

## CHAPTER 8

# Traditional Knowledge, Biological Resources and Drug Development: Building Equitable Partnerships to Conserve, Develop and Respect Biocultural Diversity<sup>1</sup>

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## 8.1 INTRODUCTION

The protection, utilisation and conservation of Traditional Knowledge (TK) have become an important global issue for many countries, cultures, organisations and peoples. The current international debates and

negotiations taking place within many international fora such as the Convention On Biological Diversity, (CBD), the World Intellectual Property organisation (WIPO) and the World Trade Organization (WTO) are focusing on reconciling many fundamental ethical, legal and moral issues. One of the most frequently discussed issues is the potential conflict between the mandates of the CBD and the Trade Related Aspects of Intellectual Property Rights (TRIPS).

WIPO is actively working to understand, define and moderate the complex evolution of the global community's attempts to respect both the IPR system and the holders of TK and biological resources.<sup>2</sup> (WIPO, 2001, 2002a, b, c, d, e, f). Two recent papers by the Head of the Genetic Resources, Biotechnology and Associated Traditional Knowledge section of WIPO have summarised the ethical, moral and legal issues with great depth, clarity and compassion.<sup>3</sup> There are many extremely capable legal experts, diplomats, scholars, social scientists and fortunately increasing numbers of Traditional Knowledge holders (earthcall.org) guiding this debate. The United States Patent and Trademark Office (USPTO) is also trying address the issues associated with patents and the protection of Traditional Knowledge.<sup>4</sup>

In the meantime, local communities and cultures continue to live and seek protection from inappropriate exploitation as well as opportunities to improve, enhance and advance their lives, communities, cultures and ecosystems. This chapter presents two examples of the process of actual direct collaboration with the holders of Traditional Knowledge and the countries in which they live. This discussion provides one other critical dimension to the discussion and debate. In Article 1 of the CBD, there are three well known objectives: the conservation of biological diversity; the sustainable use of biological diversity's components; and the fair and equitable sharing of benefits arising out of the utilisation of genetic resources. There are, however, very few specific discussions of how individuals, organisations, or corporations have worked to address and accomplish these three mandates and objectives. We hope that this chapter contribution will be of use to any groups or organisations seeking to collaborate directly with the holders of traditional knowledge.

After introducing the key issues and themes of this chapter, we will present details of two specific partnerships with the cultures and countries of Belize and Tanzania. Shaman Pharmaceuticals Inc. worked to address the complex issues mentioned above in the course of multiple years of collaboration with local cultures, national scientists and government

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agencies. With this account of two distinct collaborations, we hope to stimulate analysis, dialogue, and discussion on Traditional Knowledge, biological resources, intellectual property rights, and the equitable sharing of benefits. In following sections of this chapter, we present several examples of organisations conducting ethnobotanical research and development activities around the world.

## 8.2 BIOCULTURAL DIVERSITY AND INDIGENOUS PEOPLES

It is well known that tropical ecosystems are being destroyed at a rapid pace.<sup>5</sup> In addition to the diminishing flora and fauna, human cultures living in the forest are dwindling in numbers as well. As the ecosystems are destroyed, the cultures that depend on it are destroyed as well. The conservation of both biological and cultural diversity, or “biocultural diversity”, is essential in conserving both the ecological systems and the human cultures nurturing these systems.<sup>6</sup> Tropical ecosystems have long been a location for both industrial and scientific research. Great discoveries and achievements, as well as financial benefits, have often been accompanied by the exploitation and destruction of genetic resources.

There is no longer any doubt, however, that indigenous peoples must share in the benefits derived from products developed based on their knowledge, technology, and forest management. One of the key question is how these benefits can be distributed in the most fair and effective manner.<sup>7</sup> Obviously, each country and relationship will be different, and ensuring equitable sharing usually involves a complex series of steps. Fair and equitable benefit-sharing is often complex, but not impossible, and efforts should continue to be made.<sup>8</sup> Intellectual property rights (IPRs) are a Western concept originally established to protect commercial inventions.<sup>9</sup> Many feel that *sui generis* legislation may be needed to protect the rights of indigenous peoples.<sup>10</sup> Posey and Dutfield proposed the concept of Traditional Resource Rights (TRR), which are “equitable integrated Rights, including IPR”.<sup>11</sup> The concept of TRR may more appropriately reflect the concerns of indigenous people than IPR.<sup>12</sup> These are based on fundamental human rights and include both tangible and intangible resources. They are actually not one set, but a bundle of rights, combining various international

agreements “in an effort to build a solid foundation for more equitable systems of protection and benefit sharing”.<sup>13</sup>

## 8.3 INDIGENOUS PEOPLES’ ORGANISATIONS AND MANDATES

Indigenous Peoples are directly challenging the global IPR system. Indigenous Peoples are now leading many of the efforts in IPR, Biological Diversity, and cultural conservation.<sup>14</sup> They have set up organisations such as the Indigenous Peoples’ Biodiversity Network (IPBN), the World Council of Indigenous Peoples (WCIP), and the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA).<sup>15</sup> These are people who constitute less than 4 per cent of the world’s population, but make up 95 per cent of the world’s cultural diversity<sup>16</sup>, and are using the issued mandates and alliances to initiate steps towards positive interpretation and implementation.

The International Alliance of Indigenous-Tribal Peoples of the Tropical Rainforest (IAIP) has released a document, titled “The Biodiversity Convention—the concerns of Indigenous Peoples”, which address the objectives of the Convention on Biological Diversity (CBD) and Article 8(j) in particular, calling for support to “help indigenous peoples carry out our own process of mutual consultation on our rights, our knowledge, our biodiversity”.<sup>17</sup>

Therefore, in addition to, and possibly more important than, the many international agreements and declarations, there are existing indigenous mandates and charters, often directly stating demands on these issues. These include the aforementioned IAIP’s mandate, which explicitly condemns “those who use our biological diversity for commercial and other purposes without our full knowledge and consent”.<sup>18</sup>

Quite obviously, there are many methods of collaboration and each case is very different and holds a unique set of circumstances. In addition, each community has its own set of individual needs. Relationships and transactions will always be dynamic and case-specific.<sup>19</sup> As Clay argues in *Generating Income and Conserving Resources: 20 Lessons From the Field*<sup>20</sup>, “There is no single blueprint for success.” It is up to the individual, company, or institution to initiate these reciprocal partnerships and to follow cultural and national laws. Positive and negative examples should be documented and published so that monitoring, dialoguing, digesting, and assessing these methods are feasible exercises.

