Bioprospecting: lessons from benefit-sharing experiences

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Abstract: Biodiversity prospecting, or bioprospecting, is the exploration of biodiversity for commercially valuable genetic and biochemical resources. The Convention on Biological Diversity recognizes the sovereignty of nations over their bioresources and their rights to share in the benefits that accrue from commercialized bioproducts. Since the Convention was introduced in 1992, many biodiversity prospecting arrangements throughout the world have progressed with varying degrees of success. This paper looks at how benefits from bioprospecting have been shared among the stakeholders in the arrangements. It briefly describes lessons learned from three case studies on different continents and among various stakeholders and commercial interests.

Keywords: Anthropology; arogyapacha; biochemistry; biodiversity; bioproducts; bioprospecting; biotechnology; Convention on Biological Diversity; cultural diversity; dietary supplements; drug discovery; ethnobotany; genetic resources; medicine; pharmaceuticals; phytomedicine; sustainable development; technology transfer; tropical forests; trust funds.

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Biographical notes: Katy Moran, an applied anthropologist, has directed the Healing Forest Conservancy since 1992. The Conservancy is an independent non-profit organization founded by Shaman Pharmaceuticals, Inc., and its division ShamanBotanicals.com. The Conservancy's mission is to develop and implement a process to return benefits to countries and culture groups that have collaborated in Shaman's drug discovery process, after a product is commercialized. Previously, Moran held positions at the Smithsonian Institution and the US House of Representatives. She has conducted field research, lectured and published widely on ethnobiology and policy issues.

1 Introduction

Those concerned with the conservation of bioresources recognize that when biodiversity-rich nations benefit from their sustainable use, conservation opportunities increase. The Convention on Biological Diversity (CBD) codifies this principle in its interrelated goals of:

- 1 the conservation of biological diversity;
- 2 the sustainable use of its components, and
- 3 the fair and equitable sharing of the benefits arising out of its use.

No longer are bioresources considered the 'common property of mankind', as the CBD recognizes the sovereignty of nations over their bioresources and their rights to share in the benefits that accrue from commercialized bioproducts [1].

Since the CBD was introduced in Rio during the 1992 Earth Summit, 178 nations and the European Union have ratified the Convention, agreeing to enact legislation to implement provisions that represent national interests, yet do not impose restrictions that conflict with the objectives of the CBD. At the same time, commercial users of bioresources voluntarily attempt to comply with convention provisions in order to gain access to the raw bioresources that can be developed into bioproducts. Besides the risk of lawsuits and despoiling a company's commercial reputation, the legal search for biological resources protects future business strategies for companies to access raw bioresources. These arrangements have come to be called bioprospecting, or exploring biological diversity for commercially valuable genetic and biochemical resources [2].

It is useful to examine how these practices, by both provider countries and user companies, are actually working today and offer examples to nations in the process of establishing legal frameworks to comply with the CBD. As of the beginning of 2000, some 42 countries have introduced access and benefit sharing regulations or have laws under development. Regional frameworks, which respond to the occurrence of biodiversity regionally, are also under consideration in the five States of the Andean Commission, the Association of South East Asian Nations (ASEAN), the Organization of African Unity (OAU), and the South Pacific Regional Environment Programme (SPREP).

But there are more stakeholders than provider countries, which include local, state, regional and national government levels, and user industries, including both small and multinational companies. Many other interested parties are involved in bioprospecting relationships, often with competing agendas and conflicting interests. Major stakeholders include both the domestic and international research communities, including botanical gardens and universities. Their participation reflects the increasing commercial value of bioresources and spans a continuum from pure to applied research [3].

Also recognized as valuable to bioprospecting is the ethnobotanical knowledge of the forest-dwelling (or native, tribal, indigenous) peoples who live in or near tropical forests and possess information on the use of plants for medicinal purposes. Of the 120 active compounds isolated from higher plants and used today in Western medicine, 74% have the same therapeutic use as in native societies. This traditional knowledge is embedded in forest peoples' cultural systems and passed down generationally. Accumulated over millennia, traditional knowledge is as rich and diverse as tropical forests' biological resources, and as threatened [4].

