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This is a part of WIPO sponsored study on the role of intellectual property rights in the sharing of benefits arising from the use of biological resources and associated traditional knowledge.

Case Study Three: Nigeria



Overview

The subject of this case study is the role of intellectual property rights in the benefit-sharing arrangements surrounding the work of the Bio-resources Development and Conservation Programme (BDCP) as a part of the International Cooperative Biodiversity Group (ICBG) in the field of traditional medicine. In particular the role of patents, trade secrets and trademarks are discussed. The case examines, *inter alia*, a national patent and an ‘international’ patent application under the Patent Cooperation Treaty (PCT), with claims over TK-based pharmaceutical inventions related to the work of the ICBG. Copies of these patents are attached in Annexes 3.4.3 and 3.4.4. Based on these examples, the availability of patent protection is identified as a key requisite for generating benefits to be shared with local practitioners of traditional medicine from pharmaceutical research based on their knowledge. The central role of a Trust Fund established by BDCP for sharing these benefits in monetary and non-monetary form is highlighted. The case study also illustrates the difficulty of balancing the input of various local stakeholders of TK and biological resources, such as traditional healers’ associations vis-à-vis local community representatives.

Policy context

After the recent ushering in of democratic processes, Nigeria is strengthening its economy, civil society, and intellectual institutions. With a population of over 120 million people, 250 ethnic groups with different languages and sometimes different cultures, with a majority living in rural areas (Nnadozie, 1989), the role of agricultural and biological resources is extremely important for current subsistence and future income growth. In Nigeria there has been a long tradition of bio-trade as well as bio-prospecting for research and commercial purposes. Two of the major efforts among this spectrum of activities have been undertaken by the National Institute for Pharmaceutical Research and Development (NIPRD) and the

Bio-resources Development and Conservation Programme (BDCP), independently as well as under the auspices of the International Cooperative Biodiversity Group (ICPG), which is funded by the National Institute of Health, the National Science Foundation, the National Cancer Institute and US Aid for International Development (USAID). In addition, private sector companies such as Shaman Pharmaceuticals, Inc. have also been active in the country.

The complexity of the legal and administrative system in Nigeria is that of a federal structure where each state may legislate in certain areas while the Federal Government may legislate in other areas. In certain cases this structure poses challenges in the context of access to biological resources and associated knowledge systems. Nnadozie (1999) describes this complexity by showing that the laws dealing with patents, trademarks, industrial designs, merchandise marks, etc., are under the exclusive jurisdiction of the Federal Government, whereas land, forestry and forest resources are subject to State Law. So far as Federal reserves and national parks are concerned, forest resources therein are covered by the Federal government. He points out that the Federal authority is appreciative of the limits of its jurisdiction in the context of forest resources. Nnadozie illustrates this point by the “draft National Park (Amendment) Decree which seeks to incorporate the provisions of Article 15 of the CBD with respect to access [and] restricts its application only to National Parks and Federal reserves” (op. cit., 1999). Ajai (1996, 1997) describes the efforts which environmental lawyers have made to influence public policy on the subject. He illustrates these efforts by referring to Section 36(1) of the National Parks Decree (Decree No. 46, May 26, 1999) that prohibits any person from prospecting for genetic material from national parks without the written prior informed consent of the minister. Section 36(2) of the Decree deals with issues of prior informed consent, indigenous and community rights, and benefit-sharing, and these provisions are not restricted to the National Parks only.

The customary laws lie within the power of state governments, which can also establish customary codes. Part 4, 23 (1) of the Forestry Law [LSLN 16 of 1972. 1988.No.(5)] states that “the protection, control and management of a local government council protected forest shall be undertaken by the local government council constituting it or within whose jurisdiction it is situated, subject to the supervision and control of the state commissioner, exercised with the advice of Director-General.” Further, the law states (Part 5, 24) that “any local government council at the request of any native community within the area of its jurisdiction may, with the approval of the state commissioner, declare any area occupied by such native community, a communal forestry area”. Part 5, 26 states that “a communal forestry area shall be managed and controlled by the native community acting on the advice of the local government council and the forestry officer”. The law empowers the government’s council to make rules prescribing duties for the native communities, prohibiting or regulating the collection of forest products of any kind, their sale or modification, etc. In effect, therefore, the forest department determines broadly the framework of access and utilization of a wide spectrum of biological and genetic resources in the forest areas. The historical rights of local communities and their biodiversity-related knowledge systems have been eroded or disturbed where extensive tracts of forest lands have been granted for large scale farming (Nnadozie, 1999).

Intellectual property

Intellectual Property Act of Nigeria of 1971

The intellectual property acts of Nigeria, viz. The Patents and Designs Act of 1970, the Merchandise Marks Act of 1958, and the Trade Marks Act of 1965, and the National Office of Industrial Property Decree no 70, 1979, do not contain any specific provisions relating to traditional knowledge or community knowledge. The Patents and Designs Act of 1970 and

the National Office of Industrial Property Decree no 70, 1979 do provide for the availability of process as well as product patents, with a term of protection of twenty years from the filing date. Patents cannot be obtained in respect of plant or animal varieties, or essentially biological processes for the production of plants or animals (other than microbiological processes and their products) or for inventions, the exploitation of which would be contrary to public order or morality. Further industrial property rights that are available include those of the protection of trade secrets and trademarks. The National Agricultural Seeds Decree (1982) provides for maintaining registers of persons and/or corporations which are pursuing research on crop varieties leading to the registered release of the same for commercial production. Such registered persons or bodies can import, subject to the provisions of national phytosanitary regulations, crop varieties and/or biological materials duty free for commercial release. The Decree does not have any specific provision for landraces or farmers' varieties. The National Crop Varieties and Livestock Breeds Registration Act (1987) provides for the registration, naming, and release of old and new crop varieties or livestock breeds which meet the distinctiveness, uniformity and stability requirements. It also does not provide any specific mechanism for the protection of farmers' varieties or landraces, though it does require maintenance of a National Register for all crop varieties and livestock breeds and it requires monitoring the effects of exotic plants and animals on them. Nnadozie (1989) describes the implications of the amended Federal Environment Protection Agency Decree No.58 of 1988 which confers the Federal Environmental Protection Agency with the overall responsibility for the conservation of the environment and biodiversity and the sustainable utilization of Nigeria's natural resources. The Agency is developing the country's Biodiversity Action Plan.

Organization of African Unity Model Legislation for the Recognition and Protection of the Rights of Local Communities, Farmers, Breeders, and for the Regulation of Access to Biological Resources

The Organization of African Unity (OAU) has recently drafted "Model Legislation for the Recognition and Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources," based on a Decision by the Ministerial Council of the OAU (Addis Ababa, March 20-23, 1998). It provides, among other things, a direction for implementing Article 15 and Article 8(j) of the CBD. Under Article 5, the Model Legislation requires prior informed consent of not just the State, but also that of the local communities which would be granting access to biological resources. Under Article 6, it provides for a Public Registry, so that any person may consult and comment on the application for access to specific biological resources or knowledge about them. Under Article 8, the Model Legislation requires "guarantee to deposit duplicates of each specimen of the biological resource, or the records of community innovation, practice, knowledge or technology collected with the duly designated governmental agencies and, if so required, with local community organizations". It requires that the national competent authority and the concerned community be informed of all the findings that result from research and development of the resource.

As far as intellectual property rights are concerned, the Model Legislation requires a commitment to be undertaken by the collector of resources to

not apply for a patent over the biological resource or its derivatives and not to apply for a patent or any other intellectual property rights protection system over community innovation, practice, knowledge or technology without the consent of the original providers; compensate the state and/or concerned local community or communities for their contribution in the generation and conservation of the biological resource, and the maintenance of the innovation, practice, knowledge or technology to which access is sought; submit to the National Competent Authority a regular status report of research and development on the resource concerned and where the biological resource is to be collected in large quantities on the ecological state of the area; and abide by the relevant laws of the country particularly those regarding sanitary control, bio-safety and the protection of the environment as well as by the cultural practices, traditional values and customs of the local communities.

Under Articles 21 through 24, the OAU model law provides that:

- Local communities shall have the right to withdraw consent or place restrictions on the activities relating to access where such activities are likely to be detrimental to their socio-economic life, or their natural or cultural heritage.*
- (1) Local communities shall exercise their inalienable right to access, use, exchange or share their biological resources in sustaining their livelihood systems as regulated by their customary practices and laws.*
- (2) No legal barriers shall be placed on the traditional exchange system of the local communities in the exercise of their rights as provided for in paragraph (1) above and in other rights that may be provided by the customary practices and laws of the concerned local communities.*
23. *(1) The state shall ensure that at least fifty per cent of benefits obtained from the commercial use of a biological resource and/or community innovation, practice, knowledge or technology are channeled to the concerned local community or communities.*
- (2) The state and collector shall enter into a written contract that ensures the benefits referred to in paragraph (1) above are to be derived on behalf of the local community or communities concerned.*
- (3) Any written contract referred to above shall be entered into by the state and the collector, with the full participation and approval of the concerned local community or communities.*
24. *(1) The Community Intellectual Rights of the local communities shall be recognized at all times, and shall be further protected under the mechanism established by this legislation.*
- (2) An item of community innovation, practice, knowledge or technology, or a particular use of a biological or any other natural resource shall be identified, interpreted and ascertained by the local concerned communities themselves under their customary practice and law, whether such law is written or not.*
- (3) Non-registration of any community innovation, practice, knowledge or technology is not to mean that these are not protected by Community Intellectual Rights.*

The OAU Model Legislation further suggests an institutional arrangement providing for the development of a system of *registration* of items protected by community intellectual rights

and farmers' rights according to their customary practices and law (Article 29.6). Other provisions pertain to the development of a national information system (Article 36.1-3) to compile and document information on local knowledge and innovation practices of the community and their access to biological resources. The Model Legislation further provides for maintaining an up-to-date information system about the research and development on these resources and the knowledge about them. The cost of setting up new systems afresh is very high and each country need not develop its own system. Existing IP information systems, such as JOPAL, ESPACENET, WIPONet, etc., could provide efficient vehicles for such an information system, if properly utilized and evolved by all stakeholders. The accessibility of international intellectual property information systems to local communities and small inventors and innovators at low cost, in local language and with sufficient ease will remain an important issue to be resolved. Many European countries and the United States of America have already made their patent databases for last 20 or more years available to the general public on the Internet. The Model Legislation also provides for tracking biopiracy cases and disseminating information about the same to all the concerned bodies. The Model Legislation further provides for a Community Gene Fund, "for the benefit of farming communities whose farmer varieties have been the basis for breeding of the breeders' variety". A royalty fixed by the National Competent Authority out of the protected seeds shall be credited to this Fund. The Fund will be used to finance projects developed by the local communities with or without the participation of external experts. It is worth noting that the Model Legislation makes a specific recommendation *not* to meet salaries and administrative expenses relating to the establishment and administration of the Community Gene Fund from the Fund so that the entire proceeds go to the communities. So far no African (or other) country have enacted laws which make such provisions. The Indian Plant Variety and Farmers' Right Bill as well as the Biodiversity Bill (referred to in Case Study 2) do include provisions of this kind.

