

FFM to South America Mission to Peru

Box 1: *Peru FFM:
Country Membership
in international IP
treaties.*

<u>International IP treaties</u>	
• Paris Convention	1995
• Berne Convention	1998
• Rome Convention	1985
• Madrid Agreement	-
• The Hague Agreement	-
• PCT	-
• UPOV Convention	-
• TRIPS Agreement	2000

[...]

Box 2: *Peru FFM:
Country Membership
in TK-related treaties and
processes .*

<u>TK-related treaty/process</u>	
• UNESCO Heritage Conv.	1982
• UNESCO Cul. Property	1980
• ILO 169	1994
• IUPGR – FAO	Yes
• CBD	1993
• UNCCD	1995

The FFM to Peru took place from May 10 to 13, 1999, in the city of Lima. The Interim Mission Report, which contains information as to the persons and entities with whom WIPO consulted, is set out in Annex 4.

The presentation of the information in this section is organized under the following headings: Terminology and Subject Matter; Objectives of TK Protection; Documentation; Means of Protecting TK; and Management and Enforcement of Rights and Interests in TK.

Terminology and Subject Matter

The question of defining “property” and “private rights” came up frequently in the replies from respondents. In particular, representatives of communities from the mountain region (called “*la sierra*”) and from the Amazonian region (called “*la selva*”) often referred to collective ownership, and the belief that their intellectual property should be regarded also as collective property.¹ Part of the indigenous peoples of Peru viewed themselves as a unitary entity evolving under the aegis of a single ancestral culture. Knowledge was transmitted from generation to generation, in a sacred, unwritten “book”.²

Some respondents believed that there was at present insufficient political will to promote the view that intellectual property could also be treated as the product of collective

endeavor. Collective creativity was a reality among indigenous peoples. On a global perspective, collective property should be recognized alongside individual property, in as much as different religions and cultures are recognized and coexist.³

Objectives of TK Protection

TK is understood as encompassing a broad range of expressions relating to both the arts and technology. Respondents commented, in particular, on the following subject matter for TK protection for artistic expressions:

- oral and literary works;
- music;
- traditional handicrafts, textile designs and patterns.

Intellectual Property Needs and Expectations # 1

- Recognition of collective creativity and property.

In recent times, the topic of main concern for the indigenous communities' representatives and the Government authorities has been the protection of TK relating to technology, and in particular:

- conservation of traditional plant varieties and development of new varieties;
- use and exploitation of biological and genetic resources;
- traditional medicine;
- conservation and sustainable exploitation of the environment;

While the need to protect TK and the natural environment against predatory exploitation was paramount, indigenous peoples were reluctant to remain isolated. They have a fundamental willingness to share and exchange their knowledge. TK should be developed and enriched by combination with modern technology. Sharing TK was regarded as essential, but so was recognition of origin and ownership, respect for the inherent traditions, and sharing of economic benefits. TK should not be exploited or commercialized indiscriminately.⁴ A system for protecting TK and for compensation for the use thereof must be implemented in a manner that will allow the holders of TK to continue using and expanding their knowledge, and prevent the chain of transmission of traditional knowledge from breaking.⁵

Intellectual Property Needs and Expectations # 2

- Modalities for TK protection that do not prevent sharing and other transmission of TK.

Protection for artistic TK

Protection of traditional indigenous oral **literature** was a special need. Difficulty derived from the fact that oral traditions were being written and recorded by persons alien to the local culture. Those persons will often present themselves as the “authors” of those traditions, failing to acknowledge the original source, and will distort the tradition.⁶

Respondents felt that improved systems for the protection of traditional **music** are needed. For example, traditional Andean music was being commercialized over the Internet without proper authorization.⁷ Traditional **dances** express local traditions and popular wisdom, for example the “chapis” dances tell the experience of a *sierra* native who traveled to

the *selva* and came home. Typical *sierra* dances are popular at home and abroad. They are “studied” by foreigners and later adopted, without understanding or respect for the underlying traditions, and without prior consent or compensation.⁸ Typical dances are being “taught” by outsiders posing as natives, with the consequence that the traditional expression is distorted or “modernized”, with no control possible by the communities of origin.⁹

Appropriate protection was also lacking for the **design** of textile products originating in the native communities. The motifs and designs of traditional weavings were reproduced industrially on T-shirts and other garments and wearing apparel. Those designs were slavishly photocopied from the original works, and reproduced by local companies that compete unfairly with the native designers.¹⁰ For example, Wari¹¹ woven tapestries and bands were photographed and then given to other weavers to reproduce the original design.¹² In the Amazon region, foreign missionaries had come in to learn the technique and art of traditional textile designs, which they subsequently disseminated without obtaining authorization.¹³

Other cultural expressions exposed to insufficient protection included **astronomical calendars**. For example, the Wari calendar, a pictorial composition comprising multiple icons and figures put together in Pre-Inca times, should belong to the Wari people. Having no recognition of authorship or control over its reproduction and commercialization was regarded as unfair.¹⁴

