Biodiversity Prospecting

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1 UNDERSTANDING THE MECHANISM – HOW DOES IT WORK ?

1.1 Overview

Biodiversity prospecting (BP) is the systematic search for biochemical and genetic information in natural sources that can be developed into commercially-valuable products for pharmaceutical, agricultural, and other applications. Since most of the world's biological wealth is in developing countries and most of the financial and technological wealth is in developed countries, an ideal bioprospecting relationship would be characterized by an equitable sharing of benefits between the supplier of natural sources and the purchaser. These relationships are outlined in bioprospecting agreements.

The economic value of biodiversity is reflected in payments to the source country for the collection of samples and, usually, profit-sharing agreements for royalties, should a commercially-viable product be developed. The principle of compensation to the source country for bioprospecting was affirmed by the 1992 Convention on Biological Diversity's recognition of national sovereignty over genetic resources. An alternative to intensive resource extraction, bioprospecting is one option for ensuring conservation while exploring the potential applications of natural resources.

Medicines derived from plants originally used by indigenous peoples have an annual world market of $43 billion. The expectations for large benefits were supported by the often cited BP deal of Costa Rica's National Institute of Biodiversity, which received $1,1 mio from the US pharmaceutical company Merck in exchange for a two year research and sampling contract. However, this scale has never been repeated.
While the direct financial benefit accrued so far mostly remained small, proponents increasingly stress the link in BP projects to biodiversity conservation in the context of integrated rural development in the host country. Most also involve efforts to strengthen the technical and scientific capacity in the host country. At least initially the main gains might be achieved from the *process* of biodiversity prospecting, and not merely from a commercial product that may, or may not, appear at the end of a lengthy R&D phase. While critics (e.g. Simpson 1997) question the economic rational of BP for conservation, proponents also stress a non-economic benefit. They argue that local populations will become increasingly aware of the potential economic value of natural habitats can have on their future management decisions.

Bioprospecting is time-consuming and highly technical for the purchaser. Commitment to this venture is a long-term investment. In addition to locating and collecting samples, the research and development of a single product can take

Glossary of Terms

Access: the right to explore and collect genetic materials from a source country for the purpose of commercial research and product development. Access rights and limitations are specified by permits. Details of the times, places, methods, quantities, and assignability of collection are subject to negotiation.

Bio-piracy: Unauthorized and uncompensated appropriation of indigenous knowledge and/or access to biological resources

Broker: Independent firm that acts as an intermediary between the supplier of natural and genetic sources and the purchasing company; profits earned by splitting the collection fee charged by the supplier

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

Intellectual property rights: Intangible rights protecting commercially valuable products of the human intellect, such as traditional medicinal lore. The inclusion of IPR considerations in the bioprospecting agreement is optional, and is dependent upon the nature of the rest of the agreement, e.g., whether the agreement is limited to transfer of materials or whether there is a shared research component, and the extent to which resulting innovations draw from existing traditional knowledge.

Intensive resource extraction: Excessive harvesting of resources to the point of depletion

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

as long as 10-12 years. It also requires expertise from different disciplines, bringing together government, academic and business sectors, and indigenous people. Bioprospecting involves the exploration, extraction, classification, and development of natural resources, particularly plants. Collection practices must be planned, supervised, and monitored to prevent over-exploitation. While the extraction and initial screening are done in the source country, further screening and product development is usually done abroad. Further research and sample processing can increase the value-added of samples shipped abroad, thus increasing collection premiums for suppliers.

New medicines are discovered when pharmaceutical companies screen natural products for biologically active compounds. Genetic information is used for agriculture and animal breeding. Up-front payments for bioprospecting can be set aside for the maintenance of the natural habitats of the collected species so that they may be cultivated for continual sustainable harvesting. With its potential for generating large revenues if products are successfully developed, bioprospecting is a more suitable mechanism for long-term financing of larger conservation objectives.