**TABLE 8.1**

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**Indigenous Mandates and Charters in 1990s**

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UN Declaration on the Rights of Indigenous Peoples, 1993

Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples, 1993

The COICA/UNDP Statement, 1994

Charter of Indigenous Tribal Peoples of the Tropical Forests, 1992

Recommendations from the Voices of the Earth Congress, 1993

Kari-oca Declaration and Indigenous Peoples' Earth Charter, 1992

Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights, 1995

UNDP Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights, 1995

World Council of Indigenous Peoples: Declaration of Principles, 1984

UNDP Consultation on the Protection and Conservation of Indigenous Knowledge, 1995

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One of the most important aspects in these collaborations at all levels is the role of the indigenous groups, who must become full partners in the negotiations, and be supplied with complete information about the intended research. Highest priority should be given to their ability to accept or reject offers of research collaboration or to negotiate agreements with legal counsel on their terms. Communities will often partake in an equitable collaboration, if the researchers are open and honest about their goals and methods, as well as their commitments to the community, and can guarantee them fairly negotiated contracts and agreements. They may also rely on the reputation of other projects that groups have been involved with and what has been said about them, true or not. Because of both past and ongoing wrongs in research methods, some communities are, for good reason, hesitant to collaborate. There exists, for many, a positive view of the renewed interests in traditional knowledge and natural resources combined with fair compensation. Many

tribal and indigenous communities however, choose not to “share” their healing systems, made up of plant medicines, local ecology, spiritual care, and more.<sup>21</sup> But if equitable sharing and positive biocultural benefits can be attained, partnerships can be amicably made. As one member of Costa Rica's *KékōLdi* indigenous group has stated: “We are happy to assist scientists who want to analyse the medicinal properties of the plants in our forests. We only ask them to assist us too, in our efforts to protect our forests.”<sup>22</sup>

## 8.4 SHAMAN PHARMACEUTICALS INC.

Shaman Pharmaceuticals was a mid-stage pharmaceutical company in the process of developing traditional pharmaceuticals identified through a multi-disciplinary process of ethnomedicine and ethnobotany, biology, and natural products chemistry. In the Senate Foreign Relations Committee Hearing on the US ratification of the Convention of Biological Diversity, Shaman's CEO and founder, Lisa Conte, testified as to the significance of the Convention for the recognition of both biological diversity and cultural rights. She stressed the Convention's importance, “... because it defines not only biodiversity conservation, but also the sustainable use of biodiversity and of the equitable sharing of benefits that arise out of that use”.<sup>23</sup> She also explained Shaman's philosophy and procedures “to equitably compensate indigenous societies for their intellectual contributions to the identification of useful products in the drug discovery process”.<sup>24</sup> This was the foundation for Shaman's commitment to several layers of reciprocity, directly related to ethnomedical collaborations with communities, which are discussed below.

### 8.4.1 Shaman's focused benefit sharing and reciprocity

From the start of the company, and before the Convention on Biological Diversity (CBD) was opened for signature in 1992, Shaman Pharmaceuticals has focused on reciprocity issues through balanced collaborations between the company and the communities with which it works.<sup>25</sup> It has addressed biodiversity and conservation, as well communal compensation and reciprocity at all stages of the relationship. Because traditional knowledge is an irreplaceable cultural resource and direct acknowledgment is inherent, Shaman has set up three time frames for

reciprocity: the short, medium, and long terms. These were developed to provide benefits to communities throughout the drug discovery process. Because of the nature of the pharmaceutical industry, there is a long lead time before a drug is actually on the market, and the company thought it inappropriate to delay reciprocity until this happened. Short and medium term methods address this time issue. Short term reciprocity, which we will focus on in this chapter, devotes 10–15 per cent of the field research funds to immediate community needs, as defined directly by the community. Reciprocity can be in the form of services, or of supplies which are lacking in the community, but this is decided on by the community itself and not by Shaman.

Medium term reciprocity involves projects that transpire in several months or years, and include major parts of the CBD, technology transfer and sustainable development goals. This involves working with local universities, governments, Traditional Healers Associations, Federations, and other groups to benefit the community. These intentions are stated in Article 10(e) of the CBD, which calls for the encouragement of cooperation between government authorities and the private sector in developing methods for sustainable use of biological resources.

Long term benefits are those that are distributed after a product reaches the market. Compensation is carried out by The Healing Forest Conservancy (HFC), a non-profit organisation founded by Shaman Pharmaceuticals, to develop and implement methods to deliver long-term compensation back to the communities with which the company has worked.<sup>26</sup> The overall philosophy is that a portion of company profits will be returned to *all* communities and countries in which Shaman has worked, regardless of where the plant or information that led to its discovery was encountered.<sup>27</sup> This method was designed to provide benefits to a large number of groups, reducing the risk that exists in drug discovery for each individual group. Only a small, unpredictable percentage of products will ever reach the market, so the benefit as well as the risk is spread out among all groups to increase opportunities for compensation and speed up the return time. All of these stages have been discussed in much more detail in previous publications.<sup>28</sup>

Shaman has worked to comply with the CBD and extended the methods of reciprocity and collaboration to include opportunities that were not included in the Convention. Case studies of how Shaman worked to implement CBD policies, principles, and guidelines into applicable research practices are included in publications which provide the details

of collaborations in Nigeria<sup>29</sup>, Cameroon<sup>30</sup>, Guinea<sup>31</sup>, and Uganda.<sup>32</sup> We now add to these case studies a description in the next two sections of how partnerships were created in Belize and Tanzania.

#### 8.4.2 Belize: Ethnobotanical research collaboration

Belize is a small country about the size of the state of Massachusetts. It was previously known as British Honduras until 1973 and gained independence from Britain in 1981. It lies on the East coast of Central America in the heart of the Caribbean Basin, with Mexico bordering to the North, Guatemala to the West and South, and flanked by the Caribbean Sea on the East. On the Caribbean side lies the longest barrier reef (185 miles) in the Western Hemisphere, and the second longest in the world. Approximately 30–50 per cent of the forest is still intact—depending on whose estimates you use—and another 20 per cent is being selectively logged. Although, in some areas, like the South, contracts are being given to foreign logging companies, who control up to 200,000 acres of forest in that region.<sup>33</sup>

The *Maya* were the first known inhabitants of Belize, beginning as early as 1500 B.C. There still exists a significant proportion of *Maya* (*Yucatec*, *Mopan*, and *Kekchi*), making up 7–10 per cent of the population throughout the entire country. In the 17th century, the British arrived to cut mahogany for export. They eventually brought African slaves who now represent the 8 per cent Garifuna (Carib) population. There are actually six distinct cultural groups in Belize in addition to *Maya* (7–10 per cent), including Creole (mixed European and African) (40 per cent), Mestizo (mixed *Maya* and Spanish) (33 per cent), Garifuna (8 per cent), East Indian (3 per cent), and Mennonite (3 per cent) populations.<sup>34</sup>

Like traditional cultural practices everywhere, traditional medicine in Belize is in danger of extinction. Many of the codices (books) that were the written teachings of *Maya* medicine and its practice were burned by the Spanish Conquistadors. The practice or teaching of traditional medicine, along with other traditional practices of the *Maya*, were banned and then declined. Changing from written to oral, this continued for generations until the last few decades, when traditional teachings were felt to be irrelevant to life in the modern world. Healers, ethnobotanists, and interested younger Belizeans have made it their work to chronicle the remnants of Belizean traditional medicine before it is all lost.<sup>35</sup> Many

of the healers who still retain this knowledge are old and work is being done to capture their vast “oral libraries” of healing knowledge. One of the greatest and most well-known *Maya* doctor-priests of Belize, Don Eligio Panti, died in February of 1996. Much of his experience and knowledge died with him.<sup>36</sup> Fortunately, he had worked for years with Dr. Rosita Arvigo and Michael Balick, who recorded many of his uses of Belizean plants. Dr. Arvigo, who was his apprentice, continues to see many of Don Eligio’s patients. Don Eligio will not be forgotten, and now, neither will much of his valuable healing pharmacopoeia.