Protection for technology-related TK

Indigenous communities in Peru are preoccupied with what is perceived as “theft” of their technologically rich TK. They lack means to prevent practices that prejudice their interests and prevent the legitimate holders of TK from controlling the commercial exploitation thereof. Greater respect and protection of indigenous TK was demanded. Other complaints referred to researchers who spent several years in native communities, without any information, concrete results or feedback being received by those communities. Researchers had on occasions turned out to be little more than a cover for commercial interests wanting access to indigenous secret knowledge.¹⁵ In particular, there was concern that TK relating to natural resources could be patented by third parties without prior consent being sought.¹⁶

In respect of traditional and new plants, peasants and traditional farmers maintain and perpetuate **traditional varieties** of food crops and other plants, thus preserving biodiversity *in situ*. Farmers in the *sierra* move around to trade their seeds in communal and regional fairs, at which the best varieties are awarded prizes. Traditional varieties had properties and characteristics not found in modern “green revolution” varieties.¹⁷ The onslaught of modern economy brought with it the danger that certain traditional varieties might be lost if that traditional system of cultivation and exchange was upset. Moreover, traditional knowledge about the properties, characteristics and uses of those varieties risked disappearing faster than the varieties themselves.¹⁸

Many traditional **medicinal plants** are preserved by local indigenous communities, who have known their healing properties for years or centuries. Foreigners have tried to take that information without respecting or acknowledging the origin and source. It seemed unfair that such TK should be obtained, used and exploited without sharing the benefits.¹⁹ Shamans and traditional healers have been the guardians of traditional healing knowledge. They could feel

the repercussions that degradation of the environment has on the health of the inhabitants of the regions concerned.²⁰

Complaints were heard that traditional medicinal plants were being “pirated” by persons who exported them for processing abroad. There was no prior consent, and native communities could find themselves negotiating without full knowledge of the purpose of the extraction or the use to which the material will be put. In some cases predatory extraction occurred, without consideration for reforestation or environmental impact.²¹

Indigenous communities also possess valuable TK relevant to the sustainable exploitation and development of the environment. In particular, techniques for crop growing and **cultivation**, using traditional ceremonies and natural fertilizers. Also, traditional hydrology and **irrigation**, and **stone working** techniques are noteworthy, as well as the communities’ knowledge of **climate** and seasonal change.²²

TK is also regarded as including community-held information on the sustainable management of **forests** and wetlands, methods of **hunting** and **fishing**, house **building** and **child rearing**. For example, the traditional techniques of palm leaf weaving was being copied (with no consent or compensation) to build houses and lodges for tourists.²³

Documentation

Several provinces in the *sierra* region of Peru have limited activities aimed at registering local crop varieties, in particular for potato and other tubers.²⁴

A pioneering project aimed at establishing an inventory of traditional agricultural genetic resources of the Peruvian Andes is being developed by the University of Cusco in cooperation with eight indigenous communities in the Department of Cusco and the *Centro de Recursos Genéticos de Tuberosas y Raíces Andinas (CERGETIR)* (Center for Genetic Resources of Andean Tubers and Roots). The project focuses, in particular, on potato varieties and potato seed. It also aims at establishing an agreed protocol for accessing, trading or transferring those genetic resources, based on customary law and practices. The project will identify and describe the relevant biological resources and their associated TK relevant to their traditional uses and applications. For example, certain varieties of potato are traditionally used only for ceremonial purposes, such as weddings, and are conserved only for that use.²⁵

Intellectual Property Needs and Expectations # 3

- IP assistance and advice on documentation projects

Means of Protecting TK

Regulation of access to and benefit-sharing in genetic resources

Access to biological and genetic resources, and sharing of benefits deriving from such resources, are subjects of current preoccupation and activity in Peru.²⁶ Three legal texts, in force or under preparation, are regarded as particularly relevant, namely:

- (a) Decision 391 of the Andean Community, adopted in 1996, establishing a Common Regime on Access to Genetic Resources;²⁷
- (b) the Law for Conservation and Sustainable Use of Biological Diversity, which came into force in 1997;²⁸ and
- (c) the draft Law for the Protection of Collective Knowledge of Indigenous Peoples.²⁹

Further information on Decision 391 and the Law for Conservation and Sustainable Use of Biological Diversity may be found in **Annex A** to this chapter.

The proposal of a **Regime for the Protection of the Collective Knowledge of Indigenous Peoples** (hereinafter called “the draft Law”) is the result of a major coordination and drafting effort of the Peruvian Government. The proposed law would establish a comprehensive legal framework for the recognition and registration of collective TK relating to the use of biological resources, and rules for accessing such TK. (See **Box 3**)

The declared *objectives* of the proposed law are:

- (a) to promote respect for and the protection, preservation, broader application and development of collective TK of indigenous peoples;
- (b) to promote a fair and equitable distribution of the benefits derived from the use of such TK;
- (c) to promote the use of said TK for the benefit of indigenous peoples and humanity as a whole.

