ETHICS AND PRACTICE IN ETHNOBIOLOGY: ANALYSIS OF THE INTERNATIONAL COOPERATIVE BIODIVERSITY GROUP PROJECT IN PERU

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The aim of this paper is to discuss the various ways in which traditional knowledge can be adequately protected. Part I of the paper examines the means of protection that exist in the current legal system, and discusses whether these modes of protection are adequate given the characteristics of traditional knowledge. Part II discusses how the International Cooperative Biodiversity Group (ICBG) at Washington University in St. Louis used a combination of various methods of protection to effectively protect the traditional knowledge obtained during an ethnobotanical project in Peru. The paper concludes by discussing alternative modes of protection.

What is traditional knowledge and why should it be protected?

Anthropologist Johnson[1] defines traditional knowledge as a body of knowledge built by a group of people living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment and a system of self-management that governs resource use. The characteristics of traditional knowledge include:

- Creation over a long period of time in which it has been passed down from generation to generation;
- Constant improvements as new knowledge is integrated to the existing;
- Both creation and improvement of knowledge is a group effort.

Yet the individual's role can not be underestimated in this group effort. For instance, an Achuar (Jivaro) man bitten by a snake in an isolated area of the Peruvian rain forest was provided a snakebite remedy by a bicultural Candoshi-Achuar man who knew of this remedy from his mother's tribe, but one unknown to the Achuar. On drinking the preparation the man felt relief from pain around the puncture site, perhaps due to reduced inflammation. On return to his community he expounded the virtues of this "new" antivenomous plant, and on a return visit in six months we discovered that this treatment had become generally adopted as part of the Achuar traditional pharmacopeia, all as a consequence of one man's experience.[2]

In recent years traditional knowledge has grown tremendously in significance in view of its value to biotechnology, particularly the pharmaceutical, phytomedicinal, nutriceutical, and herbal sectors. Three-fourths of the biologically active plant-derived compounds currently in use have been discovered through follow-up research to verify authenticity of data derived from traditional sources.[3] More recent research continues to validate the importance of an ethnobotanically targeted approach to the initial discovery of therapeutics.[4,5] Such research draws on the traditional knowledge of local and indigenous communities who have custody of such resources, thereby allowing a targeted testing of specific plants for specific purposes.

Assessing the worth of drugs obtained from traditional sources both now and in the past is difficult. A few recent examples, however, provide a commonality of independent estimates in the billions. In the last decade, Japanese or Kampo traditional drug sales reached $56 billion annually.[6] Others estimate that only one-eight of the pharmaceutically important drugs have been discovered in the rain forests globally. If, as described above, as many as three-quarters of plant-derived drugs used today are of traditional origin, then in this single ecosystem, such discoveries could generate a total value of $110 billion.[7] In still another example of a single discovery dating from 1630, Peruvian indigenous people provided Jesuit priests with their traditional knowledge of *Cinchona* bark to treat intermittent fever or malaria. Since that time, crude bark, quinine (isolated in1820) and its synthetic derivatives, and also quinidine (isolated in 1833) for treating arrhythmia, have generated untold wealth, relief from suffering, and saved millions of lives. Further, the use of antimalarial drugs led to the successful habitation of vast areas of tropical and warm temperate regions of the world by all peoples, making possible new opportunities for progress and riches. Sales and other such direct and indirect benefits of these drugs over the centuries to the present are estimated at tens, if not hundreds, of billions of dollars.[8] These examples of only a modest fraction of plants used traditionally by peoples worldwide provide some measure of their enormous value when coupled to traditional knowledge.

Thus, considering its significance to the global economy and health, it is clear that traditional knowledge should be protected, and a part of the value generated from its protection should be transferred back to the authors of this knowledge, i.e., the indigenous people.

PART I
EXISTING METHODS OF PROTECTING TRADITIONAL KNOWLEDGE

The following legal frameworks can be adapted to protect traditional knowledge.

- International protection through treaties and conventions;
- National protection through national legislations controlling access to genetic material enacted in various countries, and national intellectual property legislations;
- Local protection through private contractual measures.

International Protection

The Convention on Biological Diversity (CBD) was drafted at the end of the UN Conference on Environment and Development held in Rio de Janiero in 1992. It deals with issues relating to environmental law and policy making in the context of sustainable development. The objectives of the CBD are the conservation of biological diversity, the sustainable use of its components, the fair and equitable sharing of the benefits arising out of the utilization of genetic resources including appropriate access to genetic resources, the appropriate transfer of relevant technologies, the consideration of all rights over these resources and technologies, and the availability of appropriate funding to develop these issues.

