

Public Interest Intellectual Property Advisors Bioprospecting Resource Guide

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Foreword

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About PIIPA and the IP Corps

PIIIPA is a global nonprofit, nonpartisan NGO who is a world leader and resource for developing countries and public interest organizations seeking pro bono expertise in intellectual property matters to promote health, agriculture, science, education, culture, biodiversity, and the environment.

Since 2003, PIIPA has coordinated pro bono IP services, training, symposia, and support for 140+ clients in over 38 developing countries. Our partners have included the WTO, WHO, WIPO, Ford and Rockefeller Foundations, U.K. Dept. for International Development, and The Fogarty International Center of the U.S. National Institutes of Health.

The IP Corps: PIIPA's volunteer network of 500+ IP practitioners in 50 countries brings to each project an unparalleled scope of skills, experience, and knowledge that covers all aspects of IP. Professional quality standards are applied in all public interest matters handled through PIIPA. The following services are provided through the IP Corps:

- ◆ Patent Landscape Analysis
- ◆ Negotiation of access and benefit-sharing agreements in relation to genetic resources and associated traditional knowledge
- ◆ Resolution of national, international and multinational disputes involving IP
- ◆ Negotiation of agreements facilitating access to medicines
- ◆ Drafting or review of legislation involving IP protection, e.g. in relation to genetic resources, traditional knowledge, and access to medicines
- ◆ Dispute resolution on matters involving intellectual property rights and indigenous rights
- ◆ Patent application, licensing, challenge and invalidation
- ◆ Search and analysis of patent portfolios to determine freedom to operate
- ◆ Trademark registration, licensing, challenge and invalidation
- ◆ Certification mark registration, licensing, challenge and invalidation
- ◆ Copyright counseling, licensing and litigation
- ◆ Trade secret protection, counseling and litigation
- ◆ Protection of geographical indications under national and international regimes
- ◆ Analysis of provisions and flexibilities for developing countries within the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and in negotiating Free Trade Agreements
- ◆ Analysis of the overlap between the protection of traditional knowledge and intellectual property rights

PIIPA's notable track record of performance combined with the geographical breadth of its network of professionals involved in actual practice brings significant benefit and enables developing country public interest organizations, SME's, and government agencies to raise their capacity to effectively operate in the global trade and IP landscape.

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Introduction

This Resource is intended to guide the on-line reader through the vast field of literature on 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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1. Business of Bio-prospecting

Bioprospecting has arguably always been relevant to corporate activities such as developing new products and services. However, bioprospecting has gained attention because of the growing awareness of the need for medicines to treat diseases that affect increasing numbers of the world population (AIDS, Alzheimer's, 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 – 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 product. Bioprospecting also underpins 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, 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

This concept of using biological materials for an industrial or synthetic use is the root of bioprospecting. According to Eric J. Mathur, bioprospecting is “the exploration of biodiversity for commercially valuable genetic and biochemical resources.” In theory, bioprospecting provides a powerful engine to research valuable drugs, crops, and compounds while learning from and gaining an appreciation for the world around us. Between January 1981 and June 2006 an estimated 47% of cancer drugs and 34% of small molecules were developed from natural products directly or derived from them. (http://www.princeton.edu/~aolivero/Bioprospecting/Home_Sweet_Home_page.html)

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. It 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. The 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.

Koehn, F.E. & Carter, G.T., 2005. The Evolving Role of Natural Products in Drug Discovery. *Nature Reviews Drug Discovery*, 4(3), pp.206–220.
<http://dx.doi.org/10.1038/nrd1657>

Natural products and their derivatives have historically been invaluable as a source of therapeutic agents. However, in the past decade, research into natural products in the

pharmaceutical industry declined, owing to issues such as the lack of compatibility of traditional natural-product extract libraries with high-throughput screening. However, as discussed in this review, recent technological advances that help to address these issues, coupled with unrealized expectations from current lead-generation strategies, have led to a renewed interest in natural products in drug discovery.

<http://www.ncbi.nlm.nih.gov/pubmed/15729362>

1.1.1 Pharmaceutical Industry

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 web links are also provided at the bottom of the page to related topics such as biopiracy, indigenous peoples rights, and biodiversity rights legislation.

Bioprospecting: MedicineQuest (An interview with Mark Plotkin)

<http://www.actionbioscience.org/biodiversity/plotkin.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. "Rediscovering Natural Products", *Chemical and Engineering News* 81(41) (October 13, 2003), pp. 77-91.