Source country collaboration is critical for the implementation of bioprospecting. For example, indigenous knowledge is an important source of medicinal lore and many bioprospecting projects are pharmaceutical ventures. Local residents can be paid for their maintenance and conservation of biodiversity in areas targeted for bioprospecting. Working together with companies and/or research institutions, trained locals can assist in collection and research. By involving locals in the bioprospecting process, they have a vested interest in and an understanding of conservation. The issue of intellectual property rights is controversial and centers around intellectual property protection frameworks in industrialized versus developing countries and the contributions of indigenous knowledge to new-product development.

Milestone payments are attached to various stages of drug discovery (e.g. screening, identification of active compounds) and development

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

Purchaser: Company that pays for the collection of natural resources to extract genetic information and develop commercially-valuable derivatives

Royalties: Payment for the right to use intellectual property or natural resources; can be a fixed sum, a percentage of the profits from the developed product, or both

Source country: Country from which natural resources are collected, often in the developing world

Up-front payment a) Contract Fee: It is not necessarily tied to anything in particular, but can be included in a contract as a payment to move the project forward. Typically, companies are not eager to pay such fees.

b) Research Budget: it is possible to request payments in advance for necessary items, e.g., new equipment, materials, training, travel, and so forth. Companies are likely to agree to such dedicated fees more readily than to non-specific up-front fees.

Value-added: Processing or refining a plant or other sample to increase its value when it is sold by the supplier

1.2 Key Actors and Motivations

All BP arrangements involve a pharmaceutical industry party, a host country institution, and an mentor, often a donor/development assistance agency and/or NGO. Beyond these core actors, in most cases the pharmaceutical company was working with a developed country research agency (often supported by the donor) and the host country with a public and/or private institute (collector and sometimes provider of pre-screening/processing), as well as local host communities. In several cases a broker was engaged as an intermediary between the supplying country and pharma companies.

The collection of biological samples for industry generally involves two or sometimes three direct relationships (Reid 1993):

- That between the company and the contracted collector (usually described in a contract which is legally binding under the law of the country in which the company is situated)
- That between an outside collector and in-country collaborators (usually more informally defined, although increasingly detailed in agreements of some kind, and regulated by national legislation)

- That between an ethnobotanical collector and local communities that provide traditional knowledge on collected samples which will subsequently be supplied to commercial companies (rarely defined in any agreement or regulated by national legislation).

The transfer of samples from a collector to a company is the most direct path by which biological and cultural diversity travels to commercial interests, and generally the most direct path upon which benefits return. However, there are many other groups that are indirectly involved in and affected by this exchange that are not written into two-party arrangements, but are increasingly addressed in international and national law and policy:

- Communities that live in biodiversity-rich areas where samples are collected
- National governments which, as written into the CBD, now claim national sovereignty over their country's genetic and biochemical resources
- The international community which, through documents and agreements such as the CBD, have expressed interest in the conservation and sustainable and equitable use of biodiversity.

1.2.1 Local communities

Local communities play a number of indirect and direct roles in biodiversity prospecting activities.

- Local people might be employed or only interviewed for random collection or for known species.
- Samples might be collected from communally-held lands, the product of generations of stewardship.
- Traditional knowledge might be recorded and published in academic publications or databases, which are subsequently consulted by industry researchers for leads on promising species
- Intermediary collectors might conduct ethnobotanical studies for commercial companies or research institutions, the products of which are destined for commercial development.

There are generally two main issues as stake in the relationship between local communities and biodiversity prospectors:

- The right of local communities to control over their land and the resources on those lands (including the choice of whether or not to participate)
- Their right to control and to receive adequate benefits from the recording and use of their knowledge.

1.2.2 International Community (Donors)

Donors often provide the funding that initiate the preparation of a BP arrangement. As part of their responsibilities for support of the CBD, donor programmes mostly involve technical support projects to facilitate parts or all of the BP process. Typically, a donor would mobilise its relevant national or private research institution and the technical development assistance agency.

Technical assistance can reach from the feasibility study, advice on establishment of the legal framework, capacity building on national and local level, monitoring project performance etc.

1.2.3 Pharmaceutical companies

Large international companies, either through their own research departments or through specialised enterprises, spend considerable funds on research to identify components and develop future medicine. Their motivation to participate in these arrangements is to establish and benefit from well-structured sample collection and replicable supply.

