

Valuing Local Knowledge

Indigenous
People
and
Intellectual
Property
Rights

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Chapter 14

Agreements to Collect Biodiversity for Pharmaceutical Research: Major Issues and Proposed Principles¹

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The entry into force of the United Nations Convention on Biological Diversity opened the door to bilateral and multilateral agreements becoming an internationally accepted means of negotiating access to and benefits from use of genetic resources. While providing an international statutory framework for assuring the equitable sharing of benefits, the convention provides no concrete direction for implementing this important provision.

In this chapter, the authors describe several international partnerships that seek to combine biodiversity conservation, sustainable development, and drug discovery. They present a set of legal and ethical guidelines to be followed in the negotiation of agreements leading to these partnerships, specifically with respect to the equitable distribution of benefits.—Eds.

In this chapter, we offer a checklist of proposed principles for the negotiation and formation of "biodiversity-collecting agreements," defined as agreements to collect samples of plants, animals, fungi, and microorganisms, to use them in commercial pharmaceutical research and share in resulting benefits. In addition to proposing principles, the checklist also notes several issues that are likely to arise in negotiations and offers suggestions for how parties might deal with them.

These principles build on relevant law and legal and ethical analysis, combined with our practical experience from the formation of the five agreements

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governing the International Cooperative Biodiversity Groups (ICBG), which are consortiums of U.S. and developing-country institutions that have received funding under federal cooperative agreements to conduct pharmaceutical research on samples collected from biodiversity-rich ecosystems. Each of the ICBGs had to form an agreement governing the relations among its participants, including benefit-sharing arrangements, as a prerequisite for funding.

Biodiversity has had tremendous value for humanity as the source of products vital to life. The genetic and chemical information contained in the diverse species and varieties of living organisms—as well as cultural knowledge about that diversity—are the sources of a multitude of products, such as foods, medicines, and fibers. The international exchange of biodiversity as a source of such essential products also has a long history (Kloppenbun 1988).

The terms of this biodiversity trade are, however, being redefined. International law is evolving to reflect developing concepts of equitable benefit-sharing and sustainable use, particularly with the entry into force of the United Nations Convention on Biological Diversity (Biodiversity Convention) in December 1993. Meanwhile, as parties begin the gradual process of implementing the convention through international and national laws, governments and the private sector are exploring new ways of structuring markets, institutions, and transactions in this sector of commercial trade (Grifo 1995).

In the pharmaceutical sector, in particular, there are a growing number of complex collecting agreements. There is hope that under these agreements the countries and communities that provide biodiversity for commercial use will receive a larger share of the benefits than they did under past terms of trade. Thus, such agreements could stimulate sustainable development and encourage conservation.

To achieve these outcomes, agreements will have to meet some minimum standards for equitable benefit-sharing and sustainable use. For example, they should be designed to leave the host country and community with long-term benefits such as research and development infrastructure and the capacity to add value domestically to biodiversity. The goal of such agreements, like the goal of the Biodiversity Convention, should be to ensure that this biodiversity trade is not merely another typical commodities trade in which developing countries compete to offer raw materials at the lowest price and societies within those countries garner only a small part of the overall benefits from their use. In the long run, countries will probably be able to maintain minimum standards only if they make some version of them binding under international law, most likely negotiated under the auspices of the Biodiversity Convention.

We recognize that the standards suggested here are in a sense preliminary,

for at least two reasons. First, any agreement must be tailored to its particular circumstances, which can vary widely from case to case. In particular, indigenous cultures are highly diverse and will have a range of approaches to addressing issues.

Second, the field is evolving rapidly, as agreements proliferate and as concerned interests (such as indigenous peoples) come into contact with and more involved in debates on law and policy. Tomorrow's developments will no doubt supersede the best practice of today. In the meantime, if commercial firms move forward with sampling, they should meet relevant legal and ethical standards and should at least match if not surpass the best examples from current practice.

This checklist concerns the use of biodiversity for pharmaceutical research. With adaptations, however, many of its elements may be relevant to the sampling and analysis of biodiversity for other purposes, such as industrial products or plant biotechnology. The checklist is also designed to cover research with direct commercial applications, rather than pure scientific research. Nevertheless, the potential for indirect commercial application of pure research results is rapidly growing. Academic scientists and institutions should take these principles into account as they develop codes of conduct for research.

Legal Background

International transfer of biodiversity is now, for the most part, subject to the UN Convention on Biological Diversity, signed at the Earth Summit in Rio de Janeiro by over 150 nations in June 1992. As of August 1995, the convention had been ratified or acceded to by 126 countries, plus the European Economic Community (U.N. Environment Programme 1994).

One of the three objectives of the Convention on Biological Diversity is "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources." The convention uses the term genetic resources to refer to the genetic material found in biodiversity that has value—for instance, as a source of crop varieties or biotechnological products. In many cases, samples of diverse species that are analyzed for chemicals with pharmacological activity contain genetic material and thus come within the convention's definition of genetic resources (Downes 1995a).

The convention affirms that countries that provide genetic resources have the right to share in the benefits of their use, including benefits in the form of access to biotechnologies needed to utilize fully their genetic resources. Countries are obligated to make efforts to give other parties access to their

genetic resources for "environmentally sound uses," but they have the right to define the terms of access through national legislation. Countries may gain access to other countries' genetic resources only with prior informed consent, and on mutually agreed terms.

