

BIODIVERSITY PROSPECTING: Lessons and Prospects

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■ **Abstract** Introduction of the U.N. Convention on Biological Diversity and the growth of biotechnology processes have recently led anthropologists into the rapidly moving, ethically and philosophically challenging field of bioprospecting or exploring biological diversity for commercially valuable genetic and biochemical resources. Is bioprospecting an innovative mechanism that will (a) help produce new therapeutics and preserve traditional medical systems, (b) conserve both biological and cultural diversity by demonstrating their medical, economic, and social values, and (c) bring biotechnology and other benefits to biodiversity-rich but technology poor countries? Or is bioprospecting yet another form of colonialism—"bioimperialism"—wherein the North rips off the South's resources and intellectual property rights? This article reviews the current literature on bioprospecting that lies somewhere between current polemics and calls for more anthropological research into the bioprospecting process.

BRIEF HISTORY OF BIOPROSPECTING

To alleviate the loss of the flora and fauna of our planet, at the U.N. Earth Summit in Rio de Janeiro, Brazil, the Convention on Biological Diversity (CBD) (<http://www.biodiv.org>) was opened for signature on June 5, 1992. Objectives of the CBD are (a) the conservation of biodiversity, (b) the sustainable use of its components, and (c) the equitable sharing of the benefits resulting from the commercial use of genetic resources.

Perhaps the most critical component of the CBD for biodiversity-rich countries is sovereignty over bioresources by nation states, as the treaty recognizes their right to regulate and charge outsiders for access to their biodiversity. No longer are biotic resources considered "common heritage," the pre-CBD paradigm that provided open access to bioresources. The "grand bargain" of the CBD is to balance

how all interest groups involved can gain from the use of biodiversity by recognizing the economic, sociocultural, and environmental values of bioresources and the costs of preserving them (Orlove & Brush 1996, Moran 1998a, *Nature* 1998). Since the CBD was introduced nine years ago, however, few of the 178 signatory nations have introduced legislation requiring benefit-sharing for access to their national bioresources by outsiders with commercial interests (ten Kate & Laird 1999).

At the same time, commercial users of bioresources voluntarily attempt to comply with convention provisions in order to gain access to the raw bioresources that can be developed into products. These arrangements to explore biological diversity for commercially valuable genetic and biochemical resources have come to be called biodiversity prospecting or bioprospecting (Reid et al 1993). Although the unfortunate term suggests a new form of biocolonial appropriation, with all its attendant controversy, it has, nevertheless, become the most-used term for these transactions.

The commercial collecting of biological species is certainly not new, but their value has increased owing to the demand for genetic and biochemical raw materials for biotech products (Farnsworth 1988, McChesney 1996). Bioprospecting products include pharmaceuticals, botanical medicines, agribiotech, horticulture, cosmetics, and personal care products (ten Kate & Laird 1999). Agribiotech is briefly reviewed here, but only in relationship to pharmaceuticals because it generates a different set of policy debates, such as biosafety and world food security (Cleveland & Murray 1997). This chapter is confined to reviewing bioprospecting for terrestrial plant medicines and the use of ethnobotany and benefit-sharing in natural products drug discovery, as we are experienced in these sectors. Brief examples of existing bioprospecting endeavors are presented throughout this review.

BIOPROSPECTING STAKEHOLDERS

During the decade since the CBD was introduced, the treaty has catalyzed new relationships. Biodiversity-rich countries, indigenous societies with their knowledge of the use of such bioresources as medicines, and companies that seek to discover new therapeutics through medicinal plants and indigenous knowledge now share common interests, and, often, conflicts. The value of plants for medicines is more widely recognized and the intellectual property rights (IPRs) connected with their use have been debated worldwide. Indeed, IPRs have become the metaphor to describe indigenous ownership of traditional knowledge also, generating options for contractual mechanisms to ensure benefits return to source cultures and countries (Brush 1993, Greaves 1994, King et al 1996, Gupta 1996, Mays et al 1997, Gollin 1999, Riley & Moran 2001).

Governments and Their Agencies

Most biodiversity-rich countries are located in the tropics of the south, but technology-rich countries, with resources to develop biodiversity, are primarily in the

temperate north (Kloppenborg & Balick 1995). Most southern nations are burdened with poverty, oppressive external debt, impoverished university systems, and a dearth of scientists and technology. Few have been able to collect, identify, inventory, and screen their rich biological assets, let alone develop them into products. Thus, the CBD allows northern interests to access the biodiversity of southern countries through commitments to share the technology and benefits that arise from its commercial use (Porter 1992, Glowka 1998). It is the responsibility of each CBD contracting party to devise a national biodiversity policy to document how this will work in their country, including a legal framework to implement it. Because many countries now have only a patchwork of legal provisions, such as collecting or export permits, the International Union for the Conservation of Nature, the World Conservation Union, recently published a guide (Glowka 1998). The United Nations Development Programme also offers CBD nations a guide (Prescott et al 2000), which includes case studies from the Democratic Republic of Congo, the Sultanate of Oman, the Republic of Niger, and the province of Quebec.