Dr. Arvigo, with Gregory Shropshire and Michael Balick set up the Ix Chel Tropical Research Foundation (IXTRF) in the Cayo District of Belize. IXTRF is a Belizean NGO dedicated to traditional medicine, ethnobotany, Belizean culture, and rainforest conservation. It is home to *The Belize Ethnobotany Project*, a joint project with the New York Botanical Garden to record traditional uses of plants and carry out cooperative studies, such as with the National Cancer Institute, to test rainforest plants for AIDS and cancer fighting substances.<sup>37</sup> It also assisted in the formation of the Belize Association of Traditional Healers (BATII) and the acquisition of Terra Nova, an extractive reserve for medicinal plants.<sup>38</sup> Through the project, a reference collection of plants has been built at the Belize College of Agriculture and the Belize Forestry Department. Creative approaches to reciprocity in exchange for information have been developed. A significant portion of the profits made from *Rainforest Remedies*, a medicinal plant book which Arvigo and Balick compiled and wrote on the healing plants of Belize, have gone to individual collaborating healers to help construct clinics, support apprentices, and to achieve other personal goals further enhancing traditional healing.<sup>39</sup> Conferences, classes, and lectures on ethnobotany and healing have taken place and have helped rekindle the interest of the younger generations, as well as respect for the traditional healer’s knowledge. An employee profit-sharing herbal extract industry has also been started, and is run as a cooperative venture with local farmers.

The Healing Forest Conservancy (HFC) has successfully completed several pilot projects to contribute to the discussion of long term compensation. One of these occurred in Belize in conjunction with IXTRF and BATII. Results of all pilot projects are shared with other cultural groups and countries to give them concrete examples for analysis. Because land demarcation is an important aspect and the first step towards sustainable management, it is often one of the highest priorities for

indigenous groups. When BATII sought a way to protect Terra Nova from approaching poachers and loggers, they decided that demarcating the 6,000-acre tract would help and requested assistance. The HFC and the Rex Foundation funded the surveying and demarcation of this area. This successful cooperation between a government, a traditional healers association, and outside groups is a useful example for other groups who desire to demarcate their land. This was the first major collaboration between Shaman, through the HFC, and indigenous groups and other organisations in Belize.<sup>40</sup>

#### 8.4.2.1 Prior informed consent and relationship building

Shaman Pharmaceuticals initiated interest in Belize due to its existing indigenous populations, rainforest and the continued use of traditional medicine by its people. It is one of the over 25 countries, in Latin America, Africa, and Asia that have collaborated with Shaman scientific teams. Michael Balick, an ethnobotanist with extensive field research in Belize was involved in the planning process, as was Julie Anne Chinnock, a natural products ethnobotanist at Shaman, who had lived and worked in Belize previously.<sup>41</sup> A cultural background report on Belize was prepared by Shaman’s in-house medical anthropologist as part of the pre-fieldwork preparation, a practice which has been suggested by several authors.<sup>42</sup> The Southwest part of the country was chosen due to the existing *Mopan* and *Kekchi Maya* communities there. An NGO, the Toledo Eco-Tourism Association (TEA), who had expressed interest in working with Shaman, was contacted to seek a possible collaboration with people in the community. This was a NGO set up by, and a representative of, the people in several communities of the Toledo District. It was decided after reviewing their objectives as an organisation and receiving their permission, that they would be an appropriate liaison in order to conduct an ethnomedical field research collaboration. It is important to highlight that other NGOs and groups do exist in the region, but this one appeared to have commendable objectives, was proactive in inviting us to collaborate, had one of the largest representations of the people in the communities, and was accepted by many people in the 14 village areas. Sometimes individuals, groups, or communities can represent themselves in collaborations, but sometimes they do not “have the legal, technical, social, or political expertise or power to effectively structure an exchange in their own interests and may require the assistance of other organisations such as activist NGOs.”<sup>43</sup> This is partially the case in Southern Belize,

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indigenous groups. When BATH sought a way to protect Terra Nova from approaching poachers and loggers, they decided that demarcating the 6,000-acre tract would help and requested assistance. The HFC and the Rex Foundation funded the surveying and demarcation of this area. This successful cooperation between a government, a traditional healers association, and outside groups is a useful example for other groups who desire to demarcate their land. This was the first major collaboration between Shaman, through the HFC, and indigenous groups and other organisations in Belize.<sup>40</sup>

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although many self-representative groups do exist and are currently forming and reinforcing their presence and objectives in the country.

The self-defined purposes of the TEA were to provide alternatives to ecological destruction, to set up manageable and controlled income-generating activities (including eco-tourism) as the name suggests, to improve public health and education in the district, to protect the environment, and to preserve the culture and the values of the indigenous communities. They are also actively involved in current projects to prevent illegal and destructive logging in the Toledo District.<sup>44</sup>

The Toledo *Maya* still maintain slash and burn farming (milpa) methods. In recent times, their environment is being sacrificed for short term economic gain. Timber concessions are being granted and misguided development schemes are utilising non-sustainable harvest methods.<sup>45</sup> Tourism had become an economic alternative, but was developing into another means of forest and cultural demise. There was, and remains, the immediate need for protection of the indigenous groups residing in this natural area. There are still many traditional uses of the forest in this area, with much knowledge held by the local people. This adds greater strength to the demand that these natural areas be protected from over-development.<sup>46</sup> The TEA was formed to help keep this area from biological and cultural destruction, while producing income for the communities as well. As Jason Clay has argued, “success [in resource use] will only be achieved if very specific local conditions are taken into account in the design and implementation of conservation and development strategies for each community”.<sup>47</sup> This is exactly what the TEA attempted to do by concentrating its efforts on a small number of communities and using non-timber forest products and ecotourism in an ecological and productive manner. They received commendations and recommendations from the RainForest Action Network and other groups for their efforts in conservation and sustainable development.<sup>48</sup>

#### 8.4.2.2 The prior informed consent process

Contact regarding this research project was established with the TEA in June 1994, in the form of a introductory letter of interest, a proposal to visit and do research, articles describing past collaborations, commitments and research methods, as well as an open invitation for questions and concerns. Prior Informed Consent (PIC) was requested from the healers and the communities. Although Spanish, Creole, Garifuna, and several forms of *Maya* are all spoken in Belize, English is the central language

and is spoken by most people, and therefore the most appropriate language to be used for all written correspondence. PIC is one of the most important aspects of the CBD, and in the context of TRRs and IPRs. It is an authorisation from the communities within the research jurisdiction, based on the description (in the local language) of the intended work, the possible implications, the intended benefits, and among other things, how and by whom the genetic resources will be used. This information gives the communities the ability to negotiate, comply or deny access.<sup>49</sup> The Convention on Biological Diversity addresses PIC in Article 15(5), stating that:

Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by the Party.