The convention integrates these terms of trade for genetic resources with numerous other obligations relating to the conservation and sustainable use of biodiversity. In addition to the stipulation that parties are required to take steps to open access only for environmentally sound uses, the convention requires all parties to adopt measures, as far as possible and as appropriate, to ensure that use of biological resources—which includes genetic resources—does not harm biodiversity.²

Also relevant is Article 8(j) of the convention, which requires parties to protect interests of local and indigenous communities. Parties must, as far as possible and as appropriate, take measures to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity."³ Parties must also "promote [the] wider application" of indigenous and local communities' knowledge, innovations, and practices that are relevant to sustainable use. In addition, article 8(j) also requires governments to ensure that this use is with indigenous and traditional communities' approval, and requires them to encourage fair sharing of benefits with those communities.

Traditional knowledge, innovations, and practices can be a valuable source of information on pharmaceutical uses of biodiversity, as indigenous and local communities frequently have detailed and extensive knowledge of medical and other qualities of local biota (Plotkin 1988; Reid et al. 1993; WRI et al. 1992). Where value can be derived from traditional knowledge about biodiversity, governments must guarantee the communities' right of prior approval of wider use of the knowledge when the government encourages it. Governments must also encourage equitable sharing of the benefits with those communities (Downes 1995a, 1995b).

This means that communities must have the right to allow access on their own terms—and they must have the right to forbid access altogether. Some communities may seek the legal right to make and enforce contracts with commercial firms for access to their resources. Others may object to commercialization, and they may forbid research or allow only not-for-profit research.

Before the convention came into force, genetic resources were "considered a 'common heritage' of humankind, exchanged freely among the countries of the world and owned by none" (Downes 1995a; see also Brush Chapter 7, this volume). The convention establishes a new regime in which countries con-

trol access to their genetic resources and are entitled to a share of the benefits from their use. The new regime reflects in part the concern of developing countries that they were "donating their wealth of genetic resources freely [to industrialized countries], but were receiving in return a disproportionately small share of the benefits from its use" (Downes 1995a).

The convention's basic principles reflect agreement among a rapidly growing majority of the international community. Yet countries have not worked out the practical details of how to implement the convention's benefit-sharing principles. Meanwhile the private sector's interest in commercial use of biodiversity is strong and growing. We hope in this chapter to articulate high standards of best practice that will educate involved groups, such as indigenous and local people and pharmaceutical companies, guide private sector behavior to ensure compliance with benefit-sharing principles, and, perhaps, influence future government regulation (and ultimately international standards).

The convention is not the only international law relevant to collecting agreements. In several tropical countries, the International Labour Organisation's Convention No. 169 Concerning Indigenous and Tribal Peoples requires parties to consult with indigenous people when considering exploitation of natural resources on their land, to respect their rights to participate, and to ensure benefit-sharing where possible (Downes et al. 1993).⁴ The Convention on International Trade in Endangered Species (CITES) restricts commercial trade of specimens of species listed as actually or potentially threatened by trade. International human rights laws may also be relevant (*Ibid.*)

Also relevant is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) signed at the close of the Uruguay round of talks in the General Agreement on Tariffs and Trade (GATT). Under the TRIPs Agreement, members of GATT's new administrative body, the World Trade Organisation, will have to provide specified protection for intellectual property rights (IPR), including patent protection for most newly invented pharmaceuticals. The interplay of the TRIPs Agreement with the Biodiversity Convention's provisions on IPR is yet to be resolved and could be the source of some controversy (Downes 1995b).

The International Cooperative Biodiversity Groups (ICBG) Program

In March 1991 the U.S. National Institutes of Health (NIH), the U.S. National Science Foundation, and the U.S. Agency for International Develop-

ment sponsored a conference on Drug Development, Biological Diversity, and Economic Growth (Schweitzer et al. 1991). In addition to the sponsoring agencies and government and technical experts from six developing countries richly endowed with biological diversity, participants included representatives from the pharmaceutical industry and experts in ethnobiology, traditional medicine, and intellectual property rights law. From their presentations and related workshop discussions there emerged an important set of general principles for collaboration on drug discovery.⁵

After the conference, the three agencies immediately began discussions and development of the ICBG program based on both these principles and the experience of relevant programs of all three agencies. In particular, the National Cooperative Drug Discovery Groups of the National Cancer Institute had already developed a letter of intent for the purpose of encouraging benefit-sharing with countries that provided natural sources of pharmaceuticals, which proved helpful. In June 1992 the three agencies signed a memorandum of understanding among themselves to commit funds and released a formal request for applications (RFA).

The June 1992 RFA invited applications for the establishment of International Cooperative Biodiversity Groups to address the interdependent issues of biodiversity conservation, sustained economic activity, and human health in terms of discovery of therapies for diseases of primary concern to both developed and developing countries. Potential applicants were encouraged to be creative in constructing multidisciplinary, multiinstitutional groups of developing country organizations and indigenous people and U.S. academic, NGO, and industry partners to address these goals.

The process for peer review of these applications in early 1993 was also multidisciplinary. Reviewers came from universities, museums, pharmaceutical companies, the World Bank, and environmental nonprofit groups; they had backgrounds in natural products chemistry, systematics, ecology, ethnobiology, law, and international development. In addition, the advisory board and program staff of the Fogarty International Center, the administrators of the program, and a technical advisory group made up of representatives of the three funding agencies also reviewed the proposals and participated in the selection process.

The agencies announced the award of five cooperative agreements in December 1993. Each award is five years in duration and has an annual budget of approximately \$450,000. Each ICBG constitutes a cooperative agreement between a primary investigator and the investigator's collaborators, and the U.S. Government. Cooperative agreements differ from grants and contracts in that sponsoring government agencies have substantial programmatic involvement in achieving their goals and objectives.