Non-governmental organizations (NGOs) such as conservation, development, human rights, health and other non-profit organizations, foundations, *pro bono* law firms and private consultants play growing roles as intermediaries in fostering, facilitating and evaluating bioprospecting partnerships. To level the playing field in negotiating expertise, many countries and culture groups have successfully sought outside expertise at different stages of bioprospecting negotiations from intermediaries that have some vested interest

in promoting equitable arrangements. Many intermediaries speak the local language, have worked for many years and often lived in the community and earned its trust. They play many roles in access and benefit-sharing arrangements with source countries and other entities, often becoming partners in the relationship [3].

This paper will review three existing case studies on bioprospecting in Asia, Latin America and Africa, focusing on lessons regarding benefit-sharing, the third goal of the CBD. Although there is a broad array of industrial uses for biodiversity, including biotechnology, cosmetics, crop protection, horticulture and personal care industries, this paper confines case studies and discussions to benefit-sharing from pharmaceuticals and botanical medicines [5]. There are no 'model' bioprospecting arrangements, as the case studies demonstrate. Rather, in one study the impetus came from a government research institute, another from an international environmental organization and another was primarily initiated by a small company. Since one of the most contentious questions of bioprospecting regards the use of indigenous knowledge in the discovery of new medicines, each case study includes indigenous participants, so as best to illustrate and compare such arrangements [6].

2 Comparative experiences in benefit-sharing

2.1 India

Rich in biological and cultural diversity, India houses over 45,000 species of plants, 30% that are higher plants and 400 unique ethnic groups, 75% of which are tribally organized. India's proposed Biodiversity Act strictly regulates international access to bioresources for both research and commercial use with heavy fines for breach of the Act.

The Tropical Botanic Garden and Research Institute (TBGRI) was established by the government of Kerala, India, in 1979. In 1987, the TBGRI held an ethnobotanical field study in the forests of the Western Ghats in southwest India. These forests are home to the Kani tribe, nomadic traditional collectors of non-timber forest products, who now lead a primarily settled life in tribal hamlets. The Kanis use a wild plant for energy that they called 'arogyapacha', and was identified as *Trichopus zeylanicus* by the TBGRI. It provided a lead to the development of the drug 'Jeevani' (giver of life) after the TBGRI transferred the manufacturing licence to a major Ayurvedic drug company in India. The Aryavaidya Pharmacy Coimbatore Ltd. licensed Jeevani as a tonic to bolster the immune system and provide energy for a fee of Rs 10 lakhs (approximately US\$25,000). The TGBRI agreed to share 50% of the licence fee and the 2% royalty on profits with the Kani [7].

Traditional systems of the Kanis have eroded and been replaced by those of non-tribal local communities. Rather than governance by a tribal chief (Mootha Kani), today's system, referred to as the Panchayati Raj, is based on the principle of devolution of administrative powers to the local village level under the Constitution of India. The predominantly non-tribal Panchayat's decision-making body is elected by members.

Kanis, with a population of under 17,000, live in different areas and have differing opinions on the arrangement with the TBGRI, which has interacted primarily with the Kanis from one area. This group of Kanis supports and appreciates the role of the TBGRI. However, Kanis in other Panchayat areas are offended that the TBGRI only works with one group. Some feel the benefit-sharing arrangement is superficial, since

most Kanis are not involved in the process. In September of 1995, a group of nine Kani medicine men wrote to the Chief Minister of Kerala, objecting to the sale of their knowledge to a private company.

The TBGRI acknowledges it has not reached out or communicated to all members of the Kani tribe, so, with the help of NGOs a Trust was established and registered. The TBGRI reported in 1998 that the Trust has over 500 members, but some critics feel this number falls far short of adequate representation of the Kani. In March, 1999, *Science* reported that the first payment of \$21,000 would be made and shared by the tribal community and the institute [8].

Dr. P. Pushpangadan, former director of the TBGRI, reports that arogyapacha, a perennial undergrowth, was cultivated to ensure a regular supply of the raw drug to the manufacturer [9]. But the TBGRI scientists learned that the medicinal qualities of the plant are lost, unless grown in natural forest settings. So the TBGRI organized 50 Kani families who live inside the forest to cultivate and pre-process the plant under the supervision of the TBGRI scientists. This plan, writes Pushpangadan, generates employment, as leaves of the plant are bought from the Kani who manage the semi-wild crop. Each family has one or two acres of arogyapacha under cultivation in the first year of the project and earns about Rs. 30,000 per acre. This income is expected to increase in subsequent years, as it is anticipated that the production of leaves will increase and last for 20-30 years. Since the plant can be grown only in the natural forest habitat to maintain its medicinal qualities, it seems the Kani are in an effective bargaining position to regulate and control its harvest. Pushpangadan describes arogyapacha as 'forest friendly' because it is grown under the shade of the natural forest canopy, but he does not refer to any sustainability studies on its management. Although it contributed no men, material or finances to the effort, Pushpangadan recently writes, that the State Forest Department now demands a share of the licence fee and royalties on the grounds that the plant material is collected within a forest area.

