



# The Convention on Biological Diversity: changing ethical and legal frameworks for biodiversity research and prospecting

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*The CBD policy process has provided an important forum for addressing access and benefit-sharing issues related to biodiversity, such as traditional resource rights, intellectual property rights and equity in the trade of genetic resources.*

The ethical, commercial and policy context in which biodiversity prospecting, research and conservation take place has shifted significantly over the past ten years. The Convention on Biological Diversity (CBD) reflects and has bolstered a number of these shifts, which include the following.

- Biodiversity, previously considered the "common heritage of mankind", is now considered the "national patrimony" of host countries and is under their sovereignty.
- Genetic and species diversity have commercial potential not only as a source of material, or as commodities, but also as a source of information for product development.
- The rights of indigenous peoples and local communities to control and benefit from biodiversity research, prospecting and conservation are recognized, and increasingly formalized in policy instruments as well as documents developed by indigenous peoples' groups.
- Benefits of biodiversity prospecting, research and conservation must be equitably shared.

The CBD objectives of biodiversity conservation, sustainable use and fair and equitable sharing of benefits (Article 1) reflect a balance between a range of diverse agendas and perspectives on what biodiversity is, and whom its conservation and use are intended to serve. Most of the world's biodiversity is found in inverse proportion to technological and industrial wealth (Macilwain, 1998). The CBD negotiation and implementation process has been an arena for expression of conflicts between North and South over financial and natural resources and differing conceptions of environmental problems and the meaning and value of nature (McAfee, 1999). This process has made clear what was always the case in practice - that biodiversity and genetic resources are not only biological resources but political resources as well (Redford and Richter, 1999; Alexiades and Laird, 2001).

Simply put, high-biodiversity developing countries asked to set aside or manage large areas for conservation purposes argue that they should capture a fair share of the economic revenue generated by the genetic, species and ecosystem diversity that they conserve (Sánchez and Juma, 1994). Developed countries seeking the conservation of biodiversity have sought to maintain continued access to genetic resources for academic and commercial research. The CBD reflects the agreement reached by these various groups, and has been called the "grand bargain" (Gollin, 1993). The CBD clearly links environmental concerns with emerging human rights and trade issues; while it establishes general and qualified terms for trade in genetic

resources, the CBD also acknowledges the value of non-marketed goods and services, and makes explicit ethical commitments to fairness and equity (Downes, 1994; McNeely, 1999).

## THE COMMERCIAL USE OF BIODIVERSITY: BIODIVERSITY PROSPECTING

Biodiversity prospecting, or "bioprospecting", was first defined by Reid *et al.* (1993) as: "the exploration of biodiversity for commercially valuable genetic resources and biochemicals". It encompasses a wide range of commercial activities, including the pharmaceutical, biotechnology, seed, crop protection, horticulture, botanical medicine, cosmetic and personal care, and food and beverage sectors.

The most dramatic example of a forest tree species holding commercial potential, and the associated challenges to conservation and sustainable use, is the Pacific yew, *Taxus brevifolia*, whose bark yields the cancer drug taxol. Developed from collections made in 1962 as part of the United States National Cancer Institute's research programme, taxol, marketed by Bristol-Myers Squibb Co. under the brand name Paclitaxel, has been one of the top selling drugs in recent years; in 1998 worldwide sales were US\$1.2 billion (*Med Ad News*, 1999). Wild supplies in the tree's native range from northern California in the United States to British Columbia in Canada proved insufficient to support commercial production. However, public concerns about the sustainability of *Taxus brevifolia* supply were counterbalanced by concerns that limiting wild harvest of *T. brevifolia* could restrict access to an important life-saving drug. Methods to convert the taxol precursor compound baccatin from *Taxus baccata* were developed in France, and today raw material sourcing for taxol is based in Europe (ten Kate and Laird, 1999).



**Commercial use of biodiversity presents challenges to conservation and sustainable use; for**

**example, *Pausinystalia johimbe* trees are unsustainably harvested throughout Central Africa for sale of their bark to the international pharmaceutical industry** - T.C.H. SUNDERLAND

There is considerable variation within and among the different industry sectors that use genetic resources. Differences include the following:

- **Size of industries and markets for products.** The global market for pharmaceuticals is more than US\$300 billion a year, while sales in the botanical medicine industry are not much more than US\$20 billion, and those of ornamental horticultural products lie between US\$16 billion and \$19 billion. The cosmetic and personal care industry has annual sales between US\$50 billion and \$75 billion a year (depending upon classification of companies), although the "natural" component of this industry is not more than US\$3 billion (ten Kate and Laird, 1999).
- **Share of natural products in these markets.** In the pharmaceutical industry, natural products contribute somewhere between 25 and 50 percent of total sales of products on the market (Newman and Laird, 1999). Commercial botanical medicines, ornamental horticultural products and agricultural seeds are 100 percent natural products. "Natural" personal care and cosmetic products make up less than 10 percent of global sales in this sector today.
- **Relationship between commercial products and the genetic resources from which they are developed.** In the pharmaceutical and crop protection industries, for example, commercial products might be chemically identical to the pure natural product, might derive from chemical modification of a natural product, or might be synthesized to a design based on a parent structure that comes from nature (Newman and Laird, 1999).
- **Use of traditional knowledge in research and development.** Most commercial sectors involved in biodiversity prospecting today have their roots in traditional knowledge systems - that is, histories of traditional management and improvement of food and medicinal species dating back hundreds of years, and complex cultural relationships between people and the natural world. For example, of the approximately 120 pharmaceutical products derived from plants in 1985, 75 percent were discovered through the study of their traditional medical use (Farnsworth *et al.*, 1985). However, some sectors - the horticulture, seed and biotechnology industries, for example - appear to make little direct use of traditional knowledge in their research and development (R&D) programmes today; companies do not conduct field ethnobotanical collections and only rarely, if ever, use traditional knowledge gathered from second-hand sources such as literature (ten Kate and Laird, 1999). In the botanical medicine, cosmetics and personal care, pharmaceutical and crop protection sectors, a few ethnobotanical collecting programmes supply commercial companies, but the movement of traditional knowledge to the private sector takes place primarily through publication of academic research results in literature and databases (Laird *et al.*, 2001).



***Most commercial sectors involved in biodiversity prospecting have their roots in traditional knowledge systems; pictured, a seller of medicinal plants in Bata, Equatorial Guinea - S.A. LAIRD***

## **TRENDS INFLUENCING THE DEVELOPMENT AND IMPLEMENTATION OF ACCESS AND BENEFIT-SHARING PROVISIONS OF THE CBD**

The CBD deals with biodiversity research and prospecting issues in a number of ways. Article 15 establishes the sovereign rights of States over their natural resources and encourages Parties to the Convention to facilitate access to genetic resources. Access, where granted, must be on mutually agreed terms, subject to the prior informed consent of the Party supplying resources, with the aim of sharing in a fair and equitable way the results of R&D and the benefits arising from commercial and other utilization of genetic resources. Article 16 encourages the transfer of technology to countries that provide access to genetic resources. Article 19 promotes the effective participation by providers of genetic resources in biotechnological research on the genetic resources they provide. Article 8j addresses traditional knowledge and promotes wider application of the knowledge, innovations and practices of indigenous and local communities, with their approval and involvement, and encourages the equitable sharing of benefits arising from this use or application.

The design of the CBD was influenced by a range of trends in the conservation, development and research communities, including recognition of links between sustainable development and conservation; awareness of the need to involve a range of stakeholders in resource management decision-making processes; and moves to ensure that indigenous peoples and local communities provide prior informed consent and receive benefits from these activities.

The development and implementation of the CBD is also influenced by trends outside the traditional domain of forest and biodiversity conservation, as described in the following paragraphs.

## **INCREASED SCIENTIFIC AND TECHNOLOGICAL CAPACITY FOR STUDYING AND USING GENETIC RESOURCES**

Scientific and technological advances in fields that make use of biodiversity (and in some cases traditional knowledge), such as biology, chemistry, genomics and information

technology, are rapid and have changed the way natural products are used in R&D. At the same time, new technologies such as combinatorial chemistry, ultra-high throughput screening and laboratories on a chip have dramatically accelerated the pace of R&D, including that on natural products (ten Kate and Laird, 1999).

### Increased globalization, strategic partnerships, and consolidation within the private sector

Within and across commercial sectors, companies are entering into partnerships that allow them to participate in increasingly specialized research. As a result of the increased fragmentation and specialization associated with biodiversity prospecting, no one individual or group tends to hold all the necessary technological infrastructure or expertise. Globally, complex networks of collaboration and partnership have become the norm (ten Kate and Laird, 1999). Partners to commercial companies are often academic research institutions, and one result of the trend towards collaboration and out-sourcing is increased blurring of the divide between academic and commercial research.

At the same time, many companies are consolidated through mergers and acquisitions, and lines between sectors are blurring as companies seek cross-sector synergies to develop new knowledge and novel products. Large life science companies now often combine pharmaceutical, food, seed and chemical divisions under one umbrella (Mytelka, 1999; Nayak, 1999). One result of increased consolidation is that already large companies become even larger, and corporate revenues dwarf the gross domestic product (GDP) of countries from which they seek to obtain genetic resources (Table 1). This has led to wariness on the part of high-biodiversity countries that cannot muster the same resources to negotiate and monitor partnerships.