Program Goals

The goals of the International Cooperative Biodiversity Groups Program are:

- (1) to develop and implement innovative strategies for the conservation and sustainable management of biological diversity, through
- (2) screening of organisms for discovery of compounds active against both developing and developed country diseases, as well as agricultural and veterinary purposes, so as to lead to
- (3) sustainable economic activity in the form of sharing of the benefits.

The first goal, to conserve biological diversity, encompasses the creation of incentives for the preservation of intact habitat, the increase in the knowledge base upon which conservation activities are based, and the development of long-term ecological and economic strategies to ensure the sustainable harvesting of targeted organisms and conservation of habitat.

The second goal of discovery of pharmaceuticals from natural products includes the preparation of crude materials for testing, the isolation of active agents, and the preclinical evaluation of agents from natural sources to treat or prevent cancer, infectious diseases including AIDS, cardiovascular diseases, mental disorders, and other diseases.

Medical conditions of primary concern to developing countries are important components of every ICBG. It should be noted that studies required for the later stages of drug development (e.g., formulation development, classical toxicology, etc.) and the conduct of clinical trials are beyond the scope of this program.

The third goal is the promotion of economic activity in developing countries. Combined with the first goal of conservation, this goal in effect aims at sustainable development. The goal is carried out through the use of contractual mechanisms which ensure that equitable economic benefits from drug discoveries accrue to the country of origin, community, group, or organization which facilitated the discovery. These collecting agreements will be dealt with in more detail in later sections.

In addition to sharing of financial benefits, support for research training targeted toward the needs of the developing country, provided for in collecting agreements, helps fulfill this goal. Examples are short-term, laboratory, field, and degree-linked training in systematics, ethnobiology, ethnomedicine, chemistry, cell biology, biotechnology, or production methods and quality control in pharmaceutical development.

ICBGs assist in improving the scientific infrastructure within the participating developing countries. Infrastructure support includes assistance for

herbaria, museums, and laboratories; the supply of necessary equipment in these facilities; and the enhancement of collecting and screening capabilities in the host countries, as well as limited renovation of relevant existing facilities.

Overview of the Five Awards

This overview summarizes the activities underway in each of the five awards. It does not systematically review specifics of benefit-sharing and other provisions of the legal agreements, which are discussed in the Checklist section.

Biodiversity Utilization and Conservation in Tropical America (the Suriname ICBG)

In the Suriname ICBG, Virginia Polytechnic Institute and State University (VPI), Conservation International (CI), CI-Suriname, Missouri Botanical Garden (MBG), Bristol-Myers Squibb Pharmaceutical Research Institute (BMS), the National Herbarium of Suriname, and Bedrijf Geneesmiddelen Voorziening Suriname (BGVS) examine potential medicinal agents from the Surinamese rain forest and carry out a program of educational and extension activities throughout the country.

Extracts for screening are prepared by BGVS from collections of rain forest plants made by MBG and CI. Active compounds are identified by VPI from extracts which show promise. Data generated by the interactions of these diverse collaborators are used by MBG and CI to examine the rationale for ethnobotanical selection of plant material as a potential source of new medicines.

CI is responsible for the documentation of ethnobotanical usage of rain forest plants and has launched Shaman's Apprentice programs within the study villages to ensure that ethnobotanical knowledge is passed on to younger generations.⁶ To increase the economic value of the forest in the near future, research also focuses on the identification and development of nonmedicinal forest products which can be sustainably harvested in the short run. The project also works with urban Surinamese to build a conservation ethics in the urban population through training in conservation-focused field techniques and advanced surveying technologies.

Peruvian Medicinal Plant Sources of New Pharmaceuticals (the Peru ICBG)

The ICBG led by Dr. Walter Lewis at Washington University in St. Louis works to determine the health status of indigenous people in the tropical rain forests of the northeastern Andes of Peru, to identify traditional medicines

that they use to treat their illnesses, and to determine how comprehensively these medicinal plants keep them healthy. Washington University is collaborating with the Natural History Museum and the Cayetano University, both in Lima, Peru, and Missouri Botanical Garden and Monsanto Company in St. Louis.

Primary screens of rain forest plants are conducted to test for activity against respiratory and herpes viruses, pathogenic yeasts, and tuberculosis. Researchers identify and investigate the cultivation of those medicinal plants needed in research development and for local commercial use. Use of heavily disturbed lands and sustainable and environmentally friendly cultivation methods are designed to reduce demand on forests for the supply of these important plants. Other activities are to collect, identify, and curate specimens of plants and selected groups of animals, in order to characterize the species richness of the northeastern Andean slopes of Peru.

Chemical Prospecting in a Costa Rican Conservation Area (the Costa Rica ICBG)

Cornell University, in cooperation with the Instituto Nacional de Biodiversidad (INBio) of Costa Rica and Bristol-Myers Squibb Pharmaceutical Research Institute (BMS), is examining tropical insects and other invertebrates as potential sources of new drugs against a wide range of diseases. The INBio team coordinates the collection of biological materials from the Guanacaste Conservation Area, a dry tropical forest in northwestern Costa Rica.

INBio, a nonprofit organization devoted to the goal of conserving and developing Costa Rica's biologically diverse national conservation areas through sustainable use, trains Costa Ricans to conduct field and drug-discovery studies on dry forest insects and other invertebrates. INBio scientists prepare extracts from biological materials and, in collaboration with the University of Costa Rica, carry out an antimalarial screening program. The Cornell components encompass research and training for Costa Ricans in the fields of chemical ecology and chemistry. BMS screens over a broad range of biological activities, including anticancer, antiinfective, cardiovascular, central nervous system, and dermatologically active medicinal compounds.

