The Global Biodiversity Institute/
International Institute of Tropical Agriculture

Training Course on Biodiversity, Biotechnology, and Law

1-24 March 2000
Ibadan, Nigeria

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GBDI/IITA Biodiversity, Biotechnology, and Law Training Course: West Africa
Introduction

The Biodiversity, Biotechnology, and Law Training Course for West Africa was organized by the Global Biodiversity Institute (GBDI) in association with the International Institute for Tropical Agriculture (IITA). Held at the IITA facility in Ibadan, Nigeria, from March 1-24, 2000, the training course for West Africa was the second in a series that started in East Africa in 1999. Some 50 scientists and lawyers from anglophone and francophone countries throughout the sub-region participated.

The course was divided into four modules. Module I provided an overview of "The Business of Biodiversity"; Module II took a detailed look at "The Fundamentals of Bioprospecting Negotiations" with an emphasis on equitable benefit sharing; Module III focused on "Managing Intellectual Property"; and Module IV concluded with an examination of "Biotechnology and Biosafety." For each module, experts in the relevant fields from around the world were brought in to serve as faculty members. Formal presentations were combined with interactive role-playing and working group sessions that emphasized application of the core concepts in realistic scenarios.

One of Africa's greatest strengths is the richness and diversity of its biological resources. Historically, raw materials from the continent have often been extracted for use in value-added industries in the North, with only minimal benefit for Africans. The main overall purpose of the GBDI training course is to help change this pattern, i.e., to equip Africans with the knowledge and skills necessary to leverage bio-resources for the benefit of source countries, for example by:

- ensuring conservation and sustainable use of the resources;
- protecting rights and access to resources for indigenous communities;
- negotiating equitable bioprospecting agreements that share benefits fairly among all stakeholders;
- raising awareness of key international treaties and agreements in legal and intellectual property areas;
- building capacity to develop value-added industries in Africa in areas such as pharmaceutical research and agricultural biotechnology; and
- developing appropriate legal, regulatory, and policy frameworks to enhance the enabling environment for the pursuit of these goals.

The training program takes a regional approach in order to promote interaction, sharing of experiences, and the harmonization of approaches toward solving a common problem. It tries to utilize existing sub-regional frameworks (such as ECOWAS--the Economic Community of West African States--in this case) and expand cooperative networks into other areas. The overriding philosophy is that if Africans do not develop the capacity to guide the use of biotechnology in Africa, somebody else will do it. Through inaction Africa risks a loss of control over use of genetic resources and products in its own communities. Africa must ultimately make its own decisions about what is or is not good for the continent with regard to biotechnology, and therefore must mobilize expertise, communications channels, and policy structures for the task. The course invites a thorough examination of the potential benefits of biotechnology as well as

the potential risks, emphasizing analysis of scientific merit as well as socioeconomic factors and competing values.

The West African training course was honored at the opening ceremony by a goodwill message from the Nigerian President, Chief Olusegun Obasanjo, delivered on his behalf by the Oyo State Governor, Alhaji Lam Adesina. President Obasanjo called for collaboration among African countries to protect biodiversity and harness its power to feed people and eradicate disease, emphasizing also the need to guard against health and environmental risks from biotechnology. The opening ceremony also featured an address by Chief Ebitimi Banigo, the Nigerian Minister of Science and Technology, who stressed that the loss of tropical biodiversity has become a major concern, and urged the introduction of appropriate legislation to protect Africa's genetic heritage from "international pilferage" and to protect Africa's farmers from being forced to rely on externally produced seeds.

By the conclusion of the training, participants had developed a plan to establish a network for the purpose of elucidating a regional approach to the key policy issues identified at the workshop. Known as the West African Biodiversity and Law Initiative (WABILNET), the network intends to expand its membership to include representatives who were unable to attend the workshop; to advise regional policymakers on these critical issues; to serve as an information clearinghouse through the development of a website; and to organize follow-up activities as appropriate. The American Association for the Advancement of Science (AAAS) Africa Program is currently working with WABILNET and GBDI to organize a follow-up workshop with high-level regional policymakers.

The text of this report draws from notes taken during the training workshop as well as from written materials prepared by the various faculty members, to whom we are indebted for their generous contributions of time, energy, and intellect. An evaluation of the course by the participants themselves follows at the end of the report. GBDI and IITA are also grateful to the US Agency for International Development (USAID), Monsanto, the International Service for National Agricultural Research (ISNAR), the World Intellectual Property Organization (WIPO), and the Nigerian Ministry for Science and Technology.

MODULE I:
The Business of Biodiversity

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INTRODUCTION

Module I introduced some of the basic concepts of the training course, reviewing the role of natural products in drug development and agriculture, detailing some of the most important business perspectives, and providing an overview of current market conditions. In addition, Module I outlined some of the major ethical questions and challenges involved in the potential conflict between exploitation of developing country genetic resources and equitable benefits sharing among indigenous stakeholders. Participants also broke into working groups and generated recommendations for priority setting and procedures related to formulating national, and ultimately regional, strategies for the sustainable utilization and leveraging of biological resources.

NATURAL PRODUCTS AND DRUG DISCOVERY

Plants have formed the basis for traditional medicinal systems for thousands of years, with the first records dating from about 2600 BC in Mesopotamia. They used oils from cedar and cypress, licorice, myrrh, and poppy juice, among other things--substances that are still in use today for the treatment of a variety of illnesses and infections. Ancient Egyptian, Chinese, and Indian documents show that medicine in these societies included numerous plant-based remedies and preventives. The Greeks and Arabs both contributed substantially to the assimilation, codification, and development of plant-based medicines. Today approximately 80 percent of the world's population relies on traditional plant-based medicines for primary health care.

The remaining 20 percent of the world's population also depends on plant products for health care. About 25 percent of prescription drugs dispensed in the United States contain plant extracts or active ingredients derived from plants. Out of a total of 520 new drugs approved for commercial use between 1983 and 1994, 30 were new natural products and 127 were chemically modified natural products. Some prominent plant-based medicines include:

- Quinine, the anti-malarial drug, from the bark of *Cinchona* species;
- Morphine, the analgesic, from the opium poppy;

- Digoxin, for heart disorders, from *Digitalis purpurea*;
- Reserpine, the antihypertensive agent, from *Rauwolfia serpentina*, traditionally used for snakebites and other ailments;
- Ephedrine, an anti-asthma agent, from Ephredra sinica; and
- Tubocurarine, the muscle relaxant, from *Chondrodendron* and *Curarea* species, used in the Amazon as the basis for the arrow poison curare.

Microorganisms have also been extremely important in drug applications, ushering in the "golden age of antibiotics":

- Anti-bacterial agents from *Penicillium* species;
- Immunosuppressants, such as the cyclosporins and rapamycin, from *Streptomyces* species;
- Cholesterol lowering agents, such as mevastatin and lovastatin, from *Penicillium* species;
- Anthelmintics and antiparasitic drugs, such as the ivermectins, from *Streptomyces* species; and
- A potential new antidiabetic agent from a *Pseudomassaria* fungal species found in the Congolese rainforest.

The world's oceans and marine organisms also represent a vast resource for new therapeutic agents, including:

- The pseudopterosins, with significant analgesic and anti-inflammatory properties, from the Caribbean gorgonian *Pseudopterogorgia elisabethae*;
- Manoalide, an anti-inflammatory agent, from the sponge *Luffarriella variabilis*; and
- Ziconotide and other new pain killers derived from peptides from cone snail venom.

Several key anti-cancer agents have been produced from natural sources; more than 60 percent of cancer drugs on the market are based at least in part on natural products:

- Vinblastine and vincristine were isolated from the Madagascar periwinkle, *Catharanthus rosesus*;
- Etoposide and teniposide are semi-synthetic derivatives of the natural product epipodophyllotoxin;
- Taxol was initially isolated from the bark of Taxus brevifolia in the northwestern United States; and
- Several clinically active agents have been derived from camptothecin, isolated from the Chinese ornamental tree *Camptotheca acuminata*.

Natural products should continue to be an important part of drug development well into the future. The sequencing of the human genome opens new territory in terms of our ability to identify the proteins expressed by genes associated with the onset of diseases. These proteins can be used as molecular targets for testing thousands of compounds, including natural products, in high throughput assays. Sequencing of the genomes of pathogens and parasites will also yield important clues about how best to control them.

Despite the great successes already achieved in natural products chemistry and drug development, we have barely begun to tap the potential of our molecular diversity. Only an estimated 5 to 15 percent of the 250,000 species of higher terrestrial plants in existence have been chemically and pharmacologically investigated in systematic fashion. The percentage of insects, marine organisms, and microbes investigated is far lower still. In the case of microbes, it is estimated that 95 to 99 percent of existing species are currently not even known, never mind analyzed.

There is currently great interest in exploring extreme habitats for useful enzymes from microbes, including acidophiles (from acidic sulfurous hot springs), alkalophiles (from alkaline lakes), halophiles (from salt lakes), thermophiles (from deep sea vents), and psychrophiles (from extremely cold waters).

Synthetic methods can complement natural products in the search for new drugs. For example, combinatorial biosynthesis creates the potential to generate novel molecules that enhance known bioactivity from natural products, and possibly to generate entirely new bioactivity through manipulation of biosynthetic pathways. Total synthesis of natural products, focusing on the synthesis and modification of drugs from natural sources that are difficult to isolate in sufficient quantities, can sometimes isolate and improve the essential active features of a natural product.

Acknowledging the importance of biological diversity for drug discovery and other uses, the Convention on Biological Diversity (CBD) affirms the rights of genetically rich source countries over their biological resources. As a result, organizations from the industrialized world involved in drug discovery and development now face increasing pressure to adopt policies of equitable collaboration and compensation. This issue is addressed in more detail below and in Module II.

DRUG DISCOVERY AND DEVELOPMENT

Pharmaceuticals are big business. The top 15 pharmaceutical companies generated over US$185 billion in drug sales in 1999. From the perspective of the pharmaceutical companies, there are intense performance pressures, including the need to increase output while cutting timelines and costs, the demand for lower prices from governments and managed care organizations, the need to build a critical mass in research and development (R&D) sufficient to keep pipelines flowing and competitive, and rising costs of enabling technologies for research, including genetic engineering, bioinformatics, and high-throughput screening. As a result, the industry has seen a recent wave of mergers and acquisitions, such as Monsanto joining with Pharmacia and Upjohn, or SmithKline joining with Glaxo, among others.

There are three basic stages to the drug discovery process:

- Basic Research and Feasibility Studies: Identifying promising leads, including from natural products, typically involving a team of some six people and taking 9 to 12 months.
- Programs: Identifying drag candidates, typically involving a team of 15 to 25 people and taking 1 to 3 years.
- Preclinical Studies: Identifying and testing new chemical entities, typically involving a team of 35 people or more and taking two to four years.

The whole discovery process typically takes six years or more and costs US$128 million or more. Following the discovery of a potential drug there is a development process that can be divided into four essential phases:

- Human Safety Assessment
- Demonstration of Efficacy
- Side Effects and Long-Term Use
- Post-Marketing Surveillance

The development process typically takes about six years and costs more than US$270 million. The time frame for a US Food and Drug Administration review of a new drug application is approximately two years. The entire drug discovery and development process therefore takes approximately 12 years and costs about US$400 million. The net revenues (gross sales minus production and marketing expense) for the average new drug amount to nearly US$3 billion over 25 years.

For every 10,000 to 20,000 compounds screened for possible activity in the basic research stage, about 250 will make it as far as pre-clinical testing; of those, five make it as far as clinical trials, and only one becomes an actual FDA-approved drug. US expenditures on pharmaceutical R&D have risen fromUS$2 billion in 1980 to US$24 billion in 1999. As a percentage of sales, R&D has risen from 11.9 percent in 1980 to 20.8 percent in 1999.

MARKET OVERVIEW

The market size for pharmaceuticals was US$320 billion in 1999, with an 8 to 12 percent annual growth rate in the major markets. R&D expenditures totaled more than US$40 billion (1997 figure), 12 percent of which was spent on synthesis and extraction, and 15 percent of which was spent on screening and preliminary evaluation. Less than one percent of these R&D expenditures was spent in non-OECD countries (i.e., developing countries). Leading firms include Glaxo-SmithKline, Aventis, Merck, Pfizer-Warner, Astra-Zeneca, Bristol-Myers, and Novartis.

Other markets related to genetic diversity include the following:

- Agrochemicals have a market size of about US$30 billion, with relatively slow growth. The market is highly regulated, with growing competition from transgenic crops in the major markets. R&D expenditures are approximately US$2.5 billion annually. Leading firms include Novartis, Bayer, Dow, BASF, and Dupont.

- Commercial seed sales amount to some US$30 billion per year, with R&D expenditures at approximately US$2 billion annually. Major firms include Dupont-Pioneer, Monsanto, Syngenta (formerly Novartis), Aventis, Dow Agro, Limagrain, and Seminis. Ex-situ collections (gene banks), both private and public, are the principal sources of genetic materials.

- Industrial enzymes have a market size of about US$1.5 billion, with a high growth potential, as products promise to replace synthetic industrial chemicals. Leading firms include Novo Nordisk Biotech, Genencor, Aventis, Roche Molecular, Diversa, Maxygen, and Dyax.

- Fragrances and flavors have a market size of some US$10 billion, growing annually at an average of 7.2 percent since 1992. This field has many opportunities for new product discovery, and high quality natural products can often command a premium market price.

- Herbals and botanicals have a market of nearly US$11 billion in the United States and Europe, with an annual growth rate of 16 to 18 percent in the United States. A few products dominate the market: garlic, echinacae, ginko bilboa, St. John's wort, and goldenseal. Leading US firms include American Home Products, Pharmavite, Leiner, East Earth Herbs, and Solgar; the top countries exporting to the US are India, China (mainland and Hong Kong), Germany, Mexico, Chile, Japan, Spain, Korea, and Brazil.

A number of factors affect the market for biological samples, in some ways limiting the potential for income generation through the exploitation of biological diversity. While biological diversity creates huge potential for discovery of new useful compounds, there are many sources of supply of raw samples. Biological samples also tend to be relatively expensive to collect and extract, and active compounds are expensive to isolate and replicate. Resupply is often seen as a problem, and there is increasing competition from other methods of development, including rational drug design, combinatorial chemistry, combinatorial biology, and biologics.

As a result of these factors, the price of biological samples is only slightly more than the average cost of collection, and profit is minimal from the samples alone. Prices for biological samples average around US$50 for 20 to 100 milligrams of extract.

In order to obtain significant benefits from biological resources, source countries must develop and market a unique set of biological, cultural, and technical resources in order to create greater opportunities for negotiating adequate compensation. This compensation should include measures to promote conservation, indigenous scientific and technical capacity, and sustainable development. Most bioprospecting agreements for raw samples include up-front payments, a small royalty rate (0.5 to 1.5 percent), and capacity-building (training and technology transfer).

ETHICAL AND LEGAL ISSUES

Biodiversity plays an important economic, social, and cultural role in the lives of many people, particularly indigenous and local communities. Preserving biodiversity in the face of a variety of well-documented encroachments is more than an aesthetic or strictly environmental concern; biodiversity is also a business. Agriculture, pharmaceuticals, forestry, fisheries, and tourism are all key areas that are heavily dependent upon biodiversity, attracting the attention of industry researchers and investors. Management of biological resources has a profound effect, for better or worse, on biodiversity and the ecological services that sustain life. Habitat destruction as a result of competing human needs has resulted in the loss of numerous plant and animal species, some known and others unknown. However, commercial interests can also play a role in preserving biodiversity.

The growing interaction and interdependence between local cultures and modern science in the sphere of biodiversity conservation and utilization raise both ethical and commercial questions. The pertinent issues are embodied in both the Convention on Biodiversity (CBD), which seeks to conserve biodiversity and protect community rights, and the World Trade Organization (WTO) agreement on Trade Related Aspects of Intellectual Property Rights (known as the TRIPS agreement), which emphasizes private property rights over community rights. There are substantive conflicts between the goals of TRIPS and those of the CBD (see Table 1), reflecting the lack of international consensus on these difficult questions of rights and equity.