Prof. C. O. N. Wambebe, Director General of the National Institute for Pharmaceutical Research and Development (NIPRD) at Abuja, Nigeria, provided the agreement which NIPRD enters into with the herbalist whose knowledge they use to develop drugs (see Annex 3.4.2). The agreement provides a very clear and comprehensive framework for obtaining the informed consent of the local herbalist for using his or her knowledge to develop commercial products. The NIPRD is obliged to inform the herbalists if the information provided by the herbalists already exists within the Institute or has been provided by other experts. The Institute is also obliged to furnish to the herbalist in writing, the results of every scientific test or analysis carried out on the material received from the herbalist.

Regarding intellectual property rights, Article 8 of the agreement states that

The INSTITUTE shall apply for and obtain or cause to be granted and obtained the letters of patent on the products IN THE NAME OF THE INSTITUTE after the same has been developed and processed PROVIDED THAT THE CONSULTANT HERBALIST'S NAME BE INCLUDED IN THE PATENT subject to the conditions hereinafter set forth.

Such a use of patents for the direct sharing of benefits arising from the use of biological resources and associated knowledge has not been found in any other public or private sector institutions as yet. The registration of trademarks and/or designs in any product supplied by the herbalist to the Institute are supposed to vest with the Institute from the date of delivery of the product by the consultant herbalist. However,

the discovery of the herbal products by the consultant herbalists shall be acknowledged as such in the correspondence and literature, publications of the product as much as practicable.

The Institute would provide to the herbalists at least ten per cent of the net profit as royalty. In the case of the Bio-resources Development and Conservation Programme (BDCP), such explicit agreements have not yet been developed, although in spirit they have tried to follow these concepts and have been pleading for reciprocity and accountability in such transactions for almost twenty years.

Indigenous Traditional Knowledge and Biodiversity Conservation

The creator of the Bio-resources Development and Conservation Programme (BDCP), Dr. Maurice Iwu, has pioneered benefit-sharing arrangements and pursued the subject of traditional medicine with great rigor. In an early study on traditional Igbo medicine (Report of a project sponsored by the Institute of African Studies, University of Nigeria, Nsukka (1978), Iwu describes the philosophical as well as empirical context of an investigation involving approximately 600 medicinal plants. Some of the problems encountered during the study include

- about half of the 600 plants were collected in fragments that could not be used by the taxonomists for identifying the identity of the genetic resource;
- compatibility between names in different dialects for similar or identical Igbo plants was difficult to achieve;
- there were conflicts between the same or similar names being used for different plants (a problem common to many other parts of the world);
- in a few cases, the language of the central Igbo region, i.e., *orlu – okigwe*, was used;
- differing therapeutic claims about the same use of the same plants from different locations posed contradictions in these claims;
- differing therapeutic claims about similar uses of the same plants in the context of different healing rituals posed complications to the claims;
- the multiple interpretations of different diseases posed another dilemma for the researcher. For instance, *'ogwu afo osisa'* could mean the treatment of diarrhoea for some healers or the treatment of constipation for others. Since it is not uncommon for a drug to have one activity at lower dose and the totally opposite effect at higher doses, the role of food in the healing process was considered counter-intuitive by the researcher.

Such problems of translation between different knowledge systems become complicated when some influential traditional beliefs seem incompatible with the scientific knowledge or training of the scientists. The importance of the aforementioned study lies precisely in the fact that it did not ignore such complications in the translation between different knowledge systems. Iwu included many subjective interpretations of the events, therapy, and the phenomena that he observed, because he felt that when in doubt “record and report” rather

than “ignore and omit”.¹ This is one interpretation of the intellectual dilemma when working between different knowledge systems (formal and informal, modern and traditional).

Iwu also finds some commonalities in the medical thinking of ancient Western philosophers and the Igbo world view. For instance, he finds similarity in the scepticism about the corpuscular theory (relying too much on the empirical understanding of the way parts of the body work) and the Igbo’s rejection of the explanation of diseases or health based on some microscopic constituents of material objects.

Iwu points out an important feature of Igbo indigenous knowledge which is often ignored in Western medical research. He points out that Western definitions of certain diseases and their treatment are focused on the major outstanding symptom/s, while ignoring sometimes the “subtle-but-chronic” and debilitating symptoms of the disease. He takes the example of malaria and shows that Western medicine considers the key symptom of malaria as cyclic chills, fever and headache. Various malarial drugs such as *chloroquin*, *quinine* and related compounds abolish these symptoms by counteracting the effective plasmodium species in the blood. Western medicine, he submits, does not appreciate the importance of any anti-malarial drugs which are addressed to the more serious but non-dramatic effects of malaria, such as spleno-hepatomegaly, jaundice, anaemia and hemoglobinuria. Therefore, indigenous medicines which fortify the liver or spleen are ignored in Western medicinal knowledge systems. Iwu (1978) highlights that the Igbo herbalists believe “it is only a liver weakened by malaria or exogenous chemicals that could be liable to viral attack.” In the Igbo knowledge system, malaria, diabetes, or any other disease-condition refer to a variety of complex pathological states and not to any specific isolated symptoms, as they are viewed by orthodox Western medicinal knowledge.

Iwu believes that there is no knowledge without moral responsibility and therefore he omitted some practices that he considered “dangerous or bordering on occultism”. He questions the assertion by some that Igbo medicine is not scientific. He says that the deficiency in the African healing system (in areas where such deficiencies do exist) is not the result of unscientific thinking, but of inadequate information. Before the need for such efforts was generally recognized, Iwu called “to update the information and the data bank of the traditional native healer.” Iwu (1978) had earlier questioned the futility of comparing the Western and the indigenous systems of science emerging from different observations and cultural contacts. However, the case study will demonstrate that it has been possible to build bridges between the two systems of knowledge by comparing, contrasting, and in some places creatively complementing one by the other.

While Iwu stresses that traditional medicine emphasizes not only the physical properties of the herb, but also the natural life-force within the plant and the role of ancestors and the gods in the healing process, he does recognize the possibility of dealing with this knowledge in a reductionist manner. As an example, he describes the role of a traditional healer viz., ‘*Dibia*,’ who is not just a herbalist but also the custodian of the religious life of the community. There are several methods by which one learns to be a healer. It could be through a long-term apprenticeship with an older *Dibia*, or through a divine selection after trance, dream, or even prolonged illness. Some individuals are supposed to be born as *Dibias*.

The National Traditional Medicine Policy, which is being discussed in the country, emphasizes “obvious hazards of traditional medicine practice, which should, therefore, be

¹ This is the author's interpretation of Dr Iwu's work.

regulated". The National Traditional Medicine Board primarily aims at monitoring, controlling, and standardizing the facilities and services for the practice of traditional medicine in Nigeria. There is also a proposal to develop a Code of Ethics for the Practice of Traditional Medicine, which would regulate the relationship of traditional medicine practitioners with patients, the public, and each other. Traditional medicine practitioners are expected to keep records and follow all the procedures generally followed by the orthodox medical system. During 1997 a work plan was developed to have a long-term strategy for strengthening the traditional medicine system. However, a great deal of informality still exists, i.e. the traditional herbal medical practitioners follow very informal and highly varied protocols in this regard.

History of Traditional Medicine Regulation in Nigeria

Historically, it is reported that the Federal Ministry of Health approved research into the medical properties of local herbs in 1966 at the University of Ibadan. In 1973, the International Scientific Congress on Traditional Medical Therapy was held at the University of Lagos. In 1977, a delegation of four experts was sent to India and China to examine the systems of traditional medicine in these countries. In 1979, a nationwide seminar was organized and followed by the establishment of a Board of Traditional Medicine by the Lagos State Government in 1980. In 1984, after the report of the National Investigative Committee on Traditional and Alternative Medicine, it was suggested that every state in the country should have a Board of Traditional Medicine. This recommendation was repeated in 1984 when all the State Ministries of Health were mandated to set up Boards of Traditional Medicine.



Figure 1 Ajohia. A sacred site where leftover tapir used for treating arrow heads are buried.

It is obvious that the traditional medicine system has been evolving through a variety of formal and informal processes aimed at bringing about reliability, professional discipline, authenticity and a kind of accreditation system. In a recent publication, the *Handbook Of African Medicinal Plants* (1997), Iwu traces the history of the healing arts in Africa to 3200 BC. Some of the African healing herbs which are recognized in the modern *Pharmacopias* are *calabar* (*Physostigma venenosum*), *strophanthus*, arecanuts, kino, salix, kola, the African periwinkle, and the devils claw (*Harpagophytum procumbens*). In some cases, the African *Rauwolfia vomitoria* has been found to contain a higher content of anti-hypertensive alkaloid reserpine and the anti-helminthic drug *ajmaline*, compared to the better known species of the

plant. Another outstanding example of the strength of traditional medicinal herbs is the *willow* plant, *Salix capensis*, which has been used for centuries as a pain killer and antipyretic in Africa. It contains esters of salicylic acid, which is the basis for developing a universal analgesic Aspirin.

While this wealth of medicinal plants abounds in the African region, Africa has at the same time the highest rate of deforestation in the world. In particular, Nigeria has about five per cent per year as against the global rate of 0.6 per cent. It is obvious, therefore, that the conservation of biological resources and associated knowledge systems becomes a crucial policy objective.

Institutional Context of International Cooperative Drug Development and Conservation of Biodiversity

As a part of the International Cooperative Biodiversity Group (ICBG), sponsored by the National Institute of Health, the National Science Foundation, and the US Agency for International Development, a programme for conservation and sustained economic development through drug discovery was taken up. Schuster et. al. (1999) emphasize that

One of the unique features of this ICBG is that the emphasis is on discovery and development of compounds for tropical diseases such as malaria, leishmaniasis and other parasitic infections rather than only for the treatment of diseases of global importance such as cancer, AIDS and metabolic disorders. The program is committed to the development of low-cost phytomedicines, in addition to the isolation of lead compounds for drug discovery. ... the ICBG - Drug Development and Conservation of Biodiversity in West and Central Africa aims to demonstrate that sustainable drug development is a viable alternative to the common destructive activities such as timber harvesting, as a source of forest income for local communities.