Drug Development and Biodiversity Conservation in Africa (Cameroon ICBG)

The Walter Reed Army Institute of Research, in cooperation with the University of Yaounde, Cameroon, the Smithsonian Institution, the Biodiversity Support Program (a consortium of the World Wildlife Fund, Nature Conservancy, and World Resources Institute), and Shaman Pharmaceuticals, is exploring the second-largest, continuous, moist tropical forest in the world, in

Cameroon and Nigeria, as a source of new molecular leads for drug development and as an important economic resource for communities inhabiting the area. Data from field ethnobotanical and ethnomedical studies, plus existing chemotaxonomic and pharmacologic publications, are used to generate prioritized lists of plants for drug-discovery investigation.

This approach is supplemented by random mass screens to evaluate a large quantity of additional biological samples. Extracts of natural products are evaluated for use against malaria, leishmaniasis, African sleeping sickness, and trichomonad infections.

Smithsonian Institution scientists are installing a large-scale permanent forestry plot in the Korup National Park of Cameroon, for forest dynamics research. This provides assessment of the local abundance, distribution, and dynamics of trees and shrubs with medicinal properties and the feasibility of sustainable collection or harvest of these species from natural forest or the feasibility of their plantation cultivation. Training in tropical forest management is provided for Western African students and natural resource managers, both through organized courses and through participation in the installation of the forest plot.

Bioactive Agents from Dryland Plants of Latin America (CAM ICBG)

The objectives of this ICBG are to discover pharmaceuticals and crop-protection agents from plants of arid and semiarid ecosystems in three countries in Latin America—Chile, Argentina, and Mexico (CAM)—and to promote economic activity while conserving biological resources in these fragile environments. The University of Arizona is working with the Catholic University of Chile, the National University of Patagonia and the Institute of Biological Resources (INTA) in Argentina, the National University of Mexico (UNAM), and Louisiana State University, Purdue University, and the Medical and Agricultural Research Divisions of American Cyanamid Company in the United States.

Plants are collected from poorly known floristic areas in Chile, Argentina, and Mexico, with the highest priority given to plants that have a rich ethnobotanical background. Collections are evaluated for potential biomedical target applications, including disorders of the central nervous system, intermediary metabolism, and cardiovascular and gastrointestinal systems; allergies and inflammation; cancer; viruses; bacteria; and agricultural applications in crop protection and animal health. Commercial production of biologically active compounds as specialty cash crops is also a goal. Both Latin and North American graduate students and postdoctoral fellows are being trained in chemistry, as well as the growing, large-scale extraction and processing of plant materials.

Checklist

The following 'checklist for negotiating and drafting collecting agreements combines legal analysis and ethical principles with practical experience gained during the negotiation and performance of five ICBG agreements currently underway. These guidelines build upon principles elaborated by the authors (with advice from others) during and after the ICBG application and award process, and also draw on analysis and recommendations in other venues.

The legal agreements on collecting in the ICBG program are intended to ensure that equitable economic benefits from any discoveries accrue to the country of origin, community, group, or organization that provided the source material or facilitated its discovery. Thus, they are central to achieving the goal of the ICBG program. Benefit-sharing within an ICBG is not, however, limited to the terms of the agreement; many ICBG groups made commitments to additional benefit-sharing, in addition to that contained in the agreement itself. Compliance with those commitments is a condition of disbursement of future installments of award funds.

ICBG applicants were required to include draft agreements in their applications, to ensure early consideration of compensation issues. Awardees then finalized the negotiation of agreements before funds were released. The program distributed a draft set of principles to assist awardees. Negotiating and drafting these agreements was a pioneering effort for both the three agencies providing the funding and the awardees, most of whom had never before addressed these issues. Biodiversity contracting is an evolving field, and we very much welcome suggestions for improvement, as well as information on the experience of others with collecting agreements.

The checklist suggests duties for parties likely to be involved (especially those seeking commercial gain); it also offers practical suggestions for all parties on the negotiating process and various possible outcomes. To the extent that this checklist suggests duties or obligations, they are directed primarily toward those seeking access to genetic resources or to the potentially broader category of biodiversity as a source of commercially valuable information (whether chemical, genetic, or other). It is appropriate that access-seekers have the primary responsibility for following these principles, since they are seeking to acquire a resource that is held by others. In international transactions, the resource is within the sovereign territory of another country. Also, whether the resource is within or without the United States, it may be in the custody of a local or indigenous community, often in an area that the indigenous people have inhabited for generations.

The Negotiating Process

Defining Expectations

Early interactions among the parties, who generally have very different backgrounds and expectations, set the stage and become the basis for later relationships. Local and indigenous communities, in-country and international conservation organizations, research institutions, and pharmaceutical firms are only a few of the different types of players likely to be a part of these negotiations. Early acquaintance with the diverse agendas of partners is an important step. Each party, before beginning discussions, should review its relevant goals, needs, and desires for the content of the agreement, and should seek to develop reasonable expectations about the other parties. While this seems simple and obvious, many parties appear to find it difficult and may overlook it.