In accordance with the CBD and the important need for PIC, all parties and communities involved in the collaboration with Shaman were fully informed of the company's objectives and goals and the potential for commercialisation prior to the collaborative research being conducted. This is a vital aspect in any research program and needs to be initiated at the beginning of any program and openly maintained throughout the relationship, in order to have enough time to discuss problems, goals, and aspirations before the research begins. There will always be changes and questions and the discussions should be ongoing.<sup>50</sup>

A meeting was held to discuss Shaman's request and to come to a decision on their proposal to begin collaborating. The company's objectives and methods were described to the group and the potential advantages and disadvantages discussed and debated between them. The TEA then decided that they would approve and help facilitate the research, including interviews and plant collections, and that a committee be formed to observe and monitor Shaman's work. Two interested villages extended an invitation. Permission was then granted, in writing, by the TEA Executive Committee.

Planning activities began, such as setting and verifying dates, confirming existing government permits, and picking a convenient date for a follow-up public meeting to discuss details of reciprocity. Discussions of objectives continued via phone and fax, and additional materials were sent upon request. Joint goals were expressed by both parties to be considered and discussed further at the follow-up meeting. Discussions

took place on the appropriate amount of daily salaries each healer and other workers would receive for their work on the project. Specific suggestions on salaries were given by the members of TEA and other Belizean organisations and individuals. Medium and long term benefit information was also relayed both in writing and verbally.

#### 8.4.2.3 Discussions and ethnobotanical research

The field expedition began several weeks later, with the team consisting of Balick and Chinnock, a Belizean herbal healer from the western part of the country, Polo Romero, and a Mexican medical doctor, Silvano Camberos Sanchez, trained in both medicine and ecology. Mr. Romero learned his healing methods while working in rubber, mahogany, and chicle camps. He is now a well-known healer who specialises in treating snake bites. Dr. Sanchez had extensive training in ethnobotany and had worked for 10 years with the Huichol Indians in Western Mexico.

Shaman's ethnomedical/botanical approach to drug discovery was largely based on, and begins with, the work of the field research teams. The representatives from Shaman always included an ethnobotanist and a physician. Both of these team members play key roles in the interviewing and plant collecting process. Most of the healers are experts in various disciplines, including the flora of the region that comprises their botanical pharmacopoeia and the diseases that are present in the geographic area. Having both an ethnobotanist and a physician on the research team enhanced its ability to understand the healers' botanical medicine knowledge.<sup>51</sup>

Upon Shaman's arrival in Belize and before the actual research work began, immediate informal discussions about the collaboration occurred. Individuals spoke with the ethnobiomedical team about the objectives of the research and Shaman's work with indigenous people from other countries. Healers were previously identified by members of the two communities and had accepted the invitation to collaborate. Over a 10-day period, ethnomedical interviews and research activities were carried out, while botanical voucher and bulk collections were made. The team interviewed, in total, four *Maya* healers and one village health care worker/herbalist who provided descriptions of Type II diabetes patients and the local plants used to treat them. Translators were hired in some cases to translate both *Kekchi* and *Mopan Maya*. Collectors were also hired to accompany the team when plant collections were made.

Through direct interviews, conversations, and case presentations of Type II diabetes, the team worked with the healers and discussed signs and symptoms, age groups, and disease identification. They talked about the names given to both the disease and the medicines used. In several field walks of the surrounding forest, the team located and collected botanical voucher specimens for taxonomical identification and plant collections for analysis.

#### 8.4.2.4 Focused benefit-sharing and reciprocity

The community meeting took place on a set date and at least one representative from each village attended. The meeting was composed of mostly TEA members, although several other individuals came. The meeting began with a declaration by the TEA president, that reciprocity should be distributed at the community level and that related decisions should be directed through local cultural councils: Alcalde's Association and the Toledo *Maya* Cultural Council (TMCC) representing all the indigenous people of the local communities. During our time in the field, there was one suggested healer who requested a large personal monetary payment (US\$20,000) in exchange for meeting with him. The Shaman team politely declined to accept his offer as Shaman was able to comply financially or according to our previous discussions and guidelines of compensation. These guidelines were based on Shaman's codes of reciprocity and were approved earlier and by this declaration of the Southern group in Belize. The "community benefit" approach to reciprocity is used by other groups as well. This declaration coincides with a vote taken in 1993 by BATH. They decided that reciprocity and profits in ventures with pharmaceutical companies for access to their plants should be returned to the community and not to individuals.<sup>52</sup>

The group then presented a statement of thanks for Shaman's acknowledgment of *Maya* culture and the healers' knowledge. This *acknowledgment* was and is *extremely important* to all the culture groups that we have collaborated with. It is an issue of *fundamental dignity* and *respect* which is outside the realm of money and contracts. They also expressed concerns about the false promises they were given by researchers in the past, citing specific examples of graduate students and anthropologists who had lived in their communities for lengths of time and had failed to send "even a photo or a copy of their theses or books."



The Shaman team then thoroughly explained the company's purpose and objectives, and reciprocity was discussed in great detail. Everyone in attendance introduced themselves and each individual stated their thoughts and opinions and asked questions. Ideas of short-term reciprocity were offered by the community members and one idea was formally presented to build several village nurseries to promote reforestation and the growth of non-timber crops. This project was to be part of a larger project that was then being proposed to the Belizean government. Three nurseries were to be built to initiate re-forestation, research, and employment for the members of the community. The intention was to eventually grow medicinal plants, fruit trees, and other economically viable crops to help support these communities. It also included training and workshops on sustainable crops and development. This was an opportunity which could, eventually, be open to all villagers, for education and income generating purposes.

There was another extensive long-term project suggested which was deemed unfeasible and beyond the available budget. After some discussion, a vote was taken and a majority decision was reached to proceed with the nursery project. Informational packets about the company, papers detailing past projects and collaborations, and 60 copies of *Rainforest Remedies*<sup>53</sup>, a book on Belizean Medicinal Plants, were distributed to all the attendees and for reference at the community health centres in each village.

In accordance with our standard procedures, during the course of our research we adhered to things that all responsible field research teams do. We provided emergency medical care and transport. We held a supplemental one day health clinic at the community's request, treating over 60 people with minor ailments. The clinic was held with Dr. Camberos Sanchez and the village health worker/herbalist working together. The traditional healer and Dr. Camberos Sanchez made joint evaluations of most of the patients. Some of the patients were prescribed or treated with botanical medicines from the herbalist. The Western medicines were provided by the medical physician, when needed, and were regarded as a complement to their own therapeutics.

Compensation for daily wages was given for translators, healers, collectors, and other local participants. Payment was given for food and lodging, through the TEA's existing Homestay program. As part of medium term reciprocity, a commitment was given to return and to hire people in the same communities for potential recollections. This was

done nine months later, when a plant that a local healer suggested was collected in a greater quantity for testing. The Shaman team also sent photographs and written material from their trip back to the villages. Voucher specimens of each plant collected, with collection data, were identified and mounted on archival paper and sent to the Belize College of Agriculture and the Belize Forestry Department. Test data from all analyses carried out on Belizean plants was sent to several organisations in Belize, including Ix Chel and the TEA.

#### 8.4.2.5 Observations from Belize

Here are some observations highlighting both the advancements and limitations that the team experienced. The biggest challenge that may be encountered in any work with communities is finding a group that is representative of the whole community. Although the TEA is a progressive, productive group, not all of the members of the community were fully represented by them or by any organisation that we found in the country. There were some other more encompassing groups, such as the Toledo *Maya* Cultural Council, suggested by members of the community while we were there, and these groups will most likely be facilitators for extended medium and long term reciprocity arrangements. Along these same lines is deciding on a project for reciprocity that would affect the community as a whole. The project that was chosen does have a direct impact on many people and an indirect one on even more, yet it is not something that all community members chose to participate in. There are existing factions in these communities which can make these and other decisions even more difficult.

