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Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally*

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One of the great questions of our time is how to promote global economic development, while at the same time 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),[1] which is one of a bundle of agreements concluded in 1993 as a result of the Uruguay Round of Multilateral Trade Negotiations and is now administered by the World Trade Organization (WTO), member countries of the predecessor 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 (or CBD),[2] which was concluded at the 1992 "Earth Summit" in Rio de Janeiro and has now been ratified by more than 175 countries,[3] 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 sharing 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 in the Northern Hemisphere, and the biodiversity-rich developing countries located primarily in the tropics and Southern Hemisphere.[4] For example, the United States initially refused to sign (and still has not ratified) the CBD, complaining that the CBD would impair American intellectual property rights and conceives intellectual property rights "as a constraint to the transfer of technology rather than as a prerequisite."[5] 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 products and microbiological products and processes, and that plant varieties are to be protected by patents or an effective sui generis system of protection.[6] The demonstrators argued for collective, not individual control over seeds and plants,[7] and 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.[8] 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, complaining 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.[9]

Notwithstanding these North-South conflicts, however, 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.[10] Embodied in the concept and practice of "bioprospecting,"[11] 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;[12] yet, many developing countries are currently making unsustainable use of their natural resources, as a result of which it is estimated that .25% of the world's biodiversity is lost to extinction each year due to tropical deforestation alone, at which rate, it has been estimated that up to 10% of the world's species will be extinct within 25 years.[13] To ease the pressures that are contributing 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," which 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, giving particular attention to the protection of traditional knowledge and folklore, and taking into account the stated objective of TRIPS to contribute to the promotion of technological innovation and to the transfer of 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.[14] 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.[15]

The WTO is only the latest international organization to address the interface between biotechnology and biodiversity, and will, in fact, be working with at least three other international organizations as the TRIPS Council implements the Doha Declaration. 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), which was designed as an instrument to promote international harmony in matters regarding access to plant genetic resources for food and agriculture, and now has been adhered to by one hundred and thirteen countries.[16] In November 2001, after several years of negotiations to revise the International Undertaking in harmony with the CBD and transform it into a legally binding instrument, the FAO adopted the International Treaty on Plant Genetic Resources for Food and Agriculture, which will enter into force when ratified by at least forty states.[17] Whereas the International Undertaking embraced the principle 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,"[18] subsequent FAO resolutions annexed to the Undertaking recognized that plant breeders' rights, as provided for by the International Union for the Protection of New Varieties of Plants (UPOV),[19] were not inconsistent with the Undertaking, while at the same time recognizing farmers' rights and (in apparent anticipation of the CBD) the sovereign rights of nations over their genetic resources.[20] The new International Treaty abandons the "common heritage of mankind" language altogether and focuses, rather, on farmers' rights, access to genetic resources, and benefit-sharing.[21]

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 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 biological diversity; 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. [22] Likewise, the World Intellectual Property Organization (WIPO), which is the specialized U.N. agency responsible for the promotion of intellectual property, has established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, the purpose of which is to facilitate discussion of intellectual property issues that arise in the context of 1) access to genetic resources and benefit-sharing, 2) protection of traditional knowledge, innovations and creativity, and 3) protection of expressions of folklore.[23]

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, which has provided support for a variety of multidisciplinary international partnerships among research institutions, companies, communities and non-governmental organizations to address a complex set of research, development and conservation efforts in twelve developing countries, the United States and the United Kingdom.[24]

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.[25] This project represents a milestone in the evolution of intellectual property protection for traditional knowledge and genetic resources for two interrelated reasons. The ICBG project produced both 1) 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; and 2) a provisional patent application which discloses a compound discovered by means of the disclosure of this know-how and found to inhibit the protozoan responsible for the most serious types of malaria, and 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 individuals, but also names the confederation of indigenous peoples along with the three universities as assignees (i.e. co-owners) of the patent application.[26] These two interrelated outgrowths of the IGBG-Peru Projects could well be the first local embodiment of the current global thinking about how international intellectual property 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 Undertaking to its recently promulgated International Treaty on Plant Genetic Resources for Food and Agriculture, illustrates the evolution 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."[27] By 1989, however, a resolution of the FAO, entitled "Agreed Interpretation of the International Undertaking" and included as Annex I of the Undertaking, 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.[28] 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.