Although the U.S. Senate has yet to ratify the CBD, the government is active in a multicountry bioprospecting program in which conservation and development goals are linked to the bioprospecting process. Three federal agencies, the National Institutes of Health, the National Science Foundation, and the Department of Agriculture, support the program, called the International Cooperative Biodiversity Groups (ICBG), in 12 developing countries, the United States and the United Kingdom. Goals are to improve health through the discovery of new drugs from natural sources, to conserve biodiversity while developing local capacity to manage natural resources, and to promote sustainable economic development, particularly in communities of the developing tropics. Most ICBG have some ethnomedical component to their field efforts (Rosenthal 1999).

Although each ICBG is unique, all are coordinated by U.S. academic principal investigators, with programs in anthropology, ethnobotany, natural products chemistry, or drug development. As required by grants, each has a commercial pharmaceutical partner and a counterpart institution in the host country, and each works with local national and international nongovernmental organizations (NGO). The total budget for 1999 was \$3.7 million, which includes contributions from all collaborating partners. The U.S. government has continued involvement in the projects through scientific advisory committees with representatives from each federal agency (Rosenthal 1999).

Biotech Industry

Since Watson and Crick's discovery of the double helix, no legal biotech case has been as influential as *Diamond v Chakrabarty*, in which new genetically engineered life forms were deemed patentable. The court found that a genetically modified bacterium fit Thomas Jefferson's language in the Patent Act of 1793, making a new "composition of matter" patentable (U.S. Congr. 1991). In the United States, legal, scientific, political, and economic mindsets during the 1980s shaped emerging biotechnology firms. Major federal granting agencies, such as the

National Science Foundation and the National Institutes of Health, implemented policies that encouraged corporate-university collaboration in extremely difficult and expensive biotechnology research. At Genentech of South San Francisco, for example, using biotech processes, university researchers learned how to produce huge supplies of insulin to treat diabetics. Secured by patents, venture capital supported the research as investment opportunities, creating biotech firms dedicated to research and development for a profit (U.S. Congr. 1991, Cassier 1999, Rabinow 1994).

The majority of the biotech industry is not involved in bioprospecting because most companies today favor the use of cheaper, faster, synthetic technologies over exploring for natural products (Gollin 1999, Farnsworth 1988). But biotechnology spawns ethical, social, and legal debates at the margins of pharmaceutical bioprospecting in which anthropologists have been active. They include the collaboration of big business and big science, the ethics of genetic engineering, and the patentability of life forms (Bruce & Bruce 1998). Biotechnology overlaps with ideas about genetics and racism, culture and ethnicity (Bradby 1996). Projects involving mapping of the human genome, such as Iceland's national human genome project, also have implications for anthropological studies (Palsson & Rabinow 1999). Crook (2000) debates the public safety and genetic pollution some associate with genetically modified organisms versus the ability of genetically modified organisms to alleviate world hunger and environmental degradation. Clark & Juma (1991) draw on case studies from the African Centre Technology Studies and outline an international research agenda for using biotechnology for sustainable development in developing countries.

Since the CBD was introduced, however, no pharmaceutical bioprospecting product developed by using traditional knowledge has been commercialized; no economic profit has been realized. Drug development requires expensive and time-consuming studies and clinical trials in order to secure government regulatory approval before any drug may be marketed. In the United States, a product typically takes from 10 to 15 years to materialize, after an investment of some \$300 million by the company and investors who take the financial risk to discover, develop, test, and market a new drug. For a new company, infrastructure such as buildings, equipment, and research scientists' salaries must be paid before any product generates any revenues (U.S. Congr. 1993, Baker et al 1995).

To raise such huge amounts of money to fund capital-intensive drug research and development (R&D), companies—other than financially stable, large pharmaceutical companies—depend on venture capital, stock offerings, partnerships, and the like—investments by outsiders into a company's high-risk but potentially high-gain ventures (U.S. Congr. 1991). Investors range from individuals to organizations, and their investments are secured by patents. Patents provide intellectual property protection for the invention of the company, enabling investors to regain the funds they risked for R&D if and when a product is commercialized. It is unlikely that any company or any investor would risk capital to discover or develop a drug without their multimillion dollar investment being protected

from competing companies by a patent (U.S. Congr. 1991; see also <http://www.cid.harvard.edu/cidbiotech/homepage.html>).

Only a small number of bioprospecting research expeditions begin by using ethnobotany as a discovery methodology (Cox & Balick 1994). The work soon evolves into economic botany, as the laboratory focus shifts to the plant's chemistry, biological activity, and general pharmacology/toxicology (Balick 1990). During the drug discovery processes, the active chemical constituents of the biological materials are elucidated, often modified, then patented (Tempesta & King 1994). In biotech companies, this patented information becomes a commodity in itself, in the form of chemical compounds or tissue samples that can be outlicensed, or "rented," to other commercial interests, with the company profiting from each circulation. Libraries of extracts, compounds extracted from plants collected at random, or plants used as medicines are licensed to biotech companies or large pharmaceutical firms that screen in high volume—often up to 100,000 compounds per week (Balick et al 1996).