Art. 8(j) of the CBD calls on the signatories of the Convention to respect, preserve, and maintain the knowledge, innovations, and practices of the indigenous communities. Read with other provisions of the Convention, Art. 8(j) implies that researchers should pay for the traditional knowledge made available to them, and that they have to maintain the confidentiality of such knowledge if so required. Art. 8(j) is supported by Art.18.4 that encourages countries to develop models of cooperation for the development and use of technology, particularly indigenous or traditional technology.

However, the CBD has no enforcement mechanisms of any sort. The principles espoused by the CBD can be enforced only when they are incorporated into the national access legislation of the signatory countries, should they choose to institute them.

Other newly drafted instruments have begun to supplement the CBD treatment of traditional knowledge. Art. 9(a) of the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture of 2001 deals with the need to protect traditional knowledge. Article 29 of the Draft UN Declaration on the Rights of Indigenous People of 1999 is more elaborate in its protection of traditional knowledge and other traditional resources of the people. It states that indigenous peoples are entitled to the recognition of the full ownership, control, and protection of their cultural and intellectual property. Special measures should be developed to control, develop, and protect their sciences, technologies, and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, and visual and performing arts. Chapter 26 of Agenda 21 is focused on indigenous people and is targeted toward empowering them. Paragraph 4 (a) of Chapter 26 calls on the relevant national governments to adopt policies or legal instruments that would protect the cultural and intellectual property of such people. The aim of this provision is to provide some protection over the traditional knowledge and folklore of such persons.

Therefore, the scope of international measures that have been developed merely recognizes the rights of indigenous people to their traditional knowledge. None of these

instruments specify a regime to protect such knowledge. Also, none of the instruments specify mechanisms to enforce this recognition of the rights of indigenous peoples to their traditional knowledge – they are merely persuasive in nature.

Regional and National Measures

There are many regional initiatives that govern the access to genetic resources of countries. Further, many countries – particularly developing countries – are in the process of initiating national access legislation to declare their sovereignty over the natural resources within their jurisdiction and to control access to these resources. Frequently such legislation covers the protection of traditional knowledge.

Kate and Laird[9] used a system of classification that divides national access legislation into five categories:

- Environmental framework laws that simply charge a national government to provide specific guidelines on access and benefit sharing (Gambia, Kenya, Malawi, Korea, and Uganda).
- Sustainable development or biodiversity laws provide more details than the first group. These laws also establish the principles for prior informed consent and mutually agreed terms (Costa Rica, Eritrea, Fiji, and India).
- Dedicated laws on access to genetic resources (Philippines and Brazil).
- Modifications of existing laws and regulations (Nigeria, U.S.A., and Malaysia).
- Regional measures.

National access legislation has attempted to protect traditional knowledge in two ways. Some countries attempt to protect traditional knowledge as a form of property in itself. The biodiversity laws of Peru and Costa Rica protect the rubric of community intellectual property rights, practices, and innovations of indigenous people and local communities related to the use of biodiversity and associated components. Costa Rica has created a national database where such traditional knowledge can be recorded. It also recognizes the right of indigenous people to benefit from the use of traditional knowledge. Concerned local communities are also guaranteed a share of the benefits arising from access to genetic resources. Other countries attempt to protect traditional knowledge of communities in practice. For example, Brazil's national access legislation establishes certain disclosures that have to be made by the researcher in the application to the government using Material Transfer Agreements (MTA). Such legislation places the burden on the government to protect traditional knowledge of the communities in each case.

However, national legislation in relation to traditional knowledge protection is successful in practice only if the national government involved is willing to espouse the interest of the indigenous people involved and protect such rights *for* them. This is often not the case: indigenous people may be far removed from the mainstream population or in conflict with and not usually represented in their national governments.

Another way in which indigenous people could use the national legal system to protect their traditional knowledge is by making use of the existing national Intellectual Property (IP) laws. However, strict IP laws are not suited to protect traditional knowledge. The requirements of Patent and Copyright laws set forth certain measurable criteria under which intellectual property is evaluated. Traditional knowledge does not conform to the criteria in the following ways:

- Both patent and copyright laws require a definite author to the work being protected. Traditional knowledge is created through a process of evolution that sometimes spans generations. However, this does not apply where the knowledge is the demonstrable result of an individual's innovation/invention.
- Both patents and copyrights have a time limit, which is not appropriate to the protection of traditional knowledge.
- Copyright requires "fixation" of the work, and does not recognize the frequently oral tradition through which traditional knowledge is recorded.
- Patents are granted for a single act of invention, while traditional knowledge, in most cases, is assumed to be a dynamic on-going process, though cases of individual innovation do exist.
- Finally the act of obtaining, maintaining, and enforcing patents and copyrights is expensive.[10]

Thus, national measures as they currently exist seem inadequate for protecting traditional knowledge.