Parties to Negotiations

Local Communities. Local communities, especially indigenous communities, should always be consulted regarding access to biodiversity on or near lands that they inhabit or traditionally use, whether or not collection includes documentation of their knowledge. Access seekers must identify the legitimate representatives of these communities. This may be a difficult task, in light of the wide variety of political structures among the diverse societies that inhabit biodiversity-rich countries. Adding to the complexity, the community may change its representatives from time to time, sometimes during the course of negotiations. To identify and contact legitimate representatives, some ICBGs, including the Suriname and Cameroon, relied on long-term collaborations between U.S. researchers and local community members.

Source Country's Government. A country's government, under the Biodiversity Convention, has the right to insist on prior informed consent before permitting access to the country's genetic resources. Thus, in the countries that are parties to the convention, foreign access seekers must obtain consent from the government. Biodiversity sampling is a new field for many governments, and at present, ascertaining the proper agency with whom to negotiate can be a challenge. Jurisdiction may be divided among tribal, local, regional, and national authorities or various agencies at any or all of these levels. In the future, most governments are likely to designate with oversight authority.

Other Groups and Institutions. Conservation, environmental, and development groups active in the region to be sampled should be consulted if at all possible. Depending on the type of collecting, it could be appropriate to con-

sult with community organizations of farmers or users of an extractive reserve. Biological or social scientists active in the region might also help the access seeker learn the values, interests, needs, and cultural norms of local communities (relevant as explained later).

Public Notice and Consultation

Researchers in the process of negotiating access should make reasonable efforts to notify local communities in areas where sampling will take place. This could include speaking at town meetings, addressing village councils, posting written notice, publication in local newspapers, and use of other media appropriate to the cultural setting. Access seekers should also arrange to meet with community members to discuss their plans and provide at least a summary of the information disclosures that must be provided to community representatives, as well as answer any questions the community may have.

Several of the ICBGs gave notice to and consulted with the local public. For instance, the CAM and Peru ICBGs both held public meetings in local communities to discuss the ICBG activity.

Information Disclosures

Not only do governments in source countries have the right to require prior informed consent under the Biodiversity Convention, but access seekers must obtain approval of local and indigenous communities. Consent is meaningful only if it is based on full disclosure of all relevant information.

Because the cultural and economic gaps among parties may well be vast, it is often necessary to take steps to bridge the gaps and ensure that all parties operate from adequate information bases. One solution is the mediation, dissemination of information, and cooperation of both international and local nongovernmental organizations (NGO). In the long run, however, the best solution would seem to be to empower the communities themselves to evaluate potential agreements and negotiate their own terms. This will require education, outreach, possibly technical and legal assistance, and often clarification or modification in national laws (to enable indigenous people to make legal agreements) concerning access to local resources. NGOs should play an active role in this empowerment process by forming partnerships with interested indigenous organizations and developing pilot programs to guide governments and international agencies.

Negotiators should take great care to disclose all relevant information fully to all parties. These disclosures must be in language and terms understandable by all parties, with special care taken to be certain this is true for local and indigenous people. Disclosures should be in a language readily intelligible to the local people, preferably in their own language. Disclosures should cover the following points:

- (1) the nature, extent, and probability of possible results and benefits (both short- and long-term, and including economic and other types of benefits) in realistic terms;
- (2) the nature of the samples or information to be collected, including amounts for both initial and, if necessary, later recollection; also significant environmental impacts;
- (3) the planned use of information or samples, including, but not limited to, timing, nature, and authorship of publications; physical uses of materials (e.g., in screens, etc.); use as a lead to inventions covered by intellectual property rights; and the likely end products (e.g., treatments for certain types of diseases) and their possible derivatives.

The duty of disclosure and the need for consent go beyond compliance with existing laws. Nevertheless, proposed activities ought to conform to applicable national and local laws protecting indigenous land rights and governing business with indigenous people. Each ICBG will be required to submit written evidence of such consent and disclosure, in the form of a consent form signed by communities and other informants.⁷ Most ICBGs have already submitted such forms.

Consent

After full disclosure of relevant information, the next step is for source country governments and source communities to decide whether they wish to consent to sampling. If they do not, the access seeker must respect that decision.

Cooling-Off Period

Consumer protection laws in some developed countries provide that the consumer has a chance to change his or her mind for a specified period of time after signing certain types of agreements to purchase goods.⁸ Commercial sellers of household appliances and other expensive consumer goods sometimes use pressure sales tactics; the cooling-off period allows the consumer to read the fine print carefully, study terms that are often complex and unfamiliar, and reconsider his or her decision. By analogy, collecting agreements may be equally complex and unfamiliar to many of the parties. Designating a period of time for reconsideration of agreements would further help to ensure that all parties are certain that they have a satisfactory agreement, and reduce the chance that parties will seek to renegotiate terms of agreements in the future.

Nature and Contents of the Agreement

While it is too early to judge the overall success of any agreement, experience so far reinforces the need for the following basic elements.

Agreements should be in writing. Parties should make agreed-upon translations into all relevant languages, to help avoid the confusion that can result from different translations of a single original agreement. They should also designate a country of jurisdiction and in a legally appropriate manner consistent with contract law in that jurisdiction (Downes 1993).

In the best case, local and indigenous communities should be parties to the collecting agreement; that would reflect a process in which the community participated as a full partner in negotiations. While none of the ICBG agreements met this ideal standard, in most of them the ICBG negotiated an explicit written agreement with relevant communities.⁹ In the Peru and Cameroon cases, one of the members of the ICBG negotiated an agreement with one or more local indigenous communities or community members. The agreement among ICBG members then referenced that agreement—in other words, there was a set of two linked agreements. This approach presents a number of difficulties and is not recommended. Different agreements coming out of separate negotiations may be inconsistent. Where a party has no contractual agreement with another participant, it has no direct incentive to respond to that participant's concerns, creating enforcement problems. Finally, multiple sets of negotiations consume more time and energy.

