agricultural products, as companies will otherwise simply not make the multi-million-dollar investment necessary to bring a derivative to late development, clinical trials. [FN109] The general approach of the ICBG Program to intellectual property rights has been to balance the critical role of patents in drug development with the need to protect the rights of host country organizations, communities and individuals, using an explicit set of principles, detailed in an appendix to the Request for Applications for the program, [FN110] governing the conduct of research and the development of contractual agreements among the parties to a particular ICBG project. The report also notes that, notwithstanding the legal and philosophical debates over "patenting life," no patenting of an actual organism has occurred in the ICBG projects and none is expected, as natural products research for discovery of pharmaceutical and crop protection agents rarely involve patents on living organisms. [FN111] More common are patents related to useful chemical derivatives and analogs of compounds originally isolated from a plant, animal or microorganism for specific identified uses. With respect to traditional knowledge, the policy of the ICBG Program is that when traditional knowledge is involved in the development of a patentable invention, if the traditional knowledge provider cannot be recognized as an inventor, the contribution should be treated as valuable know-how, the contribution credited in any related publications and in the patent prior art, and the providers compensated for their contributions. [FN112] A concrete example of that policy approach is to be found in the ICBG-Peru project.

***570** B. The ICBG-Peru Project

The stated purpose of the successfully completed ICBG-Peru project was to identify new pharmaceuticals based originally on ethnobotanical prescreening, while concomitantly conserving biodiversity in northern Peru by enhancing economic growth among the collaborating Aguaruna people. [FN113] The focus of the research has been both on globally important diseases and syndromes and maladies of serious concern in Peru. [FN114]

ICBG-Peru originated as a partnership consisting of three universities, a corporate partner and an indigenous organization. [FN115] The Principal Investigator is Dr. Walter H. Lewis, Professor of Biology at Washington University in St. Louis, Missouri, one of the three university members of the partnership. The other two academic partners are the Departmento de Entomologia, Museo de Historia Natural, Universidad Nacional Mayor de San Marcos in Lima, Peru, and the Departmento de Microbilogia, Universidad Peruana Cayetano Heredia, also in Lima, Peru. The corporate partner, G.D. Searle & Company, a division of Monsanto Company, headquartered in St. Louis, Missouri, was eventually forced to withdraw from the ICBG-Peru project due to the acquisition of the Monsanto Company by Pharmacia, Inc. [FN116] However, it did so only after completing all of the annual know-how royalty and milestone payments it was contractually obligated to make to the final member of the partnership, the Confederacion de Nationalidades Amazonicas del Peru (CONAP). Included within this confederation are four organizations of Aguaruna communities and peoples. [FN117]

In 1992, Dr. Lewis outlined by medical category several hundred plants currently used in modern medicine and also used medically by indigenous peoples. [FN118] He and his wife, Dr. Memory Elvin-Lewis, a Professor of

Microbiology and Ethnobotany in Biomedicine, in the Biology Department of Washington University, ***571** and others, also showed how the culturally intact South American Jivaro communities use plants now as they have for perhaps thousands of years, [FN119] selected from a highly diverse vegetation said to represent one of the richest in the world for woody plants. [FN120] The Jivaros reportedly provided western medicine with the benefits of curare as far back as the late 1930s. They supplied Squibb & Sons, New York, with crude bark extracts of Chondrodenron and Curarea (Menispermaceae), from which the active alkaloid tubocurarine was isolated, thereby revolutionizing modern anesthesiology and major surgery. [FN121] Equally, if not more significant, was the Jivaros' early use of quinine bark from Cinchona (Rubiaceae) to treat malaria [FN122]--a native treatment that received widespread notice in Europe as far back as the sixteenth and seventeenth centuries. [FN123]

In their report on the ICBG-Peru project, [FN124] Dr. Lewis and his collaborators cited two separate authorities in support of the advantages of ethnobotanically targeted research. A Belgian group is said to have reported in 1985 that selection of candidates for screening compounds, when based on traditional medicinal data compared to several other methods, gave a five times higher percentage ***572** of active leads, even though in some cases the same active compounds were isolated from botanically unrelated active plants. [FN125] A preliminary test using plants submitted to the National Cancer Institute for anti-HIV screening is said to have found that random plant collections provided 6% activity, whereas those based on ethnobotanically "powerful plants" selected by an herbal healer yielded 25% activity, a four- times greater frequency. [FN126]

Dr. Lewis's own research in Peru likewise illustrates the advantages of ethnobotanically targeted research. In pointing out how essential it is to know what part of a plant traditional healers use, the report on the ICBG-Peru project notes that the fruit of one antimalarial species is a common product with known chemistry and biological activity. [FN127] If one were to screen this species as an antimalarial without prior traditional medicinal knowledge, the fruit of the species would be the logical choice as the most significant part of the plant. [FN128] However, as the report points out, the Aguarunas never use the fruit as a treatment for malaria, but rather use only the inner bark of the plant, which like many of Lewis's samples has not, to his knowledge, been studied for antimalarial or any other biological activity and its chemistry remains unknown. [FN129] The report also points out the importance of knowing that most antimalarial extracts used by the Aguaruna are ingested as decoctions (i.e., boiled in water) over considerable periods, thereby increasing the potency of the extract and demonstrating that the toxicity of the extract to humans is apparently low, based on descriptions obtained from the Aguarunas and corroborated by Lewis in subsequent cell cultures. [FN130] This pre-selection for low toxicity becomes a valued feature of ethnomedically used extracts, notes the report, as dose increases with minimum toxicity are essential and human toxicity can prove to be a serious limiting factor ***573** to further development and commercialization of antimalarials or other therapeutics. [FN131]