1.2.4 Brokers

Brokers offer the sampling products from a country to pharmaceutical companies. While not involved in all cases, professional intermediaries often are a better alternative for a developing country than a direct contract with only a single pharma company, as they provide more flexibility and independence from that one company's decisions or economic fate. While they may initially create costs, brokers mostly can obtain higher prices for sampling services and can negotiate better royalty agreements. But also the pharma companies have an advantage, as they are less dependent on just one geographic source of samples and have a partner who guarantees reliable supply of new and, when needed, repeated supply of specific samples which were found to be potentially active.

1.2.5 Host government and host government agencies (collectors, pre-processing)

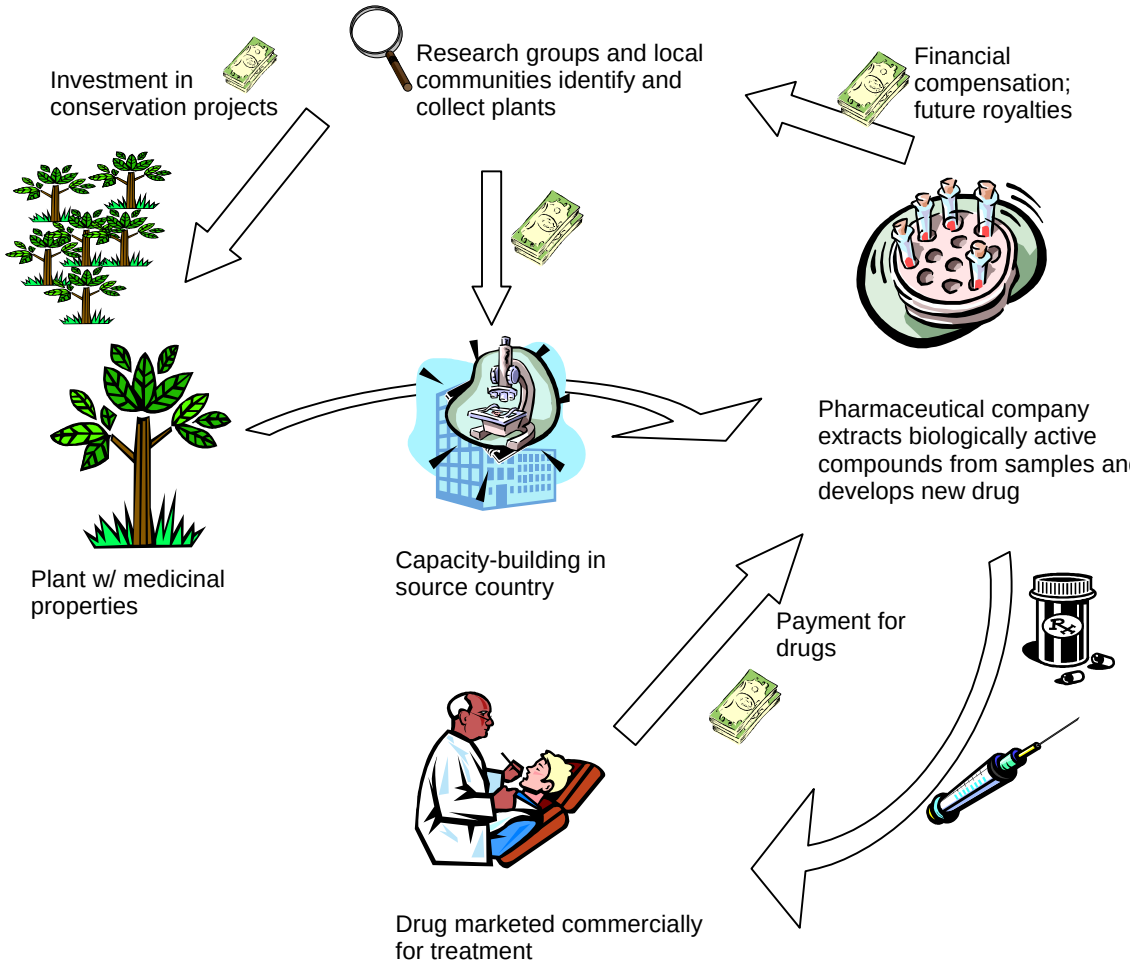
Developing country governments typically are interested in BP in order to tap additional funds, provide input and exposure of its biodiversity research institutions to international technologies, and to channel resources to its local communities. Host country agencies are public and sometimes private research or university institutes, sometimes also private companies providing sample collection and laboratory services. Their motivation is obviously to gain experience, access to latest technologies and, where feasible, income from providing as much additional, value-adding post-collection processing and screening services as possible. Host government agencies include national level ministries and institutes as well as the local administration and community leaders.