<http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals.html>

1.1.2 Agrochemical Industry

This market research report shows the trends in the agrochemical industry. The Agrochemical industry is highly consolidated and consists of insecticides, fungicides, and herbicides. Lucintel's research indicates that developing countries such as China and India are demanding higher volumes of nutritious food, which will increase demand for agrochemicals during the forecast period (2012-2017). Agrochemicals have significantly increased farm productivity in both developed and developing countries. Increased production of soybeans and sugarcane in Latin America is also driving growth in the region. Global Agrochemical Industry 2012-2017: Trend, Profit, and Forecast Analysis (Reportlinker.com, 2012)

<http://www.prnewswire.com/news-releases/global-agrochemical-industry-2012-2017-trend-profit-and-forecast-analysis-162559196.html>

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.

1.1.3 Other (Food Security, GMOs, etc.)

This webpage discusses the framework and definition of Genetically Modified Organisms. A GMO is the result of a laboratory process where genes from the DNA of one species are extracted and artificially forced into the genes of an unrelated plant or animal. The foreign genes may come from bacteria, viruses, insects, animals or even humans. Because this involves the transfer of genes, GMOs are also known as "transgenic" organisms.

GMO Education (The Institute for Responsible Technology)
(<http://www.responsibletechnology.org/gmo-education>)

Food Security News (Non-Wood News No. 7 (March 2000))
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 and 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

Traditional Knowledge has no single definition, but is generally defined as a living body of knowledge that is developed, sustained and passed on from generation to generation within community, often forming part of its cultural or spiritual identity.
http://www.wipo.int/pressroom/en/briefs/tk_ip.html

The WIPO gives a short summary and overview about traditional knowledge in relation to the Intellectual Property. On its website we can find articles related to the legal framework of TK, sessions, discussions and drafts. (<http://www.wipo.int/tk>)

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–Article 8(j)-Traditional Knowledge, Innovations and Practices (CBD)

<http://www.cbd.int/traditional>

This website is from the Convention on Biological Diversity and gives an update of the upcoming events and news on the field of TK and bioprospecting.

1.4 Bioprospecting and Biopiracy

This is a recent article from the European Parliament related to biopiracy to TK, introduces a Draft Report on development aspects of IPRs on genetic resources: the impact on poverty reduction in developing countries, prepared by Committee on Development.

<http://www.europarl.europa.eu/news/en/headlines/content/20121203STO04309/html/Biopiracy-protecting-genetic-resources-in-developing-countries>: *Biopiracy: protecting genetic resources in developing countries*

1.4.1 Bioprospecting: Legitimate Research or Biopiracy?

By Graham Dutfield

This text explains Bioprospecting and biopiracy, and the case of the Amazon. There is an explanation of both terms and *A Discourse Analysis of Biopiracy/Bioprospecting in the contemporary Amazon*.

http://iplobbypad.wikispaces.com/file/view/biopiracy_amazonia_icei.pdf

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 that 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.

<http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&dossier=7&policy=40>

1.4.2 Traditional Ecological Knowledge and Prior Art

This website contains a database for the Traditional Ecological Knowledge (TEK) prior art. <http://ip.aaas.org/tekindex.nsf>

This article explains the importance of the database mentioned above and explains the necessity of protecting indigenous economic rights.

<http://www.newtactics.org/tactic/protecting-cultural-and-economic-rights-indigenous-people-recording-traditional-ecological>

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

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.

<http://www.southcentre.org/publications/occasional/paper09/paper9-02.htm>

1.4.4 Traditional Ecological Knowledge Prior Art Database (TEK*PAD)

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) 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 (Note: last update, 2005).

<http://ip.aaas.org/tekindex.nsf>

1.4.5 Genetic Resources, Traditional Knowledge and Intellectual Property Rights Brief

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, to 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 it 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.

www.ciel.org/Publications/iprights.pdf

1.4.6 Science and Development Network (SciDevNet) Indigenous Knowledge Dossier

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 site has several links to other sources.

<http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&policy=49§ion=243&dossier=7>

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, there are still no clear-cut answers for how intellectual property rights should be defined, assigned and respected across all research contexts. Perhaps there will never be one simple answer to how to proceed. What 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.

2. Legal Framework

2.1 International

2.1.1 TRIPS (Trade Related Aspects of Intellectual Property Rights)

a. Overview

The World Trade Organization (WTO) adopted TRIPS after the 1986-1994 Uruguay Round of trade negotiations agreement. TRIPS is perhaps the most influential international agreement on intellectual property rights, including [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 minimum standards of intellectual property protection in national systems, as well as IP [enforcement provisions](#) and dispute settlement. These

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provisions can be adopted as domestic procedures for the enforcement of intellectual property rights and include civil and administrative procedures, provisional measures, special circumstances related to border measures, and criminal procedures.

Membership to the WTO, like access to international markets, requires a country to ratify TRIPS 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

Text of TRIPS agreement 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 begins from the date of the patent grant.

