

NEW HOPE FOR NEW MEDICINES FROM “FOLK” REMEDIES

OUT OF AFRICA

THE STORY THAT DR. CHARLES WEMBEBE OF THE NIGERIAN NATIONAL INSTITUTE FOR PHARMACEUTICAL RESEARCH AND DEVELOPMENT TOLD ME, AND THE REST OF A RAPT AUDIENCE, AT A FIVE-DAY MARCH 2008 CONFERENCE ENTITLED “THE 2ND GLOBAL SUMMIT ON HIV/AIDS, TRADITIONAL MEDICINE, AND TRADITIONAL KNOWLEDGE” IN ACCRA, GHANA, WAS AN EYE-OPENER.



Children outside of Osu Castle, the Seat of Government of Ghana in Accra.

“One hundred thousand Nigerian babies are born each year with sickle cell anemia (SCA), a genetically inherited disease common in West Africa. (About one in twelve African-Americans carries the SCA gene.) In addition to anemia, SCA sufferers are vulnerable to seizures, lung congestion, and organ damage from blocked blood vessels. These seizures can often be fatal. There is no known cure.

Lacking access to Western medicine, the local Nigerian population relies heavily on traditional plant-based remedies made from fresh or dried herbs prepared by traditional medical healers. Beginning in 1993, the Institute surveyed some of the herbal “concoctions” used by traditional Nigerian healers, researched them, and after toxicity studies, focused on one, a mixture of four plants, three of which are commonly used in food for human consumption. *In vitro* studies on human blood cells and *in vivo* studies on transgenic mice consistently demonstrated a dose-dependent decrease in sickling of red blood cells. Small-scale clinical studies (phase I) using healthy volunteers, starting in 1994, reported no adverse effects, and a trial was conducted on 30 SCA patients who had suffered previous vaso-occlusive seizures. Larger clinical trials in conjunction with the Children’s Hospital of Philadelphia and the Meharry Comprehensive Sickle Cell Center in Nashville, Tennessee in the United States corroborated the earlier positive results.

With a grant from the United Nations Development Programme [UNDP], the Institute filed patent applications and patents issued in Nigeria, the U.S., U.K., India, Japan and thirty-eight other countries between 1998 and 2002. Also in 2002, the Institute granted an exclusive license to a Nigerian start-up company for global marketing and distribution rights for the product under the trademark, Niprosan®. It also signed an agreement with the traditional healer that had provided the original sample for the payment of royalties on sales of the drug. In 2004, the U.S. Food and Drug Administration granted it “orphan drug” status and the World Health Organization listed it as a new “reference drug” for the treatment of SCA. While studies in Japan indicate the presence of five known aromatic aldehydes in the bioextract, the exact mechanism by which Niprosan® works remains a mystery....”

This Nigerian story of local empowerment marks a new turn in a growing trend. The growing trend is that the pharmaceutical “Industrial Age” based on organic synthesis of new drugs from base chemicals is yielding way to the pharmaceutical “Information Age” of extraction of bioactive ingredients from living organisms (“genetic resources”). Of course, that is what traditional medicine has always been about, ranging from the analgesic effect of willow bark rubbed on an aching tooth among Native American peoples (now the active ingredient in aspirin), Ayurvedic healing in India, the anti-oxidant effects of green tea in Asia and (luckily for oenophiles like me) the vaunted life-prolonging effects of “reservatrol” in the red wines of the “Mediterranean diet.”

Over the past quarter-century, the emergence of biotechnology as the key global driver of medical and agricultural R&D has accelerated the rush for access to “bioinformation” through “bioprospecting” within the richness of biological diversity. Early examples include Alexander Fleming’s discovery of the antibacterial effect of the *bacillium* mold in 1928 and Arthur Barclay’s 1966 discovery and subsequent isolation of the cancer chemotherapy drug Taxol® from the Pacific yew (*taxum brevifolia*) found in the rainforests of the Pacific Northwest. Such discoveries were the first sparks to a rising awareness of both the economic value of bioinformation for global health and agriculture and the importance of conserving the world’s endangered reservoir of biological diversity for the future well-being of humanity.

The new turn in this growing trend is that by accident of nature and history, the richest storehouses of bioinformation are tropical rainforests in the developing nations of the South (Latin America, Asia, and Africa.) These are the same countries that having signed on to the TRIPS Agreement of the World Trade Organization [WPO], are now working to strengthen

their patent systems and sending their “best and brightest,” to Pierce Law to learn how to do it. The question is, for whom?

Accusations have been lodged that multinational corporations of the North (mainly Japan, the United States and Europe) engage not just in “bioprospecting,” but “biopiracy” as well, that is, the misappropriating, patenting, and globally marketing plant-based drugs and bioextracts originating in developing countries. Since the signing of the Convention on



Professor William O. Hennessey JD '86 with Lakassa Essossiminam, president of the Traditional Therapeutic Medical Practitioners Association of Togo and of the Federation of Healers Associations of Togo.