The legal basis for ICBG-Peru project is a set of interconnected agreements, including: 1) the basic Biological Collecting Agreement, which outlines who is involved in the program, where and under what circumstances collecting can occur, and what annual collecting fees will be provided to the collaborating Aguaruna organizations by the corporate partner; 2) a License Option and a License Option Amendment Agreement between Washington University and G.D. Searle & Company, detailing a basis for their interactions and establishing royalty rates for pharmaceutical products and how these rates are to be shared; 3) a later negotiated Know-how License Agreement that prescribes an annual license fee to be paid by the corporate partner to the collaborating Aguaruna groups while their knowledge is being used in extraction and screening programs, and also establishes certain milestone payments to be paid by the corporate partner; and 4) two subsidiary agreements outlining the nature of the collaborative relationship between Washington University and the two other academic institutions involved. [FN132] Annual collection and know-how license fees paid by the corporate partner are to be deposited into a fund that will make grants to assist the Aguarunas with education and to ensure the development of new conservation and sustainable development projects within the Aguaruna communities. [FN133] Milestone payments are specified for each potential commercial product during specified research and development phases, and royalties based on net sales are specified in the event that a commercial product is released to the public. Royalties will be divided equally among the three universities and the Aguaruna peoples, with fully 75% of any royalty income returning to Peru. [FN134]

The report on the ICBG-Peru project emphasizes several points. The project documents explicitly recognize the medicinal ***574** plant knowledge disclosed by the collaborating Aguaruna peoples to be valuable know-how owned by them and representing a cultural legacy that needs to be wisely and responsibly used for the benefit of their people now and in the future. [FN135] All know-how was disclosed subject to prior informed consent and is

retained in confidence. [FN136] Also, should the resulting data prove valuable following biological and chemical experimentation, both the original know-how and subsequent research will be protected primarily through the filing of appropriate patents. [FN137] These patents will name individual Aguarunas as inventors where possible, and will in any event recognize the Aguarunas as contributors to the invention. [FN138] The Aguarunas, in turn, recognize the ownership and patrimony of the Peruvian state over the genetic material collected by the participating researchers in Peru for research purposes. [FN139] They also acknowledge the need for voucher collections to be permanently deposited and curated at both the Museo de Historia Natural in Lima and the Missouri Botanical Garden in St. Louis (one of the world's leading botanical research institutions) [FN140] and researched for non-commercial purposes at national and international depositories. [FN141] This is to be done with the understanding that biological collections obtained for the purpose of extracting compounds for commercial purposes remain under the control of the Aguarunas unless released by them and that these materials are held in trust by Washington University as recipient of the grant. [FN142]

It is a testament to Dr. Lewis's commitment and perseverance that not only did his project produce a know-how agreement with traditional knowledge holders while two other ICBG projects did not, [FN143] but also that he and two co- inventors (a senior research associate and a graduate student at Washington University) recently filed a provisional patent application with the United States Patent ***575** and Trademark Office disclosing certain antiplasmodial compounds from American plants said to effectively inhibit in vitro the leading cause of malaria. The application named the confederation of participating Aguaruna communities and organizations, along with the three participating universities, as assignees (i.e. co-owners) of the application. [FN144] While the details of the patent application must remain confidential for the moment, [FN145] the inventors and their employer, Washington University, have consented to the disclosure of the existence and general nature of the patent application. [FN146]

The ICBG-Peru report also notes that conservation and sustainable management experiments, as well as training and education, were a part of the ICBG-Peru project from the outset. [FN147] These efforts included training Aguaruna individuals to raise plants in nurseries and to plant in secondary forest plots, tree seeds and seedlings including an important medicinal plant, sangre de grado (Croton lecheri), which was planted by two Aguaruna communities in disturbed forest areas. [FN148] Another community established a committee to grow various antimalarial plants, some of which are now rare in the region due to local overexploitation. [FN149] In coordination with the Peruvian Ministry of Agriculture, seeds and seedlings for a variety of plants were distributed to interested Aguaruna communities for planting, and successful plantations have been established in a number of communities. [FN150] In addition to two workshops, which were conducted in Lima to discuss and explain the ICBG agreements, ICBG personnel trained numerous ***576** Aguarunas in field techniques, conducted workshops in Amazonas, and provided hands-on training during every field expedition, leading to two successful all-Aguaruna expeditions in 1998 and 1999. [FN151] During the course of the project ten graduate students and sixteen undergraduates from the three universities participated in laboratory and/or field research, and in 1997 five Aguaruna students entered either university or preparatory programs, with more following. [FN152]

The report concludes that the ICBG-Peru project has been a successful effort in large part due to the strong collaborative effort of all parties made possible through fair and ethical agreements forged by the partners and a commitment to discover new pharmaceuticals with the guidance of the Aguaruna people. [FN153] While more research must be completed before any commercial products can be made available for human use, the report notes that substantial preliminary data show strong correlations between high activities in specific screens and targeted plant extracts selected for their use as medicinals by the Aguaruna to treat specific infections. [FN154] On the basis of the research accomplished through the ICBG-Peru project, Dr. Lewis himself was awarded a grant by the Burroughs Wellcome Fund to continue the antimalarial research made possible by the cooperation of the Aguaruna partners. [FN155] Without the Aguaruna ethnobotanical data, the ICBG-Peru report estimates that it would have taken at least decades to identify the antimalarial species that the ICBG-Peru project accomplished in months. [FN156]

## V. Conclusion

The comprehensive report on the eight projects that were funded through ICBG Program cautions that it is still too early to say how much bioprospecting can contribute to conservation and economic development, and whether the

ICBG approach is the best way to integrate drug discovery, economic development and biodiversity conservation. [FN157] It notes that the success of bioprospecting ***577** is integrally related to both scientific interest and commercial success of natural product derivatives. The perceived value seems to vary with the introduction of each new technology for synthesizing substitutes for natural products and the time since a major new natural product drug has come to market. [FN158] While combinatorial chemistry was thought to be the latest replacement technology for natural products, the report notes that very few important leads have been generated by that technology thus far, prompting some scientists and organizations to look for ways to integrate this technology and rational drug design with natural product leads to optimize results. [FN159]

