



PUBLIC INTEREST INTELLECTUAL PROPERTY ADVISORS

c/o National Museum of Natural History, MRC 105  
Smithsonian Institution  
PO Box 37012  
Washington, DC 20013-7012 USA  
Tel +1 (202) 357-2719 Fax +1 (202) 786-3141

# **Resource Manual for Bioprospecting**

**Mary Riley**

Research Associate  
Program for Collaborative Research in the Pharmaceutical Sciences  
University of Illinois  
Email: [mriley88@hotmail.com](mailto:mriley88@hotmail.com)

**Brad Simon**

Former Address:  
Senior Director  
Legal, IP & Business Affairs  
AtomShockwave Corp.  
San Francisco, CA

Present Address:  
LL.M. Student  
Harvard Law School  
Cambridge  
Email: [bradssimon@yahoo.com](mailto:bradssimon@yahoo.com)

Present Address:  
Student  
Harvard University  
Cambridge  
Email: [bradssimon@yahoo.com](mailto:bradssimon@yahoo.com)

**Sherylle Mills Englander**

Director, Intellectual Property  
University of California, Santa Barbara  
Email: [englander@omni.ucsb.edu](mailto:englander@omni.ucsb.edu)

**Oren Livne**

Patent Manager  
University of California, Santa Barbara  
Email: [livne@omni.ucsb.edu](mailto:livne@omni.ucsb.edu)

**Carlos Osegueda Jr.**

University of California, Davis  
Email: [cosegueda@ucdavis.edu](mailto:cosegueda@ucdavis.edu)

**Justin Schnitler**

University of California, Davis  
Email: [jjschnitler@ucdavis.edu](mailto:jjschnitler@ucdavis.edu)

## INTRODUCTION

This Web Resource is intended to guide the on-line reader through the vast field of literature on the subject of bioprospecting. While this outline only represents a fraction of what is on-line, the resources listed below represent a balanced view of the subject matter, while taking into account the diverse viewpoints and debate on the subject of bioprospecting itself. Additional links are also provided for further reference and critical evaluation of the current activities and debates on this multi-faceted, ever-evolving and highly relevant topic in today's global forum.

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- 7.2.2 IUPAC – “General features of contracts for natural product collaborations”

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## 1. Business of Bio-prospecting

While it can be argued that bioprospecting activities have always been part and parcel with large-scale corporate enterprises – either in the way of new sources for materials, new product development, or new markets. However, bioprospecting has gained more attention in recent years because of the growing awareness that new drugs will be urgently needed in the near future, either to cure currently incurable diseases that affect increasing numbers of the world population (AIDS, Alzheimers, TB, cancer) or else to replace drugs that are becoming increasingly ineffective to treat health problems (such as pathogens resistant to antibiotics). Bioprospecting activities are not limited to the pharmaceutical field alone – bioprospecting can impact any industry that relies (in whole or in part) upon the access, sourcing, processing or production of genetic resources to develop a commercially viable product for the world market. Bioprospecting activities also underpin the agricultural and food security sector (agribusiness and agrochemical industries), the cosmetics, health and beauty aids industries, and the biosafety sector. Bioprospecting is also inextricably linked to sustainable economic development, biodiversity conservation and equitable use and stewardship of global natural resources. The outline below explores some of the resources on-line that cover these concerns.

### 1.1 Role of natural products in bioprospecting:

#### **Biodiversity, Biotechnology and Law Training Course for West Africa Module I – The Business of Biodiversity**

<http://www.aaas.org/international/africa/gbdi/>

This module provides a brief overview of the global market for natural products and biodiversity-based drug discovery. Describes the drug discovery process, ethical and legal issues involved in current bio-discovery arrangements, and lists leading companies in the agribusiness and pharmaceutical industries that dominate the market. Module concludes by listing priorities and agenda for West African countries in response to this expanding global market in biological resources and increased bio-discovery in developing countries.

#### 1.1.1 Pharmaceutical Industry

Pharmscape© DeMontfort University  
Leicester School of Pharmacy, U.K.

[http://www.appsci.dmu.ac.uk/pharmscape/tour\\_1.htm](http://www.appsci.dmu.ac.uk/pharmscape/tour_1.htm)

This web page provides an easily accessible and readable account of the drug discovery process, from initial discovery to development into a clinical drug. The web page discusses several issues along the pharmaceutical pipeline, such as toxicology, strategies for locating potential sources of new drugs, and the chances that a prospective drug

actually makes it through all stages to a clinically-approved, saleable product.

Bioprospecting: MedicineQuest (An interview with Mark Plotkin)  
<http://www.actionbioscience.org/biodiversity/plotkin.html>

This interview with ethnobotanist and author Mark Plotkin succinctly explores the reasons why protecting biodiversity is crucial to the discovery of new medicines and cures. Additional weblinks are also provided at the bottom of the page to related topics such as biopiracy, indigenous peoples rights, and biodiversity rights legislation.

“Rediscovering Natural Products”, *Chemical and Engineering News* 81(41) (October 13, 2003), pp. 77-91. On-line at:  
<http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals.html>

This article discusses the demise of combinatorial chemistry’s promise to discover new drugs faster than traditional natural products research for drug discovery, and how the pharmaceutical industry may once again look to natural products research for new leads because of advances in bioassay, screening, and structural elucidation technologies. The article also presents the debate over the intrinsic utility of many compounds in natural products over de novo compounds developed in the laboratory through combinatorial chemistry.

### 1.1.3 Agrochemical Industry

International Rice Research Institute – Rice Knowledge Bank –  
Agrochemicals in Perspective  
<http://www.knowledgebank.irri.org>

Although the main focus of this website is on the improvement of rice cultivation worldwide, it provides a good overview of the issues in using agrochemicals for farming, and the rising demand for agrochemicals that are safe, environmentally friendly while also improving rice yields and improving the lives of rice farmers, most of whom are in poor and developing countries. Review of the business of agrochemicals.

### 1.1.3 Other (food security, GMOs, etc.)

Food Security News (Non-Wood News No. 7 (March 2000))  
[http://www.fao.org/docrep/x4945e/x4945e02.htm#P242\\_40958](http://www.fao.org/docrep/x4945e/x4945e02.htm#P242_40958)

A publication of the Wood and Non-Wood Products Utilization Branch of the FAO Forest Products Division, this issue examines the relationship between the commercialization of non-timber forest products and biodiversity, the eradication of poverty, sustainable development and food security. Near the bottom of this issue are a series of web links that

discuss in-depth the issues relating to bioprospecting in Non-Timber Forest Products (NTFPs). Each issue also reviews the market outlook for new NTFPs.

## 1.2 Role of Traditional Knowledge

Science and Development Network (SciDevNet) Dossier:  
Indigenous Knowledge (Introduction)

<http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierfulltext&Dossier=7>

This website provides a brief overview on the value of indigenous knowledge systems and its contribution to sustainable development and the alleviation of poverty. Not only can indigenous knowledge provide a potential solution to local problems – such as time-honored remedies for local diseases, such as malaria – indigenous knowledge can be better implemented to solve local problems than frameworks or schemes that are foreign to the local context and insensitive to the peoples' lives and livelihoods in developing countries.

## 1.3 Market conditions relating to bioprospecting and TK –

- (i) ten Kate, K and Laird, S.A., *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (Earthscan 1999).

This book remains a classic survey of the various commercial and research activities based on biodiversity prospecting.

## 1.4 Bioprospecting and Biopiracy

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1.4.1 Bioprospecting: Legitimate Research or Biopiracy? By Graham Dutfield  
<http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&dossier=7&policy=40>

This web page defines bioprospecting and biopiracy, while also presenting several sides of the debate: while some believe that ethical bioprospecting is possible, others believe it is an inherently flawed enterprise and that “fairness” to the communities who provide access to the commercially valuable biological resources can never be reasonably achieved. Dutfield also critically examines reported instances of patents placed on the traditional knowledge, and the effectiveness of international legislation to protect indigenous communities and traditional knowledge.

1.4.2 Traditional Ecological Knowledge and Prior Art

<http://www.wipo.org/patent/agenda/en/meetings/2002/presentations/hansen.pdf>

This presentation provides an overview on the precarious position of traditional ecological knowledge in the Western intellectual property system – as something in the public domain to be exploited for individual gain, but which cannot be

recognized and protected as communally-held ecological knowledge. Approaches to how traditional ecological knowledge can be treated as “prior art”, and therefore not exploitable by outsiders without compensation to the holders of this knowledge, are presented.

1.4.3 The International Debate on Traditional Knowledge as Prior Art in the Patent System: Issues and Options for Developing Countries (by Manuel Ruiz)  
<http://www.southcentre.org/publications/occasional/paper09/paper9-02.htm>

This paper, available through the South Centre, outlines several ways in which treating traditional knowledge as prior art can be used to defensively protect traditional knowledge from being misappropriated by outsiders. Issues and options to consider when developing legal mechanisms for protecting traditional knowledge as prior art are also treated in-depth in Ruiz’s report. A very helpful annex is also included.

1.4.4 Traditional Ecological Knowledge Prior Art Database (TEK\*PAD)  
<http://ip.aaas.org/tekindex.nsf>

This database is a searchable archive of traditional ecological knowledge documented worldwide. The purpose of this database is to use documentation and publication of traditional knowledge (in this case ecological knowledge practices) as a way to establish it as prior art, safeguarding it from misappropriation and patenting by outsiders. This site also contains additional resources, such as the Biopiracy Hotlist and the downloadable AAAS Handbook on Intellectual Property and Traditional Knowledge

1.4.5 Genetic Resources, Traditional Knowledge and Intellectual Property Rights Brief  
[www.ciel.org/Publications/iprights.pdf](http://www.ciel.org/Publications/iprights.pdf)

A brief written on behalf of the World Summit on Sustainable Development in 2002, this report by the Center for International Environmental Law (CIEL) discusses ways in which the provisions of the CBD may be implemented nationally to promote and protect access to genetic resources and benefit-sharing as well as safeguard indigenous peoples rights to their own communally-held knowledge, and the concomitant intellectual property component therein. A very concise treatment of the relationship between the CBD and TRIPS is provided, and also addresses the importance of the participation of indigenous and local communities in the debate over how indigenous intellectual property is to be defined and protected under the laws of member countries of CBD.

1.4.6 Science and Development Network (SciDevNet) Indigenous Knowledge Dossier  
<http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&policy=49&section=243&dossier=7>

This thorough on-line resource covers both positive and defensive protection mechanisms for protecting indigenous knowledge in the public domain. The

commentary fairly and realistically assesses the utility and limitations of policy and laws to protect indigenous knowledge, and also discusses both sides of the debate to use databases to document traditional and indigenous knowledge and practices. The entire site has several links to other sources on the subject.

## **1.5 SUMMARY/POINTS TO CONSIDER**

- Bioprospecting is big business. The potential for commercial gain is large, but so are the investment costs, with a high risk that no returns will appear.
- There are several kinds of bioprospecting; it covers everything from genomics to natural products research and everything in between.
- There is considerable controversy over what bioprospecting is, when it occurs, and whether it is a morally positive, neutral, or negative enterprise. Some proponents of bioprospecting believe that it is always a positive enterprise because the commercial gain enriches society at large, and the notion that bioprospecting could ever be “unethical” is wrong-headed. Conversely, critics of bioprospecting believe that it is an inherently flawed enterprise, incapable of ever being ethically sound or morally neutral (let alone a morally positive enterprise). Many others take a middle view and believe that bioprospecting can be conducted within an ethical framework, but only if certain protocols are first established in order to safeguard the intellectual property rights of all the parties in collaboration, especially the indigenous groups whose traditional knowledge is providing the lead for a potential new drug, new agricultural practice, or new cultural expression.
- While the literature focusing on bioprospecting is voluminous and will only increase over time, there are still no clear-cut answers for how intellectual property rights should be defined, assigned and respected across all research contexts. And perhaps there will never be one simple answer to how to proceed; what instead might evolve are parallel sets of guidelines and protocols corresponding to specific kinds of bioprospecting research, from which individual groups and companies can decide and tailor how they want to conduct collaborative research, with equitable benefit-sharing in the case of a commercially viable product.

## **2. Legal Framework**

### **2.1 International**

#### **2.1.1 TRIPS (Trade Related Aspects of Intellectual Property Rights)**

##### **a. Overview**

TRIPS was adopted after the 1986 -1994 Uruguay Round of trade negotiations agreement by the World Trade Organization (WTO). TRIPS is perhaps the most influential international agreement on intellectual property rights. It outlines several important trade related aspects of intellectual property.

The agreement protects patents, [copyright](#), [trademarks](#), geographical indications, industrial designs, trade secrets, and new plant varieties. Its goal is to have intellectual property protection that will contribute to technical innovation and the transfer of technology while enhancing social welfare. The agreement provides equal treatment for all trading partners in the WTO. TRIPS requires that signatory states implement with minimum standards of protection for intellectual property in national systems, as well as enforcement provisions and methods of intellectual property dispute settlement. The [TRIPS enforcement measures](#) ensure that property right holders can effectively enforce their rights. These measures can be adopted as domestic procedures for the enforcement of intellectual property rights. They include civil and administrative procedures, provisional measures, special circumstances related to border measures, and criminal procedures.

Membership to the WTO requires a country to ratify TRIPS in order to gain access to multiple international markets available through WTO. Over three quarters of WTO member are developing or least developed countries.

TRIPS homepage on WTO website.

[http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm)

Text of TRIPS agreement

[http://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm)

#### **b. TRIPS/Patents**

Overview: Section 27.1 of the TRIPS agreement requires that patents are made available for all inventions including products, process, and all fields of technology. Patents under TRIPS survive for 20 years and must be disclosed by publication [Article 29]. The 20-year time limit begins from the filing date, but the enforcement of rights only begin from the date of t h e p a t e n t g r a n t .

The agreement states three exceptions that countries may rely on to exclude otherwise patentable subject matter. These are: 1) inventions contrary to public order or morality [Article 27.2]. 2) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals [Article 27.3(a)]. 3) Plants and animals, including the biological processes for the production of plants or animals other than non-biological microbiological processes (not including microorganisms). Furthermore, effective *sui generis* method of protection for plant varieties must be adopted if the member chooses not to adopt a patent protection model.

#### **c. TRIPS controversies:**

(i) Overview: Much controversy has developed between the fusion of trade and intellectual property. Many argue that patenting restricts the availability of important products including pharmaceuticals. Such arguments contend that high prices of pharmaceuticals associated with patent monopolies are a key barrier to achieving broader treatment access in public and private health sectors, especially in developing nations. Developing



nations have demanded an equitable access to needed medicine in areas of health without the morass of policies and patent obstacles.

(ii) DOHA DECLARATION

**Overview:** On November 2001, the WTO adopted the DOHA DECLARATION on TRIPS in response to the criticism by developing nations that pharmaceutical patents were creating obstacles in gaining access to important medicines. The declaration stresses the importance to implement and interpret TRIPS in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines. It emphasizes that TRIPS does not, and should not, prevent member governments from acting to protect public health. It affirms governments' right to use the agreement's flexibilities in order to avoid any reticence the governments may feel.

Text of Doha declaration:  
[http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm)

(iii) Pharmaceuticals/ Pre Doha:

This article addresses the problems that developing countries are facing in providing proper health care to their population. Developing countries are demanding a declaration by the WTO on their position to drug access. For example, the position by the Zimbabwe minister is that TRIPS rules should not impede WTO members from adopting measures to protect public health. The minister seeks flexible policies to ensure access to affordable medicines without necessarily constituting a violation of intellectual property rights. The Zimbabwean delegation stressed that numerous nations, such as South Africa, have faced legal problems due to the lack of clear interpretations of the TRIPS accord. During the WTO debate, the United States and Switzerland, countries that are home to the world's leading pharmaceutical laboratories, rejected the idea that TRIPS rules are obstacles to obtaining medications at low cost.

<http://www.aegis.com/news/ips/2001/IP010905.htm>

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This memo provides a model for governmental use of compulsory licenses (authorization to use patents without the permission of the patent owner). The compulsory license model is to be used as a tool to increase access to medicines in developing countries. The model has five important features: 1) the system must not be overly legalistic, expensive to administer, or easily manipulated by litigation. It is recommended that the parties rely upon an administrative process, 2) The government use provisions should be strong. No developing country

should have statutory public use provisions that are weaker than the US, German, Irish, or UK provisions, 3) The system of setting compensation should be relatively predictable and easy to administer, 4) Production for export should be permitted, 5) There should be a provision for authorization of the use of patents to address public health emergencies.

[http://www.cptech.org/ip/health/cl/recommendedsta  
tepractice.html](http://www.cptech.org/ip/health/cl/recommendedsta<br/>tepractice.html)

This web site provides a list of different patent law schemes in developed countries. The list includes on what grounds compulsory licenses are issued, who makes the licensing decision, what provisions must be met for governmental use of patents, how compensation is determined, and notable patent exceptions.

<http://www.cptech.org/ip/health/cl/examples2.html>

(iv) Pharmaceuticals/ Post Doha

This opinion to the DOHA agreement, acknowledges the merits of the DOHA decision that permits developing countries to override drug patents and make and/or import generic copies of pharmaceutical products to meet their public health needs. However, the opinion notes that the rules regarding the method of obtaining such drugs was left open. Since DOHA, there has been retrogression on the parts of the developed countries- in particular the United States, EU, Japan and Switzerland. These countries are trying to negotiate a solution that will allow the fewest medicines permissible to treat very limited number of illnesses. European Commission (EC) is pushing for a set of highly restrictive "safeguards" on exports, including requirements on the packaging of generic products and notification to patent owners and the WTO. These obligations and others are allegedly designed to control diversions, or leakage, of generic products into developed country markets where they could supposedly undercut patented drugs. The paper proposes regimes, with particular attention to coherence with internationally and democratically agreed upon principles of human rights, gender equality and sustainable development.

[http://64.233.167.104/search?q=cache:sljfehFltLoJ:  
www.genderandtrade.net/WTO/TRIPS\\_PH.pdf+pat  
ent+Trips+pharmaceutical+controversy&hl=en&ie=  
UTF-8](http://64.233.167.104/search?q=cache:sljfehFltLoJ:<br/>www.genderandtrade.net/WTO/TRIPS_PH.pdf+pat<br/>ent+Trips+pharmaceutical+controversy&hl=en&ie=<br/>UTF-8)

Professor Chander, at UC Davis School of Law, discusses how the lack of needed drugs in developing

countries is caused by the high cost of such medicines. For example, the anti-AIDS drug cocktails that are sold in U.S. for \$10,000 a year can be generated in Indian laboratories and sold for \$300 a year. Professor Chander notes that the problem with TRIPS is that the compulsory licenses are limited to the supply of domestic markets and not for export. Unfortunately, many countries do not have the manufacturing capacity to create pharmaceuticals and must import from other countries. DOHA was an attempt to solve the compulsory license issue, noting the gravity of public health concerns. Countries agreed to solve this issue of compulsory licensing before the end of 2002, but as of March 2003 no such agreement has been manifested. On December 2002, the EU, Japan, and Switzerland were ready to agree to a compromise to the issue, but the United States stopped the compromise. The United States felt the compromise was beyond the DOHA agreement, arguing that the agreement only targeted HIV/AIDS, tuberculosis, malaria, and a handful of other specified epidemics. Professor Chander's position is that the DOHA DECLARATION was not limited to the diseases specified in the text.

[http://writ.news.findlaw.com/commentary/20030306\\_chander.html](http://writ.news.findlaw.com/commentary/20030306_chander.html)

On May 27 2002 the Zimbabwe Minister of Justice made an emergency declaration suspending the country's obligations under the TRIPS agreement with respect to patents on antiretroviral (ARV) and other drugs used in the treatment of HIV/AIDS. This constitutes the first time a country has invoked the DOHA DECLARATION on TRIPS and Public Health. Web page provides several links that discusses the debate and issues surrounding the DOHA DECLARATION.

[http://www.eldis.org/ipr/news/2002jun\\_13\\_zimbabwe.htm](http://www.eldis.org/ipr/news/2002jun_13_zimbabwe.htm)

Announcement by the Office of United States Trade Representative (USTR), implementing an interim plan permitting poor countries to override patents on drugs produced outside their countries in order to fight current and future health epidemics. Such provisions were especially made to combat HIV/AIDS, tuberculosis, malaria and other diseases that pose national health crises. This announcement was made after the failed negotiations with WTO to rule on a consensus dealing with developing countries' access to patented medicines.

<http://usinfo.state.gov/ei/Archive/2003/Dec/31-624484.html>

Article discusses the divergence between the goals of the DOHA DECLARATION and the intellectual property provisions proposed by the United States Trade Representative (USTR) within the Free Trade Area of the Americas (FTAA). If the planned measures were accepted, it would require a higher standard of protecting and enforcing IPRs on medicine that is already required by the WTO. The result would pose a serious threat to access to affordable medicines and public health in Latin America and the Caribbean. For example, the US is seeking 5-years of exclusive rights for test data. Granting 5-years of data exclusivity would have the affect of establishing a 5-year ban on compulsory licensing. Under the DOHA DECLARATION, WTO members have the freedom to determine the grounds upon which to grant compulsory licenses. However, the US wants to limit the compulsory licensing to government use for only three circumstances: non-commercial use, situations of national emergency or other situations of extreme urgency, and to remedy anticompetitive practices. On August 30, 2003 WTO reached a temporary agreement that permits countries to issue compulsory licenses to export generic versions that have no manufacturing capacity. Proposed FTAA text would prohibit compulsory licensing for export altogether. Hence, countries that cannot produce medicines themselves would be unable to obtain low cost drugs from a foreign manufacturer in a country where a patent is on file.

[http://www.healthgap.org/press\\_releases/03/111903\\_HGAP\\_BP\\_FTAA\\_miami.pdf](http://www.healthgap.org/press_releases/03/111903_HGAP_BP_FTAA_miami.pdf)

This paper discusses Canada's proposed Government Bill C-56. The bill would amend the current Canadian Patent Act to provide for the issuance of compulsory licenses that would allow generic pharmaceutical manufactures to make and export generic versions of patented pharmaceutical products to developing countries lacking their own manufacturing capacity. The bill does not authorize compulsory licensing of pharmaceuticals to only treat specific diseases, nor is it limited to exporting to countries facing an "emergency" or other circumstances of extreme urgency. Some areas of the bill that must be considered before being passed are: 1) Provisions permitting patent-holders to block licenses for generic manufacturers, 2) Limited list of pharmaceutical products, 3) Denial of

benefit to some developing countries that are not WTO members, 4) No provision for NGOs to procure generic medicines.

[http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/PatentActAmendment\\_Update.pdf](http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/PatentActAmendment_Update.pdf)

This article discusses the problem of the high cost of medicines, which impedes the access to vital drugs in both developed and under developed countries. The current system of extending marketing monopolies on medicines worldwide prevents the very competition that reduces prices and increases access to life-saving medicines. The 20-year patent monopoly is provided to those manufactures that complete the research and development. The article suggests that the current business model that uses a single payment method for both cost of research and development has affected the cost of drugs. Alternatively, it proposes a new trade framework and business models for an effective virtual R&D market. One such measure would be to develop worldwide policies that encourage and reward innovation, while allowing competitors to build on each others' ideas, and protecting consumers from unreasonable prices. Other alternatives methods would require countries to maintain a GDP-related contribution to research and development, while being free to choose how they finance it. New methods of research - such as non-profit collaboration or prizes for exceptional ideas - would allow innovation to be rewarded directly, removing the need for marketing monopolies, and allow competition. Drugs could then be sold close to the cost of manufacture.

[http://plosbiology.org/archive/1545-7885/2/2/pdf/10.1371\\_journal.pbio.0020052-L.pdf](http://plosbiology.org/archive/1545-7885/2/2/pdf/10.1371_journal.pbio.0020052-L.pdf)

## **2.1.2 Convention on Biological Diversity (CBD):**

### **a. Overview**

CBD is an international treaty on the conservation and sustainable use of biological diversity. It was created in 1992 at the Earth Summit in Rio De Janeiro. Over 150 governments signed the document and since then more than 175 countries have ratified the agreement. Its three major goals are: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources. It also covers the rapidly expanding field of biotechnology, addressing technology development and transfer, benefit-sharing and biosafety. The treaty recognizes national sovereignty over all genetic resources, and provides that access to valuable biological resources be carried out on "mutually agreed terms" and subject to the "prior informed consent" (PIC) of the country of origin. When a microorganism,

plant, or animal is used for a commercial application, the country from which it came has the right to benefit. Such benefits can include cash, samples of what is collected, the participation or training of national researchers, the transfer of biotechnology equipment and know-how, and shares of any profits from the use of the resources.

The CBD also recognizes the close and traditional dependence of indigenous and local communities on biological resources and the need to ensure that these communities share in the benefits arising from the use of their traditional knowledge. Member governments have undertaken "to respect, preserve and maintain" such knowledge and practices, to promote their wider application with the approval and involvement of the communities concerned, and to encourage the equitable sharing of the benefits derived from their utilization.

Official website: <http://www.biodiv.org/default.aspx>

**b. Bonn agreement:** (Created in 2002, during CBD's sixth meeting)

The guidelines cover areas related to genetic resources, as well as fair and equitable sharing of the benefits arising from their utilization. The guidelines should assist parties in creating an overall access and benefit sharing strategy, and identifying the steps involved in the process of obtaining access to genetic resources and benefit sharing. Specifically, these voluntary guidelines are meant to establish legislative, administrative or policy measures, negotiating contractual agreements for access and benefit sharing. The content of the guidelines coincides and directly supports several interpretations and concerns raised by developing countries including India, Brazil, and the Africa Group in the TRIPS Council under the review of Article 27.3(b) of the TRIPS Agreement. According to the Bonn agreement, the guidelines of prior informed consent include the following elements: consent of the national authority (including provincial and local authorities) and of indigenous and local communities; mechanisms for the involvement of relevant stake holders; reasonable timing and deadlines; specification of the type of uses; direct linkage with mutually agreed terms; detailed procedures for obtaining the consent; and a description of the general process for access.

1. Official website:

a) <http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp>

2. BONN text:

a) <http://www.biodiv.org/decisions/default.aspx?m=cop-06&d=24>

3. <http://www.southcentre.org/info/southbulletin/bulletin48/bulletin48-03.htm>

**c. Countries implementing CBD:**

Article that discusses InBIO (Instituto Nacional de Biodiversidad), an institution developed in Costa Rica to promote bioprospecting and conservation efforts of Costa Rica's resources by developing negotiations and contracts with industrialized enterprises. InBIO has been successful in creating several agreements with foreign bioprospecting organizations. InBIO has seven key aspects that are manifested in their agreements: 1) Direct payments in cash or knowledge exchanges, 2) Payment of a significant percentage of the initial budget of the project [10%] and the returns of the commercialization of the products [50%], 3) Cooperation

clauses that stipulate the gradual transition of the investigation processes to the supplier country, in order to create new jobs and the achievement of industrial development, 4) Minimum exclusivity, 5) Agreement on the samples property and patents property, 6) The use of chemistry synthesis, semi-synthesis and domestication of the living sources, in order to avoid the continuous extraction of the biotic material, 7) Legal mechanisms that will provide protection to all parties. Several examples of benefit sharing agreements are cited in this paper.

[http://r0.unctad.org/trade\\_env/docs/Benefit\\_Sharing.pdf](http://r0.unctad.org/trade_env/docs/Benefit_Sharing.pdf)

The Department of Environment and Heritage of Australia discusses its approach to the CBD. The goal is to guarantee that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia. The Department of Environment and Heritage's key policy aims include: providing greater certainty for industry and researchers; requires the introduction of terms and conditions of access to Australian resources that Australia would be prepared to meet if introduced by other countries; respects indigenous biodiversity knowledge and its holders; requires consultation with stakeholders and indigenous peoples; and is flexible while encouraging cooperation between jurisdictions. The policies establish a common basis for new or revised legislation in all of Australia, creating a legal framework to promote biotechnology industry, acknowledging that this act is consistent with BONN guidelines. Further it ensures that traditional biological knowledge in the scientific, commercial and public domains proceeds only with the cooperation and control of the traditional owners of that knowledge and that the use and collection of that knowledge results in social and economic benefits to the traditional owners.

<http://www.deh.gov.au/biodiversity/science/access/nca/pubs/understanding.pdf>

This briefly summarizes the role of the CBD, as well as other national, regional, international and non-state initiatives in creating access to genetic resources and benefit-sharing systems. The different regimes offer insights into the relationship between international laws and access and benefit sharing (ABS). It proposes elements that should be included in an international system on ABS, as proposed at the World Summit on Sustainable Development in 2002. It suggests that such an international administration must have clear goals, be legally binding and should be broad in scope. Only in this fashion will countries be able to create a system that includes the environmental, social and economic aspects of sustainable development.

[http://www.cisd.org/pdf/brief\\_biodiv.pdf](http://www.cisd.org/pdf/brief_biodiv.pdf)

Web site discusses World Wildlife Fund's (WWF) position on the access and benefit sharing as related to genetic resources. They support the efforts in promoting access to genetic resources and benefit sharing. However, WWF is concerned with the slow and unequal efforts to use the BONN guidelines to improve the natural resource management and

guarantee benefits to indigenous and local communities. To address these concerns WWF calls on the conference of the parties of the CBD to increase and broaden capacity building exercises, improve information sharing on lessons learned across nations and expand the dialogue and participation on the establishment of an international regime on access to genetic resources and benefit sharing.

<http://www.panda.org/downloads/policy/cbd/wwfcop7absfinal3.do>

c

### 2.1.3 Convention for the Protection of New Varieties of plants (UPOV)

**a. Overview-** UPOV was established in 1961 and it was revised in 1972, 1978 and 1991. Its objective is to provide and promote an effective system of plant variety protection with the aim of encouraging the development of new varieties of plants for the benefit of society. The UPOV Convention provides a *sui generis* form of intellectual property protection, which has been specifically adapted for the process of plant breeding. The 1991 convention requires member countries provide protection to new plant varieties by way of Plant Breeder's Rights. Not all members are required to be bound by the 1991 convention. Original members can decide to be bound by a previous agreement. Unlike the previous UPOV agreement, there is no farmer's or breeder's exemption for protected species. It is now up to the national governments to implement separate legislation with respect to this practice. Many UPOV members are also WTO members and therefore obliged to protect plant varieties by a *sui generis* protection system (as a result of the TRIPS Agreement that requires protection of plant variety either through: (a) patents, (b) effective *sui generis* systems, or (c) any combinations thereof. ) While the precise meaning of *sui generis* under TRIPS is unclear, the use of the UPOV plant protection system generally fulfills this requirement. As a result the use of UPOV for plant protection is a mechanism for complying with the TRIPS Agreement.

Official UPOV website: <http://www.upov.int/>

**b. UPOV controversy-** Because *sui generis* has not been clearly defined, there has been much controversy as to the interpretation of *sui generis* and what is considered an effective *sui generis* scheme. Many argue that *sui generis* permits countries to create their own protection for plant varieties. While others advocate that UPOV's plant breeders rights system is the best *sui generis* protection available. Many developing countries disfavor using the UPOV standard.

The South Asia Watch on Trade, Economics & Environment (SAWTEE) and the International Center for Integrated Mountain Development (ICIMOD), together with several other regional organizations, has developed a program to protect mountain farming communities. SAWTEE states that most developing countries have chosen to implement their own *sui generis* systems. Most developing countries have chosen the *sui generis* system. However, developed countries, through bilateral pressure tactics (including during the accession of new countries to the WTO), are trying to impose their own model, known as International Union for the Protection of New Plant Varieties (UPOV) on the developing countries. Developed countries have gone on record claiming UPOV as the only effective *sui generis* model, thus facilitating the process of its backdoor entry into the WTO system. These moves by the developed countries, made at the insistence of the multinational seed companies based in their respective countries, are calculated to restrict the farmers' rights with the twin objectives of: a) making farmers



dependent on them for the purchase of seeds “at any price”; b) driving the farmers (who are their competitors by virtue of being able to supply nearly 80 percent seed requirement in the developing countries) out of the market and establishing control over the entire market.

[http://www.sawtee.org/Third\\_Regional\\_Consultation\\_Sri\\_Lanka.html](http://www.sawtee.org/Third_Regional_Consultation_Sri_Lanka.html)

Web site that criticizes the globalization of IPR campaign and the interests of transnational corporations housed in the North. The web site alleges that UPOV is currently selling itself as the ready-made solution for compliance with TRIPS. Even though TRIPS makes no mention of UPOV, UPOV wants every developing country to believe that joining its ranks is the simplest and most logical means to comply with the former trade regime. However, countries do not have to join UPOV to implement a *sui generis* system as compliance with TRIPS. The web site provides ten reasons why not to join UPOV.

<http://www.southcentre.org/southletter/sl34/sl34-10.htm>

Memorandum discusses how much of the genetic biodiversity is found on the southern hemisphere in developing countries. Their food security often depends on traditional agriculture, cultural systems and the knowledge and ability to use different plants and plant varieties of indigenous peoples and farming communities. Developing countries often agree to join the UPOV for its preferential trade relations with the EU or development assistance. However, small-scale farmers in these developing countries are negatively affected because they must now buy seeds patented by companies. Traditionally, small-scale farmers have saved seeds for cultivation and exchanged and sold them locally. For example, in Sub-Saharan Africa 90 percent of food production is based on seeds saved for cultivation and in India the percentage is 70. In industrialized countries, too, farmers prefer to save seeds rather than buy new ones. UPOV guarantees companies that trade in seeds extensive rights to protect seeds and a monopoly position in the markets, which affect the overall food security and, community rights of indigenous people.

[http://www.kepa.fi/english/cancun/trips\\_agreement/index\\_html?printable](http://www.kepa.fi/english/cancun/trips_agreement/index_html?printable)

#### **2.1.4 United Nations Educational, Scientific and Cultural Organization (UNESCO)**

**a. Overview:** UNESCO works as a laboratory of ideas and a standard-setter to forge universal agreements on emerging ethical issues. The organization also serves as a clearinghouse that disseminates and shares information and knowledge, while helping member states to build their human and institutional capacities in diverse fields. In short, UNESCO promotes international co-operation among its 190 member states and six associate members in the fields of education, science, culture and communication.

Official Website:

[http://portal.unesco.org/en/ev.php@URL\\_ID=3328&URL\\_DO=DO\\_TOP\\_IC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php@URL_ID=3328&URL_DO=DO_TOP_IC&URL_SECTION=201.html)

**b. Safeguarding Traditional Cultures: A Global Assessment of the 1989 UNESCO Recommendation on the Safeguarding of Traditional Culture and Folklore** (Center for Folklife and Cultural Heritage, Smithsonian Institution, Washington, DC). This volume is from the conference entitled “A Global

Assessment of the 1989 Recommendation on the Safeguarding of Traditional Culture and Folklore: Local Empowerment and International Cooperation” held at the Smithsonian Institution in Washington, D.C., from June 27–30, 1999. Though the United States is not a member of UNESCO and the Smithsonian not officially charged with representing official policy, long standing concern and involvement with the issues of traditional culture and folklore brought the two institutions together to organize the conference which addressed many aspects of Traditional Knowledge and UNESCO’s efforts in this area.

<http://www.folklife.si.edu/unesco/>

### c. UNESCO TK, Farmers Rights and *Sui generis* protection

Final declaration by Pacific Island territories for protection of indigenous cultures and their intellectual property. Declaration stresses the need for a collective voice for the Pacific Islands in the international forum and for concrete and effective measures at national, regional and international levels in the region. Declaration consists of: 1) the definition of traditional knowledge and expressions of the indigenous cultures of the Pacific Islands, 2) the Pacific position on the international debate on the protection of traditional knowledge and expressions of indigenous cultures, 3) recommendations for a policy of regional harmonization of the protection of traditional knowledge and expressions of indigenous cultures, 4) recommendations for technical assistance and support of a homogenous system of legal protection, identification, conservation and control of exploitation, of indigenous culture in the countries and territories.

[http://www.unesco.org/culture/copyright/folklore/html\\_eng/declaration.shtml](http://www.unesco.org/culture/copyright/folklore/html_eng/declaration.shtml)

Additional UNESCO-WIPO declarations:

a) WIPO-UNESCO African Regional Consultation on the Protection of Expressions of Folklore (Pretoria, South Africa)

<http://www.wipo.int/documents/en/meetings/1999/folklore/index.htm#africa>

b) WIPO-UNESCO Regional Consultation on the Protection of Expressions of Folklore for Arab Countries (Tunis, Tunisia)

<http://www.wipo.int/documents/en/meetings/1999/folklore/index.htm#arab>

c) WIPO-UNESCO Regional Consultation on the Protection of Expressions of Folklore for Latin America and the Caribbean (Quito)

<http://www.wipo.int/documents/en/meetings/1999/folklore/index.htm>

## 2.1.5 The World Intellectual Property Organization (WIPO)

a. **Overview:** an international organization dedicated to promoting the use and protection of works of intellectual property. Headquartered in Geneva, Switzerland, WIPO is one of the 16 specialized agencies of the United Nations system of organizations. It administers 23 international treaties dealing with different aspects of intellectual property protection. The Organization counts 180 nations as member states. In 1981, WIPO-UNESCO jointly adopted a Model Law on Folklore.

Official website:

<http://www.wipo.int/about-wipo/en/overview.html>

*Traditional knowledge and cultural expressions:* WIPO web page, which provides links to issues, news, and resources, relating to traditional knowledge, genetic resources, and cultural expressions (folklore).

<http://www.wipo.int/tk/en/index.html>

#### **b. WIPO TK, Farmers Rights and *Sui generis* protection**

October 2003- WIPO announces that the WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), will be accelerating its work in the international dimension of intellectual property (IP) and genetic resources, traditional knowledge (TK) and folklore. IGC first met in April 2001 to discuss how intellectual property systems may protect TK, expressions of folklore, and how to handle issues of genetic resources. The IGC has fostered exchange of practical understanding of the approaches available for legal protection of traditional knowledge and cultural expressions. A detailed overview of the work of the IGC is provided in document WIPO/GRTKF/IC/5/12 ( available in [Adobe PDF](#) and [MS-Word](#) formats).

<http://www.wipo.int/pressroom/en/releases/2003/p362.htm>

<http://www.grain.org/bio-ipr/?id=364>

March 2004- The IGC decided on concrete steps for accelerated international work on protection of traditional knowledge (TK) and folklore. This was the first meeting of the IGC since its mandate was renewed by the WIPO General Assembly in October 2003 with instructions to accelerate its work and focus on the international dimension of intellectual property (IP) and genetic resources, TK and folklore. During its meeting from March 15 to 19, the IGC commissioned the development of two complementary sets of core materials for TK and for folklore. In each case, the IGC approved the development of an overview of policy objectives and core principles for protection, and an outline of the policy options and legal mechanisms, backed up by precise analysis of the implications of each option. The African group of countries submitted a text on objectives, principles and elements of an international instrument. This proposal received widespread support in the Committee as a framework for its work. The Committee also considered a range of practical steps to enhance the participation of representatives of TK holders, and launched a new website: <http://www.wipo.int/tk/en/igc/ngo/index.html> to disseminate position papers of IGC observers that would enhance awareness of the perspectives and concerns of TK holders.

[http://www.wipo.int/edocs/prdocs/en/2004/wipo\\_pr\\_2004\\_378.html](http://www.wipo.int/edocs/prdocs/en/2004/wipo_pr_2004_378.html)

WIPO introduces a group case study on the use of intellectual property systems by indigenous communities in Australia. The publication, entitled, 'Minding Culture: Case Studies on Intellectual Property and Traditional Cultural Expressions' <http://www.wipo.int/tk/en/studies/cultural/minding-culture/studies/finalstudy.pdf>, was written for WIPO by Ms. Terri Janke, an Australian lawyer and a descendant of the Meriam people of the Torres Strait Islands, Australia. The studies were created to assist WIPO in responding to

intellectual property systems in the areas of traditional cultures and knowledge. The case studies provide traditional communities, as well as policymakers, legislators and other stakeholders, with realistic, empirically-based options and new ideas for future policy development.

[http://www.wipo.int/edocs/prdocs/en/2004/wipo\\_pr\\_2004\\_377.html](http://www.wipo.int/edocs/prdocs/en/2004/wipo_pr_2004_377.html)

Paper written by Dr. Patricia Kameri-Mbote covering topics on community, as well as farmers and breeder's rights in Africa. Kameri-Mbote notes that there is reluctance in many developing countries to implement TRIPS provision because the underlying IPR regimes that are based on western concepts of property rights are alien to the cultural, historical and institutional context of most developing countries. This paper analyzes the international and Kenyan legal framework for the protection of biodiversity and plant varieties. It seeks to identify cross cutting issues and trends pertinent to the protection and enforcement of community, farmers' and breeders rights through *sui generis* systems. It advocates that countries should seize the opportunity to implement *sui generis* systems provided through TRIPS to protect plant varieties. Kameri-Mbote provides example guidelines on formulating *sui generis* policies and legislation, which entails community rights, farmer's rights, breeder's rights, benefit sharing, and institutional and administrative frameworks. She dismisses the use of UPOV because of its patent rights that in turn create monopolies that favors countries with highly industrialized agricultural sectors.

<http://www.ielrc.org/Content/A03021P.pdf>

## 2.2 National

### 2.2.1 Background

In most instances, national governments are solely responsible for implementing intellectual property laws and granting individuals, groups and companies intellectual property rights to their creations in a manner consistent with international obligations. While they differ from country to country, copyright, trademark, patent, and other intellectual property laws have largely been harmonized throughout the world due to various international treaties and conventions. Despite this movement toward standardization of national laws, differences in terms of protection and additional IPR developments do exist. This section contains various links to sites highlighting national intellectual property legislation and recent developments of relevance to access and benefit sharing arrangements.

### 2.2.2 Intellectual Property Rights Variations

- a. WIPO Guide to Intellectual Property Law Worldwide  
<http://www.wipo.int/about-ip/en/ipworldwide/index.html>

This site identifies the intellectual property legislation in 219 nations, along with their adherence to bilateral and multilateral treaties. Individual profiles are given for each country that provides information on country specific legislation and activities, administrative structures,

and on governmental and non-governmental bodies for information and enforcement. Full-text reproductions of national legislation are not given.

- b. Caslon Intellectual Property Guide:  
<http://www.caslon.com.au/ipguide5.htm>

This page highlights intellectual property developments in particular countries and regions. Summaries for recent national developments in intellectual property law are given for the following: the USA, European Union, UK, Canada, New Zealand, China, and Japan.

- c. WIPO: Collection of Laws for Electronic Access  
<http://clea.wipo.int/clea/lpext.dll?f=templates&fn=main-h.htm&2.0>

Collection of Laws for Electronic Access (CLEA) database is an international electronic archive of national intellectual property legislation. It provides full-text reproductions of national legislation in English. The CLEA database also includes the texts of selected laws in French and Spanish. The CLEA database also bibliographic references to many more pieces of legislation not translated.

- d. Collection of national copyright laws  
[http://portal.unesco.org/culture/en/ev.php@URL\\_ID=14076&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/culture/en/ev.php@URL_ID=14076&URL_DO=DO_TOPIC&URL_SECTION=201.html)

- e. Researching Intellectual Property Law in an International Context  
<http://www.llrx.com/features/iplaw2.htm>

This site contains various links to international intellectual property regimes as well as links to a large number of national intellectual property laws.

- f. Examples of national legislation:
- a) Andean Community (2002): [Decision 486 on a Common Regime on Industrial Property](#)
  - b) Organization of African Unity (OAU) (1999): [Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders and Regulation of Access to Biological Resources](#)
  - c) Peru (2002): [Law 27811 on the Protection of Collective Knowledge of Indigenous Peoples Related to Biological Resources](#)
  - d) Philippines (1996): [Executive Order 247 on Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By Products and Derivatives, for Scientific and Commercial Purposes and Other Purposes](#)

### 2.3 Rights and Interest of Indigenous People

While historical trends in international law previously facilitated the colonization of indigenous peoples and their lands, modern international law's human rights programs have gradually become more responsive to indigenous peoples' desires to survive as distinct communities in control of their own lives. This has become particularly more evident in the international system over the last several years. The United Nations and other international institutions have come to exhibit a renewed focus on many concerns and interest of indigenous peoples. The most prominent of these concerns that has been addressed is indigenous peoples' right of self-determination. Self-determination has been generally defined as the right for all peoples to determine their own economic, social and cultural development. In exercising this right of self-determination, indigenous peoples argue for recognition that they are also to be in control of their cultural and intellectual property. This section contains various links addressing these topics.

### 2.3.1 Position of Indigenous people within state legal framework

#### a. Self-determination and international law

(i) The Principle of Self-Determination and Indigenous Peoples Under International Law, James Anaya

<http://www.austlii.edu.au/au/other/IndigLRes/car/1997/3/speeches/pleary2/anaya.htm>

This paper is based on a chapter in James Anaya's book, *Indigenous People in International Law*. The paper's main focus is to address the meaning of self-determination. Anaya establishes the core ideas behind the principle in order to give a greater view to the scope and content of self-determination as a principle of international law. Anaya also discusses the general reasons that resistance has arisen in acknowledging the principle. Anaya discusses that the foundation of most of the resistance is the misconception that self-determination equates to indigenous peoples having a right to choose independent statehood or some other form of political arrangement.

(ii) Indigenous Affairs: Self-Determination

<http://iwgia.inforce.dk/graphics/Synkron-Library/Documents/IndigenousAffairs/selfdetermination.pdf>

This issue contains an article by John Henriksen addressing the scope of self-determination and the intended beneficiaries of this principle. The issue also contains several articles highlighting specific indigenous peoples' struggles for self-determination.

(iii) General link to other Self-Determination writings

<http://www.iwgia.org/sw228.asp>

b. Some examples of self-determination and international law:

The right of self-determination has been recognized in many international instruments. It is embodied in the Charter of the United Nations, the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights. The common article of these covenants provides that:

1. All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development.
2. All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefits, and international law. In no case may a people be deprived of its own means of subsistence.
3. The States Parties to the present Covenant, including those having responsibility for the administration of Non-Self-Governing and Trust Territories, shall promote the realization of the right of self-determination, and shall respect that right, in conformity with the provisions of the United Nations.

(i) International Covenant on Civil and Political Rights  
<http://www1.umn.edu/humanrts/instree/b3ccpr.htm>

(ii) International Covenant on Economic, Social and Cultural Rights  
[http://www.unhchr.ch/html/menu3/b/a\\_ceschr.htm](http://www.unhchr.ch/html/menu3/b/a_ceschr.htm)

(iii) Charter of the United Nation  
<http://www.un.org/aboutun/charter/>

### 2.3.2 Some declarations from indigenous groups:

Despite international recognition of the rights of indigenous peoples, the knowledge and way of life of indigenous people are still perceived to be threatened. As a result of this, various initiatives and declarations have been launched to protect the rights of indigenous peoples. Many of these declarations focus on the perceived limitations of existing intellectual property laws and the future development of sui generis legislative frameworks to protect indigenous cultural and intellectual property rights. These declarations or soft laws, though not legally binding, are regularly used to exert moral and political influence in order provide direction for the creation of these beneficial sui generis systems.

a. Mataatua Declaration  
<http://users.ox.ac.uk/~wgtrr/mataatua.htm>

The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples was drawn up in June 1993 in New Zealand. In the declaration, indigenous delegates from fourteen countries stated their right to self-determination and proclaimed indigenous peoples as the exclusive owners of their cultural and intellectual property. The declaration further offers recommendations to indigenous peoples in developing policies and practices reflective of this. The declaration's policy recommendations call for such things as: (1) indigenous people defining for themselves their own intellectual and cultural property, (2) a recognition that existing protection mechanisms are insufficient for the protection of indigenous people's intellectual and cultural property rights, and (3) establishing appropriate mechanisms for monitoring the commercialism of indigenous cultural property in the public domain. The declaration also offers detailed recommendation to states and international agencies in developing appropriate policies that recognize indigenous peoples as the guardians of their customary knowledge, who have the right to protect and control dissemination of their knowledge.

b. Other Declarations

(i) Kari-Oca Declaration

[http://www.tebtebba.org/tebtebba\\_files/susdev/susdev/karioca.html](http://www.tebtebba.org/tebtebba_files/susdev/susdev/karioca.html)

The Kari Oca Declaration was written at the World Conference of Indigenous Peoples on Territory, Environment and Development held in Rio de Janeiro in May of 1992. At the Conference, indigenous representatives from all over the world met together to write the document asserting their basic and fundamental rights. The Kari-Oca Declaration broadly asserts indigenous peoples' rights to their land and traditions, and their commitment to protect the resources under their control for future generations. In addition to this, the declaration establishes a framework outlining the relationship between indigenous peoples and the international community

(ii) Indigenous Peoples Earth Charter

[http://www.tebtebba.org/tebtebba\\_files/susdev/susdev/earthcharter.html](http://www.tebtebba.org/tebtebba_files/susdev/susdev/earthcharter.html)

The 109-point Earth Charter elaborates on the principles of the Kari-Oca Declaration. It denounces specific practices which threaten indigenous societies and cultures, such as population transfer schemes and toxic and nuclear waste dumping on indigenous lands. It also demands that indigenous treaties be taken seriously by governments and calls for UN enforcement of them. It also proposes that the United Nations, at the request of affected indigenous peoples, be given the authority to send indigenous representatives, in a peacekeeping capacity, into territories where conflicts arise. The Charter demands that governments demarcate indigenous lands and grant indigenous people autonomy over them. It emphasizes the importance of indigenous people cultivating local crops



for local consumption and it holds that indigenous peoples have a right to maintain their traditional way of life.

(iii) Declaration of Belem

<http://users.ox.ac.uk/~wgtrr/belem.htm>

The Declaration of Belem is a product of the First International Congress of Ethnobiology (1988), which was convened by indigenous peoples, scientist, and environmentalists in order to discuss and formulate a policy to prevent the destruction of cultural and biological diversity. Within the Declaration, an acknowledgment is given to the pivotal role that indigenous peoples play in maintaining biodiversity. The Declaration further outlines the responsibilities of scientists and environmentalists in addressing the needs of these local communities. Notably, the Declaration calls for mechanisms to be created that recognize indigenous specialists as proper authorities to be consulted in all programs affecting them, their resources, and their environments. The Declaration also calls for procedures to be developed to compensate native peoples for their knowledge and for the use of their biological resources.

(iv) Suva Declaration

<http://users.ox.ac.uk/~wgtrr/suva.htm>

In supporting the initiatives of the Mataatua Declaration and the Kari-Oca Declaration, the Suva Declaration recognizes the rights of indigenous peoples of the Pacific to self-governance and independence and ownership of lands, territories and resources. In the statement these rights are seen as the basis for the preservation of indigenous peoples' knowledge and culture. The statement also calls for a recognition of the limitations of current intellectual property laws and the need for protective measures to ensure against possible exploitation.

(v) The Manila Declaration

<http://users.ox.ac.uk/~wgtrr/asomps.htm>

(vi) General link to statements, declarations, charters, resolutions and recommendations by organizations representing indigenous and local communities

<http://www.biodiv.org/programmes/socio-eco/traditional/instruments.asp>

<http://users.ox.ac.uk/~wgtrr/decin.htm>

### 2.3.3 Examples of State Legislation Relating to Indigenous Knowledge

## a. Indigenous Peoples' Rights Act

<http://www.grain.org/docs/philippines-ipra-1999-en.pdf>

The Indigenous Peoples' Rights Act was signed into Philippines law in 1997. The law seeks to recognize, protect, and promote the rights of indigenous peoples in the Philippines through a variety of implementing mechanisms. The act specifically defines a range of rights of indigenous peoples, but with much focus towards giving proper recognition to the indigenous peoples' rights to self-governance and to their ancestral domains.

## b. Peru: Legislation implementing protection regime for the collective knowledge of indigenous peoples derived from biological sources.

<http://www.grain.org/brl/peru-tk-2002-en.cfm>

This legislation by the Peruvian government establishes a special protection regime for the collective knowledge of indigenous peoples that is connected with biological resources. The regime's objective are to (a) To promote respect for and the protection, preservation, wider application and development of the collective knowledge of indigenous peoples; (b) To promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge; (c) To promote the use of the knowledge for the benefit of the indigenous peoples and mankind in general; (d) To ensure that the use of the knowledge takes place with the prior informed consent of the indigenous peoples; (e) To promote the strengthening and development of the potential of the indigenous peoples and of the machinery traditionally used by them to share and distribute collectively generated benefits under the terms of this regime; (f) To avoid situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions.

## c. Panama:

<http://www.grain.org/brl/panama-tk-2000-en.cfm>

The purpose of this law is to protect the collective rights of intellectual property and traditional knowledge of the indigenous communities upon their creations such as inventions, models, drawings and designs, innovations contained in the pictures, figures, symbols, illustrations, old carved stones and others; likewise, the cultural elements of their history, music, art and traditional artistic expressions, capable of commercial use, through a special registration system, promotion, commercialization

of their rights in order to stand out the value of the indigenous cultures and to apply social justice.

#### **2.3.4 Protocols to meet with outsiders**

a. Hopi:

<http://www.nau.edu/hcpo/hcpo/index.html>

Due to perceived abuses, misrepresentation and exploitation of the rights of the Hopi people, community guidelines were established in order to protect their intellectual and cultural resources. This protocol for research, publication and recordings, requires that the Hopi Tribe be consulted for all projects or activity involving Hopi intellectual resources and that such projects or activity be reviewed and approved by the Hopi Office of Historic and Cultural Preservation. This is to be accomplished through a permitting process or other contractual agreement. Proposals for permission shall address, at a minimum, the following: (1) Intent and benefit to the Hopi tribe, (2) Risks associated with the activity, (3) Detailed mechanism for informed consent, (3) Mechanisms for protecting the right to privacy of the Hopi people, (4) Fair and appropriate return, (5) Review of the research, (6) Ownership.

b. Alaska Native Knowledge Network:

<http://www.ankn.uaf.edu/standards/knowledge.html>

This contains suggested guidelines for indigenous peoples to address issues of concern in the documentation, representation and utilization of traditional cultural knowledge by such individuals as researchers, authors and publishers. These guidelines are party specific but generally call for measures to ensure interested parties take necessary steps in obtaining informed consents, and that appropriate efforts are undertaken in order to ensure that any representation of cultural content is accurate, contextually appropriate, explicitly acknowledged and approved by proper authorities.

### **3. Ethical Codes and Institutional Policies and Guidelines for Bioprospecting.**

Ethical codes, which may be mandatory or aspirational, generally set forth underlying principles for research, whereas guidelines and policies often supplement ethical codes and tend to provide more practical advice as to “best practices.” This section contains links to numerous ethical codes, policies and guidelines put forward by (i) research institutions, (ii) state governments, intergovernmental and non-governmental organizations, and (iii) private corporations. Codes and Guidelines can be very useful in bioprospecting arrangements even where members of organizations to which the codes and guidelines apply are not involved, as they can provide some indication of relevant “best practices.”

### 3.1 Professional Societies and Research Institutions Ethical Codes and Guidelines

3.1.1 1996 Proposed Guidelines for Researchers and Local Communities Interested in Accessing, Exploring and Studying Biodiversity; developed by the Biodiversity & Ethics Working Group of Pew Conservation Fellows.

<http://www-geography.berkeley.edu:16080/ProjectsResources/BRP/BRP.pdf>

This Directory of Guidance Documents Relating to Biodiversity and Cultural Knowledge Research and Prospecting was compiled for the Biodiversity & Ethics Working Group of Pew Conservation Fellows By Tegan Churcher, Research Asst. for Dr. Ashok Gadil & Dr. Bernard Nietschmann; Department of Geography, University of California and Environmental Energy Technologies Division Ernest Orlando of Lawrence Berkeley National Laboratory Berkeley, CA in June 1997. This document describes in detail biodiversity research protocols proposed by the Pew Conservation Fellows, and provides a survey of biological and cultural research and prospecting protocols, along with a bibliography. The principles underlying the Pew guidelines are as follows: (1) Research should be an educational process leading to mutual learning among researchers and the collaborating individuals, communities and institutions; (2) Just as the propriety rights of scientific knowledge are well established and respected, such rights are due to the producers and providers of traditional knowledge and contemporary innovations from local communities; (3) Research should be based on respect for the local cultural values and norms; (4) Benefits should accrue to all partners in a fair and equitable manner; and (5) Informed consent should be obtained within limits of practicality.

3.1.2 Botanic Gardens

a. Royal Botanic Gardens, Kew: Principles on Access to Genetic Resources and Benefit-sharing for Participating Institutions

(i) Principles:

<http://www.rbgkew.org.uk/conservation/principles.html>

In furtherance of the CBD, The Convention on International Trade in Endangered Species of Wild Fauna and Flora, the Principles sets forth key elements relating to the acquisition, use, and supply of genetic resources; advocates the use of written agreements where required by law and in accordance with “best practices”; calls for the fair sharing of benefits not only with the source country, but also other stakeholders; addresses record maintenance; and calls on participating institutions to develop and implement policies to effectuate the Principles.

(ii) Participants:

<http://www.rbgkew.org.uk/conservation/endorsements.html>

b. Missouri Botanical Garden, Natural Products Research Policy [http://www.mobot.org/MOBOT/Research/applied\\_research/policy.shtml](http://www.mobot.org/MOBOT/Research/applied_research/policy.shtml)

Contains specific guidelines and requirements relating to contracting and benefit sharing, including that an appropriate percentage of the profits generated by any products developed will return to the source-country, that the source-country will have "first right of refusal" to develop an appropriate and sustainable supply of raw biological source materials necessary for the continued research development and/or eventual commercial production of any product, and that opportunities for research originating as a direct result of any program are shared in an equitable manner between the Missouri Botanical Garden (MBG) and collaborating source-country institutions. In addition, the Policy recognizes that the success of a research program aimed at the commercial development of a natural product depends upon the substantial intellectual contribution of all of the participants, and sets forth some guidelines on intellectual property treatment, including (i) patents for all inventions arising from collaborative research will be the responsibility of commercial partners, (ii) the MBG will only enter into commercial research agreements with a provision insuring that royalties will be paid to source-country in the event a discovery is marketed and generates profits, and (iii) in the event that a discovery is commercialized, MBG will use reasonable efforts to ensure that all royalties will be paid to an appropriate source-country organization, and the MBG will not receive any percentage of such royalties.

### 3.1.3 International Society of Ethnobiology (ISE), Code of Ethics

<http://guallart.dac.uga.edu/ISE/SocEth.html>

The purpose of this Code of Ethics is: to optimize the outcomes and reduce as much as possible the adverse effects of research (in all its forms, including applied research and development work) and related activities of ethnobiologists that can disrupt or disenfranchise indigenous peoples, traditional societies and local communities from their customary and chosen lifestyles; and to provide a set of principles to govern the conduct of ethnobiologists and all members of the International Society of Ethnobiology (ISE) engaged in or proposing to be engaged in research in all its forms, especially collation and use of traditional knowledge or collections of flora, fauna, or any other element found on community lands or territories.

### 3.1.4 Society for Economic Botany, Professional Ethics in Economic Botany: A Preliminary Draft of Guidelines

<http://users.ox.ac.uk/~wgtrr/seb.htm>

Addresses ethical issues faced by economic botanists, related both to their data collection needs and methods, and to the dissemination and use of their findings. This document presents guidelines for professional behavior for members of the Society for Economic Botany and outlines responsibilities to the public, those studied, host governments and institutions, the profession, and sponsors. For example, it requires members to communicate clearly and honestly to all informants, the objectives and possible consequences of ones' research. Several provisions apply to bioprospecting: If the research has a commercial objective, the member must make that explicit and disclose what the commercial results might reasonably be expected to be. In addition, the member will respect any request for confidence made by those providing data or materials, provided that the maintenance of such confidence does not compromise other ethical considerations. When materials or information obtained from informants can reasonably be expected to have commercial payoff, the member should arrange with employers for

equitable economic compensation for the individual(s) and will do all in their power to ensure that compensation is paid.

### 3.1.5 American Anthropological Association, Code of Ethics

<http://www.aaanet.org/committees/ethics/ethcode.htm>

The Code of Ethics addresses in some detail issues around informed consent, among other topics. It provides that anthropological researchers should obtain in advance the informed consent of persons being studied, providing information, owning or controlling access to material being studied, or otherwise identified as having interests which might be impacted by the research. It is understood that the degree and breadth of informed consent required will depend on the nature of the project and may be affected by requirements of other codes, laws, and ethics of the country or community in which the research is pursued. Further, it is understood that the informed consent process is dynamic and continuous; the process should be initiated in the project design and continue through implementation by way of dialogue and negotiation with those studied. Researchers are responsible for identifying and complying with the various informed consent codes, laws and regulations affecting their projects. Informed consent, for the purposes of this code, does not necessarily imply or require a particular written or signed form. It is the quality of the consent, not the format, that is relevant.

### 3.1.6 American Folklore Society, Statement of the American Folklore Society On Research with Human Subjects

<http://www.afsnet.org/aboutAFS/humansubjects.cfm>

In addition to an admonition against exploiting individual informants for personal gain, the AFS States calls for a fair return to informants for all services. There is also an obligation to reflect on the foreseeable repercussions of research and publication on the general population being studied. As part of obtaining informed consent, the anticipated consequences of the research should be communicated as fully as possible to the individuals and groups likely to be affected. Unlike several other professional codes of ethics which mandate or at least privilege written agreements, the AFS Statement posits that written agreements are inconsistent with building trust: “The nature of the relationships that folklorists build with their consultants, however, is such that a written, signed, legally effective document would be inimical to the relationship upon which folklore research is based. Folklorists cannot go as guests into people's home communities, build trust and friendships, and then present a legal document for signature. Nor can they ask for signatures to be witnessed. Informed consent is given orally, and possibly can be recorded on audio- or videotape, but introducing a written legal document into the folklorist-consultant relationship would generally prove an insult to the consultant and bring folklore research to a halt. Institutional review boards should alter or waive the requirements for written informed consent in the case of folklore and other forms of ethnographically based research.”

## 3.2 International Governmental Organizations

### 3.2.1 Bonn Guidelines

<http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp>

<http://www.biodiv.org/decisions/default.aspx?m=cop-06&d=24&print=1>

The Bonn guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization were recognized as a useful first step of an evolutionary process in the implementation of relevant provisions of the Convention related to access to genetic resources and benefit-sharing. These voluntary guidelines are meant to assist Parties, Governments and other stakeholders when establishing legislative, administrative or policy measures on access and benefit-sharing and/or when negotiating contractual arrangements for access and benefit-sharing.

### 3.2.2 The International Code of Conduct for Plant Germplasm Collecting and Transfer

<http://www.fao.org/ag/agp/agps/pgr/icc/icce.htm>

The International Code of Conduct for Plant Germplasm Collecting and Transfer is a voluntary code developed by FAO and negotiated by its Member Nations. The Code aims to promote the rational collection and sustainable use of genetic resources, to prevent genetic erosion, and to protect the interests of both donors and collectors of germplasm. The Code is based on the principle of national sovereignty over plant genetic resources. The Code proposes procedures to request and/or to issue licenses for collecting missions, provides guidelines for collectors themselves, and extends responsibilities and obligations to the sponsors of missions, the curators of genebanks, and the users of genetic material. It calls for the participation of farmers and local institutions in collecting missions and proposes that users of germplasm share the benefits derived from the use of plant genetic resources with the host country and its farmers.

### 3.2.3 The Manila Declaration Concerning The Ethical Utilisation of Asian Biological Resources.

<http://sunsite.wits.ac.za/iupac/reports/1996/6812andrews/manila.html>

Developed at the Seventh Asian Symposium on Medicinal Plants, Spices, and other Natural Products (ASOMPS VII) which was held in Manila, Philippines from 2 to 7 February 1992 and was attended by 283 scientists from 31 countries. This Declaration contains an appendix containing a code of ethics for foreign biological sample collectors and one with bioprospecting contract guidelines.

### 3.2.4 The Melaka Accord. This Accord carries the Manila Declaration forward by calling for specific legislative steps at the national and regional levels.

<http://sunsite.wits.ac.za/iupac/reports/1996/6812andrews/melaka.html>

## 3.3 State Governmental Guidelines

### 3.3.1 US International Cooperative Biodiversity Groups (ICBGs)

<http://www.fic.nih.gov/textonly/programs/icbg.html#Introduction>

This links to the general information page at the Fogarty International Center, which administers the International Cooperative Biodiversity Groups (ICBG) Program. This program provides funding for investigating the relations between drug discovery, biodiversity conservation, and sustainable economic growth. Funding for this program has been provided by six components of the National Institutes of Health (NIH), the Biological Sciences Directorate of the National Science Foundation (NSF) and the Foreign Agriculture Service of the USDA. The cooperating NIH components are the Fogarty International Center (FIC), National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA) and the National Heart, Lung, and Blood Institute (NHLBI).

The main premise of the ICBG's is that "efforts to examine the medicinal potential of the earth's plants, animals and microorganisms are urgently needed, since enduring habitat destruction and the resulting diminishment of biodiversity will make it increasingly difficult to do so in the future. 40-50% of currently used drugs have an origin in natural products." The ICBG program is designed to guide natural products drug discovery in such a way that local communities and other source country organizations can derive direct benefits from their diverse biological resources. Benefit-sharing may provide clear incentives for preservation and sustainable use of that biodiversity.

### 3.3.2 Resources on Access, Intellectual Property and Benefit-Sharing Relevant to the ICBG Program

#### a. ICBG Resources

<http://www.fic.nih.gov/textonly/programs/icbgresources.html>

This page links to several useful documents on the web addressing intellectual property, access and benefit sharing, primarily in the Conventional on Biodiversity context, as well as academic articles.

#### b. Request for Applications for ICBG Funding

<http://grants1.nih.gov/grants/guide/rfa-files/RFA-TW-03-004.html>

This links to the most current request for applications (RFA) to the ICBG program. The RFA contains specific requirements and guidance on genetic resource access, benefit sharing, intellectual property ownership, biodiversity conservation, and economic development.

### 3.3.3 Belgian Co-ordinated Collections of Micro-organisms as co-ordinator (BCCM): Micro-Organisms Sustainable Use and Access Regulation (MOSAICC).

<http://www.belspo.be/bccm/mosaicc/>

<http://www.belspo.be/bccm/mosaicc/docs/code.pdf>

MOSAICC is a voluntary Code of Conduct. It is developed to facilitate access to microbial genetic resources (MGRs) and to help partners to make appropriate agreements when transferring MGRs, in the framework of the Convention on Biological Diversity (CBD)



and other applicable rules of international and national laws. MOSAICC is a tool to support the implementation of the CBD at the microbial level; it can also serve as a model when dealing with genetic resources other than MGRs.

### 3.3.4 Australia

#### a. Commonwealth Public Inquiry into Access to Biological Resources in Commonwealth Areas

<http://www.deh.gov.au/biodiversity/science/access/inquiry/index.html>

The Inquiry's proposed scheme provides for an access permit and a benefit-sharing contract. Under the scheme, a party seeking access to biological resources in Commonwealth areas is required to apply for an access permit. Appropriate governmental agencies would review the request, and make a recommendation to the Minister for the Environment and Heritage to grant or refuse the permit. While the assessment is underway, the applicant would be required to negotiate, with the holder (or owner) of the biological resources, a benefit-sharing contract which covers the commercial and other aspects of the agreement. The contract would be based on a model contract developed and agreed by Governments, industry, Indigenous organisations and other stakeholders. The contract would only have effect if the Minister issues an access permit.

#### b. National Principles of Intellectual Property Management for Publicly Funded Research

<http://www.nhmrc.gov.au/research/general/ipman.pdf>

The purpose of developing the National Principles of IP Management for Publicly Funded Research is to assist researchers, research managers and their research institutions, in ensuring that they have access to best practices for the identification, protection and management of IP, and therefore, to maximise the national benefits and returns from public investment in research. The intention of the National Principles is simply to improve the commercial outcomes from publicly funded research where a commercial outcome is appropriate. The National Principles are expected to evolve over time in the light of the experiences of the funding agencies, research institutions and researchers. Organisations may wish to develop their own detailed IP management strategies within the framework of these principles to best suit their particular environments and needs. The NHMRC recognizes that further consideration needs to be given to intellectual property issues in health and medical research involving indigenous people and communities, and

#### c. Bioprospecting and Indigenous Knowledge in Australia: Valuing Indigenous Spiritual Knowledge and its Implications for Integrated Legal Regimes; By John Hunter & Chris Jones

<http://ls.wustl.edu/centeris/Confpapers/Hunter-Jones%20final%20draft.htm>

This paper discusses issues associated with the capacity of western law in understanding and protecting indigenous knowledge related to the bioprospecting of indigenous medical knowledge in an Australian context. More specifically the focus is upon indigenous spiritual knowledge. It is suggested that central to this project is the right of indigenous peoples in self-determination, self-identification and the right of verifying the authenticity of representations about such knowledge.

### 3.3.5 New Zealand, Ministry of Economic Development: Proposed Principles and Policy Objectives for Bioprospecting.

<http://www.med.govt.nz/ers/nat-res/bioprospecting/discussion/bioprospecting-06.html#TopOfPage>

This government document discusses policy and legal issues relating to bioprospecting in the context of New Zealand's economic development, while safeguarding associated environmental, social and cultural values, by: establishing clear rules about access to biological resources; ensuring bioprospecting policy recognizes the principles of the Treaty of Waitangi; establishing mechanisms to facilitate the capture of benefits from bioprospecting activities; and gathering information on bioprospecting activities to ensure New Zealand can track the use of its biological resources.

## 3.4 Non-Governmental Organization Guidelines

### 3.4.1 Program for Traditional Resource Rights (PTRR)

<http://users.ox.ac.uk/~wgtrr/>

The Program for Traditional Resource Rights is dedicated to furthering the rights of all 'indigenous and local communities embodying traditional lifestyles' (as identified in the Preamble to the Convention on Biological Diversity). By acting as a base for information, research and publicity the Program aims to extend to Indigenous peoples and local communities knowledge of appropriate mechanisms for protecting the integrity of their knowledge and resources. The Program is a self-funded network affiliated with - and based at - the Oxford Center for the Environment, Ethics and Society (OCEES), Mansfield College, University of Oxford.

- a. Guidelines for Equitable Partnerships in New Natural Products Development; Recommendations for a Code of Practice  
By Dr Anthony B. Cunningham

<http://users.ox.ac.uk/~wgtrr/cunning.htm>

These Recommendations start from the premise that governments must accept responsibility for establishing or implementing national policies for the conservation and use of biological diversity, and proceeds by setting forth guidelines

relating to licensing access, collecting responsibilities and procedures, responsibilities of sponsoring organizations, intellectual property and national development, and monitoring support.

- b. The Global Coalition for Biocultural Diversity Covenant on Intellectual, Cultural and Scientific Resources: A basic code of ethics and conduct for equitable partnerships between responsible corporations, scientists or institutions, and indigenous groups

<http://users.ox.ac.uk/~wgtrr/gbcd.htm>

This Covenant is proposed as a model that can be tried in many parts of the world by many partners to “produce a new category that will replace IPR with a more powerful and decisive concept that, ideally, will catalyze the replacement of markets for temporary gain with trade based upon long term commitments that result in mutual advantages--turning businesses from being vanguards of destruction into equitable partners with local communities in the conservation of biological and cultural diversity”. According to the Covenant, the first concern of indigenous peoples is their right not to sell, commoditize or have expropriated from them certain domains of knowledge and certain sacred places, plants, animals and objects. All other elements of the Covenant are preconditioned by this basic right, which is considered a fundamental element of self-determination. Several of the basic principles focus on equity, non-exclusivity, confidentiality, economic diversification, and judicial recognition and registration of this agreement, followed by appropriate legal protection to enable the indigenous group to protect its knowledge and biogenetic resources.

- c. Suggested Ethical Guidelines for Accessing and Exploring Biodiversity By Professor Anil K. Gupta; Based on a Pew Conservation Scholars Initiative to develop ethical guidelines to access Biological Diversity

<http://users.ox.ac.uk/~wgtrr/gupta.htm>

### **3.5 Private Companies and Industry groups**

#### 3.5.1 Bristol-Myers Squibb Company

<http://www.bms.com/static/ehs/perfor/data/humanr.html#bioprospect>

#### 3.5.2 BIO "Biotechnology's Foreign Policy", Carl B. Feldbaum, President Biotechnology Industry Organization June 10, 2002

<http://www.bio.org/news/speeches/20020610.asp>

BIO is developing a set of principles for its members, most of whom are inexperienced in negotiating for access to biological resources in developing countries and especially with local authorities. The principles would include provisions for informed-consent and benefit-sharing. First and foremost that BIO member companies must respect the laws of nations and cultures of localities where they perform research.

### 3.6 Practical Pointers for Industry:

- Ethical codes and institutional guidelines occasionally impose legal obligations on certain groups and individuals, but more commonly are set forth as aspirational principles and “best practices” for the applicable members of the organizations to which they are intended to apply.
- Typical issues addressed in bioprospecting codes and guidelines include informed consent, confidentiality, benefit sharing, conservation, intellectual property ownership, and permissible use.
- There are, as can be seen above, variations—for example whether written or verbal agreements are considered best practice.
- As part of any bioprospecting negotiation, all parties should research applicable codes and guidelines, in addition to applicable laws and local customs and make an informed assessment of the role such codes and guidelines might serve.
- Organizations and institutions that have not adopted ethical codes and guidelines relating to bioprospecting and biodiversity research might consider initiating a process to develop them. A discussion of process issues for developing such codes and guidelines is discussed in the book *Biodiversity and Traditional Knowledge*, Sarah A Laird (ed), chapters 2 and 3 (Earthscan, 2002). It is important to consider both process and substance as integral elements of ethical codes and guidelines for bioprospecting.

## 4. Negotiation Issues

The more parties that are involved in a negotiation, and the greater the cultural differences of those parties, the more important it is to focus at the outset on the *process* of negotiation. The complexity of multiparty negotiation is significantly compounded by geographic and cultural differences. The articles and materials below discuss a range of issues including: handling multiparty negotiations effectively, addressing cultural differences in negotiations and conflict, the potential role of “third party neutral” facilitators or mediators, so-called “best practices” of obtaining prior informed consent, and culturally influenced negotiation styles.

### 4.1 Interest-based Negotiation

<http://www.colorado.edu/conflict/peace/example/fish7513.htm>

Summary by Tanya Glaser of “Getting to Yes: Negotiating Agreement Without Giving In” by Roger Fisher and William Ury (New York: Penguin Books, 1983).

In this classic text, which advocates interest based, win-win, negotiation over positional, win-lose, negotiation Fisher and Ury describe four principles for effective negotiation: 1) separate the people from the problem; 2) focus on interests rather than positions; 3) generate a variety of options before settling on an agreement; and 4) insist that the agreement be based on objective criteria.

#### **4.2 Issues in multi-party complex negotiations**

<http://hbswk.hbs.edu/item.jhtml?id=3898&t=strategy>

“Making the Most of Multiparty Negotiations” by Lawrence Susskind”

This article discusses the challenges of multiparty negotiation and the steps that can be taken to properly prepare, working effectively in coalitions, and managing group interactions.

#### **4.3 Possible role of mediation/multi-party facilitation in the agreement process**

<http://www.triangleassociates.com/resource/artfac3.html>

“Reflections: Breaking the Patterns” by Alice Shorett

This article discusses the role of process rules in public policy disputes, and has useful pointers for any multiparty negotiation process, especially the potential role of neutral third party facilitators.

#### **4.4 Prior Informed Consent Processes**

Although “prior informed consent” is one of the principles of the Convention on Biological Diversity, the CBD provides little guidance on how PIC should be obtained. The following papers and articles discuss the challenges and considerations, along with recommendations, on obtaining prior informed consent in different cultural (and inter-cultural) settings. This is an area where, although “best practices” are being sought, the varying cultural contexts need to always be at the forefront of consideration. What is a “best practice” in one setting might be ineffective or inappropriate in others. However, a recurring theme is the to first focus on the process, and ensuring that it is an inclusive one.

##### **4.4.1 “Politics, culture and governance in the development of prior informed consent and negotiated agreements with indigenous communities”**

Joshua Rosenthal, Fogarty International Center, National Institutes of Health (September 4, 2003)

<http://ls.wustl.edu/centeris/Confpapers/PDFWrdDoc/PICFinal.html>

##### **4.4.2 “The Philippines: A Bridle on Bioprospecting?” by Oscar B. Zamora**

The Convention on Biological Diversity (CBD), now ratified by over 165 parties, reaffirms as international law that countries have national sovereignty over their biological diversity. Further, the Convention says

that access to genetic resources should be regulated by the parties along two principles: prior informed consent and mutually agreed terms. The CBD only lays down principles which individual countries have to translate into laws and regulations. The Philippines provides an example of how this might be done.

<http://www.grain.org/publications/jun972-en.cfm>

#### 4.4.3 “Developing a Regime to Protect Indigenous Traditional Biodiversity - Related Knowledge” by Henrietta Fourmile-Marrie

Traditional biodiversity-related knowledge of biological resources can provide leads to industry researchers, saving valuable time and money in the research and development process. But it is also important for the long term economic security and sustainable development that Indigenous communities in Australia secure a stake and participate in this and any other industries based on Australia's biological wealth and its management. Indeed, for many of Australia's Indigenous communities, their long-term sustainable economic development may also depend on their capacity to generate new intellectual property from their traditional knowledge; to create new products derived from their natural resources. Contractual means for protecting traditional knowledge, such as biodiversity contracts, non-disclosure clauses to protect certain kinds of information, and licensing agreements are important considerations.

<http://www.law.murdoch.edu.au/balayi/v1n1/fourmile.shtml>

#### 4.4.4 “Ethics and Practice in Ethnobiology and Prior Informed Consent with Indigenous Peoples, Regarding Genetic Resources” by Roger Chennells

Issues of intellectual property, prior informed consent, and benefit-sharing in the appropriation of indigenous knowledge are raised in the context of the San of Africa, and selected aspects of the benefit sharing agreement relating to Hoodia concluded on 24 March 2003, are discussed in the light of the general principles underlying the Biodiversity Convention.

<http://ls.wustl.edu/centeris/Confpapers/ChennelFinalApril2003.htm>

#### 4.4.5 CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY Fifth meeting Nairobi, 15-26 May 2000 UNEP/CBD/COP/5/1. REPORT OF THE PANEL OF EXPERTS ON ACCESS AND BENEFIT-SHARING

Identifies the following key principles in the development of prior informed consent procedures:

- (1) An applicant must supply sufficient information to allow for informed consent, including the best scientific and commercial information, and information regarding relevant social, cultural and environmental issues.
- (2) The provider must be allowed to request further particulars.
- (3) The information should be provided in a manner and language comprehensible to the provider.

(4) Consent should be construed strictly.

(5) Prior informed consent of indigenous and local communities is dependent on clear recognition and protection of their rights, knowledge and innovation and practices. For this reason the development of sui generis legislation may need to be considered.

<http://www.biodiv.org/doc/meetings/cop/cop-05/official/cop-05-08-en.pdf>

## 4.5 Cross-cultural Communication Issues

### 4.5.1 “Mapping Cultures: Strategies for effective intercultural negotiations” by Chris Moore and Peter Woodrow

“Few 'maps' exist to describe how different cultures resolve conflict, often leading to misunderstanding and less than optimal agreements. This article offers a framework for understanding cultural differences and negotiating accordingly.”

[http://ccrweb.ccr.uct.ac.za/two/8\\_1/p04\\_mapping\\_cultures.html](http://ccrweb.ccr.uct.ac.za/two/8_1/p04_mapping_cultures.html)

### 4.5.2 Intercultural Conflict Management: A Mindful Approach

By Stella Ting-Toomey

After noting that intercultural miscommunication and misattributions often underscore intercultural conflict the author of this paper defines intercultural conflict as “the perceived or actual incompatibility of values, norms, processes, or goals between a minimum of two cultural parties over content, identity, relational, and procedural issues.” The author concludes by noting that “[w]hile the study of intercultural conflict is a complex phenomenon, understanding conflict along the individualism-collectivism continuum and the personal variation continuum (e.g., the independent and interdependent self across a spectrum) serves as the beginning step in understanding conflict variations among different clusters of cultures.”

<http://www.personal.anderson.ucla.edu/richard.goodman/c4web/Mindful.htm>

### 4.5.3 This web site describes the “Intercultural Conflict Style Inventory” (ICS), which is an assessment tool used in different settings to identify culturally-learned approaches for managing disputes in terms of direct or indirect strategies for resolving disagreements and emotionally expressive or restrained approaches for dealing with conflict. Combining these approaches results in four cross-cultural conflict styles: discussion, accommodation, engagement, and dynamic. Each of these styles has different implications for conflict resolution and communication in general.

[http://hammerconsulting.org/ics\\_inventory.html](http://hammerconsulting.org/ics_inventory.html)

## 4.6 Practical Pointers

- Think about, discuss, and agree on the process of negotiation early, before focusing on the substance.
- Ensure and facilitate effective inclusion of all relevant “stakeholders” throughout the process.

- Aim for a process that surfaces underlying interests, and consider, where culturally appropriate, interest based over positional negotiation.
- Consider face to face meetings whenever possible.
- Research, appreciate, and address cultural differences—which might relate to communication styles on the one hand, and difference in values on the other, and often both.
- Minimize assumptions, maximize discussion.
- Research and learn from prior “case studies” regarding bioprospecting negotiation and especially prior informed consent.
- Take “best practices” into account.

## **5. Bioprospecting/Access and Benefit-Sharing Case Studies**

NOTE: In all of the examples below, there is quite a body of literature on-line detailing all sides of the bioprospecting debate. For instance, Diversa has been in the news numerous times because of its landmark bioprospecting agreements with several organizations (Yellowstone, INBio, etc.). But, depending on the point of view of the reporter (or news organization) concerning bioprospecting, the bioprospecting activities of Diversa have been cast in either a positive or negative light. Because some viewpoints hold that ethical bioprospecting, with a level playing field for all parties involved in any benefit-sharing agreement, is impossible to achieve, the reports some news organizations produce inevitably conclude that any company’s bioprospecting activities are inherently inequitable toward indigenous and traditional communities.

### **5.1 Companies Engaged in Equitable Bioprospecting**

#### **5.1.1 Aveda**

<http://www.aveda.com>

Long committed to business partnerships with indigenous peoples, the Aveda Corporation has gained the reputation of working to support indigenous rights, sustainable development, and biodiversity conservation. Aveda has long depended upon indigenous communities for sourcing the ingredients used in the company’s line of cosmetics, beauty and skin care products. Aveda has recently shown its sensitivity towards indigenous intellectual property rights: the company recently abandoned its Indigenous<sup>TM</sup> trademark and beauty products line once it learned of the response by indigenous groups to the company’s use of the term to market products. (Ironically, Aveda says it originally adopted the Indigenous term in order to draw attention and raise awareness of values and wisdom held by indigenous peoples See Press Release at <http://www.aveda.com/about/press/indigenous.asp>).

#### **5.1.2 Diversa**

<http://www.diversa.com>

Diversa Corporation uses genomic technologies to discover and produce novel compounds, particularly commercially valuable molecules with applications in the pharmaceutical industry, as well as enzymes and small molecules with the potential for



agricultural, chemical, or industrial applications. For example, Diversa has signed agreements for bioprospecting in micro-organisms in several countries including Costa Rica, Bermuda, Indonesia and Mexico, as well as a bioprospecting agreement with Yellowstone to research a commercially promising class of microorganisms known as thermophiles. However, Diversa's bioprospecting activities have attracted controversy; for example, a lawsuit was filed in response to the Yellowstone-Diversa bioprospecting agreement (see <http://www.icta.org/legal/yellow.htm>) although eventually it was resolved at least in part. See also [http://www.diversa.com/presrele/2000/view\\_release.asp?id=20000419](http://www.diversa.com/presrele/2000/view_release.asp?id=20000419), as well as the notation on Yellowstone National Park below on this webpage.

### **5.1.3 InBIO (Instituto Nacional de Biodiversidad)**

<http://www.inbio.ac.cr/es/default.html>

Established in 1989, InBIO was established to research the biological diversity of Costa Rica for its commercial potential in an ecologically sustainable manner. InBIO has been in the news numerous times (both positive and controversial accounts) for its innovative bioprospecting partnerships with pharmaceutical corporations and other companies. While some see InBIO as an innovative, enterprising research company, representing the best of all worlds in ethical bioprospecting, critics of bioprospecting in general are suspicious of InBIO's activities and are quick to report negatively on any new research the organization undertakes (see <http://www.grain.org> for examples). InBIO has been both hailed and derided for its goals of commercializing biological resources combined with sustainable development and conservation.

### **5.1.4 Yellowstone National Park – Park Issues: Bioprospecting and Benefit-Sharing**

**Chapter 9 from *Yellowstone Resources and Issues 2004***

<http://www.nps.gov/yell/publications/pdfs/handbook/ch9.pdf>

This chapter reviews what thermophiles are and the making of the historic Yellowstone-Diversa bioprospecting agreement (CREDA) in 1997, including also the controversy and lawsuit that followed. It reports that while the agreement between Yellowstone and Diversa was upheld in the district court in 2000, the earlier court suspension on the agreement will remain in place until Yellowstone completes an Environmental Impact Study (EIS) – the result of which possibly being precedent-setting for all national parks interested in entering into bioprospecting activities with outside companies in the future.

### **5.1.5 Pharmaceutical Companies Partnered with International Cooperative Biodiversity Groups (ICBGs)**

<http://www.fic.nih.gov/programs/icbg.html#Continuing%20ICBGs>

This site profiles each of the continuing ICBG programs currently in operation, in countries as diverse as Papua New Guinea, Vietnam, Laos, Panama, Madagascar, Uzbekistan, Kyrgyzstan, Nigeria, Cameroon, Argentina, Chile and Mexico. Within these ICBGs, several companies are research partners and parties to the benefit-sharing agreements drafted by each ICBG to ensure equitable sharing of any benefits resulting

from research (e.g., Wyeth, Bristol-Myers Squibb, Diversa, Novartis, Dow Agrosciences, and Phytomedics, Inc.). While none of these companies, on their own websites, specifically highlight their participation in the ICBG Program, many of the companies listed do feature web pages citing their commitment to sustainable development, human rights, providing access to affordable health care and other global concerns.

### 5.1.6 The Body Shop

<http://www.thebodyshop.com/web/tbsgl/values.jsp>

The Body Shop has long had the reputation of providing a fair and equitable market for small communities and indigenous groups worldwide, since The Body Shop uses natural, sustainably grown ingredients as source ingredients in their cosmetics, hair, skin and beauty care product lines. The Body Shop also lists a variety of other causes they support, either directly or indirectly, on their website. While some investigative reports by journalists in the early 1990s attempted to show that The Body Shop is not as committed as it purports to be to the small communities from which it sources its raw materials, The Body Shop has withstood the test of time and is doing well as a business today, grounded in the same principles upon which it was founded in the 1970s. (Much of the criticism towards The Body Shop seems to have been directed at its using a “green consumer” message to promote sales and to distinguish itself from other businesses, while at the same time expanding rapidly worldwide, not unlike Starbucks or any other typically “self-interested” corporation on the market. This criticism may have stemmed just as much from sentiments that The Body Shop’s primary customers are relatively affluent individuals (living in the developed world) who believe they are making a big difference in the world by simply buying The Body Shops’ beauty products).

## 5.2 Case Studies on Biodiversity

<http://www.biodiv.org/doc/case-studies/default.aspx>

This webpage, through the Convention on Biological Diversity website, lists a number of case studies that provide models for designing access to genetic resources and benefit-sharing schemes. Several of the publications outline the progress of the ICBGs, highlight various partner-companies (such as pharmaceutical and agribusiness corporations), including one early publication reporting on the “new” Yellowstone-Diversa Agreement in 1997. While many of the reports are at least few years old, together they provide a chronology of thought, reflections, and recommendations for the rapidly-evolving set of issues connected to access and benefit-sharing, and for which there are no “one-size fits all” or simple answers.

## 5.3 SUMMARY/POINTS TO CONSIDER:

- For every positive report about a company’s bioprospecting activities on-line, it is highly likely that there will be negative report about the very same activity. These reports, both positive and negative, must be taken in view of the larger, ongoing debate on bioprospecting – realizing that there are rigid viewpoints on both sides that will use any example of a company’s bioprospecting activity to support *any* viewpoint about bioprospecting. Therefore, it is up to you, the

reader, to critically assess both the report itself of any bioprospecting activity as well as the source of the report itself. An website with an activist (or corporate) agenda, for example, may be more likely to have a strongly biased viewpoint on bioprospecting (either positively or negatively) than would a website that simply reports the news in a balanced fashion.

- Whether a company's bioprospecting activities are ethical and sufficiently concerned about the issues of access to genetic resources and benefit-sharing for all involved can only be assessed by critically evaluating the kinds of benefits being provided, and by being realistic in what kinds of benefit-sharing schemes any company can set up. For example, some critics of bioprospecting cite the unfairness of, say, a royalty rate of only 3% going to a community that was involved in identifying leads for a new drug or botanical supplement – but without mentioning that a royalty rate of 3% is actually a typical rate of return for any inventor who agrees to a company “developing” their idea into a finished product (the usual royalty rate is anywhere between 1% and 5%, depending on the terms of the agreement). For royalty rates to be any higher usually implies that the cost and responsibilities for developing the final product are correspondingly shared by the parties as well (for example, the case of the Sarawak Government and a national pharmaceutical company, both assuming the costs of developing a new anti-AIDS drug, but then also expecting to split the royalties from any new anti-AIDS drug 50-50).
- Because the idea of ethical bioprospecting is a relatively new one, and is viewed as a way to redress decades (if not centuries) of legal wrongs, there are many who are downright suspicious that ethical bioprospecting can actually work – and there are many who believe that it is simply one more way that a company claims (falsely) it acting responsibility as a corporation. The only way we will be able to know whether or not this new paradigm for bioprospecting will work, and even enter the mainstream of corporate business practices, will be to watch for and critically evaluate the kinds of benefit-sharing arrangements that companies create over time – and to allow time to pass before fully judging whether or not a specific benefit-sharing scheme actually works. Hopefully in another 5 to 10 years there will be that many more access and benefit-sharing arrangements in place between companies and traditional communities that can be evaluated for their ability to support ethical and equitable bioprospecting research activities.
- The kinds of benefits that are provided by a company to the other parties (usually the “source” or “host” communities, groups or countries) are often tailored to what the other party has negotiated for, and do not always take the form of benefits that someone outside of the arrangement would expect to see as a benefit. In many of the ICBG (drug discovery) benefit-sharing agreements, for example, short-term and medium-term benefits are included as part of the benefit-sharing scheme with the host countries, institutes and communities because it is understood that the long-term benefits outlined in the agreements are not likely to be realized (because of the nature of drug discovery research in general). Other kinds of benefits, such as capacity-building, technology transfer, educational training, community outreach, community economic development, and other benefits are included in the benefit-sharing scheme, as well as the more “traditional” benefits (such as royalties and monies placed into trust funds).
- It is important to keep in mind that much of what companies are doing, when they attempt to implement access and benefit-sharing arrangements as recommended

by the Convention on Biological Diversity, is trying to translate these bioprospecting ideals to real-world bioprospecting research projects. It may turn out that some current ideas for benefit-sharing, while looking good on paper, may be practically and logistically more difficult to implement than currently understood and for reasons currently unforeseen. Part of the process of creating “best bioprospecting practices” worldwide will be the usual trial and error; hopefully the reports of “what works” in practice will guide future bioprospecting activities and keep other companies from making similar mistakes when drafting their own benefit-sharing arrangements. Until more time has passed and more benefit-sharing arrangements have been fully operationalized, we simply will not know which of these will meet with greater success and “win-win” for all parties involved.

## 6. Types of Access and Benefit Sharing Agreements

**6.1 Background:** There are numerous agreements that may be employed when bioprospecting activities are contemplated. These agreements serve various purposes, which include securing necessary governmental approvals, sharing benefits with the traditional communities or the national park where samples are collected, protecting intellectual property interests, and protecting the parties from legal liabilities. The basic agreements are:

*Collaboration/Partnership Agreements:* These agreements typically describe the total sum of activities that will be occurring, and are useful when a mutual understanding is needed concerning the roles and activities of each of the participating organizations and entities (including traditional communities and governments) that will be performing bioprospecting activities.

*Permits:* Permits are required by many governmental agencies prior to the collection of materials in territories within their jurisdiction.

*Licenses:* Once a potentially viable property is located, a license agreement is entered into between the owner of the intellectual property (“licensor”) and the entity that desires to use the intellectual property (“licensee”) to govern how the property is to be used and (when appropriate) to specify compensation to the owner for the use. Sometimes, license terms are embedded within other agreements, such as a collaboration agreement or a material transfer agreement, in anticipation of discovering viable properties.

*Material Transfer Agreements (“MTAs”):* Material Transfer Agreements are used when physical samples, such as biological or chemical compounds, are exchanged between two parties. Generally, MTAs are entered into to protect the intellectual property rights of the provider and to limit the liability of the provider with respect to the recipient’s activities, although MTAs may also contain license terms governing the recipient’s commercial use of the provided material.

*Research and Development Agreements:* These agreements related to the terms for funding, and performing, research projects and address the relationships between the party funding the research and the party(ies) performing the research.

## 6.2 Types of Agreements.

### 6.2.1 Sample Agreements (excluding governmental permits).

- (i) World Intellectual Property Organization: Traditional Knowledge and Cultural Expressions Contracts Database.  
<http://www.wipo.int/tk/en/databases/contracts/summaries/index.html>

This database contains many types of model agreements and actual agreements related to bioprospecting. It includes material transfer agreements, licensing agreements, benefit-sharing agreements, collaboration agreements and research agreements. The database collection is an ongoing effort so this database will continue to expand.

- (ii) National Institutes of Health, National Cancer Institute: Standard Forms and Agreements. <http://tbt.nci.nih.gov/forms.html>.

In recent years, the U.S. National Cancer Institute has become involved in the terms related to bioprospecting for materials used in its studies. Several standard agreements on this website relate to bioprospecting, including the Cooperative Research and Development Agreement (CRADA), which is used when U.S. government owned materials (whether an invention at NIH or plant samples collected in a National Park) are developed for commercialization, as well as material transfer agreements and a Letter of Collection to establish an understanding with a foreign country on how its materials will be used for NCI research.

- (iii) Outline of Issues to Address and Language to Consider in a Biodiversity Prospecting Agreement Chapter 10 and Appendix 10.1, from *Biodiversity and Traditional Knowledge: equitable partnerships in practice*, by Michael A. Gollin.  
<http://www.rbgekew.org.uk/peopleplants/manuals/biological/annexes2.htm>

This document contains an outline of the contract terms that should be considered for inclusion in agreements related to bioprospecting, and a sample agreement with detailed terms and language that covers most issues associated with collecting materials in a foreign country, including sharing commercialization revenue with the host country.

- (iv) Exploiting South Africa's Horticultural Potential: The National Botanical Institute and Ball Horticulture  
[http://www.biowatch.org.za/Benefit\\_sharing.doc](http://www.biowatch.org.za/Benefit_sharing.doc)

This paper discusses three case studies of bioprospecting in South Africa.

### 6.2.2 Sample Governmental Permits/Requirements.

- (i) Permits: Most countries and many local governmental entities have permits that must be obtained prior to the collection of materials from its territories. Many include questions concerning how the fruits of commercialization will be shared with the country and its citizens. The terms of collection permits vary widely. A few sample permits requiring explanations of benefit-sharing include:
  - (a) Parks and Wildlife Commission of the Northern Territory, Australia: Application for a Permit to Undertake Scientific Research on Wildlife. <http://www.nt.gov.au/ipe/pwcnt>.
  - (b) Environmental Protection Agency, Guyana: Application for Scientific and/or Commercial Research on Biodiversity in the Co-Operative Republic of Guyana. <http://www.epaguyana.org/downloads/ApplicationBiodiversityResearchGuyana.pdf>
  - (c) U.S. National Parks Service: Benefit Sharing Agreements. [www.nature.nps.gov/benefitssharing/contents.htm](http://www.nature.nps.gov/benefitssharing/contents.htm) (includes sections discussing legal authorities and a FAQ).
- (ii) Governmental Requirements concerning Protection of Biotechnological Inventions.

World Intellectual Property Organization: Information Provided by WIPO Member States concerning Practices Related to the Protection of Biotechnological Inventions, April 30 to May 3, 2001.

[http://www.wipo.int/documents/en/meetings/2001/igc/pdf/grtkfic1\\_6.pdf](http://www.wipo.int/documents/en/meetings/2001/igc/pdf/grtkfic1_6.pdf)

As part of ongoing research, WIPO conducted a survey of member states with a variety of questions related the scope of patent protection available in the state over animals, plants, and micro-organisms. This survey is useful for understanding the legal limits of intellectual property ownership in various countries which, in turn, limit the terms of agreements entered into for bioprospecting in the states' territories.

### 6.2.3 Articles concerning the structure/types of Bioprospecting Agreements.

- (i) Gollin, M.A., "Elements of commercial biodiversity prospecting agreements," chapter 10 in *Biodiversity and Traditional*

*Knowledge: Equitable Partnerships in Practice*, edited by Sarah Laird. (Earthscan 2002).

This is a useful summary of the various types of agreements and when they should be used. It is a practical guide with clear explanations and several case studies. It compares biodiversity prospecting contracts to other types of contractual arrangements, and provides the core elements of biodiversity prospecting contracts. Examples of language from a range of negotiated contracts are provided to indicate current options agreed upon, in an annex available on the web.

- (ii) Gollin, M.A., "Outline of issues to address and language to consider in a biodiversity prospecting agreement," annex 10.1 in *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*, edited by Sarah Laird. (Earthscan 2002), See [file://www.rbgekew.org.uk/peopleplants/manuals/biological/annexes2.htm](http://www.rbgekew.org.uk/peopleplants/manuals/biological/annexes2.htm); Available at: [www.rbgekew.org.uk/peopleplants/manuals/biological/annexes2.htm](http://www.rbgekew.org.uk/peopleplants/manuals/biological/annexes2.htm)
- (iii) The WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) compiled an on-line, searchable database of biodiversity-related Access and Benefit-Sharing Agreements, Available at <http://www.wipo.int/tk/en/databases/contracts/summaries/index.html>
- (iv) *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*, Chapter 10, edited by Sarah Laird

This is a useful summary of the various types of agreements and when they should be used. Practical guide with clear explanations and several case studies.

- (v) The Global Biodiversity Institute/International Institute of Tropical Agriculture: Training Course on Biodiversity, Biotechnology, and Law. <http://www.aaas.org/international/africa/gbdi/GBDI-Ibadan.pdf>

Module II of this training course, developed for teaching in West Africa in March 2000, discusses "The Fundamentals of Bioprospecting Negotiations", which includes a description of the various types/purposes of agreements, issues to consider during the drafting and negotiation of agreements.

- (vi) *Bioprospecting in Practice: A Case Study of the Suriname ICBG Project and Benefits Sharing under the Convention on Biological Diversity*. <http://www.biodiv.org/doc/case-studies/abs/cs-abs-sr.pdf>

This article dissects one particular negotiation, identifying the various parties, the expectations and needs of the parties, and the content/implementation of the resulting agreement.

## 7. Important Contractual Terms to Consider

This section contains resources on and examples of typical terms that have been included and should be considered in bioprospecting/ABS agreements. Included with each of the listed sub-sections are links to information that define the terms, provide an analysis or discussion of the terms, or include actual agreement language. Most online resources discuss bioprospecting agreements in their entirety so the listed resources are likely to provide information on many of the listed subsections.

The contractual terms can be considered to fall into the following main categories:

- Access and collection – materials, traditional knowledge, scientific information, etc.
- Type of relationship – exclusive vs. nonexclusive, number of parties involved, the roles and responsibilities of each of the involved, etc.
- Commercialization – steps to be made towards commercialization and limitations.
- Financial benefits – royalties and fees, payments from and to whom, products on which payments will be made, etc.
- Non-financial benefits – conservation, training, education, etc.
- Intellectual property – what rights are attainable, who will secure those rights, who will own those rights, and what rights are retained.

### 7.1 Role and responsibilities

In any commercial agreement there are key roles and responsibilities to consider in bioprospecting/ABS agreements. These roles and responsibilities range from who will identify and collect samples to who will commercialize any promising products.

#### 7.1.1 Guidelines for Equitable Partnerships in New Natural Products Development

**Recommendations for a Code of Practice (Conclusions of the Workshop on Drug Development, Biological Diversity and Economic Growth, National Cancer Institute of the US National Institutes of Health, Bethesda, Maryland, 1991)**

<http://users.ox.ac.uk/~wgtr/cunning.htm>

Compiled by Dr. Anthony Cunningham, these Guidelines list a Code of Practice, or ethical protocols for researchers, sponsoring organizations, governments and other parties involved in the natural product development process. The Code includes procedures covering collection, licensing, intellectual property concerns, and evaluation and monitoring of biodiversity.



### **7.1.2 The Conservation Finance Guide on Bioprospecting – a joint project of the Conservation Finance Alliance**

<http://guide.conservationfinance.org/chapter/index.cfm?Page=5>

Discusses the design of bioprospecting agreements and provides a worksheet to help set out the various terms and responsibilities involved in those agreements.

## **7.2 Common Features**

### **7.2.1 IUPAC - “General features of contracts for natural product collaborations”**

<http://sunsite.wits.ac.za/iupac/reports/1996/6812andrews2/index.html>

This technical report by IUPAC provides a summary of agreement features and discusses sample terms.

### **7.2.2 IUPAC – “General features of contracts for natural product collaborations”**

<http://sunsite.wits.ac.za/iupac/reports/1996/6812andrews2/agreement.html>

This technical report by IUPAC provides an agreement template to show what is included in a typical collaborative agreement, including rights, responsibilities, and benefit-sharing provisions.

### **7.2.3 WIPO - Traditional Knowledge and Cultural Expressions – Contracts Database**

<http://www.wipo.int/tk/en/databases/contracts/summaries/index.html>

This database provides on-line several examples of model agreements, as well as actual agreements, employed to protect the intellectual property concerns of the parties involved in collaborative arrangements. Each of the contracts provides an example of agreed upon roles and responsibilities for each of the involved parties. The WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore has worked over the past several years to bring greater attention to the issue of intellectual property rights protections for communally-held knowledge, resources, expressive cultural forms, and other forms of cultural property not protected by conventional (Western) intellectual property law systems.

### **7.2.4 Global Biodiversity Institute/International Institute for Tropical Agriculture Biodiversity, Biotechnology, and Law Training Course for West Africa Module II: The Fundamentals for Bioprospecting Negotiations**

<http://www.aaas.org/international/africa/gbdi/mod2a.html>

A course primarily designed those in developing countries, this module provides an overview of the issues that need to be addressed in establishing a contractual agreement

for benefit sharing. Bioprospecting activities, the kinds of agreements commonly used to ensure benefit-sharing, points for negotiation, discussion topics and the general principles underlying the construction of a contractual benefit-sharing agreement are also outlined.

### **7.3 Access to materials (genetic/biological)**

#### **7.3.1 Andean Pact: Common System on Access to Genetic Resources**

<http://users.ox.ac.uk/~wgtrr/andpact.htm>

Outlines for all member signatory countries of the Cartagena Protocol the objectives, aims, scope, principles and procedure for governing access to genetic resources in keeping with the provisions of the Convention on Biological Diversity. Unofficial UN translation from Spanish to English.

#### **7.3.2 Micro-Organisms Sustainable Use and Access Regulation: International Code of Conduct (MOSAICC)**

<http://www.belspo.be/bccm/mosaicc/docs/code.pdf>

From the Belgian Co-ordinated Collections of Micro-organisms (BCCM), penned by Philippe Desmeth at MOSAICC. Lists terms of agreement and model documents, including a model Material Transfer Agreement and a Prior Informed Consent application form in Section II.

#### **7.3.3 Commonwealth Public Inquiry into Access to Biological Resources in Commonwealth Areas**

<http://www.deh.gov.au/biodiversity/science/access/inquiry/index.html>

Extensive document discussing proposed scheme for regulating and monitoring access to biological resources in Australia. The inquiry report concludes that there is no mechanism in place for access to genetic resources that is consistent nationally, and provides recommendations for future legislation to correct this.

#### **7.3.4 The Model Law Of The Organization Of African Unity On Community Rights And On The Control Of Access To Biological Resources (Third World Network)**

<http://www.twinside.org.sg/title/oau-cn.htm>

A Model Law created to guide African nations in drafting and passing legislation concerning access to genetic resources.

#### **7.3.5 Status and Trends in Access to Genetic Resources and Traditional Knowledge in Sri Lanka**

<http://www.biodiversityasia.org/books/abs/Chapter%2013.pdf>

This paper reviews recent conservation and sustainable use legislation passed in Sri Lanka that is designed to protect genetic resources, while critically appraising its ability to fulfill the objectives of the Convention on Biological Diversity (CBD). Both the strengths and weaknesses of the new legislation are highlighted, with recommendations for increased stakeholder participation in the national access and benefit sharing process.

## 7.4 Collection process and documentation

### 7.4.1 The FAO Global System: The International Code of Conduct for Plant Germplasm Collecting and Transfer

<http://www.fao.org/ag/agp/agps/pgr/icc/icce.htm>

Provides guidelines (primarily to governments) for permit issuance, monitoring, and regulation of the collection and transfer of germplasm. The Code is based on the principle of the CBD that nations exercise sovereign rights over genetic resources and therefore have the right to implement and enforce rules that uphold this right. Also includes a list of terms; responsibilities of governments, collectors, sponsors, curators and users; and evaluation and monitoring the observance of the Code itself.

### 7.4.2 Manila Declaration (1992) Seventh Asian Symposium on Medicinal Plants, Spices and Other Natural Products (ASOMPS VII)

<http://nimura.tripod.com/manila.htm>

Recommendations are provided regarding research, collecting and harvesting of plants and natural products. Many of the tenets formulated here later influenced the Philippines Biodiversity legislation passed in 1997.

### 7.4.5 People and Plants Online – Collecting Programmes Exclusive and Non-Exclusive relationships

<http://www.rbgekew.org.uk/peopleplants/dp/dp2/issues.htm>

Provides a basic overview of the issues involved in conducting ethical ethnobotanical research, including intellectual property rights and the use of indigenous knowledge. Also includes a glossary of terms and recommendations for ethical collecting, documentation, benefit-sharing and protection of indigenous intellectual property and traditional knowledge.

## 7.5 Types of benefits: ABS agreements can provide for a range of benefits, including financial (fees, royalties), conservation, and capacity building.

### 7.5.1 International Conservation Union (IUCN) Sharing the Benefits from Genetic Resource Use (Biodiversity Brief 3)

[http://www.iucn.org/themes/wcpa/pubs/pdfs/biodiversity/biodiv\\_brf\\_03.pdf](http://www.iucn.org/themes/wcpa/pubs/pdfs/biodiversity/biodiv_brf_03.pdf)

This concise publication reviews the use of royalties and trust funds to generate and manage monetary benefits directed to communities participating in bioprospecting arrangements. Additionally, short-term and medium-term benefits to communities, as well as long-term benefits are discussed as equitable measures for communities' providing access to genetic resources.

**7.5.2 Implementing IPR and Benefit-Sharing Arrangements: Experiences in the University of Illinois at Chicago–Vietnam-Laos ICBG**

<http://www.uic.edu/pharmacy/research/icbg/Paper-Proceedings-JBASymposium.pdf>

This article describes the establishment of Trust Funds as well as a royalty-sharing scheme (under the Memorandum of Understanding) to govern benefit-sharing among all of the parties involved in the UIC-based-Vietnam-Laos ICBG. Also candidly explains the progress and obstacles in implementing short-term, medium-term and long-term benefits to the host countries and communities over the course of the ICBG project.

**7.5.3 Equitable Sharing of Biodiversity Benefits: Agreements on Genetic Resources**

<http://www.fic.nih.gov/programs/oecdub.html>

Authored by Joshua Rosenthal, this paper discusses all aspects of benefit-sharing arrangements, including: (1) the kinds of benefits that may be derived from bioprospecting agreements; (2) who should receive benefits; and (3) negotiations and the structure of the benefit-sharing agreement. While this report dates back to 1996 (and is in large part based on the provisions of the CBD and subsequent Conferences of the Parties), the basic issues it identifies are still as pressing and true in the present day.