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. [Article 27.3(3)(b)].

c. TRIPS controversies:

(i) Overview:

Much controversy has developed between the fusion of trade and intellectual property. Many argue that patents restrict the availability of important inventions, especially pharmaceuticals needed to treat people, especially in developing nations. Developing nations demanded increased access to needed medicine patent obstacles.

(ii) DOHA Declaration and the Amendment of TRIPS

Overview: On November 14, 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 to support 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

On December 6, 2005, the TRIPS Agreement was [amended](#) to adopt an August 30, 2003 [Decision by the General Council](#) to establish the Paragraph 6 System of the Doha Declaration, which provides additional flexibilities to facilitate access to medicines under TRIPS.

(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 sought 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.who.int/intellectualproperty/topics/ip/tHoen.pdf>

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/recommendedstatepractice.html>

This website 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>

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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 193 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. Implementation: National Biodiversity Strategies and Action Plans (NBSAPs)

NBSAPs are the principal instruments for implementing the Convention at the national level ([Article 6](#)). The Convention requires countries to prepare a national biodiversity strategy (or equivalent instrument) and to ensure that this strategy is mainstreamed into the planning and activities of all those sectors whose activities can have an impact (positive and negative) on biodiversity. (See <https://www.cbd.int/nbsap/default.shtml>)

c. Bonn agreement

(Created in 2002, during CBD's [sixth meeting](#)) Prior to the 2010 Nagoya Protocol (see below), a major achievement under the Convention framework was the adoption of the Bonn guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization (see [Decision VI/24](#)).

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:
 - b) <http://www.cbd.int/decision/cop/default.shtml?id=7198>

d. Cartagena Protocol on Biosafety to the Convention on Biological Diversity

On 29 January 2000, the Conference of the Parties to the Convention on Biological Diversity adopted a supplementary agreement to the Convention known as the [Cartagena Protocol on Biosafety](#). The Protocol seeks to protect biological diversity from the potential risks posed by [living modified organisms](#) resulting from modern biotechnology. It establishes an [advance informed agreement \(AIA\)](#) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The Protocol contains reference to a [precautionary approach](#) and reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development. The Protocol also establishes a [Biosafety Clearing-House](#) to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol.

e. Nagoya Protocol (adopted in 2010)

The [Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization \(ABS\) to the Convention on Biological Diversity](#) is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

The Nagoya Protocol on ABS was adopted on 29 October 2010 in Nagoya, Japan and will enter into force 90 days after the fiftieth instrument of ratification. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity. For a comprehensive discussion of the Nagoya Protocol, and access to benefit sharing, visit: https://cmsdata.iucn.org/downloads/an_explanatory_guide_to_the_nagoya_protocol.pdf



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 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

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

e. 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_TOPIC&URL_SECTION=201.html

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.

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

Traditional knowledge and cultural expressions: This website 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 and again in 2011 the WIPO announced that the WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), will expedite its work in those areas, specifically, to undertake text-based negotiations to reach an agreement on a text (or texts) of an international legal instrument (or instruments) which will ensure the effective protection of TK, TCEs and GRs. The IGC website, including draft articles, is here: <http://www.wipo.int/tk/en/igc/>

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 here:

http://www.wipo.int/export/sites/www/tk/en/resources/pdf/tk_brief2.pdf

For a list of resources available on the WIPO traditional knowledge, traditional cultural expressions and genetic resources website, the following document prepared by the Secretariat is available:

http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_21/wipo_grtkf_ic_21_inf_9.pdf

March 2004- The ICG 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 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.

2.1.6 Declaration on the Rights of Indigenous Peoples (DRIP)

This Declaration was adopted in 2007 by the United Nations General Assembly and establishes a universal framework of minimum standards for the survival, dignity, well-being and rights of the world's indigenous peoples. The Declaration addresses both individual and collective rights; cultural rights and identity; rights to education, health, employment, language, and others. It outlaws discrimination against indigenous peoples and promotes their full and effective participation in all matters that concern them. It also ensures their right to remain distinct and to pursue their own priorities in economic, social and cultural development. The Declaration explicitly encourages harmonious and cooperative relations between States and indigenous peoples.

DRIP expressly confirms the rights of indigenous people to their Intellectual Property

The DRIP mandates that states shall provide redress to indigenous people with respect to their cultural, intellectual, religious and spiritual property taken without their informed consent or in violation of their laws, traditions and customs. (Art. 11). It confirms that indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the

manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions. (Art. 31). For the High Commissioner for Human Rights' webpage regarding indigenous Peoples, visit:

<http://www2.ohchr.org/english/issues/indigenous/index.htm>

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

WIPO Guide to Intellectual Property Law Worldwide <http://www.wipo.int/wipolex/en/>

WIPO Lex is a one-stop search facility for national laws and treaties on intellectual property (IP) of WIPO, WTO and UN Members. It also features related information that elaborates, analyzes and interprets these laws and treaties. It provides streamlined access to reference material of key importance for optimal information on the global IP System.