The report concedes that when the high profile bioprospecting efforts on the part of Shaman Pharmaceuticals, Inc., [FN160] took a significant downturn in 1999, [FN161] as the company abandoned pharmaceutical development to pursue marketing botanical dietary supplements, some commentators read this (probably unfairly) as an indicator of the future of natural products and ethnomedical knowledge for drug discovery. [FN162] The report goes on to note that ***578** growth in the botanical dietary supplements market is itself an important economic development, leading several of the ICBG projects to pursue work in this area. [FN163] The ICBG report is not alone in calling attention to this emerging market. The previous year (admittedly, before the East Asian currency crisis shook world markets), a report prepared for the Conference of the Parties to the CBD on two benefit-sharing case studies noted more generally that the phytomedical industry was experiencing growth of between 13.5 to 15% per year, and that many of the points made about this industry also applied to the nutraceutical, natural personal care, and cosmetic industries. [FN164] One estimate of the U.S. herbal medicine industry's retail sales in 1994 came to $1.6 billion, while estimates of markets in the EU were $6 billion, in Asia $2.3 billion, and in Japan $2.1 billion, with sales of herbal medical products in China alone said to be $5 billion in 1995. [FN165] The CBD report also notes that the World Health Organization estimates that 80% of the world's population still relies on traditional medicine and that 85% of traditional medicine is based on plants. [FN166] In many biodiversity-rich developing countries efforts are being made to study and standardize traditional medicine in order to provide affordable, effective, and culturally appropriate local health care. [FN167] If implementation of the patent requirements of the TRIPS Agreement***579** turns out to result in dramatic increases in the price of pharmaceuticals in developing countries, as many predict it will once the transitional period for implementation of the product patent provisions of TRIPS expires on January 1, 2005, [FN168] this will undoubtedly only intensify these efforts.

In any event, valuing traditional knowledge and bioprospecting entirely by the extent to which they lead directly to the development of commercially viable products may be employing an inadequate metric. As the organizers of the ICBG program note, drug discovery is a high-risk science, and biodiversity prospecting is essentially a research tool and succeeds best when treated as such. [FN169] If all research were valued entirely by the extent to which it leads directly to the development of commercially viable products, the contribution of academic research as a whole to the development of basic human knowledge would be seriously undervalued.

As the organizers of the ICBG Program also note, while ethnomedical information is of interest to both academic and industrial scientists, it is difficult to integrate into the large-scale high-throughput operations commonly used by the major pharmaceutical companies, and may thus be more useful in academic environments, government laboratories, and to companies with flexible research systems that can be customized to take advantage of traditional knowledge. [FN170] Filtering traditional knowledge through the medium of academic research may likewise be in the best interests of traditional knowledge holders themselves. As the ICBG Program illustrates, academic researchers are well situated to play a mediating role between indigenous or local communities and the global marketplace, and have in fact already been instrumental in implementing the CBD's goals of promoting the conservation and ***580** sustainable use of biodiversity and the fair and equitable sharing of the benefits arising out of its utilization.

In any event, the ICBG Program provides a number of valuable local examples of the current global thinking concerning the relationship of intellectual property, genetic resources and traditional knowledge protection and tends to confirm that the interface between biodiversity and biotechnology is indeed one of interdependence rather than fundamental conflict.

[FNa1]. The ubiquitous environmental slogan, "Think Globally, Act Locally," is said to have originated with Rene Dubos as advisor to the United Nations Conference on the Human Environment in 1972. See R.A. Eblen & W. Eblen, The Encyclopedia of the Environment 702 (1994).

[FNaa1]. Thomas & Karole Green Professor of Law, Washington University, St. Louis, Missouri, U.S.A. This article is an outgrowth of paper presentations at three international conferences during the past year: The International Seminar on the Role of Intellectual Property Protection in the Field of Biodiversity and Traditional Knowledge, at Manaus, Brazil, September 9-11, 2001, co- sponsored by the Brazilian National Institute of Industrial Property and the European Commission; the CIER-Lustrum Seminar on the Protection of Cultural Identity and Indigenous Knowledge, at the University of Utrecht, November 16, 2001, sponsored by the Centre for Intellectual Property, which is publishing an earlier version of this article; and the Symposium on Traditional Knowledge, Intellectual Property and Indigenous Culture, at the Benjamin N. Cardozo School of Law, Yeshiva University, New York, February 21-22, 2002. The author gratefully acknowledges the research assistance of Mr. Kultaran Chohan, LL.M in Intellectual Property & Technology Law, Washington University, 2002; and Ms. Veena Ramani, LL.M, 2002, and J.S.D. candidate, Washington University. The author also benefited from the insightful suggestions of Dr. Nuno Pires de Carvalho, Head of the Genetic Resources, Biotechnology and Associated Traditional Knowledge Section of the World Intellectual Property Organization, who graciously read and commented upon an earlier draft of this article.

[FN1]. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, Legal Instruments - Results of the Uruguay Round, Vol. 31, 33 I.L.M. 81 (1994). Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (Dec. 15, 1993), 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement], available at http://www.wto.int (last visited May 2, 2002).

[FN2]. United Nations Convention on Biological Diversity, June 5, 1993, S. Treaty Doc. No. 103-20 (1993) [hereinafter CBD], available at http:// www.biodiv.org.convention/articles.asp (last visited May 2, 2002).

[FN3]. See http://www.biodiv.org/publications/guide.asp?id=action (last visited May 2, 2002).

[FN4]. See Charles R. McManis, The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology, 76 Wash. U. L. Quarterly 255 (1998)[hereinafter McManis] and sources cited therein; see also David R. Downes, How Intellectual Property Could be a Tool to Protect Traditional Knowledge, 25 Colum. J. Environment'l L. 253, 257-64 (2000) [hereinafter Downes].

[FN5]. McManis, supra note 4, at 256 (quoting U.S. State Department Dispatch, **Convention** on **Biological Diversity**, in 3 U.S. Dispatch 423 (1992)). For a critique of the U.S. position on the CBD, see McManis, supra note 4 at 260-65, and Michael Gollin, The **Convention** on **Biological Diversity** and Intellectual Property Rights, in Biodiversity Prospecting: Using Genetic Resources for Sustainable Development 289-302 (Michael Gollin ed. 1993) [hereinafter Gollin].

[FN6]. See TRIPS Agreement, supra note 1, Art. 27.

[FN7]. McManis, supra note 4, at 257.