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,"[29] the 1989 resolution recognized the need to balance the rights of plant breeders (formal innovators) and farmers (informal innovators). The resolution thus explicitly recognized that 1) plant breeders' rights were not incompatible with the Undertaking; 2) 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[30]) 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 3) that the term "free access," as used in the Undertaking, does not mean free of charge.[31] By 1991, in apparent 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, nevertheless endorsed the point that nations have sovereign rights over their plant genetic resources.[32]

The new International Treaty on Plant Genetic Resources for Food and Agriculture abandons the "common heritage of mankind" language altogether and instead 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.[33] The Treaty recognizes that these objectives will be achieved by closely linking the Treaty, not only to the FAO, but also to the CBD.[34] 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 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; while Parts IV and V of the Treaty lay out an elaborate multilateral system of access and benefit-sharing and supporting components for same.[35] 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.[36] 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.[37] Among the measures listed in Article 8 for promoting in-situ conservation is the requirement contained in Article 8(j), which 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. [38]

To that end, the CBD Conference of the Parties (COP) established a Working Group to address the implementation of Article 8(j).[39] 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.[40] The first phase of the Programme of Work will focus on specific tasks for implementing the first, fourth, sixth, and seventh elements of the Programme.[41] 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.[42] The Working group was due to hold its second meeting in Montreal, Canada, in February of 2002.[43]

The COP has 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.[44] To that end, the COP has invited both WIPO and WTO to explore the relationship between the TRIPS Agreement and the CBD.[45]

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 26 to October 3, 2000, the WIPO General Assembly established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.[46] The Intergovernmental Committee met twice in 2001 and is scheduled to meet a third time in June of 2002.[47] 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 that the Committee is to discuss, and includes specific tasks that the Committee might wish to consider with respect to intellectual property issues that relate to access to genetic resources and benefit-sharing, and the protection of traditional knowledge, innovations and creativity.[48] For the Committee's second and third meetings, the Secretariat has prepared a number of follow-up documents on specific tasks about which consensus developed at the Committee's first meeting.[49]

The first task that the Committee will take up is the development of “guide contractual practices” guidelines and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing.[50] The second set of tasks that the Committee will address is concerned with the protection of traditional knowledge and its status as prior art in existing patent systems.[51] A third, more controversial set of tasks, about which no consensus has as yet been reached, relate 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 the providers of same, that will facilitate access to genetic resources and benefit-sharing.[52]

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.[53] 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).[54] 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 do not necessarily have the expertise to develop technically accurate clauses that balance public policy objectives and the private interests of various stakeholders.[55]

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.”[56] This document 1) describes the most important categories of public policy frameworks which are relevant to contractual agreements for access and benefit-sharing; 2) 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; and 3) articulates certain operational principles for the development of guide contractual clauses.[57] On the agenda for discussion at the Intergovernmental Committee’s third meeting in June 2002 is yet another WIPO document suggesting possible format for a database of contractual practices and clauses relating to intellectual property, access to genetic resources and benefit-sharing.[58]

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.[59] 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.[60] 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, noting 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.[61] The document goes on to identify four conceptual issues that will 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 dealing with legal and administrative problems created by "regional [i.e. transnational] traditional knowledge."[62]

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.[63] The WIPO overview document summarizes the existing forms of intellectual property protection currently available for traditional knowledge, 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."[64]