2.3 Rights and Interest of Indigenous People

While historical trends in international law 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, 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.



2.3.2 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://www.wipo.int/tk/en/databases/creative_heritage/indigenous/link0002.html

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.uncsd2012.org/index.php?page=view&nr=892&type=230&menu=38>

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.dialoguebetweennations.com/ir/english/kariocakimberley/KOCharter.html>

"IP resources the right size, at the right time, in the right place" www.piipa.org

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://ethnobiology.net/what-we-do/core-programs/global-coalition/declaration-of-belem/>

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.

For general link to statements, declarations, charters, resolutions and recommendations by organizations representing indigenous and local communities, visit:
<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

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. <http://www.wipo.int/wipolex/en/details.jsp?id=5755>

- b. Peru: Legislation implementing protection regime for the collective knowledge of indigenous peoples derived from biological sources.
<http://www.wipo.int/wipolex/en/details.jsp?id=3420>

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:

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.
<http://www.wipo.int/wipolex/en/details.jsp?id=3400>

- d. Alaska Native Knowledge Network:

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

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

Biodiversity Research Protocols – OSTI - 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: (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.

<http://www.osti.gov/energycitations/servlets/purl/554205-4Md9IU/webviewable/Directoryofguidancedocumentsrelatingtobiodiversityandculturalknowledgegeresearchandprospecting.pdf>

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.rbgekew.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.rbgekew.org.uk/conservation/endorsements.html>

b. Missouri Botanical Garden, Natural Products Research Policy

This policy 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. <http://www.wlbcenter.org/>

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

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.

<http://ethnobiology.net/what-we-do/core-programs/ise-ethics-program/code-of-ethics/>

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

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.

<http://www.econbot.org/about/index.php?sm=03>

3.1.5 American Anthropological Association Code of Ethics

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 that 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.

<http://www.aaanet.org/committees/ethics/ethicscode.pdf>

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

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.”

<http://www.afsnet.org/?page=HumanSubjects>

http://www.wipo.int/tk/en/databases/creative_heritage/researchers/link0015.html

3.2 International Governmental Organizations

3.2.1 Bonn Guidelines

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.

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

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

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

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.

<http://www.fao.org/docrep/x5586e/x5586e0k.htm>

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

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.

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

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. It is also known as the ASOMPS VIII (Asian Symposium on Medicinal Plants, Spices and Other Natural Products).

<http://old.iupac.org/reports/1996/6812andrews/melaka.html>

3.3 State Governmental Guidelines

3.3.1 US International Cooperative Biodiversity Groups (ICBGs)

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 ICBGs 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.

<http://www.icbg.org/>

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

This is the main website of the ICBG program to find information about its activities. This page links to several documents addressing intellectual property, access, and benefit sharing, primarily in the Convention on Biodiversity context, as well as academic articles.

a. ICBG Resources

<http://www.icbg.org/>

<http://www.icbg.org/resources/abs.php>

b. Request for Applications for ICBG Funding

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.

<http://www.icbg.org/resources/index.php>

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

3.3.3. Belgian Coordinated Collections of Micro-organisms as coordinator (BCCM): Micro-Organisms Sustainable Use and Access Regulation (MOSAICC).

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.

http://www.belspo.be/belspo/research/biological_en.stm#BCCM

3.3.4 Australia

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

<http://www.environment.gov.au/biodiversity/publications/inquiry/>

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 that 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 organizations 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.arc.gov.au/pdf/01_01.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 maximize 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. Organizations 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

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.

http://bahai-library.com/hunter_jones_bioprospecting_australia

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

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.

<http://www.med.govt.nz/sectors-industries/natural-resources/pdf-docs-library/biodiscovery/bioprospecting-harnessing-benefits-for-new-zealand.pdf>

3.4 Non-Governmental Organization Guidelines

3.4.1 Program for Traditional Resource Rights (PTRR)

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.

<http://orgs.tigweb.org/programme-for-traditional-resource-rights-ptrr>

a. The ISE Global Coalition for Biocultural Diversity

The purpose of the Global Coalition is “to encourage the permanent and meaningful dialogue between indigenous peoples, scientists and environmentalists in order to develop a unified strategy to defend the biological and cultural diversity of planet Earth.

<http://ethnobiology.net/what-we-do/core-programs/global-coalition/>

b. 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://www.sristi.org/papers/B29.htm>

3.5 Private Companies and Industry groups

3.5.1 Bristol-Myers Squibb Company

<http://www.bms.com/pages/default.aspx>

http://www.bms.com/sustainability/environmental_performance/Pages/default.aspx

3.5.2 BIO "Biotechnology's Foreign Policy"

By Carl B. Feldbaum, President Biotechnology Industry Organization June 10, 2002

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.