[FN8]. Id. at 257-58. For recent examples of "gene piracy," see Downes, supra note 4, at 278 (Example # 1: The Tumeric Patent), 279-80 (Example # 2: The Ayahuasca Patent); Graham Dutfield, Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties (1999) [hereinafter Dutfield] at 65 (Case Study 5.4 The Tumeric Patent) and 67 (Case Study 5.6 The Quinoa Patent) (1999). For an early example, see infra note 124. Although the specific focus of the protests in India in 1993-94 were U.S. patents on a process and a resulting product that gave longer "shelf-life" to a natural insect repellant contained in neem tree seeds, which has long been used as a natural insect repellant in India, that case is distinguishable from the foregoing examples, as the inventor in that case arguably added value to the traditional use of neem seeds and thus invented something new, at least within the meaning of U.S. patent law. See Downes, supra note 4, at 280-81 (Example # 3: Patents and the Neem Tree). For a discussion of the U.S. patent law novelty requirement and how it creates misunderstanding in cases such as the neem patent controversy, see infra note 85. For evidence that some Indian inventors do understand this feature of U.S. patent law and how it can benefit them, see Dutfield, supra, Appendix 1 (noting that since 1995 seven U.S. neem-related patents have been awarded to Indian nationals, six to Indian scientific institutions).

[FN9]. See India--Protection for Pharmaceutical and Agricultural Chemical Products, AB-1997-5 (WTO App. Body, 1997) (finding in favor of the U.S. and EU). Under TRIPS Art. 65(2), developing countries had until January 1, 2000 to implement most provisions of TRIPS, but under Art. 65(4), a developing country is entitled to an additional five years to implement product patent protection to areas of technology not theretofore protectable in its territory. That transitional period, however, is subject to TRIPS Articles 70(8), 70(9), which specify that where a Member does not make available on the date of entry into force of the WTO Agreement (i.e. January 1, 1995) patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under TRIPS Article 27, it shall provide a means by which applications can be filed for such inventions (the mailbox provision), and where the application is for a product that is the subject of a patent in another Member, shall provide "exclusive marketing rights" to the product for a period of five years after obtaining marketing approval in that country. See TRIPS Agreement, supra note 1, Articles 65, 70.

[FN10]. See, e.g., McManis, supra note 4, at 269-79; Nuno Pires de Carvalho, From the Shaman's Hut to the Patent Office: How Long and Winding is the Road?, 40 Rev. ABPI 3-38 [Review of the Brazilian Association of Intellectual Property] (May/June 1999) (Introduction and Part I); 41 Rev. ABPI 3-17 (July/Aug. 1999) (Part II) [hereinafter Carvalho, From the Shaman's Hut]; Michael Blakeney (ed.), Intellectual Property Aspects of Ethnobiology (1999) [hereinafter Blakeney (ed.)]; Downes, supra note 4; Dutfield, supra note 8; M. Spectar, Patent Necessity: Intellectual Property Dilemmas in the Biotech Domain & Treatment Equity for Developing Countries, 24 Hous. J. Int'l Law 227 (2002) [hereinafter Spectar, Patent Necessity]; Jim Chen, Reconciling Intellectual Property with Biological Diversity: A Blueprint for Effacing Humanity's Footprint, (forthcoming); Kerry ten Kate & Sarah A. Laird, The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit- Sharing (1999) [hereinafter ten Kate & Laird].

[FN11]. See Joshua P. Rosenthal, Drug Discovery, Economic Development and Conservation: The International Cooperative Biodiversity Groups, 37 Pharmaceutical Biology 5 (Supplement 1999) [hereinafter Rosenthal, ICBG].

[FN12]. See Joshua P. Rosenthal et al., Combining High Risk Science with Ambitious Social and Economic Goals, [hereinafter Rosenthal et al.] in Rosenthal, ICBG, supra note 11, at 6-7; see also Benefit Sharing Case Studies: Aristoclaus korupensis and Prunus Africana, Convention on Biological Diversity, Conference of the Parties, 4th Sess., United Nations Environment Programme, UNEP/CBD/COP/4/Inf. 25 (Apr. 20, 1998) [hereinafter UNEP Benefit Sharing Case Studies], at 41 (stating that the odds of developing a pharmaceutical products are estimated at 1 in 10,000 samples screened, and further noting that, in contrast to large-scale random screening of compounds, phytomedical research focusing on species of known interest and relying on traditional knowledge about the species increases the chances of product development per species).

[FN13]. Rosenthal et al., supra note 12, at 6, citing V.H. Heywood & R.T. Watson (eds.), Global Biodiversity Assessment (Cambridge University Press for the United Nations Environment Programme) (1995).

[FN14]. Doha WTO Ministerial 2001: Ministerial Declaration, WT/MIN(01)/ DEC/1, Nov. 20, 2001, adopted Nov. 14, 2001, para. 17 and 19; see also Doha WTO Ministerial 2001: Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/ DEC/2 (Nov. 20,2001, adopted Nov. 14, 2001), available at http:// www.wto.org (last visited May 3, 2002).

[FN15]. Id.

[FN16]. Id.

[FN17]. See http://www.wto.org/english/tratop_e/t_news_e.htm (last visited May 2, 2002).

[FN18]. Subsequent to the Doha Declaration, a fourth international agency, the World Health Organization, announced the launch of a global plan to help countries regulate traditional or alternative medicine and preserve and protect traditional medical knowledge. See "WHO Launches Global Strategy on Traditional and Alternative Medicine," May 16, 2002, at http://www.who.int/home-page/ (last visited May 28, 2002).

[FN19]. International Undertaking on Plant Genetic Resources [hereinafter International Undertaking], at http://www.fao.org/ag/cgrfa/IU.htm (last visited April 30, 2002).

[FN20]. Id.

[FN21]. International Treaty on Plant Genetic Resources for Food and Agriculture [hereinafter International Treaty], at http:// www.fao.org/ag/cgrfa/News.htm (last visited April

30, 2002). See infra notes 30-31 and accompanying text.

[FN22]. See infra note 40 and accompanying text.

[FN23]. See infra notes 48-50 and accompanying text. For extensive academic commentary on intellectual property aspects of bioprospecting and traditional knowledge protection, see Blakeney (ed.), supra note 10.

[FN24]. See generally Rosenthal, ICBG, supra note 11. See also infra notes 86-112 and accompanying text.

[FN25]. Id.

[FN26]. See infra notes 113-157 and accompanying text.

[FN27]. See infra notes 145-147and accompanying text.

[FN28]. International Undertaking, supra note 19, Art. 1.

[FN29]. Id. Agreed Interpretation of the International Undertaking, Annex I, Resolution 4/89, at 11-29, 25th Sess. of the FAO Conf. (Nov. 1989).