This research did stimulate much discussion in the community, and created links where they did not exist before. People met to discuss the threat of losing their important traditional knowledge and culture. The research, as well as the discussions, reinforced the interest in traditional knowledge. The Belizean herbal medicine book, *Rainforest Remedies*<sup>54</sup>, was widely valued and more copies were requested by and sent to schools and community organisations. Many children participated, watched the research and collection activity and expressed a new interest in the healers. This project also helped to generate discussions for future research and benefit sharing projects with Shaman and others. It also eased some of their doubts about working with researchers and helped prepare them for negotiations regarding the sharing of future equitable benefits.

During the course of our work, a US researcher, Jeffrey Augello, a student at the School for International Training, requested to accompany us in the field. He had previously studied Shaman's objectives and observed and documented our work. He had discussions with numerous people in the communities before, during, and after the team was there. He then compiled a report entitled *Bridging the Gap: An Analysis of the Pharmaceutical Industry and Their Emerging Role in the Conservation Movement* which was distributed later in the US and Belize. Mr. Augello's unbiased observations were very much an asset to our research. As part of his assessment, he came to four main conclusions about the community's opinion of our methods and research:

1. The majority of villagers showed support and participated in the project;
2. Those who knew Shaman's purpose, but chose not to participate, still supported the research;
3. Those who knew little about the company or project, showed little reaction or interest;
4. Those who knew even less or were unaware of the company or project, were interested in participating in the future and learning more about the project.

For the purposes of self-assessment, there were additional lessons which we collectively learned overall through our own observations and all channels of feedback:

1. It is important to continue to attempt to *identify* an organisation that *represents all or the majority of the communities' interests*, or to personally contact all representative parties and groups in the communities in which we work.
2. It is essential to keep *prior informed consent* as an integral part of the conception and planning of a project. This should be done well *in advance of the research* taking place to accommodate communication limitations, and so that the largest number of people have the opportunity to participate in the collaboration and decision making discussions.
3. *Feedback*, in the form of relevant publications and results, should be provided to the communities, especially schools, clinics, and health care centres to further their knowledge and interest in traditional healing and medicine.

4. *Reciprocity* should be initiated from the community and be focused on strengthening the majority of the community directly or indirectly. Reciprocity should be an issue discussed before, during, and after the entire research process, so as to allow time and thought for a realistic assessment of the risks and options, and the value of intellectual and natural resources.

#### 8.4.2.6 Follow-up and conclusion

For several years after the field research occurred, there was frequent multi-lateral communication between Shaman, the TEA, the individuals who assisted in the research, the Belizean government, and others. A Biodiversity Task Force Working Group was formed by the Belizean Department of Forestry in order to discuss the key issues unfolding related to research and natural resource collections. The TEA has proceeded with the nursery project using the funds supplied by Shaman. They have built three nurseries in separate villages and are planning to expand the projects to more villages and incorporate them with their Community Conservation Areas for further research, education, and income-generating projects. They have held several workshops on botany, nursery and agroforestry practices in these communities and are currently growing a variety of species in the nurseries. The test results of the plants collected in Belize that Shaman sent back are being shared with the local traditional healers and health workers. The TEA was awarded the world prize for socially responsible tourism in Berlin in 1996.

By utilising a combination of the various laws, declarations, and mandates that now exist, and striving to comply with the CBD, stressing factors such as PIC and focused benefit sharing at various stages, effective research combined with fair and equitable benefit-sharing and reciprocity can be a foundation for equitable partnerships.

#### 8.4.3 Tanzania: Ethnobotanical research collaboration

Tanzania has a population of 30 million and over 100 cultural groups. Traditional medicine is thriving in Tanzania as it is throughout the rest of Africa.<sup>55</sup> Many African nations, such as Nigeria, have officially incorporated traditional medicine practitioners into their national public health care programs.

In 1991 Shaman was contacted by Mr. David Scheinman of the Tanga AIDS Working Group (TAWG) and Rural Development Associates (RDA). The TAWG is an interdisciplinary group that links physicians, health workers, traditional healers, people living with AIDS (PLWAs) and social scientists. TAWG focuses on increasing research on medicinal plants that show promising results in the treatment of HIV/AIDS patients in Pangani, Tanzania.<sup>56</sup> The core focus of TAWG is to treat people living with AIDS (TAWG has treated 4,000 people as of 2004) with traditional medicines, provide compassionate care and conducts applied ethnomedical research. The efforts of TAWG was sought to bridge the gap between traditional and hospital medicine, and to provide much needed integrated health care to PLWAs.

The initial collaboration involved Shaman providing literature searches on the biology, chemistry and efficacy of many of the plants utilised to treat people living with AIDS. The literature data provided by Shaman indicated that there was data which supported the use of several of the treatments used by the traditional healers, including a treatment for oral thrush, a major opportunistic infection caused by AIDS. This type of data was important and well received by the TAWG.

In 1992 one of the authors, Steven King, visited the Tanga region, met with healers, patients, and nurses from the hospital and other biomedical staff. As part of this initial process, Shaman provided a US\$2,000 contribution to support the collection, preparation and delivery of traditional plant medicines to patients in the Tanga area.

Through discussions and correspondence, Shaman and TAWG agreed to proceed with an exploratory visit by a Shaman-trained physician who was also a skilled ethnobotanist. In 1993, Dr. Charles Limbach worked for one month in the Tanga region and trained local healers, physicians and technicians in Shaman's ethnobotanical field research methods. The skills learned in this exploratory collaboration were utilised by the TAWG group to further their own primary objectives and to collaborate with Shaman and with other international and national organisations.

#### 8.4.3.1 Relationship and capacity building

In 1994 scientists from the Institute of Traditional Medicine (ITM) at the Muhimbili University College of Health Sciences in Dar es Salaam contacted Shaman about a potential collaboration. One of the ITM's mandates is to research and provide recommendations on the safety and

efficacy of traditional plant medicines of importance to public health in Tanzania. The ITM had been collaborating with the United States National Cancer Institute (NCI) as well. In this relationship, medium term focused benefit sharing was initiated first, followed by a workshop exchange as a form of capacity building and technology transfer.

In September 1994, Shaman sponsored the Director of the ITM, Dr. Rogasian Mahunnah, to attend a meeting on intellectual property rights held in Costa Rica by the American Society of Pharmacognosy. Dr. Mahunnah then visited Shaman's facilities in California to review our facility and operations. Shaman then began financially supporting the research programs of the ITM, including US\$11,274 for an ITM diabetes research project. The ITM also requested literature searches and equipment for their laboratory facility.