The programme has used a combination of four approaches, namely

- the development of drugs which address the priority health needs of the United States and the participating countries,
- the inventorization of native species and indigenous knowledge,
- capacity building to achieve the goals of the research programme, and
- strengthening the scientific infrastructure in the host developing country.

The programme is administered by the Fogarty International Center at the US National Institute of Health. Unlike most other projects, in this programme most of the processing and biological testing of the plant material is performed within the Group rather than in the institutions outside the Group. The idea was to build a team of scientists who will discover lead plants and develop active molecules into drugs. Selected plant products will then be developed to the pre-clinical stage before starting negotiations with commercial partners. However, the sharing of benefits is not delayed until the development of drugs and their commercialization is completed. The access fee, capacity building training and institutional development, conservation plots, strengthening of infrastructure for traditional healers, etc., are started right from the beginning without waiting for actual leads to be generated. Shaman Pharmaceuticals Ltd. had agreed to share royalties with local communities participating in the program even if no drug was actually developed from the lead provided by a specific local community. And the drugs might have been developed from the leads from elsewhere. The first newsletter of BDCP (1996) recognized this dilemma by describing the practical thresholds of instituting effective benefit-sharing arrangements:

While the process benefits are guaranteed, and in many ways more fruitful, product of this type of collaboration (really are).... the fine-workings of the flow of cash that is used as a measure of fairness and responsibility, and which creates the most interest. As a result, there is a popular fixation on documents themselves, to the detriment, in some cases, of the relationships upon which they are based. It took, for example,

more than a year and many contentious meetings to draft an intellectual property rights agreement for the ICBG project. This was due largely to the wildly disparate institutions and outlooks involved in the program”, and the lack of shared expectations in the beginning.

The central office for the BDCP programme is located at the Walter Reed Army Institute of Research and the key institutions and organizations collaborating during the first phase of this bold initiative include the Division of Experimental Therapeutics of the Walter Reed Army Institute of Research, the Bioresources Development and Conservation Programme (BDCP), the Smithsonian Institution, the University of Ibadan (Nigeria), the University of Yaounde (Cameroon), the University of Dschang (Cameroon), the Biodiversity Support Program (a consortium of the World Wildlife Fund, the Nature Conservancy and the World Resource Institute), the Pace University, New York, the Southern Research Institute of Alabama, the University of Utah and Shaman Pharmaceuticals, Inc. During the second phase of the African ICBG the composition of the Group has changed.

The BDCP planned to follow various approaches to the selection of plants, such as random screening, selection based on ethno-medical uses, reliance on leads from literature reviews and chemical analysis approach. Efficiency of the identification approach could be gauged from the fact that there was a correlation of more than 85 per cent between indigenous knowledge and the modern therapeutic effects. Some aspects of the plant selection plan were based on the information provided by Shaman Pharmaceuticals, Inc., and as a part of its corporate contribution to the BDCP programme, the company also provided a high level of ethno-medical support to the project team. The compliance of Shaman Pharmaceuticals, Inc. with the selected articles of the Convention on Biological Diversity (CBD), as stated by them, is given in Annex 3.4.1.

Intellectual Property Rights

Patents US 5019580 and WO 91/09018

The intellectual property rights acquired over value-added biological resources and associated knowledge are expected to generate profits from which benefits would be shared with the Trust. These intellectual property rights include not only patents but also the trademark of the new company, the copyright of the descriptions and citations about the validity of herbal drugs, etc. However, this case study will focus on two patent applications filed for inventions related to the work of Shaman Pharmaceuticals and the ICBG Programme. The two patents, namely US 5019580 and WO 91/09018, are contained in Annexes 3.4.3 and 3.4.4.

On December 19, 1989, Shaman Pharmaceuticals, Inc. filed a patent application (no. 452,902) for “Dioscoretine and its Use as a Hypoglycemic Agent”. The patent application contains 13 claims and 4 Drawing Sheets. The inventor named in the application is Prof. Maurice M. Iwu, the Director of the Bio-resources Development and Conservation Programme (BDCP). The statement of the technical field in which the invention lies states that,

This invention relates to a novel biologically active compound, more particularly dioscoretine, isolated originally from tubers of Dioscorea dumetorum. The novel compound of the invention is useful as a hypoglycemic agent and thus provides a new

and useful agent and pharmaceutical composition for the treatment of diabetes mellitus.

The application cites 4 references, all of which are publications of non-patent literature, published in the USA or Europe. While the non-patent literature references of the application do not include traditional medicinal knowledge of Nigeria, the second section of the patent application, which describes the Background of the Invention recognizes that:

*The common yellow yam *Dioscorea dumetorum* has been used by herbalists and practitioners of West African folk medicine for treatment of diabetes, as a topical anesthetic as well as an arrow poison and as a bait for monkeys [see generally, Corley et. al. 1985, Tetrahedron Lett. 26 (13):1615-1618]. Additionally, *D. dumetorum* tubers are used as famine food, although it is well-known that the yams must be carefully prepared by soaking for several days in running or salt water and boiling overnight. In fact, several cases of serious poisoning have resulted from ingestion of improperly prepared tubers (Undie et al., 1986, J. Ethnopharm. 15:133-144).*

For use in herbal medicine for treatment of diabetes, a decoction is prepared by steeping the peeled tuber in native gin, distilled from fermented palm wine containing about 30-70% ethanol (termed 'kai-kai.') for about three days. The decoction is boiled until the color changes from yellow to brown and is then administered to patients in small cupfuls. Undie et al. (supra).

*In a preliminary investigation, Undie et al. (supra), have shown that crude extracts of *D. dumetorum* possess hypoglycemic activity when administered to experimental animals. The authors stated, however, that several constituents were present in the extracts and nothing could be known with respect to what constituent was responsible for the observed hypoglycemic effects.*

In this section of a patent application, "Background of the Invention", the patent applicant normally sets out any existing problems or difficulties which the invention overcomes. Previous solutions to the problem are described, preferably in a way which clearly sets out the difference between the present and previous solutions. In this case the previous solutions included the traditional medicinal practices of herbalists and healers of Nigeria. The application specifies that *D. dumetorum* was also used in traditional medicine for the treatment of diabetes.

This patent application does indicate the country of origin of the plant genetic resource which was utilized in the invention. Section 6, "Extraction and Isolation of Discoretine" states that

*Tubers of *Dioscorea dumetorum* were collected at Ankpa Local Government Area in the Benue State of Nigeria. The authenticity of the material was confirmed by Dr. J. C. Okafor of the Forestry Division Anambra State Ministry of Agriculture, Enugu. A voucher specimen has been deposited at the Pharmacy Herbarium University of Nigeria, Nsukka. Tubers of *D. dumetorum* were sliced into chips and sun dried for 4 days.*

The patent was granted by the United States Patent and Trademark Office (USPTO) on May 28, 1991. The patent is classified according to the International Patent Classification (IPC) under Main group 221.00 of the IPC Subclass C 07 D.

On December 18, 1990, Shaman Pharmaceuticals, Inc. filed an “international application” under the Patent Cooperation Treaty, administered by WIPO, for “Dioscoretine and its Use as a Hypoglycemic Agent”. In this international application the states designated for which protection was sought included Austria, Belgium, Canada, Switzerland, Germany, Denmark, Spain, France, Great Britain, Greece, Italy, Japan, Luxembourg, the Netherlands and Sweden. For more detailed information on the Patent Cooperation Treaty see Box 7.

Text Box 7:**The Patent Cooperation Treaty - An Overview**

The Patent Cooperation Treaty is administered by the World Intellectual Property Organization (WIPO) and makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an “international” patent application.

The Treaty regulates in detail the formal requirements that any international application must comply with. Among all the contracting States, the applicant indicates those in which he wishes his international application to have effect (“designated States”). The effect of the international application in each designated State is the same as if a national patent application had been filed with the national patent office of that State.

The international application is then subjected to what is called an “international search.” That search is carried out by one of the major patent offices. The search results are provided in an “international search report,” that is, a listing of the citations of such published documents that might affect the patentability of the invention claimed in the international application. The international search report is communicated to the applicant who may decide to withdraw his application, in particular where the said report makes the granting of patents unlikely.

If the international application is not withdrawn, it is, together with the international search report, published by the International Bureau of WIPO and communicated to each designated Office. If the applicant decides to continue with the international application with a view to obtaining national (or regional) patents, he can wait until the end of the 20th month after the filing of the international application or, where that application claims the priority of an earlier application, until the end of the 20th month after the filing of that earlier application, to commence the national procedure before each designated Office by furnishing a translation (where necessary) of the application into the official language of that Office and paying to it the usual fees.

The procedure under the PCT has great advantages for the applicant, the patent offices and the general public:

- (i) the applicant has eight or 18 months more than he has in a procedure outside the PCT to reflect on the desirability of seeking protection in foreign countries; he is assured that, if his international application is in the form prescribed by the PCT, it cannot be rejected on formal grounds by any designated Office during the national phase of the processing of the application; on the basis of the international search report, he can evaluate with reasonable probability the chances of his invention being patented;
- (ii) the search and examination work of the patent offices of designated States can be considerably reduced or virtually eliminated thanks to the international search report and, where applicable, the international preliminary examination report that accompany the international application;

(iii) since each international application is published together with an international search report, third parties are in a better position to formulate a well-founded opinion about the patentability of the claimed invention.

The development of the PCT system is shown by the fact that, in 1979, 2,625 international applications were received by the International Bureau, while the corresponding numbers were 67,0007 in 1998.

It is to be noted that the patents cited were granted prior to entry into force of the CBD. They were governed by the research agreement with Shaman which provided for a benefit-sharing plan. The ICBG Programme has not resulted in the grant of any patents so far, although four applications have been filed or are under preparation. The second patent is related to the antiparasitic activity of indole alkaloids of *Picralima nitida* and related compounds.

A share of the royalties generated from commercializing the technology and licensing the exclusive rights granted by the patent will be contributed by Shaman Pharmaceuticals, Inc., to the Trust Fund established for benefit-sharing with the traditional healers and local communities in Nigeria and other countries that have been working with the ICBG Programme.

Intellectual Property and Benefit-sharing Plans

The key principles of the benefit-sharing plan are that:

- benefit-sharing should start not after the product is developed but right from the stage of the access agreement;
- while cash may be provided where necessary to individuals, communities, and other stakeholders, non-material compensation will also be given sufficient attention;
- the revenues generated from the project will be exclusively used for the goals of the ICBG, i.e. the conservation of biodiversity, drug development, and economic development of rural communities;
- local communities, through various institutions, including healers' associations, would be empowered to make decisions regarding method and extent of compensation and choice of projects;
- the African members of ICBG will be involved at every stage of drug development, so as to equip them with the capacity to pursue drug development on their own.