In all fairness, it must be remembered that the TBGRI process for benefit-sharing with the Kanis evolved in a policy vacuum, well before the CBD was introduced. The lessons learned from mistakes made in this case study did not have the luxury of precedent, or of guiding legislation by the national government, but developed procedures in an *ad hoc* manner gradually over a dozen years. This occurred despite the fact that all project participants were nationals, and did not involve any international trade, companies or institutions. When governments enact restrictive regulations, it inhibits scientific research, whereas simple, flexible access laws discourage 'biopiracy', encourage innovations and minimize the transaction costs of bioprospecting for all.

Likewise, the absence of an intact traditional system of governance by the Kani crippled the decision-making processes that are enjoyed by culture groups with a lesser degree of acculturation. The trust fund that was initiated after complaints from the Kanis about equity cannot be considered legitimate unless the people who contributed to the process from which revenues are generated, are the same ones who control the funds to some degree. Since wealth and technology are as concentrated in the North as poverty and biodiversity are in the South, what is 'equitable' in the bioprospecting process is difficult to define. Equity is a relative term and can be determined only by the participants in the process. It means not only equitable compensation, but equal standing among participants in making decisions about what form benefits should take.

Even though the Kani are quite powerless in relation to a large Indian government research institution, their uncontested right to deny access to bioresources or traditional knowledge would have supplied strong leverage during access negotiations, had the bioprospecting arrangement been negotiated today. The right to deny access is widely recognized and these processes are now undertaken well before any bioprospecting activities begin. No collecting permits are issued until such contractual agreements are negotiated, after the prior informed consent process. There must be a written understanding among all relevant stakeholders of rights, obligations, roles, and ownership, of who shares how much in what kinds of benefits, when. It defines exactly who the state and/or national authority is, whether it be the State Forest Department, the TBGRI, or some other entity that can make a claim as a stakeholder [10].

In its wording, the CBD lumps together 'indigenous and local communities', even though there are several anthropological criteria that clearly differentiate indigenous peoples from being defined simply as local communities. This case study demonstrates the dangers of assuming that the indigenous Kani and local communities share the same values, traditions and methods of governance.

Another question concerns the sustainability of the present system of sourcing arogyapacha, since there is no information on sustainability studies connected to methods of managing and harvesting the plant. Clearly, environmental impacts on the forest, as well as sustainability studies, are required if it is anticipated that the need for arogyapacha will increase and last for 20-30 years [11].

2.2 Suriname

The International Cooperative Biodiversity Group (ICBG) was launched in 1991 with funding from the US government, sponsored by the National Institutes of Health (NIH), the National Science Foundation (NSF) and the US Agency for International Development (USAID). Three interrelated goals of the ICBG include health improvement through the discovery of new drugs from natural sources, conservation of biological diversity and sustainable economic development. By 1994 ICBG projects were held in Suriname, Costa Rica, Argentina, Chile, Mexico, Peru, Cameroon and Nigeria [12].

Suriname is located in the centre of a two billion-year-old Pre-Cambrian formation known as the Guayana Shield. This region of northern South America is the most extensive and least disturbed major tropical wilderness, with more than 90% of its original forests still intact. The interior of Suriname is covered with undisturbed Neotropical Amazonian forest and largely uninhabited. With a land area of 166,000 square kilometers and a human population of 412,000, Suriname is one of the least densely populated countries in the world.

The five year old Suriname ICBG's bioprospecting program was proposed by the Suriname office of Conservation International (CI), an international non-governmental organization (NGO) and the Saramaka Maroons. Maroons are descendants of escaped African slaves who have lived in the Suriname forest for nearly three centuries. Although they are not indigenous to the area, the Saramaka Maroons meet several anthropological criteria in definitions of 'indigenous' including forest dwelling, use of a local language and tribal social organization [13]. The cooperative partnership also includes the Virginia Polytech Institute and State University, Missouri Botanical Garden, Bristol Myers-Squibb

Pharmaceutical Research Institute and Bedrijf Geneesmiddelen Voorziening Suriname (BGVS), a pharmaceutical company owned by the Surinamese government.