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

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

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.

<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).

4.2 Issues in multi-party complex negotiations

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. <http://hbswk.hbs.edu/item.jhtml?id=3898&t=strategy> “Making the Most of Multiparty Negotiations” by Lawrence Susskind”

4.3 Possible Role of Mediation/Multi-Party Facilitation in the Agreement Process

Alternative dispute resolution can help resolve public policy disputes. This 2012 six-page brochure from the Hawai’i State Judiciary’s Center for Alternative Dispute Resolution targets policymakers, encourages public participation, and provides some guidelines for suitable and unsuitable circumstances.

http://www.courts.state.hi.us/docs/CADR/cadr_prs_PubPol.pdf

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 “The Indigenous Peoples Guidebook for Free Prior Informed Consent and Corporation Standards,” by First Peoples Worldwide

This 56-page guidebook was produced as part of a United Nations training designed by the First Peoples Worldwide organization and held in May of 2012. It provides guidance for indigenous communities involved in corporate negotiations. It contains information on all international treaties or instruments with Indigenous rights standards in both the public and private sectors.

http://www.firstpeoples.org/publish/FINALfinal_guidebook_5.10.12.pdf

4.4.2 “Crafting Future Just Biodiversity Laws & Policies,” by the World Future Council

This 2011 51-page report provides some recommendations for just biodiversity laws and policies, a survey of the best existing biodiversity laws in several countries, and samples of sectoral policies, such as in the areas of marine policies or national forest policies.

http://www.worldfuturecouncil.org/fileadmin/user_upload/PDF/WFC_CISDL_Biodiversity_Laws_and_Policies_Report.pdf

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.



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://law.wustl.edu/centeris/Papers/Biodiversity/PDFWrdDoc/ChennelFinalApril2003.pdf>

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 articles offers a framework for understanding cultural differences and negotiating accordingly.”

<http://www.mediate.com/articles/cdr1.cfm>

4.5.2 “Biodiversity Conflict Management: a Report of the Bioforum Project.”

This 2005 report documents the results of the European Commission's attempts to create a European forum allowing dialogues among diverse stakeholders to reduce biodiversity conflicts. Some 130 stakeholders collaborated on case studies of potential conflicts in 25 European countries around the five thematic areas of forests, grasslands, uplands, freshwater systems and agricultural landscapes. It provides several guidelines on good practices.

http://www.unibuc.ro/prof/risnoveanu_g/docs/res/2012sepBiodiversity_Conflict_Management_-_A_report_of_the_BIOFORUM_project.pdf

4.5.3 "Intercultural Conflict Style Inventory" (ICS)

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://www.icsinventory.com/>

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 and 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

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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

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. (See, for example Aveda's story on sourcing indigenous sandalwood oil from Western Australia Aveda showed its sensitivity towards indigenous intellectual property rights: in 2003 the company abandoned its IndigenousTM 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.

<http://www.aveda.com>

http://www.aveda.com/cms/discover_aveda/ingredients/popup_ingr_sandalwood.tmpl).

<http://web.archive.org/web/20041209090841/http://aveda.aveda.com/about/press/indigenous.asp>

5.1.2 Virenium (previously Diversa)

Virenium Corporation is an industrial biotechnology company that develops, using microbial diversity, and commercializes high performance enzymes for animal health and nutrition, grain processing, oilseed processing, oilfield services and other industrial processes. . Before 2007, Virenium (then Diversa also used genomic technologies to discover and produce novel compounds, particularly commercially valuable molecules with applications in the pharmaceutical industry, as well as small molecules with the potential for agricultural, chemical, or industrial applications. For example, Diversa has signed agreements for bioprospecting in microorganisms in several countries including Costa Rica, Bermuda, Indonesia, Russia and Mexico, as well as a bioprospecting agreement with Yellowstone to research a commercially promising class of microorganisms known as thermophiles. However, Virenium's bioprospecting activities have attracted controversy. For example, a lawsuit was filed in response to the Yellowstone-Diversa bioprospecting agreement.

<http://www.verenium.com/ourwork3.html>

<http://www.thefreelibrary.com/Court+puts+Yellowstone+deal+on+hold.-a054492446>

<http://www.thefreelibrary.com/Federal+Court+Upholds+Diversa's+Agreement+with+Yellowstone+National...-a061570000> as well as the notation on Yellowstone National Park below

5.1.3 InBIO (Instituto Nacional de Biodiversidad)

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/entries?q=Inbio&archived=yesfor> examples). InBIO has been both hailed and derided for its goals of commercializing biological resources combined with sustainable development and conservation.