It was hoped that the research would not only lead to the isolation of chemicals but also to the standardization of indigenous phytomedicines. The knowledge base of local healers would be enhanced and the capacity of the local scientists to conserve biodiversity would be supported. All the stakeholders who have contributed in the identification and processing of medicinal plants and subsequent drug development will be compensated as appropriate, including traditional healers. Every contribution will be acknowledged in the patents and publications arising out of the work. The existing intellectual property rights systems might not be adequate for the purposes of the ICBG. The group also “recognizes that the need to label ideas, access to instruments of protection, and monitoring for possible infringement, expert

witness, and legal assistance are necessary factors in the equitable distribution of the benefits of this project” (Bio Resources News Letter, 1. 1996. BDCP).

The right of individuals to their private land as well as to the community resources would be respected in the allocation of benefits, but ICBG also took note of the fact that information provided by the individual informant or healer might not be his/her exclusive property but might belong to the cultural resources of the community or the village at large. This led to several ethical issues. In the first issue of the Bio Resource newsletter (1996), the editor stated,

As has been pointed out by several investigators, exploration of chemical leads in tropical countries poses enormous ethical and political issues which must be addressed in any program that aims to use ethnobotany as a major plant selection criteria... A ... concern which has been broached by Gollin (1992) deals with the modern fundamental issue of ownership patterns in different parts of the world and especially in traditional societies where most of biodiversity belongs to what could be appropriately classified as public domain.

Given this ethical dilemma the programme has provided for channeling the benefits to the host countries and the local communities near the project site. In the absence of a universally applicable model, the group decided to experiment with various kinds of reciprocities and norms of equitable benefit-sharing. The proposed types of compensation for the short-term and immediate compensation include:

- collection fees to individuals and communities,
- long-term benefits in the form of royalties, and
- training and capacity building.

Shaman followed the approach of obtaining the clear prior informed consent of various host countries and institutions. Different kinds of short-, medium- and long-term benefits were disclosed and ethnobotanical research was not started until an agreement had been reached. A team of physicians and ethnobotanists from Shaman collaborated with a team of scientists from the University of Nigeria at Nsukka and the BDCP. This team worked closely within the Nigerian Union of Medical Herbal Practitioners. Copies of all the ethnomedical and botanical collection forms along with the voucher specimens of the medicinal plants were deposited both at the University of Nigeria and the BDCP Office at Nsukka. The scientific papers published from the research include Nigerian scientists as well as traditional healers. It was made clear that technology and resource transfer for capacity building initiated in 1990, when collaboration began, would continue throughout the duration of collaboration, even if no commercializable product was developed from Nigerian plants. From 1990 to 1996 an amount of USD 210,000 has been provided to Nigerian stakeholders. Part of this money has enabled significant capacity building at BDCP, the augmentation of the Phytotherapy Research Laboratory of the University of Nigeria at Nsukka, the Traditional Healer Organization and the rural communities. These benefits have been provided even before any drug had been developed.

Katy Moran (1998) in her case study of the BDCP, describes various factors involved in the evolution of benefit-sharing arrangements. Carlson, et. al. (1997) describe the steps taken to establish prior informed consent and outline one of the unique features of Shaman’s policy, which is to share, “a percentage of its profits (with) all the indigenous communities and

countries with which it has worked, regardless of where the actual plant sample or traditional knowledge originated” (1997: 33).

King, et. al. (1999) reviewed the ongoing global concern with so-called biopiracy. He highlights that annual retail sales of over-the-counter herbal remedies in Germany in 1996 alone were about US 3.5 billion dollars (Blumenthal, et al., 1998) and the same source was quoted to suggest that total sales in Germany, France, Italy, Spain, U.K., and Netherland were USD 7 billion. This volume of sale could have significant impact on the plants, the environment, the countries, and the cultures from whom the knowledge and these biological resources are obtained. King, et. al. (1999) regret the fact that the international conservation community has neglected the huge impact of the botanical medicine industry on tropical people, plants, and eco-systems.

The Community Perspective

There are two primary communities with whom BDCP works closely in this project. The first one is the community of traditional healers through their national union as well as state-level associations. The second one includes the communities at the village level where conservation, biodiversity monitoring, sustainable extraction and other rural development activities are being planned. BDCP gave considerable thought to the definition of the term “community” and resolved to follow a very practical approach. The reliance was placed to existing traditional institutions of leadership, authority and cultural and social cohesion.

The trust fund, i.e., The Fund for Integrated Rural Development and Traditional Medicine, is aimed at enhancing the capacity of traditional practitioners. The trust fund is expected to support local projects, help build herbal clinics, botanical gardens and monitor various activities. There is a view that it should not focus on helping only individuals but also help communities.

The First Trustees were: Chief (Dr.) A. A. Omotosho, Dr. Ohyu Azija, Professor I. Abdu-Aguye, Cosmos Obialor, Professor E. N. Sokomba, and Professor M. Iwu. Prof. Sokombo is the trustee as well as Secretary to the Board of Management which includes ten members. The members include His Royal Highness Eze E. E. Njemanze; Chief Omotosho, President of the National Union of Traditional Medical Practitioners (NUTMP); Dr. (Mrs.) Ohyu Azijah; Chief Ozonnamalu, Alhaji Baba Alhassan Bangbara, Prof. Ibrahim Abdu-Aguye, Prof. Robert Boroffice, Mr. Cosmos Obialor, Dr. Tolu Fakeye and Prof. Sokombo. BDCP had developed contact with these people through its earlier work in the field of drug development. Mr. Kent Nnadozie, Consultant Lawyer, helped in setting up the trust and constituting the board of management. Various officials of established unions and associations of healers were involved. BDCP has also had a very close coordination with the government in the formulation of national policies.

Traditional knowledge of healing

Traditional healers draw upon a knowledge base of several generations, apart from constantly making their own innovations. They believe in the super-natural powers of deities like “Ifa,” who is worshipped and has the power to heal. It is understood that the blessings of “Ifa” are available only when one follows a code of conduct properly, does not eat forbidden food, and treats the relevant diseases according to the directions.



Figure 2 Mr. Alanemu Dusu, traditional healer, explaining one of his remedies.

Many diseases are not considered natural. For example, it was natural to have stress, but one could be affected by stress caused by bad forces, witchcraft, or other disturbances in one's life. The same disease may be caused by different factors in different people and hence the treatment is individualized. The factors which Chief Omotosho takes into account include how long a person has been suffering, since chronic diseases cannot be solved the same way as newly caused diseases. Once every year, the Nigerian Union organizes a training for local healers. Unlike modern medicine where a disease tends to come back, in traditional medicine it may go slowly but does not tend to come back again.

Nowadays, the traditional healers take notes and write up their diagnosis, whereas earlier they did not do that. The knowledge was treated as a common property and shared widely, though there are healers who keep it secret. Chief Omotosho almost articulated the rationale for modern intellectual property rights when he said, "*if I share, you can improve upon it, make my knowledge more useful, if I keep it to myself, my know-how cannot be improved upon*". He did feel, however, that unauthorized access to a healer's knowledge is not acceptable. If a firm develops a medicine based on a healer's knowledge, it should share the technology of making that medicine with the healer. Generally, the orthodox system of medicine and traditional medicine do not work together. For example, modern medicine does not have any treatment for blood pressure. It merely keeps it in check. Traditional medicine claims to have a treatment for the purpose.

Some healers pursue farming, healing and other occupations together, while other focus only on healing. The son of Chief Omotosho has studied modern medicine and may be able to modernize traditional medicine. Usually it takes at least two years for a person to understand the basics of traditional medicine and become a traditional medical practitioner. The healer also has to have an in-depth knowledge of taxonomy so that he can identify the plants and their components properly. Sometimes one has to spend at least two and a half years to develop this capability of identifying leaves and plants.

The State has not supported traditional medicine very much and there are not many hospitals practicing traditional medicine exclusively. There is no center for medical research in Nigeria managed and owned by traditional healers (except the one set up by BDCP). Consequently, the traditional practitioners have to do individual research and experiments to find out the relative efficacy of mechanical grinding versus manual grinding, appropriateness of different

packaging instruments, methods of increasing shelf life, etc. Unless a school of traditional medicine is established, the blending between the two systems of medicine, as achieved in China, may not be achieved in Nigeria.

Some examples of traditional medicine were also given to illustrate the way the knowledge systems work. For example, *Oruwo* leaves are washed, squeezed in water, and then drunk and fever will disappear within fifteen to twenty minutes. The same leaves are also used in Chinese Traditional Medicine. There are about 4000 medicines of this kind in Nigeria.



Figure 3 Children watch as local plants are prepared for use in traditional medicine.

With respect to benefit-sharing, Chief Omotosho pointed out that the fundamental value which should guide one's professional conduct is basic ethics. The basic duty in medical practice to help others should not be compromised. His preference was that only the respondents who provided the leads for developing modern medicine based on traditional medicine should get the benefits. When asked about the role of the community which conserves the plants, the interviewed healers confirmed that the community should receive a share of the benefits derived from the application of their knowledge. However, according to Chief Omotosho, the individuals who get the benefits should share it with the community.

Mrs. Azijah, who heads the Jos branch of the Nigerian Union Medical Herbal Practitioners and was recommended to the post of Lecturer in Traditional Medicine at the University of Jos, shared the view of Chief Omotosho about benefit-sharing. Mrs. Azijah has been authorized to check the documents of any medical healer or seller in her region and register him or her with her association. In her region in northern Nigeria there was not much erosion of biodiversity, but those who are responsible should try to conserve the plants. Her association in Jos, a region in northern Nigeria, has developed a norm that without the knowledge of their healers' association nobody can collect the plants. They also put some members of the Association on surveillance duty. Chief Omotosho was from the tropical forest region, whereas Mrs. Azijah is from the Savannah region. Both of them felt that there should be information transfer agreements which create legal certainty around the transfer of their knowledge. At the same time, Mrs. Azijah² pointed out that if someone was too protective about their knowledge, then he or she was considered greedy by the community. She felt, "knowledge is provided by God, I cannot exclude others from it. You take it to do better things. If I don't get millions, and thus I decide not to give it, then it is bad behaviour."

² The fact that both healers agreed on the need for sharing their information with others, indicates the common ethics underlying their knowledge systems.