[FN30]. See International Convention for the Protection of New Varieties of Plants (UPOV), as revised at Geneva, 1991, reprinted in, International Treaties on Intellectual Property 48-64 (Marshall A. Leaffer ed., 1997) available at http://www.upov.int/eng/convntns/index.htm (last visited May 2, 2002).

[FN31]. International Undertaking, supra note 19, Annex I.

[FN32]. Id. See Farmers' Rights, Annex II, Res. 5/89, at 11-29, 25th Sess. of the FAO Conf. (Nov. 1989).

[FN33]. Id., Annex I.

[FN34]. Id., Annex III, Resolution 3/91, Twenty-sixth Session of the FAO Conference, Rome, 9-27, Nov. 1991.

[FN35]. International Undertaking, supra note 19, Art. 1.

[FN36]. Id.

[FN37]. Id.

[FN38]. CBD, supra note 2, Art. 1(Objectives). For a detailed discussion of the CBD and its relationship to the TRIPS Agreement, see McManis, supra note 4. For a more extended discussion of the CBD, the FAO Undertaking, and the Mataatua Declaration of the Cultural and Intellectual Property Rights of Indigenous Peoples, which was the outgrowth of the first international conference of the world's indigenous peoples, held in June 1993, see Michael Blakeney, The International Framework of Access to Plant Genetic Resources, in Blakeney (ed.), supra note 10.

[FN39]. Id., Art. 8 (In-situ Conservation); Article 9 (Ex-situ Conservation).

[FN40]. Id., Art. 8(j). This obligation, however, is subject to two qualifications that make it virtually meaningless. In-situ conservation is obligatory on member countries only "as far as possible and as appropriate," and the obligation of a member country to protect traditional knowledge is made "[s]ubject to [the member country's] national legislation ...."

[FN41]. See http://www.biodiv.org/programmes/socio- eco/traditional/default.asp (last visited June 3, 2002).

[FN42]. See http://www.biodiv.org/programmes/socio- eco/traditional/background.asp.

[FN43]. Id.

[FN44]. Id.

[FN45]. Id.

[FN46]. Id. The Relationship of the Convention on Biological Diversity with the Commission on Sustainable Development and Biodiversity-related Conventions, Other International Agreements, Institutions and Processes of Relevance, Conf. of the Parties Decision IV/15.

[FN47]. Id., Conf. of the Parties Decision IV/9, para. 16, V/16, para. 14.

[FN48]. See http://www.wipo.int/globalissues/igc/index.html.

[FN49]. Id.

[FN50]. WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore--An Overview, WIPO/GRTKF/IC/1/3 (Mar. 16, 2001) [hereinafter WIPO overview document].

[FN51]. See infra notes 52-53, 62, 66, 74 and accompanying text.

[FN52]. See WIPO, Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit- Sharing, WIPO/GRTKF/IC/2/3 (Sept. 10, 2001).

[FN53]. See WIPO, Progress Report on the Status of Traditional Knowledge as Prior Art, WIPO/GRTKF/IC/2/6 (July 1, 2001).

[FN54]. See, WIPO Overview Document, supra note 50, at 15-16; see also infra notes 78-84 and accompanying text.

[FN55]. Id. at 12.

[FN56]. Id. at 13.

[FN57]. Id. at 14.

[FN58]. See supra note 52.

[FN59]. See WIPO Overview Document, supra note 50, at 14.

[FN60]. Id.

[FN61]. Id.

[FN62]. WIPO, Possible Format for an Electronic Database of Contract Clauses and Practices Concerning Access to Genetic Resources and Benefit-Sharing, WIPO/GRTKF/IC/3/4 (not yet published), at http:// wwww.wipo.int/globalissues/igc/documents/index.html.

[FN63]. WIPO Overview Document, supra note 50, at 20.

[FN64]. Id.

[FN65]. Id. at 20-21.

[FN66]. Id. at 20-21. Cf. WIPO, Traditional Knowledge--Operational Definitions, WIPO/GRTKF/IC/3/9 (not yet published, but slated for discussion at the third meeting of the Intergovernmental Committee), available at http:// www.wipo.int/globalissues/igc/documents/index.html.

[FN67]. Id. at 21-23. For an example of a transnational intellectual property issue, see Dutfield, supra note 8, at 87 (Case Study 6.1 Could Basmati Rice be Protected by a Geographical Indication?)

[FN68]. Id. at 23. For a summary of different sui generis approaches, see Dutfield, supra note 8, at 79 (Box 6.2 Different Sui Generis Approaches), listing five possible approaches: 1) Intellectual property rights for communities (versus individual innovators); 2) community intellectual rights and collective rights to prevent usurpation by foreign interests; 3) modified plant variety protection (to include community or farmers' rights funds based on royalties on protected seeds, grace periods for filing on farmers' varieties, and exclusion of certain farmer-controlled plant varieties); 4) comprehensive biodiversity legislation governing access, biosafety, intellectual property rights and communal rights; and 5) sectoral community rights regimes for specific categories of biodiversity (e.g. medicinal plants and associated indigenous knowledge systems); see also infra note 69.

[FN69]. Id. at 23-25 (citing Convention Establishing the World Intellectual Property Organization, July 14, 1967, Art 2(viii), 1967), reprinted in International IP Treaties, supra note 30, at 564). The WIPO overview document specifically mentions as possible models for sui generis protection the UNESCO-WIPO Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions (1982); United Nations Environmental Programme, Possible Elements of Sui Generis Legislation to Protection the Knowledge, Innovations and Practices of Local and Indigenous Communities, UNEP/CBD/COP/5/8, Annex VI; and a number of national models developed by non-governmental organizations; see also Carvalho, From the Shaman's Hut, supra note 10, Part II (describing a proposal for a sui generis database system for the protection of traditional knowledge).

In an important recent development, Portugal, in Decree Law No. 118/2002, April 20, 2002, published in the Journal of the Republic on April 20, 2002, has established a sui generis intellectual property regime for the protection of traditional knowledge associated with plant genetic resources. The author is indebted to Dr. Nuno Pires de Carvalho, who is acknowledged at the outset of this article and is cited supra note 10 and infra notes 82-84 and accompanying text, for calling the author's attention to this development and providing an annotated English translation of portions of Decree Law No. 118/2002, which is attached as an Appendix to this article.

[FN70]. Id. at 25.

[FN71]. Id. at 26.

[FN72]. See supra note 53.

[FN73]. Id. at 22.