Country (GDP ranking)/company	GDP	Health care revenue	Pharmaceutical sales
United States (1)	8 083 400		
Japan (2)	4 706 877		
Germany (3)	2 128 903		
China (7)	962 389		
Brazil (8)	808 147		
Australia (14)	390 493		
South Africa (34)	129 803		
Malaysia (40)	97 240		
Bangladesh (62)	31 359		
Merck & Co (USA)		23 637	13 282
Johnson & Johnson (USA)		22 629	7 696
Ecuador (64)	19 428		
Novartis Group (Switzerland)		16 377	9 7327
Sri Lanka (75)	15 139		
Bristol-Myers Squibb (USA)		14 996	9 932
American Home Products (USA)		14 485	11 076
Glaxo Wellcome Plc (UK)		13 087	13 087
SmithKline Beecham Plc (UK)		12 784	7 498
Pfizer Inc. (USA)		12 504	9 239

Costa Rica (77)	12 067		
Côte d'Ivoire (81)	10 453		
Cameroon (86)	9 247		
Fiji (132)	2 183		
Guyana (160)	695		
<i>Sources: Med Ad News, 1998; Euromonitor, 1998.</i>			

### Privatization of biological resources through expanded intellectual property rights

The patent system - paralleling scientific and technological advances - has undergone a process of regulatory globalization and harmonization, and the scope of what is regarded as patentable has "quietly expanded" (Drahos, 1999). In recent years, patent offices have begun to issue patents for the discovery of information already existing in the natural world, such as the genetic sequences of living organisms, and for plants, animals and microorganisms containing genes that have been modified in the laboratory. The Agreement on Trade-Related Intellectual Property Rights of the World Trade Organization (WTO) has incorporated these tendencies. This trend has led to concerns associated with increased privatization of the natural world, inequitable ownership of resources and knowledge, and appropriation of developing country resources and traditional knowledge systems by private corporations (Dutfield, 1999; Shiva, 1998; Ekpere, 1999).

### NATIONAL ACCESS AND BENEFIT-SHARING MEASURES

The CBD, as a framework convention, lays out legally binding objectives and overall obligations and rights of parties, but specific activities are regulated by protocols to the convention or other instruments such as national law. Access and benefit-sharing legislation developed to date can be grouped into five categories (Glowka, 1998): environmental framework laws; sustainable development, nature conservation or biodiversity laws; dedicated stand-alone national laws and decrees on access to genetic resources; modification of existing laws and regulations; and regional measures (Table 2).

<b>ABS legislative strategy options</b>	<b>Selected countries pursuing these options</b>
General Environmental Framework Laws (which only enable future legislation on access and benefit-sharing)	Gambia, Kenya, Malawi, Republic of Korea, Uganda
Framework sustainable development, nature conservation or biodiversity laws (which establish some access and benefit-sharing principles but require further legislation)	Costa Rica, Eritrea, Fiji, Mexico, Peru
Specific, stand-alone national laws or executive orders regulating access to genetic resources	Philippines and, at the state level, Sarawak (Malaysia)
Modification of existing laws and regulations - such as those governing wildlife, national parks, forestry and fisheries - to include access and benefit-sharing provisions	Nigeria, Malaysia and, at the state level, Western Australia (Australia)
Regional framework legislation (establishing common principles and procedures but requiring follow-up national legislation)	The countries of the Andean Pact (Bolivia, Colombia, Ecuador, Peru and Venezuela); also under discussion by countries of the Association of Southeast Asian Nations (ASEAN) and the Organization of African Unity (OAU)
<i>Source: Barber, Glowka and La Vina, 2001, based on Glowka, 1998.</i>	

Cases in which particular species showed commercial promise have helped to spur development of access and benefit-sharing measures in many countries. For example,

random collections in the 1980s of the biologically diverse flora of the forest of Korup National Park in Cameroon produced a number of interesting leads, most strikingly the anti-HIV compound michellamine-B, derived from the forest liana *Ancistrocladus korupensis*. Although research on this compound is now stalled because of its toxicity, it showed tremendous promise in the United States National Cancer Institute's research programme for many years. The apparent commercial potential of *A. korupensis* influenced Cameroon's 1994 Law Regulating Forestry, Wildlife and Fisheries and the 1996 Framework Law on the Environment, which include provisions asserting national sovereignty over genetic resources and requiring prior informed consent and benefit-sharing from any commercial use of Cameroon's genetic resources. As a result of this case, a Prime Ministerial Committee was formed to address issues relating to medicinal plant commercialization, and widespread public attention was paid to the benefits that Cameroon would receive as a result of research on its biodiversity (Laird, Cunningham and Lisinge, 2000).