The following *general principles* are established:

- (i) Access to collective TK for scientific, industrial or commercial purposes requires prior informed consent from the relevant community or people (Article 7). This may also apply, under certain conditions, to TK in the public domain (Article 12).
- (ii) The present generations of indigenous communities are responsible for preserving, developing and administering collective TK for their own benefit and that of future generations (Article 8).
- (iii) Protection under the law applies to TK belonging collectively to one or more indigenous peoples, but not belonging individually to any of its individual members. Collective TK is regarded as part of the cultural heritage of the indigenous peoples (Article 9 and 10).

Box 3**Main Features in the Peruvian draft Law on TK Protection:**

- Access to collective TK for scientific, industrial or commercial purposes requires *prior informed consent* from TK holders.
- Collective TK that is not in the public domain is *protected* against disclosure, acquisition or use, including third parties having obtained the information under confidentiality
- The *burden of proof* as to the legality of the access, use or disclosure of TK is on the defendant.
- A *register of collective TK* is established; the register is not public, and recordal of TK is optional for TK holders.
- TK *license contracts* must include, in particular, clauses on royalties for use of licensed TK, down payments and a percentage of future sales of products developed from licensed TK.
- A *Fund for the Development of Indigenous Peoples* is established to finance projects for the development indigenous communities.

The draft Law defines the scope of rights of indigenous communities in respect of their TK, and the actions and remedies available to protect that TK. An indigenous community in possession of collective TK is legally protected against any unauthorized or unfair disclosure, acquisition or use of that knowledge, insofar as such TK is not in the public domain (Article 40). This protection extends to third parties having obtained the information under obligation of confidentiality.

Indigenous communities may take legal action against any person infringing their rights in their collective TK, and may request and obtain injunctions and damages. The burden of proof as to the legality of the access, use or disclosure of collective TK is on the defendant (Articles 41, 42 and 43).

A *register of collective TK* of indigenous peoples is envisaged. This would serve to preserve collective TK and provide supporting information to protect better the interests of the holders of the TK (Article 15). Recordal of TK would be optional (Article 14). The register of collective TK would not be public, and could only be accessed with prior written consent from the recording community or people (Article 19). The community that has recorded its TK on the register may request that information regarding that TK be notified to one or more foreign patent offices to be taken into account when assessing the patentability of a third party's invention, or the validity of a granted patent (Article 20).

Special provisions regarding the formalities and contents of TK *license contracts* are included. Such contracts must be in writing (Article 23), and must establish clauses relating, in particular, to the following matters (Article 24):

- Fees and royalties to be paid to the indigenous people for use of their collective TK. Both down payments and a percentage of future sales of products developed on the basis of said TK should be provided.

- Information to the holders of the licensed TK regarding the purpose, risks, implications of the envisaged uses of the TK, including the possible value of such uses.
- Obligation by the licensee to inform licensor periodically on progress in R & D, industrial or commercial activities regarding products developed on the basis of licensed TK.

The draft law establishes a **Fund for the Development of Indigenous Peoples**, with the purpose of contributing to the overall development of indigenous peoples by financing projects and other activities (Article 34). Indigenous communities could obtain funding by submitting their projects to the Fund's Administrative Committee (Article 35). The Fund would be financed by contributions from the State, international cooperation grants, and a percentage of the economic returns obtained from the exploitation of inventions and other technology developed on the basis of licensed TK (Article 39).

Contract

Several respondents mentioned that contractual arrangements had started to be used by TK holders in Peru as a means of structuring and regulating access to TK and to genetic resources associated with TK. Holders of TK were seeking and obtaining advice from different quarters as to the manner in which access contracts should be approached. Some respondents informed that communities were advised to exercise caution when agreeing to part with their TK or to transfer biological resources, and that they should require compensation in exchange for their information.³⁰

Some respondents were skeptical about relying only on clauses guaranteeing returns from future but uncertain commercial exploitation of innovations developed on the basis of licensed TK or transferred biological material. They rather recommended that TK licenses and material transfer agreements involving TK include clauses providing for technical and scientific training aimed at reducing technological dependence, establishment of fiduciary funds for the development of the communities providing the TK or the material, up front payments and milestone payments not linked to product development by the licensee.³¹

Two examples of contracts for the transfer of biological material and related know-how and TK were the "Biological Collecting Agreement" and the "Know-how License Agreement", concluded in 1996 to run for several years. Those contracts originated in a grant awarded by the International Collaborative Biodiversity Group Program (ICBG), financed by several foreign aid and health-related agencies of the United States of America. The project for Peru brought together Washington University in St. Louis, Missouri (WU), G.D. Searle & Co., a subsidiary of Monsanto (Searle), the Museum of Natural History of the National University of San Marcos (Museo), Peruvian University Cayetano Heredia (UPCH), the Central Organization of Aguaruna Communities of the Upper Marañon (OCCAAM), the Federation of Native Aguaruna Communities of the Nieva River (FECONARIN), and the Aguaruna Federation of the Domingosa River (FAD), in affiliation with the Confederation of Amazonian Nationalities (CONAP).³²

Intellectual Property Needs and Expectations # 4

- IP advice and assistance is the negotiation, drafting and enforcement of access and other contracts.