Biological Diversity [CBD] in 1992, international organizations—including the World Health Organization [WHO], Food and Agriculture Organization [FAO], World Intellectual Property Organization [WIPO], and the WTO—have been lining up on various sides of the “bioprospecting” debate over who should own and who should have access to the health-creating (and wealth-creating) information in biodiversity. Some of the most vitriolic critics of strong patent systems believe that global protec-

tion for intellectual property must give way to free access for all.

However, Wembebe’s Institute and others like it are bucking that criticism, countering it with the idea that patents can bring to the countries where such bioinformation in the form of genetic resources and traditional knowledge is found, the benefits not just of innovative health products, but sound economic development and hard cash as well.

At the epicenter of the drive to bring Western medicine and traditional healing together in Africa has been the HIV/AIDS epidemic, which kills over three million people a year. Access to Western medicine in Africa is virtually non-existent. (There is one Western-trained medical doctor for every 40,000 people in Ghana.) Western medical research has provided the world (including three million of the nearly forty million people living with HIV/AIDS in Africa) the anti-retroviral “cocktails” they need to boost their immune systems. The

United States government, pursuant to the Leadership Against Global HIV/AIDS, Tuberculosis, and Malaria Act of 2003, has supplied treatment for over one million people with HIV/AIDS—most of them in Africa. But people with AIDS don't die of AIDS; they suffer from and succumb to the opportunistic infections that take advantage of a depressed immune system. It is in the second focus, the fight against the opportunistic infections facilitated by HIV/AIDS-engendered immunodeficiency, that the role of traditional African medicine becomes apparent, particularly with regard to treatment of skin rashes, dysentery and diarrhea, and pain. The drive extends to other tropical diseases as well, and especially to malaria (which kills over two million people a year.)

Wembebe told his audience that “what is needed is vision, a strategic plan, a focus, commitment, and passion for implementation of the plan, aggressive resource mobilization, a willingness to do deals with traditional healers and nutritionists, and a multidisciplinary approach marshalling skills in law, business, technology, government policy-making, and traditional culture.” Budding technology transfer offices (TTOs) in academic and government research institutions in Nigeria, Ghana, and other African countries will play a pivotal role, on the one hand, in reaching out and building trust with local traditional healer communities that may have been refining treatments for decades or centuries to identify medicinal or nutritional bioactivity in indigenous plants by sheer trial and error. On the other hand, such TTOs need to have the knowledge skills to build an indigenous capacity both to create and manage a global portfolio of intellectual property assets, and to negotiate with (or create their own) modern profit-driven pharmaceutical companies to introduce and supply innovative drugs to a global health market, reducing search costs and lead time by having the head start that access to traditional knowledge might provide.

The challenges are overwhelming. The traditional healer communities woefully lack knowledge of and trust in intellectual property protection, particularly patent and trade secret protection and how it works. Modern investment-driven companies see access to information formerly free for the tak-

ing now available for a fee, and may believe (or feign belief) that the knowledge traditional healers could provide is worthless (or worse.) It is a wonderful tapestry of serious and competent workers on all sides of cultural and economic divides, peppered with self-promoters and charlatans, “witch doctors,” and cold capitalist bargaining. Assuming that expectations on both sides can ever be realistic, and assuming that facilitating institutions such as Wembebe’s continue to meet success in bringing knowledge of best intellectual property practices to traditional communities, more examples of such success stories are going to be written and spoken of in the years to come.

This is where Pierce Law is playing its own role in building that bridge. Thanks to a generous donation from Gerry Brill JD '91, I was able to bring copies of *IP Management in Health and Agricultural Innovation: A Handbook of Best Practices*. The *Handbook* is a comprehensive resource on current intellectual property management issues and approaches, and offers information and strategies for utilizing the power of intellectual property while remaining aware of how it relates to the public domain. Visit www.ipHandbook.org.

These extensive materials are now in the libraries of the Association for the Promotion of Traditional Medicine of Senegal, the Traditional Therapeutic Medical Practitioners Association of Togo and Federation of Healers Associations of Togo, the Ghanaian Ministries of Health, Food and Agriculture, Justice, and Education, the Ghana Food and Drugs Board, Ghana AIDS Commission, Ghana Federation of Traditional Medicine Practitioners Associations, National Commission on Culture, Directorate of Traditional and Alternative Medicine, University of Ghana, Kwame Nkrumah University of Science and Technology, Noguchi Memorial Institute of Medical Research (Ghana), Centre for Scientific Research into Plant Medicine, the Komfo Anokye Teaching Hospital, and His Majesty Otumfuo Osei Tutu II, the reigning 16th King of the Ashanti Kingdom.

This is not just a Nigerian story, but a Pierce Law story as well, about creating intellectual property protection that is truly in the global public interest.