TRADITIONAL MEDICINE AS A TONIC FOR DEVELOPMENT

A report as compiled by The World Intellectual Property Organization (WIPO), A United Nations agency dedicated to the use of intellectual property (patents, copyright, trademarks, designs, etc.) as a means of stimulating innovation and creativity.


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BACKGROUND

Created by scientist Dr. Maurice Iwu in 1992, Bioresources Development and Conservation Programme (BDCP) is a non-profit and non-governmental organization (NGO) in the Federal Republic of Nigeria (Nigeria). Since its establishment, BDCP has collaborated with local, national and international partners in order to support the country’s human and biological resources while developing its traditional knowledge – including traditional medicines.

The NGO has pioneered policies and partnerships that support investigations into the often unrealized economic and health restoration potential of traditional medicines. At the same time, BDCP has supported Nigerian scientists while raising the socio-economic profiles of the country’s traditional health practitioners (THPs).

PICTURE: Approximately 4000 medicines have been found to exist within the THP community including remedies derived from the Benolive tree (pictured), a plant species of the genus Moringa (Photo: Ton Rulkens)

BDCP, moreover, has forged imaginative joint ventures between THPs and scientists in Nigeria and international scientists such as Lisa Conte – an entrepreneur who founded Shaman Pharmaceuticals Inc. (Shaman PI) in San Francisco, the state of California, the United States of America (USA). Through its collaboration with Shaman PI, a drug manufacturer established in 1991, the NGO was able to facilitate a benefits-sharing agreement between THPs, Nigerian scientists and the pharmaceutical company.

In part due to these partnerships, BDCP developed its capacity and placed the economic future of traditional healers and scientists in Nigeria on a sound path to development. In addition, the NGO is preserving the environment in the country via a number of conservation programs.
Endowed with a rich mix of human and natural resources (there are over 250 cultural groups and vast areas of tropical forest in the country), Nigeria has had a long history of traditional knowledge based on plant remedies. Passed down through generations of THPs, it is estimated that such knowledge has served 80% of the population’s healthcare needs, highlighting the important role that it has played in the nation’s healthcare history.

THPs (and their knowledge), moreover, have not only been vital to health outcomes (a result of a medical condition that affects lifespan or quality of life) in Nigeria; they have also been the repositories of an enormous amount of medicinal traditional know-how. Indeed, approximately 4,000 traditional medicines have been found to exist within this community. Such knowledge spans thousands of plant species including Guinea grains (Aframomum melegueta; a spice used to treat microbial infections), Ainslie (Langenaria breviflora; a fruit used as a pain remedy by women in labor) and Garcinia Kola (a fruit-producing forest tree that has provided medicines to treat throat infections).

For centuries, however, traditional healers had confined their knowledge of plant based remedies to a tight-knit community who guarded it as well-kept secrets. Since the early 20th century, ethnobiologists – anthropologists who study THPs and their plant based remedies – have taken an increasing interest in collecting data (including the names of plants and the ailments that they treat) from this secluded community.

From the early 1990s, moreover, THPs have come under the growing attention of bioprospectors including BDCP, Shaman PI and others engaged in bioprospecting – the search for biological samples and compounds in plant species with a view to commercializing the remedies thereby derived.

These scientists, furthermore, have engaged THPs in an effort to discover the active ingredients at the core of traditional treatments. Indeed, hundreds of pharmaceutical products currently in use around the world have been derived from plants. Of those plants, 75% were from tropical forests in Africa and South America that were discovered following studies of THPs and their traditional remedies.

With this in mind, BDCP has worked with a number of partners including the Nigerian government and pharmaceutical companies in order to raise the profile of THPs. In addition, the NGO has created a database of traditional healers’ remedies with a view to manufacturing and commercializing any new treatments that may follow while sharing any resulting benefits equitably with stakeholders.