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.[65] The WIPO overview document suggests that Member States may wish to consider revising existing criteria and developing new criteria that would allow the effective integration of traditional knowledge documentation into searchable prior art.[66] To that end, the WIPO Secretariat has produced a follow-up document, entitled "Progress Report on the Status of Traditional Knowledge as Prior Art."[67] This document suggests a number of practical ways for responding to the current inability of patent examiners to discover relevant traditional knowledge already in the public domain as prior art when they examine patent applications. These include 1) compiling and prioritizing an inventory of existing traditional knowledge-related periodicals that document and disclose 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 2) creating an electronic exchange of public domain traditional knowledge documentation data through online databases and digital libraries.[68] On the agenda for discussion at the Intergovernmental Committee's third meeting in June 2002 are 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.[69]

The fourth and final category of issues relate to the enforcement of rights in traditional knowledge.[70] The WIPO overview document notes that the most urgent need in this regard is to reduce the transaction costs for enforcement of those rights, as the current mechanisms for enforcement are prohibitively expensive and complicated.[71] The document specifically notes that the few Legal Aid organizations that exist to represent traditional knowledge holders have difficulty raising funds for cases concerning intellectual property and suggests possible institutional structures for a coordinated exercise and enforcement of rights in traditional knowledge.[72]

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 that might regulate and facilitate access to genetic resources and benefit-sharing.[73] 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—1) the use of intellectual property rights as a mechanism "to support, in user countries, prior informed consent requirements in provider countries;" and 2) the recording of interests in inventions that arise from access to or use of genetic resources.[74]

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 put forward in a number of 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.[75] These include 1) whether the requirement would also apply when the invention concerns synthesized substances that were isolated or derived from active compounds of an accessed genetic resource and, if so, what should be meant by "derived;" 2) whether and how the requirement would apply for genetic resources accessed from multilateral systems for facilitated access to genetic resources, which may be established in the agricultural sector; and 3) what would be the consequences of non-compliance with the requirement, ranging from fines to invalidation or revocation of the patent.[76] 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.[77]

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.[78] 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,[79] such a requirement could be made a condition for enforcement of patent rights, utilizing well established equitable doctrines of unclean hands and fraudulent procurement.[80] As a practical matter, non-compliance with any particular disclosure and prior informed consent requirements will likely only be discovered once a patent issues and enforcement is sought in any event. By addressing non-compliance with disclosure and informed consent requirements at the enforcement of rights, rather than the acquisition of rights, stage of the patent process, patent systems will be able to concentrate on scrutinizing the minority of issued patents that turn out to have real economic value.

So much, then, for 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 (ICBG) Program

An illustration of how the foregoing global thinking can be acted upon locally is to be found in the International Cooperative Biodiversity Groups (ICBG) Program, an experimental program funded by the U.S. Government through the National Institutes of Health, the National Science Foundation, and the Department of Agriculture, which supports multidisciplinary international partnerships among research institutions, companies, communities and non-governmental organizations to carry out a complex set of research, development and conservation efforts in twelve developing countries, the United States and the United Kingdom.[81] The ICBG program is said to be one of the first large-scale and coordinated efforts to implement the access and benefit-sharing objectives of the CBD in specific projects.[82]

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 conservation and economic growth.[83] 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 Agricultural) requested proposals to establish multidisciplinary projects addressing these objectives. [84] According to the terms of the request, proposals were required to address each of the foregoing 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.[85] 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. The panel strongly endorsed the concept of the program and made a number of specific proposals for improving it, including broadening the research to include agricultural research, whereupon a second cycle of five-year funding awards occurred, renewing three of the initial projects and including three new ones, one of which subsequently became embroiled in controversy and was eventually terminated.[86]

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 have involved at least some work with terrestrial plants (largely in and from tropical forests), all have conducted research in multiple disease areas simultaneously, most have involved an ethnomedical component in their field efforts, and most include collaboration with at least one industrial partner that finances its own research and development activities.[87] Together, 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, and anthropologist, a plant taxonomist, and an ethnobotanist.[88] One project, the University of Arizona-Latin America ICBG, is working entirely in arid and semiarid areas.[89] Another, the Cornell University-Costa Rica ICBG, focused primarily on insects and other arthropods.[90] Two projects (the Cornell-Costa Rica ICBG and the Smithsonian-Panama ICBG) focused their field work primarily on

ecological cues regarding chemistry.[91] The Suriname ICBG sought to compare the success rate of ethnobotanical and random collection strategies,[92] while the ICBG-Peru project relied primarily on ethnobotanical prescreening.[93] 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.[94]