Private Contractual Measures

Contractual arrangements have traditionally been used as a means to arrive at a consensus in transactions involving the access to genetic resources and benefit sharing therefrom. They catapulted into importance following the much publicized Merck-INBio agreement,[11] and have since continually been cited as a mechanism that can be used to resolve the contentious positions adopted by the developed nations on one hand and the biodiversity rich nations on the other hand regarding the protection of traditional knowledge among other questions.[12] Various committees, including the expert panels of the CBD and the World Intellectual Property Organization (WIPO) have released several reports that comment on the importance of such contractual arrangements. These reports also contain model clauses that the parties to the agreement could use, so that the interests of the provider of biodiversity and/or traditional knowledge, the recipient of the same, and the local community involved are all protected.

The CBDs intersessional working group on Art. 8(j), and other related provisions of the CBD,[13] reported on contractual agreements that may be used during the transfer of traditional knowledge. The report states that concerns of local communities involved that need to be addressed by the MTA include access to community land and territories (e.g., sacred spaces, etc.), confidentiality agreements to protect the knowledge being transacted,

rights either to authorize public dissemination of results or to protect such information through IP laws, rights to repatriation, i.e., to receive research results based on the use of their knowledge, and joint ownership of IP that results from such transfers. The report also recognizes the peculiar nature of traditional knowledge and attempts to incorporate clauses in MTAs that protect the local communities involved, that is, clauses recognizing that the traditional knowledge being transferred is community owned, and therefore that benefits resulting from such knowledge transfer should be equitably distributed throughout the community, and that the transfer of such knowledge will not detract from the right of the local community to continue to use the knowledge. However, the report makes the assumption that traditional knowledge is community owned and developed, and does not make provisions for individual invention and innovation. Nor does it consider that the IP of the indigenous peoples may need protection during research and development phases leading to pharmaceutical commercialization, for if the information is in the public domain it is unlikely that major new therapeutic products will ever be developed and marketed.

Also relevant is the report of the second session of the intergovernmental committee of the WIPO on intellectual property and genetic resources, traditional knowledge, and folklore.[14] This document focuses exclusively on determining what the contents of a model MTA would be, taking into account both the concerns espoused by the CBD and the need to protect intellectual property.

Where the MTA involves the transfer of traditional knowledge, it should involve a "provider" of material, a "recipient" of material, and a local community. The agreement should provide that the expressed informed consent of the concerned local community has been obtained prior to entering this agreement. Prior informed consent involves holding discussions with the local communities in their local language. Such agreements normally provide that the transfer of materials will in no way detract from the right of the local communities involved to continue to use knowledge and material as per traditional practices.

Apart from the specific benefits that depend on the parties to the agreement, MTAs typically provide for certain general types of consideration to the provider for the transfer of material, assuming that traditional knowledge has been created by the community as a whole. One type of payment is through royalties, either a lump sum for the material being transferred or a share of net profits that result from the commercialization of either the material being transferred or the derivatives thereof. Another type of compensation involves shared ownership rights of the intellectual property rights (IPRs) that accrue from the transfer of material. Alternatively, the MTA could leave the question of joint ownership of IPRs open and condition the right of the recipient to commercially use or patent an invention without the authorization of the provider or the local community. This allows another opportunity at negotiating an equitable solution.

However, as these regulations of CBD and WIPO are not mandatory, MTAs cannot be the sole means for protecting traditional knowledge on account of the differences in bargaining power between the research organization and/or corporation on one hand and the indigenous community on the other.