In the United States, drug development includes preclinical studies in animals to assess which molecule produces the highest level of pharmacological activity and the lowest level of toxicology. Phase I human clinical studies determine the safety of the drug candidates in healthy volunteers. In phase II trials, increased numbers of actual patients help test and determine dosage and formulation. Final proof of safety and efficacy is produced in phase III clinical trials. If the data are adequate, a new drug application is submitted to the Food and Drug Administration. It can take up to 2 years before the Food and Drug Administration supplies permission to market a drug. Every country has its own unique requirements for marketing drugs and does not necessarily accept data from other countries (ten Kate & Laird 1999).

Horrobin & Lapinskas (1998) narrate the enormous problems faced by a company attempting to develop herbal medicinal resources. Anderson (2000) states that it is "[a] valuable corrective to the one-sided presentations so typical of anthropological writing in which corporations are represented as villains. In these complex matters, all sides deserve a hearing, and the wise ethnobotanist will not judge prematurely."

Science and Medicine

There are, however, more bioprospecting stakeholders than provider countries (including local, state, regional, and national governments) and user industries (including both small start-up and multinational biotech companies). Major stakeholders include both the domestic and international research communities, including botanical gardens and universities. For their screening programs, a majority of companies outsource plant samples from brokers that collect, taxonomically identify, ship, and resupply materials to users (ten Kate & Laird 1999).

International research institutions are obligated to the national access legislation in countries where they perform these broker functions. To insure consistency with

the CBD, after a lengthy deliberative process, the Common Policy Guidelines for Participating Botanic Gardens were institutionalized by most gardens (ten Kate & Laird 1999). International plant research spans a continuum from pure to applied research and reflects the increasing commercial value of bioresources and the vitality of biodiversity for human health. Today, one fourth of pharmaceutical products are based on, or derived from, plants (Farnsworth 1988). In developing countries, 80% of the population depend on plant medicines for their primary health care (Farnsworth 1988, ten Kate 1995, Balick et al 1996). Work by Grifo & Rosenthal (1997) is the result of a conference sponsored by the National Institutes of Health, the National Science Foundation, and the National Association of Physicians for the Environment held at the Smithsonian Institution to explore the human health consequences of biodiversity loss.

Prendergast (1998) demonstrates the wide range of anthropological interests in economic botany. A review of ethnopharmacology by Etkin (1988) documents the field's ecological perspective, both biobehavioral and multidisciplinary. In contrast to general compilations that document the medical use and constituents of plant substances, Etkin shows that biobehavioral studies explore both biological and behavioral parameters that contextualize human-plant interactions and their impact on human health.

Many ethnobotanists active in biopropecting have urged professional associations of scientists to develop codes of conduct to guide members through the new ground rules brought about by the CBD. They include, among others, the American Society for Pharmacognosy, the Society for Applied Anthropology, the International Society of Ethnobiology, and the Society for Economic Botany, most of which have posted draft guidelines on their websites (Prance 1991, Berlin & Berlin 1994, Cox & Balick 1994, King et al 1996, Brush & Stabinsky 1996, Cleveland & Murray 1997).

Civil Society

Bentham (2000) broadly defines civil society as “all associational forms in society other than the state or the market” and sees it as the prerequisite and foundation for a democratic society. Many nonprofit development agencies base grants to governments that are buttressed by a strong and vibrant civil society, as they serve to buffer the challenges of reform and social change (Comaroff & Comaroff 1999). Widely accessible and affordable technology has revolutionized global communications in recent years and made it possible for civil society activists to join forces for maximum impact. Nontraditional international actors mobilize information strategically to help create new issues and to persuade, pressure, and gain leverage over much more powerful organizations (Zarembko 2001).

Some forms of civil society, however, have devastating effects—anthropologists find them “ethnocentric and insidious” and difficult to distinguish from other self-interested groups (Hitchcock 1994). The new communications freedom also brings

up questions of representativeness—if anyone can speak, who speaks for whom and who decides this? Problems have arisen in local discussions on bioprospecting, which often originate in forums hosted by an NGO with a specific agenda. Forum results, often a statement by an individual or a small group who support that agenda, are then circulated around the world via the Internet as representative opinions of a larger group. Slick NGO networks skew the debate by presenting their version of public opinion in a determined direction (Hann & Dunn 1996; see also <http://www.rafi.org>, <http://www.grain.org/index.htm>).

To level the playing field in bioprospecting negotiations, many countries and culture groups have successfully sought outside expertise from intermediaries (Guerin-McManus et al 1998). Typically, intermediaries have some vested interest in promoting an equitable exchange on mutually agreed-to terms for access to genetic resources. NGOs representing civil society in such areas as conservation, development, human rights, health, and other nonprofit organizations, foundations, and pro bono law firms play growing roles in fostering, facilitating, and evaluating bioprospecting partnerships (Mays et al 1997). Many intermediaries speak the local language, have worked and often lived in the host community, and have earned its trust (Green 1998). They play different roles in access and benefit-sharing arrangements with source countries and other stakeholders, often becoming partners in the relationship.