Through a Statement of Understanding, the Suriname ICGB established a benefitsharing plan with a US\$60,000 total advance payment from Bristol Myers Squibb Pharmaceutical Research Institute into the Forest Peoples' Fund (FPF), with additional contributions of \$20,000 a year as the ICBG is renewed. The FPF is a mechanism, which CI Suriname helped broker, through which 'up front' benefits and future royalties from new drugs developed can be returned to the Saramaka people. Along with compensating the Saramaka Maroons for their ethnobotanical contributions, the FPF creates conservation incentives, finances sustainable management projects, provides research and technology exchanges and supports other socially and environmentally sound projects. A board of directors consisting of two representatives from the Indian community (one Saramaka and one Amerindian), two from CI Suriname, and one from Suriname's Department of Interior was created to review proposals for ways to spend the advance payment and any future royalties from drug sales. It was agreed that funds would be used for projects involving community development, biodiversity conservation and health care. If any products are commercialized from ethnobotanical collections, 50% of Suriname's share of any future royalties will go to the FPF and the other 50% will go to various ICGB partners in Suriname. If a drug is derived from random collections, the FPF's share is reduced to 30%, while 70% goes to other ICGB partners.

Green [14], a consultant who speaks both Saramakan and SrananTongo, evaluated the Suriname project during a site visit in 1998. He learned that before the project began, Saramaka leaders held numerous palavers (kutus), after which their paramount chief and local chiefs (Kapitenis) voted for Saramakas to participate in the project. They considered ways to use the donated funds that supplied ongoing income generation to benefit whole communities. CI (Suriname and Washington) played a crucial guiding role in this, although the by-laws of the fund were written by Surinamese participants and are governed by the laws of Suriname. About half the available \$60,000 funds was spent on local income generating projects. The FPF purchased outboard motors and developed a canoe taxi service to transport people and goods up-river to Saramaka territory. Other funds were used to train local people to cater food for ecotourism; to purchase sewing machines and train women to sew school uniforms for sale to parents; and to supply tools and training for a commercial gardening project. Another project trained people in woodcarving, carpentry and furniture-making. A community-based organization, called Afinga, helped to coordinate these microenterprise initiatives. All of these small scale projects have the potential to generate much-needed cash for the Saramakas of the upper Suriname river area where the ICBG is implemented.

Originally, according to Green, the ICBG agreement held no special provision for royalty sharing with traditional healers, an important consideration of ethnobotanical drug discovery. In Suriname, virtually all ethnobotanical knowledge made available to the IGBC project was supplied by healers, rather than from general or popular plant knowledge. While fully supporting local development initiatives, traditional healers expressed a preference for being paid a small amount for their participation as ethnobotanical collecting developed. Since it was locally recognized that the ICBG and the FPF came to Saramaka territory because of the wisdom of local healers, the presence of the ICBG project and especially the funds made available through the FPF, increased the healers' prestige in the community.

Bioprospecting is complicated. It involves the development of drugs by megacompanies in faraway countries, use of alien technologies, complicated and time consuming legal and governmental approval processes and highly complex relationships between a bewildering array of public and private organizations, both foreign and domestic. Some communities need significant help from intermediaries to participate in the process [14]. The lesson from the Suriname case study is how smoothly the bioprospecting process can move along when time and resources have been spent beforehand and when the stated goals of all partners are not in conflict, but interrelated. In Suriname, for example, the drug discovery process creates economic value for biologically diverse organisms, which in turn creates development funds and incentives for conserving biodiversity, satisfying the goals of all stakeholders [15].

Conservation International [16] helped pioneer the use of trust funds to target specific revenues for communities or projects in many countries. In Suriname, the Saramaka have a social and cultural identity distinct from the dominant society. They are geographically and linguistically isolated, which makes them particularly vulnerable to outsiders. Management of the FPF, however, is independent of outsiders, allowing the communities to determine how to use their benefits through their own cultural institutions without outside interference.

The question of individual compensation arises and is dealt with here. Typically, acknowledgment of the contribution of healers from indigenous societies in the discovery of new medicines that have historically benefited humankind is missing. This recognition is important because it enhances the prestige of individual healers within indigenous communities, countries and internationally, just as it does for Western scientists. And formal recognition of the healers' contributing role generates pride in the Saramaka culture and motivates its conservation.