PART II
PROTECTION OF TRADITIONAL KNOWLEDGE AND INDIGENOUS RIGHTS IN THE ICBG-PERU PROJECT

Within the International Cooperative Biodiversity Group (ICBG) program exists a harmonious interdependence between biotechnology and biodiversity in which the practice of bioprospecting encompasses a three fold goal to promote human health, economic development, and conservation of diversity.[15] Indeed, the success of this goal depends on the existence of and ready access to biodiversity, but many countries are currently making unsustainable use of their natural resources, and it has been estimated that up to 10% of the world's species will be extinct within 25 years.[15, 16]

The ICBG is a grant program administered by the Fogarty International Center and financed by the U.S. National Institutes of Health, National Science Foundation, and Department of Agriculture. The theme underlying the ICBG program is the concept that the discovery and development of pharmaceutical and other useful agents from natural products can promote economic opportunities and enhanced research capacity in developing countries while conserving the biological resources from which these products are derived. Thus, the intent of these grants is to promote the conservation of biological diversity through the discovery of bioactive agents from natural products, and to ensure that benefits accruing from both the research process and any discoveries are shared with the country of origin.[17]

Sharing benefits from the research process and from drug discoveries that could be made in the future create incentives for conservation and provide alternatives to destructive use. Therefore, these projects involve all aspects of the CBD: increasing access to the biological resources and traditional knowledge of developing countries, providing for sustainable use of such biodiversity, and entering into fair and equitable benefit-sharing arrangements with developing countries and concerned institutions in such countries.

Washington University (WU) in St. Louis was awarded an ICBG grant in July 1994 to conduct research on "Peruvian Medicinal Plant Sources of New Pharmaceuticals." Two universities in Lima, Peru, Universidad Peruana Cayetano Heredia (UPCH) and Universidad Nacional Mayor de San Marcos, Museo de Historia Natural (USM), and the corporation G.D. Searle and Co. were the original partners who submitted the application. A Letter of Intent had been signed between these partners and the Consejo Aguaruna y Huambisa (CAH), representing one Aguaruna Federation and only those Huambisa living along the Río Santiago. A formal agreement between the

CAH and the partners proved impossible, and lengthy discussions were terminated in January 1995. However, in February1995, negotiations began with the Organización Central de Communidades Aguarunas del Alto Marañón (OCCAAM), an organization with a good reputation in Peru and the one originally cited in the grant application. At the end of October 1996, agreements were signed in St. Louis with the indigenous organization Confederación de Nacionalidades Amazónicas del Perú (CONAP) who represented three (and later four) Aguaruna Federations (including OCCAAM) in the Departments of Amazonas and San Martín, all of whom became collaborators in the project and a partnership of equal standing with each of the three universities. A strong relationship continues today with members of these federations.

CONAP is an administrative and facilitating organization for about 18 indigenous groups in north-central Amazonian Peru. Its president is elected by these groups for terms of six years. César Sarasara was president in 1996 and he continues in that office today. Each federation (clan) is headed by a leader elected for a three-year term. Communities within each federation who wish to participate in the ICBG produce an Acta signed by the apu (chief) and those persons who wish to voluntarily participate (a majority and usually all). The collaborating federations are: OCCAAM, Federación Aguaruna del Río Domingusa (FAD), Federación de Cominidades Nativas Aguarunas del Río Nieva (FECONARIN), and later Organización Aguaruna del Alto Mayo (OAAM).

The grant was funded 1994-1999 (extended to 2000) to identify new pharmaceuticals based on ethnobotanical pre-screenings while concomitantly conserving biodiversity in northern Peru by enhancing economic growth among collaborating Aguaruna people.[4] The project was to serve both globally important diseases as well as those of serious concern in Peru. Field research with full collaboration of the Aguaruna federations was achieved from 1996 through 1999. G.D. Searle & Co withdrew as a partner from the ICBG in 1999. The company was no longer conducting pharmaceutical research with plants (only microorganisms), and even their research in nutriceutical supplements was terminated that year. However, Searle did continue to provide up-front payments to the Aguaruna Fund as agreed through 1999.

The project was ethnobotanical in nature, i.e., it involved the use of the knowledge of the Aguaruna people about plants used in their traditional medicine to conduct assays focused on specific diseases and syndromes. Ethnomedicinal data provided details of what and how plants were used, their parts, and under what circumstances. Most bioprospecting is random in nature and involves the collecting of plants without regard to ethnobotanical data, and the poor level of bioactivity usually obtained reflects this randomized approach.[4,5,18]

The ICBG- Peru project involved all possible combination of stakeholders, i.e., the academic researcher represented by WU, UPCH, and USM, the commercial prospector, represented by G.D. Searle, a division of Monsanto Co., the indigenous

community groups represented by CONAP, and the government of Peru through the Ministry of Agriculture

The project is particularly notable in that it used each form of protection mentioned in Part I of this paper in addressing the various aspects of traditional knowledge protection. Thus, the project incorporated each of the principles laid down in the various international instruments, as well as the documents brought out by organizations, such as CBD and to some extent WIPO.