Some of the conservation organizations active in bioprospecting issues are Conservation International in Suriname (<http://www.conservation.org>; see also Guerin-McManus et al 1998), the International Union for the Conservation of Nature globally (Glowka 1998), and the World Resources Institute in Costa Rica (Reid et al 1993). The Bioresources Development and Conservation Programme (<http://www.Bioresources.org>) is a Nigerian NGO organized in 1991 as the focal point for collaborative bioprospecting research relationships, such as the ICBG. Goals are to build technical skills in Nigeria so bioresources are a viable vehicle for sustainable development. Bioprospecting programs generate pharmaceutical leads that target therapeutic categories for tropical diseases suffered in Nigeria, such as malaria, leishmaniasis, and trypanosomiasis (Iwu 1996a,b).

The National Biodiversity Institute, INBio, a private, nonprofit, public interest association, was established by the Costa Rican Ministry of Environment and Energy in 1991 (Reid et al 1993). Its aim is to promote sustainable development of biotic resources through a strategy of “save, know, use.” INBio has a Central research institute in San Jose and 28 research stations and employs almost 200 people. In 1991, INBio and the multinational pharmaceutical company Merck and Co. entered into a landmark million-dollar, 2-year contractual relationship, later renewed, to develop Costa Rica’s rich biological resources through bioprospecting (Reid et al 1993). Since then, INBio has signed commercial research agreements with Bristol-Myers Squibb, INDENA for phytochemicals, Phytera for the development of cell cultures from plants and medicines, and the British Technology Group for the development of a bionematicide from a tropical legume (ten Kate & Laird 1999).

Indigenous Cultures

Ethnoscience is also recognized as valuable (Ford 1978, Linden 1991, Berlin 1992, Moerman 1996, Iwu 1996a,b) but is used by only a small segment of bioprospectors (Farnsworth 1988). According to Schultes (1988):

The accomplishments of aboriginal people in learning plant properties must be a result of a long and intimate association with, and utter dependence on, their ambient vegetation. This native knowledge warrants careful and critical attention on the part of modern scientific methods. If phytochemists must randomly investigate the constituents of biological effects of 80,000 species of Amazon plants, the task may never be finished. Concentrating first on those species that people have lived and experimented with for millennia offers a short-cut to the discovery of new medically or industrially useful compounds.

Although they are based on natural products, indigenous medicines are not “found” in nature. They are products of traditional knowledge. Elisabetsky (1991) explains:

To transform a plant into a medicine, one has to know the correct species, its location, the proper time of collection (some plants are poisonous in certain seasons), the solvent to use (cold, warm or boiling water; alcohol, addition of salt, etc.), the way to prepare it (time and conditions to be left on the solvent), and finally, posology (route of administration, dosage).

For pharmaceuticals, concentrating bioprospecting efforts on the traditional use of plants focuses leads for screening and can result in a more efficient and less expensive drug discovery process (Elisabetsky & Castilhos 1990). Likewise, leads from the traditional process of plant preparation for healing provide clues to the type of chemical compounds in plants under investigation (Schultes & Raffauf 1990). Of the 120 active compounds isolated from higher plants and used today in Western medicine, 74% have the same therapeutic use as in native societies (Farnsworth et al 1985). Rather than randomly collecting and screening plants, it can be a more efficient strategy for some companies to use indigenous knowledge as a lead to pinpointing promising plants for new medicines (King et al 1997). Organisms can be chosen for bioassays through leads unique to the area and cultures where they are located (McChesney 1996).

Shaman Pharmaceuticals, Inc. (<http://www.shaman.com>) is a small, California-based company that focuses on the discovery and development of novel pharmaceuticals from plants with a history of native use (Burton 1994, King et al 1996, Carlson et al 1997a, Oubre et al 1997). This ethnobotanical/chemotaxonomic approach produced a highly focused selection of plant candidates for screening and development, notably *sangre de grado*, commonly used for a variety of ailments throughout Latin America (Carlson & King 2000). Meza and colleagues (Meza 1999, Meza et al 1998) developed a manual and a technical book for the sustainable sourcing of *sangre de grado*, an abundant, pioneer plant that produces

a red latex (Carlson & King 2000). Resulting from ecological and management studies funded by and conducted during Shaman Pharmaceuticals' operations in Latin America, the manual is a practical guide for the propagation, cultivation, and sustainable management of the source for raw materials for Shaman's leading drug candidate (King et al 1997).

EVOLVING BIOPROSPECTING ISSUES

Intellectual Property Rights

Intellectual property rights (IPRs) spring from European philosophical traditions that create rights over intangible information. In today's industrialized world, their underlying rationale is that IPRs are commercial monopoly rights for a limited time period that provide incentives for further investment in developing future innovations. IPRs are often defined and protected in the form of patents, plant breeders' rights, trade secrets, copyrights, and trademarks, and patent law is most commonly used to protect the right to benefit financially from scientific innovations (Axt & Corn 1993, Mays et al 1997, Glowka 1998, Gollin 1999).