[FN74]. WIPO, Inventory of Traditional Knowledge-based Periodicals, Gazettes and Newsletters, WIPI/GRTKF/IC/35 (not yet published); WIPO, Inventory of Existing Online Databases Containing Traditional Knowledge Documentation Data (not yet published); WIPO, Review of Existing Intellectual Property Protection for Traditional Knowledge, WIPO/GRTKF/IC/3/7 (not yet published); and WIPO, Elements of a Sui Generis System for the Protection of Traditional Knowledge, WIPO/GRTKF/IC/3/8 (not yet published) available at http:// www.wipo.int/globalissues/igc/documents/index.html (last visited May 2, 2002).

[FN75]. WIPO Overview document, supra note 50, at 26.

[FN76]. Id. at 27.

[FN77]. Id.

[FN78]. See supra note 54 and accompanying text.

[FN79]. WIPO Overview document, supra note 50, at 15-16 (citing UNEP/CBD/COP/5/8, para. 125).

[FN80]. Id.

[FN81]. Id. at 16. TRIPS Article 27 specifies the subject matter of and standards for patent protection; Article 29 specifies the disclosure requirements that patent applicants are to meet; Article 32 requires opportunity for judicial review of any decision to revoke or forfeit a patent; and Article 62 specifies procedures for the acquisition and maintenance of intellectual property rights. See TRIPS Agreement, supra note 1, Arts. 27, 29, 32, 62.

[FN82]. Nuno Pires de Carvalho, Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing The TRIPS Agreement: The Problem and The Solution, 2 Wash. U. J. L. & Pol'y 371 (2000). Dr. Carvalho received his J.S.D degree from Washington University in 1993. The author was privileged to serve as Dr. Carvalho's dissertation advisor.

[FN83]. Id. at 379-89.

[FN84]. Id. at 389-401 See also Geertrui van Overwalle, Belgium Goes its Own Way on Biodiversity and Patents, 24 Eur. Intell. Prop. L. Rev. 233-34 (May 2002), who notes, 1) that Recital 27 of the E.U. Biotechnology Directive specifies that "if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known" and 2) that although Recital 27 adds that "this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents," and opinions apparently diverge as to the legal significance of recitals that are not duplicated in an article of an E.U. Directive, the Belgian government has nevertheless made the first move to implement an origin indication requirement in its patent law, having successively proposed to amend Belgian patent law to state that an invention is contrary to ordre publique and morality, within the meaning of Article 4 § 2 of the Belgian Patent Act of 1984, when it is developed on the basis of plant or animal material that is imported in violation of the law of the country of origin of the material (the first draft proposal) or collected or exported in breach of various articles of the CBD (the second draft proposal).

[FN85]. While the requirement in most national patent systems that patent applications be published eighteen months after they have been filed might expose non-compliant applications prior to issuance of a patent, the likelihood that developing countries or non-governmental organizations, to say nothing of indigenous or local communities, will have sufficient resources to systematically monitor patent publications around the world is not great, and the expense of challenging applications before a patent issues and the commercial value of the invention is known would in any event be an inefficient use of those resources. Moreover, under current U.S. patent law, see 35 U.S.C. § 122(b)(2)(B), pre-grant publication can itself be avoided by certifying that the invention disclosed in the application has not and will not be the subject of a patent application in another country or under a multilateral international agreement that requires publication eighteen months after filing. Thus, the U.S. pre-grant publication procedure will do little to expose "biopirates" intent on obtaining U.S. patent protection. It should also be noted that U.S. patent law, unlike many patent systems, does not utilize an "absolute novelty" rule for obtaining a patent, see 35 U.S.C. § 102(a), but specifically permits the patenting of inventions known or used in foreign countries, so long as the invention is not patented or disclosed in a printed publication in the U.S. or a foreign country, the aim being to encourage importation of technology into the U.S. Claims of "biopiracy" are sometimes based on a misunderstanding of this facet of U.S. patent law. See, e.g. supra note 8, discussing the neem patent controversy.

[FN86]. See generally Rosenthal et al., supra note 12.

[FN87]. Id. at 7, citing J. Schweitzer et al., Summary of the Workshop on Drug Development, Biological Diversity and Economic Growth, 83 J. Nat'l Cancer Inst. 1294-98 (1991).

[FN88]. Rosenthal et al., supra note 12, at 7.

[FN89]. Id. at 10.

[FN90]. Id.

[FN91]. For a description of these programs, see infra text accompanying notes 92-99. For a discussion of the project that was terminated see Rex Dalton, The Curtain Falls, 414 Nature 685 (2001) (reporting on the termination of the Maya ICBG project due to growing distrust among the Mexican collaborators after criticisms by the Rural Advancement Foundation International (RAFI), a non-governmental advocacy group, that the ICBG project's creative effort to communicate the project's purposes through drama was being used as a smokescreen to obscure the researchers' real objective-- namely commercialization); see also Joshua Rosenthal et al., The Curtain Has Fallen on Hopes of Legal Bioprospecting, 416 Nature 15 (2002) (pointing out certain inaccuracies in the earlier news report).

[FN92]. Rosenthal et al., supra note 12, at 10.

[FN93]. Id.

[FN94]. See Barbara N. Timmerman et al., The Latin-American ICBG: The First Five Years, in Rosenthal, ICBG, supra note 11, at 35.

[FN95]. See A. Sittenfeld et al., Costa Rican International Cooperative Biodiversity Group: Using Insects and Other Arthropods in Biodiversity Prospecting, in Rosenthal, ICBG, supra note 11, at 55.

[FN96]. Rosenthal et al., supra note 12, at 10.

[FN97]. Id; see also David G.I. Kingston et al., The Suriname International Cooperative Biodiversity Group Program: Lessons from the First Five Years, in Rosenthal, ICBG, supra note 11, at 22, 30-31 (reporting that, regrettably, it was not possible to reach a final conclusion on this question, in part due to the reluctance of the Saramaka people to allow open access to their ethnobotanical knowledge). However, the Suriname ICBG project was nevertheless sufficiently successful, overall, that it became one of the three original ICBG projects to be extended for another five years, and was even expanded to include bioprospecting in Madagascar, as well as Suriname. The Missouri Botanical Garden has been involved in this ICBG project from the outset.