**RESEARCH AND DEVELOPMENT**

Before the arduous work of collecting data on Nigeria’s medicinal traditional knowledge began, BDCP, Shaman PI and various organs of the Nigerian government (the Partners) established clear protocols for working with THPs in the country.

Because traditional healers had historically worked in relative isolation from established structures of government and business, from the beginning the Partners ensured that the relationship with traditional healers was based on transparency as a principle for
gaining trust. They also ensured that THPs’ capacity for self-sufficiency was strengthened and a mechanism for equitably sharing any benefits accrued from the collaboration was established.

One of the earliest interventions in the process of engagement with healers was to improve their capacity to represent their own interests through the formation of cooperatives. To this end, vital support was provided by the Partners and the African branch of International Cooperative Biodiversity Groups (Africa ICBG), an organization that supports drug discovery, biodiversity conservation and sustainable economic growth.

Having formed such cooperatives (including the Nigerian Union of Herbal Medical Practitioners), THPs have been able to centralize their membership, install codes of conduct and standards (which set minimum entry qualifications for practitioners, for instance) and raise their members’ professional profile. By uniting into cooperatives, moreover, THPs haven been able to combine their interests and lobby stakeholders (including the Nigerian government) from a strengthened position.

With the groundwork for bioprospecting investigations in Nigeria laid down, the Partners began the scientific stage of the research and development (R&D) process which established a taxonomy or classification of the various plant species employed by THPs in the country. Part of this process involved researchers from Shaman PI and BDCP engaging in a series of interviews with traditional healers who were asked, for instance, to rank the plants used in their remedies in order of importance or value.

Although this was not an infallible approach (because it did not necessarily predict potential commercialization or efficacy outcomes), it allowed the scientists to focus their R&D on the plants that had already showed remedial promise in the past. These interviews also provided feedback support to the healers in their medicinal practice by enabling them to benefit from new information about plants based on scientific literature provided by the Partners.

Having collected and screened various plant specimens and recorded them into a vast database or pharmacopeia, the R&D process was transferred from the field to laboratory screening where the plants’ apparent health properties were investigated. The most promising leads were thereafter subjected to fractionation – a process where a solid, for example, is separated into its constituent parts – in Shaman PI’s R&D facility in the USA. Subsequently, modern chemical analysis techniques were used to examine the structures of these plants in order to reveal their active compounds – the part of a drug that causes biological effects in a subject.

BDCP’s collaboration with Shaman PI was a fruitful merging of international pharmaceutical interest and goals with local scientific aspirations and THPs’ know-how. Because of the pharmaceutical company’s pioneering, ethnographic driven approach to drugs research – where investigations are initially directed by the knowledge of traditional healers rather than via in situ laboratory tests – Shaman PI was able to work closely with traditional communities and create a reciprocal business model with its partners around the world, including BDCP.

For instance, via the pharmaceutical company’s Healing Forest Conservancy (or the Conservancy) – a non-profit organ established in 1990 to carry out R&D and implement benefits-sharing policies for Shaman PI – traditional healers in the country could expect to receive royalties from any commercialized products based on research inspired by their traditional knowledge.

In conjunction with such future incomes, short-term payments or “access fees” to traditional healers, local guides, plant specimen collectors and other helpers were already being paid (at the beginning of the research) by Shaman PI. Such payments were
facilitated by an independent organization established by BDCP called the Fund for Integrated Rural Development and Traditional Medicine (the Fund).

The Fund, which was launched based on a US$40,000 donation from the Conservancy, was managed by an independent board of directors whose members included government officials, respected members of the community and representatives from THPs’ cooperatives. The Conservancy, moreover, was able to engage in four ethno-botanical field expeditions with BDCP and traditional healers. These expeditions began only after prior informed consent with confidential, private and fair compensation agreements with THPs was established.

Such agreements, in addition, were in part based on the Convention on Biodiversity (CBD), a global treaty sponsored by the United Nations (UN) that has addressed aspects of biodiversity and the equitable sharing of benefits.