There are confusing misconceptions about, as well as genuine philosophical objections to, patents, including the morality of patents relating to life-forms (Greely 1998, Bruce & Bruce 1998). In the United States, for example, no living or dead plant found in nature can, itself, be legally patented (35 U.S. Code #101). But if there has been a horticultural or genetic change created by a plant breeder, a novel horticultural form of a rose, for example, it is an invention and can be patented by the innovator. Patents on living organisms in pharmaceutical bioprospecting are uncommon. Typically, patents are granted for scientific advances during the isolation and modification of chemical derivatives and analogs of compounds originally isolated from a plant for an identified use (Rosenthal 1999). Another misconception is that patents relating to traditional knowledge infringe on performing indigenous cultural practices, but, in fact, indigenous rights to use their tangible and intangible cultural resources in both traditional and innovative ways are not affected by patents (Wagner 1987, Rosenthal 1999).

Some bioprospecting source countries think that patents on products create monopolies at the expense of those providing the original material. A recent patent challenge on tumeric, however, demonstrates that the system can work and that patent claims that are not truly novel can be overturned (Gollin 1999, Pollack 1999, *Science* 1999). Companies see patents on natural products derivatives as protection from competing companies and an essential mechanism to recoup their R&D investments. They seek global expansion of a legal framework for proprietary rights to the new drugs they develop (UNCTAD 2000, ten Kate & Laird 1999).

Article 8(j) of the CBD requires contracting parties to (a) respect, preserve, and maintain the knowledge, innovation, and practices of indigenous and local communities embodying traditional lifestyles; (b) promote their wider application

with the approval and involvement of their holders; and (c) encourage equitable sharing of benefits derived from their use. Because these provisions are directed to states, implementation is subject to their national legislation.

The Agreement of Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization sets minimum requirements for the protection of IPRs, including novelty, non-obviousness, and usefulness. Indigenous knowledge, however, fails the novelty requirement, so most countries' IPR regimes do not provide for its protection or for benefit-sharing from bioprospecting (Axt & Corn 1993). The World Intellectual Property Organization (<http://www.wipo.org>) is now completing a status report to address this omission and influence evolving legislation on indigenous IPRs (UNCTAD 2000, Blankeney 1999).

The policy of the ICBG program is that when traditional knowledge is involved in a patentable invention, if the provider cannot be recognized as an inventor, the contribution should be treated as valuable "know how." In any related publications and in the patent, the contribution must be credited as prior art. Prior art citations formalize the contribution of such knowledge but do not claim any monopoly rights to use. In fact, the absence of a prior art citation may constitute grounds to deny or invalidate a patent (Rosenthal 1999).

New processes, consistent with other forms of IPR, also attempt to ensure equitable sharing of benefits from bioprospecting while protecting it from exploitation and extinction (Hitchcock 1994, Simpson 1997). Glowka (1998) describes such endeavors: traditional resource rights are bundles of rights that can be used for protection, compensation, and conservation (Posey & Dutfield 1996); community registers, or peoples' biodiversity registers, are data banks of local knowledge within India (Anuradha 1997); community intellectual rights from the Third World Network is primarily defensive because it protects communities from commoditization of their knowledge and resources (Singh Nijar 1996); and know-how licenses were used in an ICBG by the Aguaruna in the Peruvian Amazon as contractual legal instruments applied to intellectual property (Tobin 1997).

Although IPR discussions under the auspices of the CBD continue, many companies, including Shaman, the ICBG commercial partners, and others, have developed contractual legal instruments under which bioprospecting is conducted that reflects the spirit of the CBD. Contracts typically define objectives of the partnership, terms of material transfer, the rights and responsibilities of collaborators, and the types and amounts of benefits (Rosenthal 1999). Contractual agreements among bioprospecting partners are widely considered the mechanism of choice to gain access to genetic resources and traditional knowledge and to deliver benefits to source culture groups and countries. In contrast to patent law, contracts can be designed to fit differing relationships between collaborators (Laird 1993, Rubin & Fish 1994, Shelton 1995, Putterman 1996, Hunter 1998).

Cleveland & Murray (1997) point out some neglected theoretical and empirical aspects of the current IPR debate. The article primarily discusses IPRs for agricultural biotechnology, rather than pharmaceutical bioprospecting, which generates a very different set of policy debates. More informative is the wide range of

comments that follow the Cleveland & Murray article. Alcorn states that the authors fail to acknowledge that issues of "indigenous peoples" are far different from those of "local people," groups that are lumped together throughout the CBD. They fail to acknowledge the validity of being indigenous, argues Alcorn, and to capture the real conflicts and defining differences between competing perspectives. Fowler agrees and adds that IPR processes must differentiate between agricultural and pharmaceutical bioresources. He states that CBD IPRs "favor bilateral deals" for pharmaceutical benefit-sharing, whereas agricultural debates focus on multilateral arrangements for benefit-sharing. Authors of this review argue later about the importance of distinguishing between agricultural and pharmaceutical bioprospecting issues (Moran 2001).