There are few laws and regulations in force at present that have been explicitly enacted to govern access to genetic resources or to clarify the questions related to private versus community rights. Most countries face significant new challenges regarding administrative competencies and jurisdictions for regulating access to genetic resources, particularly given the partially conflicting directives of the major international treaties. Although CBD predates TRIPS, it is not clear which treaty takes precedence when conflicts occur; TRIPS has enforcement and penalty provisions, CBD does not, but both treaties have equal nominal authority. Thus the dearth of legal, institutional, and scientific capacity to deal with these complex biodiversity, trade, and property rights issues is exacerbated by the lack of clarity within the international policy framework.

Table 1. CBD vs. TRIPS	
Main CBD issues	❑ Conservation of biodiversity ❑ Sustainable use of its components ❑ Fair and equitable sharing of benefits on derived products ❑ Protection of traditional access to genetic resources and technology
Main TRIPS issues	❑ Reduce distortion and impediments to international trade ❑ Promote effective and adequate protection of intellectual property rights (IPR), including for plant varieties and other genetic innovations ❑ Ensure that measures and procedures to enforce IPR do not themselves become barriers to legitimate trade
Potential Conflicts	❑ TRIPS asserts IPR protection on life forms; CBD asserts national sovereignty and right to prohibit such protection ❑ CBD promotes equitably shared benefits from use of biological resources and protection of traditional knowledge; TRIPS promotes private appropriation of benefits with no mechanism for acknowledging role of traditional knowledge from which industrial applications may derive
Potential Resolutions	❑ Article 1 of TRIPS provides some flexibility, allowing domestic law to exceed minimum protection standards--a provision that could allow member nations to enact legislation to protect traditional knowledge ❑ Article 27.2 of TRIPS allows for the exclusion from patentability based on public order or morality ❑ Article 27.3b of TRIPS allows for the development of unique IPR protection systems for plants, animals, and essentially biological processes, creating an opportunity to develop alternative IPR regimes appropriate to the needs and conditions of traditional communities

In addition to sustainable utilization for conservation purposes, biodiversity management affects economic development, food security, and stakeholder issues such as access and property rights and the equitable sharing of benefits. In many cases the various issues and approaches have not been sufficiently articulated or integrated within countries, and government officials are poorly informed to set appropriate policies. The authoritative scope of different agencies and departments with regard to these issues is unclear, and adequate modalities for cooperation and coordination among agencies often do not exist. To make matters worse, a "turf mentality" is commonly exhibited by agencies, which compete with each other for power and resources more often than they seek ways to share them. The end result is a good deal of confusion about the issues and contradiction among policies.

Stakeholders include providers of biological resources, such as states and local communities, users of the resources, including scientific institutions, private sector firms, and again local communities, and other parties, such as nongovernmental organizations (NGOs) and keepers of ex situ genetic resource collections for conservation and research. The fundamental challenge of biodiversity management is to involve all these stakeholders in the policy process and to balance their needs and share benefits and responsibilities equitably.

A great deal of discussion, at the GBDI/IITA Training Course as well as in this field in general, focused on the issue of community rights in the context of increasing commercial interest in the biological resources of the developing world. Course faculty emphasized that any technical discussion on the protection of local community rights must:

- avoid being paternalistic in approach;
- consider first what is to be protected and why, e.g., the nature of the material and its ownership, who will protect it, and against whom protection will be enforced;
- ensure continuous dialogue with and genuine participation by communities; and
- facilitate increased awareness of the available mechanisms that current IPR systems may offer and possible new ways for the enhancement of such protection without compromising the core objectives of the CBD.

Of critical importance is the need for coordination and a regional approach, as there is strength in numbers; a united front for West Africa decreases the chances of anybody circumventing policies intended to benefit the countries of the region. Some general policy objections highlighted in Module I include:

- Options must not become closed and finite;
- Domestic capacities to assimilate transferred technology should be increased while also encouraging domestic innovative capacities;
- Acceptable sustainable solutions must be designed to respond to regional, national, and local conditions and involve full participation of all relevant stakeholders, including communities;
- The lure of protectionism should be balanced against the real needs for economic and technological improvement of local communities and developing countries as a whole.

WEST AFRICAN AGENDA

Discussion centered on how West Africa should proceed in order to protect its interests and participate effectively in the biological resources market, starting with the overall philosophical perspective. Three basic questions were identified as framing the assessment and action agenda process: Where are we now? Where do we want to go? How do we get there?

Participants also sketched out a process by which progress can be made in this area, consisting of six essential steps:

1) Set up a permanent, influential organizational structure comprising members from each key institution and involving NGOs and other stakeholders, e.g., a national steering committee charged with determining the status and direction of biological resources policy and coordinating the roles of the various agencies;

2) Review existing policies, strategies, and laws (including contract law, intellectual property rights, wildlife laws, and enforcement procedures) in order to determine the extent to which the current legal and policy framework addresses the pertinent challenges;

3) Assess existing bio-resources and knowledge (including plant, animal, and microbial resources, human resources, infrastructure and facilities, and financial and market resources) to understand better the strengths and weaknesses of the nation;

4) Formulate a policy regime for use of bio-resources, i.e., define institutional roles and responsibilities and set priorities, e.g., sustenance of the environment, commercialization/utilization of biological resources, local capacity-building, equitable benefit sharing, etc.;

5) Implement policies and laws, i.e., draft new laws and regulations as necessary, or revise/adapt existing legislation (including efforts to educate and sensitize all stakeholders to the issues and each others' needs, establish incentives and penalties, formulate specific projects, identify collaborators, and manage information); and

6) Periodically evaluate and review policies and overall strategy, ensuring the receipt of feedback from all stakeholders, with a particular emphasis on the overall socioeconomic effects of the policies.

GROUP BREAKOUT

The group broke into smaller groups to tackle the following mission: to formulate a strategic action plan for sustainable exploitation and development of biological resources and bioprospecting. Each group took on four key tasks:

- Identify the institutions that should be involved
- Outline a process for developing the strategy
- Identify basic components of the strategy and list their key elements
- Develop four early action items, capacity-building activities, or pilot projects

Each group came up with similar recommendations, based on prior discussions. There was a strong consensus that the steering committee should involve all stakeholders, including government ministries (e.g., science and technology, justice, planning, foreign affairs, agriculture, environment, trade, forestry, education, health) as well as private industry, NGOs, traditional healers associations, chambers of commerce, universities and research institutes, and representatives of local communities.

The groups determined that the process for developing a strategy should include consultations with stakeholders, synthesis of their input (seeking areas of common concern and trying to resolve any conflicts), identification of key objectives, development of an action plan with an articulation of specific programs and activities, creation of working groups and subcommittees, a review of the existing legal and political framework, and implementation, with a review on some regular basis, e.g., every three years. The basic components of the strategy, in support of this process, are a clear and sensible legal regime, political stability, a sound economic infrastructure, and the establishment of the national steering committee to coordinate the process.

Suggested early action items included (in no particular order): compiling an inventory of local bio-resources and creating a database; performing a review of the existing legal and political framework; engaging in community education/enlightenment campaign through seminars, workshops, community groups, etc; strengthening human resource capacity through training and technology transfer; initiating a foreign investment drive (ministry of commerce visits); and developing a sustainable utilization strategy for biological resources.

MODULE II:
THE FUNDAMENTALS OF BIOPROSPECTING NEGOTIATIONS
Constructing a Contractual Agreement for Benefit Sharing

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Nicolas Mateo, former director, INBIO, Costa Rica
Beatrice Chaytor, Foundation for International Environmental Law and Development, UK

INTRODUCTION

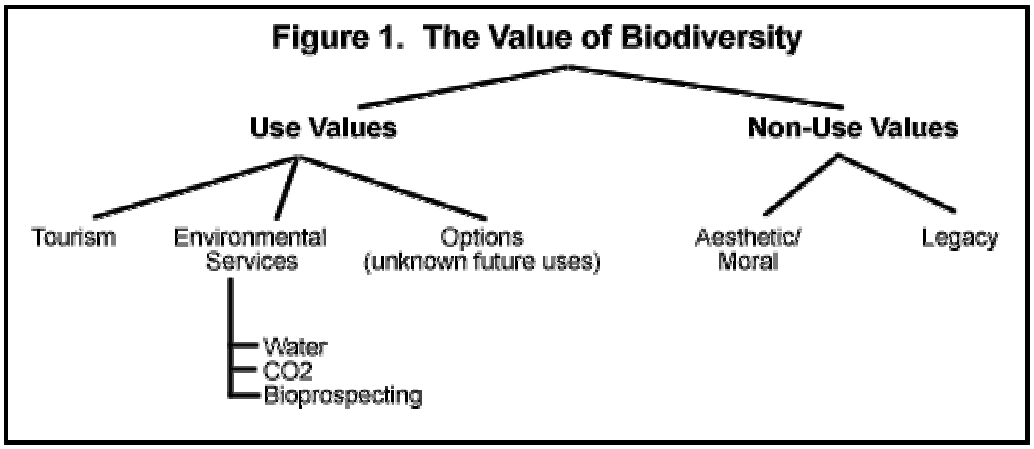
The term "bioprospecting" refers to the search for valuable compounds in nature, e.g., active molecules with the potential for use in drug development. Because of the enormous economic potential of drug development and its utilization of indigenous knowledge and resources, bioprospecting is a controversial area for which legal and ethical principles have not yet been fully explicated. Stakeholders include pharmaceutical companies, university researchers, national governments, and indigenous communities, each with claims to various rights and benefits pertaining to the practice of bioprospecting.

Bioprospecting can take many forms, and at its worst the practice is known as "biopiracy," i.e., the unauthorized and uncompensated acquisition of valuable biological resources. It is in response to such practices that efforts are now being made (including by this workshop) to define and assert the rights of developing countries and their indigenous communities. Thus the purpose of Module II was to focus on constructing equitable contractual agreements governing access rights, intellectual property rights (IPR), and benefit sharing. Faculty members focused on:

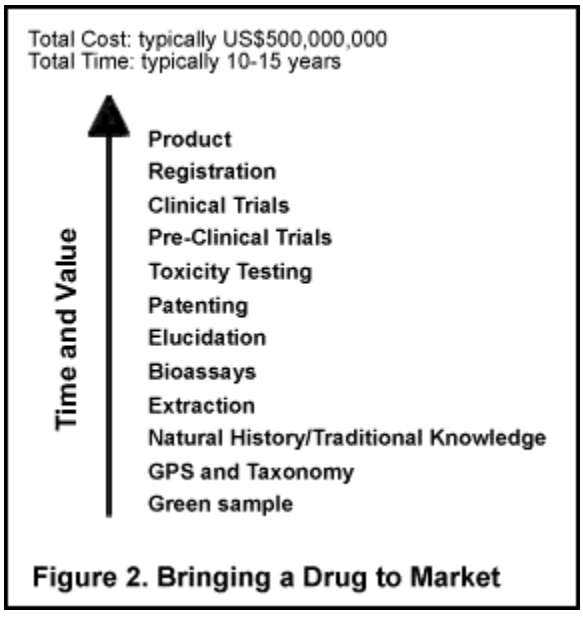
- placing bioprospecting into perspective in relation to the overall context of biodiversity conservation;
- explaining the various types of agreements that can be made;
- clarifying the types of rights and benefits at stake; and
- identifying ways of negotiating equitable agreements, both in principle and by reference to actual bioprospecting agreements, e.g., the INBIO-Merck agreement and the Yellowstone National Park-Diversa agreement (see below).

BIOPROSPECTING IN PERSPECTIVE

Bioprospecting is only one part of the overall biodiversity conservation picture, and possibly quite a small part. Biodiversity is to be valued for many reasons, some of which relate to its uses and some of which do not (see Figure 1). As exciting as the prospect of new drug discovery may be, for both the potential health benefits and the potential financial returns, biodiversity conservation cannot be predicated upon this possibility alone.



Bioprospecting is not a gold mine, cautioned faculty; dreams of generating hundreds of millions of dollars for developing countries are not likely to be realized, at least not in the near term. To date not a penny in royalties has been collected by Costa Rica as a result of the INBIO-Merck bioprospecting agreement. Drug development is an expensive and long-term process (typically half a billion US dollars and 10-15 years, see Figure 2), and royalties are not paid until revenue starts coming in. However, other types of payments can meanwhile accrue, and INBIO has earned some US$3 million in up-front fees and in-kind contributions since the 1991 agreement was implemented. Still, judging by the Costa Rican example the main benefits of bioprospecting are not financial, but consist of scientific and educational benefits (increased knowledge), environmental benefits (conservation), and capacity-building (training and technology transfer).



TYPES OF AGREEMENTS

There are several forms that bioprospecting agreements can take, depending upon the objectives of the parties and the desired scope of the agreement. Within any type of agreement, everything is negotiable. Basic agreement types include permits, material transfer agreements, licenses, and cooperative research and development agreements.

Permits convey the right to access biological materials, e.g., samples of plants or microbes. The permit can limit the type and amount of material to be collected, the collection area, the time allowed for collection, acceptable methods for collection, who will do the collecting, and so forth.

Material Transfer Agreements (MTAs) convey the right to transfer specimens to third parties after collection, as another way of maintaining some control over access to the materials by the owner of the source. MTAs can be used in conjunction with permits and do not include a benefit-sharing component.

Licenses determine how the collected material can and cannot be used, and can be used in conjunction with permits and MTAs.

Cooperative Research and Development Agreements (CRADAs) can combine permits, MTAs, licenses, and more in a single agreement. They often comprise two parts: a "statement of work" that specifies roles and obligations of each party; and "general provisions" including legal details and assignment of rights.

TYPES OF RIGHTS AND BENEFITS

The essence of a bioprospecting agreement is in defining and allocating the various rights and benefits to be conferred. The primary rights include:

- the right to access the natural resources; and
- intellectual property rights pertaining to any resulting innovations.

Types of benefits include:

- economic benefits;
- capacity building (training and technology transfer);
- scientific benefits (data sharing, species inventories); and
- promise of future supply (continued access to resource in the event of successful research).

All rights and benefits are subject to negotiation, and their exact distribution will vary from agreement to agreement. Benefit sharing does not necessarily have any effect on intellectual property rights, although decisions about IPR can be included in any agreement.

NEGOTIATING AN AGREEMENT

The particular combinations, types, and allocations of rights and benefits comprising a bioprospecting agreement are limited only by the imaginations of the contracting parties. Workshop faculty provided an overview of some basic options based on existing experience.

Access Rights

As noted above, access rights and limitations are specified by permits. The details of the times, places, methods, quantities, and assignability of collection are all subject to negotiation between the parties. Applications can also be subjected to peer review prior to issuance of a permit.

Intellectual Property Rights

The subject of intellectual property rights is dealt with in greater detail in Module III; in this context it may suffice to note that rights associated with innovations resulting from research on biological materials can be subject to negotiation. The inclusion of IPR considerations in the bioprospecting agreement is optional, and is dependent upon the nature of the rest of the agreement, e.g., whether the agreement is limited to transfer of materials or whether there is a shared research component, and the extent to which resulting innovations draw from existing traditional knowledge. There may also be other pertinent IPR questions. For example, can a newly discovered and useful but naturally occurring and unaltered microbe be patented? If so, should rights belong to the bioprospector alone or shared with the owners or inhabitants of the source area? These are battles that are now being fought at the negotiating table as well as in the courts.

Economic Benefits

Economic benefits can include such varied items as license fees, royalties, milestone payments, ethnobotanical premiums, contract fees, and research budgets, each of which is discussed briefly in turn below.

- *License fees:* License fees are attached to the transfer and use of collected material only; they do not include any provision for benefits from any subsequent products of research on the material.

- *Royalties:* Royalties are a percentage of revenue from sales of a product derived from research on the collected biological material. One of the most important subjects for negotiation here is how to determine the amount on which the percentage is based, i.e., gross or net revenues. If net, what categories of expenses will be allowed as deductions before calculating the royalty payment? In particular, will the considerable R&D expenses be deductible? The company will most likely want to deduct R&D, and these are legitimate expenses, but as a counter-argument there are also the conservation and maintenance costs of the state to consider. The decision about calculating the base amount can also affect the negotiated royalty rate, but in general it is probably true that the less that is deducted from the gross, the higher the royalty payments will be. As noted above, royalty payments are a long-term consideration, and are not likely to be seen sooner than 10-15 years down the line, if ever.

  The percentage rate is the other major consideration in negotiating royalty payments. The difficulty here is that there is not yet enough of a market to fix an established rate, but a range of 1-5 percent is currently in use.