[FN98]. See Walter H. Lewis et al., Peruvian Medicinal Plant Sources for New Pharmaceuticals (International Cooperative Biodiversity Group Peru), in Rosenthal, ICBG, supra note 11, at 69.

[FN99]. See Rosenthal et al., supra note 12, at 10.

[FN100]. Id.

[FN101]. Id.

[FN102]. Id. at 12. For a discussion of the "high risk" nature of pharmaceutical drug discovery, see generally Rosenthal et al., supra note 12 and accompanying text.

[FN103]. Id. at 13.

[FN104]. Id. at 15.

[FN105]. Id.

[FN106]. See, e.g., Andrew C. Revkin, Biologists Sought a Treaty; Now They Fault It, N.Y. Times, May 7, 2002, at D1 (reporting that the **Convention** on **Biological Diversity** has "spawned paralyzing biological bureaucracies built on the widespread belief that any scientist collecting samples--whether for a drug company or a dissertation--is bent on stealing genetic material and making a fortune," with the result that "in many tropical regions it is easier to cut a forest than to study it."). In response to such concerns, the Sixth Meeting of the Conference of the Parties of the CBD, held at The Hague, Netherlands, on April 7-19, 2002, adopted new guidelines designed in part to "improve the way foreign companies, collectors, researchers and other users gain access to valuable genetic resources in return for sharing the benefits with the countries of origin and with local and indigenous communities." See http://www.biodiv.org/doc/meetings/cop/cop-06/other/cop-06-pr-end-en.pdf.

[FN107]. Rosenthal et al., supra note 12, at 15-16.

[FN108]. See id. at 17; see also UNEP Benefit-Sharing Case Studies, supra note 12, at 41 (noting that while traditional knowledge serves as a direct lead for most new phytomedical product development, in the pharmaceutical industry the role of traditional knowledge tends to be more peripheral and supplementary, and that both industries tend to rely on literature and databases, thus severing the link between access and benefit-sharing).

[FN109]. Id.

[FN110]. Id. at 18.

[FN111]. Id.

[FN112]. Id.

[FN113]. Lewis et al., supra note 98, at 69.

[FN114]. Id.

[FN115]. Id. at 70.

[FN116]. Conversation with Dr. Walter H. Lewis (February 15, 2002).

[FN117]. See Lewis et al., supra note 98, at 70 (including the Organizacion Central de Comunidades Aguarunas del Alto Maranon (OCCAAM); Federacion Aguaruna del Rio Domingusa (FAD); Federacion de Comunidades Nativas Aguarunas del Rio Nieva (FECONARIN); and Organizacion Aguaruna del Alto Mayo (OAAM)).

[FN118]. Walter H. Lewis, Plants Used Medically by Indigenous People, in Phytochemical Resources for Medicine and Culture 33-74 (H.N. Nigg & D. Seigler eds., 1992).

[FN119]. Lewis et al., supra note 98, at 70 (citing Walter H. Lewis, Memory Elvin-Lewis, et al., Role of Systematics When Studying Medical Ethnobotany of the Tropical Peruvian Jivaro, in Systematic Botany--A Key Science for Tropical Research and Documentation 189-196 (I. Hedberg ed., 1988)).

[FN120]. Lewis et al., supra note 98, at 71 (citing Alwin H. Gentry, Tree Species Richness of Upper Amazonian Forests, 85 Proc. Nat'l Acad. Sci. U.S.A., 156-59 (1988)).

[FN121]. Lewis et al., supra note 98, at 71 (citing Lewis, Elvin-Lewis et al., supra note 112, and R.C. Gill, White Water and Black Magic 383 (1941)).

[FN122]. Id.

[FN123]. See, e.g., Kenneth Dewhurst, John Locke (1632-1704): Physician and Philosopher 58-60 (1963), noting that while traveling in France in 1678 the later celebrated philosopher and political theorist, John Locke, who was also a medical doctor, received a letter from another noted English physician, Dr. William Sydenham, giving him important details on the use of Peruvian bark in the treatment of agues (i.e., fevers), a treatment that had been introduced into England twenty years earlier as the "Jesuits' powder" and was in fact Cinchona, or Quinine. The slow acceptance of the bark as a specific remedy for agues in fever-ridden (but staunchly Protestant) England was apparently due not only to its association with the Jesuits but also its high cost, which led to the sale of many bogus preparations. Dewhurst also notes that much to Syndenham's annoyance, the apothecary, Sir Robert Talbot, used the bark as a secret remedy, but that Locke himself nevertheless prudently cut out the words "cortex Peru" from Sydenham's letter. No reference is made to any benefit- sharing arrangements with the native Peruvians originally supplying the bark, who in any event had been decimated in massacres and by imported diseases for which they had no immunity. See Jared Diamond, Guns, Germs, and Steel: The Fates of Human Societies 67-81 (1999).

[FN124]. See Lewis et al., supra note 98.

[FN125]. Id. at 71 (citing D. A. Van den Berghe, et al., Present Status and Prospects of Plant Products as Antiviral Agents, in Advances in Medicinal Plant Research 47-99 (A.J. Vlietinck & L. Van Hoof eds., 1985).

[FN126]. Id. (citing Michael J. Balick, Ethnobotany and the Identification of Therapeutic Agents from the Rainforest, in Bioactive Compounds from Plants 22-39 (D.J. Chadwick & J. Marsh eds., 1990).

[FN127]. Id. at 71.

[FN128]. Id. at 72.

[FN129]. Id.

[FN130]. Id.

[FN131]. Id.

[FN132]. Id. at 73. Redacted copies of these documents are on file with the author, who was privileged to sit in on the negotiation of the know-how license in 1995, and submitted a memo to the attorney representing G.D. Searle & Co., emphasizing the importance of demonstrating the value of ethnobotanical research and intellectual property protection in the developing world prior to the expiration of the developing world's transitional period for completing implementation of the patent provisions of the TRIPS Agreement. For a summary of the transitional provisions of TRIPS, see supra note 9.

[FN133]. Lewis et al., supra note 98, at 74, 80.

[FN134]. Id. at 74.

[FN135]. Id. at 73

[FN136]. Id.

[FN137]. Id.

[FN138]. Id.

[FN139]. Id.