Gupta comments on the article by calling for full disclosure on where and how source plant material is acquired under patent applications. Brush thinks that failures to resolve IPR disputes demonstrate the wide gulf between international discussions and the willingness of nations to act. Because rights are socially mediated, Brush argues, a "new class of rights" must be negotiated in the appropriate political arena. Downes, an environmental lawyer, comments that the inflammatory charges of "biopiracy" need more anthropological research for empirical evidence to cut through such rhetoric (Cleveland & Murray 1997).

Greaves (1994), in an early and important anthropological volume addressing IPR issues in which bioprospecting case studies are presented, addresses the current debate on the merits of intellectual property systems to protect cultural knowledge and biological diversity. Compensation to indigenous peoples, it is argued, could both internationally validate their knowledge of the biodiversity they manage and provide them with an equitable reward for sharing it, thereby compensating biological stewardship and encouraging conservation (Brush 1993). An early issue of the *Cultural Survival Quarterly* (Clay 1991), as well as a recent issue, is dedicated to IPRs. Riley & Moran (2001) provide a compendium of articles on tools that work to protect indigenous IPRs. The titles suggest how IPR has evolved among anthropologists in just a decade. An interdisciplinary analysis of the value and use of medicinal plants and traditional knowledge in the pharmaceutical industry, focusing on economic rationales for biodiversity conservation is documented by Swanson (1995).

During the past decade, regional coalitions and federations of indigenous peoples worldwide have joined forces in a spirit of solidarity to discuss IPRs and related issues (N. Am. Congr. Latin Am. 1994). Federations have committed their discussions into charters, declarations, and other statements, then disseminated them for public use (Varese 1996). The Charter of the Indigenous-Tribal Peoples of the Tropical Forests was promulgated in Malaysia in 1992. Article 44 of the Charter states that the traditional technologies of members can make important contributions to humanity, including developed countries: They claim control over the development and manipulation of their traditional medicinal knowledge (Colchester 1994). Coalitions and federations comprise groups such as the Coordinating Body for the Indigenous Peoples' Organization of the Amazon Basin

in Amazonian countries, where more than 200 tribes are located, the South and Meso American Indian Information Center, and the World Rainforest Movement (Morris 1992). Many of these groups participated in two workshops on traditional knowledge and biodiversity, held in Spain and sponsored by the CBD, to put forward mechanisms to achieve the objectives of Article 8(j) (Burgiel et al 1997, UNEP 1997). International human rights instruments supply additional fundamental principles for IPR legislation, including the U.N. Working Group on Indigenous Populations and the intergovernmental process initiated by the U.N. Commission on Human Rights mandated to consider the Draft U.N. Declaration on the Rights of Indigenous Peoples (Shelton 1995, Anaya 1996, Blankeney 1999, Bowen 2000).

At the time of its incorporation as a for-profit corporation in 1989, Shaman Pharmaceuticals, Inc., also founded and continues to financially support the Healing Forest Conservancy (http://www.shaman.com/Healing_Forest.html), a nonprofit foundation established specifically to develop and implement a process to return benefits to Shaman's 30 collaborating countries and some 60 culture groups after a product is commercialized. Benefits from commercial products will be shared equally among all countries and culture groups that participate in Shaman's drug discovery process, no matter where the plant or knowledge originated. The Healing Forest Conservancy developed a constitution, a legal instrument available on the worldwide web, under which indigenous groups legally organize to receive monetary benefits (Moran 1998b). The company uses Agreements of Principles, legally enforceable contracts, to establish the terms under which Shaman conducts research. Culture groups' rights to prior informed consent, confidentiality, privacy, and fair compensation form the philosophical underpinnings of the company and its principles for research. Several publications supply detailed descriptions of Shaman's operations globally, including its lengthy prior informed consent process (Burton 1994, Carlson et al 1997b, Richter & Carlson 1998, Duncan 1998).

Benefit Sharing

The third goal of the CBD, "the equitable sharing of the benefits resulting from the use of genetic resources," has taken many forms: monetary benefits for source countries include bioprospecting fees and fees for each sample, a percentage of the research budget dedicated to locally preferred use, development of alternative income-generating schemes, and a commitment by the company to obtain future plant supplies in the source country. To date, INBio's bioprospecting agreements have contributed more than \$3 million to conservation areas, universities, and other groups affiliated with INBio. Resources totaling over \$210,000 were provided to Nigeria from 1990 to 1996 by Shaman (ten Kate & Laird 1999).

Nonmonetary benefits include the acknowledgment of contributions in publications or joint authorship, joint research, training and increased scientific capacity, free access to technology, equipment and products, and research results and coownership of IPRs. Since 1993, over 1400 developing country collaborators

from 12 countries have received formal training in degreed as well as technical training programs from the ICBG. Both INBio and Shaman have made capacity-building contributions in collaborating countries as well (ten Kate & Laird 1999, King & Carlson 1995, Rosenthal 1999).