The representatives of the Aguaruna and Huambisa organizations participating in those agreements regarded this experience as a breakthrough in the recognition of their TK ownership, and an example of indigenous communities' capability to negotiate access to their TK.³³ Other observers, including foreign NGO's, were somewhat more critical since they disagreed with the "sale" of the country's genetic resources.³⁴

The Biological Collecting Agreement entitles WU, Museo and UPCH to obtain samples of biological materials and medicinal plants from a defined collection area, and to obtain *information regarding the historic use by the collaborating Aguaruna native communities of plant resources for medicinal purposes*. The preamble clauses explain that WU, Museo and UPCH wish to collect and study the biological diversity of plants and certain animals in the collection area, to *obtain medicinal data of plants* used in that area, and to *screen* plant extracts obtained therefrom for biochemical or biological activity *for purposes of development of new pharmaceutical products*. The Agreement also contains a Code of Conduct - see **Box 4**.

In conjunction with the Biological Collecting Agreement (hereinafter "the agreement"), a "Know-how License Agreement" (hereinafter "the know-how license") was concluded between Searle and the collaborating native communities, in recognition of the fact that the plant extracts provided under the biological collection agreement may involve the use, in whole or in part, of the know-how of the Aguaruna and Huambisa peoples. The know-how license deals with the *use of the know-how of the Aguaruna people for the research and development of new medicinal and pharmaceutical products*.

Prior to the Biological Collecting Agreement, WU and Searle had concluded a License Option Agreement, which gives Searle access to the plant extracts collected by WU and UPCH.

Further information on the provisions in the **Biological Collecting Agreement** and the **Know-how License Agreement** noteworthy in connection with TK are contained in **Annex B** to this chapter.

TK protection in other policy areas

The *Asociación de Defensa y Desarrollo de las Comunidades Andinas del Perú (ADECAP)* (Association for the Defense and Development of the Andean Communities of Peru) conducts development projects and activities in the mountain Department of Huancavelica, in Tayacaja province. It concerns indigenous communities with some 130,000 inhabitants living between 2,800 and 4,500 meters above sea level. Some 80% of that population remain monolingual Quechua³⁵ speakers, in spite of efforts to introduce Spanish. ADECAP aims at developing that region mainly in the areas of education, health and agricultural productivity. Development projects are implemented and executed by the communities themselves, with support from the Association.³⁶

Box 4**Agreed Code of Conduct**

The Parties to the Biological Collection Agreement agreed to practice guidelines of conduct and ethics associated with the collection of biological material and ethnobotanical information, and the recognition of IP. The following items in the agreed code of conduct are noteworthy:

- Collaborate with Aguaruna organizations, communities, and individuals, as well as others to develop multilingual and multicultural educational and training programs and other projects needed to enhance the cultural and linguistic recognition of the Aguaruna People and to improve the quality of life in Collaborating Communities.
- Collaborate in projects of conservation in order to maintain the biodiversity of the ecosystem.
- Develop programs of economic value at community and regional levels by restoring and enhancing economically significant plants and by other means.
- Take a socially responsible approach in their associations with the Aguaruna People, including a full feedback of scientific and other findings and results.
- Help secure the recognition of traditional indigenous knowledge as inventive and intellectual, and, therefore, worthy of protection in all legal, ethical, and professional frameworks.
- Respect the right of privacy of informants and the confidentiality of information received.
- Respect local social values, traditions, and customary law and practice among the Aguaruna People when residing in their communities and at other times.
- Not deplete populations of biological material nor collect species suspected of being rare or endangered.
- Collect only the requisite amount of biological material needed for making plant and animal vouchers and extracting plant collections.
- Exhibit particular sensitivity in collecting of material used by the informants, particularly when cultivated in home gardens and often in limited supply.
- Be respectful of traditional Aguaruna medicinal information and practice, mindful of potentially striking differences between Aguaruna medicine and western medicine.
- Collaborating Organizations and Communities are entitled to seek exclusion from collection activities with an individual or institution that commits a serious or fundamental breach of the code.
- Be respectful of the taboos and spiritual aspects of the Aguaruna People with regard to genetic resources and know-how.
- Be respectful when collecting information regarding the treatment of women, particularly when women healers do not wish to disclose information to men. In this regard, such information shall only be provided to ICBG women investigators.
- All information collected regarding the practices or innovations of the Aguaruna People, relevant to the means for the preparation of compounds, infusions, or poultices, etc., shall not be disclosed to third parties, nor utilized for the development of any product without the prior consent of the Collaborating Organizations.
- The investigators shall maintain a closed-access database of the knowledge, innovations, and practices of Aguaruna Peoples collected during the course of the ICBG Project. Access to the database shall be on a need-to-know basis and shall be restricted to that necessary in order to achieve effective realization of the project's ends.