- *Milestone Payments:* In a milestone payments system, certain "success points" that trigger fee payment obligations are identified, such as the point at which bioassays confirm activity, or when the particular active molecule is identified, or the stage of patent application or pre-clinical trials, etc. Therefore if the process is cut off at some point for any reason, e.g., the

compound is found to be toxic to humans, the payments will also stop. Milestone payment obligations will tend to reduce the amount of up-front payments (see below), but by reducing risk may amount to a greater total payment if all goes well.

- *Ethnobotanical Premium:* An ethnobotanical premium is some form of payment that reflects the value of traditional, indigenous knowledge, as such knowledge can provide valuable clues that significantly shorten and simplify the drug discovery process.

- *Contract Fee/Up-front Capital Contribution:* An up-front fee of this kind is not necessarily tied specifically to anything in particular, but can be included in a contract as a payment to move the project forward. Typically, companies are not eager to pay such fees.

- *Research Budget:* A payment towards the research budget is another form of up-front payment. Using the research budget to identify specific costs, it is possible to request payments in advance for necessary items, e.g., new equipment, materials, training, travel, and so forth. Companies are likely to agree to such dedicated fees more readily than to non-specific up-front fees.

Capacity Building

Companies are often quite willing to invest in capacity-building, i.e., technology transfer and training, as it is in their interest to ensure that samples are handled properly. Support for capacity-building can come in various forms, such as by direct transfer of technologies, payments to support acquisition of tools or knowledge, support for training programs, joint research activities, and so on.

Scientific Benefits

There should be inherent scientific benefits to the bioprospecting agreement, including provisions for the sharing of research information and other data, expanding the scope of species inventories and other types of ecosystem knowledge, et cetera. Improvements to the knowledge base can also contribute to the improvement of education at all levels. Another related benefit is the promotion of conservation itself. Indeed the scientific and educational effects may well turn out to be the primary benefit of the bioprospecting agreement, far outweighing any monetary gain.

Promise of Future Supply

The promise of future supply is a two-way benefit by which the company is guaranteed that the source material will continue to be available in the event that successful research results occur. This condition can be linked to the economic benefits and involve up-front or milestone payments, or both.

Some General Principles

Workshop faculty concluded this section by stressing some important general principles about bioprospecting and the art of negotiating a successful agreement.

- It is extremely important to identify the costs of participating in the bioprospecting agreement as early and accurately as possible, for the protection of both parties. Understanding the real costs is the only way to negotiate a fair and reasonable up-front fee, and if the costs greatly exceed expectations, the entire project can collapse. The budget can extend for several years

and include such varied components as materials collection, transportation, taxonomy, information systems, extraction equipment, bioassays, communications, administration, subcontracting, and so forth.

- There is usually a trade-off between up-front payment amount and the royalty rate, i.e., the higher the up-front payment, the lower the royalty rate, and vice-versa. Up-front payments represent greater certainty and rewards in the near term, whereas the only certainty about royalty payments is that they will not appear for a long time, if ever. On the other hand, if a successful drug is developed from the biological materials, royalties have the potential to dwarf an up-front fee. Therefore the balance between royalties and up-front fees is a function of present needs, long-term perspective, and tolerance of risk.

- Find out as much as you can in advance about the company with which you will be negotiating. You must understand the company's particular strengths and weaknesses before you can know what benefits to request.

- It is important to develop a close, positive working relationship with the company. Not only will the agreement function better with a greater level of trust and mutual interest, but unanticipated opportunities and benefits may also arise. In the case of Yellowstone National Park and Diversa, beneficial information sharing occurred that was well outside the scope of the agreement, simply because the parties were on good terms and were able occasionally to help each other out. Were the relationship more adversarial, such "side" benefits would not likely have materialized.

- Beware of anyone who claims to be an expert in bioprospecting—there is no such thing! There is not yet enough experience in the world for anyone to make this claim; everyone is still learning and finding their way in this field.

- It is advisable for a country to begin its bioprospecting experience with a pilot project that has a focus on demonstrating some benefits early on in the process. In other words, do not focus on royalties, as these will not appear for some time, but rather on technology transfer, up-front payments, conservation, and so forth. The important point is to show the benefit and future potential of such agreements to the communities, as a useful tool in improving the quality of life.

- There should be some clear in-country or even regional understanding about the desired objectives of pursuing bioprospecting agreements before the process of dealing with foreign interests is engaged.

- Most importantly: If you take absolutely no action at all, you will receive absolutely nothing in return; this is the only complete certainty. And the longer you delay action, the less you will receive in return. Faculty advised the group: "You only need three things: vision, leadership, and a lot of hard work."

DISCUSSION POINTS

Some of the important issues that arose in discussions concerned the relevant legal framework in West Africa and the question of how to protect the interests of local communities. With regard to the former, there was a consensus that the legal framework for bioprospecting in West Africa is incomplete and unclear at best. Some laws do exist, but they are neither consistent nor

comprehensive, and in any case enforcement remains an open question. While these circumstances do create uncertainty, it is also true that the situation is similar in the rest of the world as well, and that successful bioprospecting agreements have been concluded in this "legal vacuum." In short, there is no reason to wait for a complete and rational legal framework to evolve before beginning to explore the possibilities of bioprospecting. Indeed the experience gained in formulating bioprospecting agreements will help to inform the legislators as they seek sensible policies for the region.

The question of local communities and how to involve and compensate them is one of the most difficult issues in bioprospecting. In the case of both Yellowstone-Diversa and InBIO-Merck, the land from which the resources were taken was unoccupied. Sometimes the same will be true in the African context, when dealing with national parks, but sometimes it will not. Indeed it can be expected that sometimes the desired resources will not only be in inhabited areas, but that the knowledge of the inhabitants will play a crucial role in determining the desirability of the resources. Traditional healers and other community members may have specialized knowledge of the indigenous resources that will be extremely valuable to the bioprospecting endeavor; therefore mechanisms for equitable compensation must be developed. The alternative is not only unfair exploitation of these communities, but the real possibility of actual hostilities.

It will be necessary to involve the communities as full partners in the bioprospecting process in order to ensure that their needs are met fairly in accordance with their contributions, and also to ensure that national and regional goals are not undermined. For example, it is not known to what extent companies may now be going into rural areas and collecting biological materials without official permission, using indigenous knowledge and resources for paltry or no compensation. For this reason, several workshop participants have pointed to the need for a greater educational and sensitization effort, so that all national stakeholders (including communities, nongovernmental organizations, universities, researchers, and policymakers) can come to a better understanding of each other and how better to work together more effectively. The only way to ensure that these sectors of society are harmonized in working toward common goals is to identify the needs of each and to share benefits fairly. This process is not a simple one, but it is integral to the process of identifying national and regional priorities. The more clearly these priorities are identified, the more success can be expected in dealing with foreign interests.

GROUP BREAKOUT SESSIONS

During Module II workshop participants broke into smaller working groups at certain points to focus on various tasks. The results of these breakout sessions in benefit-sharing and national priority-setting are summarized here.

Benefit Sharing Exercise

Workshop participants broke into five groups, each charged with the same task of creating a basic benefit-sharing agreement. In particular, the groups were told to assume that they represented a university committee, and that they must choose only three types of benefits to receive, i.e., they could not "have it all." Choices of benefits included up-front payments, milestone payments, royalties, intellectual property rights, or some form of capacity building (e.g., technology transfer). The groups were also advised to bear in mind a set of objectives, and to ensure that the benefits chosen matched those objectives.

All five groups chose to receive up-front payments and capacity-building. Three groups chose milestone payments as the third benefit; one chose royalties; and one creative group chose a split between royalties and milestone payments, with milestone payments to be deducted from future royalties. None of the groups chose to retain intellectual property rights.

In sum, each group was risk averse, in choosing to receive earlier and more certain benefits (up-front and milestone) over potentially greater, but future and uncertain benefits (royalties and IPR). With regard to money, in other words, sooner was thought to be better.

In the Merck-InBIO agreement, Merck agreed to pay US$1 million for the first two years, part up front and the rest in installments every six months, plus royalties; Merck also retained IPR. Workshop faculty noted that, in hindsight, InBIO would perhaps have preferred milestone payments to royalties.

Another observation made by faculty was that although the groups were charged only with representing university project leaders, they all demonstrated admirable vision by considering the viewpoints of other groups, including nongovernmental organizations (NGOs) and local communities. In actual practice, sharing benefits among NGOs and communities would most likely require separate sub-negotiations in advance.

On the question of how to compensate the local communities, the groups arrived at a combination of solutions, including sharing a percentage of payments and royalties; buying the IPR from the community outright; and conservation support, to be managed jointly by NGOs and the community.

National Priorities

In this exercise workshop participants broke into groups according to nationality to discuss their respective priorities in terms of biodiversity conservation in general and bioprospecting in particular. Most of the groups felt that their countries needed some sort of national steering committee on biodiversity to review, improve, and coordinate the laws and policies pertaining to conservation—issues ranging from reforestation and wildlife management to waste disposal and community outreach. Nigeria has an existing policy on biodiversity and a national committee as well as a center for genetic resources; even so, the Nigerian group felt that there was a need for better coordination of the laws and institutions responsible for overseeing and enforcing them. Each group also emphasized the necessity for stronger conservation and education measures.

A number of common themes emerged clearly from the national reports, suggesting the utility of a regional approach to the issues. Therefore the national breakout sessions were followed by a collective identification and examination of common priorities, each of which is described briefly below.

- *Conservation and Sustainable Development:* This area covers several interrelated issues, including sustainable use of biological resources or, more generally, sustainable development. A particular emphasis was also placed on poverty alleviation, i.e., that the benefits of socioeconomic development must be shared equitably and not concentrated in the hands of a wealthy few. The role of biodiversity conservation in development is manifested in several forms, including bioprospecting, eco-tourism, agroforestry, and essential environmental services. Priorities include halting environmental degradation and developing sustainable use patterns, protecting endangered species, and documenting traditional knowledge.

- *Capacity-Building:* There was broad agreement that capacity-building in terms of developing human resources and the technology base must occur on a number of different levels. Improved research and development capacity was identified as a high priority, including building better-equipped facilities, using state-of-the-art tools like GPS (geographic positioning systems) and GIS (geographic information systems) for mapping biodiversity, and training more scientists and technical people in key fields, e.g., microbiology. Collaborative research on endemic diseases and other priorities of the region is one way of furthering this goal. In addition, training for "society at large" was called for, including biodiversity education at all levels, with a special emphasis on raising public/community awareness of conservation issues (including but not limited to bioprospecting). The point was made that technology transfer can also include the development of indigenous technologies for dissemination within and outside the region. From a regional perspective, some participants suggested that a West African center of excellence for biotechnology and pharmaceutical research should be established.

- *Regulatory and Institutional Framework:* As noted above, participants clearly felt that there was a need for harmonization of laws on biodiversity, taking a more comprehensive approach with improved monitoring and enforcement. An organizational structure should be established to facilitate consultation among all stakeholders in the process of formulating and revising the relevant laws; improved networking among national institutions was highlighted in this regard. At the regional level, participants recognized the role of ECOWAS (Economic Organization of West African States) in coordinating policies and attracting funds where national governments alone often cannot; SADC (the Southern African Development Community) has for some time been playing an active role in this area for the southern region of the continent. The possibility was raised of taking economic integration to the level of creating a free trade zone within West Africa so as to increase the size of the market for indigenous products and be better able to protect the region's resources. A similar measure is currently being considered in Central America.

- *Public Education/Awareness:* The level of public awareness of biodiversity issues was felt to be low. Because of the importance of these resources to Africa's socioeconomic development, and as part of the effort to raise the priority of these issues on national policy agendas, an ongoing education/sensitization effort is required at all levels of society. There is a variety of mechanisms that can be used for the purpose of education, including electronic and mass media, nature clubs, local schools, churches, and adaptations of the folklore tradition. There is a need to define the focus of education for each stakeholder group. At InBIO, for example, they have emphasized children (e.g., through a "bioliteracy" program) and decisionmakers (e.g., through policy issue seminars). Particular mention was also made of the need for sensitivity to cultural contexts, e.g., using local languages and addressing local needs.

- *Knowledge Base:* Each national group expressed the desire to build the knowledge base through more and better research, documentation, and dissemination. Priorities include building databases of biodiversity and traditional knowledge; keeping abreast of current information, tools, and trends in science; discovering and promoting sustainable use of biological resources; promoting non-use ("moral" or aesthetic) values as well as functional and economic values of biodiversity; creating appropriate fora for the inclusion of traditional healers and "ecosystem managers" for educational and policymaking purposes; investigating the potential and challenges of eco-tourism as an economic and conservation strategy; building institutional capacity in various sectors in order to develop authoritative repositories of knowledge in key areas; and drawing on international sources of expertise to fill

knowledge gaps, e.g., in taxonomy, with an emphasis on creating mutually beneficial international exchanges.

- *National Fora/Regional Networking:* Several issues emerged during the discussion of creating national fora and focal points and improving regional networking. One was the importance of gender issues in any national or regional discussion. The importance of women as food producers and otherwise as users and managers of biodiversity was highlighted, to the extent that any negotiations should include women, any policy documents should include a gender component, and any resources allocated should have provisions for the inclusion of women as recipients.

  A general discussion of creating national focal points as a way of organizing a regional approach to biodiversity conservation yielded a two-track approach: on the one hand, true national focal points, e.g., ministries for the environment, should be identified for the purpose of developing a regional approach, with the Organization of African Unity (OAU) or ECOWAS serving as an information clearinghouse; also, the workshop participants themselves should constitute themselves as a network in order to further the goals identified in Ibadan. The workshop participants represent a unique assembly of high-caliber experts in science and law, with specialized knowledge in biodiversity issues as graduates of the GBDI/IITA training workshop, and with institutional affiliations that make them especially capable of developing and promoting an agenda within West Africa. Thus participants agreed to stay in touch electronically to further develop these ideas. The American Association for the Advancement of Science offered use of its online conferencing system (http://caucus.aaas.org) in service of this goal.

MODULE III:
Managing Intellectual Property

Faculty:
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Tomoko Miyamoto, World Intellectual Property Organization (WIPO), Geneva, Switzerland
Rosemary Wolson, Intellectual Property Manager, University of Cape Town, South Africa

INTRODUCTION

Module III began with a visit to IITA's Plant Genetic Resources Unit (GRU), which has catalogued some 41,000 varieties of 200 different species of agricultural plants, mostly cowpea, yam, cassava, and soybean. IITA has several objectives in this area, including collection, characterization, documentation, improvement, and distribution of germplasm for immediate use, and conservation and storage for future generations. The organization conducts research in improving germplasm conservation methods, applies state-of-the-art diagnostic techniques to ensure safe transfer of seed and vegetative propagules, and employs disease eradication methods to free germplasm from seed-borne infected pathogens. Also, IITA helps strengthen national capacities through the organization of specialized training courses and workshops, individual training and graduate-level research support, and provision of advice and consultation.

IITA makes its samples available freely for research purposes, with the stipulation that the researcher cannot claim intellectual property rights (IPR) on products based on the original material. Recently the institution has been somewhat hampered in its mission, as countries are beginning more frequently to require material transfer agreements (MTAs) reflecting IPR concerns, sometimes impeding the acquisition of new samples for IITA's collection.

Against this background, workshop participants proceeded to immerse themselves for the next week in the details of intellectual property laws (led by Mike Roth of Monsanto), key international treaties (led by Tomoko Miyamoto of the World Intellectual Property Organization), and an examination of university-based technology transfer offices as a mechanism for managing the growing linkages between university research and commercial application (led by Rosemary Wolson of the University of Cape Town in South Africa). Given the current tensions between concepts of private versus public control of biological resources (for example the conflicts between CBD and TRIPS, see Module I), the visit to GRU was perhaps a particularly appropriate way to begin this workshop module. While the main thrust of the module was to provide a detailed overview of relevant IPR-related laws and management techniques, there was considerable discussion of the philosophical context in which IPR issues exist.

Tomoko Miyamoto began her presentation by asking the question: Why protect intellectual property? She noted that the question can be considered from a human rights perspective as well as an economic development perspective. An examination of the history of IPR laws suggests that the overall point of the legislation is to find the right balance between the rights of an innovator and those of society at large. The questions with which IPR legislators (and society) must contend include:

- Who should benefit from protection?
- What activities should be encouraged?
- What degree of protection is necessary?

FORMS OF PROTECTION FOR BIOLOGICAL INVENTIONS

There are three basic forms of protection available to innovators: statutory (legal forms, including patents and plant breeders' rights); "mixed" (a combination of legal and court-provided protection, including trade secrets and "unfair competition" laws); and property-based protection. Faculty focused mainly on patents, plant breeders' rights, and trade secrets.

Patents

The presentation on patents was based mostly on US law, with reference to some key differences between US and European standards (e.g., animals are patentable in the United States but not in Europe). Patents cover machines, manufactures, compositions of matter, and processes; they prohibit making, using, selling, and importing without permission of the patent-holder, for a 20-year period (there is a narrow exemption for research). To be patentable, an innovation must be new, useful, and non-obvious. In addition, the inventor must make an "enabling disclosure," i.e., a disclosure of sufficient information about the invention that a person skilled in the relevant art can duplicate it. Patentability does not ensure commercial success: of a total of some six million patents granted in the United States, only a few thousand have resulted in products available in the market.

In terms of the requirements, "newness" is determined by comparison to the state of the art, regardless of whether existing comparable products or processes are patented; "utility" is a fairly low standard, in that it is not difficult to demonstrate some use for a given innovation, yet the stated use must be quite specific; "non-obviousness" is the most difficult determination, and takes into account the failure of others to solve the same problem, any commercial success achieved, synergistic effects (getting more from the whole than the sum of the parts), or the very recognition of the problem (i.e., an obvious solution to a non-obvious problem). The patent-seeker must identify the difference between the prior art and the invention, and the patent examiner must make the determination whether these differences would have been obvious "to the worker of ordinary skill."

The "enabling disclosure" is a sort of bargain between the patent owner and the public. The patent-seeker must disclose the secrets of the patent so it can be used by others at the end of the protected period, so the useful innovation is not lost to the world, e.g., in the event of the inventor's death. The requirements are that the disclosure must permit the invention to be practiced fully according to the best method known at the time of filing (but not necessarily improvements made subsequent to filing, which can be significant). For biological materials, deposits of samples may be used in fulfillment of this requirement. (In fact many valuable germplasm samples are available to anyone through the US patent office for a $300 fee. If the patent is held only in the United States, it is quite possible for a Nigerian, for example, to obtain and utilize valuable biological innovations in this way.)

The benefits of patents, from the seeker's point of view, include the affirmative protection against copying ("innocent" infringement not allowed, and extra penalties for willful infringement); the

narrowness of the research exemption; the lack of a "saved seed" exemption, preventing competition from customers; the known term of protection; and the substantial jurisprudential experience in patent law. The disadvantages of patents, again from the seeker's point of view, are that the high standards make them difficult to obtain; enabling deposits create a potential "leak" of protected information; the term is finite (although known, and considerable at 20 years); and every standard of protection is a potential source of defense against infringement.

Plant Breeders' Rights

For the most part, plant breeding innovations have not been covered adequately under patent law; therefore, Plant Breeders' Rights (PBRs) were developed as an alternative, to deal more specifically with the special circumstances that plant breeders face. PBRs are similar to patents, having a 20-year term of protection (25 years for trees and vines), but have their own requirements and standards. The standards are that the breed in question must be new, distinct, uniform, and stable. The latter three standards are often collectively referred to as DUS standards. "Distinct" is a kind of substitute for a patent's "non-obvious" requirement, and is a fairly low standard in that any new feature of the plant, even strictly visual features, can render it distinct; "uniform" means that all the plants in the breed are the same; and "stable" means that the plant is true-breeding generation after generation.

Obtaining breeders' rights is far less daunting than applying for a patent—the process is almost as simple as filling out a form, the cost is less (no attorney's fees required, but there is still a $2500 filing fee), and the decision time is shorter. Therefore these rights can offer valuable protection for small farmers, researchers, or biotechnology companies wishing to commercialize a new discovery. Mike Roth noted that the large firms will always be able to out-spend small ones on research and legal matters, but they cannot necessarily out-think the smaller firms' scientists. Plant Breeders' Rights represent a legal tool the "small fish" can use to protect themselves in "shark-infested waters."

The benefits of PBR from the seeker's point of view include the lower standards for obtaining rights; the easier, shorter application process; the specificity to plant varieties; widespread acceptance in many countries (they are required under TRIPS); the known term; and the ease of policing compared to patents. The disadvantages from the seeker's point of view include the breeder's exemption permitting research use; the farmer's saved seed exemption, meaning customers can become competitors; the limited term; the fact that compliance is not universal; and the limited jurisprudential experience in the area to date. As noted in group discussion, several of these "disadvantages" are also advantages from other points of view, e.g., those of researchers and farmers.

Trade Secrets

A trade secret, as the name implies, is valuable commercial information protected by virtue of its being known only to the firm using it, i.e., by being secret. Although keeping a secret is essentially a private matter entailing private risk, some legal support is offered for trade secrets (including under TRIPS), with infringement based on misappropriation or a breach of a confidential relationship; still, once the secret is out, it is no longer a trade secret. In order to be protected under the law, a trade secret must be protected by reasonable measures. Keeping an innovation as a trade secret rather than applying for a patent or breeders' rights may be a desirable option, depending on the type of innovation and whether it can reasonably be expected to remain secret.

The benefits of a trade secret include an unlimited term (as long as the secret remains secret); its applicability to a wide variety of technologies; the lack of standards to meet; and criminal penalties for infringement, with substantial jurisprudential experience. The disadvantages include complete loss of protection if the secret is disclosed; the existence of well-established defenses against infringement (including claim to independent discovery, inadvertent disclosure by owner, and reverse engineering); the requirement of a "separate, actionable wrong-doing" for infringement; and the lack of protection compliance in many countries.

Utility Models

Utility models can be considered as "small patents" for "small inventions," and are available as an alternative to patents in several countries. They were used in Japan very successfully as that country attempted to catch up technologically with the West. Utility models are more easily accessible, with lower requirements for the inventive step in the innovation. They also have lower fees and a shorter term than patents, and are sometimes limited to specific types of innovation, such as products only. There are no international standards for utility models.

DISCUSSION

Several points were raised in discussion that helped to put these IPR theories and mechanisms into an African context.

- With regard to breeders' rights, the question was raised whether the rules do not favor big companies over small farmers and scientists at universities and research institutes; although the process is less expensive than for patents, the fees may still be out of reach of many small innovators, who also may not have the resources for DUS testing. Roth responded that, in the European system, the farmer is not responsible for doing the DUS test; she just submits the sample to the responsible government office. Roth also added that asexually reproduced plants, e.g., flowers and potatoes, are relatively easy and inexpensive to breed, and as such are not beyond the reach of the small farmer (unlike maize, which can be quite complicated to breed).

- The controversial issue of applying for patents on genes was raised and discussed at some length. Here the line between invention and discovery can be very fine. A gene exists already; if it is identified and isolated, i.e., discovered, but is otherwise unaltered, can it be patented? Some feel that if in the process of identifying and isolating the gene a significant problem was solved in an ingenious way, and/or that the gene is removed from its natural context and applied to new uses, then it is patentable. But what exactly should be patentable: the process of isolating the gene; the gene itself; a modified gene; usage of the gene in products or processes; gene fragments or "tags"? Furthermore, who is the inventor? Gene identification can be "just a list of sequences coming out of one machine and into a word processor or a database with no human intervention." No patent or court system has given us the final word on this issue as yet.

- With regard to public versus private responsibility for access to seeds, several points were made. In much of West Africa, research institutes are funded by governments and donors. When new varieties are invented, the results are in many cases considered to be in the public domain; the seeds may be sold on a competitive basis, but there is no IPR component, no restriction on saving seeds, and so forth. It was noted that in the case of Nigeria there is a national seed service that distributes seeds to farmers after a process of testing and selection.

Unfortunately, the research part of the system is often subverted by "leakages" at the testing stages; sometimes when the researcher goes to the test farm to obtain crop yield results, she finds the produce at the local market, making accurate data collection impossible. Illicit transport of seed (i.e., smuggling) is also common in the region, making enforcement of any rules or rights extremely difficult.

- More generally, the issue was raised of whether the public good is better served by a regime driven by IPR and commercial interests or one driven by keeping research results in the public domain and making improved germplasm available as widely as possible. The classical "free market" response is that the private sector is better equipped to innovate, disseminate, and provide service given the incentives that property rights provide. IPR's prevention of copying is supposed to stimulate ever greater innovation. Critics argue that profit motives and property rights agreements like TRIPS hurt the poor, draw resources from the South to the North, and have no place in the critical realm of food supply.

  An analogy can be made to the "open source" software paradigm, also known as "copyleft," in which software code is made freely available for anyone to study and submit improvements, with nobody making a claim to IPR. The system has produced top quality software that is constantly improving, including popular Unix operating systems such as Linux and FreeBSD. This paradigm actively shuns property rights and has completely different incentives, which clearly work to improve and disseminate the product. Should seeds be like software?

  Unfortunately, the workshop, like the rest of the world, has failed to resolve this ideological issue definitively. It can be mentioned in this context, however, that breeders' rights can be considered a kind of middle ground, as they provide a reasonable level of protection and make fairly generous exemptions for research use and farmer-saved seeds.

- The question was also raised as to who has the right to apply for intellectual property protection in a case where there are several potential applicants, e.g., an individual researcher, his institution, and the government or other funding organization. Roth replied that in most cases initially the right belongs to the individual breeder, but that in many cases that right is shared with the employer. In the United States, the decision to allow universities and individual scientists to retain a share of IPR on government-funded research has led to the university playing a greater role in the innovations marketplace. (In addition, universities are also uniquely well able to bring private sector competitors together into research consortia, with appropriate agreements as to responsibilities and benefit-sharing, and are able to "make things happen that wouldn't otherwise happen.")

- Along the same lines, one workshop participant noted that putting a strong IPR regime into place in West Africa will not by itself guarantee that innovation and commercialization will ensue, or that Africans will benefit by it. He stressed the importance of the overall enabling environment, including allowing individual scientists to gain from commercial exploitation of their research. Roth noted that this blurring of lines between sectors—academic, government, industry—is a growing feature of the information age. Many individuals are increasingly wearing multiple hats, e.g., a professor sitting on the board of a private company and serving on a government committee. Policymakers will need to take this reality into account, in biodiversity conservation and use schemes and many other endeavors.

CONTRACTUAL MODELS FOR MANAGING IPR

Workshop participants reviewed several different sample license agreements based on actual deals involving patented biological resources and building contractual walls around trade secrets. In addition to defining basic roles and performance responsibilities, the agreements are intended to:

- establish confidentiality, which survives the term of the agreement;
- prevent employee "siphoning" (recruiting employees of contractual partner or inducing them to provide confidential information);
- limit rights to and use of protected materials;
- ensure access to testing site, data, and research results;
- forbid reproduction of breed or testing procedures;
- specify protection of original materials as well as subsequent byproducts, e.g., seeds, grain, plants and other materials produced from hybrids including DNA, RNA, pollen, etc.,
- ensure right to terminate agreement at any time;
- insert a "grant back" clause for a free, non-exclusive license for inventions based on the agreement;
- specify which state or nation's laws will govern the agreement; and
- forbid the assignment of responsibility to third parties without first obtaining consent.

IMPORTANT IPR INSTITUTIONS

Some important IPR-related institutions were reviewed by Module III faculty, and are briefly described below.

- WIPO: The World Intellectual Property Organization (WIPO) is an international organization dedicated to ensuring that the rights of creators and owners of intellectual property are protected worldwide. Nearly 90 percent of the world's countries are members of WIPO.

- WTO: The World Trade Organization (WTO) was established in 1995 as the successor to GATT--the General Agreement on Tariffs and Trade. The mission of the WTO is to reduce trade barriers between nations.

- UPOV: The International Union for the Protection of New Varieties of Plants (UPOV) is an intergovernmental organization with headquarters in Geneva, Switzerland. It is based on the International Convention for the Protection of New Varieties of Plants, as revised since its signature in Paris on December 2, 1961. The objective of the Convention is to provide intellectual property protection for new varieties of plants.

- ARIPO: The African Regional Industrial Property Organization (ARIPO) is a regional intellectual property rights organization for anglophone Africa, with member states from western, southern, eastern, and central Africa. ARIPO was originally founded in 1976 with assistance from WIPO and the UN Economic Commission for Africa.

- OAPI: The African Organization of Intellectual Property (OAPI) is similar to ARIPO, but serves francophone Africa.

IMPORTANT IPR TREATIES

Faculty also reviewed significant IPR-related laws and treaties. The most-discussed treaties are summarized here.

- Paris Convention (1883): Makes it easier to file for a patent in multiple countries. Before the Paris Convention, one would have to file (and pay for) applications in all desired countries at once. Paris Convention creates a grace period of almost one year during which the application can be filed in other countries, using the filing date established at the time of the first application. The Paris Convention has approximately 110 members.

- Bern Convention (1886): The Bern Convention lays the groundwork for the international protection of literary and artistic works. The Convention allows a foreign author to invoke the rights applicable to the country where his/her work is performed. The treaty has about 159 member states.

- PCT (1970): The Patent Cooperation Treaty (PCT) permits an inventor to file what is called a PCT patent application. The PCT streamlines patent applications across several countries at once, and extends the grace period awarded under the Paris Convention to 20 or even 30 months. About 88 countries adhere to the PCT.

- UPOV (1961, 1978, 1991): The UPOV treaty for the protection of new plant varieties was originally signed in 1961, and was later revised in 1978 and again in 1991, with not all members signing each revision. There are currently 45 states that are members of at least one of the UPOV treaties.

- TRIPS (1995): The TRIPS Agreement is the most comprehensive multilateral agreement on intellectual property, covering copyright and related rights, trademarks, geographical indications including appellations of origin, industrial designs, patents including the protection of new varieties of plants, layout-designs of integrated circuits, and undisclosed information including trade secrets and test data.

GROUP BREAKOUTS

Workshop participants broke into small groups by country (or in some cases grouped by close sub-region) in order to assess national patent laws. Their reports are summarized below, although the information should not be considered authoritative since in many cases, as the participants themselves noted, they were not experts in their nations' patent laws.

Group One: Niger, Cameroon, Cote d'Ivoire

In these countries there are no national patent laws per se, only artists' rights. Patenting law is handled through OAPI, for which there are national offices. Applications and decisions are handled at the national level. There are also no laws for protection of new plant varieties. The problems identified were seen as common among the three nations, and include a lack of information on patenting; no controls on genetic research; low awareness of genetic research; and a lack of incentives for scientists.

Group Two: Liberia

The Liberians were uncertain as to whether patent laws existed; they were not aware of any. However, they reported that patenting is certainly uncommon, and that the culture of innovation in Liberia is such that results tend to get published rather than protected.

Group Three: Ghana

There is a patent office and a copyright office in Ghana. Ghana's 1982 patent law is based on international treaties, and the country is a signatory to several major treaties. There is currently no national law on plant varieties, but steps are being taken to adopt UPOV. Problems identified include a lack of public awareness of patent benefits (innovations occur but are generally not patented); seed rights are seen as a particularly difficult issue as the country does not wish to restrict its farmers; monitoring and enforcement of property rights is difficult in the predominantly rural communities; and accessing data on patents and patent law is problematic. The group called for more education, including seminars and workshops on patent benefits for scientists and engineers, as well as the teaching of IPR laws at universities (not just law schools); the development of a sui generis regime to address protection of traditional knowledge; and other systematic efforts to document and protect traditional knowledge.

Group Four: Sierra Leone and The Gambia

National laws for patents exist but are archaic and need updating. The Gambia has a new copyright law currently under formulation; neither country has plant breeders' rights. Problems identified include a low level of awareness of IPR issues in all sectors of society; a lack of local legislation to operationalize treaties to which the countries are a party; and a lack of skilled personnel in the field of patent law. The group called for an awareness-raising effort among policymakers, capacity-building among IPR specialists, legislation to ensure compliance with treaties, and membership for their nations in ARIPO.

Group Five: Nigeria

There are four or five different statutes relating to IPR (for patents, trademarks, copyrights, etc.), administered through various offices, and the country is a party to major international treaties. Problems identified include: old, decentralized, and unnecessarily complicated IPR rules and procedures; exclusion of plants from protection; lack of adequate policy framework for overall strategic planning; lack of IPR awareness in all sectors; and a lack of trained manpower. Suggested solutions included training programs for the legislature focusing on the importance of patent law; an overall review and harmonization of existing laws (by skilled, well-informed reviewers); and the establishment of a centralized administrative body for IPR.

During this session it was also suggested that countries considering the adoption of UPOV should make sure to familiarize themselves with the OAU document on protection of breeders' rights, which attempts to avoid perceived problems with the 1991 UPOV Act, and protects traditional knowledge and communities.

UNIVERSITY TECHNOLOGY TRANSFER OFFICES

"Technology Transfer" is a phrase that evokes different meanings for different people, as demonstrated by a definitions exercise led by Rosemary Wolson to start this session. It can be interpreted broadly or narrowly; it can imply transfer of technology from the developed world to

developing countries, or a two-way transfer between South and North; it can mean a transition of technology between the public and private sectors; it can have socioeconomic dimensions involving changing the balance between the "haves" and "have-nots." Even the definition of technology can be slippery, with some people limiting it to equipment and others including techniques, processes, and know-how. One form of technology transfer that still does not commonly spring to mind for many people involves a flow of research innovations from the academic to the commercial sector. This type of transfer, while in itself not necessarily new, is increasingly becoming formalized through the establishment of university technology transfer offices.

A university technology transfer office (TTO) is responsible for coordinating all activities relating to commercial interest in university research, including licensing technologies, negotiating and approving contracts, soliciting partnerships, setting and reviewing milestones, supporting and advising campus entrepreneurs on start-up companies, and protecting and exploiting IPR as appropriate. The presentations and discussions in this section were focused on universities, but the concept may also be applicable to public research institutions. The main point is that, given an enabling legal and policy environment, there are emerging opportunities to generate income streams from university research activities, e.g., by licensing university-developed technologies to the private sector.

University interest in technology transfer occurs in the context of a changing environment for research and development (R&D), including an increasing emphasis on the importance of intellectual property rights, a greater role for agricultural biotechnology, and a decrease in the level of government funding for research in many countries. Government, university, and industry partnerships have become fairly common, as for example in the private sector either licensing technology developed at universities with government funding, or funding university research directly. At the same time, in many places there has been an increase in individually based contract research, i.e., individual university researchers signing contracts with private firms independently of any official university participation. In such cases, universities have not received benefits, although university resources may have contributed to the innovations in question. TTOs were developed in response to all these considerations.

Many of the West African countries represented at the workshop had some mechanism for dealing with technology transfer at the university level, but did not have a fully dedicated TTO. At most there might be a small consultancy unit within the university, with some capacity for income generation. Several participants noted that universities commonly transfer agricultural innovations to farmers (e.g., seeds, new methods, plant varieties), more as a social service than a strategy for income generation. Some West African governments have mechanisms to support small businesses, providing seed money and insuring against losses, and these functions may be adaptable to university use. In Ghana a technology transfer "service model" exists, with little emphasis on income generation, but with some commercial research application development supported by grants. The University of Science and Technology in Kumasi is making efforts to link to industry through by transferring technology to small- and medium-scale enterprises. In almost every country, there are good examples with the potential for expansion.

A key development that enhanced the ability of universities and their individual researchers to reap the rewards of federally funded innovations in the United States was the Bayh-Dole Act of 1980, which allowed universities and small businesses to retain intellectual property rights (e.g., receive patent protection and grant licenses) on innovations deriving from federally funded research. The result has been to increase commercialization of federally funded inventions, with universities and researchers receiving greater benefits from their inventions and transferring

technology more quickly from the lab to the marketplace. South Africa and other countries have looked to the US Bayh-Dole Act as a potential model for similar legislation.

Faculty underscored the importance of institutional culture when considering establishing a technology transfer office at a universities. Is the university ready, in a philosophical sense, for entrepreneurship? Is this path ultimately a desirable way for universities to go? In discussions, the point was raised that the trend is controversial. Some participants noted the danger that universities might become increasingly co-opted by industry for use as private development labs, potentially at the expense of the universities' broader educational mission and basic research functions. Too much emphasis on entrepreneurship may detract from researchers' teaching duties as well as from vital research in areas where opportunities for commercialization are not readily apparent. If the focus at universities becomes purely one of seeking near-term gains by shortening the transition from laboratory to market, more basic research--and its potential to generate longer term but revolutionary discoveries--may be sacrificed. In addition, there is a fundamental difference between the private sector emphasis on intellectual property rights protection and the traditional university emphasis on openly publishing research results for the general good. In short, the line between the social functions of universities and the private sector is in danger of becoming blurred, to the detriment of the traditional university functions.

While these kinds of concerns are certainly important and valid, a consensus was reached that greater participation in technology transfer activities at the university may be a necessity in an environment of decreasing government support for research. The important point becomes the careful management of the enterprise, seeking the optimal balance between commercialization of innovations, on the one hand, and basic research and teaching, on the other. In this regard, close attention must be paid to how incentives are structured and how benefits are shared.

One participant also made the point that the culture of universities is radically different from the culture of for-profit companies in the private sector, and that therefore a great deal of sensitization and training will also be necessary if universities intend to shift more towards commercialization of research results. There has traditionally been little if any focus on commercialization at universities. If this direction is undertaken, great effort must be expended in creating the enabling environment, including "transforming the minds" of researchers to prepare them for a new and different culture. Another responded that this "cultural gap" is probably more pronounced among the more senior faculty members, and that the younger researchers, brought up in a changing environment, may be far more ready to make such a transition smoothly. Even so, university administrators must be aware that the endeavor will involve more than opening a TTO and hiring some staff. The effort will require close coordination among research, finance, human resources, and other administrative units of the university.

There are several basic technology transfer models from which to choose, including the "service" model, the income generation model, and the economic development model.

Service model: In the service model, each university researcher is supported equally, regardless of the amount of money involved in their innovations, even at the expense of greater income generators; profits are a lower priority than equity, but the approach probably will require constant university subsidies.

Income Generation Model: The income generation model is about maximizing income streams and requires the university to be very business-minded in its approach. The goal is for research to become self-supporting, selecting only profitable projects and neglecting researchers working in less commercially promising areas.

Economic Development Model: In this model, the focus is on creating or encouraging start-up companies, possibly foregoing licensing agreements on better terms with large, established firms, in order to stimulate local economic development.

These various approaches can of course also be mixed, with some large and lucrative licenses established, creating wealth that can then be spread around the university and in support of local economic development. One of the key challenges for the university is to develop benefit-sharing formulas that encourage and reward individual researchers for their innovations, yet share enough of the benefits with the rest of the university community to avoid a destabilizing "have and have-not" scenario within the institution. Therefore it is vital for the university to engage in sensitization and training, get allies on board within the institution, and work closely with finance and human resources on pay equity issues and distribution policies for income generated.

Operating a TTO

A TTO needs certain things immediately in order to function: office space, an adequate budget, and competent staff (plus access to additional expertise). Ideally, the office space will be convenient and easily accessible, both to university constituents and to potential private sector partners. The budget will play a key role in determining the quality of the staff, and should include provision for market research, promotional materials, obtaining patents, access to databases and other information resources, Internet access and a dedicated website, attorney and consultant fees, and office equipment. Staff will probably require training. The ideal technology transfer officer has a combination science, legal, and business skills; he or she will have some technical expertise, some business sense, marketing and negotiating skills, political and conflict management skills, and an understanding of essential legal concepts. Additional expertise may need to be hired occasionally on a consultancy basis, although it may also be possible to rely on internal skills and talents, including business students.

The success of a TTO depends upon maintaining a good relationship with researchers; close communication with administrative support personnel; access to and support from key university decisionmakers; the free flow of information among all stakeholders; an ongoing education and training effort; and clear, coherent policies that are flexible, yet consistent, and not in conflict with external policies and legislation.

Faculty noted that an excellent resource for universities seeking help in starting or maintaining a TTO is the Association of University Technology Managers (AUTM), a US-based collegial association that has proven to be open, accessible, and helpful. The AUTM website (www.autm.net) is the best starting point for further information and contacting representatives for advice and assistance.

Intellectual Property Issues

A university TTO is likely to deal with patents, copyrights, trademarks, trade secrets, and tangible research property in the course of fulfilling its functions. Intellectual property policies should be clearly established in one or more university documents, as appropriate.

One of the first issues to be decided is who will hold the property rights--the university, the individual researcher, or possibly even the private sector partner. In the South African example, IPR is held by the university in most cases, with occasional exceptions. If the individual researchers are not awarded IPR, they must be compensated in some other way, such as by

sharing royalties with either the individuals or their research accounts, or both. Often, a maximum cap is placed on the amount of royalties that can be received by an individual, with any excess shared in some way with the rest of the university.

It is helpful to have standard contracts on file representing a desirable starting point for negotiations. In general it is advisable to keep agreements as fair and as simple as possible, while covering essential elements such as confidentiality agreements regarding disclosure of inventions and assignment of rights and responsibilities. Types of agreements include sponsored research agreements, sub-contracts with third parties, material transfer agreements, exclusive and non-exclusive licenses, and non-disclosure agreements (e.g., for a specified time period). Universities should be aware that it can be problematic when students become involved in "secret" research subject to non-disclosure agreements, since they may wish to file their results as part of their theses or course work. Some universities allow secret theses, others do not; students may simply be excluded from certain types of research.

Marketing Intellectual Property

A university that wishes to market its research innovations faces the challenge of how to find the best licensee for particular purposes. As noted above, the university may wish to serve local economic development goals by partnering with small local firms or spinning off start-up ventures of its own; conversely, it may seek stability and maximum profits by partnering with large, established firms. In either case, an understanding of the relevant industry is indispensable; good personal contacts are also vital.

One caveat faculty noted is that the licensing process--even before a deal is actually made--reveals confidential information and provides access to university researchers. Just having serious conversations with firms about the possibility of entering into a licensing agreement may involve some risk. Ideas can be stolen and key people can be lured away from the university. Therefore it is important to take steps to protect information and ensure mutual commitment. Letters of intent prior to any disclosure are helpful, and some agreement about how to handle confidentiality. Both parties to the agreement will want some measure of confidentiality, so there will be a common interest in trying to accommodate each other. It is useful, for example, to find out the extent of the firm's existing knowledge in the particular research area in question. Disclosure statements for this purpose can be useful for both parties. It is advisable to seek legal counsel in this area before proceeding.

Negotiating is an art, and the tactics used will depend largely upon the kind of partners and research involved. Licensing to nonprofit organizations will involve different concerns than licensing to for-profit firms. When dealing with nonprofit organizations, for example, the university typically will want to track usage of its research materials using material transfer agreements; prohibit or limit release to third parties; limit liability for applications; ensure access to results; and receive acknowledgement of the university role in the innovation. For-profit agreements are usually somewhat more complicated, depending on the intended use of the research results. The university may specifically wish not to be acknowledged in relationship to the end product (to avoid public relations and legal liability risks of the "university approved" label, for example). In addition, the university may want to be more careful about limiting the field of use of the research results and to institute some sort of policing mechanism, e.g., to protect against potential negative social or environmental effects.

Negotiation Exercise

The challenges of negotiation were highlighted in a group-breakout exercise in which participants were divided into small groups, each comprising a private sector licensee committee and a university licensor committee, pitted against each other with the mandate to negotiate a mutually acceptable licensing agreement. The technology in question was the "Money Tree," developed by the university. Both licensee and licensor groups were given their own proprietary information regarding goals, requirements, rules, resources, and restrictions; in addition, some information was known to both groups. Some of the proprietary information held by the two groups was designed to create intractable roadblocks preventing the successful conclusion of the negotiations, i.e., an agreement could not be reached if both groups adhered strictly to the rules they had been given. The rules of the exercise are presented below.

The Technology: Money Tree

1. It produces green fruits after three years of growth.
2. Fruit contains large amounts of antioxidants and antioxidants have great medical importance.
3. Fruit is good as a basic food and provides excellent nutrition.
4. Composed leaves make excellent fertilizer.
5. Wood is furniture quality.
6. Additional research is needed to learn of all the additional products that can be obtained from the Money Tree.

The Licensor: University of Ibadan

1. This is its first invention of any value.
2. Licensing Office staff wants to license the Money Tree.
3. Administration wants money from a Money Tree license.
4. Researchers need additional support for continuing Money Tree research.

The Licensee: West African Forestry Resources Ltd. (WAFeR)

1. Has number of successful products in the marketplace.
2. Markets its products in a number of countries.
3. Does not carry out in-house research.
4. Has large cash reserves.

Summary of Terms of Draft License Agreement

1. Exclusive license for Nigeria only
2. Two-year term
3. Right to sublicense
4. Initial fee of 500,000 Naira
5. Royalty rate of 15 percent
6. Sublicensee royalty rate of 55 percent
7. Minimum royalties of 600,000 Naira
8. Monthly reports required
9. Licensor pays for intellectual property rights protection everywhere
10. Licensor can terminate with 10 day notice
11. Licensee can terminate with 240 day notice

To be negotiated:

1. Exclusive or non-exclusive license
2. Term of license
3. Right to sublicense?
4. Up-front payment
5. Running royalties
6. Sublicensee royalty rate
7. Minimum royalties
8. Which party responsible for IP protection, enforcement, etc.
9. Termination
10. Any other terms

All of the above information was known to both parties at the beginning of the exercise. In addition, each party received its own secret "fax" after the negotiations were well underway, as follows:

Proprietary Information for WAFeR (licensee):

1. WAFeR has just been taken over by Ghana Agroforestry Products Incorporated (GAP), from Accra, Ghana.
2. You must get a license to the Money Tree--orders from the new owners
   a) The license must be for at least 15 years
   b) The front-end payment must be as low as possible and should not exceed 300,000 Naira
   c) The license must be exclusive for the world; sublicensing is not important
   d) Royalty rates should not exceed 5 percent and should only cover the tree, not its products
3. Failure in reaching an agreement as close as possible to the parameters set above could result in the loss of your jobs as well as your co-workers' jobs.
4. If you succeed, you and your team will be rewarded with significant salary increases and bonuses.

Proprietary Information for University of Ibadan (licensor)

1. The Vice-Chancellor of the University has said you and your team must license the Money Tree. Reasons include: publicity for the university, government questions about relevance of university research, plus the fact that the Vice Chancellor is getting impatient at the lack of results of the Licensing Office
2. You must license the Money Tree:
   a) The license term is not important
   b) The front-end payment should be as high as possible; it should exceed 500,000 Naira
   c) The license should not cover more than West Africa
   d) Royalty rates should be at least 5 percent and should cover the tree and its products
   e) Continued research support is very important, should get a minimum royalty of one million Naira per year
3. Failure in reaching an agreement within the parameters set above could result in the closure of the brand new License office
4. If you succeed, you and your team will be rewarded with two extra days of vacation this year

The main points of contradiction therefore are the amount of the up-front payment (with one side demanding a minimum of 500,000 Naira and the other side setting a 300,000 Naira limit); the geographic scope (with one side wanting to limit scope to West Africa and the other side

demanding worldwide exclusivity); and the product scope (with one side wanting royalties on the tree and all derivative products and the other side wanting to limit coverage to the tree itself). In practice, most of the breakout groups also experienced negotiating difficulties over the royalty rate itself and the guaranteed annual minimum payment.

The various breakout groups arrived at a range of different solutions to the negotiation puzzle, with up-front payment amounts ranging from a low of $250,000 to a high of $600,000; royalty rates ranging from 5 to 10 percent; license term ranging from 2 years to unlimited; a variety of exclusivity and non-exclusivity solutions; etc. One negotiating lesson that was underscored was the importance of appealing to a higher authority in case of an impasse. Just as in the exercise, in real life negotiators may be limited as to what they can agree to on their own; the higher up the authority chain one goes, the greater the amount of flexibility one generally finds.

MODULE IV:
Biotechnology and Biosafety

Faculty:
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INTRODUCTION

Biotechnology is an area of potentially major importance to Africa, in terms of both trade and the alleviation of hunger and disease among the poorest sectors of the population. It is also a controversial area that is criticized as highly dangerous as often as it is hailed as a potential savior of the world's hungriest people. Module IV focused mostly on agricultural biotechnology.

Proponents of agricultural biotechnology point to the fast-growing global population, arguing that most of the planet's arable farmland is already being used and that the use of genetically modified (GM) crops is the best hope of alleviating widespread hunger and starvation. Commonly cited benefits of food biotechnology are increased yields (without overtaxing soils); hardier varieties that can withstand heat and drought; enhanced nutritional--and medicinal--value; improved storability; and built-in pest resistance that may decrease the need for chemicals.

Critics argue that modifying the genetic structure of crops involves too many unknowns and is inherently risky, i.e., that GM crops may have unintended environmental effects such as the creation of uncontrollable weeds; that the foods themselves may represent health risks; that benefit claims are exaggerated, e.g., that breeding for pest resistance does not reduce dependence on pesticides; and that other claims are misleading, e.g., that it is inaccurate to say that genetic engineering is no different from time-honored traditional plant breeding techniques.

Trade issues are also integral to any discussion of biotechnology, and are equally controversial. There is on the one hand concern that exports of GM foods may not be welcome in foreign ports as a result of public concerns such as those mentioned above. On the other hand, there is also the converse concern, that nations' ability to set their own safety standards and labeling requirements may be nullified as anti-free trade under World Trade Organization agreements. In other words, regulating trade and differentiating between GM and non-GM foods are highly contentious issues that have yet to be fully resolved in the international arena.

In a widely publicized article highlighted by Module IV faculty members, M.S. Swaminathan wrote about the promise of the "gene revolution," but cautioned that "to capture such benefits we must squarely face the profound ethical and safety issues of biotechnology. These are complicated by the issues of proprietary science. Protests have been staged by farmers and citizens' groups in a number of countries on ethical or ecological grounds. There is also the genuine fear that proprietary science can confer monopolistic control over a key human need: food security. These fears can be addressed by promoting enlightened and transparent policies together with collaborative research that taps the knowledge of farmers and the capabilities of private and public institutions. Confrontation can give way to cooperation only if there is

unbiased dialogue on risks and benefits." ("Harness the Gene Revolution to Feed the World," International Herald Tribune, October 23, 1999)

In the spirit of constructive dialogue, Module IV seeks a balanced perspective on the threats and opportunities represented by biotechnology, with an emphasis on "biosafety"--the development of credible, participatory safety procedures that can help to establish a viable middle ground between those who say "go" and those who say "no."

BIOTECHNOLOGY

Faculty members defined biotechnology as new techniques from cellular and molecular biology designed to improve the genetic makeup and agronomic management of crops and animals, or to develop new drugs, vaccines, and therapies. Module IV devoted most of its time to agricultural biotechnology. Transitions in the world of agriculture have been driven by scientific advances, expansion of markets (regionally and globally), an increase in private sector activity, and concerns over the sustainability of food supplies and agricultural practices.

China was given as an example of a country that has been active in exploring the possibilities of biotechnology. Chinese scientists have, for example, developed an insect-resistant cotton from public funds, and it, along with similar products introduced by Monsanto, has been in great demand among farmers. The Chinese strategy was to limit Monsanto's product to two provinces, learning from the farmers' experiences there and reserving the rest of the market for Chinese products. The strategy has enabled China to compete effectively in biotechnology, at least within its own borders, while engaging selectively in international trade; in order to enter the international arena fully, strong intellectual property rights (IPR) protections and biosafety measures are necessary.

Cuba is another example of a country that has been highly successful in biotechnology, and under some extraordinarily adverse conditions. Despite the continued US embargo and the loss of external support following the breakup of the Soviet Union, Cuba has become one of the world's leaders in medicinal biotechnology. Cuban scientists have produced vaccines for dengue fever, hepatitis B, and meningitis B, and developed promising antibody therapies to fight cancer. Cuba's biotechnology industry is now worth hundreds of millions of dollars per year and its products collectively rank among the country's top exports.

Clearly, there are lucrative markets for the products of biotechnology, and opportunities even for developing countries to become involved and reap the benefits. At the same time, the prospect of genetic engineering--whether applied to crops, livestock, medicine, or human beings--triggers a range of ethical, environmental, health, and safety concerns that must be addressed.

Farmers have always been eager to take advantage of new crop varieties that improve yields. Faculty asserted that in order to import new wheat seeds during the "green revolution," the first thing India had to put in place was "fences and police," because of the intensity of demand among farmers. Similarly, many farmers are interested in acquiring genetically modified seeds that promise to make their work easier and more profitable.

However, demand is tempered by concerns over the type of modifications that are made. The now-infamous "terminator" gene developed (and eventually abandoned) by Monsanto caused a public outcry, for several reasons. The terminator gene renders seeds sterile, so that farmers need to buy new seeds each planting season. While some farmers wanted the seeds anyway,

feeling that the advantages outweighed the disadvantages, others objected to the enforced dependence on the seed company. Additionally, farmers and the general public raised concerns over "gene flow," i.e., that the terminator gene could be unintentionally passed on to other crops, with potentially disastrous results.

Training course participants discussed these and other potential concerns over GM foods, including the potential negative effects on ecosystems, human health, and crop diversity. With regard to concerns raised about displacement of traditional crops, participants were somewhat divided. Some emphasized that consumer preference would ultimately decide, and that only inferior crops would be displaced. Others stressed that food tradition is extremely important in Africa, to the extent that many people will go hungry if their preferred choice of food is unavailable, rather than settle for available alternatives, because of culturally derived preferences or taboos.

Much discussion also centered on pest resistance. Some participants expressed concern over the effect on ecosystems, i.e., if hungry insects are no longer interested in pest-resistant crops, they are likely to turn to something else instead--something we cannot predict. The food chain--both upwards and downwards--might be affected in undesirable ways. In addition, the inherent usefulness of breeding for pest resistance was questioned: a narrow focus on repelling successful pests is likely to result only in previously less successful pests rising to occupy that environmental niche, while a broader resistance may repel even beneficial insects. Insects are notoriously adaptable creatures, so that genetic manipulation may not ultimately reduce dependence on chemical pesticides in any event. Finally, some participants raised the fear that in-bred pest resistance might also be toxic to humans in the long term.

Some of the more pro-GM faculty members argued that most of the public's concerns were a result of ignorance, and that foods have been genetically modified for some ten thousand years through traditional breeding techniques, and that the only difference is that genetic engineering allows for more precise alterations. Other faculty members and participants stressed that there were important differences, such as the introduction of genes from other species and indeed from other kingdoms, e.g., the use of animal genes to modify plants. Consensus emerged that the safety of GM foods should not be taken for granted, and that safety measures should be implemented. A point of debate that persists is whether the burden of proof should be on the public, to show that a GM product is harmful, or on the firm, to show conclusively that it is safe. Other questions include how much risk is acceptable, and what are the risks of not employing biotechnology? Risk management and risk communication are subjects beyond the immediate scope of the training course, but it is clear they are integral to the process of public debate and the definition of the terms on which biotechnology will ultimately be accepted or rejected.

GOVERNMENT PRIORITIES

Public opinion is not the only constraint on biotechnology, which currently represents only a small percentage of total agricultural research expenditure in Africa. The application of biotechnology to agricultural research requires new investments, changes in resource allocation, and new expertise and responsibilities among policymakers and scientists. Benefits and risks need to be identified and weighed, productivity constraints need to be understood, and decisions need to be made regarding the extent to which biotechnology is appropriate under a given set of national conditions, as well as what the priorities of biotechnology research should be.

ISNAR conducted surveys in 1998 of biotechnological research in Mexico, Kenya, Indonesia, and Zimbabwe, with data covering the period from the mid-1980s to the late 1990s for a total of 34 public and private research organizations. The ISNAR survey showed that public sector institutions accounted for upwards of 90 percent of expenditures on biotechnology, yet only a few public sector institutions were using advanced research techniques; most were only in the early stages of developing the capacity for biotechnology research. Private sector biotechnology research has been virtually absent, in contrast to the developed world, where upwards of 70 percent of such research is performed by private firms. This trend may be reversing in developing countries, as noted in Module III, with an increasing emphasis on private investment and IPR. The public sector may have difficulty keeping up with the private sector; the entire CGIAR research budget is only a small fraction of the research budget of one large biotech company.

In addition, the ISNAR study found that most of the existing agricultural biotechnology research focused on crops, rather than livestock. Finally, the number of researchers grew faster than the amount of money allocated, resulting in an overall decline of funding per researcher. In short, technical capacity and financial resources for biotechnology are currently very limited in these countries.

Policy and management issues involved in encouraging responsible biotechnology include enhancing managerial capacity in public research organizations, creating strategies and setting priorities, managing biosafety and intellectual property, assessing funding implications, considering public-private partnerships, and delivering products to end users. The research agenda, and biotechnology's place within it, must be determined by a country's particular priorities. Biotechnology is most likely to have an appropriate role where conventional research has been unable to solve a priority problem. Therefore, defining a clear research agenda is an important preliminary step in managing biotechnology.

Whether or not a given country is interested in investing in its own biotechnology development capacity, some capacity for priority setting and policymaking remains essential in light of biotechnology's growing global importance. Imports of biotechnology products can raise as many policy questions as biotechnology research itself, e.g., what testing and safety standards have been used? Similarly, in-country private investment, whether local, foreign, or multinational, may raise important policy considerations as well: What policies will provide incentives for the research to address pressing local needs? Patent applications may force a country to determine policies on the fly if it is not prepared. For example, Uganda had to decide very quickly about Monsanto's terminator gene patent application when it came through the Patent Cooperation Treaty system. Therefore it is important for countries to anticipate likely scenarios and be prepared to respond.

Priority setting is not a trivial consideration. Rather, it is a highly complex process of consulting with stakeholders, documenting, disseminating, and receiving information, and ultimately making difficult choices among research areas to find those that promise to have the most desirable impact within the limitations of available resources. Faculty emphasized that priority setting should be a structured, formal process, and presented several different models that can be employed. Regardless of the method of priority setting used, however, certain key points emerged as fundamental to the process:

- The method should have a transparent and formal structure in order to ensure logical consistency, resolve conflicting demands, and strengthen the quality of the results;

- The quality of the results depends on the quality of the inputs;
- The process must be ongoing and include periodic re-evaluation, with frequency balanced against the costs incurred;
- Participants in the process include decisionmakers, economists, researchers, clients (including farmers and private sector interests), and, as some people argued during discussions, NGOs and other members of the community at large;
- Priority setting can have a top-down or a bottom-up structure, or can combine the two approaches;
- Decisions are determined by objectives, which can include efficiency and economic growth, equitable distribution of benefits, food security, and sustainability of the resource base; not all objectives are mutually compatible;
- Basic priority-setting steps include: identification of research objectives; definition of alternatives; definition of criteria and methods; assessment of performance and comparison with alternatives; and approval and implementation of priorities;
- Success factors include: good inputs (method, criteria, and information); participation of stakeholders; consensus building; support of key agencies and individuals.

One of the primary challenges, easily overlooked, is how to involve the "silent stakeholders" such as small farmers. Decisionmakers must actively seek the input of these groups. Participants urged that managers of priority-setting efforts should not "just sit in the office," but should go out into the field and speak with representatives of farmers' associations, for example. If there are no such organizations, the manager can approach community centers or go through local chiefs. Throughout Africa, small farmers are a crucial part of society, and their input is needed, their needs and priorities must be understood.

Once agricultural biotechnology priorities have been determined, it is important that the research has stable, long-term funding if it is to have a reasonable expectation of scientific success and development impact. Political support is therefore an essential element to the biotechnology endeavor, and will necessarily involve documenting and publicizing research impacts, establishing open communications channels, engaging all stakeholders in a participatory process, building strong relationships among key players, and broadening the funding base, e.g., by promoting public-private partnerships and including a range of government agencies.

BIOSAFETY

Measures to ensure the safety of genetically modified organisms are indispensable to the conduct of research in this area. New technologies have risks that demand careful consideration in advance of wide-scale adoption in the field. Biosafety measures are necessary as a matter of sound public policy; they are also increasingly required as a precondition for donor funding of biotechnology research.

There are two main areas of concern: environmental/ecosystem effects and human health. More particularly, specific concerns include:

- Weediness: There is some concern that the herbicide-resistance trait introduced into crops might be passed on to non-targeted species, which could foster tough new weed varieties that would be difficult to control.

- Geneflow: Geneflow refers to the transferability of traits among domesticated and wild plant species, i.e., it is a general concern that traits introduced into a target species could be passed on to other species unintentionally, with unpredictable results (with "weediness" being just one example). Built-in resistances to pests and herbicides that are desirable in a target species might be highly undesirable if translated to other species, and could create significant disruption of ecosystems over time.

- Toxicity and Allergenicity: The long-term human health effects of crops that have been genetically modified, e.g., for pest resistance and herbicide resistance, are not known. How much testing is enough? With whom should the burden of proof reside? Is labeling ever or always necessary? Is labeling sufficient?

- Pest and Pathogen Effects: The concern here is over non-target species effects, such as virus resistance resulting in mutations that produce new viruses, pest resistance resulting in mutations that produce novel pests, or non-targeted insects suffering from introduced pest-resistance traits.

These concerns have prompted both developing and industrialized countries to implement biosafety guidelines governing testing, safe use, and handling of GM crops in the environment. In West Africa, all countries have ratified the Convention on Biodiversity (CBD), in which biosafety is a priority. Nigeria and Cote d'Ivoire have developed biosafety guidelines already; Cameroon, Mauritania, Ghana, and Niger are at the initial stages of delineating a regulatory framework for biosafety. Many countries, within and outside West Africa, are participating in negotiations to develop an International Biosafety Protocol, as called for by the CBD. Ideally, international protocols would be based on strong national protocols, yet in practice there are only 40 to 45 national biosafety systems currently in place worldwide; thus there is a need for prompt action at the national level in those countries that are not currently active in this area.

Sufficient experience exists from which to draw the general outlines of an effective biosafety system. In addition to the safety guidelines themselves, proper oversight of GM crops must also involve a communications structure that allows for the participation of all stakeholders; a biosafety review process; and mechanisms for ongoing feedback and evaluation. Meeting these management challenges requires multilateral education and sensitization efforts and coordination of numerous government agencies, universities and research institutions, private-sector interests, individual scientists, and the public, as for example represented by NGOs or community organizations. The management challenge is to establish a system in which all these elements function well together and produce decisions that safeguard human health and the environment.

Building a Biosafety System

In general terms, the biosafety management strategy begins with identifying the key players and soliciting their early participation in the review process, building an atmosphere of openness, and educating decisionmakers about the key role of the biosafety system in building public acceptance and minimizing health and safety risks.

The first task is to define the overall framework of the biosafety system. What are the objectives of the system? What is the scope of oversight, e.g., agriculture, medicine, etc.? What products

will require review, and where are the boundaries, e.g., on new products derived from already-approved products? Who are the participants and what are their rights and responsibilities? Who ultimately holds decisionmaking authority? How will decisions be implemented, e.g., through new laws, or by using existing legislation?

Faculty asserted that biosafety guidelines, in order to be effective, must be:

- Science-based (to evaluate risks);
- Flexible (to incorporate new knowledge); and
- Transparent (to allow the public to review and evaluate procedures).

Costs

Developing an effective biosafety system may well require substantial training, e.g., to raise awareness of policymakers, introduce ethical and safety issues to researchers, increase the technical capacities of biosafety reviewers, and to promote regional harmonization of standards. There is currently a limited pool of people qualified to evaluate the safety of GM organisms. Of the people who have relevant expertise, many are private sector firms or researchers who might have a conflict of interest with the review committee's mandate. Finding the appropriate people to serve on biosafety review committees, and training them if necessary, is therefore one of the greatest initial challenges facing policymakers.

Training and education are not the only costs of the biosafety system. Other costs include the administration of the system; the establishment of public relations mechanisms; the loss of productivity represented, for example, by the participation of scientists who could otherwise be conducting research; the organization of meetings and consultation with experts; access to and collection and dissemination of information; and performance of public outreach. Who should pay for these necessary services? Recommended strategies include pooling resources among agencies; charging application fees for submitting GM organisms for approval; capitalizing on investments by, for example, offering incentives to keep trained people in the country; and taking an anticipatory rather than a reactive approach to biosafety issues.

Information and Risk Assessment

Another difficulty is simply the knowledge gap. There are many unknowns in this area, particularly pertaining to the long-term effects of GM organisms on human health, biodiversity, ecosystem balances, and other environmental effects. Therefore the process of information collection and reporting during laboratory and field testing is essential to building the store of human knowledge in these areas. Whether testing leads to commercialization of products, given these uncertainties, is a question that can only be resolved by the application of rigorous science and risk assessment in combination with informed public policy, ideally driven by democratic processes in which many voices are heard.

While science plays an essential role in providing decisionmakers with physical facts, the ongoing process of review, evaluation, and decision is not simply a matter of calculation based on scientific inputs. The process necessarily involves value judgements as well. For example, there is no such thing as a zero-risk option for biotechnology (or for anything else); every possible decision, including the decision not to adopt any biotechnology, involves some measure of risk. Therefore risk assessment is not a process of determining a risk-free direction. Rather, it is a

process of balancing risks against benefits, determining types and acceptable levels of risk for any given decision, and minimizing the likelihood and extent of negative impacts through the management of risk, e.g., through preventive and prepared-response measures.

The information gathering and decisionmaking processes must be transparent precisely because these evaluations do involve value judgements; the question of whose values are represented must be dealt with democratically if a stable, just, and effective system is to be implemented. National committees on biosafety should have broad representation of stakeholders--not just "experts" but concerned lay people as well.

In order for information to be useful, people must have access to it and the capacity to use it in a meaningful way. This principle applies both to the technical people involved in scientific reviews and to the public at large. Thus an information strategy is needed in order to deliver useful information to those who need it. Information costs should be budgeted, open communications lines should be established, and future needs should be anticipated.

Where does the information come from? A variety of sources can be used. Faculty stressed the importance of building local capacity to perform reviews of biotechnology, rather than relying exclusively on foreign experts and their reviews. Nations should have the capability of determining their own priorities, in order to handle imported goods properly and regulate products generated by in-country research, whether conducted by foreign or local researchers. Outside expertise may also be tapped as appropriate, understanding and factoring in any inherent biases of the information sources. Expertise in genetic research exists in Africa; it needs to be enhanced and better organized for the task of biosafety management.

Measures of Success

Measures of success include guidelines that clearly define objectives, responsibilities, and procedures; people who are knowledgeable, well trained, and confident; reviews that are based on sound science and are realistic about risks and benefits; and an evaluation system that actively seeks and uses feedback. In addition, decisions made by national biosafety committees should have substance and legal weight, so that compliance is the norm and progress occurs, i.e., it is not necessary to revisit the same issues over and over again. Finally, a good measure of success is a system in which all stakeholders are actively involved, including NGOs and the public, and in which periodic reviews of decisions and outcomes are made.

The role of the public bears special mention, as it was the topic of a good deal of discussion among participants. There is a tendency among some scientists and policymakers to view the public as a troublesome and ignorant entity that simply needs to be educated about the benefits of biotechnology. This tendency can be seen in recommendations that stress public relations and education, i.e., an outward flow of information, while overlooking the importance of actual public participation in the policy dialogue, i.e., a corresponding inward flow. Several participants objected to this omission. It may be conceded that there are many misconceptions about biotechnology among the general public, and that greater educational and outreach efforts are necessary. However, it is not true that all public concern can be written off as ignorance; there are legitimate concerns that must be respected and addressed. For people to trust the system that is supposed to protect them, they must feel that it truly represents their interests. Genuine democratic participation is the most effective way of ensuring public acceptance and informed policy, and as such is one of the key measures of a successful biosafety system.

Case Study

Faculty presented a case study of biosafety in Egypt. The Egyptian biosafety system was instituted in 1995, following an intensive workshop on biosafety held in Cairo in 1994 involving the Agricultural Genetic Engineering Research Institute (AGERI), the Agricultural Biotechnology for Sustainable Productivity (AGSP), and the Egyptian National Agricultural Research Project, along with other international agricultural organizations and seed companies. The guidelines were drafted very quickly, from the January 1994 workshop to the issuance of the guidelines in January 1995, and were based on US and European guidelines.

The Egyptian biosafety guidelines are not legally binding, with only advisory status; they lack details regarding review, decisionmaking, and reporting processes; and they have not been well publicized within the country. The initial biosafety committee comprised ten scientists, but was later expanded to include 30 people. However, the committee included only technical members, despite a specification in the guidelines recommending the inclusion of non-technical members. Nevertheless, the guidelines have functioned since 1995, with 23 permits for field trials issued and three GM crops moving toward commercial release. Findings on the Egyptian experience to date include:

- Relevant safety issues were not always raised in the review procedures; for example, geneflow and pest resistance concerns were not considered.
- Significant delays were experienced during the application and review procedures.
- There is a need to streamline the seed registration process.
- There has been no mechanism for public feedback and no strategy in general for public relations.
- There have been no reporting requirements at the end of field tests.
- The system includes no funding for information acquisition or attendance at meetings and workshops for education and training.

After discussing the case study, participants broke into working groups for the purpose of making biosafety system recommendations in four key areas: guidelines, people, review process, and feedback mechanisms. Their recommendations are summarized below.

- Guidelines: The first priority recommended was to define the legislative framework, i.e., clarify what relevant laws and regulations are already in place, what new ones may need to be written, and what enforcement and punitive mechanisms will be associated with the biosafety process. Participants recommended the establishment of an inter-ministerial body, with the secretariat within the Ministry of Environment, to coordinate government policy and serve on a national committee on biosafety.
- People: Participants recommended that a national committee on biosafety should include farmers' associations, industry representatives, universities, research institutes, NGOs, churches, and other "opinion leaders," as well as a range of government ministries (agriculture, environment, trade, finance, commerce, justice, science and technology, health, education) and mass media contacts. Priorities included developing clear terms of reference for the committee and ensuring public participation in decisionmaking.

- Review process: Again participants called for a clarification of the existing legal regime and the establishment of a national biosafety review committee with broad representation to monitor and control genetically modified organisms. Other recommendations included the creation of a publicly accessible database of genetic research developments and product approval applications, and an investment in training and information access to build local institutional capacity for performing biosafety assessments.

- Feedback mechanisms: Recommended mechanisms included consultations with experts (actively seeking multiple points of view), publications to help keep the public informed and better able to respond, and open channels of communication with stakeholders, including researchers, private firms, farmers, NGOs, et cetera.

Participant recommendations were closely aligned with the recommendations generated by the review committee that analyzed the Egyptian biosafety system. Other recommendations in the Egyptian case included:

- Revise guidelines to include a clear statement of purpose with specific objectives and a detailed "road map" with instructions and examples; upgrade status of biosafety committee to have legal authority to ensure compliance with recommendations.

- Institute a secretariat for administration of the national biosafety committee, responsible for information collection and dissemination; broaden the funding base to include multiple ministries; rotate committee membership; consider ad hoc technical committees rather than a standing subcommittee; consider delegating laboratory and greenhouse approval requests to an international biosafety committee.

- Improve procedures by creating realistic timelines for review and decisionmaking; include financial support for information acquisition and meeting attendance; commission risk assessment studies tailored to Egypt's particular circumstances; assign national laboratories to certify food and feed safety.

- Define a feedback process; create a strategy for public awareness, e.g., train spokespersons in risk communication and use mass media.

In conclusion, a consensus among participants emerged that biotechnology is to some extent inevitable, and has great potential to benefit Africa; the continent must better prepare itself through capacity-building measures in research, industry, and biosafety regulations.

GENETIC RESOURCES AND INTERNATIONAL COLLABORATION

There are two basic ways to conserve genetic diversity: *in situ* (in the natural environment, as in national park lands or on farms) and *ex situ* (removed from the natural environment, as in genebanks). With in situ conservation, dynamic evolutionary processes continue to operate, including the possibility of mutation and the threat of extinction. With ex situ conservation, the long-term safety and integrity of genetic resources is maintained by collecting and preserving seeds, living plants, cuttings, and tissue cultures. If a plant becomes endangered in situ, it can be moved to a genebank for ex situ conservation.

The functions of a genebank include maintenance and expansion of germplasm collections, long-term conservation, including multiplication and regeneration, characterization and evaluation of

samples, data management, exchange of germplasm among researchers, and the promotion of germplasm use to enhance crop productivity. Ex situ conservation in genebanks is a safe and cost-effective method of preserving the genetic diversity of crops and wild species of plants, as long as the seeds can tolerate desiccation and storage at low temperatures.

Biotechnology in this context refers to developing an understanding of crops and other plants at the genetic level to enhance their use and conservation. In the International Rice Research Institute (IRRI), for example, the main applications of biotechnology are in vitro culture of seedlings and the study of genetic diversity using a range of molecular markers. Understanding of the genome of one crop can also yield useful clues about others. For example, there is great similarity among the genomes of wheat, rice, and maize. Isolating the gene responsible in one plant for a particular key trait, such as plant height, offers valuable clues to the same trait in the others.

Biotechnology and Ex Situ Conservation

The CBD is primarily concerned with in situ conservation and protecting the environment as a public good and for sustainable and traditional use. Ex situ conservation is quite a different matter, with its own set of issues and its own well-functioning system of cooperating research institutions that predates the CBD by many years. The research institutions comprising the Consultative Group on International Agricultural Research (CGIAR), for example, freely exchange germplasm among scientists and distribute seeds to farmers in addition to their conservation and internal research functions. The CGIAR system has the world's largest collection of plant germplasm, with tens of thousands of accessions for each of the major world food crops, held as common "global property." The advent of biotechnology has enhanced research efforts, and has also contributed to an increase in concern over IPR and introduced certain constraints on the exchange of biological materials.

The multilateral agricultural genebank system is no longer free of legal and commercial concerns as it had been, for the most part, for so many years. Germplasm is still exchanged, but it goes out under material transfer agreements (MTAs) that specify how and by whom the material is used, reporting requirements, and conditions on subsequent development. Recipients of this public germplasm are not supposed to seek IPR protection on the materials. However, if in the course of subsequent research significant new developments are made, the new products may qualify for IPR protection. In that event, the enhanced material will not be contributed back to the international genebank and made freely available for further research purposes; it will be privately held and commercially developed. Private firms, in other words, are able to draw from the public genebanks without necessarily giving anything back to the system.

To the extent that private commercial development and IPR protection become dominant in agriculture, the open public research model for agriculture potentially becomes increasingly irrelevant. Genebanks could become more like museums than active research centers, and could ultimately become unsustainable. If the genebank system breaks down, the collections would be repatriated, with uncertain implications for the continued conservation of these genetic resources. There are also fears that biotechnology will reduce crop biodiversity, and that the increasing privatization of crop genetics will hurt poor farmers and exacerbate hunger among the world's poor (see below under "Biotechnology and Food Security in Africa").

These potential negative outcomes are not the inevitable consequence of biotechnology or of IPR concerns. The situation is complex, with numerous factors coming into play and shaping the future direction of farming and agricultural research. The shift between public and private

research is a trend being explored in all its various implications, as public international research institutions attempt to find their role in the changing system. Benefit-sharing, grant-back, and disclosure requirements, for example, are all negotiable terms that can be governed by contracts and MTAs. International research institutes and private firms may ultimately complement each other, researching different crops and breeding different traits for different clienteles. GM crops can be used in combination with traditional crops and traditional methods, so that "biotechnology versus agroecology" is something of a false dichotomy. Whether GM crops benefit poor farmers and enhance food security depends largely on what traits are being enhanced; storability, for example, is often more of a concern for poor farmers than herbicide resistance or even higher yields. Nutritional and medicinal value is being added to crops, enhancing health maintenance and disease prevention. Where the private firms may not find profitability, the public research system may still fill a valuable function.

Investing in Biotechnology

The use of biotechnology as part of a genebank conservation or food security strategy has cost implications that each research institution must evaluate on its own terms. The adoption (or non-adoption) of biotechnology should be shaped by the overall conservation goals and priorities. Pertinent questions include: Will biotechnology enhance access to or management, conservation, and use of genetic resources? What alternatives to biotechnology can be used in the genebank to accomplish similar ends? What are the resource implications (human, equipment, operating expenses) of sustaining a biotechnology program? What are the trade-offs for not making the biotechnology investment? How will investment in biotechnology affect the allocation of resources to other essential areas of genetic conservation?

Faculty recommend that any investment in biotechnology should be made at a level that is consistent with the overall resources and mandate of the particular genebank, i.e., the investment should be sustainable over the long term. The basic elements of a strong conservation program must be in place already before even considering an investment in developing biotechnology capabilities.

Discussion centered on the issue of training, capacity-building, and brain drain. There are several different models for capacity-building and training, including developing African centers of excellence, sending students abroad for training, or bringing instructors to Africa for limited time periods. One of the difficulties of capacity-building is that, once they are trained and have acquired marketable skills, people from developing countries can often find opportunities abroad that tempt them to leave their home countries in favor of more secure futures elsewhere. The likelihood of this kind of "brain drain" increases when students receive their training abroad, where more opportunities present themselves. While individuals have every right to pursue those opportunities that best protect themselves and their families, African policymakers must try to build training systems that provide incentives for people to stay in home countries.

Building centers of excellence is one way to make working in Africa more attractive. As a training model, bringing instructors to African universities or training centers can train more people for less money than it would cost to send those students abroad. In addition, training at home makes it less likely that people will leave.

INTERNATIONAL COLLABORATION IN BIOTECHNOLOGY

International collaboration is one way for African institutions to increase their biotechnology research and evaluation capacities. Collaboration can create opportunities to monitor and access new developments and opportunities in agricultural research; provide support for local capacity-building, including training, information, and infrastructure development; and enable access to advice and expertise on research and research management. There are international research programs for both plants and livestock, global and regional networks dedicated to particular crops or geographical areas, specific programs organized by donor agencies, and organizations that specialize in providing advisory services on policy and research issues.

International technology transfer can be divided into four basic categories:

- Direct transfer: introduction of a crop variety or other product without any modification;
- Adaptive transfer: adaptation of a crop variety or other product to local economic and climate conditions;
- Science transfer: research-enabled development of new crops or other products; and
- Capacity transfer: training, education, and advice.

Crop research is currently the biggest area for international programs, with cereals (especially rice) as the top investment area, followed by root crops and perennials. Livestock research has been conducted less extensively, with a focus on tropical animal diseases, particularly with regard to cattle. The second most important component of international biotechnology programs after research is training, with many opportunities to be found in the international agricultural research centers, and in Europe and the US at public institutes and universities. However, the training activities are concentrated mostly at the doctoral and post-doctoral levels, leaving a significant gap at the university and masters level. A third focus of international biotechnology programs is advice on policy and management, with many research programs including a minor focus on these issues.

The primary expected products of international collaboration in biotechnology are disease-free planting material; biocontrol agents (pest and herbicide resistance); transgenic plant varieties; and new diagnostics and vaccines for livestock diseases.

Faculty emphasized several cautions with regard to management considerations at collaborating African institutions:

- Priorities for international programs are usually determined by funding organizations; African institutions should set their own priorities and be careful to determine whether available opportunities correspond to their own agendas;
- Limitations based on institutional capacity must be understood realistically, as most research and training opportunities are at an advanced level; support for building local capacity should be built into projects wherever possible;
- Products from international collaboration may require biosafety review, which triggers the need for further institutional capacities (see above discussion under Biosafety); product

development and diffusion is also likely to require the participation of the private sector, and IPR considerations need to be specified for each collaborator.

Participants broke into small working groups to examine case studies, identify constraints and indicators of success, and make recommendations. Group findings are summarized as follows:

- Success factors: technology transfer and training (preferably within Africa) occur; close involvement of scientists and decisionmakers from early on in the collaboration; good organization and planning; development of improved crop varieties;

- Constraints: mismanagement of resources; brain drain; rushing to complete agreements; lack of support for training up to M.Sc. level; low funding in general; initially limited awareness and capacity; erratic supplies of electricity;

- Recommendations: increase funding for national agricultural research centers; conduct training in Africa; develop local biosafety evaluation capacity and ensure enforcement of regulations; ensure capacity-building element in collaborations; develop participatory priority-setting system; improve electricity supply.

BIOTECHNOLOGY AND FOOD SECURITY IN AFRICA

Biotechnology has the potential to improve African food security, depending on a variety of factors, including what crops and particular traits are modified, how GM crops fit into the overall agricultural management system and complement traditional techniques, and whether GM seeds are affordable to small farmers. The number of undernourished people in the world may increase by as much as 50 percent by the year 2015 according to some estimates, and many people are looking to biotechnology as a tool that can mitigate that trend.

Faculty emphasized that absolute quantity of food supply is only one factor, and not the most important one, in determining the extent of hunger in the world. In all, there are three essential considerations:

- **Availability**, i.e., the amount of food that physically exists;

- **Access**, mainly meaning sufficient income to buy food or the ability to produce one's own food; and

- **Utilization**, which includes:
  a) allocation within the household, i.e., cultural and personal patterns of control over income and food that determine who eats what, especially in times of scarcity; and
  b) health, i.e., physical ability to utilize food, which can be impaired by illnesses such as diarrhea.
  Therefore socioeconomic considerations such as sanitation, availability of clean water, and the role and status of women all play key roles in food utilization.

Availability is not generally considered to be the biggest problem; most people concede that there is probably enough food in the world to feed everybody, if distribution was equitable and income was not a factor. The most important issue is access to food, i.e., the ability to buy or produce food. Social, economic, and political considerations are therefore paramount. Inequities in Africa resulting in poverty, war, and civil strife are in this sense food access issues. Low

agricultural productivity, a collapsing natural resource base, and natural climate variability aggravated by global warming, e.g., floods and droughts, also contribute to hunger in Africa. Ultimately, there are fundamental questions about national and international political economies that need to be addressed, e.g., how to reduce or eliminate poverty, if these issues are truly to be resolved. The question in this context is whether in the shorter term biotechnology can ameliorate some of these difficulties and improve access to food by the poor.

What kinds of agricultural biotechnology might address the particular needs of African farmers and the poor? Several areas were highlighted as useful target traits for genetic modification:

- Drought resistance;
- Shorter growth cycles;
- Low input requirements (fertilizers, labor);
- Low use and maximum retention of soil nutrients (i.e., crops that are good in fragile soils);
- Avoidance of need for complex seed distribution systems (i.e., easy planting);
- Improved storability;
- Hardiness, even at the expense of higher yields.

Essentially, these suggestions point to the need to help "the little guy." Most private research is currently focused on pest and herbicide resistance, which are not the most important concerns of small farmers. Faculty noted that it is relatively easy (and more profitable) to develop new technologies to help big commercial farmers with extensive fertile land and intensive inputs. On the other hand, large farms can also have positive ripple effects, creating employment, raising incomes, and stimulating demand for other types of services that help the economy overall. Research needs to find an appropriate balance between the needs of large and small farmers if biotechnology is going to make a difference in African food security.

The share of biotechnology research as a proportion of total agricultural research in Africa is currently marginal--less than three percent--and is heavily dependent upon donor funding. The public sector predominates, with very little participation by the African private sector. Yet publicly funded agricultural research in Africa has been declining in real dollars since 1981, with an increasing number of researchers, so that the per-researcher funding level is fairly dismal. Either public funding will have to be increased, or private investment in biotechnology to benefit poor farmers will have to be stimulated somehow. Creative approaches to public-private collaboration may also be useful in this regard.

Traditionally, agricultural research has been considered a classic public good, with all the hallmarks that justify public spending: long-term, high-risk research; benefits accruing to people who do not pay; lack of competition in basic research; difficulty of obtaining full IPR protection; and association with other public goals related to food security and environmental protection. Most of the growth in private sector research has been in non-farm areas, avoiding conflict with the public research paradigm. Agricultural biotechnology falls somewhere in between these two areas, on the border between private and public good, raising some key questions:

- How can biotechnology firms be induced to invest in crops that are important to poor people, such as yams, cowpeas, and plantains?
- How can biotechnology firms recoup huge investment costs from poor farmers, especially if they replant their own seed stock?
- What innovations can legitimately be privately appropriated under patent law?
- How can environmental and health protection be assured?
- How can we ensure absence of abuse by monopolist powers in a market dominated by a small handful of huge seed companies?

Faculty suggested that the answer is that the private sector cannot by itself guarantee research that will benefit the poor and that will protect health and the environment. Some degree of public subsidization will remain necessary on global and national levels, both to support research directly and to stimulate private investment in key areas.

On the global level, public funds are required to assure adequate research on crops and livestock that are most important to the poor. These funds can support international agricultural research centers, or can subsidize private involvement by covering fixed research costs. Nationally, public subsidization can encourage biotechnology firms to transfer technology where they are unlikely to recapture variable costs and to avoid complicated seed distribution systems. The public sector also has the responsibility to ensure biosafety and to set appropriate IPR guidelines.

GBDI/IITA Biodiversity, Biotechnology, and Law Training Course: West Africa
Course Evaluation

Each participant prepared an overall evaluation of the training course at the end of the three weeks, summarizing both strengths and weaknesses from their individual perspectives. Extracts from their evaluations are quoted below, in no particular order.

"The training course has opened my eyes to the complex issues involved in bioprospecting and equitable sharing of the benefits derived from the sustainable use of genetic resources among all the stakeholders. This is a course that should be recommended for all students of biological sciences, agriculture, political science, environmental sciences, and the law…The training program was well organized and the resource persons were highly knowledgeable in their respective areas. I am, however, suggesting that there should be a forum where the resource persons meet prior to the training session for harmonization of their presentations so as to prevent repetition of the same issues." *S.R. Ajibade, Nigeria*

"This course has helped to broaden my view of what is happening in the international scene as regards issues pertaining to biodiversity, biotechnology, and law…I was particularly impressed by the caliber of the resource people." *Njoku Chioma, Nigeria*

"It would be helpful to receive information on the scope and plan of course…prior to its commencement. Getting all [reading] materials at once at the beginning of the course would also be helpful. [The course was] extremely thorough…I would add a few things: 1) I think more background is needed for two key agreements: CBD and TRIPS. This could include a history of the "seed wars," patent law, and a history of key advances in biotechnology…2) more on-the-ground reality checks…Specifically, some time needs to be dedicated to existing problems and issues that currently impact biodiversity as well as how these issues will pose problems to the introduction of biotechnology where it doesn't yet exist. 3) a session or more to brainstorm issues that came up in role play…there were some issues that continually came up, such as educational campaigns for government and schools. Perhaps what could be done is a session on how to be a trainer, how to organize within the schools, strategies to communicate with government, how to build networks, etc." *Kris Peterson, United States*

"The training course was well organized…In future efforts should be made to make the hand-outs available to the participants before each lecture commences so that participants can follow the teaching…The course has…provided me with information on the current status and development in the field of biodiversity and biotechnology and also gave me a better understanding of other professions, e.g., the law…I believe that the time frame for the training course was rather short to cover the subject matter, and would like to suggest that future training courses should be extended to four weeks." *Gladys Adams, Nigeria*

"The communications to the participants with regards to their travel arrangements were not very efficiently handled [for] me and my two other colleagues from The Gambia. This aside, the course has been very well thought out and organized…One of my greatest satisfactions comes

from the improved understanding I have of necessary legal frameworks that govern the use of bioresources…The collection of presenters [was] very well chosen. I suggest that next time efforts should be made to cut down the length of the training by about one week. I believe this should be feasible because some of the presentations, especially those on legal issues, seem to be very similar…Overall, this is one of the best training programs I have attended (if not the best)." *Baboucarr Manneh, The Gambia*

"The course itself stands to create a better West African position on biodiversity conservation. Most of the resource persons seemed to be very knowledgeable about their subject areas. Some of the subject areas should be combined [where] one person could cover both [areas]…There was a very serious bias [against] forestry. You need to include facilitators in forestry research…[taking] into consideration that the issue of biodiversity conservation focuses on forest loss and habitat protection." *Ben Donnie, Liberia*

"With regard to facilitators, I think…efforts should be made to select Africans who know better about the reality of the continent…In general, the course was well organized." *Mahamane Larwanou, Niger*

"Concerning the organization of the course, the facilitators and materials were perfect. But the timing was very short, therefore there is a need to consider the duration of the course." *Victoria Cole, Liberia*

"My overall assessment of this course is that it has been a tremendous success in enlightening most of us who had vague or little ideas on bioprospecting, biodiversity, and the legal aspects of these issues. I particularly learned a lot from the lucid presentations of the expert facilitators from the various countries that had put in place the necessary legislation on biosafety and its attendant implications…I was particularly moved by the warm and friendly interactions among the participants. This went a long way to make the course very lively and exciting…I hope this spirit of brotherhood will be translated into action in our drive to actualize the outcome of this training for the development of our sub-region." *M.T. Moseray, Sierra Leone*

"The training course was very good and targeted burning issues in biodiversity, biotechnology, and law. Resource persons were highly qualified and gave good lectures…Documents for lectures should be photocopied and distributed in advance to participants whenever possible. Meals should be diversified if participants are to be fed by the organizers." *Jean-Marie Fondoun, Cameroon*

"I particularly enjoyed the lectures and the role-play exercises. However, we seemed always to rush through the outcome of the role play. The conclusions should have been summed up properly. One major thing I learned from this course was that we all have a role to play in conserving our biodiversity and that all stakeholders should be involved from the beginning and indigenous input should be acknowledged and rewarded…With respect to the social aspect, a little more social activity could have been organized in the evenings." *Yaa Osei, Ghana*

"The [training workshop] provides the basic and comprehensive background to the complexities involved in biodiversity, biotechnology, bioprospecting, and bioconservation. The need for the promulgation of all the necessary laws required for access, benefit-sharing, and biosfaety was forcefully highlighted at the workshop. The role of public education and awareness-building in each country was emphasized throughout. The necessity for regional networking in bioresource inventory, value determination, and bioresource utilization was made clear. The workshop organization was superb and the members of the faculties were experienced in their various fields

of expertise…It is suggested that in the future the organizers should insist on evaluating and approving the CBs of delegates, particularly from the government ministries…the caliber of participants from the government ministries should be at the level of Assistant Directors and above." *Olusanya Olutogun, Nigeria*

"The organization of the course was in my opinion a superb job done. I must, however, comment that the sheer volume of information given to participants was done in such a way that the time frame appeared to me to be rather short to permit people to both absorb and react appropriately. You may wish to look into the possibility of extending the course a few days." *I.J. Uche-Okoro, Nigeria*

"The course has been organized in a very efficient manner with the teaching aids and methods being excellent. The modules were arranged in such a way that understanding was made easy." *Gbadamosi Lanre, Nigeria*

"The wealth of useful information will serve as a valuable resource guide for future activities, both theoretically and practically…In addition to the detailed, diverse array of useful and contemporary concepts, issues, facts, and opinions, the interactions with professionals from Africa, Europe, South America, and the United States created a unique global interactive academic environment. This course could quite easily be developed into a graduate or postgraduate course and would be among the more significant courses available today." *Eleanor Nunn, United States*

"The training course, in general, was very helpful and informative for me…It clearly appeared during the course that West African countries have a common need for clear legislation in biodiversity use in order to protect our principal richness and to acquire consistent benefit for our development. The high quality of the lectures and the good choice of examples reinforce my experience and open new fields for me…[For the future] it should be interesting to 1) emphasize and spend more time on the different levels (ecosystem, species, genes) and values of biodiversity, and maybe to have more field training; 2) increase the political impact [by inviting] the focal points for biodiversity of the different countries…3) think about the language limitation for francophone countries [such as] by using simultaneous translation." *Konate Souleymane, Cote d'Ivoire*

"The content of the course was good. I found that there was very little time allotted for discussion, which I thought was very important. There was often no summation of group presentations by facilitators, except Dr. Stryker's, which he did very brilliantly. There was too little time for us to process the large amount of information we received. The workshop should be planned in such a way that people don't sit for long hours on end. There should have been more activities that allow for breaks in sedentary periods." *Carol Markwei, Ghana*

"The program is so rewarding. It is full of information…The resource people are well seasoned and knowledgeable in their areas…Initially I thought I might not follow the law aspect, which is far from my profession…By the end of the module…law, which I feared most, was an area I loved the most." *Nkechi Enwerem, Nigeria*

"In my opinion the course has been well organized. Its objective is broad, its scope is wide andpenetrating, and its contents rich and in depth. The selection of the resource persons is worthy fo note. They are experts in their own fields and their delivery…is excellent. [The workshop] also exposed our weakness and lack of capacity to tackle these issues…If we must survive a

collective and regional approach must be pursued…The course was a huge success." *Paul Ojeogwu, Nigeria*

"Module I provided us with important lessons in R&D in the pharmaceutical industry. However, there seems to be the idea that the lectures were designed to promote understanding of transnational corporations' positions. I think we can emphasize more the benefits accruing to some of the African countries in dealing with the multinational pharmaceutical firms. Module II, the course on contractual agreements and benefit-sharing, was great…Module III…is a very relevant module…and some useful information was imparted. But I wish that there will be a more in-depth treatment of TRIPS…Module IV…is a very important module. But it seems to have been handled in haste. The faculty members were excellent, except for one or two…Perhaps you may consider use of more African experts. Duration: three and a half weeks is a bit too long….Good organization. Good selection of the participants to reflect institutional and disciplinary representation…I personally believe this is an excellent program for addressing current issues." *George Owusu Essegbey, Ghana*

"The course broadens…intellectual and professional horizons with a concentrated clarion wake-up call for developing countries, particularly (West) African states…The eye-opening course was revealing, incisive, and even indicting to the developing countries. It however provides or recommends to us opportunities available [and] stimulation to commence initiatives…Representation from the business sector and local communities was virtually non-existent…Only a few legal experts were involved as resource fellows." *J.E. Jigah, Nigeria*

"The idea and implementation of the course are brilliant and excellent, respectively. The course content is broad, concentrating mainly on policy, including legal issues. However, due to the varied backgrounds of the participants, less emphasis was placed on the science/technology of biodiversity and biotechnology. The course will assist participants from the university sector to advise their universities on the need to mount undergraduate and post graduate programs on biodiversity, biotechnology, and law. Short-term courses may be mounted also for bioresource managers and policymakers to enlighten them on the latest management techniques of bioresources." *Anthony Okeke, Nigeria*

"The course content and its organization are very good; however, I would like to recommend that in future the course should [include greater emphasis] on animal genetic resources." *Bonto Faburay, The Gambia*

"I would suggest that 3 to 5 hours of introductory chemistry and/or biology be included [for non-scientists]…to give them an understanding of basic genetic and scientific principles to be discussed…I would appreciate it if faculty members in the future are made to send their presentations at least two weeks ahead so as to enable production of these papers. It is a lot easier to follow a presentation if the papers are before you." *Simusola Akintola, Nigeria*

"The course handled the major aspects of the field like the prospecting, technological, business, economics, legal angles, etc., but I wish it could have thrown more light on the end products." *Rita C. Amakeze, Nigeria*

"I want to appeal to the organizers that the future training course should include forest tree species, particularly in their biotechnology…We need to bear in mind that the forest tree species are the determinant of the diversity of natural ecosystems." *Omokafe A. Ugbogu, Nigeria*

"[The course] serves as a most timely and useful contribution to the capacity-building efforts of the countries represented. The course was well structured to cover the salient issues. The resource persons were well selected in terms of their professional backgrounds, countries, and interest in promoting knowledge in these issues." *Sama Monde, Sierra Leone*

"The training course, though long in time frame, is very well organized. The various speakers were experienced international scholars and practitioners who imparted knowledge very well. The topics in the four modules were appropriately chosen and segmented in presentation…The integration of biodiversity, biotechnology, and law into a single course was very innovative and highly commendable." *J.A. Ekpere, Nigeria*

"The training course is well organized with all necessary relevant topics. The use of well knowledgeable and informed resource persons in various aspects of the course is highly commended…The training provided full information on the current status and development of the course themes…Meanwhile, the course should be organized in such a way that will involve the policymakers such as members of relevant committees of both legislative arms of government and the executive members." *Akinyeye Akintoye, Nigeria*

"Looking back, I would be hard put to find areas where there is need for marked improvement…One area I would like to suggest some thinking about is the case studies/group sessions. Would it be possible in future to devote some more attention to this to ensure that the groups come out with detailed and more practical solutions/answers?" *Alex Muoka, Nigeria*

"The program exposed the absolute lack of coordination in law, policy, and science on how Nigeria and West Africa should approach bioresources and the contentious issue of biotechnology. The program also emphasized the immediate need for West Africa to determine its attitude to issues on bioresources access, benefit sharing, and several other contentious issues. However, I noticed that there was an absolute failure to emphasize (except in a very perfunctory manner) the disadvantages or the alternative arguments to biotechnology." *Akintoye Akintokun, Nigeria*