<http://www.inbio.ac.cr/en/>

5.1.4 Yellowstone National Park–Park Issues: Bioprospecting and Benefit-Sharing Chapter 9 from Yellowstone Resources and Issues 2004

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 remained in place until Yellowstone completed an Environmental Impact Study (EIS) in 2009, and the National Park Service (NPS) issued in 2010 a Record of Decision to implement benefits sharing service wide. Director's Order #77-10 defines NPS benefits sharing, lists fundamental benefits-sharing principles, describes basic benefits-sharing procedures, addresses related ethics and confidentiality, assigns responsibilities for administering benefits sharing, and outlines reporting requirements

<http://www.nps.gov/yell/planyourvisit/upload/247-8-10b.pdf>

<http://parkplanning.nps.gov/document.cfm?documentID=49044>

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

This site profiles each of the ICBG programs currently in operation in Costa Rica, Fiji, Indonesia, Madagascar, Panama, Papua New Guinea, Philippines, or competing programs in countries as diverse as Jamaica, Jordan, Madagascar, Philippines, Vietnam, Laos, Peru, Uzbekistan, Kyrgyzstan, Tajikistan, Kazakhstan, 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 (now Pfizer), Bristol-Myers Squibb, Diversa (now **Virenium**), Novartis, Dow Agrosciences, Eisai Pharmaceuticals 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

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citing their commitment to sustainable development, human rights, providing access to affordable health care and other global concerns.

<http://www.icbg.org/groups/>

5.1.6 The Body Shop

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). The Body Shop was taken over by L’Oréal in 2006.

<http://www.thebodyshop.com/values/index.aspx>

5.2 Case Studies on Biodiversity

As mentioned above, there are many sources reporting and analyzing cases related to bioprospecting and access and benefit sharing.

5.2.1 Case studies hosted on the CBD web-site

CBD Knowledge base currently lists more than 12000 documents which could be searched (under an “Other cases” tab) by keywords in titles, using “prospecting” or bioprospecting” or by organization names (“Diversa” or Yellowstone). Such searches retrieve only a few but highly relevant 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 and highlight various partner-companies (such as pharmaceutical and agribusiness corporations), including one early publication reporting the “new” Yellowstone-Diversa Agreement in 1997. While many of the reports go back to 1990s, 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.

The broader search could be done by browsing by the subject “Access to Genetic Resources and Benefit Sharing” (under an “Other cases” tab), which lists more than 850

entries, mostly the meeting documents (The latter could be searched, for example by Google by a query *prospecting OR bioprospecting site: cbd.int/doc/meetings/* which would enable full-text document search. Alternatively, ABS WG, ABSEM or ICNP, etc. meeting documents could be browsed.

<http://www.cbd.int/case-studies/default.shtml>

5.2.2 ABS case studies web-page at CBD

This dedicated web-page summarizes some case studies prior to the Nagoya Protocol and includes links to two research reports commissioned by CBD Secretariat:

UNEP/CBD/COP/4/Inf.7. (1998) "Synthesis of Case Studies on Benefit Sharing" and CBD Technical Series #38 "Access and Benefit-sharing in Practice: Trends in Partnerships across Sectors" (2008). It also links a number of external sources, some of them would be highlighted below.

<https://www.cbd.int/abs/casestudies/default.shtml>

5.2.3 Selected case studies published by different research organizations

- a. Wynberg, R., Schroeder, D. & Chennells, R. eds., 2009. *Indigenous peoples, consent and benefit sharing lessons from the San-Hoodia case*, Dordrecht: Springer. 363 pp. ISBN 978-90-481-3123-5

<http://link.springer.com/book/10.1007/978-90-481-3123-5/page/1> (only abstract, two first pages and list of references for each chapter is available for free)

The book consist of 18 Chapters and comparisons discussing challenges of the most famous Bioprospecting cases from Africa, India, South America, focusing on many policy questions related to Access and Benefit Sharing Agreements and Prior Informed Consent.

- b. Secretariat of the Convention on Biological Diversity (2008). *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors*. Montreal, Technical Series No. 38, 140 pages. (Written by Sarah Laird and Rachel Wynberg)

<http://www.cbd.int/doc/publications/cbd-ts-38-en.pdf>

Volume [Part] II (see p. 40-98) of this publication contains detailed analysis of seven case studies, presented at the sixth meeting of the Working Group on ABS in 2008.