She also felt that if she did not tell others, they would not know that she had shared the knowledge with outsiders. Therefore, she should not be expected to share the identity of people with whom she shares her knowledge. She did want that her name should appear, no matter how small, on any medicine made from her knowledge. *Monetary compensation alone was not the major consideration, rather recognition should be there as the most important thing.*

There were several suggestions made by both Chief Omotosho and Mrs. Azijah about the way traditional healing systems could be strengthened. The Federal Government could take steps to develop model information transfer agreements, in consultation with the Healers' Union.

The union or association should be responsible for sustainable extraction of biological resources from the local ecosystems. Outsiders would not know the individuals and they should seek to establish their contacts through the Healers' Associations. One should also think of a system for the registration of knowledge in "Local Knowledge Registeries". There should be a system of empowering associations to document the knowledge according to given rules and regulations and the individuals providing knowledge should be compensated. The healers felt that different groups might have different norms about how knowledge should be collected, pooled, shared (with or without price), acknowledged, and valorized. It is necessary that outsiders realize the ability of local healers to make informed choices about various knowledge transactions, given sufficient opportunity to understand the complexity at their own pace.

BDCP's work with traditional healers also involved setting up a Clinic in 1992 which is owned and managed by the local healers themselves. The National Union of Herbal Medical Practitioners has no control over this facility, though some of the members of the local healers' associations are affiliated with the National Union. Shaman Pharmaceuticals have invested both in kind and in cash in this programme. The healers and modern medical doctors sometimes jointly diagnose the patients or even a board is set up to enable the diagnosis of cases which are difficult and where a group of traditional healers need to work together.

A community knowledge system

The Umowere village provides an example to understand the way local communities deal with biodiversity and associated knowledge systems. The village has a highly diverse ecosystem with undulated topography and various food, trees and crops like maize and sorghum.



Figure 4 Members of the Umowere community returning from a collection tour of local medicinal plants.

The villagers primarily consume yams and cassava. Originally the forest around the village was a teak forest, but now it is being transformed into a multi-species forest and has 41 different species. BDCP has set up a monitoring plot and also a conservation plot. The level of economic development in the village is low. The people are extremely hard working and enterprising. The women pursue several processing activities other than household chores, such as food processing, extracting oil, processing yams, cassava, edible and non-edible seeds and other minor forest produce.

There are several traditional technologies, contemporary innovations and important traditional institutions in the village, which pertain to the conservation and sustainable utilization of medicinal plant genetic resources. These include, *inter alia*,

- certain *sand harvesting structures*: given the undulated topography, farmers use a whole variety of soil and water conservation structures to prevent soil erosion. The soil in the vicinity of the village is sandy loam and silty clay. Farmers build small structures with the help of poles or logs to impound the sand at the time of rain. The lighter particles of soil overflow, whereas sand fills up the small ditches so made. This sand is collected and used for construction activities. While processing grated cassava the villagers keep a strainer vessel (with holes all around) having grated cassava in the flowing water of a stream. The water passes through the cassava (through the holes) over night and in the process the anti-nutritive factors are supposed to be washed or drained away. Women taste the cassava so washed to make sure that it is safe and then serve it to their family members. Such traditional technologies relate both to the conservation of medicinal plant diversity and to the traditional knowledge provisions of the UN Convention to Combat Desertification.

- the so-called *Azohia*: there is a traditional institution, namely *Azohia*, which consists of a small grove near an old tree where the dead bodies of either rule breaking people are buried or of those who died of some serious illness. When an old healer dies, the residual medicines, of which the children often do not know the use, are thrown into that place. This is a place in which nobody is supposed to go and of course by implication it helps in conserving a wide variety of medicinal plant diversity. The *Azohia* is situated around an old *achi* tree (*Brachystegia eurycoma*). Apart from residual medicines, the herbal poisons, used for fighting by poisoning the tips of the arrow, were also reportedly thrown away in the *Azohia* bushes.

A similar institution exists in the form of a stream in which no fish is collected. The institution demonstrates that there is a strong tradition of conservation of plant species as well as aquatic systems. The streams are considered sacred in general and the life of the stream and the life of fish are supposed to be related. Different streams are supposed to have different custodian gods. The concept of the sacredness of some streams in which fish is not caught is generally captured in the native belief of “*ndu nmiri ndu azu*”, i.e., “life in the stream and life in the fish.” Perhaps, these streams may have had many spawning sites for the fish and therefore people did not want fish to be caught when they were full, as is the case when they are spawning. (Kent, 1999, personal communication).

Tradition under transition

There are numerous pressures of modernization and transition at work in the village. The introduction of intellectual property rights and benefit-sharing arrangements for local biological resources and knowledge systems would themselves constitute a part of these transformative factors. It is therefore essential to understand how traditions, lifestyles and institutions that have sustained traditional knowledge formations and genetic resource *in situ* are currently changing. Numerous examples express the villagers' changing understandings of traditional medicine, biodiversity conservation, the role of the community, and the value of its knowledge and plants.

There are farmers like David Dike who buy modern English medicine for headaches. He claimed that local herbalist did not share their knowledge sufficiently. On the other hand, there were healers, like Mr. Letusogu, who felt that sharing the knowledge was useful because it might help in the development of modern medicine, since this would benefit the world at large. So far as their own benefit was concerned, they would appreciate if a road could be built and electricity provided. The issue arises whether those who conserve and share their knowledge freely must remain poor just because they have different ethics, which from the conservation point of view may be considered superior.

Another villager, Mr. Alaneme Duru, and his family were suffering from severe poverty. There were some trees in Mr. Duru's garden land which were mature but could not be cut (since the area was in a protected area). However, mature bamboos were cut and sold earlier, but could no longer be sold. Incidentally, this impoverished man is the one who donated his land and forest for the purposes of community forest conservation as a part of BDCP project. The case of Mr. Duru is an example illustrating the conservation ethic of local communities which is often tied with generosity in poverty. He and his brother felt that their contribution would perhaps be remembered in posterity and that is all they had expected out of the donation of land. He pointed out that his children did not want to remain in the forest and did not bother much about traditional medicine.



Figure 5 Traditional healer collecting local plants and hunting for small animals.

A young lady, Mrs. Osebi Lillian, felt that the local community should be approached before anybody took their knowledge from one or the other member of the community. She also acknowledged that not everybody had the talent to be a herbalist. When asked about her future ambitions, she said that she wanted to learn English medicine and did not have much interest in native medicines. Some of those who were present mentioned that Christianity might have led to a decline of native medicine. An example was given of the *achi* tree which was revered by the family in whose land it was located. However, when a couple of cases of infant mortality took place in the family, the local priest asked the young people in that family

to burn the sacred *achi* tree so that their supposed faith in the local deity might not prevent them from using modern medicine. The elder person of the family was not very happy with the decision of the children. There is a tension in the local culture between the traditional institutions and the influx of modern values. This dilemma raises questions about the future of a knowledge system in which culture, biodiversity and medicinal plant knowledge are closely intertwined.



Figure 6 Young community members of the Umowere village on a hunting expedition. Will they take an interest in traditional medicine?

The dialogues given above indicate that a community, traditional as it might be, does not represent a homogenous view point. The tension exist between:

- traditional medicine and modern medicine,
- proprietary information vs. community-wide sharing of information,
- changing aspirations of young people who want to become modern doctors vs. continuing the profession of traditional medicine practitioners.

The transition of traditions under the pressures of religions, markets and modernization may be relevant for devising incentives that make the role of the traditional healer more recognized and respected.³ Unless this happens, young people might not like to learn and improve the traditional knowledge systems and erosion of the knowledge systems will inevitably follow. Intellectual property rights and benefit-sharing arrangements should provide incentives and benefits that stem this erosion.

³ It is for this reason that associations of grassroot inventors, such as the Society for Research Into Sustainable Technologies and Institutions (SRISTI, 1993, Gupta 1990, 1995, 1997, 1999), have suggested that incentives for biodiversity conservation and sharing of local knowledge should not include only monetary but also non-monetary form of rewards and compensation for individuals as well as communities. The portfolio approach to devising appropriate sets of incentive mixes for various social and cultural setting is likely to generate more sustainable alternatives than reliance on any one instrument.



Figure 7 Transmission of Traditional Knowledge: Mr. Cosmos, who works with traditional medicine, explains his views in the course of a discussion with community members of the Umowere village.

Benefit-sharing

In the context of the BDCP, there are primarily seven kinds of benefits that have been provided so far:

- (a) Biodiversity conservation plots and herbal medical gardens
- (b) Support to the individuals (herb collectors, traditional healers, etc.)
- (c) Support to the Herbalist Medical Practitioner Union
- (d) Research and development through local research centers, herbal clinics and processing units
- (e) Support to universities
- (f) Support to the government
- (g) Support by the commercial partner to the Trust Fund and other collaborative activities

a) Biodiversity conservation plots and herbal medical gardens

There were four conservation sites at Imo, Cross River, Ebonyi and Rivers states. A monitoring plot of one hectare each had been identified at each of these sites. In addition, there was a three-hectare plot at Umukabia village, including one hectare as a monitoring plot, one hectare for community biodiversity conservation, and one hectare for a community herbal garden. Two local farmers, namely Mr. Johnson Lereneous and Mr. Alaneme Duru, reportedly donated the land for this community forest area although they are both extremely poor. Data has been collected on the conservation plot for all plants above a particular girth size. People can collect the medicinal plants for their own use as well as for sale from the herbal gardens.

b) Support to individuals (herb collectors, local expert healers)

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- 1(a) Healers have been given cash for their services at the rate of 5000 Nira per interview.
 - 1(b) For each plant which is selected for screening an amount of 5000 Nira is paid for the collection of the plant.
 - 2 If the larger quantity of particular plant material is required for laboratory analysis, BDCP goes to the same healer from whom the information was collected and pays 200 Nira per kilo gram of the plant material. In some cases the material is also collected from traditional plant gatherers.

c) Support to the Herbalist Medical Practitioners Union

Support to the Herbalist Medical Practitioners Unions (HMPU) was provided in several states: Niger, Taraba, Lagos, Enumbra, Imo, Snegu, Jos, Benve, Oyo, Edo, Cross River State, and Ebony. There are two kinds of support to the HMPUs. One is in cash and the second is in kind, in the form of technical assistance, botanical assistance, collaboration with allopathic physicians and joint diagnosis of complex sicknesses. At the University of Jos, assistance has included purchase of land to set up a traditional medical hospital, a herbal garden to grow species under threat, and technical assistance to the existing clinics to be upgraded eventually.