Summary of Intellectual Property Needs and Expectations

- ❑ Recognition of collective creativity and property.
- ❑ Modalities for TK protection that do not prevent sharing and other transmission of TK.
- ❑ IP assistance and advice on documentation projects
- ❑ IP advice and assistance is the negotiation, drafting and enforcement of access and other contracts.

Annex A

Decision 391 of the Andean Community

The Andean Community, established in 1969, comprises Bolivia, Colombia, Ecuador, Peru and Venezuela. The highest body of the Andean Community is the Commission. It is mandated to adopt legislation that is binding on the Member States, on matters relating to the development and coherence of the Andean common market. Andean common legislation issues mainly in the form of Commission “Decisions”.

A Common Regime on Access to Genetic Resources was established by Decision No. 391 (hereinafter “Decision 391”). It includes provisions that deal with TK relating to genetic and biological resources. The preamble of Decision 391 recalls that the Andean countries are multi-ethnic and pluricultural, and recognizes that the knowledge, innovations and practices of the native, Afro-American and local communities associated with the genetic and biological resources, have a strategic value in the international context. It also recognizes the historic contribution made by the native, Afro-American, and local communities to the biological diversity, its conservation and development, and the sustainable use of its components, as well as the benefits generated by that contribution.

For the purposes of access to genetic resources, Decision 391 defines “intangible component” as any valuable knowledge, innovation, or individual or collective practice, associated with a genetic resource, its by-products or the biological resource in which they are contained, regardless of any protection by intellectual property rights. It also establishes the right and authority of native, Afro-American and local communities to decide in respect of their knowledge, innovations and traditional practices associated with genetic resources and their by-products.³⁷

Decision 391 lays down the procedure to obtain authorization to access and use genetic and biological material originating in the Andean countries. The procedure starts with an application by the party(ies) wanting the access, which is published for public scrutiny and comments. Following acceptance of the application, an access contract is drawn up, to which the applicant and the Member Country concerned are parties. The contract must take into account the interests and rights of the providers of the genetic or biological resources, and of any relevant intangible component. If access is requested to resources or related by-products in conjunction with an intangible component, the contract must include an annex providing the terms and conditions for the distribution of benefits deriving from the use of that component.

Decision 391 establishes enforcement mechanisms and sanctions for non-compliance with its procedures. Unauthorized access to genetic or biological resources, or the associated traditional knowledge is actionable. Any person carrying out transactions with regard to by-products of such genetic resources or products synthesized therefrom, or in respect of the associated intangible components, that are not covered by an access contract, is liable to sanctions including fines, confiscation of infringing material, temporary or definitive closing of establishments and disqualification from future access to biological material. Additionally, access to biological resources may be suspended, cancelled or revoked, compensation for damages may be required, and other civil and criminal sanctions may apply.

The Member Countries may not acknowledge intellectual property rights on genetic resources, by-products or synthesized products, or associated intangible components obtained or developed on the basis of biological or genetic resources accessed in a manner inconsistent with the provisions of Decision 391. The Member Country concerned may bring action to invalidate such rights in the countries where they have been granted. The IP Offices of Member Countries are required to obtain from patent applicants the registration number of the access contract and a copy thereof where the claimed product or process has been obtained or developed on the basis of genetic resources originating in one of the Member Countries.

Law for Conservation and Sustainable Use of Biological Diversity

The Law for Conservation and Sustainable Use of Biological Diversity entered into force in 1997 with a view to facilitating compliance with the Convention on Biological Diversity. The Law recognizes the importance and value of native communities' knowledge, innovations and practices for the conservation and sustainable use of biological diversity (Article 23). It also recognizes the need to protect that knowledge and to establish systems to promote its use under the principles of prior informed consent and fair and equitable distribution of benefits deriving from that use.

The Law provides that native communities' knowledge, innovations and practices associated to biological diversity are part of the cultural heritage of those communities (Article 24). Native communities are therefore entitled to decide on the utilization of their traditional knowledge. Scientific research on the knowledge, conservation and industrial and medicinal application of genetic resources, through both traditional and modern biotechnology, is declared a priority of national public interest (Article 26).

[Annex B follows]

Annex B

Highlights of the Biological Collecting Agreement and the Know-how License

Biological Collecting Agreement

Collaborating communities and know-how. Aguaruna communities cooperate with WU, Museo and UPCH in the identification of medicinal plants and their uses for medicinal purposes. WU, Museo and UPCH undertake not to request, accept or otherwise obtain know-how or medicinal plants with historic use for medicinal purposes that are available within the collection area from any person, institution or organization other than the collaborating communities. Any such know-how or medicinal plants obtained from other persons, institutions or organizations not members of the collaborating communities must be returned to the providers or destroyed, and any written record of such know-how must be transferred to CONAP for return to the providers.