**Leaves of *Ancistrocladus korupensis* drying in the sun at Korup National Park, Cameroon, in preparation for shipping to the United States National Cancer Institute for drug development - S.A. LAIRD**

Similarly, the adoption of the Sarawak Biodiversity Ordinance in 1998 arose partly in response to awareness raised by the case of *Calophyllum lanigerum*, collected from forests in Sarawak, Malaysia in 1987 by botanists from the Sarawak State Forestry Department and a United States university. When this species yielded the anti-HIV compounds (+)-Calanolide A and (-)-Calanolide B, an agreement was signed between the Sarawak State Government and the United States National Cancer Institute. In 1996 the United States company Medichem Research and the Sarawak Government formed a joint venture to carry through the clinical development of these compounds, to facilitate investigation of other drug candidates from Sarawak's forests and to train Malaysian scientists (ten Kate and Laird, 1999). Although no commercial products have emerged from the joint venture to date, the case indirectly led to the development of the new ordinance, which established a new legal and administrative structure for access and benefit-sharing - including the creation of the Sarawak Biodiversity Council,

which has the power to regulate access, collection, research, experiment, protection and utilization of Sarawak's biodiversity, including the removal of any of the biodiversity from the state.



**Researchers, government representatives, NGOs and others meet at Limbe Botanic Garden, Cameroon, to discuss *Ancistrocladus korupensis* (growing in the foreground) and issues relating to commercialization of medicinal plants and the benefits that Cameroon would receive - S.A. LAIRD**

National access and benefit-sharing measures have advanced complex issues and trends, but have regularly encountered difficulties. A common problem has been a shortage of expertise and understanding within governments and NGOs of the industries they hope to regulate through these measures. In order to draft effective access and benefit-sharing measures, governments must have information available on the scientific, technological and marketing profile of each industry. They must understand how best to maximize benefits through partnerships. They must be familiar with biodiversity contracts and how they can reflect best practices to date, and with innovative ways of sharing financial benefits through mechanisms such as trust funds.

Addressing access and benefit-sharing issues requires an empirical and flexible approach. For example, the Philippines pioneered the first comprehensive access and benefit-sharing measure, and has subsequently adapted and adjusted the national regulations in light of practical experience. In May 1995, following a process of national consultation, Executive Order No. 247 "Prescribing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-Products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes" was signed by President Fidel V. Ramos. In June 1996, Department Administrative Order No. 96-20, "Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources" was issued by the Department of Environment and Natural Resources. The Executive Order requires anyone seeking access to genetic resources to conclude either an Academic Research Agreement or a Commercial Research Agreement with the Government (Barber, Glowka and La Vina, 2001). Representatives of the pharmaceutical industry and many academic researchers found the Executive Order and Implementing Rules and Regulations to be overly bureaucratic and costly in practice, and companies criticized a requirement to license technology to the Philippines. In response, the government is redesigning administrative and other elements of the regulation to ensure it does not act as a direct disincentive to research.

The following are some of the central lessons offered by the experience of implementing an



access and benefit-sharing measure in the Philippines (Barber, Glowka and La Vina, 2001).

- Stakeholder participation is essential in developing, enacting and implementing access and benefit-sharing policies, laws, rules and regulations.
- Defining the scope and coverage of a national access and benefit-sharing regulation is a priority concern.
- The potential impacts on scientific research activities must be carefully considered in designing and implementing national access and benefit-sharing measures.
- Creative approaches to obtaining consent from and sharing benefits with local communities, including indigenous peoples, need to be explored and developed.
- An efficient and effective institutional system should be put into place to implement the measure.
- Executive orders, rather than legislative acts, can be useful as a way of exploring and testing approaches to regulating access and benefit-sharing, but they are also inadequate.
- In regions where countries share genetic resources, national frameworks alone are inadequate and regional mechanisms may be required.

Reported changes in industry practice in response to the CBD and national access and benefit-sharing measures include: a decrease in collecting activities, consolidated in fewer countries where laws and procedures are clear and efficient, and an increased focus on domestic collection; greater recourse to material held in *ex situ* collections; an increased reliance on intermediaries as brokers of access and benefit-sharing relationships, as well as suppliers of samples; and the increased use of material transfer agreements to clarify terms of partnerships (ten Kate and Laird, 1999).