In addition, the Fund for Integrated Rural Development and Traditional Medicine (FIRD-TM), i.e. the trust fund described below, also has provided support to individual traditional medical practitioner as well as the unions.

d) Research and development through local research centers, herbal clinics, and processing units

A clinic has been set up at Ninth Mile Corner in addition to the research and development center. Research on the standardization of traditional medicines, safety, increasing shelf life, screening of various plant leads for pharmaceutical properties, joint diagnosis, record keeping, etc., are pursued at this research center. Intermediate or final processing of several herbs for developing products which are marketed by Axxon Biopharma also takes place. In addition, an international center has been set up to certify herbal products for their safety and therapeutic efficiency.

e) Support to universities

Several universities have been supported, such as the University of Nigeria at Nenugu, the University of Jos, the University of Abu, etc. At the University of Jos support has been given for a herbal medical garden, collaborative research with traditional medical practitioners, equipment and training, etc. Children's libraries have also been supported.

f) Support to the government

Policy formulation and analysis, workshops, computer support for database development for traditional medicine, research, etc., have been supported at national as well as regional levels.

The criteria of support by BDCP are the following:

While no formal agreement is entered into, previous experience in collecting information is taken into account. Whosoever collaborates is compensated and a token money is given to primary collaborators who were interviewed. A community will also benefit as a part of ongoing activities through the trust fund or otherwise, although the primary responsibility for compensation is towards the providers of information. However, community interests are looked after through clinical facilities, trust funds, and other such initiatives including support for conservation activities.

In the interview sheet the name of the provider is recorded in writing so that one can go to the same healer who provided the lead for bulk collection. The healer or provider of the genetic resource or knowledge is informed that drug development from the local lead might take a long time. If the drug is developed and marketed, royalties will be shared. However, even if no drug is developed based on the lead provided, the knowledge providers would still get a share of benefits as and when the same are generated.

A Trust Fund for Benefit-sharing: The Fund for Integrated Rural Development and Traditional Medicine (FIRD-TM).

Various stakeholders in the benefit-sharing chain are:

- Individual healers who provide knowledge,
- communities which may provide leads and/or conserve the biodiversity,
- the association of healers which help in maintaining professional quality and responsibility,
- scientists in Nigeria and
- scientists in the USA (in BDCP as well as in Shaman Pharmaceuticals or Walter Reed Army Medical Research Center).

In the years 1994 and 1995, when Shaman Pharmaceuticals got involved, it was quite excited by the level of interactions between local healers and the BDCP. At that time, a decision was taken to contribute financially to the trust fund to help traditional healers improve their practice.

In October 1997, Shaman gave USD 40,000 to BDCP. A management committee was constituted with the help of the Healing Forest Conservancy, a charity organization set up by Shaman Pharmaceuticals. Mr. Kent Nnadozie, consultant lawyer, helped in setting up the trust and constituting the board of management. BDCP does not impose any decisions on the management committee and BDCP can only make recommendations. In 1998 various herbalist associations and unions were invited for the inaugural meeting and aims and objectives of the trust fund were explained. The chairman of the Board of Directors, which works quite autonomously, is His Royal Majesty Eze E. E. Njemanze.

The general principle for allocating financial resources from the Trust Fund is the following:

- Sixty per cent was kept in fixed deposit of which only the interest will be used.
- Above 40 per cent of the fund i.e., 40,000 USD, was set aside to be used during 1999-2000. Of the 40 per cent:

- 20 per cent was to be used for the Biodiversity Conservation Act of the National Institute,
- 10 per cent for educational purposes,
- 30 per cent for the Traditional Healers' Association for group projects or micro-credit funding,
- 30 per cent for community development associations for village projects,
- 5 per cent for women, especially widows,
- 5 per cent for childrens' welfare.

There have been some tensions on the issue of the allocation of funds to the communities vis-à-vis the healers' union. The decisions so far have favoured the healers unions partly because they are better organized and are also well represented on the Board. The community projects have been deferred until the income from the interest gets accrued in the second year. In addition, the Board has also been concerned about the sustainability of project investments. Generally, the requirements for a community project are that it should have some kind of organization, bank account, list of the key members, nature of activities and duration, apart from the local contribution towards employment and development. The project format also

requires information about the guarantor. Basically the form is organized for formal organizations and rural organization, and healers' organizations, informal as they are, may generally not be able to fulfill all the requirements. The BDCP has only one representative on the Board of Directors and therefore it cannot interfere too much with the decisions.

Sharing by the commercial partner

Shaman Pharmaceuticals has as a matter of its policy decided to share parts of its profit with all the communities with whom it works, even if the commercialized product has no relationship with the knowledge provided by a particular community. This ensures that the benefits are more widely shared than would have been the case if there was a strict one to one correspondence between product development and benefit-sharing. The trust fund was actually started in 1999 and so far all the money, i.e. 41,600 Nira have been given to traditional healers.

Out of the total funds, 50 per cent were given to the trust fund, the remaining 50 per cent, i.e. USD 40,000, were given in a ration of 2:3 to providers of know-how as well as scientists and the research programme for tropical diseases. The company set up to commercialize the herbal products, i.e. Axxon Biopharma, would pay royalties from the sales to the trust fund and other research programmes. It may also sell equity to raise resources. So far about 85,000 USD have been contributed by Dr. Iwu as a personal loan to Axxon Biopharma. Axxon Biopharma has developed herbal products using public domain knowledge.

Dr. Bankole Sodipo, Head of the Association of IPR Attorneys, felt that Nigeria had to go a long way in recognizing and supporting the rights of local communities, folk artists and small inventors and innovators. He felt that there was a great potential for Nigerian society to become inventive and innovative. He gave the example of a patent on a medicine developed in Nigeria for checking internal bleeding. This invention had received the WIPO Gold Medal and fortunately, in this case, the Nigerian army supported the research. But in most cases, policy or institutional support is lacking.

In his view, the clans, taboos, cults, etc., were various ways in which intellectual property rights were exercised in traditional Nigerian societies. He gave an interesting example of indigenous IPR as practiced in the Benin Kingdom. Only one family could record the activities of the court in bronze caste. Nobody else was allowed to do so. Even the one family which did it had to be initiated into the cult.

Lessons Learned

The case study demonstrates the potential that the development of biological resources, particularly for pharmaceutical purposes, have for generating surplus and sharing benefits. Several intellectual property rights have been used in this case. Trade secrets have been used

by Axxon Biopharm to manufacture herbal medicines / food supplements, based on the traditional medicinal knowledge prospected under BDCP. Axxon Biopharm is a company set up in the US to sell food supplement drugs, based on the research in the BDCP clinic, and has a registered a trademark to distinguish its goods and services from those of other undertakings. Shaman Pharmaceuticals, which has screened a large number of plants for various ailments thus contributed support for local healers, communities, and R&D centers without receiving any commercial returns from a product based on Nigerian biological resources and associated traditional knowledge. The local community which collects the plant material is paid in cash and in kind.

In the initial years the trust fund set up by BDCP provided benefits to the traditional medical practitioners only. The local communities would receive support in the later years. Various other interventions such as procurement of herbal materials and setting up of herbal gardens have helped the communities apart from the payment of small amounts to individual respondents. Such tensions are very difficult to resolve by BDCP because of the autonomy it has given to the trust. Perhaps a few community representatives on the trust could have helped in changing the priorities.

The process of developing a commercializable drug is indeed very costly and even advanced companies have to decide whether to license the lead to a large multinational pharmaceutical company or to go for several stages of clinical trials followed by manufacture of the drug. The local communities are generous in sharing their knowledge and yet hardly any publications were found in which inventors were given joint authorship.

The case study highlights the extent to which monetary and non-monetary benefits can be shared among the strategic partners in biodiversity conservation through drug development. Several questions remain unanswered, such as striking an appropriate balance between the interest of organized groups like traditional healers and that of unorganized groups like local communities and unregistered healers. The case also demonstrates the declining respect for local knowledge within local communities and the doubt among the elders about long term viability of their knowledge systems. It is becoming evident that the current pattern of reciprocity, admirable as it is, may not be sufficient in making the local knowledge systems dynamic, such that the younger generation may want to grow up as herbal medical practitioners.

The local institutions for conservation of biodiversity and natural resources provide the context of local technical knowledge. The sacred institutions for conserving trees, rivers, and plants are all part of this institutional context, as are customary legal systems. Unless the

benefit-sharing system looks at these institutions as an organic whole of the traditional knowledge system, it may not suffice in arresting the serious threat of TK erosion.⁴

The traditional life style also accommodates within itself some contemporary innovations. Unless a robust system of recognition, respect and reward is in place, these institutions may start floundering. Small innovations, when recognized, do not merely help one individual creative person. The message goes to the peers in the local community that innovations matter and that one does not have to adapt and adjust with inefficiency (which may exist in various farms or household operations). The case of a simple cooker developed by local women using old empty condensed milk containers is a good example.

The efficiency of the traditional knowledge system can also be enhanced by blending the same with modern science and technology, as the BDCP is attempting. But for such a blend to take place in a sustainable manner, much greater discussion is required among the respective experts. Such a dialogue is taking place in Jos and also Enugu to some extent.

Systematic documentation and a registration system of local herbal knowledge when properly disseminated among potential investors and entrepreneurs might generate more widespread benefits even at a smaller scale to revitalize the traditional knowledge systems.

This case highlights the role which academic researchers, particularly ethnobotanists, can play in valorizing local knowledge and in generating and sharing benefits with local communities, healers and other stakeholders. It has been realised that short term benefits may do more harm than good unless a long term sustainability is built into the benefit-sharing framework. The concept of Trust Funds is useful in this regard, although in this scheme the voice of traditional herbal healers has received greater recognition than the voice of local communities and their leaders.

The case study highlights several issues with regard to the sharing of information in local languages, participation of the communities in benefit-sharing, and participative research by informal and formal experts.

- The sharing of benefits by Shaman Pharmaceuticals through BDCP even before any drug was developed is considered to be a good practice.
- The commitment to share benefits with all the communities from whom Shaman has sourced any material at any time, even if the final products emerged from only one lead provided by only one community, is a novel idea and is worth implementing more widely within benefit-sharing frameworks.
- The creation of an autonomous Trust Fund is a positive step but as it stands at present it is biased against effective participation by the communities and their representatives. The sequence in which various investments have been made from initial monies shows the problem. It might be useful to keep in mind that the relatively greatest investment in conservation was made by the poor tribal people in the villages near Owere, when they donated a piece of land for a community garden and conservation plots. Some distinctive recognition, award or benefit may be designed for them.

⁴ The case of local traditional ecological institutions is crucial for the conservation of biodiversity as well as associated knowledge systems. Future discourse on the subject should include the mechanisms for conservation and augmentation of such institutions. In some cases, these insititutions will need to be reinvented in order to include more secular and consensual objectives.