[FN140]. For the Missouri Botanical Garden's involvement in the ICBG project in Suriname and Madagascar, see supra note 97. For its involvement in biodiversity prospecting projects elsewhere in Africa, see UNEP Benefit-Sharing Case Studies, supra note 12, at 6, 10-14; McManis, Biodiversity and Biotechnology, supra note 4, at 273.

[FN141]. See Lewis et al., supra note 98, at 73-74.

[FN142]. Id. at 73-74.

[FN143]. See supra notes 91, 97 and accompanying text. See also Dutfield, supra note 8, at 43 (Case Study 5.2 The Aguarunas and Their Know-how Agreement with Searle).

[FN144]. A copy of this application, with appropriate notice of its confidentiality, is on file with the author.

[FN145]. The provisional patent application was filed in order to preserve patent rights prior to the publication of the dissertation of one of the three co-inventors. Conversation with Dr. Walter H. Lewis, supra note 116. Publication of this dissertation will be sufficient under U.S. patent law to put any part of the invention disclosed therein into the public domain if a patent does not issue on the invention, see 35 U.S.C. § 102, and will in any event make the research available to interested academics and others. However, until the publication of the patent application or issuance of a patent, the invention may be entitled to a modicum of legal protection for any part of the invention that is not deemed to have become "publicly known or readily ascertainable" through publication of the dissertation. See generally Charles R. McManis, Intellectual Property and Unfair Competition in a Nutshell 324 (2000).

[FN146]. E-mails on file with the author.

[FN147]. Lewis et al., supra note 98, at 80-81.

[FN148]. Id. at 80.

[FN149]. Id.

[FN150]. Id. at 81.

[FN151]. Id.

[FN152]. Id.

[FN153]. Id.

[FN154]. Id. at 81-82.

[FN155]. Id. at 82.

[FN156]. Id.

[FN157]. Rosenthal et al., supra note 12, at 19.

[FN158]. Id.

[FN159]. Id.

[FN160]. For a summary of the high-profile activities of this company, which has relied primarily on collaborative agreements with indigenous and local communities, see McManis, Biodiversity and Biotechnology, supra note 4, at 272, 275, and authorities cited therein. See also Donald E. Bierer, Thomas J. Carlson & Steven R. King, Shaman Pharmaceuticals: Integrating Indigenous Knowledge, Tropical Medicinal Plants, Medicine, Modern Science and Reciprocity into a Novel Drug Discovery Approach (May 1996), at http://netsci.org/Science/Special/feature11.html (last visited May 28, 2002). But cf. Yahoo Market Guide, at http://biz.yahoo.com/p/s/shph.ob.html, which in its Expanded Market Guide on Shaman Pharmaceuticals, notes that on January 5, 2001, Shaman filed a Chapter 11 reorganization petition for protection under federal bankruptcy law in the United States Bankruptcy Court, Northern District of California. As a part of the reorganization, Shaman has petitioned the court to sell certain of the tangible and intellectual property assets of the company to generate sufficient funds to pay existing, qualified creditors.

[FN161]. See Rosenthal et al., supra note 12, at 19 (noting that the downturn in Shaman's fortunes occurred when, contrary to expectations of Shaman scientists and management, the U.S. Food and Drug Administration ruled that the number of patients in the phase II trials of their antiviral agent, SP-303, had to be doubled after the first 400 cases were reviewed).

[FN162]. The report notes that some evidence to the contrary was provided by an announcement later in 1999 that Glaxo Wellcome had signed a $3 million agreement with a Brazilian company, Extracta, to receive a wide variety of plant, animal and microorganism samples for screening, some identified by ethnomedical knowledge. See Rosenthal et al., supra note 12, at 19. See also Ten Kate & Laird, supra note 10, at 253-257, describing the research agreements between the Costa Rican National Biodiversity Institute (INBio), a non-profit organization established by the Costa Rican Ministry of Environment and Energy (MINAE) whose mission is to save, know, and use Costa Rican biodiversity, and a number of companies, including Merck and Co. (signed in 1991); Bristol-Myers Squibb (1993); the Swiss-U.S. company Givaudane Roure for the development of new fragrances (1994); the Italian manufacturer INDENA for the development of new phytochemicals and phytomedicine (1996); the German service and contract research company Analyticon (1996); the Costa Rican company La Pacifica and the British Technology Group for the development and possible commercialization of a bio-nematicide from a tropical legume (1994); the U.S. biotech company, Phytera for the development of cell cultures from plants; and the U.S. biotech company, Diversa Corporation (formerly Recombinant Biocatalysis, Inc.) (1995, renewed and expanded in 1998). To date, these bioprospecting agreements have contributed more than $2.5 million to MINAE, Costa Rican conservation areas, public universities, and other groups at INBio, particularly its Inventory Program. Id.

[FN163]. Rosenthal et al., supra note 12, at 19.

[FN164]. UNEP Benefit Sharing Case Studies, supra note 12, at 31. See also ten Kate & Laird, supra note 10, at 78-79 (noting that the botanical medicine industry, which is part of

the larger dietary supplements market, is experiencing rapid growth world-wide, with annual growth rates of 10-20% in most countries) and 262 (noting that the "natural" personal care and cosmetics market is likewise growing rapidly, with estimated average annual growth of 8-25%).

[FN165]. UNEP Benefit Sharing Case Studies, supra note 12, at 31.

[FN166]. Id. at 33.

[FN167]. Id. See supra note 18, noting that the World Health Organization recently announced the launch of a global plan to help developing countries regulate traditional or alternative medicine and preserve and protect traditional medical knowledge.

[FN168]. See, e.g., WHO to Address Trade and Pharmaceuticals (May 22, 1999), at http://www.who.int/inf-pr-1999/en/pr99-wha13.html (noting that some states "fear that TRIPS requirements for intellectual property rights could lead to a higher cost burden for newer, patent-protected essential drugs," quoted in David P. Fidler, Neither Science nor Shamans: Globalization of Markets and Health in the Developing World, 7 Ind. J. Global Legal Stud. 191, 210 (1999). See generally Spectar, Patent Necessity, supra note 10. For a discussion of the TRIPS transitional provisions, see supra note 9.

[FN169]. See supra note 107 and accompanying text.

[FN170]. See supra note 108 and accompanying text; see also supra note 162, detailing the successful bioprospecting efforts of the Costa Rican non-profit research organization, INBio.

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