## PROTECTED AREAS AND ACCESS AND BENEFIT-SHARING

Protected area managers are increasingly confronted with access and benefit-sharing issues resulting from the commercial implications of collections made within protected areas, as in the case of *Ancistrocladus korupensis* in the Korup National Park in Cameroon discussed in the previous section. Protected area managers are also seeking innovative partnerships with companies and researchers to supplement declining or chronically inadequate budgets. For example, the National Institute of Biodiversity (INBio) in Costa Rica conducts collections in protected areas through commercial partnerships with companies such as Diversa and Bristol-Myers Squibb (United States), Givaudane Roure (Switzerland-United States), Indena (Italy), Analyticon (Germany), La Pacifica (Costa Rica) and the British Technology Group (United Kingdom) as a way to fund biodiversity research, conservation and support for the national system of Conservation Areas. INBio was established by the Ministry of Environment and Energy as a private non-profit organization to help conserve, study and use the country's biological diversity. As laid out in a cooperation agreement between the Ministry and INBio, INBio will provide roughly 10 percent of the total annual budget of any project to the country's Conservation Areas, and 50 percent of any financial benefits from commercial product development resulting from collections in protected areas. As of 1999, INBio's biodiversity prospecting agreements had yielded more than US\$390 000 to the Ministry, US\$710 000 to Conservation Areas and US\$710 000 to public universities, as well as US\$740 000 to cover INBio activities, particularly the national biodiversity inventory (ten Kate and Laird, 1999).

In another example, the enzyme DNA polymerase (Taq polymerase) was obtained from a thermophile named *Thermus aquaticus* collected under a no-obligation scientific research permit in 1966, in thermal pools in Yellowstone National Park in the United States. This enzyme is used in a wide range of biotechnological applications and generates annual sales greater than US\$200 million (Lindstrom, 1997). In contrast, the annual operating budget of the United States National Park Service is around US\$20 million. This experience led the United States National Park Service to examine options for controlling access to resources and requiring benefit-sharing, and resulted in the 1997 Cooperative Research and Development Agreement between Diversa Corporation and Yellowstone. Under this agreement, Diversa will provide the park with up-front financial payments, equipment, training and royalties should a commercial product be developed using park resources (ten Kate, Touche and Collis, 1998; Chester, 1996). However, watchdog groups were concerned that the public was not consulted,

the details of the agreement remained confidential and the potential environmental impacts of collections were not known (Smith, 1999). As with national legislation, working out the details of new access and benefit-sharing partnerships between companies and conservation institutions will require transparent public consultations and flexible, innovative approaches.

## BIODIVERSITY RESEARCH AND THE CBD

The CBD and national access and benefit-sharing measures regulate both academic and commercial research. Indeed, distinctions between the two are increasingly blurred. Academic researchers often undertake contracts for companies, and academic data flow to the private sector through publications and databases. As a result, it is important for both academic and commercial researchers to ensure that the manner and terms under which all research takes place are equitable for local groups. There remains a need to instill in the academic community - which sets the standards for most research - an appreciation of the new ethical and legal envelope within which research takes place, and of new demands that biodiversity research should contribute concretely to wider social and conservation objectives while furthering scientific understanding (Alexiades and Laird, 2001; Orr, 1999; Greaves, 1994; Farnsworth and Rosovsky, 1993).

In addition to international and national-level policy and law, access and benefit-sharing policies are being developed for research institutions, and professional research groups are developing codes of ethics and research guidelines that incorporate the objectives of the CBD. Examples of institutional policies include the University of South Pacific *Guidelines for biodiversity research and bioprospecting*, the Limbe Botanic Garden in Cameroon's *Policy on access and benefit-sharing*, and the *Common policy guidelines to assist in the preparation of institutional policies based on the "Principles on Access to Genetic Resources and Benefit-Sharing for Participating Institutions"* developed by a consortium of botanic gardens and research institutions. Codes of ethics, research guidelines and other documents that address issues related to access and benefit-sharing and respect for traditional resource rights include those of the International Society of Ethnobiology, the Society of Economic Botany, the American Society of Pharmacognosy, the American Anthropological Association and the Asian Symposium on Medicinal Plants.

## CONCLUSION

The Convention on Biological Diversity has provided an invaluable forum for the exchange of ideas and promotion of agendas that have received limited governmental attention elsewhere. In the area of access and benefit-sharing these include traditional resource rights, concepts of equity in the trade and exchange of genetic resources, prior informed consent from local communities and broader issues raised by relationships among companies, researchers and local groups. Many of these concerns are manifested at the unique intersection of environmental, trade and ethical issues in the CBD. However, access and benefit-sharing is in some ways a new package of policy issues, and will require many years of local, national and international innovation, dialogue and trial and error to implement effectively in practice.

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