- c. *The Access and Benefit Sharing Agreement on Teff Genetic Resources: Facts and Lessons*, Lysaker: Written by Regine Andersen and Tone Winge. Fridtjof Nansen Institute. 2012. 159 p. + Annexes <http://www.fni.no/doc&pdf/FNI-R0612.pdf>

This report analyses why the agreement between the Ethiopian Institute of Biodiversity Conservation and the Dutch company Health and Performance Food International ("HPFI") on access to teff genetic resources in Ethiopia which was entered into force in 2006, actually failed in 2009 when HPFI company was declared bankrupt. This failure of the agreement, once considered the most

advanced in sharing benefits under CBD, “left Ethiopia with fewer possibilities for generating and sharing the benefits from the use of teff genetic resources than ever before”. The Report concludes recommends provisions for future ABS agreements and for the implementation of the CBD. (Note: Other relevant Fridtjof Nansen Institute (FNI) reports found on FNI web-site:

<http://www.fni.no/publ/biodiversity.html>

- d. Queensland Biodiscovery Collaboration: The Griffith University AstraZeneca Partnership for Natural Product Discovery - An Access & Benefit Sharing Case Study Written by Sarah Laird, Catherine Monagle, and Sam Johnston Yokohama, UNU-IAS, April 2008, 58 pages

http://www.ias.unu.edu/sub_page.aspx?catID=7&ddIID=681

This report was prepared by United Nation University - Institute of Advanced Studies (UNU-IAS) and examines the Natural Product Discovery partnership between Griffith University, an Australian University based in the State of Queensland, and the pharmaceutical company AstraZeneca.

- e. Towards Access and Benefit-Sharing Best Practice: Pacific Case Studies DSEWPac. 2012, 39 p. (written by Daniel Robinson (The Univ. of New South Wales.)

http://www.abs-initiative.info/uploads/media/ABS_Best_Practice_Pacific_Case_Studies_Final_01.pdf

The report analyses four Pacific cases studies, and includes details on monetary and non-monetary benefits provided under ABS agreements in this cases. Basic Guidelines is offered for researchers seeking to be complaint with the principles of the Nagoya Protocol and for governments adopting the Nagoya Protocol. The Australian Government commissioned the publication.

- f. Bioprospecting case studies discussed by Fifth Global Forum on Bioethics in Research (GFBR) (Paris, 22-23 April 2004)

http://www.gfbronline.com/fifth_wsprog.htm

Two hotly debated cases were discussed on this Forum: "Maya ICBG" (Luis E. Garcia Barrios, ECOSUR, Mexico, 12 p.) and "The San people and the Hoodia Plant" (Roger Chennells, South African San Institute 10 p.), see also Meeting Report, p.3-4

- g. Cragg, G.M. et al., 2012. The impact of the United Nations Convention on Biological Diversity on natural products research. *Natural Product Reports*, 29(12), pp.1407–1423. goo.gl/aHXEYq (a short link to a full text of the article posted the ResearchGate.com by one of authors)

The chapter discusses the experiences of the US National Cancer Institute and the US government-sponsored International Cooperative Biodiversity Groups program in the establishment of international agreements in the context of the Convention of Biological Diversity's objectives of promoting fair and equitable collaboration with multiple parties in many countries, and includes some specific lessons of value in developing such collaborations.

- h. Selected publications on natural drug discovery as a source for further research on bioprospecting case studies
- i. Newman, D.J. & Cragg, G.M., 2012. Natural Products As Sources of New Drugs over the 30 Years from 1981 to 2010. *Journal of Natural Products*, 75(3), pp.311–335. <http://dx.doi.org/10.1021/np200906s>

Reviewers note, “the utility of natural products as sources of novel structures, but not necessarily the final drug entity, is still alive and well”. Authors also “draw the attention of readers to the *rapidly evolving recognition that a significant number of natural product drugs/leads are actually produced by microbes and/or microbial interactions with the host from whence it was isolated*” and therefore [authors] consider that this area of natural product research should be expanded significantly.

The article has a free supporting information in an Excel table listing all 686 drugs approved from 1981 to 2010 and having natural products as a source. 123 of such drugs were approved from 2004 (10 years after CBD entered in force), including 4 botanicals (“NB”), 10 natural products (“N”), 45 natural product derivative (semi-synthetic modification) (“ND:), 64 synthetic drugs, 26 of which use pharmacophore from natural product (“S*” or “S*/NM”), and 40 are natural product mimics (“S/NM”). These data could be used for investigation of the origin of the source and compliance with CBD. (A drug record contains generic and brand drug name, year of approval, scientific reference, and type of natural product source using codes described above).