Together, the groups have collected over 11,000 samples from some 5800 species of plants, 550 species of insects, and 500 species of fungi.[95] At least 260 compounds of interest have been isolated in the first six years of the project, of which approximately 50 are novel and 25 are considered active leads, and while compounds have been studied in animals in at least six therapeutic areas, none has as yet reached clinical trials.[96] Over 1400 persons have received formal training through the program, 90% of which represent developing country participants and 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.[97] The governments of a number of the developing countries involved (i.e., Mexico, Argentina, Chile, Peru, and Suriname) have used the ICBG projects as testing ground for their developing policies on access and benefit-sharing.[98]

The comprehensive report on the project 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 supports the objectives of the CBD.[99] From the experience gained thus far, the report draws the following additional conclusions: 1) While business and legal issues are ever-present, 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; 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.[100] 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 by the industrial partners, and traditional knowledge 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.[101]

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 multimillion dollar investment necessary to bring a derivative to late development clinical trials.[102] 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, 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 project and none is expected, as natural products research for discovery of pharmaceutical and crop protection agents rarely involve patents on living organisms.[104] 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.[105] A concrete example of that policy approach is to be found in the ICBG-Peru project.

B. The ICBG-Peru Project

The stated purpose of the now 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.[106] The focus of the research has been both on globally important diseases and syndromes and maladies of serious concern in Peru.[107]

ICBG-Peru originated as a partnership consisting of three universities, a corporate partner, and an indigenous organization.[108] The Principal Investigator is Dr. Walter H. Lewis, Professor of Biology at Washington University in St. Louis, Missouri, U.S.A., 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. While the corporate partner, G.D. Searle & Company, a division of Monsanto Company, headquartered in St. Louis, Missouri, U.S.A., was eventually forced to withdraw from the ICBG-Peru project due to the acquisition of the Monsanto Company by Pharmacia, Inc., [109] it did so only after completing all of the annual know-how royalty and milestone payments that it was contractually obligated to make to the final member of the partnership, the Confederacion de Nationalidades Amazonicas del Peru (CONAP): Administration for and advisor of Aguaruna Jivaro organizations and people; Cesar Sarasara (President). Included within this confederation are four organizations of Aguaruna communities and peoples.[110]

In 1992, Dr. Lewis had outlined by medical category several hundred plants currently used in modern medicine and pharmacy that have also been used medically by indigenous peoples.[111] He and his wife, Dr. Memory Elvin-Lewis, who is a Professor of Microbiology and Ethnobotany in Biomedicine in the Biology Department of Washington University, and others had also shown how the culturally intact South American Jivaros use plants now as they have for perhaps thousands of years,[112] selected from a highly diverse vegetation that is said to represent one of the richest in the world for woody plants.[113] The Jivaros are said to have provided western medicine with the benefits of curare as far back as the late 1930s, by supplying Squibb & Sons, New York, with crude bark extracts of Chondrodenron and Curarea (Menispermaceae), from which the active alkaloid tubocurarine was isolated, and which, in turn, revolutionized modern anesthesiology and major surgery.[114] Equally, if not more significant, according to Lewis and Elvin-Lewis, was the Jivaros' early use of quinine bark from Chinchona (Rubiaceae) to treat malaria[115]—a native treatment that received widespread notice in Europe as far back as the sixteenth and seventeenth century.[116]

In their report on the ICBG-Peru project,[117] 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 of active leads, even though in some cases the same active compounds were isolated from botanically unrelated active plants,[118] and 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.[119]

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, and that 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.[120] 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 to his knowledge never been studied for antimalarial or any other biological activity and its chemistry remains unknown.[121] 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.[122] 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 to further development of and commercialization of antimalarials or other therapeutics.[123]