There is no "model" for the process of benefit-sharing, but trust funds have become the method of choice to return monetary benefits from bioprospecting to culture groups. In the form of a foundation, nonprofit corporation, or common-law trust, such trusts operate as permanent endowments, revolving or sinking trust funds in hard currency to avoid inflation shrinkage, either off-shore or in the country of origin (Moran 1998b).

The Fund for Integrated Rural Development and Traditional Medicine, an independent trust fund, was established by the Bioresources Development and Conservation Programme as the financial mechanism to distribute bioprospecting benefits among Nigerian stakeholders for sustainable development in rural areas. The board, balanced to reflect these interest groups, is composed of leaders of traditional healers' associations, senior government officials, representatives of village councils from various ethnic groups, and technical experts from scientific institutions. The predominance of traditional solidarity systems, such as tribal associations and professional guilds of healers, supplies a social structure to ensure community participation. Diverse culture groups in Nigeria receive funds through traditional healers' organizations and villages consistent with their governing customs. Town associations, village heads, and professional guilds of healers are empowered to make decisions regarding projects in their localities. Those funded follow the criteria of promoting conservation of biodiversity and drug development, as well as the socioeconomic well-being of rural cultures. At the local level, technical skills gained from benefit-sharing help standardize and promote phytomedicines, disseminating and sharing information that benefits traditional healers and the health of the communities they serve (Iwu 1996a, Moran 1998b, Laird 2000).

LESSONS AND PROSPECTS

Roles for Anthropologists

Can bioprospecting produce new drugs, preserve traditional medical systems, and deliver capacity-building technologies to the developing world while conserving biodiversity? Despite the fact that no pharmaceutical company has yet marketed any bioprospecting product, the above efforts have already brought considerable monetary and nonmonetary benefits to developing country collaborators. Drug discovery, for the ICBG and INBio, for example, is only one bioprospecting objective, and time will tell whether all ambitious goals can be met (Rosenthal 1999).

As the world moves from free to controlled access to genetic resources, the "common heritage" of the past is now called biopiracy. Caught up in North/South politics, there have been calls for today's bioprospectors to pay the price for

yesterday's paradigm. Such rhetoric threatens opportunities for economic development, technology transfer, and capacity-building in tropical countries; potential breakthroughs in medicine and abandonment of research that may never be completed as the extinction rate of biocultural diversity accelerates (Shiva 1997, Kimbrell 1997; see also <http://www.grain.org/index.htm>, <http://www.rafi.org>).

More anthropological studies that sort out, describe, and analyze bioprospecting's ethical issues and stakeholders' behaviors are needed (Durant et al 1996, Fundación Sabiduría Indígena & Kothari 1997, Skinner 1999). Empirical data open the process to constructive criticism and enable the bioprospecting dialogue to evolve beyond the rhetoric that dominates much of today's discussion of this complex process. Also, the health, development, and conservation components of bioprospecting are basic to applied anthropology. In such multidisciplinary collaboration, nonsocial scientists often find their bioprospecting attempts caught up in problems they cannot resolve because of little or no preparation or experience in the social processes, or they fail to recognize that every society has mechanisms useful to conservation, including grass-roots affiliations, that are rarely noticed or prioritized by outsiders.

Differentiate Between Indigenous Peoples and Local Communities

What has not yet been adequately addressed by the CBD is how the on-the-ground stewards of biodiversity, the "indigenous and local communities embodying traditional lifestyles" referred to in Article 8(j), can share in bioprospecting benefits (Cleveland & Murray 1997). One reason this critical issue remains unresolved is that the wording of the CBD is ambiguous and confusing. It lumps indigenous peoples and local communities together throughout the document without separating them into discrete groups (Moran 2001).

With some exceptions, indigenous peoples have minority status within modern nation states. They primarily seek collective rights and self-determination for use of their biological and cultural resources. This is different from local communities—typically small farming communities that have socioeconomic aspirations similar to those of the national culture. Most farmers identify with the nation states in which they live, typically speak the national language, and practice the religion of the majority (Palmer 1996, Maybury-Lewis 1997). Lumping indigenous peoples into farmers' groups directly undermines indigenous efforts for self-determination and creates concerns that they will be immersed under farmers' movements and their specific concerns subordinated to those of the more powerful and numerous farmers' groups (Moran 2001).

Indigenous knowledge of the use of plants for medicines is typically generational, often sacred, and always deeply imbedded in culture (Reichel-Dolmatoff 1976), whereas farmers' manipulation of germplasm for improved crops is usually individual and more secular. Changes to improved crops are brought about by human manipulation, but the chemicals within wild plants are valuable by themselves in the use of natural compounds for medicines. Likewise, when developing new products, the processes are different. To improve crops, useful genes are transferred

or put into plants to create new varieties. The discovery of new medicines, however, particularly pharmaceuticals, comes about by a series of steps to take useful chemicals out of a medicinal plant. Although distributing benefits from these agricultural and medicinal products requires completely different processes, the CBD wording binds them together. This haphazard process of labeling societies allows those with vested interests to exploit the very concerns that the CBD was created to resolve (Moran 2001).