Sharing of Benefits

Collecting agreements should arrange for distribution of benefits among all parties. In particular, the source community or communities should receive a share of the benefits. Sharing of benefits may take a variety of forms, including nonmonetary benefits as well as monetary compensation. For instance, the Biodiversity Convention indicates that sharing of benefits could include training; access to biotechnologies derived from genetic resources; sharing of results of research and development; and cooperation on scientific research.

Agreements should be drafted to ensure that providers of samples receive a share of the benefits where the resulting invention that is commercialized is the actual isolated product, or where the invention is a product structurally based on the isolated natural product, that is, wherever the natural product provides the lead for development of the invention. In all such cases, benefits must flow back to the in-country institution, local communities, and other entities designated by the source country government.

Benefits should also be shared from discoveries from organisms collected directly and from discoveries from all other organisms collected with these organisms. For example, the positive activity of an extract taken from a vascular plant might actually be due to an associated microorganism perhaps unknowingly collected at the same time. Agreements should be drafted to ensure that benefits and protections apply equally to any associated organism, as well as to the organism that was the intended subject of collection.

Immediate versus Contingent Compensation. Whatever the form of compensation, its timing needs to be considered with the needs of the parties in mind. That communities urgently need resources for basic needs, that there is an urgent need for immediate conservation incentives, and that it is possible that samples will lead to no major discoveries—all these facts argue for immediate compensation. Types of compensation that could begin to flow early on are training, equipment donations, initial payments, and payments for samples delivered. Providers generally will have to choose some balance between receiving immediate compensation, which they can receive regardless of whether samples are the basis of products, or taking a share of future benefits, which could give them larger benefits but puts them at risk of receiving nothing if none of the samples contributes to future products.

Distribution of Compensation. An equitable share of the benefits should go to all those who contribute to product development by providing either samples, information about samples, or information that helps lead to samples. Such contributors should if at all possible be parties to the agreement, and they should receive benefits in any case. Types of contributors may include research institutions, indigenous people, and local communities.

Economic benefits should flow back to the area in which the source sample was found. In most of the ICBGs, indigenous or local people within a reasonable geographic proximity were considered important recipients, and the ICBGs have sought to make them parties to agreements with at least some of the ICBG participants. Local benefits can serve as conservation incentives if the local people are made fully aware that the benefits result from the biodiversity in their area; access seekers can also seek to work with local communities to develop targets and structures for benefits that encourage conservation.

Monetary Compensation. Public attention has generally focused on monetary compensation such as fees for samples, up-front payments, and profit sharing through donation of a percentage of royalties from the sales of products. While monetary compensation should be part of any agreement, it is not the sole type of compensation that is available.

In addition, negotiators should keep in mind that arrangements for compensation should take into account power relations within the community or within households, including relations based on distinctions by gender or social status. Access seekers should develop an understanding of the cultural milieu and should be exceedingly cautious in negotiating compensation terms.

For example, payments into trust funds managed by community or joint community-project boards rather than cash payments to a single authority or individual may be more effective in support of conservation, and for admin-

istration of services like health or education. Several ICBGs have elected to set up trusts with local, regional, and sometimes international members, and with charters which outline funding priorities. Determining which arrangements might be best will demand discussion among all stakeholders and may still not fully address all their concerns.

Laird comments that in negotiating the amount of payments for samples, biodiversity providers should keep in mind that prices in the past have ranged from \$50 to \$250 per kilogram. Access seekers have paid as much \$1,500 for specific items. Extracts from collected organisms may be priced at \$200 or more for a 25-gram sample. The terms of innovative collecting agreements can, however, expand and enhance the overall package of services and information provided with samples, thus justifying higher prices (Laird 1993).

Traditional knowledge, for example, adds significant value to the package. Thus, several ICBG agreements provide for additional payments where the research and development process benefits from traditional knowledge. Market prices for traditional knowledge are, however, not well established.

Institutional stability of in-country partners is also valuable for access-seekers who may seek additional supplies of samples in the future. Similarly, systematic collection, organization, and storage of information relating to samples, including taxonomic identification, adds value. More generally, social and political stability in the source country is rewarding in that it makes the long-term supply of information and samples more reliable.

The market is not well established for royalties for shares of benefits from future discoveries based on samples. Agreements providing for such royalties are a relatively new phenomenon, and the royalty amounts in most such agreements have not been publicly disclosed. Consistent with this, parties to the ICBG agreements have not disclosed the price terms of their agreements.¹⁰ As a practical matter, parties have an interest in keeping those terms secret to the extent they anticipate making other similar agreements in the future, as their ability to negotiate stronger future deals is compromised if terms are made public.

Nonmonetary Compensation. Examples of nonmonetary compensation might include:

- (1) screening for therapeutic potential, particularly when the focus is on therapeutics for developing-country diseases which are normally ignored by developed-country pharmaceutical firms, and sharing of results with in-country institutions or communities;
- (2) providing training in relevant areas such as pharmacology, biochemistry, or taxonomy; and
- (3) equipment purchases and donations and other infrastructure development.

For instance, while the Suriname agreement itself does not provide for nonmonetary compensation, the ICBG funding will enable BGVS's acquisition of equipment for extracting plant samples, and BMS has agreed to transfer other laboratory equipment to BGVS. All of the ICBGs provide for training of in-country personnel.