#### 8.4.3.2 National level prior informed consent and agreements

Shaman submitted an Agreement of Principles to the ITM and Muhimbili. This contractual agreement had been utilised by Shaman in multiple countries. In each previous case, collaborating countries, NGOs and culture groups modified and negotiated a variety of aspects of the agreement. In Tanzania, the Board of the Muhimbili University reviewed the draft agreement and began a process of negotiation. While the agreement was being negotiated Shaman was invited to Tanzania to conduct a capacity-building workshop and to initiate collaborative field research. Shaman sent an ethnobotanist and physician team, comprising of Ms. Rowena Richter and Dr. Kariem Ali, to conduct the workshop and field research.

The ITM had expressed interest in evaluating Shaman's ethnomedical field interview methodology. The ITM scientist planned to combine our methods with their own expertise to enhance their capacity to engage in plant medicine research for public health issues in Tanzania. Once the Shaman team had obtained the required research permits they conducted a four-day workshop. The workshop was held in Tanga, Tanzania in collaboration with the previously described TAWG. With their previous success in integrating traditional medicine, healers, health care workers and the local hospital, TAWG provided expertise for the workshop. The workshop involved 14 participants, representing five Tanzanian community health and conservation organisations. The four days involved lectures, interview techniques, and all technical aspects of documenting the preparation of phyto-medicines.

#### 8.4.3.3 Prior informed consent and focused benefit-sharing in Mwanga and Moshi districts

Two weeks before the workshop and the field research, a scientist from the ITM visited the villages that the Shaman team hoped to work with. Those communities that wished to potentially collaborate gave their prior informed consent to meet with the field teams.

Before the research teams visited any villages in Mwanga, traditional healers and traditional birth attendants representing each village met with the research teams in a central location. A total of 44 men and women attended the meeting, including the chairman and secretary of the Mwanga Association of Healers, and district medical officer. Speaking in Swahili, Tanzania's national language, Shaman's research and development focus was described and explained to them. The meeting lasted for several hours and the representatives of the villages related their past negative experiences with researchers who had not provided compensation or reciprocity and who never returned to share their results. The Shaman team described its multiple levels of focused benefit-sharing, and informed them that each healer would be paid for their time, knowledge and expertise. After a dialogue between the parties, the representatives gave their prior informed consent for the teams to conduct the interviews. It was also requested that the same group meet again a second time after the interviews in the villages had been conducted. The research team conducted the research over the next five days. The second meeting began with the Shaman research team inviting comments on their work. The healers mentioned that it would have been better if more time had been allowed to discuss the plant medicines during the interviews.

The discussion then moved on to the immediate focused benefit-sharing arrangements. In every Shaman research collaboration, 10–15 per cent of the overall budget is designated for immediate focused benefit-sharing with the communities. The funds in this case, a sum of US\$6,750, was divided equally between the Mwanga and Moshi districts. The people of each district determined how they wished to allocate the funds for the benefit of their respective communities. The Shaman team learned that the timing of the benefit-sharing discussion was important. The team had followed the advice of the chairman of the Mwanga Association of Healers, Mr. Milkiel Msemo, and had not brought up the topic of focused community benefit-sharing at the first meeting. Several healers at the meeting informed the Shaman team that they had demonstrated proper

respect by discussing focused community benefits at the second meeting after the work was done. The Shaman team was told that if they had brought this topic up at the initial meeting, it would have easily been misinterpreted as insulting behaviour.

At the time of this research project, the Mwanga Association of Healers had been experiencing internal strife, and the meeting and the research team's visit helped re-invigorate the organisation. One of their revised goals was to work more closely with the physicians in the government hospitals for the benefit of their patients. The group agreed that the establishment of a central office would help their organisation gain strength, as well as credibility, and help them towards their goal of increased integrated collaboration. The association was not ready to build this facility at that time and they asked us to hold the funds that we had committed until they were ready to begin construction. The Shaman team agreed and the director of the ITM later facilitated the transaction. The association built what they had visualised, which comprised offices, wards and a laboratory. The Government of Tanzania gave them 15 acres of land on which these structures were built. A medicinal plant garden was planned for another plot of land.

In the Moshi district, prior informed consent was discussed and granted in each of the five villages. After the discussions, one individual healer chose to not participate. When the interviews were completed, each village determined how they wished to utilise the resources made available to them under the focused benefit-sharing arrangements. They requested that the Shaman team purchase and deliver building materials to them rather than giving them the actual funds. This request was honoured by the Shaman team. The Village of *Uchira* decided to purchase the materials necessary to install electricity and lights in the local health clinic so that women delivering babies at night would be able to do so with adequate light. The *Mayuyuni* village had a partially constructed health clinic made from local bricks and they elected to purchase 45 bags of cement to complete its construction. Women in the village of *Mayuyuni* had been travelling to the nearest clinic to deliver babies, often having to pay as much as a year's wages for transportation. The community was therefore eager to complete their clinic. Two other villages elected to buy mattresses, sheets and blanket for their clinics. The women participated actively in the decisions made on the type of focused benefits that each village chose to receive. It appeared that they influenced the

choices made in the five communities and steered the discussions towards issues that affected women, children and childbirth in the community.

#### 8.4.3.4 Follow-up, data return and conclusions

After the field research described above, the Shaman/ITM team returned to Dar es Salaam and presented a summary of its work to the physicians and officials at Muhimbili. Copies of the data forms and duplicates of the plant herbarium specimens were deposited at the ITM, Tanzania Forestry Research Institute and the National Herbarium. There was also continued focused benefit-sharing in the medium term. After this the Shaman team returned to the United States, and a taxonomist at the Missouri Botanical Garden identified the plants. These determinations, along with newly published scientific names and supporting literature, were sent to the botanists at the ITM for them to review. Shaman also provided an additional US\$11,274 for a second phase of research support for ITM's research programs. Shaman also continued to return data from the biological assays on Tanzanian plants, as part of its agreement with Tanzania.<sup>57</sup> This data return has proved beneficial to the treatment of patients in Tanzania.

One specific plant, called *Zingiri*, demonstrated activity in an in-vitro cell-based assay of herpes simplex, a viral infection that is often pronounced in people with weak immune systems. Prior to learning of the Shaman anti-viral data, Mr. Kassomo, a regional traditional healer had been utilising *Zingiri* to treat mouth sores. After learning of this lab data, Kassomo began treating patients suffering from herpes zoster and other herpes viral infections. The results were promising. As a result, this well-known local plant medicine has become widely utilised in the Tanga Aids Working Group treatment programs. Mr. Kassomo began to deliver the plant medicine to the Bombo Hospital and it is also being utilised to treat fungal infections.<sup>58</sup> Mr. Kassomo has become well-known for his herpes treatments and patients come to him from Kenya and Tanzania to receive treatment. Shaman did not pursue any research or development on this plant or any compounds from it. This is an example of an important local public health benefit.

In September 1996 an ethnobotanist, a physician from the ITM and four *Masaai* were sponsored by Shaman to attend a meeting of the International Society of Ethnobiology in Nairobi and a public health workshop was conducted by Dr. Thomas Carlson, the head of Shaman ethnomedical field research.

The relationship between Shaman and Tanzania was initiated as a long term partnership. Between the years of 1992–1997 a total of US\$226,577 was invested in a combination of research support, focused benefits, purchases of research materials and reciprocity. The numerous partners in Tanzania continue to collaborate with a diverse set of national and international partners to research, develop, utilise and conserve the rich biocultural diversity of this country.