2.3 Nigeria

Today, Africa has one of the highest rates of deforestation in the world. The continent is estimated to have about 216,634,000 ha. of closed forest areas and an annual deforestation rate calculated at about 1%. Located in West Africa, the Federal Republic of Nigeria is the continent's most populous nation. It suffers an annual deforestation rate of 5.0%, compared to a global rate of 0.6%. To contend with such statistics, Nigeria modified its national parks law to attract and encourage conservation funding by establishing biodiversity prospecting requirements.

The Nigerian population, estimated as over 100 million in 1995, includes over 250 distinct ethnic groups, some numbering fewer than 10,000 people. Most are concentrated in specific geographic areas. The Hausa and Fulani (or Peul) in the north, the Yoruba in the southwest, and the Igbo in the southeast comprise about 65% of the population. Traditional leaders, such as chiefs, healers, clan and lineage heads, are a major social force in communities, where numerous community development associations provide fora for citizens to identify, discuss and prioritize problems and to seek means to solve them [17].

The oldest component of the Nigerian health sector consists of traditional healers and birth attendants, who are the *de facto* providers of primary health care in Nigeria, estimated to serve about 80% of the population. Healers provide client-centred, personalized health care that is culturally appropriate, holistic and tailored to meet the needs and expectations of the patient. Since healers share the cognitive understandings

and cultural values of those they treat, they serve a function broader and more complex than their medical counterparts in the modern sector.

Nigerian healers are not strictly 'traditional', however. The term 'traditional', in this case, refers to healing practices that have endured over time because of their continuing usefulness. Traditional healers in Nigeria are adaptive, incorporating into their healing repertoire modern components that adhere to their cultural values. Most healers want to learn how to treat illness more effectively, so they are highly motivated to cooperate with the modern health sector [18].

The Bioresources Development and Conservation Programme (BDCP) is a multiethnic international NGO based in Nigeria that builds technical skills so that bioresources are a viable vehicle for improved health care and sustainable development [19]. The BDCP views science and technology as useful tools to be adapted to the local cultural framework, rather than as a modern alternative to the contributions of community members. One of the objectives of the BDCP is to use local bioresources and knowledge to target therapeutic categories for tropical diseases suffered in Nigeria such as malaria, leishmaniasis, and trypanosomiasis.

In 1990, Shaman Pharmaceuticals, Inc. established a research relationship with Nigerian scientific institutions, and the BDCP became the focal point for collaborative research. Shaman is a small San Francisco company that uses ethnobotany as well as isolation and natural products chemistry to discover and develop novel pharmaceuticals [20]. Nigerian scientists proposed initial discussions with healers and traditional leaders to talk about a collaborative relationship with Shaman for bioprospecting. The BDCP visited communities where members had worked for several years. Typically, each community or village state is autonomous, with its own chief and government. Their community decision-making process includes the village chief, his advisors, traditional healers and the elders. Before bioprospecting began, discussions covered topics such as the intentions and goals of the project; how and where the plants would be analysed; and their potential for commercialization and benefit-sharing. After lengthy discussions over a year, the groups felt that Shaman shared a common purpose with them consistent with their cultural values concerning human health and agreed to collaborate through an Agreement of Principles [21].

Four ethnobotanical field expeditions were conducted. By choice of Nigerian collaborators, immediate and medium-term benefits from the expeditions took the form of workshops and training programs on public health, botany, conservation and ethnobotany; support for a medicinal plant reserve; supplies for village schools; botanical collection supplies for a herbarium; laboratory equipment for scientific research on plants that treat parasitic diseases prevalent in West Africa and support for Nigerian scientists to apply modern analytical techniques. Fulfilling company policy, immediate and medium-term benefits, such as those above, totalling over US\$200,000 (two hundred thousand dollars) have been distributed through programs to the various stakeholders in the collaboration as the expeditions occur. The company regularly reports laboratory results to participating communities, and general literature on the project is published with both Nigerian and US authors [22].

At the time of its incorporation in 1990 as a for-profit corporation, Shaman founded the Healing Forest Conservancy (the Conservancy), an independent non-profit foundation. The Conservancy was established specifically to develop and implement a process to return long-term benefits to Shaman's collaborating countries and cultures,

after a product is commercialized. Through the Conservancy, Shaman will donate a percentage of profits from commercial products to all company collaborators (some 30 other countries and culture groups) for as long as Shaman has a profit. The Conservancy will distribute these long-term benefits, equally, to all the countries and cultures that are Shaman collaborators, regardless of where the plant sample or traditional knowledge that was commercialized originated [23].