The legal basis for ICBG-Peru project is a set of interconnected agreements that include: 1) the basic Biological Collecting Agreement, which outlines who is involved in the program, where collecting can occur and under what circumstances, 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, providing 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.[124] 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 make small grants to ensure the development of new conservation and sustainable development projects within the Aguaruna communities.[125] Milestone payments are specified for each potential commercial product during specified research and development phases, and royalties based on net sales are specified should a commercial product be 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.[126]

The report on the ICBG-Peru project emphasizes 1) that these project documents explicitly recognize that the medicinal plant knowledge disclosed by the collaborating Aguaruna peoples is valuable know-

how owned by them, and that it represents a cultural legacy that needs to be wisely and responsibly used for the benefit of their people now and in the future; 2) that all know-how has been disclosed subject to prior informed consent and is retained in confidence; and 3) that should such 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., which will name individual Aguarunas as inventors where possible and will, in any event, recognize the Aguarunas as contributors to the invention.[127] 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, and 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[128]) and researched for non-commercial purposes at national and international depositories, 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.[129]

It is a testament to Dr. Lewis's perseverance that he not only succeeded in negotiating and implementing a know-how agreement with traditional knowledge holders while two other ICBG projects did not,[130] 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 and Trademark Office that disclosed certain antiplasmodial compounds from American plants that effectively inhibit in vitro the leading cause of malaria, and named the confederation of participating Aguaruna communities and organizations, along with the three participating universities, as assignees (i.e., co-owners) of the application.[131] While the details of the patent application must remain confidential for the moment,[132] the inventors and their employer, Washington University, have consented to the disclosure of the existence and general nature of the patent application.[133]

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.[134] These efforts included training Aguaruna individuals to raise plants in nurseries and to plant tree seeds and seedlings in secondary forest plots, including an important medicinal plant, sangre de grado (Croton lecheri), which was planted by two Aguaruna communities in disturbed forest areas, while another community established a committee to grow various antimalarial plants, some of which are now rare in the region due to local overexploitation.[135] 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.[136] In addition to two workshops, which were conducted in Lima to discuss and explain the ICBG agreements, ICBG personnel trained numerous 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.[137] During the course of the project, 10 graduate students and 16 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 subsequently following.[138]

The report concludes that the ICBG-Peru project has been a successful effort in large part because of the strong collaborative effort of all parties made possible through fair and ethical agreements forged by the partners and because of a commitment to discover new pharmaceuticals with the guidance of the

Aguaruna people.[139] While more research must be completed before any commercial products could 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.[140] 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.[141] Without the Aguaruna ethnobotanical data, the ICGB-Peru report estimates that it would have taken decades, at least, to identify the antimalarial species that the ICBG-Peru project accomplished in months.[142]

V. Conclusion

The comprehensive report on the 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.[143] It notes that the success of bioprospecting is integrally related to scientific interest and commercial success of natural product derivatives, the perceived value of which seems to wax and wane 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.[144] While combinatorial chemistry was supposed to be the latest replacement technology for natural products, the report notes that very few important leads have been generated by that technology to date, prompting some scientists and organizations to look for ways to integrate this technology and rational drug design generally with natural product leads to optimize results.[145]

The report concedes that when the high profile bioprospecting efforts on the part of Shaman Pharmaceuticals, Inc.[146] took a significant downturn in 1999,[147] 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,[148] but notes that 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.[149] The ICBG report was 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.[150] 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.[151] 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.[152] 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.[153] If implementation of the patent requirements of the TRIPS Agreement turns out to result in dramatic increases in the price of pharmaceuticals in developing countries, as it inevitably must, this will undoubtedly only intensify these efforts.

In any event, valuing either traditional knowledge or 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 effort, which succeeds best when treated as such.[154] 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.[155]

Moreover, filtering traditional knowledge through the medium of academic research may turn out to be in the best interests of traditional knowledge holders themselves. As the ICBG program illustrates, academic researchers seem to be well situated to play a mediating role between indigenous or local communities and the global marketplace, and have in fact already played an instrumental role in the implementing the CBD's goals of promoting the conservation and sustainable use of biodiversity and the fair and equitable sharing of the benefits arising out of its utilization.