Furthermore, part of Shaman PI’s R&D budget was dedicated to improving local facilities in Nigeria. Between 1990 and 1996, the pharmaceutical company provided US$200,000 – via the Fund – to BDCP and its partners, including THPs. Based on this investment, several traditional healers in Nigeria have been able to develop and package their own remedies which have been sold locally.

The Conservancy also helped to support Nigerian scientists based at the NGO by providing them with research grants that aided their botanical investigations at several institutions including Shaman PI and the Smithsonian Institute, one of the world’s largest museums and research institutes based in Washington, District of Columbia (DC), in the USA.

Apart from its collaboration with Shaman PI, BDCP has partnered with several institutions from around the world which have assisted the NGO with evaluation and investigation of biological samples. Some of BDCP’s partners in this regard include universities in the Republic of Cameroon (Cameroon), the Republic of South Africa, the United Kingdom and the USA.

The NGO has also developed R&D facilities of its own that can perform several scientific processes including chemical analysis and standardization of plants and organic certification and authentication of cultivated plant species. Utilizing logistical support provided by Africa ICBG and other help from THPs’ cooperatives, BDCP established trials to cultivate various plant species such as the potentially poisonous Calabar bean (Physostigma venenosum – a plant whose potency was identified following interviews with healers).

Based on the resulting taxonomy, plant nurseries and gardens including a reference herbarium (a housed collection of preserved plant species) have been established in Nigeria under BDCP management.

Finally, the NGO has expanded its capacity to carry out a number of R&D functions including: plant collection; fractionation; ethnobiological surveying and economic value assessment; environmental conservation; ethnobotanical training for new scientists; and local capacity building for THPs via provision of funds and farming equipment.

**PATENTS**

From the beginning, both BDCP and Shaman PI were keenly aware of the importance of using the intellectual property (IP) system as a means of securing IP assets which can be leveraged to attract investors and open new opportunities for development. To this end, in 1989 Dr. Iwu and Shaman PI filed a patent for dioscoretine and its use as a hypoglycemic agent (for the treatment of diabetes) via the United States Patent and Trademark Office (USPTO). A year later, the invention received international protection via the Patent Corporation Treaty (PCT) System managed by the World Intellectual Property Organization (WIPO).
Of the hundreds of pharmaceutical products currently in use around the world, 74% were derived from plants such as the Sap tree (pictured), which is native to Africa and South America (Photo: Ahmad Fuad Morad)

Moreover, Dr. Iwu and other partners have filed patents including one for antifungal and antiparasitic compounds (1999) and alkaloids of picralima nitida used for treatment of protozoal diseases (1991) via the USPTO and the PCT System.

IP MANAGEMENT AND LICENSING

Despite its attractive IP assets, Shaman PI ended its collaboration with BDCP and was forced into closure due, in part, to an unfavorable global economic climate in the late 2000s. Moreover, (in 2011) the pharmaceutical company was unable to develop its most promising remedies beyond the last hurdle (called Phase III trials) imposed on drugs manufacturers by the Food and Drug Administration (FDA), an agency of the US government responsible for public health regulations and standards.

However, Shaman PI’s founder, Dr. Conte, was able to raise US$650,000 which she used to buy the company’s IP assets – including those that were co-owned with BDCP. With these assets, the entrepreneurial scientist was able to enter new licensing agreements with other firms and gain new investors and thereby raise over US$85 million that she invested in order to establish Napo Pharmaceuticals Inc. (Napo), a drug manufacturer based in San Francisco, the state of California, USA.

In 2012, Ms. Conte owned six percent of Napo, a company which has distribution licensing agreements with Direct Relief International (a medical NGO based in California, USA) and Glenmark Pharmaceuticals (who have distributed Napo’s drug Crofelemer in the Republic of India).

Moreover, the company had secured licensing agreements with Global, LL (an investment company in California, USA with an interest in distributing the Crofelemer drug for the American, Japanese and European Union markets – pending FDA approval) and AsiaPharm Group Ltd, in the Peoples Republic of China. As of 2012, the Crofelemer drug (which treats chronic diarrhea in patients living with HIV/AIDS) was expected to have a worldwide market of over US$300 millions.