Prior informed consent. The individual or individuals providing the know-how, and the elected community leader, must sign an informed consent form, in Spanish and Aguaruna languages, prior to communication of know-how or of medicinal plants. Evidence of community collaboration is documented by the approval of the relevant community assembly as recorded in the minutes of the assembly, by a signature by the Apu (leader) and a representative of the project. The field coordinator also signs the form to the effect that confirmation has been obtained from the leaders of the collaborating communities prior to accepting their collaboration. Information regarding the historic use of medicinal plants may not be collected before the informed consent form is complete. That information must be held in confidence until protection is established or a release obtained.

Use of medicinal plants, plant extracts and know-how. The right of WU, Museo and UPCH to use transferred medicinal plants, plant extracts and know-how terminates on the date of termination of the know-how license. However, research activities of a non-commercial nature being carried out by WU, Museo and UPCH on the date of termination may continue, but this does not entitle any publication of confidential information of collaborating communities, including know-how, nor the application for intellectual property rights over any product, process or new plant variety without prior informed consent. On termination of the know-how license WU, Museo and UPCH must return, destroy or otherwise dispose of all transferred medicinal plant collections, plant extracts and know-how, and to terminate any ongoing commercial R&D activities related thereto, with the exception of biodiversity and voucher collections deposited in museums for scientific study.

Collection area restriction. WU, Museo and UPCH undertake not to elicit or otherwise obtain information regarding tangible or intangible resources from any individuals or communities other than the collaborating communities and individuals from those communities. In the event of receipt of any know-how from non-collaborating communities, such information must be treated as confidential information of the Aguaruna People, and the know-how is deposited with CONAP who must return it to the providers. Except as provided in the know-how license, the know-how may not be used for commercial purposes.

Ownership of resources. Plants collected for extraction and extract samples provided for use in screening programs of WU, UPCH or Searle remain the property of the Aguaruna people, subject to Peru's sovereign rights over its biological resources. The knowledge of plants, plant parts and preparation methods used for medicinal purposes are the property of the Aguaruna people. Those intangible resources are recognized as historic assets of the Aguaruna people. Museo is given the right to maintain collections of those plants and distribute them to internationally renowned herbaria and museums, but may not use or allow to be used those collections for commercial purposes. Publications of scientific or educational nature are permitted, provided that such publications may not include confidential information, including know-how, of the collaborating communities without prior informed consent.

Reporting. WU, UPCH and Searle must provide information to CONAP on advances made in the investigation of the chemical and screening analysis of the plant extract collections, including information as to their potential commercial value. While the publication of non-confidential scientific material is encouraged, the publication of confidential information, including know-how, not in the public domain requires the prior informed consent of the collaborating communities.

Collection fees. Searle must pay the collaborating organizations a collection fee for each medicinal plant collection, but not less than a minimum fee per annum.

Royalty Payments. Searle must pay royalties to WU, UPCH, Museo and the collaborating organizations on the basis of net sales of licensed products. The rate of the royalty depends on the greater or lesser lead value added during the plant extract screening process. Licensed products are defined as products developed by Searle on the basis of plant or plant extracts obtained through the agreement, or created through the direct or indirect use of know-how disclosed by the collaborating organizations or members thereof.

Use of funds. Royalties, fees and other payments are paid to a joint account of the collaborating organizations. These funds are to be used by the collaborating organizations to ensure equitable sharing of benefits among the Aguaruna people through projects to promote education, health, conservation, and sustainable management of natural resources.

Ownership of inventions and patents. Inventions made or developed under the agreement belong to the inventor(s). If medicinal plants, plant extracts or know-how of the Aguaruna people are directly or indirectly utilized in the development of an invention, the resources of the Aguaruna people must be recognized, and written consent of the collaborating organizations must be obtained prior to filing of a patent application. Any application for a patent on a product developed for the same or similar purposes as the historic use by the Aguaruna people must clearly recognize the role of the Aguaruna people in the invention contained in the application.

Confidentiality. Information and materials exchanged between the parties, not covered by specified exceptions, are regarded as confidential information. Their use and communication to third parties is restricted accordingly.

Collaboration and training. The agreement provides for the exchange of knowledge and expertise to achieve the goals of the agreement. Training among the collaborating communities is envisaged, and students therefrom are encouraged to apply for scholarships to attend the universities participating in the project. Field courses and workshops in collection and other practices are to be held for the collaborating communities. Collaborating organizations and INDECOPI (the Peruvian Intellectual Property Institute) will receive database software to store and search ethnobotanical and ethnomedicinal information.

Code of conduct. WU, UPCH, Museo undertake to carry out their activities under the project in a manner consistent with the highest standards and codes of ethics proposed by the International Society of Ethnopharmacology, the Society of Ethnobiology and the Society of Economic Botany. They also agree to abide by a Code of Conduct annexed to the agreement, in respect of the collection of biological materials and ethnobotanical information, and the recognition of IP rights. (See **Box 4 above**).