On October 20, 1997, in Abuja, Nigeria, the BDCP launched the Fund for Integrated Rural Development and Traditional Medicine (FIRD-TM) during an international workshop on medicinal plants. The FIRD-TM is the vehicle to receive and channel benefits in an equitable and consistent manner from many contributors, including the IGBC, of which the BDCP is a member. Funds are directed to source communities from which commercially useful bioresources and ethnobotanical knowledge is derived. The BDCP facilitated the establishment of the Fund and is its sponsoring entity. The Fund, however, has an independent board composed of leaders of traditional healers associations, senior government officials, multiethnic representatives of village councils and technical experts from scientific institutions. Diverse culture groups in Nigeria will receive resources from the Fund through traditional healers' organizations and villages consistent with their governing customs. Town associations, village heads and professional guilds of healers are empowered to make decisions regarding use of the funds for projects in their localities. Those funded will follow the criteria of promoting conservation of biodiversity and drug development, as well as the socioeconomic development of rural cultures.

At the Fund's inauguration, the Healing Forest Conservancy donated \$40,000 to the FIRD-TM for a pilot project, to test the efficiency and efficacy of the trust fund process, using a step-by-step process to assess the feasibility of future trust funds for benefit-sharing. During the inauguration ceremony, the Association of Indigenous Pharmaceutical Manufacturers and the Orange Drug Company of Nigeria pledged additional monies to complement the Conservancy's donation [18].

The pilot Conservancy project generated a 21 page constitution, which supplies a legally enforceable mechanism, under domestic law, for a trust fund, written *pro bono*, by Morrison & Foerster, Ltd. in Washington DC. Under the Constitution, trustees of the fund, as a collective entity, may institute legal proceedings in their capacity to achieve trust fund objectives. The Conservancy Constitution is a template to use for the benefit-sharing actions of the Conservancy in many different countries that is flexible enough to respond to unique conditions in countries where Shaman collaborates. It supplies a legal mechanism to disburse widely financial resources, over a long time frame, and within varied sectors of society.

The Constitution provides for the distribution of benefits to all stakeholders in accordance with the following guidelines:

- 1 At least 50%, but not more than 70%, of available funds shall be distributed to traditional healers' organizations and community development funds.
- 2 At least 10%, but not more than 15%, of available funds shall be distributed to national universities and other national institutions that share a commitment to the aims and objectives of the Fund.
- At least 10%, but not more than 15%, of available funds shall be distributed to the sponsoring entity for its furtherance of conservation and development activities.

After ten years and \$170 million, in early 1999 Shaman Pharmaceuticals abandoned attempts to take any of its discoveries through the Food and Drug Administration regulatory process, as future time and costs for additional clinical trials proved prohibitive [24]. ShamanBotanicals.com was incorporated as a private, wholly-owned subsidiary of Shaman Pharmaceuticals to leverage the company's research and development by launching its first botanical dietary supplement, SB Normal Stool Formula on August 1, 1999 [25]. The product delivers a standardized extract from the sap of Sangre de Drago, the Croton lechleri tree, to prevent fluid loss and promote normal stool formation in the intestine to those suffering from side effects of HIV therapies, cancer therapies and irritable bowel syndrome [26]. ShamanBotanicals.com is selling SB Normal Stool Formula through existing retail channels, including mass market (food, drug and mass stores), multi-level marketing and the Internet. This and future products will be differentiated by their origins, their quality and Shaman's continuing commitment to benefit-sharing, sustainability and conservation.

For many years, Shaman invested in studies on managing and harvesting Sangre de Drago in Latin America, as the source of a future product. Ecological and distribution studies, as well as studies on yield and sustainability totaling US\$1 million have been carried out at sites from Mexico to Paraguay [27].