-
- The dynamics of local social and economic conditions do not forebode a very optimistic future for TK. The young people in the community, curious as they are, do not see the TK-based knowledge systems as a means of livelihood in the future. It is here that benefit-sharing systems need considerable strengthening.
 - The institutional structure for protection of TK is weak and thus large scale unauthorized use and reproduction of TK is going on. Customary systems of governance and law have not been adequately recognised and given an adequate role in benefit-sharing systems. The rights of local communities and informal experts as well as the scope of protectable subject matter need to be clearly defined, based on legal standards provided by existing international instruments, such as the TRIPS Agreement and the CBD. Intergovernmental institutions and specialized agencies for intellectual property, such as WIPO, may develop non-binding guidelines to provide guidance for professional and corporate genetic resource users in implementing benefits sharing arrangements which fully respect the intellectual property rights they have acquired for their massive investments. Such arrangements would take into account that local communities and individual healers and herbalists have made no less valuable investments in creating and maintaining local genetic resources and related knowledge systems which commercial users today find so meaningful and relevant.
 - The sharing of benefits by BDCP even in the case where they have used public domain traditional knowledge is a good precedence. However, further steps will be needed when local knowledge is collected and local language communication with the communities both orally as well as in written form is essential.
 - The protection of the brand name of new herbal products through trademarks and certification marks is useful for generating market recognition and identity, as shown in the case of Axxon Biopharm, Inc. In turn, it helps in generation of revenue and consequent benefit-sharing. The protection of distinctive signs related to certain products of local communities could be explored since these products are based primarily on the local knowledge and practices of these communities. This could help them license the use of these distinctive signs to future users of their knowledge and it may avoid use of such signs which may lead to confusion in the minds of the public.
 - The benefit-sharing frameworks by other institutions in Nigeria offer equally interesting lessons about the acknowledgement of local healers in inventions, the development of formal contracts with knowledge providers, and an elaborate benefit-sharing system. The National Institute for Pharmaceutical Research and Development (NIPRD) has provided an interesting model for acknowledging local contributions to its research and for implementing reciprocity towards traditional knowledge holders.

In this case, inventorship was not shared with the local healers or TK experts, because the specific knowledge used in the invention was common among local communities. This is an issue which requires considerable further study and exploration. When a patent application is filed for an invention utilizing genetic resources or related traditional knowledge, should the TK be cited as prior art under non-patent literature references or should there be requirements which provide for the disclosure of ownership interests in such knowledge, similar to the required statements for certain other ownership interests in the invention (e.g., requirements to state rights to inventions made under government sponsored research and development, etc.). In the present case study, the use of the plant for diabetes was known to the local

community, while the community did not know the exact compound or mode of action of the active ingredient. Some associations of traditional knowledge holders have maintained that the acknowledgement of contributions of local knowledge providers and innovators should be required for TK-based patent applications. They have maintained that such disclosure requirements are a form of acknowledgement of traditional knowledge which would promote the conservation of TK systems, because through such acknowledgement of TK communities would learn more about the value of their own knowledge and thus may have increased incentives to conserve.

Case 3: Nigeria

Annex 3.4.1

Table 2: Shaman Pharmaceutical, Inc.’ Compliance with the Convention on Biological Diversity

Convention on Biological Diversity Shaman’s Compliance

Preamble, paragraph 10 and paragraph 12: “The fundamental requirement for the conservation of biological diversity is in *in-situ* conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species (CBD, 1992).”

“The close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitable benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components (CBD, 1992).

”Shaman recognizes the importance of indigenous and local people in *in-situ* conservation. Shaman wants to collaborate with indigenous and local people because Shaman recognizes the invaluable traditional knowledge, innovations, and practices of the peoples.

Article 1: “The conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and technologies, and by appropriate funding (CBD, 1992).”

All people and communities who collaborate with Shaman receive immediate, medium and long-term compensation. The field research team consists of scientists from the University of Nigeria at Nsukka or the BDCP. On each of the four expeditions Shaman conducted, the scientists were financially compensated and expenses were paid for the days they collaborate on agreed upon terms with Shaman for ethnobotanical research. The total daily wage compensation paid to Nigerian Western-trained scientists for the four expeditions was \$12,000 U.S. dollars. In 1995 \$3000 U.S. dollars (\$2000 in 1995 and \$1000 in 1996) was given to the Nigerian Union of Medical Herbal Practitioners, Enugu State Branch, Nine Mile Corner. This organization represents hundreds of herbalists who used the resources to strengthen the infrastructure of the Union as well as to improve the facilities at their traditional medicine clinic. They used benefits to establish a community-based medicinal plant farm.

Article 6(a) and (b) “Develop national Strategies, plans, or programs for the conservation and sustainable use of biological diversity.....(CBD, 1992).”

“Integrate,...., the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programs and policies” (CBD, 1992).

Lisa Conte, president and CEO of Shaman pharmaceuticals, Inc. testified to support the U.S. ratification of the CBD (Conte, 1994). Shaman Pharmaceuticals and Healing Forest Conservancy channels money into projects aimed at conserving Biodiversity.

Article 7 (a) and (b): “Identify components of biological diversity important for its conservation and sustainable use (CBD, 1992)”.

Monitor...biological diversity...paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use;” (CBD, 1992).

In 1994 and 1996 a Nigerian scientist attended a six week course in Biodiversity monitoring held in the U.S by the Smithsonian Institution. Shaman provided \$ 10,000 U.S dollars to sponsor his participation. Numerous plant presses, clippers, and GPS units have been donated to the BDCP and to staff members of the University of Nigeria at Nsukka. Financial

support for capacity building was also provided to a collaborating institution , the Enugu State Herbarium.

Article 8(a) and (j) “Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity (CBD, 1992).”

“Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from utilization of such knowledge, innovations, and practices (CBD, 1992).

Two workshops sponsored by Shaman were conducted in 1993 and 1996 on ethnomedicine, botany, and conservation to Nigerian botanists, ecologists, conservation officers, chemists, pharmacologists, and physicians. All Shaman Pharmaceutical ethnomedical and botanical field research documents were given to participants. Shaman Pharmaceuticals sponsored three (Nigeria ‘93 & ‘96, Cameroon ‘94) ethnobotany and conservation training programs. Shaman Pharmaceuticals co-sponsored a workshop on ‘Ecology, Cultural Transition, and Human Health’ at the International Society of Ethnobiology Annual Meeting in Nairobi, September 1996. The ten day course was conducted in three villages and was designed for host country Western-trained scientists, local community members and traditional healers to acquire skills integrating fields of biological ecology, anthropology, and public health. The Healing Forest Conservancy and BDCP sponsored a workshop to develop a code of ethics at the International Society of Ethnobiology Annual Meeting in Nairobi in September 1996.

Article 9(b): “Establish and maintain facilities for ex-situ conservation of research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources (CBD, 1992).”

Resources contributed to help establish a Herbarium at the BDCP office. Contributed a GPS unit and botanical collection supplies to the BDCP office. Worked with and provided funding to the Enugu State herbarium, within the Department of Forestry, Enugu State.

Article 10 (d) and (e): “ Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced (CBD, 1992).”

“Encourage cooperation between the government authorities and the private sector in developing methods for sustainable use of biological resources (CBD, 1992).”

In the two Cross River State villages Shaman provided immediate financial resources to supply village schools with books, tables and chairs, as well as a fund to help pay for the school teachers. In 1994 a Nigerian scientist attended a six week course in Biodiversity monitoring held in the U.S. by the Smithsonian Institutions. Shaman provided \$5000 U.S. dollars to sponsor his participation. Shaman Pharmaceuticals obtained plant research permits through the National Agency for Scientific and Engineering Infrastructure in Lagos, a unit within the Federal Ministry of Science and Technology, based in Abuja.

Article 11: “Each Contracting Party shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable uses of components of biological diversity (CBD, 1992).”

Shaman scientists provided BDCP-Nigerian scientists with ethnomedical field research materials to study malaria, leishmaniasis, and trypanosomiasis so as to better understand the plant medicines used to treat these diseases. These are not disease targets on which Shaman is focusing, but BDCP requested materials to develop better medicines to treat tropical parasitic diseases in Africa. Treated traditional herbalist’s husband for malaria with mefloquine. Paid for hospitalization of three sick children from the Cross River state.

Article 12 (a): “Establish and maintain programs for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for such education and training for the specific needs of developing countries (CBD, 1992).”

\$8000 U.S. dollars was given to support the 1995 BDCP conferences and ethnobotany workshops in LIMBE and Douala, Cameroon. In the two Cross River State villages Shaman provided immediate financial resources to

supply village schools with books, tables and chairs, as well as a fund to help pay for the school teachers. In 1994 a Nigerian scientist attended a six week course in Biodiversity monitoring held in the U.S. by the Smithsonian Institutions. Shaman provided \$5000 U.S. dollars to sponsor his participation. A Training Course on “Ethnobiology and Field Taxonomy Training” was held at the Limbe Botanic Garden in Cameroon during October 1995. The workshop was sponsored by Shaman Pharmaceuticals and organized by BCDP for Pan-African participants to acquire skills on field methods in ethnobotany, plant taxonomy, and conservation.

Article 13 (a): “Promote and encourage understanding of the importance of, and the measures required for, the conservation of biological diversity, as well as its propagation through media, and the inclusion of these topics in education programs (CBD, 1992).”

Shaman and the Healing Forest Conservancy attends meetings for many organizations such as the International Society of Ethnobiology, American Society of Pharmacognosy, American Society of Applied Anthropology, International Cooperative Biodiversity Group, and The Pew Working Group on Biodiversity and Ethics to discuss and educate themselves and others.

Article 15.5 and 15.6 “Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by the Party (CBD, 1992).”

“Each Contracting Party shall endeavor to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with full participation of, where possible in, such Contracting Parties (CBD, 1992).”

Shaman establishes Prior Informed Consent with scientists at the University of Nigeria at Nsukka, appropriate government agencies, and with village communities. Once a mutually agreed upon relationship is established ethnobotanical research proceeds.

Article 16.2 and 16.4 “...In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights...(CBD, 1992)”

“Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilities access to, joint development and transfer of technology... for the benefit of both governmental institutions and the private sector of developing countries ...(CBD, 1992).”

Shaman abides by all local, national, and international policies on patent rights and intellectual property rights. Three of the authors of this paper are Nigerian collaborators. Publications of data by Shaman from research on Nigerian plants includes Nigerian authors. Communicated Shaman’s lab results on Nigerian plants back to the Nigerian scientists. Contributed resources to both the Phytotherapy Research Laboratory at the University of Nigeria at Nsukka and the BDCP to improve their infrastructure to do research on medicinal plants.