Share Risks and Benefits Throughout the Bioprospecting Process

Shaman Pharmaceuticals, Inc., was restructured because of costs of future clinical trials for the company's first drug, which subsequently was launched as a dietary supplement, not a pharmaceutical. In the case of Shaman, however, the company's benefit-sharing principles are still intact, and considerable revenues can be generated from the botanical income stream while pharmaceutical research continues. In 1997, for example, the U.S. dietary supplement market for herbals or botanicals was nearly \$4 billion (King et al 1999; see also <http://www.ShamanBotanicals.com>).

A major lesson of the Shaman case comes from the time, costs, and risks associated with drug discovery, a burden shouldered primarily by the company, but with critical implications for benefit-sharing to source countries and culture groups. Spreading the risks and benefits among all stakeholders increases opportunities for bioprospecting benefits and lessens risk. Royalties may never materialize because of the tremendous costs, long time frame, unpredictability and volatility of the market, and the many other potential pitfalls of drug discovery. Some sort of upfront benefits, monetary or nonmonetary, as well as "milestone" payments up to the time for royalties are essential during the bioprospecting process (Putterman 1996, Fundación Sabiduría Indígena & Kothari 1997).

Share Benefits Within Nation States Equitably

Article 8(j) signals an important international acknowledgment that traditional knowledge is valuable to modern society. However, the CBD, which formalizes the sovereignty of nations over their biodiversity, merely "encourages" equitable sharing of benefits arising from traditional knowledge, innovations, and practices. The CBD has not yet established mechanisms to accomplish this equitably within nations.

The political climate of the governments under which indigenous groups live is critical to the CBD's success. Because they are huge stakeholders, governments must include indigenous peoples in national discussions on interpreting and implementing the CBD, as is required for all signatories. If states are to be effective at preserving the worlds' biocultural diversity, all stakeholders must participate. The process must be democratic, built from the bottom up, not imposed from the top down. This also means guarding against paternalism and letting indigenous groups determine for themselves the extent to which they choose to participate. Different culture groups hold different beliefs about entrepreneurship, which can

be a double-edged sword when introduced into nonmarket economies (Pritchard 1998). At the same time, however, many communities seek greater access to markets. These differences should never be an excuse to exclude indigenous groups from the sustainable use of biodiversity, for this is their, and only their, decision to make.

Acknowledge All Contributions

Missing in all this is recognition and acknowledgment of the contribution from indigenous societies in the discovery of new medicines that have historically benefited humankind. Recognition validates indigenous systems within countries and internationally, just as it does for Western scientists. It also spotlights the unique identity of traditional cultures groups at a time when they are organizing to pursue self-determination (Daes 1993, Fundación Sabiduría Indígena & Kothari 1997).

Sustainable Use of Phytomedicines, Herbal Medicine, or Dietary Supplements

The international conservation community is neglecting the huge impact of the herbal medicine industry on medicinal plants sold not as processed pharmaceuticals (King et al 1999). Concerned representatives from a small portion of the fast-growing phytomedicine industry now attempt conservation and sustainable use measures, but virtually no companies are addressing the third goal of the CBD—benefit-sharing with source groups and countries. Herb and phytomedicine companies pay a low price for large volumes of medicinal plant biomass from tropical ecosystems, package it in their own facilities, then sell the products at an inflated price in northern countries (Leaman et al 1998). Despite the CBD, the industry still enjoys a period of uncontrolled, undocumented, and poorly managed free access to medicinal plants and cultural knowledge throughout the world (Brevoort 1995, King et al 1999).

Importance of Biocultural Diversity Conservation Globally

Too often, when the importance of biodiversity conservation is discussed for its value to human health, it refers to the health of residents of industrialized nations. The attitude is that biodiversity must be preserved to enlarge the pharmacopoeia of Western medicine, which provides therapeutics primarily for Western societies. Less discussed is the vitality of biodiversity to the health of 80% of the world, populations that depend solely on medicinal plants for their primary health care (Berlin et al 1999, Iwu 1993, Farnsworth 1988). Preserving biodiversity for the benefit of human health means preserving it for those in the tropics already using it, as well as for distant populations that may know it only in some refined or synthetic form, at some unspecified future date.

Finally, discussions of biodiversity and its local, national, and international medical utility should never be disaggregated from the rich, complex, and diverse

cultural and biological matrix from which it evolved. One of the most important goals of biodiversity prospecting is to help conserve the vast diversity of languages, cultures, peoples, and other organisms that inhabit this earth. One of the challenges that faces anthropologists, ethnobotanists, physicians, entrepreneurs, and development professionals is to creatively utilize biodiversity prospecting as one of many tools to maintain and manage the fertile, but fragile, diversity of people, plants, cultures, and ecosystems that are under constant threat of extinction.

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