## 8.5 ORGANISATIONS UTILISING TRADITIONAL ETHNOBOTANICAL KNOWLEDGE IN RESEARCH AND DEVELOPMENT PROGRAMS

### 8.5.1 International Cooperative Biodiversity Group (ICBG) projects in Nigeria, Cameroon, Suriname, Peru, Vietnam, Laos and Mexico

The objectives of the International Cooperative Biodiversity Groups (ICBG) are to focus on natural products drug discovery, economic development and biodiversity conservation. The accomplishments of this program over the past 10 years are impressive and the specific programs have been described in detail elsewhere.<sup>59</sup> In addition to the bioactive compounds isolated, scientists trained and research conducted, the program has been the most transparent government-sponsored international experiment conducted to date, testing the various processes and methods of implementing the guiding principles of the Convention On Biological Diversity. The ICBG program requires and has a strong focus on prior informed consent. The ICBG participants must demonstrate agreements that provide for the protection of traditional knowledge and IPR contracts that are linked to benefit sharing.

The ICBG program provided 11 major grants between 1993 to 2002. Ethnobotanical and ethnomedical research has been utilised in varying degrees in nine of these 11 major grants. All of these nine major grant programs also utilised a variety of other research and collection activities. The research programs that put the largest emphasis on ethnobotanical and ethnomedical knowledge in the drug discovery process were the programs implemented in Cameroon and Nigeria<sup>60</sup>, Peru<sup>61</sup>, Vietnam and Laos<sup>62</sup>, Surinam and Madagascar<sup>63</sup>, and Mexico; a program that was ultimately cancelled.<sup>64</sup>

The ICBG programs are highly dynamic and complex in their goals, methods and accomplishments. No single, simple objective can be identified, measured or highlighted. Several of these programs placed a high priority on anti-malarial and anti-parasitic diseases such as the *Drug Development and Conservation of Biodiversity in West Africa*<sup>65</sup> program and *Peruvian Medicinal Plant Sources of New Pharmaceuticals*.<sup>66</sup> In the West African program, ethnomedical field research methodology yielded a 69 per cent activity rate out of 500 anti-malarial extracts tested. Activity rates of 40–48 per cent were reported for other parasitic diseases such as *leishmania* (40 per cent) and *trypanosomiasis* (48 per cent). In addition, a total of 47 isolated and characterised molecular leads for drug development activities were isolated in this program as of 1999.<sup>67</sup>

The ICBG program in Peru has also demonstrated the importance of collaborating with traditional healers who treat malaria. This research team demonstrated that anti-malarial-targeted ethnomedicinal plants utilised by the *Aguaruna* communities yielded a statistically significant number of anti-malarial extract leads when compared to plants collected on a random.<sup>68</sup>

The demonstrated utility of ethnobotanical research to identify anti-parasitic extracts and compounds around the world should lead to increased collaboration with traditional healers in many cultures. It is likely that a number of infectious diseases can be effectively managed with local botanical and phytomedicines. These treatments are being evaluated and, when shown to be safe and effective, should be made available as standardised extracts in regional public health programs. There are efforts underway to do this in Africa, Southeast Asia and Latin America.

### 8.5.2 South Africa, the *San* Bushmen, Phytopharm plc and P57

The South African Council for Scientific Research and Industrial Research (CSIR) received a patent on an extract of the *Hoodia* cactus in 1996. This *Hoodia* cactus has been part of the traditional knowledge of the *San* Bushman of Southern Africa for centuries. The *San* use this species to suppress appetite and thirst when they search for food in the desert or during times of famine. In 1997 CSIR licensed this extract, now called P57, to a small British pharmaceutical company Phytopharm plc. This development stage

product P57, derived from the traditional knowledge of the *San* Bushman, is being investigated for its ability to treat obesity and has a very large sales potential. In the United States, it is estimated that there are 35–65 million obese people. In 1998, Phytopharm plc subsequently licensed P57 to Pfizer Pharmaceuticals, one of the largest pharmaceutical companies in the world. In 2001, the *San* Bushman threatened to take legal action against CSIR because no access or benefit-sharing agreement had been made with the *San* to allow CSIR to patent and license this extract based on the indigenous knowledge of the *San*.<sup>69</sup> In March 2002, the *San* and CSIR created a memorandum of understanding which recognised the *San* as the custodians of traditional knowledge associated with the uses of a large variety of plant materials, including the *Hoodia* cactus.<sup>70</sup> The *San* in turn acknowledged that it was necessary for the CSIR to protect the work that had been done in isolating the active ingredient in the plant by patenting it in the CSIR's name. Finally, in March of 2003, the CSIR issued a press release stating that the *San* and CSIR had created a benefit-sharing agreement for the potential anti-obesity drug P57. This was the reverse of how the process *should* have taken place: the CSIR should have initiated the PIC, access and benefit sharing process *before* beginning work on the *San* Bushman pharmacopeia.

In July 2003, Phytopharm plc announced that Pfizer had decided to halt its clinical development of P57 for the treatment of obesity and to return all rights to Phytopharm. Phytopharm has indicated that a great deal of pre-clinical and clinical data had been generated with Pfizer and that they would now seek another partner to complete the product development.<sup>71</sup>

The problems with the timing of the access and benefit-sharing process and agreement highlight the importance of following proper procedures when working with the holders of traditional knowledge. The ethnobotanical knowledge of the *San* Bushman and the discovery of P57 is, however, another example of the effectiveness of collaborating with the holders of traditional knowledge.

### 8.5.3 Ethnobotanical research in Samoa: The antiviral compound *Prostratin*

*Prostratin* was identified during field studies in Western Samoa, by Dr. Paul Cox, an ethnobotanist from Brigham Young University and

currently the Director of the US National Tropical Botanical Garden. His primary sources for information about this plant were two Samoan healers, Mariana Lilo and Epenesa Mauigoa, both of whom died in 1993. The healers were using the bark from the stem of the mamala tree to treat a disease they called *fiva samasama*—"yellowing fever," or hepatitis. The bark was used to treat viral infections; the leaves were used to treat back pain; and the root to alleviate diarrhoea. These elderly women also taught Dr. Cox details of 121 different herbal remedies from 90 species of flowering plants.<sup>72</sup>

Selected samples of these native remedies were sent to scientists at the US National Cancer Institute (NCI), where plant-derived substances are routinely screened for activity against different diseases. In 1992, Dr. Michael Boyd and his colleagues at NCI isolated the active chemical from the samples, *Prostratin*, and discovered its powerful effects against HIV, which suggested that *Prostratin* could be used to activate viral reservoirs.<sup>73</sup> HIV reservoirs are a barrier to curing the HIV infection. They may persist for up to 60 years in some patients and are where latently infected cells continue to be present after acute HIV infection. These latently infected cells are invisible to the immune system and are not susceptible to available anti-viral drugs. Many international leaders pursuing HIV and AIDS research and therapy now see latent virus activation as a possible strategic requirement for future advances in the therapeutics of HIV infection and AIDS.<sup>74</sup>

The Medical Director of the AIDS Research Alliance (ARA), Stephen J. Brown, M. D., took notice of NCI's work with *Prostratin* in 1999 and began to direct research on the compound. Most recently, a study in the November 15, 2001 issue of the journal *Blood* confirmed the earlier work of researchers at several institutions—including NCI, ARA and UCLA—where it was learned that *Prostratin* exhibited dual action, inhibiting HIV replication while activating dormant, or "latent," HIV.<sup>75</sup>

In one study, researchers at the NCI and Jefferson Medical College in Philadelphia demonstrated that *Prostratin* could activate dormant HIV in cells taken from HIV-positive patients. The authors suggest that future studies should examine combination therapies involving *Prostratin* and other anti-HIV drugs to activate pockets of dormant HIV in the hope of eradicating the virus.