BDCP, meanwhile, has relied on the technical expertise and knowledge capital in part developed via its collaboration with Shaman PI to launch two new spin-off enterprises. Axxon Biopharm Inc. (Axxon) is a pharmaceutical company, and BDCP subsidiary, based in the state of Maryland, in the USA. The company creates a range of natural pharmaceutical products including a brand called Ethnobotanica.

Another BDCP spin-off, Intercedd Health Products (IHP), is a company based in Nigeria that produces and markets drugs developed by the International Center for Ethnomedicine and Drug Development (InterCEDD), an R&D center based in Nsukka, Nigeria, that was established by BDCP.

BRANDING, COMMERCIALIZATION AND FINANCING

BDCP and its subsidiaries are aware of the need to raise their brand profile in order to attract investors and customers and win financing for their projects. Apart from Ethnobotanica, Axxon has produced an exciting line of remedies – based on the NGO’s drug development program – such as Streptol (a natural throat and cold tonic), Buchu Blend (which promotes urinary tract health) and DM Blend (which helps to maintain healthy blood sugar level).

Such remedies, moreover, have been commercialized in Nigeria via locally based pharmaceutical companies and brands including IHP. With a robust range of products including Erovit (for age related illnesses), Physogen (for treating diabetes), and Hepavital (for liver ailments), IHP markets remedies produced by InterCEDD.
In order to promote and commercialize these products while enhancing its reputation for quality, BDCP has initiated publications (including authoritative industry books and articles for journals), attended and held industry conferences and launched brand awareness events and exhibitions. Indeed, the NGO has organized several conferences in Africa that highlight the benefits of traditional medicine and address issues and themes such as ethnomedicine, bioprospecting and biodiversity conservation.

**PICTURE:** Axxon’s remedies, including those derived from Garcinia (pictured), have been commercialized in Nigeria via IHP, a subsidiary of BDCP (Photo: BDCP)

Working with other bioprospecting organizations in West Africa, in 2000 BDCP launched a regional strategy – called “Promoting the Role of Traditional Medicine in Health Systems” – to raise the public profile of herbal medicines and THPs. The following year, the organization was among others who lobbied the heads of government who declared a Decade of African Traditional Medicine (2001 - 2010). A key point in the plan of action adopted at the declaration was for member states and organizations – such as BDCP – to carry out sensitization and popularization campaigns for traditional medicines.

Commensurate with this declaration was the inauguration of the 31st of August as African Traditional Medicine Day (ATMD). ATMD was launched by African stakeholders in order to boost the role of traditional medicine in healthcare systems and raise awareness of its important role for health outcomes on the continent.

During the Decade of Africa, 46 countries on the continent – in collaboration with partner organizations and companies – formulated national traditional medicine policies and frameworks regarding efficacy, safety, and quality of traditional remedies and the practices of THPs. For its part, BDCP assisted in the development of the Nigerian Traditional Medicine Policy, a policy framework of the country’s Ministry of Health.

Furthermore, working with many organizations including the Nigerian Natural Medicine Development Agency, a parastatal entity with a mandate to develop natural medicines policies, the NGO has celebrated an annual two day exhibition called “HerbFest”. HerbFest promotes biotechnological business ventures and investment opportunities via seminars and displays of products derived from herbal and other plants.

In addition, BDCP has relied on a number of public and private organizations in order to finance its research. The organization has benefitted from funds provided via Africa ICBG that were secured from the United States Agency for International Development. Other BDCP partners have included the National Science Foundation, the United States Department of Agriculture and the Walter Reed Army Institute of Research (WRAIR).
ENVIRONMENT

West-Central Africa, including Nigeria, has one of the largest equatorial forests on the continent. Rich in animal and plant species, these forests have been a constant source of sustenance and inspiration for a variety of traditional knowledge for the people in the region. Since the 1850s, however, estimates have showed that tropical forests in Africa had declined by at least 20%. While the global rate of arboreal decline has been about 0.6%, in Nigeria the rate was 5%.