Negotiations

The Prior Informed Consent procedure was divided into two phases. In the first phase, research collectors mainly talked with leaders of the stakeholders to acquaint them with the project, obtain their consent to talk with members of the indigenous communities, and to attend the Aguruana Congress (IPAAMAMU). The meetings also tried to map out the broad conditions for agreements being reached between the universities and the corporate partner and the stakeholders. A series of meetings were held in order to acquaint everyone with the ICBG-Peru project: its goals, aims, and nuances. Two rounds of meetings and workshops were held in order to introduce the project with representatives of WU, UPCH, USM, Searle, and representatives of the Aguaruna people consisting of CONAP and two lawyers, leaders, and staffs of the four regional federations, and significantly the annual Aguaruna IPAAMAMU meeting which included most players of the four federations and representatives of other groups.

Apart from introducing the project, these meetings also established the nature of the benefit-sharing arrangement that would be instituted between the indigenous people and the commercial partner in particular. The following benefits (among others) were agreed to:

- A flat collection payment for plant samples collected annually over four years.
- A license fee paid as long as Searle continued to make use in assays of plant extracts accompanied by traditional medicinal intellectual property.
- Milestone payment during the development of new products.
- A shared royalty payment based on net sales of products.
- Favorable terms of supply and distribution of products in Peru
- Intellectual property rights, such as sharing in patent ownership.

Obtaining Prior Informed Consent from Indigenous Communities

From indigenous communities, consent was obtained through a detailed system of local administration. A field coordinator was appointed who was a member of an Aguaruna community and who had long-term contacts throughout the regional federations. He knew members personally in many communities and was well-respected, and he spoke both Aguaruna and Spanish. The coordinator traveled to the communities

that had agreed to participate in the project and also to those whose members were interested in learning more about the project. He held town meetings with men and women and provided them with the following information:

- What the project was about in some detail: collecting, research, and what might be produced.
- What rights the people would have and how their knowledge would be protected.
- The concept of informed consent: he would explain the PIC document in Aguaruna, emphasizing the fact that it was voluntary, and that anyone could withdraw from the agreement at any time.
- He explained the benefits that the federation, community, and individual would obtain from the project: payments to assistants and informants, payments for food and lodging, payments for plant samples collected and used in research, and potential long-term benefits. He outlined the Aguaruna Fund which would be established with earnings from collecting and user fees. This income would be divided equally between the three (and later four) federations, the Fund monies being dispersed through grant applications and low interest loans. Confidentially and protection of their knowledge through the issuing of patents would provide long-term benefits and the recognition of intellectual property of Aguaruna individuals and communities in patents issued by the U.S. PTO.

Discussions moderated by the community chief were lively events with opinions being expressed by most members present, men and women alike. When requested the coordinator would withdraw, further discussions would occur, and if the results were positive, a community Acta would be drawn up and members of the village would provide a signature or mark by his or her name in agreement. This was followed at that time or at a latter date by the signing of the PIC document by those who were willing to participate. The terms of the document included:

- That consent was voluntary.
- Purpose of the project was to obtain plants and information of their use in traditional medicine, the material and information being used in research which could lead to the development of new pharmaceuticals.
- Participation would involve plant collecting and providing information, such as the common name of plants, use of plants, plant part used, methods of preparation and use, storage, and preference compared to other plants to treat particular diseases or conditions.
- Participant could withdraw from activity without prejudice.
- The Intellectual Property Rights (IPR) of the participants to be protected. If the participation of informant leads to a discovery or an invention, the informant and community will be acknowledged and if a product is commercialized the federations, and hence all communities and members, will be compensated through the Aguaruna Fund. Special recognition of the community and informant who provided the data would also be included in, for example, patents.

- Reasonable measures to be taken to protect the confidentiality of information provided.

Once the PIC was obtained, access to the genetic resources would begin. This was a process that was ecologically and economically sustainable, and involved the stakeholders in the process. The coordinator would lead the community through a workshop in which the following were explained: how to collect plant herbarium vouchers and their purpose, how to collect samples for drying to be used for extraction, how extraction proceeded using their wide use of decoctions as a model, and what to provide in field notebooks for each collection that would receive a unique field number. Notebook data would be more fully explained to show the need for many aspects of the plants to be included, although focusing on the informant who would lead the discussion regarding its use. The informants name and age would also be recorded.