In any event, the foregoing comparison of the current global thinking on the relationship of intellectual property, genetic resources and traditional knowledge protection with such local research and development activities as those initiated under the auspices of the ICBG project tends to confirm that the interface between biodiversity and biotechnology is indeed one of interdependence and not simply one of fundamental conflict.

* 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).

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[1]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.

[2] 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).

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

[4]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, Biodiversity and Biotechnology] and sources cited therein.

[5] Id. at 256, quoting U.S. State Department Dispatch, Convention on Biological Diversity, in 3 U.S. Dispatch 423 (1992).

[6] See TRIPS Agreement, supra note 1, Article 27.

[7] McManis, Biodiversity and Biotechnology, supra note 4, at 257.

[8] Id. at 257-58. For recent examples of "gene piracy," see Graham Dutfield, Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties [hereinafter Dutfield] at 65 (Case Study 5.4 The Tumeric Patent), 67 (Case Study 5.6 The Quinoa Patent)(1999). For an early example, see infra note 116.

[9] India—Protection for Pharmaceutical and Agricultural Chemical Products, AB-1997-5 (WTO App. Body, 1997).

[10] McManis, Biodiversity and Biotechnology, supra note 4, at 269-79. See also Michael Blakeney (ed.), Intellectual Property Aspects of Ethnobiology (1999)[hereinafter Blakeney (ed.)]; Dutfield, supra note 8.

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

[12] 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 United Nations Environment Programme, Benefit Sharing Case Studies:Aristoclaus korupensis and Prunus Africana, UNEP/CBD/COP/4/Inf. 25, April 20, 1998 [hereinafter UNEP Benefit Sharing Case Studies], at 41 (stating that the odds of developing pharmaceutical products are estimated at 1 in 10,000 samples screened, and going on to note that, in contrast to large-scale random screening of compounds, where phytomedical research focuses on species of known interest and relies on traditional knowledge about the species, the chances of product development per species is greater. See, e.g. infra notes 118-19 and accompanying text.

[13] 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).

[14] Doha WTO Ministerial 2001: Ministerial Declaration, WT/MIN(01)/DEC/1, Nov. 20, 2001, adopted Nov. 14, 2001, ¶¶ 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. Both documents are available at http://www.wto.org (last visited May 3, 2002).

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

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

[17] International Treaty on Plant Genetic Resources for Food and Agriculture [hereinafter International Treaty], available at http://www.fao.org/ag/cgrfa/News.htm (last visited April 30,2002).

[18] See infra notes 27-29 and accompanying text.

[19] International Convention for the Protection of New Varieties of Plants (UPOV), as revised at Geneva, 1978, reprinted in International Treaties on Intellectual Property 48-64 (Marshall A. Leaffer, ed., 1997)[hereinafter International IP Treaties]. See also http://www.upov.int/index_en.html (last visited May 2, 2002).

[20] See infra note 32 and accompanying text.

[21] See infra note 33 and accompanying text.

[22] See infra note 38 and accompanying text.

[23] See infra note 46 and accompanying text. For extensive academic commentary on intellectual property aspects of bioprospecting and traditional knowledge protection, see Blakeney (ed.), supra note 10.

[24] See generally Rosenthal, ICBG, supra note 11. See also infra notes 81-105 and accompanying text.

[25] See infra notes 108--110 and accompanying text.

[26] See infra notes 124-133 and accompanying text.

[27] International Undertaking, supra note 16, Article 1.

[28] Id., Annex I, Resolution 4/89, Agreed Interpretation of the International Undertaking, Twenty-fifth Session of the FAO Conference, Rome, 11-29, Nov. 1989.

[29] Id.

[30] Id., Annex II, Resolution 5/89, Farmers' Rights, Twenty-fifth Session of the FAO Conference, Rome, 11-29, Nov. 1989.

[31] Id., Annex I.

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

[33] International Treaty, supra note 17, Article 1.

[34] Id.

[35] Id.

[36] CBD, supra note 2, Article 1(Objectives). For a detailed discussion of the CBD and its relationship to the TRIPS Agreement, see McManis, Biodiversity and Biotechnology, 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.

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

[38] Id. Article 8(j)

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

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

[41] Id.

[42] Id.

[43] Id.

[44] Id., Conference of the Parties Decision IV/15, 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.

[45] Id., Conference of the Parties Decisions IV/9, ¶ 16 (invitation to WIPO), and V/16, ¶ 14 (invitation to WTO).

[46] See http://www.wipo.int/tk/en/igc.

[47] Id.

[48] WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore—An Overview, WIPO/GRTKF/IC/1/3, March 16, 2001[hereinafter WIPO overview document].

[49] See infra notes 50-52, 56-57, 61, 67-69 and accompanying text.

[50] 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.

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

[52] See WIPO overview document, supra note 48, at 15-16. See also infra notes 73-80 and accompanying text.

[53] Id. at 12.

[54] Id. at 13.

[55] Id. at 14.

[56] See supra note 50.

[57] Id.

[58] 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).

[59] WIPO overview document, supra note 48, at 20.

[60] Id.

[61] 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), as noted at http://wwww.wipo.int/meetings/en/archive.asp.

[62] 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?)

[63] Id. at 23. For a summary of different sui generis approaches, see also Dutfield, supra note 8, at 79 (Box 6.2 Different Sui Generis Approaches), listing five possible approaches: 1) Intellectual property rights for communities; 2) community rights and collective rights; 3) modified plant variety protection; 4) comprehensive biodiversity legislation; and 5) sectoral community rights regimes (e.g. for medicinal plants).

[64] Id. at 23-25, citing Convention Establishing the World Intellectual Property Organization, signed at Stockholm, July 14, 1967, Article 2(viii), reprinted in International IP Treaties, supra note 19, 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.

[65] Id. at 25.

[66] Id. at 26.

[67] See supra note 51.

[68] Id. at 22.

[69] 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).

[70] WIPO overview document, supra note 48, at 26.

[71]Id.at 27.

[72] Id.

[73] See supra note 52 and accompanying text.

[74] WIPO overview document, supra note 48, at 15, citing UNEP/CBD/COP/5/8, ¶ 125.

[75] Id.

[76] Id. at15-16.

[77] Id. at 16.

[78] 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 & Policy 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.

[79] Id. at 379-89.

[80] Id. at 389-401.

[81] See Rosenthal, ICBG, supra note 11, at 5. See also http://www.fic.nih.gov/programs/research_grants/icbg/ (last visited January 20, 2010).

[82] Rosenthal et al., supra note 12, at 15.

[83] 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).

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

[85] Id. at 10.

[86] See Rex Dalton, The Curtain Falls, 414 Nature 685 (2001) (reporting on the termination of the Maya ICBG project growing distrust among the Mexican collaborators after criticisms by the Rural Advancment 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—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).

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

[88] Id.

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

[90] 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.

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

[92] 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. Id.

[93] 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.

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

[95] Id.

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

[97] Id. at 13.

[98] Id. at 15.

[99] Id.

[100] Id. at 15-16. See supra note 12 and accompanying text.

[101] 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 its role 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).

[102] Id.

[104] Rosenthal et al., supra note 12, at 18.

[105] Id.

[106] Lewis et al., supra note 93, at 69.

[107] Id.

[108] Id. at 70.

[109] Related by Dr. Walter H. Lewis in a conversation with the author, February 15, 2002.

[110] These include the Organizacion Central de Comunidades Aguarunas del Alto Maranon (OCCAAM); Federacion Aguaruna del Rio Domingusa (FAD); Federacion de Cominidades Nativas Aguarunas del Rio Nieva (FECONARIN); and Organizacion Aguaruna del Alto Mayo (OAAM). Lewisn et al., supra note 93, at 70.

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

[112] Lewis et al., supra note 93, at 70, citing Walter H. Lewis, Memory Elvin-Lewis, et al., Role of Systematics When Studying Medical Ethnobotany of the Tropical Peruvian Jivaro, in I. Hedberg, (ed.), Systematic Botany—A Key Science for Tropical Research and Documentation 189-196 (1988).

[113] Lewis et al., supra note 93, 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).

[114] Lewiset al., supra note 93, at 71, citing Lewis, Elvin-Lewis et al., supra note 112, and R.C. Gill, White Water and Black Magic 383 (1941).

[115] Lewis et al., supra note 93, at 71.

[116] See, e.g., Kenneth Dewhurst, John Locke (1632-1704): Physician and Philosopher 58-60 (1963) who notes 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. Dewhurst notes that the slow acceptance of the bark as a specific remedy for agues in fever-ridden England was not only its association with the Jesuits but also its high cost, which led to the sale of many bogus preparations. Dewhurst also notes that the apothecary, Sir Robert Talbot, used the bark as a secret remedy, much to Sydenham's annoyance, but that Locke prudently cut out the words, "cortex Peru" from Sydenham's letter. No mention is made of any particular benefit-sharing arrangements with the native Peruvians who had originally supplied this 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).

[117] See Lewis et al., supra note 93.

[118] Lewis et al., supra note 93, at 71, citing D. A. Van den Berghe, et al., Present Status and Prospects of Plant Prouducts as Antiviral Agents, in A.J. Vlietinck & L. Van Hoof (eds.), Advances in Medicinal Plant Research 47-99 (1985).

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

[120] Id. at 72.

[121] Id.

[122] Id.

[123] Id.

[124] 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 for G.D. Searle & Co. emphasizing the importance to Searle and the U.S. pharmaceutical industry generally of demonstrating support for ethnobotanical research 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.

[125] Id. at 74, 80.

[126] Lewis et al., supra note 93, at 74.

[127] Id.

[128] For the Missouri Botanical Garden's involvement in the ICBG project in Suriname and Madagascar, see supra note 92. For its involvement in biodiversity prospecting projects elsewhere in Africa, see UNEP Benefit-Sharing Case Studies, supra note 12, at 6, & 10-14; and McManis, Biodiversity and Biotechnology, supra note 4, at 273.

[129] Id. at 73-74.

[130] See supra notes 86, 92 and accompanying text.

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

[132] 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 109. While publication of this dissertation is sufficient to put the invention into the public domain for patent law purposes, if a patent does not issue on the invention disclosed therein and will in any event make the invention available to interested academics, the legal requirements for preserving trade secret protection for the invention are not necessarily as demanding, as this form of protection will only be extinguished when the invention is deemed "publicly known or readily ascertainable." See generally Charles R. McManis , Intellectual Property and Unfair Competition in a Nutshell 324-24 (2000).

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

[134] Id. at 80-81.

[135] Id.

[136] Id. at 81.

[137] Id.

[138] Id.

[139] Id.

[140] Id. at 81-82.

[141] Id. at 82

[142] Id.

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

[144] Id.

[145] Id.

[146] For a summary of the high-profile efforts of this privately held company, which relies primarily on collaborative agreements with indigenous and local communities, see McManis, Biodiversity and Biotechnology, supra note 4, at 272 & 275, and authorities cited therein.

[147] The ICBG report notes 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. See Rosenthal et al., supra note 12, at 19.

[148] The report notes that some evidence to the contrary was provided by an announcement later in 1999 that Glaxo Wellcome had signed a $3million agreement with a Brazilian company, Extracta, to receive a wide variety of plant, animal and microorganism samples for screening, some identified by ethnomedical knowledge. Rosenthal et al., supra note 12, at 19.

[149] Id.

[150].

[151] Id.

[152] Id. at 33.

[153] Id.

[154] See supra note 100 and accompanying text.

[155] See supra note 101 and accompanying text.