Article 17.2 “Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programs, specialized knowledge, indigenous and traditional knowledge...”(CBD, 1992).

From 1993 to the present Shaman routinely communicates research results back to Nigerian scientists, the University of Nigeria at Nsukka, and the BDCP. This also includes the taxonomic determinations on any plants collected. In addition, all copies of all ethnomedical and botanical data from the field research expeditions are given to Nigerian scientists and the above institutions.

Article 18.1 “The Contracting Parties shall promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity; where necessary, through the appropriate international and national institutions (CBI, 1992)”.

Three of the Nigerian scientists have visited Shaman Pharmaceutical’s laboratories. Peter Awachi, PhD, was a visiting scientist in natural products chemistry at Shaman from January 1994 through March 1995. Shaman sponsored Dr. Awachi to learn modern analytical techniques unavailable to him in Nigeria.

Article 19.1 “Each Contracting Party “take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries which provide the genetic resources for such research, and where feasible in such Contracting Parties”. (CBD, 1992).

Each Contracting Party “take measures to provide for participation in biotechnology research activities by the developing countries which provide the genetic resource (Conte, 1994).”

BETWEEN

NATIONAL INSTITUTE FOR PHARMACEUTICAL RESEARCH AND DEVELOPMENT

AND

CONSULTANT HERBALIST

Dated this.....day of.....1997

WHEREAS:

1. The “INSTITUTE” is a scientific and technological-oriented public Institution established to undertake research and development work into (among other things) drugs and pharmaceutical raw materials from indigenous natural resources or materials and the evaluation, standardization and rational utilization of traditional medicine.
2. The “CONSULTANT HERBALIST” has acquired useful information, facts and knowledge in respect of the use of herbal products for the management, treatment and/or cure of and other ailments and he is engaged in the practice of Herbal medicine.
3. The “CONSULTANT HERBALIST” is willing to make these information, facts and discoveries in respect of the herbal products available to the “INSTITUTE” for use in the management and/or cure of and other ailments for the overall benefit of the public.
4. The “INSTITUTE” has requested, and the “CONSULTANT HERBALIST” has agreed, to provide services and information set out herein on herbal products for development and use in the management of and other ailments.
5. The “CONSULTANT HERBALIST” is willing and has agreed to supply the “INSTITUTE” with herbal materials (in their compounded forms) for the treatment of and other ailments for scientific identification, evaluation, analysis, development and/or improvement.
6. The “CONSULTANT HERBALIST” hereby gives consent to the “INSTITUTE” and the “INSTITUTE” hereby accepts to conduct research into, develop and process the said herbal products into suitable pharmaceutical drugs in dosage forms for commercial and industrial utilization towards the management or treatment of and other ailments.

NOW THIS AGREEMENT WITNESSETH:

In consideration of the mutual Covenants and Agreements herein contained, the parties hereto do hereby agree as follows:

1. The “CONSULTANT HERBALIST” hereby permits the “INSTITUTE” to conduct research into, develop and process the said herbal products into standard pharmaceutical drugs in dosage forms and to ensure due scientific evaluation, purification, standardization and safety of the said products for use in the management of and other ailments aforesaid.
2. The “CONSULTANT HERBALIST” shall disclose to the “INSTITUTE” his existing collections of the plant or herbal materials in their compounded forms at the moment (and fully subsequently) in respect of and other ailments for scientific identification, evaluation and development and literature search on such compounded plants/materials and shall at all times endeavor during the continuance of this Agreement to make available to the “INSTITUTE” any collection at his disposal upon request.

reasonable time after receiving such request supply compounded plant samples for the scientific evaluation as the “INSTITUTE” shall specify and diligently proceed with the preparation of such samples and deliver the same as required by the “INSTITUTE”.

6. The “INSTITUTE” shall subject the various extracts and fractions obtained from the medicinal plants used to prepare the herbal products to scientific evaluation for safety and efficacy provided that and it is hereby agreed that the “INSTITUTE” shall in all events furnish the “CONSULTANT HERBALIST” in writing with the result of every scientific test or analysis carried out on any herbal product/material received from him.
7. The “INSTITUTE” shall diligently proceed at Abuja or such other designated places within and outside Nigeria as the “INSTITUTE” may determine to conduct research and development work into the evaluation, preservation, purification, standardization, safety and rational utilization of the herbal products and formulate same into dosage form for commercial and industrial use and to apply and obtain the grant of patent in respect of the products at the cost, expense and techniques of the “INSTITUTE” and in a manner mentioned herein before in the proceeding clauses.
8. The “INSTITUTE” shall apply for and obtain or cause to be granted and obtained the letters of patent on the products in the name of the “INSTITUTE” after the same has been developed and processed provided that the “CONSULTANT HERBALIST’S” name be included in the patent subject to the conditions hereinafter set forth.
9. The either party shall use every reasonable means to protect, preserve and secure the interest and person of the other and the efficacy and safety of the products and shall not subject each other to public ridicule, adverse publicity and derogatory treatment during the subsistence of this Agreement.
10. The “CONSULTANT HERBALIST” shall be at liberty to continue to use, apply and utilize the herbal products which he has prepared and/or may continue to prepare in future by his own technique notwithstanding that the same or similar product has been referred to the “INSTITUTE” for scientific evaluation and formulation, provided however that the “INSTITUTE” does not guarantee the safety, purity, and quality or standard of such products. Nothing in this Agreement shall be construed as implying that the “CONSULTANT HERBALIST” is prohibited from citing his relationship with the “INSTITUTE” in any advertisement of his practice if and only if the consent of the “INSTITUTE” is first sought and obtained in writing.
11. Any information acquired by the “CONSULTANT HERBALIST” in the course of his services, transactions and operations under this Agreement regarding the sample preparation process, research and development work and details of the formulae of the products shall be treated by him as secret and confidential and shall not be disclosed by him without consent and authority in writing of the “INSTITUTE” provided that, and it is hereby agreed that, the “INSTITUTE” shall not unreasonably withhold such consent.
12. The “CONSULTANT HERBALIST” shall not during the continuance of this Agreement be engaged in a transaction similar with the one here in evidence with any other person, firm, company or organization anywhere in Nigeria in respect of products of any description or kind similar to, or competitive with, those of the “INSTITUTE” without the previous consent in writing of the “INSTITUTE”.

observance of the terms contained in this Agreement, information and assistance relating to and in furtherance of research and development of the herbal product.

15. The "INSTITUTE" shall endeavor in every reasonable and proper way and to the best of its ability to publicize the result of its Research and Development of the herbal products and for that purpose advertise such in Magazines, Journals, Periodicals, Weeklies, Newspapers or on radio and television in such manner as may be necessary.
16. IN CONSIDERATION of the foregoing provisions, the "INSTITUTE" shall at the point of commercialization of products derived from the "CONSULTANT HERBALIST'S" input negotiate on behalf of the "CONSULTANT HERBALIST" for some royalty of at least 10% of the net profit to accrue to the "CONSULTANT HERBALIST".
17. IN FURTHER CONSIDERATION of the services rendered by the "CONSULTANT HERBALIST", the "INSTITUTE" shall make payment to him as follows:
 - a) Without prejudice to any other remedies the "INSTITUTE" may have against the "CONSULTANT HERBALIST", the "INSTITUTE" shall have the right at any time by giving 3 months notice in writing to the "CONSULTANT HERBALIST" to terminate the Agreement in any of the following events:
 - i. If the "CONSULTANT HERBALIST" commits a deliberate breach of any of the terms of this Agreement which he refuses to rectify even upon demand.
 - ii. If the "CONSULTANT HERBALIST" dies, compounds with his creditors or takes or suffers any similar action in consequence of debts.
 - iii. If from any cause the "CONSULTANT HERBALIST" in the reasonable opinion of the "INSTITUTE" is prevented from performing his duties hereunder for a continuous period of six (6) months or for a total of eight (8) months in any period of (12) twelve calendar months.
 - iv. If the "CONSULTANT HERBALIST" is guilty of any conduct which in the reasonable opinion of the "INSTITUTE" prejudicial to the "INSTITUTE'S" interest.
 - v. If the "CONSULTANT HERBALIST" purports to assign the burden or benefits of this Agreement provided that the floating of a company by the "CONSULTANT HERBALIST" to undertake the practice of herbal medicine or for his practice shall not be taken as a breach hereof, provided that the "INSTITUTE" is duly notified any its consent obtained in writing.
 - b) If the "INSTITUTE" ceases to carry out research and development or deal in such drugs as were previously mentioned, this Agreement shall forthwith terminate unless the business or any part of it (being a part concerned in the manufacture or sale of such drugs or any class of them) has been transferred to any other organization and the rights and obligations of the Company hereunder have been assigned to that other organization after one month's notice of such assignment in writing has been given by the "INSTITUTE" to the "CONSULTANT HERBALIST".

between the parties hereto are hereby superseded.

- 20. If any dispute arises as to the construction of the provisions of these presents or implementation of the terms, the parties shall appoint one independent Arbitrator or constitute a panel of 3 Arbitrators who Herbalist, in addition to other remedies available to him, may on the 90th day of the breach terminate this Agreement forthwith.
- 21. The "CONSULTANT HERBALIST" or his personal representative shall upon the termination of this Agreement immediately deliver up to the "INSTITUTE" all facilities and property belonging to the "INSTITUTE" which may be in his possession or under his control.
- 22. This Agreement shall have effect in substitution for all previous Agreements and arrangements whether written or oral or implied by the "INSTITUTE" and the "CONSULTANT HERBALIST".
- 23. The Agreement shall not in any way constitute or be presumed to constitute a partnership between the parties hereto or make them in any way liable as partners of or as agents for one another. The "CONSULTANT HERBALIST" shall relate with the "INSTITUTE" as an independent contractor.
- 24. The Waiver by either party of any breach of any terms of this Agreement shall not prevent the subsequent enforcement of that term and shall not be deemed a waiver of any subsequent breach provided that a breach, once rectified, shall not, for any purpose whatsoever, be taken into account.

25. *The Agreement embodies the entire understanding of the parties in respect of research and development. And for the purpose of this clause the provisions of the Arbitration Acts, 1990 shall apply.*

IN WITNESS WHEREOF the parties hereto have executed this presents the day and year first above written.

SIGNED, SEALED AND DELIVERED BY:
 for and on behalf of the "INSTITUTE" DIRECTOR-GENERAL/CHIEF EXECUTIVE

IN THE PRESENCE OF:

Name:

Address:

Occupation:

SIGNED, SEALED AND DELIVERED BY

IN THE PRESENCE OF:

Name:

Address:

Occupation: