Bioprospecting, Traditional Knowledge, and Benefit Sharing

Humankind has always been—and will always be—completely dependent on the Earth, therefore our treatment of it is paramount to our survival. We have relied particularly on its wealth of biological resources and its biodiversity. For millennia, a balance has existed between the production and consumption of resources. The impact of people on the environment has made relatively few irreversible changes over this time. That is, until recently. Suddenly, the impact of these environmental changes on human activities (such as agriculture, increasing populations, industrialization, and rising rates of consumption and standards of living) has became clear. The root of biodiversity loss and environmental degradation is the notion that biodiversity is the "common heritage of mankind" (*sic*) and must be preserved for future generations. This means that, while the environment belongs to no one, it is entirely our collective responsibility.

Beginning some 50 years ago, biodiversity losses began to increase at an alarming pace. Desertification became a recognized problem in many regions of the world with ensuing biodiversity loss. By the late 1970s, biodiversity loss, desertification, and even climate change, had begun to receive significant international attention as more and more people began to recognize that the Earth's resources were finite and that our activities were unsustainable. Due to a accelerating depletion of resources, these resources began to have increasing economic value. Deep concern over an environmental crisis was widely expressed for the first time in an international forum at the United Nations Conference on Environment and Development, commonly known as the Earth Summit, held in Rio de Janeiro, Brazil, in 1992. Concurrent to these activities, biotechnology emerged and with it came the promise of creating life-saving new drugs from genetic resources. Modern biotechnologies allowed new and novel uses of biological resources, giving additional value to biodiversity. At the confluence of these world events new concerns emerged over ownership, over the contributions of generations past, and over traditional knowledge (TK) held by indigenous populations. In short, equity concerns arose.

Equity is a moral issue that has repercussions with respect to the distribution of benefits and environmental conservation. However, equity is in the eye of the beholder; different individuals come to different conclusions about what is equitable and about how to achieve equity. Unfortunately, market systems created to place a *price* on equity do not work because market systems are constrained in what they measure. Furthermore, with regard to indigenous knowledge, because its products are intangible, once the knowledge or information is disseminated, control over the knowledge is lost. From an objective standpoint, that knowledge has no

Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. 16: Bioprospecting, Traditional Knowledge, and Benefit Sharing. In *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (Krattiger A, RT Mahoney, L Nelsen et al.). MIHR (Oxford, UK), PIPRA (Davis, USA), Oswaldo Cruz Foundation (Fiocruz, Rio de Janeiro, Brazil), and *bio*Developments-International Institute (Ithaca, USA). Available online at www.ipHandbook.org.

direct monetary value unless the knowledge can be *translated* into a market-based commodity (or service), whereby the value of different contributions (knowledge, technology, labor, capital, and so forth) can be quantified and traded.

In addition to these problems, the western system of **IP (intellectual property) rights, particularly patenting, is based on the premise that anything that is already known cannot be protected**. Indigenous knowledge is often communal, has been disclosed, and has been passed on from previous generations. The very nature of indigenous knowledge, therefore, does not meet the criteria for intellectual property in today's IP system. Not surprisingly, some people view the use of TK in modern science as a form of biopiracy, which is the unfair acquisition of biological resources and/or associated know-how. Some even argue that the modern IP rights system has harmful effects on indigenous peoples.

Karjala[1] breaks down these arguments into two distinct issues:

- **Biopiracy**: to what extent do patent systems exploit traditional indigenous knowledge?
- **Patenting of living organisms**: how can we justify patenting gene-sequence and gene-product information taken from living organisms (especially humans) when these are naturally occurring substances? And if patented, how do we answer the ethical questions surrounding such patents?

Karjala argues that the core of the biopiracy problem is not patenting inventions derived from traditional indigenous information, but rather **biopiracy is unfair acquisition (misappropriation) of knowledge and the inequitable distribution of benefits derived from developing such information into valuable commercial products**. But he cautions against exclusive information rights outside the patent and copyright regimes for indigenous peoples, pointing to the need for incentives for product development. Provided that traditional information is given voluntarily and that fair compensation is paid to the group who owns the information, it is not the use of TK in a patent that is inherently wrong. Therefore, the question becomes one of how to provide for equitable benefit sharing of TK that finds its way into patent applications and is subsequently commercialized.

Policymakers ought to formulate methods for equitable access to the TK held by indigenous societies and for compensating its owners. However, this issue involves a delicate balance: access should be granted only via authorized permission, yet the price that is assessed for permission to bioprospect should not be so high that it dissuades companies and individuals from seeking access.

Although nothing in extant patent statutes or international IP/trade agreements requires that naturally occurring chemicals (such as DNA sequences and genes and their natural products) be treated as patentable subject matter per se, these can be patented once utility and novelty requirements are met. Patenting natural products, however, is not the unique concern of indigenous peoples. It is also a concern of policymakers in developing and developed countries.

Furthermore, patents on upstream "inventions," (in this context, isolated genes) might inhibit subsequent downstream research and development. This is because the upstream patenting of natural products (such as specifically isolated gene sequences) would effectively eliminate downstream incentives for inventive activity. Also, such patents would inhibit information flow, thus promoting over investment in the search for genes and under investment in the utilization of genes for advanced applications.

The important ethical issues raised by gene-related patents include whether:

- private control over genes or their products monopolizes the "common heritage of mankind"
- patents denigrate human life by reducing it to a commodity
- patents may be inconsistent with individual or collective privacy
- patents promote or inhibit distributive justice when they are concentrated in a few economically developed countries. A related concern is that patents on crop varieties might threaten biodiversity.

Importantly, Karjala notes that t**hese issues affect both indigenous and non-indigenous**

populations. In addition, where there are differences in how costs or benefits are distributed, patenting is not necessarily the problem. In negotiating technology transfer and access, the author proposes that careful cost/benefit analyses should guide decisions.

Interpreting the concept of the common heritage of mankind broadly, one can include nearly everything (in other words, the common heritage is not limited to indigenous peoples). Therefore the concept does not represent an ideal paradigm for building a legal strategy. Hence, traditional patent law is a better approach. The real question is not whether a gene or a gene product should be protected as the common heritage of humankind, but whether or not it is even an invention within the well-established strictures of patent rules and regulations.

As for the commoditization of genes, it is difficult to see how this would impact most indigenous societies that, for the most part, are far removed from the commodity markets of developed countries. Furthermore, the human genes at issue would most likely confer some sort of positive advantage and would therefore not implicate either privacy concerns or stigmatization. Once again, patent law would likely most effectively address genes with potential commercial value. Nevertheless, freely available information should not be protected by IP rights. If IP protection is appropriate, possibly other forms of statutory protection would be more suitable, such as breach of confidence or privacy rights.

One critical concern is whether patenting conflicts with indigenous knowledge and value systems. In a theoretical sense, patents can significantly add costs to new inventions and thereby act as barriers. However, when one balances the costs and benefits of patent law in developing counties, there may be little correlation between access and patent status. Furthermore, as Karjala points out, **there would be essentially no financial loss to owners of patented biotechnology products if they were to sell at cost in such countries**, assuming no redirection of such biotechnology to more lucrative markets. However, the prevention of product "leakage" would entail enforcement capacity, and this sort of distribution is not feasible without strict market segmentation.

Costanza, Christofersen, Anderson, and Short[2] add to this analysis of bioprospecting by presenting **practical examples of how indigenous peoples and companies can reach agreements** that are fair by most standards and conducive to further collaboration. The authors explain that international agreements such as the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources (ITPGR) provide a broad framework for protecting and utilizing genetic resources.

For bioprospecting activities, companies choose countries that have unique and protected ecosystems, a solid legal framework, sufficient political will, fair and equal treatment for all access seekers, and strong science experts or institutions to partner with. Countries will seek partnerships with foreign companies and universities that adhere to international conventions and best practices, and that have an established track record. Guiding principles for a successful partnership between collaborators in the host country and a company include a commitment between parties to maintain a fair, trusting, long-term relationship, with an efficient and reasonable authorization process, and equitable sharing of benefits between partners.

However, international agreements do not provide detailed guidance on structuring the relationships between parties involved in commercial bioprospecting activities. Companies involved in the exploration, screening, and use of genetic resources have begun to accumulate experience with building such relationships, including selecting countries with rich biodiversity, selecting partners, and drafting terms in biodiversity access agreements (BAAs) that govern these relationships.

In order to be successful, these BAAs must have a clear definition and assignment of legal rights to all genetic resources involved. Informed consent from all domestic parties affected by the bioprospecting, including landowners and managers, must be attained prior to partnership. There must exist a clear delineation of rights to patent and commercialization of the products derived from these endeavors. Each BAA is a confidential document, which supports a lack of competition

among the partners to the agreement, and does not allow the transfer of proprietary technologies or technical capacity to third parties or exclusivity.

Identification of the parties to the BAA can be complicated because there may be multiple agencies within a country that have authority over access to genetic resources. There may also be multiple parties, such as landowners or company managers who could legally prevent access to or receive compensation for the resource if and when they are affected by the biodiversity prospecting. Each country that is a signatory to the CBD has a responsibility to establish a *national focal point for access and benefit sharing*,[3] a designated individual and national office that is able to identify all necessary authorities and potential claimants for the partnership.

The rights that need to be spelled out in a BAA include rights to retain or distribute samples, rights to intellectual property under different scenarios, (such as conditions of discovery and invention) and rights to publish discoveries and inventions. Responsibilities, such as the handling of reporting, communications, and administrative filings also need to be spelled out.

The parties should come to an understanding about the relative importance or value of each of their contributions (such as carrying out sampling, cleaning, or analyzing). This will directly affect the equitable sharing of any benefits arising from collaborative activities. Given the nature of bioprospecting and the regions where bioprospecting is often conducted, the full scope of returns is understood to include both financial and nonfinancial components (that is, various sources of potential value to the individual parties). The possible returns can also be divided roughly into short-term, medium-term, and long-term time frames. Thus, a BAA has enormous flexibility for structuring the terms of compensation to the parties. While advanced payments, sample fees, running royalties, and milestone payments—terms typical of many technology agreements—are available for financial benefit sharing, there are many more possibilities, including the provision of equipment and infrastructure, sharing of IP rights or rights to product sales, funding of related research, and assistance with conservation services.

Despite progress on the technical side, a BAA almost always creates controversy. The natural response of governing authorities is to move slowly, fearing criticism from competing domestic interests and international groups that watch out for cases of undervaluing biodiversity and nonsupport for economic development. Many such groups consider the private sector to be inherently corrupt; thus, no matter what benefits are offered the arrangement is perceived to be inequitable. Ironically, this reaction reflects negatively on those companies taking the lead in supporting the CBD and creates strong disincentives to engage in bioprospecting or to share information about such endeavors. This in turn, decreases the very value of biodiversity resources. In the end, the **commitment of both parties to a sustainable and rational use of biodiversity in a way that both encourages commercial development and protects the unique resources of the Earth** is as important as the technical aspects of deal making.

The technical aspects of technologies, however, must still be mastered. Indeed, there is an emerging new regime, Thornström[4] calls it a "world order," regarding biological matter: an international regime which govern access to genetic resources and the sharing of benefits arising from their use. The chapters by Thornström and by Thornström and Björk,[5] explore the *what*, *why*, and *how* of this new regime. The authors provide the reader with a comprehensive road map for understanding the details and finding the correct path to compliance with the laws, rules, and regulations that cover access in a given country.

The new regime is driven by **access and benefit-sharing (ABS) systems**, which apply to research carried out for either scientific or commercial purposes. ABS involves accessing organisms, or parts thereof, and related TK, that are obtained (accessed) from a country that is party to the CBD. In addition, other international treaties, accords, and agreements have also added new legal ABS regimes legislation through the acquisition and use of biological material and related information.

Everyone (tourists, nature conservationists, scientists, photographers, journalists) is subject to these new ABS regulations, but the ABS

system especially affects scientists and researchers who seek to access and use proprietary genetic resources, other biological matter, and related information, such as TK and farming know-how. In national legislation, such knowledge may be treated as intellectual property or confidential trade secrets, putting it outside the public domain and not subject to *any* form of unauthorized appropriation. Violation by foreign parties (such as scientists conducting unauthorized collection activities) of the new ABS regimes may result in a range of negative and stringent consequences; fines and/or imprisonment, denial of future visits to the collection site or country, increased transaction time for obtaining formal access permits, and/or denial of access to colleagues of the violator. Obviously, it's important to know how to properly proceed.

To understand the fundamental principles of ABS, one needs to know the relevant rules, regulations, laws, customs, and conditions for benefit sharing in the country where one intends to conduct research and/or collect samples. Basic questions to ask before collecting include:

- Under which conditions may I, as a scientist, *enter* another sovereign state's territory in my scientific capacity?
- Under which conditions may I, as a scientist, *collect* biological material and related information?
- Under which conditions may I, as a scientist, *carry out or export* biological material and related information from that sovereign state's territory?
- Under which conditions may I, as a scientist, make *further use* of collected biological material and related information?

Thornström and Björk present a practical overview of the principles and procedures underlying ABS regimes that will be useful to various types of research and access situations. The authors also provide a series of template documents as illustrative examples of what might be necessary, depending on the specific requirements of the collection activities. To assist in understanding the various ABS scenarios and the documents, potentially applicable letters and agreements are presented as examples, such as letter of intent, research permit, prior informed consent (PIC), mutually agreed terms (MAT), model or material transfer agreement (MTA), and confidentiality agreement.

Although all of this might seem daunting initially, **the documents are necessary, and in a growing number of countries are required by law**. Careful planning and management will pay off in the long term, since they minimize the possibility of misunderstandings and other problems and, in turn, can reduce the chance that legal problems will arise. Perhaps most importantly, these ABS regimes are in place to facilitate the building of solid, equitable, and sustainable networks for future partnerships.

Drawing on the experiences of exemplary partnerships, Soejarto and colleagues[6] explain an organizational model for the responsible governance of bioprospecting arrangements between institutions in developed and developing countries based upon the **International Cooperative Biodiversity Groups** (ICBG) program of the U.S. National Institutes of Health (NIH). The model assumes that resources and expertise from both the North and the South are required for bioprospecting to succeed. Incentives need to be properly aligned for both regions to be fully engaged and committed. To align incentives, the ICBG model offers a clear definition of the benefits that might arise from a project, a clear recognition of all parties involved, negotiation guidelines for the parties, and a formal structure for the resulting agreement. The agreement contains the scope and objectives of the project, the long-term benefit-sharing scheme, and milestones, as well as terms for IP ownership, informed consent, and royalty distribution. Details of how the ICBG model works in practice are illustrated with an example of one such bioprospecting arrangement between the University of Illinois at Chicago (UIC), research institutes in Vietnam and Laos, and GlaxoSmithKline.

Informed consent was another critical issued to be covered. In this case, informed consent offered provisions for the collection and use of plant/genetic materials and for individuals and their communities regarding traditional **me**dicinal

use or uses of a plant. In addition, prior informed consent was to be secured before the implementation of the work. The governments of Vietnam and Laos were acknowledged as the owners of the genetic materials and their derivatives in their respective countries.

Fundamentally, the ICBG model recognizes and emphasizes the importance of several parties and the outcomes they seek. Often overlooked in typical international research consortia and business agreements, these additional parties include poor communities and the regional authorities in locations where biodiversity prospecting is to be conducted. The additional objectives include biodiversity conservation, institutional capacity building, and regional economic development. The standards established by the ICBG program emphasize the core principles of capacity building and community reciprocity. Bioprospecting activities such as those outlined in this chapter, in which poor communities in developing countries are cooperating with clear understanding and goodwill, can thus serve as a model for future similar agreements and initiatives.

This is not to say that the conceptual systems of developed countries work are transferable to developing countries, as the final two chapters of this section demonstrate. According to Hansen and Van Fleet,[7] indigenous knowledge, or TK, particularly that which involves a region's native flora and fauna (biodiversity), is not fully amenable to the legal constructs of intellectual property. Fundamentally, TK is cumulative, communal, and largely undocumented in the formal literature. Because of these characteristics, **TK often does not fulfill novelty requirements for establishing IP rights** or the condition that ownership of the intellectual property resides with an individual or individuals. Indeed, in the case of TK, it may be exceedingly difficult to identify the original individual inventors or authors, or even the current holders or curators of the knowledge. Finally, because TK is largely unrecorded but exists as "living" knowledge passed from individual to individual orally or through observation and apprenticeship, it is largely unavailable for consideration by IP offices of novelty within the complete repository of human knowledge.

But despite these difficulties in applying the criteria for intellectual property to TK, a number of forms of IP rights protection (primarily trade secrecy, geographical indications, plant variety protections, and patents) can be and have been used to establish ownership over elements of TK. However, the imperfect fit of TK into the definition of intellectual property has led to two interrelated dilemmas:

- In some cases, those who were not part of the indigenous community from which the TK originated may be able to use, and even to establish ownership over, elements of the TK without acknowledgment of (or recourse to) that indigenous community
- Those in indigenous communities who do hold TK may not be able to establish ownership, or even gain acknowledgment from others.

To address the first dilemma, anyone should make sure TK is disclosed, which will establish it as prior art. There are a variety of strategies to assist in establishing prior art status of TK. For the majority of TK, a defensive disclosure in the public domain (such as via a public registry) can prevent illegitimate IP claims over existing TK. For TK to which IP protections more easily apply, the TK holders may be able to themselves file applications. In addition, governments should require prior informed consent to be obtained from indigenous communities or national authorities when engaging in activities that could lead to the claiming of IP rights based on TK.

To address the second dilemma—that of maintaining control over TK—indigenous holders of TK can seek to use forms of IP protection. Hansen and Van Fleet discuss the advantages and disadvantages of the various options available. At least initially, most TK approximates a trade secret, and so it might easily be maintained within the original community as a trade secret. However, before the knowledge is more widely disseminated it may be necessary to use other forms of IP protection, including geographic

indication, trademarks, plant variety protection, petty patents or utility models, or patents.

In the longer term, governments may create new forms of IP protection that accommodate the fundamental characteristics of TK (such as under the aegis of sui generis systems of plant variety protection as defined under the Trade-Related Aspects of Intellectual Property Agreement). In addressing the dilemma of control over TK, several issues outlined in the CBD ought to be worked out within national legal systems. **Of these issues, the foremost are conditions for granting/gaining access to genetic resources and any TK about them and requirements for equitable sharing of revenues or other benefits that might accrue from the development and use of TK-based technology in markets around the world.**

All of these approaches to preserving and protecting TK require a clear identification and attribution of specific TK claims. This can be a complex endeavor, but TK is important and often even essential to the survival of indigenous communities. It may also be an important source of life-giving technological innovation that could benefit millions around the world. The ultimate goal is to develop practical solutions within our legal frameworks that encourage indigenous communities both to sustain their traditions and to equitably share their knowledge with the wider world so that all may benefit.

Ammann[8] raises a different concern about how we think about food in developing countries and its impact on the developing world. He argues that **the commonly held distinction between organic and technologically intensive agriculture (focused on genetically modified organisms, or GMOs, or more specifically transgenic crops) has inhibited pragmatic approaches to creating agricultural management systems that build on local conditions, help alleviate poverty, respect local cultures and traditions, and draw upon a successful relationship with science.** This distinction between organic and technologically intensive agriculture is based on a deeper rift between systems of indigenous TK and western scientific knowledge, a rift that Amman contends is not only unproductive (hindering communication and exchange between the two) but artificial—reflecting differences in "worldviews, unfounded theories, or quasi-religious beliefs" held by respective proponents.

Still, the distinction between organic and technologically intensive agriculture is enormously significant. The designation of a technology as organic versus transgenic can attach very different regulatory requirements and offer different marketing opportunities for the technology, thus strongly influencing how and whether it is used and what its potential value is.

Ammann challenges the commonly held distinction between organic and transgenic technologies and proposes a series of tests of the definitions and principles advanced to define and distinguish the two. While they are different in some aspects, Amman finds none of the major distinguishing principles claimed by organic versus transgenic technology able to stand up to scrutiny. These include:

- the intrinsic genetic integrity of crop species genomes (crop species genes are not intrinsically more stable when considered transgenic or organic)
- the unnaturalness of transgenesis (transgenics are just as "natural" as organics)
- stability and predictability of progeny (organics and transgenics have stable and predictable inheritance patterns that are reproducible over time)
- unnaturalness of monocultures (irrespective of organic or transgenic status, growing all one type of either crop plant is not the natural state of the environment)
- erosion of biodiversity by transgenic technologies (transgenics have not been shown to decrease levels of biodiversity)
- systemic environmental superiority of organic versus transgenic crops (the overall conception that organics are superior to transgenics as a whole is not substantiated)

It is difficult, if not impossible, to consistently maintain a clear divide with respect to organic and biotechnology-based agricultural technology and methods. Yet, Ammann observes, "**power structures knowledge," and interests on both sides are using and benefiting from a substantiation of**

the distinction between organic and transgenic agriculture.

Practical solutions to agricultural production—and practical solutions to medicine—could indeed benefit many if only we could manage to build bridges between TK and science-based knowledge systems and draw upon the best existing ideas and practices of both. ■

All chapters refer to: *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. 2007. A Krattiger, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez, and SP Kowalski (eds.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org. The online version contains for each chapter a detailed Editor's Summary, Implications, and Best Practices.

1 Chapter 16.1 by DS Karjala titled Biotechnology Patents and Indigenous Peoples, p. 1437.

2 Chapter 16.4 by C Costanza, L Christofersen, C Anderson, and JM Short titled Deal Making in Bioprospecting, p. 1495.

3 www.cbd.int/world/map.asp.

4 Chapter 16.2 by CG Thornström titled Access and Benefit Sharing: Understanding the Rules for Collection and Use of Biological Materials, p. 1461.

5 Chapter 16.3 by CG Thornström and L Björk titled Access and Benefit Sharing: Illustrated Procedures for the Collection and Importation of Biological Materials, p. 1469.

6 Chapter 16.5 by DD Soejarto, C Gyllenhaal, JA Tarzian Sorensen, HHS Fong, LT Xuan, LT Binh, NT Hiep, NV Hung, BM Vu, TQ Bich, BH Southavong, K Sydara, JM Pezzuto, and MC Riley titled Bioprospecting Arrangements: Cooperation between the North and the South, p. 1511.

7 Chapter 16.6 by SA Hansen and JW Van Fleet titled Issues and Options for Traditional Knowledge Holders in Protecting Their Intellectual Property, p. 1523.

8 Chapter 16.7 by K Ammann titled Reconciling Traditional Knowledge with Modern Agriculture: A Guide for Building Bridges, p. 1539.

FOR GOVERNMENT POLICYMAKERS

- ✔ Equity is a moral issue that has repercussions with respect to the distribution of benefits and environmental conservation. Thus, **equity is in the eye of the beholder.**

- ✔ The western system of IP rights, and particularly of patenting, is based on the premise that anything that is already known cannot be protected. Indigenous or traditional knowledge (TK) is often communal, has been disclosed, and has been passed on from previous generations. **The very nature of indigenous knowledge, therefore, does not meet some of the criteria for intellectual property protection** (such as novelty).

- ✔ In the longer term, **new forms of IP protection that are more amenable to the fundamental characteristics of TK** could be created by governments, such as under the aegis of sui generis systems of plant variety protection (PVP), as defined under the TRIPS Agreement.

- ✔ **Indigenous communities** often play a significant role as gatekeepers to a country's potential biodiversity wealth. They are the regional specialists with respect to the flora and fauna. Their knowledge can often exceed that of leading scientists.

- ✔ Patent laws per se do not "create" biopiracy. Rather, **biopiracy is a form of misappropriation**, unfair acquisition, and inequitable sharing of benefits with respect to biological resources.

- ✔ Policymakers ought to formulate methods for **equitable access to TK** held by indigenous societies and for compensating the TK's owners. However, this issue involves a delicate balance: access should be granted only via authorized permission, yet the price that is assessed for permission to bioprospect should not be so high that it dissuades companies and individuals from seeking access.

- ✔ Countries should consider implementing an **access and benefit sharing** (ABS) regime that balances equitable access to biological resources, as well as related TK, with opportunities arising from R&D expertise of potential foreign partners in development. Such policies should be grounded in, and consistent with, the Convention on Biological Diversity and the TRIPS Agreement.

- ✔ ABS regimes, including **the process for obtaining permits, should be transparent** and easily available to any scientist or institution that wishes to enter into biodiversity prospecting or collection activities. A complex system discourages foreign bioprospectors and may inhibit national researchers in their activities.

- ✔ The commonly held **distinction between organic and biotechnology-based agriculture** inhibits pragmatic approaches to creating agricultural management systems that build on local conditions, help alleviate poverty, respect local cultures and traditions, and benefit from a successful relationship with science. The world has much to gain by **reconciling organic and biotechnology-based agriculture** though realizing any gain will have to deal with the "**power structures of knowledge**," and overcome limitations imposed by those people who maintain the distinctions.

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.

FOR SENIOR MANAGEMENT

(UNIVERSITY PRESIDENT, R&D MANAGER, ETC.)

- ✔ The technology transfer office should work with senior management to establish **policies and systems for accessing indigenous or traditional knowledge** (TK), bioprospecting activities, and benefit sharing in an equitable manner.

- ✔ Equity is a moral issue that has repercussions with respect to the distribution of benefits and environmental conservation. Thus, **equity is in the eye of the beholder.**

- ✔ Given the complexity of the health and agricultural industry and the enormous variety of applications and products that could be developed through the **biodiversity access agreement** (BAA), it is very difficult to know the profit margins for a company, product, or application ahead of time. Technology transfer, as well as information and data sharing, in the long run, may be more important than royalties.

- ✔ With adequate funds often lacking in public sector research centers, international donors should seriously consider loans or grants for training and equipment purchases. **Entering into bioprospecting activities, the public sector has much to gain by:**
  - having a clear institutional policy
  - building national scientific capabilities, and along with it, the possibility of adding value to biodiversity elements, which increase the negotiating strengths and benefit sharing stipulated in contract agreements
  - having internal capacity for negotiations, which includes adequate legal and counseling skills about the main aspects of commercial and environmental law

- ✔ Managers can identify which **nonmonetary benefits** companies could provide (such as capacity building,and technology transfer), that would be of greatest use to the institution. This approach will enable flexibility in benefit sharing and sustainability in the R&D relationships.

- ✔ Public sector institutions can provide important **intellectual and programmatic leadership in how cross-cutting agricultural research programs** can build bridges between TK and science and between organic agricultural and science-based agricultural practices. In so doing, they will help to advance the state of knowledge, the regulatory structure, and public perceptions of agricultural systems.

- ✔ The commonly held **distinction between organic and biotechnology-based agriculture** inhibits pragmatic approaches to creating agricultural management systems that build on local conditions, help alleviate poverty, respect local cultures and traditions, and benefit from a successful relationship with science. The world has much to gain by **reconciling organic and biotechnology-based agriculture** though realizing any gain will have to deal with the "*power structures of knowledge*," and overcome limitations imposed by those people who maintain the distinctions.

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.

FOR SCIENTISTS

- ✔ **Scientists and anyone else accessing biodiversity must ask, and answer, the following questions prior to initiating collecting activities:** Under which conditions may I *enter* another sovereign state's territory in my scientific capacity? Under which conditions may I *collect* biological material and related information? Under which conditions may I *carry out or export* biological material and related information from that sovereign state's territory? Under which conditions may I make *further use* of collected biological material and related information?

- ✔ Scientists must be aware, not only of the biological and sociological value of indigenous or traditional knowledge and related genetic resources, but also of their **potential commercial value**. Hence, investigations and research ought to be conducted within guidelines set by the technology transfer office, for example, appropriate and timely disclosure of any potential inventions.

- ✔ **Interactions with foreign colleagues and collaborators** ought to be established according to institute or university policy guidelines, guidelines that are established to both preserve and reap the full value of these national natural resources.

- ✔ When working with colleagues from foreign countries, you should be aware that those colleagues may be authorized to make **collections of biological materials** only under specified circumstances. Before proceeding with joint activities, check with your institution's technology transfer office to make sure that all the requirements have been met.

- ✔ It is essential to understand the fundamental principles of the Convention on Biological Diversity (CBD) and Access Benefit Sharing (ABS) regimes. These exist to both **protect the resources of your country as well as to encourage collaborative projects in R&D that would foster a broad and equitable distribution of benefits** flowing from the development of the country's biological resources.

- ✔ The commonly held **distinction between organic and biotechnology-based agriculture** inhibits pragmatic approaches to creating agricultural management systems that build on local conditions, help alleviate poverty, respect local cultures and traditions, and benefit from a successful relationship with science. The world has much to gain by **reconciling organic and biotechnology-based agriculture** though realizing any gain will have to deal with the "**power structures of knowledge**," and overcome limitations imposed by those people who maintain the distinctions.

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.

FOR TECHNOLOGY TRANSFER OFFICERS

- ✔ The three guiding principles for a successful relationship in bioprospecting and related endeavors are a **commitment to maintaining a fair, trusting, long-term relationship**; efficient and reasonable authorization; and the equitable sharing of benefits between a company and its collaborators in the host country.

- ✔ The western system of IP rights, and particularly of patenting, is based on the premise that anything that is already known cannot be protected. Indigenous knowledge is often communal, has been disclosed, and has been passed on from previous generations. **The very nature of indigenous knowledge, therefore, does not meet some of the criteria for intellectual property protection** (such as novelty).

- ✔ A **successful biodiversity access agreement** includes a clear definition and assignment of legal rights to all genetic resources involved; prior informed consent from all domestic parties affected by the bioprospecting (including landowners and managers); a clear statement of rights to patent and commercialize products derived from discoveries made; and terms of confidentiality. The BAA also establishes a noncompetitive relationship between the parties; trust that no transfer of proprietary technologies or technical capacity involved under the agreement will occur with respect to third parties; and that no exclusivity requirements exist.

- ✔ Patent laws per se do not "create" biopiracy. Rather, **biopiracy is a form of misappropriation**, unfair acquisition, and inequitable sharing of benefits with respect to biological resources.

- ✔ **Prior informed consent** is an important principle in bioprospecting. This should include informed consent in the case of collection and use of plant/genetic materials, as well as informed consent of individuals and their communities regarding traditional medicinal use or uses of a plant.

- ✔ When dealing with **foreign bioprospectors**, your office will function as the gateway and regulator of their activities. As such, technology transfer officers will provide oversight to negotiating agreements for equitable sharing of rewards, defining access, discussing possible patentability, and protecting the rights of the indigenous peoples who are the stewards of these resources.

- ✔ Negotiating access to your country's genetic resources, biodiversity, and TK will require a balanced, nuanced approach. **Equitable benefit sharing** must simultaneously ensure fair returns to your country, yet not inhibit the R&D initiatives of foreign partners. Solid agreements will benefit all parties: your country, your partnering organization, and the country or community that provides the resource. Extreme situations, such as an expectation of immediate windfall returns or wanton biopiracy by outsiders, will freeze the resources and ultimately lead to their demise.

- ✔ Both monetary and **nonmonetary benefits** may be attractive to the university or institute; both, therefore, should be considered. Nonmonetary benefits could include training opportunities for scientists and donation of equipment.

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.