<http://pubs.acs.org/doi/suppl/10.1021/np200906s>

- j. Cragg, G.M. & Newman, D.J., 2013. Natural products: A continuing source of novel drug leads. *Biochimica et Biophysica Acta (BBA) - General Subjects*, 1830(6), pp.3670–3695. <http://dx.doi.org/10.1016/j.bbagen.2013.02.008> (This is a free review article, accessed 7/25/2013)

This review traces natural products drug discovery, outlining important drugs from natural sources that revolutionized treatment of serious diseases. It discusses the historical role of traditional medicine, plants and marine organisms and microorganisms and other natural sources in drug discovery, and gives examples of recent drug approvals from natural sources. The author notes that, “*it is clear Nature will continue to be a major source of new structural leads, and effective drug development depends on multidisciplinary collaborations.*”

5.3 Summary / Points to Consider

- 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 relatively new, and is viewed as a way to redress decades (if not centuries) of legal wrongs, there are many who are suspicious that ethical bioprospecting can actually work – and there are many who believe that it is simply one more way that a company claims that it is acting responsibly 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,

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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/>

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.

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

In recent years, the U.S. National Cancer Institute became involved 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, and 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) Deal Making in Bioprospecting, Chapter No. 16.4, by Charles Costanza et al., in *Intellectual Property Management in Health and Agricultural Innovations: A Handbook of Best Practices*, 2007 (eds. A. Krattiger, R.T. Mahoney, L. Nelsen, et al.)

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, with a focus on financial and nonfinancial benefit sharing, and a brief discussion of some pitfalls.

<http://www.iphandbook.org/handbook/chPDFs/ch16/ipHandbook-Ch%2016%2004%20Costanza%20et%20al%20Deal%20Making%20in%20Bioprospecting%20rev.pdf>

- (iv) South Africa's bioprospecting, access and benefit-sharing legislation: current realities, future complications, and a proposed alternatives, by Neil Crouch et al., in the South African Journal of Science, 2008, http://www.scielo.org.za/scielo.php?pid=S0038-23532008000500009&script=sci_arttext
This paper discusses South Africa's bioprospecting legislation, shortcomings of the current permit process, and a proposed CDB-compliant model.

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) Research Permit Procedures for Foreign Universities, Research and Development Institutions, Companies and Individuals, regarding Research and Development Activities in Indonesia, from the Ministry of Research and Technology of the Republic of Indonesia (2012).
http://www.ristek.go.id/file/upload/lain_lain/frp/BUKU%20Prosedur%20FRP%202012%20_ENGLISH%20VERSION%20%2017%20JULY%202012_.pdf
- (b) Research & Collecting Permits in Costa Rica, from the Texas A&M University.
<http://soltiscentercostarica.tamu.edu/content/research-collecting-permits>
- (c) Guidelines for Receiving and Shipping Biological Materials, from the University of Minnesota.
http://www.dehs.umn.edu/bio_pracprin_std_ship_guide.htm
- (ii) Governmental Requirements concerning Protection of Biotechnological Inventions.

World Intellectual Property Organization: a listing of studies and articles on biotechnology and IP from 1998 to the present, followed by links to related WIPO pages and other relevant organizations

<http://www.wipo.int/patent-law/en/developments/licensing.html>

6.2.3 Resources concerning the structure/types of Bioprospecting Agreements

- (i) Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts (2009), (eds. Shakeel Bhatti, Santiago Carrizosa, Patrick McGuire and Tomme Young), from The World Conservation Union.

This 334 page-document analyzes the common and divergent issues between regular contracts and bioprospecting contracts, with detailed tables, breaking down each part of biocontracts.

<http://data.iucn.org/dbtw-wpd/edocs/EPLP-067-4.pdf>

- (ii) 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.
- (iii) 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 The Conservation Finance Guide on Bioprospecting – a joint project of the Conservation Finance Alliance

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

<http://conservationfinance.org/guide/guide/indexc2f.htm>

7.2 Common Features

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

This technical report by IUPAC provides a summary of agreement features and discusses sample terms. A Sample agreement can be found at this site.

<http://old.iupac.org/reports/1996/6812andrews2/index.html>

7.2.2 WIPO - Traditional Knowledge and Cultural Expressions – Contracts Database

This database provides 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. <http://www.wipo.int/tk/en/databases/contracts/>

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

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.

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

7.3 Access to materials (genetic/biological)



7.3.1 Andean Pact: Common System on Access to Genetic Resources

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 is available.

<http://www.iatp.org/documents/andean-pact-draft-decision-common-system-on-access-to-genetic-resources-0>

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

Model documents and agreements made available by the WIPO.

<http://www.wipo.int/tk/en/databases/contracts/texts/bccm.html>

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

Extensive document discussing proposed a 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.

<http://www.environment.gov.au/biodiversity/publications/inquiry/>

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)

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

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

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

This presentation reviews the approaches, outcomes, challenges etc that Sri Lanka is going to pass through to protect genetic resources.

<http://www.cbd.int/doc/meetings/nr/4nrcbw-asi-01/other/sri-lanka-en.pdf>

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/focus/e/96/06/06-e.htm>

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