Recognition and Acknowledgment. The acknowledgment of the contributions of local and indigenous people is another important form of nonmonetary compensation. At this stage, there is no academic standard for this type of citation. Nor do typical IPR systems require such acknowledgment in applications for patents. Nevertheless, access seekers should include appropriate attributions in publications, presentations, and other fora (Gupta 1994). Such measures are arguably required under article 8(j) of the Biodiversity Convention, which directs governments to ensure respect for indigenous traditional innovations (which can include genetic resources) and knowledge (Downes 1995a).

It is important to note that access seekers must ascertain the wishes of local and indigenous communities in this respect. Public acknowledgment should be done accordingly; in some cases communities may prefer that information or its source not be disclosed. In addition, access seekers should keep in mind that acknowledgment does not dispose of the obligation to share benefits, and communities may require sharing of other kinds of benefits as well.

Intellectual Property Rights (IPR). It is often presumed that protection of IPR through some legal mechanism is necessary for the dissemination and transfer of new findings through commercialization (Mays et al., this volume). Agreements ought to demonstrate an awareness of the different types of IPR available at different stages of product development and for different types of products. For instance, in research and development stages that are too early for patenting, trade secret protection may be applicable in some countries. Even at the end-product stage, patents may not be available (because they are not permitted for that type of product under national law, or because the product is a plant instead of an invention, or because the innovation is too incremental to count as a patentable invention).

Negotiators should be aware of alternatives such as trade-secret protection or petty patenting, if available. Finally, it is conceivable if not likely that the way in which traditional knowledge is related to the product could justify patent or trademark protection for some aspect of indigenous culture.

Currently, the laws of many developing countries do not permit patent protection for pharmaceuticals, as well as products in certain other economic sectors. This would be relevant if drug development or marketing is likely to be done in a developing country. Similarly, patent laws are not internation-

ally consistent in their treatment of the rights of the first applicant versus the discoverer of a patentable entity. Negotiators should be aware of these differences. Negotiators should also be aware that over the long term, intellectual property standards in many countries will probably be harmonized as countries belonging to the World Trade Organization (WTO, GATT's successor) phase in the requirements of the TRIPs Agreement (Downes 1995b).

If indigenous people's knowledge is involved in collecting, access seekers must make sure that they respect any indigenous concepts of intellectual property. They must disclose their plans, and if indigenous authorities object that sacred knowledge or substances should not be made public or should not be commercialized, they must respect those objections. So far, ICBGs have not reported that this issue has come up.

Research Results: Public Access versus Proprietary Information.

There may be a tension between the traditional scientific ethics of public access to information and the partners' desire for confidentiality of information, especially information with potential commercial value, pending protection through patenting.¹¹ In addition, providers of samples may wish to limit or condition access to the samples and related information, such as traditional knowledge, in order to ensure that commercial researchers share benefits from their use of those samples and information. Parties to agreements should explain to the providers of such knowledge and samples that it could be used more widely, and should ensure that their wishes regarding dissemination are respected. For instance, providers may prefer that information is disclosed only to certain parties, or only for certain uses, or only after certain periods of time, or only on specified terms such as sharing of resulting economic benefits or public acknowledgment of indigenous contributions. Agreements should specify how these issues are resolved.

All of the ICBG agreements provide that the pharmaceutical company partners have the exclusive right to use information obtained under the agreement, for a specified period of time. In some agreements, the local communities also have a similar right. Some agreements also specify that after the commercial partner's exclusive right expires, the ownership and control of samples and associated information returns to an institution or entity in the host country.

In all of the ICBGs, the arrangement is structured so that a public institution in the host country retains a full database of research findings. Certain categories of information are public, while others are limited-access; in particular, they are screened from the commercial partner in the ICBG, because the information might have commercial value. This is to ensure that any commercial user pays for value received in the form of information about biodiversity.

Other Issues

When contracts are made between a pharmaceutical company and other partners, providers should be sure to include methods for monitoring research and development to track drug leads derived from samples provided. For instance, they can require reporting from the pharmaceutical company on research and development activities and results.

Another sometimes-used approach is to provide samples with identification codes and only limited additional information. With existing technologies, if the user finds a sample especially interesting, it must request additional samples, which signals the provider that the sample may have special commercial potential.

While the coding technique has obvious benefits for the providing institution, the drawback is that the scientific name of the organism collected is often linked to a great deal of information that would streamline the drug-discovery process. In some ICBG groups, partners developed a strong sense of partnership, collaboration, and trust, and felt that they could forego this precaution. In others, with more of an arm's-length business relationship, non-commercial partners did not feel comfortable relinquishing the additional information, or chose to reveal it later in the drug development process.

Another significant issue is the amount of time a party is allowed exclusivity in the right to investigate a particular sample. Although for the most part the screens of the large pharmaceutical firms target very similar diseases, further evaluation of an extract might include exploration of its potential in veterinary medicine, agriculture, or other industry. Short periods of exclusivity could allow providers to expand their opportunities for investigation by seeking other partners more quickly if other parties to the agreement do not exhaust all possible screens. The contract should make clear the rights of all parties in the event that one party does not wish to pursue the development of a discovery.

A related issue is how to arrange for long-term storage and ownership of samples. Given the rapid improvements in screening technologies, samples may have commercial potential into the future for a growing range of uses. Parties should define future rights relating to samples over the long term.

Sustainability and Environmental Protection

Much of the discussion of collecting agreements has highlighted the potential for supporting *sustainable* commercial use of biodiversity-rich ecosystems. In the market economy as currently structured, the market will not give private actors such as those discussed here incentives to ensure conservation or sustainable use; and they will have no reason to build such factors into their agreements.