PICTURE: Rich in animal and plant species, including the Madagascan periwinkle (Catharanthus roseus; pictured), forests in West Africa have provided inspiration for a variety of plant based traditional medicines (Photo: E. Lewis)

Coupled to relatively high poverty rates (US$2,300 per capita gross domestic product) in a country where 75% of the population are rural dwellers who rely heavily on forest products (2009 estimates by the USA’s Department of State), the case for intervention in Nigeria became apparent.

In support of the country’s environment, BDCP’s biodiversity and conservation program (the B&C program) has established mechanisms to collate and publish data on plant species in the country with a view to inform and influence policy decisions. The data has allowed policy makers (both in local and central government) to make decisions over which species to cultivate or protect as well as to devise regulatory strategies that protect the environment and assist local economic development.

The B&C program, moreover, has worked with the Smithsonian Institute’s Center for Tropical Forest Science and launched long-term conservation projects such as community tree planting projects, biodiversity monitoring plots and establishment of buffer zones and extraction reserves. In addition, the initiative has trained taxonomists and conservationists in Nigeria.

Working with residents of the Umukabia village (some of whom are employed as a result), in the state of Imo, BDCP has been able to help them diversify the local teak forest into a multi-species area (with 41 different plant species) which contains monitoring and conservation plots. Other plots have been established including those in the Akampa Deep Forest Farm and Oban-Boshi-Okwangwo forest in Nigeria and in the Korup National Park and the Pygeum Project (where the endangered medicinal plant prunus africana – an evergreen tree – is farmed) in Cameroon.

Indeed, the organization has assisted rural communities in sustainably cultivating trees for food, fuel, wood and as barriers to erosion and soil degradation including a restoration project (in 2011) for native mangroves and Nyapa palms in the cross river estuary of Nigeria. According to Dr. Iwu, the restoration project across the estuary “was the first time [in Nigeria] that a degraded forestry has been completely restored to its prime condition through the application of modern ecology and bioscience [methods].”

PUBLIC HEALTH

As the global population approached 7 billion in 2012, it was estimated that at least 4 billion of that number relied on plant based traditional medicines for their primary healthcare needs (according to the World Health Organization (WHO) – a specialized agency of the UN that has a mandate for health). The WHO, moreover, estimated that over 33% of people in developing countries had no regular access to basic essential medicines and, in the poorest countries, over 50% of the population lacked access to major healthcare providers (in 2010).
Because most of these people could not afford drugs produced in developed countries, by 2000 the WHO Regional Committee for Africa had recognized the potentially significant role that traditional medicines have played and could play in primary healthcare outcomes in such regions. Members of this committee urged an increase in policies and strategies to streamline traditional medicine production in the developing world.

BDCP’s alliance with Shaman IP was at the vanguard of collaborations between private, public and NGO partnerships in researching tropical diseases (including malaria and Ebola fever) and their remedies. With more than 90% of malaria victims living in sub-Saharan Africa, the NGO’s Global Health Project – which has been run with the help of Africa ICBG – has prioritized tropical disease research into phytomedicines (or remedies derived from plants). The NGO, moreover, has been at the forefront of efforts to develop top grade traditional medicines that are produced to the highest standards of ethics, efficacy and safety.

In collaboration with the National Traditional Medicine Board in Nigeria, BDCP has proposed monitoring and standardization strategies for THPs and their medicines including the establishment of a code of ethics for practitioners. Under such a code, THPs will be expected to, for example, keep records of the treatments they provide and follow set procedures on a par with those established in Western or orthodox medicinal practice. In support of this, the NGO helped to establish a Herbal Pharmacovigilance Project in Nigeria where adverse effects of herbal medicine could be recorded. In this and other ways, BDCP intends to ensure both the skill of THPs and safety of patients.