Cultural conservation. The ICBG members expressly agree to comply with Article 8(j) of the Convention on Biological Diversity.

Ethical obligations in relation to genetic resources. The ICBG participants undertake not to collect or accept any samples of genetic material of human origin for commercial exploitation. They also undertake not to use the know-how of Aguaruna people for research or development of new plant varieties or other living organisms, and not to apply for any patents, breeders rights or other IP rights over any new plant varieties or other living organisms developed using medicinal plants, plant extracts and know-how of the Aguaruna people without their prior informed consent. Such consent may not be unreasonably refused, but refusal based on ethical beliefs of the Aguaruna people may not be considered unreasonable.

Know-how License Agreement

Definition of know-how. Know-how is defined as the knowledge, innovations, practices, expertise and secrets of the Aguaruna and Huambisa peoples with regard to the use of biological resources for medical purposes.

Definition of licensed product. A licensed product is any natural or synthetic product, process, method or commercially valuable pharmaceutical substance or composition developed by Searle or its partners on the basis of plant or plant extracts obtained through the biological collection agreement, or created through the direct or indirect use of know-how disclosed by the collaborating organizations or their individual members.

Grant of license. The collaborating organizations (CONAP, OCCAAM, FAD and FECONARIN) grant a non-exclusive license to Searle to use the know-how of the Aguaruna and Huambisa peoples to make, use, sell, offer for sale and import licensed products. The know-how may not be used for commercial, scientific or R&D purposes, except as provided in the license agreement. Sub-licensing by Searle is allowed only to an affiliate of Searle, to third parties for the purposes of screening, to universities, hospitals, pharmacists and physicians for evaluation, testing or commercial distribution

and use of the licensed products, to contract manufacturers engaged to make the products for sale, and to WU and UPCH.

License fees. Searle paid the collaborating organizations a license execution fee at the signing of the agreement, and must pay a fixed annual fee while the license remains in force. License fees are adjusted annually in line with inflation on the basis of the Consumer Price Index (CPI) in the United States of America.

Milestone payments. Milestone payments are due by Searle where the development of a licensed product reaches commercial stages. Such payments are due upon filing of an investigative new drug application, or a new drug application, for a licensed product with the United States Food and Drug Administration.

Royalty Payments. Searle must pay the collaborating organizations a royalty on the basis of net sales of licensed products. For each licensed product that becomes covered by a patent granted in any country, royalties must be paid for sales of licensed products in that country from the date of the first sale throughout the life of the patent and for five years after its expiration. For each licensed product that is not covered by a patent, royalties must be paid for sales during 20 years from the date of the first sale.

Intellectual property rights. Any patent applications for licensed products must include full details of the resources utilized and their traditional use by the Aguaruna and Huambisa peoples as disclosed to Searle. Inventorship is determined by the applicable laws or treaties. If an Aguaruna or Huambisa person qualifies as an inventor, he must be included as such in any relevant patent applications. Searle has a right of first refusal in the event the rights of such Aguaruna or Huambisa inventors are to be assigned or an exclusive license is to be granted.

License to collaborating organizations. Searle grants the collaborating organizations a non-exclusive license under the patents issued to Searle for licensed products. Such license is only for R&D purposes in products and processes for the conservation and sustainable use of biological resources, not for any commercial use. Any unpublished and unpatented information, innovations and inventions developed by the collaborating organizations under this license is regarded as included within the know-how license already granted to Searle, and payment therefore is covered by the royalties and fees agreed under the know-how license. Searle has a right of first refusal in respect of patents or other rights received by the collaborating organizations on products or processes based on the R&D allowed by the license granted to them by Searle.

Freedom for traditional uses. Aguaruna and Huambisa indigenous peoples are free to continue making and selling their traditional medicinal products for use in their traditional methods. However, products and methods patented by Searle on the basis of licensed products are not regarded as being traditional medicinal products.

Privacy and publicity. Searle may not make any promotion of any product, including advertising and press releases, that incorporates, information regarding the Aguaruna and Huambisa peoples, or any visual representation thereof or of the Peruvian Amazon without prior written consent. The parties must agree on the manner in which the role of the Aguaruna and Huambisa peoples will be acknowledged in connection with the know-how license agreement.