A major lesson of this case study is the time, costs and risks associated with drug discovery, a burden shouldered primarily by the company, but with critical implications for benefit-sharing to source countries and culture groups. Spreading the risks and benefits among all stakeholders increases opportunities for benefits and lessens risk. Royalties may never materialize due to the tremendous costs, long time frame, unpredictability and volatility of the market and the many other potential pitfalls of drug discovery. Some sort of up-front benefits, monetary or non-monetary, as well as 'milestone' payments such as those that went to Nigeria, are essential. Shaman Pharmaceuticals, Inc., was restructured due to costs of future clinical trials for the company's first drug, which consequently was launched as a dietary supplement, not a pharmaceutical. In the case of Shaman, however, the company's benefit-sharing principles are still intact and considerable revenues can be generated from the botanical income stream, while pharmaceutical research continues. In 1997, for example, the U.S. dietary supplement market for herbals or botanicals was nearly \$4 billion, with a \$5 billion 1998 projection and compounded yearly growth rate of 15-25%.

The BDCP goals of discovering and marketing bioproducts for diseases important to Nigeria is itself a lesson in opportunities brought about through bioprospecting. Too often, when the importance of biodiversity conservation is discussed for its value to human health, it refers to the health of residents of industrialized nations. The attitude is that biodiversity must be preserved to enlarge the pharmacopoeia of Western medicine, which provides therapeutics primarily for Western societies. Less discussed is the vitality of biodiversity to the health of 80% of the world, populations that depend solely on medicinal plants for their primary health care. Preserving biodiversity for the benefit of human health means preserving it for those in the tropics already using it, as well as for distant populations that may know it only in some refined or synthetic form at some unspecified future date.

This case study also demonstrates how biodiversity-rich yet financially-poor tropical nations, such as Nigeria, can increase conservation and research funding and gain valuable training and technology. Since the economic values of biodiversity are seldom

accountable in market valuations, strategies like bioprospecting bring added financial support for conservation. Countries can choose whether to supply natural products in the form of extracts, rather than raw unprocessed material, to foreign investors or to establish their own medicinal plant, phytochemical or pharmaceutical industry.

3 Lessons and conclusions

3.1 Monetary and non-monetary benefits

Benefit-sharing can take financial, conservation, social and scientific forms and must be decided during the prior informed consent process, before any bioprospecting permits are issued. As case studies demonstrate, opportunities for financial compensation include upfront payments and medium term benefit-sharing as research progresses. Many companies offer stakes in equity, profit sharing and joint venture opportunities. Royalties occur only if and when a drug is marketed, but it is risky to rely only on resources that may never materialize.

Cases that supplied support for conservation activities illustrated how cultural, as well as environmental, conservation can be accomplished. Acknowledging the contribution of healers supplies proof of the continuation of a traditional profession. It promises an economic future from preservation of the cultural patrimony by which healers train and pass on their heritage to future generations of practitioners.

In Nigeria, significant social benefits include development of low cost phytomedicines and conserving the primary source of health care in the country. Participation of nationals in research on tropical diseases through technology transfer, training, and joint research publications builds the technical capacity of nationals during the discovery process.

3.2 Training and technology transfer

The Kani benefit from training and sourcing agreements to cultivate high-value raw material for processing into phytomedicines. Such training supplies income-producing opportunities to rural communities that are best located to manage, collect, and protect species. Inventories that describe local use can be undertaken in the local language, which protects ethnobotanical information from outsiders and leaves a documentation of cultural knowledge within the community. Training also generates employment by outsiders who are interested in bioprospecting and increases the capability of gene-rich countries to perform these services.

National governments benefit from training programs by gaining a technological infrastructure for science and commerce, yielding jobs and taxes. Fees can be charged to outsiders with commercial or research interests, allowing debt-ridden tropical nations to forgo short-term profits from logging, cattle-grazing, and monoculture development projects that destroy forests. There are several entry levels, including: collecting procedures, inventories, bioassays, re-collection, harvesting, herbarium specimen storage, taxonomic identification, cataloguing and management of collections. Training increases the capacity of biodiversity-rich countries to assess and evaluate their resources, to generate biological databases and to enter into the natural products industry if they choose to do so.

3.3 Trust funds

While trust funds are now widely recognized as the method of choice to distribute benefits, it is important to acknowledge the consent and support of each host country government for the activities of the fund. This minimizes the risk that trust funds are perceived as a threat to the sovereign right of the host country government to exploit its own natural resources. However, this acknowledgment should not be viewed as undermining the independence of trust funds and their autonomous operating authority as a non-governmental organization. Their precise legal status will depend on laws of the host country where the fund is established. It is important that the fund be able to obtain the benefits normally associated with non-profit and charitable entities, such as exemption from taxation, so it can offer the added value of attracting other sources of funds. Its NGO status reinforces the independence of the fund from the host government and permits it to participate in other NGO fora.

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