The impetus for conservation and sustainable use must come from outside the agreement itself. For example, it can come from an institutional commitment from at least one party to the agreement; that party can then insist that the transaction be structured to ensure sustainability. In the case of the ICBG program, the incentive for conservation and sustainability comes from the funder that made these goals part of the RFA and retains the power to cancel future funding installments if an ICBG does not comply with RFA guidelines. The funding agencies will monitor compliance by requiring annual reports and through occasional site visits.

Or the impetus can come from legal standards that apply to such agreements. Nations implementing the Biodiversity Convention must develop standards for such agreements that ensure sustainable use (as well as compliance with other principles of the convention already discussed). Many nations already have in place laws on conservation of wildlife, such as laws implementing CITES. Consistent with this, the RFA for the ICBG states that "all national and international regulations regarding collection and importation of organisms must be strictly adhered to. Assurance must be provided that all requisite permits from the relevant governments will be procured."

When awardees enter into agreements with public authorities for permission to collect within certain territories, these agreements should specify that activities will be done sustainably and in compliance with environmental laws. Although the initial sampling for analysis is unlikely to have significant environmental impact, later recollection may. And if a product is derived from a sample there is always the potential for commercial harvesting, and hence for overexploitation. Agreements include plans for continued supply of plant materials in a sustainable manner from signatory countries and sources whenever possible.

Renegotiation

No matter how carefully crafted, no agreement will anticipate all future issues, and parties may seek to reopen negotiations. In fact, this has already transpired with one ICBG. Parties may wish to renegotiate as the state of the art of benefit-sharing mechanisms evolves. In addition, even with rigorous attempts at creating a level playing field for all parties to negotiations, the relevant knowledge of one or more parties may increase, leading to a desire to renegotiate. Often the need to renegotiate can be minimized by keeping the duration of the agreement relatively short. This approach has, however, disadvantages; for instance, markets may change and indigenous people may not be able to negotiate as positive a return; or industrial partners may change their research priorities and no longer be interested in obtaining the materials subject to the agreement. Another alternative might be to craft agree-

ments such that they allow renegotiation of portions of the agreement without invalidating the entire agreement.

Conclusion

Biodiversity collecting agreements will not solve the biodiversity crisis, alleviate the complex of land tenure issues often at the root of the upheaval and loss of indigenous cultures, nor undo the scores of ills of international development. They may, however, be among the many important tools that can help address at least some of these problems.

Commercial investigation of biodiversity is proceeding. The Biodiversity Convention sets up a general framework for encouraging such commercial use as a means for promoting sustainable development and conservation; the convention is now in force as law for 102 nations, including nearly all biodiversity-rich countries. As commercial use proceeds, it is essential that arrangements for use are as equitable and sustainable as possible. Arrangements must be adapted to diverse cultural, geographic, economic, biological, and other circumstances. One of the great virtues of legal contracts is precisely their flexibility. It is for this reason that we have elected to provide guidance in the form of principles and suggestions rather than detailed standards or model agreements.

Notes

1. The opinions in this article are those of the authors and do not represent the views of their respective institutions.
2. Like most of the convention's conservation obligations, this one is qualified by the phrase "as far as possible and as appropriate." While this phrase gives countries flexibility, it does not give them complete discretion (Downes 1995a).
3. Article 8(j)'s obligation is "[s]ubject to [each party's] national legislation." As with other qualifying language, this phrase does not give the party complete discretion (Downes 1995a). Rather, this "caveat" makes clear that parties can maintain the general legal concepts and structures that they use to govern indigenous affairs, such as legal definitions of indigenous tribes (Chandler 1993).
4. The convention has been ratified by Bolivia, Colombia, Costa Rica, Mexico, Norway, and Paraguay, and entered into force in September 1991. Personal communication with International Labour Office, Washington, D.C., January 30, 1995.
5. Both Dr. Rodrigo Gamez, the director of the Costa Rican conservation organization INBio, and Dr. George Albers-Schonberg of the multinational pharmaceutical company Merck, Sharp and Dohme, made presentations at the conference. They did not, however, discuss the Merck-INBio agreement on biodiversity sampling for pharmaceutical research, which drew significant press attention after it was signed and

made public in September 1991, although they pointed out the potential benefits of collaboration between institutions such as INBio and industry. The Merck-INBio agreement and the development of the ICBG program were simultaneous but largely independent processes in the evolution of biodiversity sampling.

6. The local people are primarily Maroons, who are nonindigenous although they have lived in the area for generations.
7. There is currently a need for publication and exchange of examples of consent forms, since it is difficult to craft a document that covers the numerous and complex elements necessary for full disclosure in terms that are comprehensible in diverse cultural settings. For instance, access seekers must explain the range of possible future uses of the biodiversity and/or knowledge to be collected and the amount of possible economic benefits, such as revenues from product sales, without either understating or exaggerating the potential payoffs.
8. In the United States, for instance, federal law gives consumers a three-business-day "cooling-off" period when they purchase from a door-to-door salesperson (United States 1994).
9. In the Peru agreement, negotiations on draft agreements are continuing among researchers, local communities, and Monsanto. In the Costa Rica agreement, the ICBG participants determined that there were no local communities in the collection area.
10. While the contracts, on file with the National Institutes of Health, are public documents subject to the U.S. Freedom of Information Act (FOIA), FOIA exempts from disclosure certain commercially sensitive information, which is generally understood to include price terms in commercial contracts.
11. Note that in the United States the courts will protect as trade secret information that has competitive value, where companies take reasonable steps to conceal it.

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