Each community would select two individuals, a man and woman, who would act as field assistants to the coordinator and researchers when they arrived at the community. The assistants would be paid a daily stipend from the grant negotiated by the coordinator. They were usually young, knew Spanish, and were thus able to communicate with the older, more knowledgeable members in Aguaruna so that full field data could be recorded in Spanish or English. They would also assist the coordinator in handling community details, such as costs of room and board per person and the per diem fee for each informant to be paid from the Aguaruna Fund. Assisstants also helped with the processing of vouchers and preparing and drying samples for extraction.

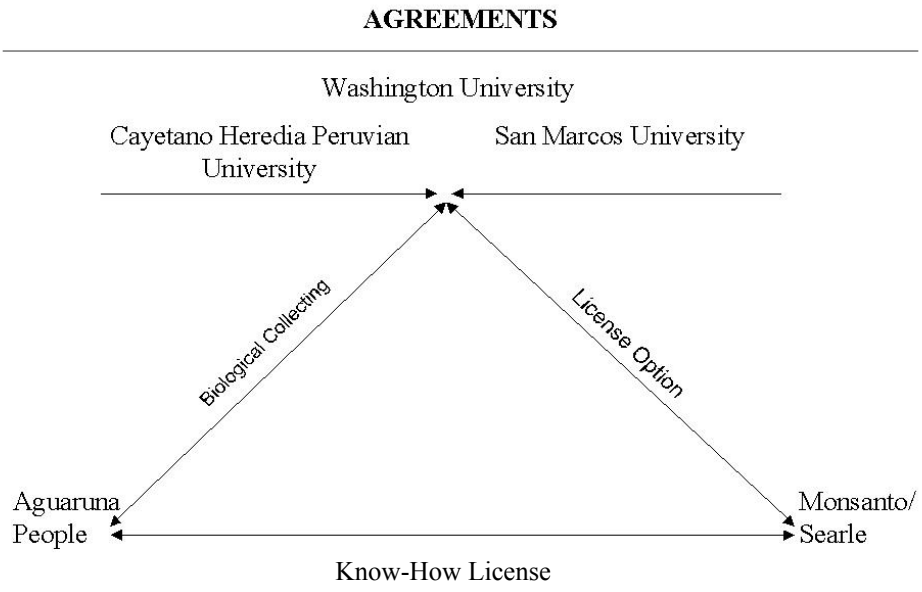
During the town meeting the community also selected about five informants consisting of the most informed men and women healers. The informants would accompany the researchers on day-long expeditions into the surrounding forest and as interesting medicinal plants were found they would provide details about the plants. The name of the informant would be noted along with the information given for eventually assigning IPR. Such visits lasted about one week, and repeat trips were often made.

Agreements

Before collecting began, researchers and stakeholders entered into a series of detailed discussions that recorded their agreement on all pertinent issues. The agreements were (Fig. 1):[19]

- *License Option Agreement and the Amendment thereto* provided the royalty rates for pharmaceutical products, established how they would be shared and provided the basis of interaction between the researchers and the commercial partner.
- *Biological Collection Agreement* outlined who would be involved in collecting, where collecting could occur and under what circumstances, and what annual collecting fees would be provided. This is the agreement between the researchers, the source country institutions, and the indigenous people.

- *Know-how License Agreement* described annual license fees to be paid by the corporate partner to collaborating Aguaruna federations while their knowledge was being used in extraction and screening programs, and also milestone payments at different times during the discovery and development phases prior to drug commercialization. This agreement is one of its kind between an American corporation and an indigenous group.
- *Subcontract Agreements* with the two Peruvian universities described the field collection program with USM and the plant extraction program and functional assays of specific diseases to be conducted by UPCH.



Each agreement recognizes that the traditional knowledge of the indigenous people is their cultural legacy and that the people have a right for such knowledge to be protected *from* the public domain. They state that such knowledge is being provided voluntarily and is being retained in confidence. Should such information prove valuable, then the original IPR of the indigenous people over such knowledge would be preserved through the filing of appropriate patents, and by the inventors assigning shared ownership of the patents to the indigenous federations. The agreements also recognize the ownership and patrimony of the Peruvian state over certain tangible resources (whole plants) collected by the researchers in Peru for scientific purposes and for making extracts, fractions, and isolating compounds of potential commercial use as new pharmaceuticals. The agreements assure that collecting activities do not endanger natural populations of the plant species or their habitats and that a program of restoration to help conserve medicinal and other plants would be initiated.