Commensurate with such development strategies, the organization’s benefits-sharing and capacity building mechanism has also ensured the full and active participation of local partners based on transparency, trust, sustainability, and the equal sharing of knowledge and rewards. By collaborating with town associations, village heads, and professional guilds of healers and workers, the NGO and its partners have been able to spread best practice and know-how. This process has encouraged THPs to identify their contributions to the discovery process through product or ideas labeling.

In so doing, traditional healers have been able to keep better records, develop their own products (with labeling and attribution to a particular healer) and improve their skill. The intended result has been improvements in product safety and diversity and accountability in the THP community with the added benefit of increased incomes.

**BUSINESS RESULTS**

BDCP has been a trailblazer in ethnobotanical and bioprospecting research in Africa. Because of its growing expertise and influence in this sector, the NGO has provided consultancy services for various organizations including the African Union and the Ministry of Environment and the National Agency for Food and Drug Administration in Nigeria.
Indeed, partly due to the conservation knowledge gained from collaborating with Shaman PI, the Smithsonian Institute and Africa ICBG, BDCP was appointed the United Nations Development Programme’s lead consultant for development of Nigeria’s first National Biodiversity Strategy and Action Plan.

The organization has established several offline databases of African medicinal plants and helped to create an equivalent digital inventory called the Computerized Information System of African Medicinal and Aromatic Plants. By working with InterCEDD, for instance, BDCP has been able to screen over five hundred plants for efficacy against tropical diseases. Due to the high cost of developing these drugs, as of 2012 the NGO was seeking partners in the industry in order to take the drugs through the various stages of drug development set by various health organizations including the FDA in the USA.

Because Nigeria is a Contracting Party of the CBD, any royalties from the commercialization of these products will be shared equitably with THPs and local communities in the country.

Moreover, in collaboration with Africa ICBG, the Smithsonian Institute and WRAIR, the NGO has been able to yield several chemical compounds with the potential for treating tropical diseases including malaria, sleeping sickness (Trypanosomiasis) and leishmaniasis (a potentially fatal disease of the organs caused from the bite of a sand fly).

In addition, the NGO’s spin-off companies, Axxon and IHP, and other affiliated organizations (including two research institutes and a commodities trading company), had developed an exciting range of organically produced and originally sourced remedies. Some of these products have been marketed locally via companies such as Neimeth Pharmaceutical International Plc., based in Lagos, Nigeria.

In 2012, BDCP had trained several Nigerian scientists (on biodiversity, biotechnology, and ethnobiology), positively influenced IP legislation in favor of THPs on the continent, helped establish traditional medicine university courses in the region, and expanded to include several programs and offices in Africa, including Cameroon, and the USA.

THPs, meanwhile, have been placed on a sound track to development while the delicate environment and plant species that they rely on has been preserved for future generations of healers and researchers.

The Magic of Collaboration

BDCP has been a successful bridge-maker between traditional health practitioners in West Africa and orthodox, pharmaceutical companies in the developing and developed world. The NGO has managed to raise its profile and that of THPs and scientists in Nigeria via well planned partnerships with industry, government and traditional rural communities.

By strategically leveraging of its IP assets, moreover, BDCP has modernized its production processes while preserving Nigeria’s medicinal customs and conserving the country’s environment. In the process, bioprospecting companies are re-discovering historically hidden sources of new medicines that are affordable and in need of development for millions of people at risk from tropical and other diseases.
RANGE OF PRODUCTS FROM INTERCEDD HEALTH PRODUCTS

GARCINIA IHP
A product backed with over 10 years of scientific research
MORINGA LEAF POWDER
NATURE'S MIRACLE PLANT

MORINGA LEAF TEA
NATURE'S MIRACLE PLANT
Moringa oleifera Plant From Our Farm
Coleus forskohlii
INTERCEDD AND SOME OF THEIR EQUIPMENT