- ¹ For example, at the meeting with representatives of the *Confederación de Nacionalidades Amazónicas del Perú (CONAP)* (Confederation of Amazonian Nationalities of Peru), Lima, May 11, 1999, and of the *Asociación de Defensa y Desarrollo de las Comunidades Andinas del Perú. (ADECAP)* (Association for the Defense and Development of the Andean Communities of Peru), May 13, 1999.
- ² Meeting with Mr. César Sarasara, President, *Confederación de Nacionalidades Amazónicas del Perú (CONAP)* (Confederation of Amazonian Nationalities of Peru), Lima, May 11, 1999.
- ³ Meetings with Mr. Jorge Noriega, *Centro de Estudios y Promoción del Desarrollo (DESCO)* (Center for Development Studies and Promotion), Lima, May 11, 1999, and with Mr. César Sarasara, see above.
- ⁴ Meetings with Mr. Mario Álvarez, *Asociación de Defensa y Desarrollo de las Comunidades Andinas del Perú. (ADECAP)* (Association for the Defense and Development of the Andean Communities of Peru), and with Mr. Wrays Pérez, *Asociación Interétnica de Desarrollo de la Selva Peruana (AIDSESP)* (Inter-Ethnic Association for the Development of the Peruvian Rain Forest), Lima, May 13, 1999.
- ⁵ Meeting with Mr. Erik Pajares, *Centro para el Desarrollo del Indígena Amazónico (CEDIA)* (Center for the Development of Amazonian Indians), Lima, May 13, 1999.
- ⁶ Meetings with Mr. Mario Álvarez and Mr. Wrays Pérez. Lima, May 13, 1999. See above.
- ⁷ Meeting with Mr. Alejandro Argumedo, *Asociación para la Naturaleza y el Desarrollo Sostenible* (Association for Nature and Sustainable Development) and Indigenous People's Biodiversity Network (IPBN), Lima, May 12, 1999.
- ⁸ Meeting with Mr. Mario Álvarez. See above.
- ⁹ Meeting with Mr. Wrays Pérez. See above.
- ¹⁰ Meeting with Mr. Alejandro Argumedo. See above.
- ¹¹ Wari is one of the largest Pre-Inca civilizations in pre-Columbian South America. Its center was in the present day region of Ayacucho, Perú (some 450km. Southeast of Lima).
- ¹² Meeting with Mrs. Tarcila Rivera, *Centro de Culturas Indias Chirapaq* (Chirapaq Center for Indian Cultures), Lima, May 13, 1999.
- ¹³ Meeting with Mr. Guillermo Arévalo, *Instituto de Difusión e Investigación de la Medicina Amazónica (IDIMA)* (Institute for the Dissemination and Research of Amazonian Medicine), Lima, May 13, 1999.
- ¹⁴ Meeting with Mrs. Tarcila Rivera. See above.
- ¹⁵ Meeting with Mr. Lelis Rivera, *Centro para el Desarrollo del Indígena Amazónico (CEDIA)* (Center for the Development of Amazonian Indians), Lima, May 13, 1999.
- ¹⁶ Meeting with Mrs. Tarcila Rivera. See above.
- ¹⁷ Meeting with Mr. Mario Álvarez. See above.
- ¹⁸ Meeting with Mr. Miguel Holle, *Centro Internacional de la Papa (CIP)* (International Center for Potatoe), Lima, May 10, 1999.
- ¹⁹ Meeting with Mr. Mario Álvarez. See above.
- ²⁰ Meeting with Mr. Guillermo Arévalo. See above.
- ²¹ Meeting with Mr. Guillermo Arévalo. See above.
- ²² Meetings with Mr. Mario Álvarez and with Mr. Wrays Pérez. See above.
- ²³ Meeting with Mr. Wrays Pérez. See above.
- ²⁴ Meeting with Mr. Miguel Holle. See above.
- ²⁵ Meeting with Mr. Alejandro Argumedo. See above.
- ²⁶ Meeting with government authorities at the Ministry of Foreign Affairs, May 10, 1999.
- ²⁷ *Decisión 391 de la Comisión del Acuerdo de Cartagena; Régimen Común sobre Acceso a los Recursos Genéticos.*
- ²⁸ *Ley sobre la Conservación y el Aprovechamiento Sostenible de la Diversidad Biológica; Law No. 26839, of 1997.*

[Endnote continued from previous page]

- ²⁹ *Propuesta de Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas*. The draft law was published for comments in the Official Newspaper “El Peruano”, on October 21, 1999, and subsequently on August 31, 2000. The text can be accessed at the INDECOPI website at www.indecopi.gob.pe
- ³⁰ Meeting with Mr. Lelis Rivera, Executive Director, *Centro para el Desarrollo del Indígena Amazónico* (Center for the Development of Amazonian Indigenous Peoples), May 13, 1999.
- ³¹ Meeting with Mr. Alejandro Argumedo, and Mr. Miguel Holle. See above.
- ³² Meeting with Mr. Erik Pajares, see above, and with representatives of the *Confederación de Nacionalidades Amazónicas del Perú (CONAP)* (Confederation of Amazonian Nationalities of Peru), Lima, May 11, 1999.
- ³³ *Idem.*
- ³⁴ *Idem.*
- ³⁵ Quechua is a family of native South American languages, and was the basic language of the pre-Columbian Inca civilization. It is presently spoken mainly in the mountain areas of Ecuador, Peru and Bolivia.
- ³⁶ Meeting with Mr. Mario Álvarez. See above.
- ³⁷ Decision 391, Articles 1 and 7, respectively.

[End of Annexes and document]