Conservation and Education

Initial conservation aims were achieved by training the Aguaruna to raise plants in nurseries and to plant seedlings in secondary forest areas. Seedlings of cedrela and sangre de drago, for example, were planted in up to 15 ha secondary forest areas near several communities in two federation regions. Antimalarial plants, which had been depleted due to over-exploitation by the Aguaruna, were replanted in plantations in a third federation area..

The ICBG-Peru project also trained members of the Aguaruna community in assisting with the project and for those persons interested in general principles of botanical field collection in both parataxonomy and paraethnobiology. Graduate students from Washington University and/or USM participated in every field expedition, and these students as well as technical staffs were trained in laboratories of UPCH and WU, and for biodiversity studies at the herbaria of USM and the Missouri Botanical Garden (MO).

Confidentiality

The ICBG-Peru project developed various steps to protect the confidentiality of traditional knowledge which had been entrusted to it. All in-house researchers and collaborating labs signed confidentiality agreements. All plant dried samples destined for extraction were assigned random codes, none of which were associated with original field collecting numbers, nor gave clues to a plant's taxonomic identity. Databases created as a result of the research were password protected and encrypted. Biodirected assaying of extracts, their fractions, and compounds isolated therefrom were all coded using the code suffixed with appropriate additional identifiers.

As part of repatriation, complete CD databases with research results were provided in strict confidence to CONAP, UPCH and USM to share, and the Ministry of Agriculture's INRENA (redacted). These will be updated periodically as additional taxonomic determinations are made.

Benefit Sharing and Capacity Building

The project ensured that source-country participants receive adequate benefits as a result of their participation in the project and in respect of their rights over knowledge. The benefits that were provided are summarized below:

- *Peruvian Ministry of Agriculture.* In pre-grant award discussions with the Vice-Minister of Agriculture to consider government participation and appropriate capacity building, we were advised not to partnership with a government agency, but rather to consider in exchange for our use of genetic resources of the country assisting major universities in teaching and research by enhancing their abilities to conduct and fulfill their educational missions. In the Vice-Minister's opinion, helping them and thus by

enhancing education we would be providing an important service to the country as a whole. Thus, payments and fees were made only to the Ministry's INRENA for obtaining permits to collect and export material, for renovations and furniture at the Imazita agricultural field-station used by the field researchers during the grant and left for their use, and for seeds and seedlings of potentially useful crops provided to both indigenous people, mestizos, and agricultural researchers.

- *Two Source-Country Universities, UPCH and USM*. As subcontractors under the ICBG-Peru grant, the universities each received a portion of grant funds to support their specific research responsibilities outlined in the proposal. These funds supported salaries, purchases of supplies and equipment, and travel costs as needed for the participating researchers and training of technical staffs and students in both the field and laboratory. One or more sets of plant and animal collections were provided to the Museum of Natural History at USM, and a complete set of dried plant materials was supplied to UPCH for extraction. These institutions were provided in confidence databases of field collections for all material obtained during four collecting years and subsequently researched using mostly biodirected assays. Infrastructural support included a field vehicle, metal specimen cabinets, computers, printers, a wide range of laboratory equipment, and many used items from Searle to assist in their overall programs. Attendance at scientific meetings, research institutions, and enhanced publications were all part of university capacity building.
- *Four Affiliated Aguaruna Federations*. Payments from Searle of collection and license fees were made annually to the Aguaruna Fund established and operated by the three and later four federation leaders together. Sums were paid to the fund at the beginning of the year and kept in a U.S. dollar account until needed. CONAP was provided 18.5% of the funds as overhead in compensation for its administration of the program in Lima. The remainder of the Fund was dispersed for community efforts, like building wells, purchasing engines, and developing radio communications and plantations for sustainable products, all based on individual or community applications to the federation leaders. Part of this money was set aside for women as low interest loans to develop cottage industries, such as weaving, planting of marketable foods, art work, etc. to be sold in mestizo communities and coastal cities mostly to tourists. Funds were also kept aside for educational purposes for students to attend grammar school or university in regular or remedial programs. Payments were provided for books, tuition, clothing, hostel room and board, and transportation. The Aguaruna Fund also reimbursed each informant who participated in the field research program.

Payments from the ICBG-Peru budget were used to assist CONAP with equipping its office in Lima, limited travel and communication costs, and legal obligations associated with the grant. Salaries of the Aguaruna field coordinator (full-time) and his assistants (part-time) were also paid from the ICBG budget, as were payments to the two field assistants from each community assisting with collecting, and for food, lodging, and transportation costs in and between communities.