Data from Dr. Jerome Zack at UCLA indicates that *Prostratin* can induce replication of the latent pool of virus without initiating T-cell replication.<sup>76</sup> Highly active antiretroviral therapy (HAART) often reduces viral load to undetectable levels and can significantly delay progression to symptomatic AIDS. But HIV remains hidden or dormant in various "reservoirs" of the body, and the viral "rebound" that almost always occurs when antiretroviral therapy is discontinued is largely due to continued replication of HIV within these reservoirs despite HAART.

Dr. Zack has described his next research steps<sup>77</sup>:

Further in-vitro studies will be performed to fully define the effects of *Prostratin* on cells in the immune system. Collaborative studies are planned to assess the effects of *Prostratin* in SIV models, with the eventual intent of bringing this type of approach to clinical trial in infected patients.

Ultimately, the likelihood is that *Prostratin* will be tested as an adjunct to HAART—possibly in combination with additional therapies to boost immune response or target cells that are actively producing the virus. Recently published data has amplified the importance of trying to solve the problem of the latency of the HIV virus.<sup>78</sup> Clearly this compound, derived from a partnership with indigenous healers, has already provided significant medical and scientific advances in field of basic AIDS therapy research.

In August 2001, the AIDS Research Alliance signed an agreement with the Prime Minister of Samoa that was facilitated by Dr. Cox, guaranteeing that a total of 20 per cent of all ARA profits from the development of the antiviral drug *Prostratin* would be returned to Samoa according to the following formula: 12.5 per cent to the government, 6.7 per cent to the village, and 0.4 per cent to each of the families of the two healers who participated in the research. Prior to this national-level agreement, the village council of Falealupo, Samoa negotiated a covenant called "The Falealupo Covenant." This agreement focused on the equitable transfer of benefits as part of the process of collaborative field research. As of 2001, more than US\$480,000 in benefits—including schools, medical clinics, water supplies, an aerial rainforest canopy walkway and an endowment for the rainforests—have been transmitted as a result of this covenant.<sup>79</sup>

### 8.5.4 MerLion Pharmaceuticals Pte. Ltd., Singapore

MerLion Pharmaceuticals was founded in 2002 as one of Singapore's first drug research and development companies. MerLion was created through the privatisation of the former Centre for Natural Products Research (CNPR). The CNPR was established in 1993 to screen natural products samples for new pharmaceutical leads. MerLion acquired all the assets of CNPR, including the natural product library of GlaxoSmithKline (GSK), which is one of the world's largest and most diverse natural product samples. The natural product library of GSK includes natural products derived and isolated from soil samples, marine organisms and terrestrial plants. This GSK natural product library, like most large natural product collections, is likely to contain a relatively small number of plants collected based on their use by indigenous peoples of Southeast Asia and other regions of the world. The approach of MerLion is based on high throughput screening, natural product chemistry and medicinal chemistry. Their focus is on the discovery of novel bioactive compounds. MerLion has already established screening partnerships with large pharmaceutical companies such as Fujisawa Pharmaceuticals Co. Ltd., Merck & Co. Inc. and Abbot Laboratories. The company does not conduct ethnobotanical field research. MerLion does, however, explicitly state its company policy: "A significant portion of any royalty payment is expected to be shared with the indigenous local communities in which the samples were collected to support science training and education."<sup>80</sup>

### 8.5.5 Napo Pharmaceuticals Inc.

One example of a late stage product that is based on collaboration with indigenous people and traditional knowledge is the anti-diarrhoea compound SP-303. This compound was originally developed by Shaman Pharmaceuticals Inc. It was purchased by Napo Pharmaceuticals Inc. in December 2001.

SP-303 was isolated from a plant that is utilised by indigenous people in the Northwestern Amazon basin of South America to treat diarrhoea and other gastro-intestinal problems.<sup>81</sup> SP-303 works via a novel mechanism of action that inhibits the secretion of chloride ions without causing constipation or other side effects associated with opiate-derived anti-motility drugs.<sup>82</sup> SP-303 is well suited to treating cholera and 900,000

doses have been provided for free, as a dietary supplement, to 26 countries in Latin America, Africa and Southeast Asia. There are two pathways through which this compound is being developed for international utilisation. One pathway is the traditional pharmaceutical development of the compound for Irritable Bowel Syndrome (IBS-D diarrhoea predominant), and HIV-associated diarrhoea in both developed and lesser developed nations. The other path is being pursued by a non-profit pharmaceutical company to develop and distribute this compound as a very low cost treatment for paediatric diarrhoea in the biodiversity-rich countries. Paediatric diarrhoea kills more than two million people each year and access to safe, low-cost anti-diarrhoea therapies are urgently needed.

Napo Pharmaceuticals Inc. has adopted the long-term benefit-sharing obligations of Shaman Pharmaceuticals Inc. Napo Pharmaceuticals will utilise the Healing Forest Conservancy (HFC) as the mechanism to implement the long-term benefit-sharing process described in the earlier sections on Shaman Pharmaceutical's benefit-sharing processes.

## 8.6 RESPECT, DIGNITY AND INTELLECTUAL CREDIT

Some of the most important concerns of indigenous peoples that have collaborated with Shaman Pharmaceuticals Inc. were the issues of respect, dignity, intellectual credit and acknowledgement. In fact the Western IPR system has not yet been able to appreciate or reconcile this fundamental issue. Indigenous peoples wish to be recognised and accorded proper respect for their intellectual contributions to the world's pharmacopia. The US patent system does not allow for a healer, who may have guided scientists to a plant that has yielded important pharmaceuticals, to be recognised as a true "inventor." The list of pharmaceuticals that have been developed based on traditional knowledge is well-known.<sup>83</sup> The authorship of a scientific paper and contracts that provide for benefit-sharing does not address this problem. Textbooks in high schools and medical schools should confer the appropriate intellectual credit to the relevant indigenous communities as a matter of dignity, ethics and respect for the past, present and future innovations that indigenous peoples have provided to the global health care system.



## 8.7 CONCLUSION

The complex legal and policy issue associated with the use of traditional knowledge and biological resources will require medium and long term international analysis, negotiation and some changes in the international regimes of access and benefit-sharing. This process of change will require time, patience and active listening to traditional and indigenous communities. During this process of change, some traditional communities will continue to seek equitable opportunities to develop and conserve their traditional knowledge and biological resources. The authors hope that the experiences described in this chapter may provide some useful examples so that local partnerships can be created in the midst of the international negotiations on access, benefit-sharing and legal regimes. There is no doubt that cultural diversity and biological diversity is disappearing at a dramatic rate. Any and all approaches that can support the long term vitality of communities and their ecosystems should be pursued in a respectful and collaborative manner.

### ENDNOTES

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