Some members of the Aguaruna communities were trained in collecting and determining of plants to Latin families. All were constantly reminded of the importance of their traditional medical knowledge and language, and the naming and classifying of their plants. Toward the end of the field research, the Aguaruna field coordinator and his assistant directed two of their own field expeditions. The results were spectacular.

A provisional patent submitted to the U.S. Patent and Trademark Office on January 31, 2002 was recently followed by an updated nonprovisional utility application dated January 31, 2003. Submissions were based on the plant antimalarial know-how of the collaborating Aguaruna with subsequent research by the inventors who showed those compounds responsible for activity individually and in combination against the malarial-causing organism in vitro and in vivo. In the patent it was noted that informants signed prior informed consent documents and all information was obtained voluntarily. Informants and their communities were named individually for each of the three plants involved in the application. The inventors assigned equally (25%) shared ownership of the U.S. patent to the four partners of the ICBG-Peru program, i.e., WU, UPCH, UNMSM, and CONAP on behalf of the four federations, and the assignments have been accepted. To our knowledge this is the first example of joint ownership of a U.S. patent by an indigenous group, at least in Latin America.

Further basic research may be conducted with these antimalarials, or alternately the IP may be licensed following an appropriate agreement and up-front fee payment to a company willing to develop and eventually commercialize the protected compounds, and also provide appropriate milestone and royalty payments to be divided equally to the four partners. The plan is to conduct most clinical trials in South America to provide efficacy and low toxicity data, and possibly also to manufacture the product in South America for use largely in tropical countries. By so doing, together with hoped for supplements from WHO and other global organizations, the cost will be within reach of those needing antimalarial products the most.

CONCLUSIONS AND RECOMMENDATIONS

The description of the ICBG-Peru project makes it clear that it succeeded in part by making use of each of the available modes of protection described in Part I of the paper. The project incorporated the goals of the CBD by accessing genetic material and traditional knowledge with the PIC of the people involved. It recognized the rights of the indigenous people to their traditional knowledge and compensated them fairly. It also recognized the sovereign rights of the government of Peru, provided them with benefits, particularly by involving source country institutions and transferring back knowledge and technology to the country. The project has also attempted to fulfill the mandate of conservation and sustainable harvesting.

The project harnessed the U.S. national IP laws by filing a patent based on the traditional knowledge obtained from the Aguaruna and by transferring benefits of the patent back to the indigenous people.

Finally, negotiations with the indigenous communities followed each of the recommendations put forth by the expert committees of the CBD and to some extent, the WIPO.

The ICBG-Peru project succeeded in its mandate to protect the traditional knowledge of indigenous people as it was uncompromisingly fair on three principles: communication, confidentiality, and compensation.[20]

However, the project was not without its share of controversies. That with the Consejo Aguaruna y Huambisa at the beginning of the project highlights the fragmented nature of most indigenous communities and the difficulty of treating them as a composite whole for the purpose of identifying "authors" of the knowledge as well as for distributing benefits. One commentator pointed out the unrealistic and heightened economic expectations of the Aguaruna people as a result of the project and their disappointment when Searle withdrew from the project in its final year.[21]

Another important question to consider is how many researchers would be willing to go through the process taken by the ICBG-Peru project in order to obtain the consent of the indigenous community and to protect the traditional knowledge so obtained. Research institutions like the Missouri Botanical Garden are in the process of framing institutional codes of conduct that incorporate the principles of the Convention on Biological Diversity and other instruments. It remains to be seen if other institutions will follow this lead.

We propose that certain changes in international law are needed to incorporate these principles in normal research practice. Considering the value being generated by traditional knowledge to the global economy, world trade organizations with their enforcement mechanisms seem appropriate fora to target. Since strict Intellectual Property law will not adequately protect traditional knowledge, an adaptation of the same seems called for. Developing countries have frequently proposed the Agreement on Trade Related Intellectual Property Rights (TRIPS agreement). They have proposed that the rights of the collective holders of traditional knowledge be recognized, and that the source of the traditional knowledge be specified.[1] Once the rights of communities to the knowledge are recognized, and/or their individuals, such communities will be automatically compensated for the exploitation of their rights. Until then we recognize that the best specific protection is through the filing of utility patents.

At the same time, governments need to be encouraged to enhance the capacity of indigenous people to negotiate with interested parties, as well as to strengthen their

bargaining power. This can be accomplished by affirming the rights of indigenous people to their traditional knowledge in national legislation. Governments should also assist them during the negotiation process to develop agreements that ensure that principles established by international organizations are followed.

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