1.2.6 NGOs

International NGOs can be involved both at the international level, initiating and later implementing the support provided by their governments, reaching down to the national and local level in the developing country. Apart from their interest in increasing funding available for local community development, they see bioprospecting arrangements as an important tool to increase the value local people attribute to their natural resources, thus motivating the sustainable use and conservation of resources. Increasingly, they defend indigenous people's rights.

Local NGOs assist the host communities to understand and make best use of the opportunities in sharing their traditional knowledge as well as providing random samples of their local species. They defend their interest in the often complicated negotiations, assist in capacity building, and sustainable use of the resources gained in the BP process.

1.3 A simplified cycle of Bioprospecting Benefits



1.4 Types of Bioprospecting agreements

There are no typical bioprospecting agreements. Their concrete form depends on the pursued objectives, the legal framework, the national nature conservation strategy, etc. The structure, scope of activities, priorities, and procedures vary according to their purposes, the situation of the host country, and the objectives of the parties. Within any type of agreement, everything is negotiable. Basic agreement types include permits, material transfer agreements, licenses, and cooperative research and development agreements.

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

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

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

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

1.5 Strengths and Weaknesses of Bioprospecting Agreements

Strengths

- Protects biodiversity in biologically-rich areas
- Compensation for the use of biodiversity resources – user pays principle
- Resulting flora and fauna database furthers scientific knowledge about the area's biology
- An incentive for surveying a source country's interior areas
- Promotes technology transfers, research assistance, training, and information-sharing: capacity-building opportunities for local biotechnology institutes and scientists
- Promotes regional biotechnology industries in the developing world
- Provides developing economies access to pharmaceutical technology and equipment
- Business expansion and more employment opportunities
- Improved local drug development capacity to help in the treatment of local diseases
- Attracts foreign investment in products/product potential
- Helps preserve, document, and value traditional knowledge and native practices
- Wider use of traditional medicines in areas where modern medicines are unavailable or unaffordable
- Promotes community-based conservation and awareness

Weaknesses

- Product development success rates, and therefore market demand, have been low, so returns to local community are slow or uncertain
- Drug development is costly and time-consuming
- Up-front compensation is limited and short-term and companies often resist larger-scale, long-term royalties-sharing
- Research and production techniques are still being developed
- Valuation and willingness-to-pay difficult to quantify for potential products
- More promising alternative scientific techniques to generate raw samples, such as *in vitro* synthesis
- Enforcement to trace a chain-of-custody from an organism to the commodity is difficult- vulnerability to abuse when royalties are not paid to the original providers
- Risk of "bio-piracy," exploitation, and intellectual property theft:
- because of a lack of well-established legal rights to these resources, and because of prevailing cultural and political structures, local knowledge of medicinal plants could be utilized for identifying natural extracts without appropriate compensation.
- Systems of intellectual property rights (IPR) do not offer sufficient protection to traditional knowledge, nor is it clear that establishing IPR regimes is the solution. A plant or organism with medicinal properties may have been discovered by several different peoples in different parts of the world at different time periods, making it extremely difficult to establish and reward "rights" of discovery. Synthesis also complicates this process by creating compounds that are so far removed from the original extracts that royalties and rights are hard to claim.
- Property rights over traditional knowledge may be inimical to certain cultures.
- Local peoples could lose future access to the resource in question in case of rights disputes, unsustainable harvesting of resources or with introduction of strict conservation measures that restrict local access.
- Simple compensation schemes for nature-extracts can have a negative effect on conservation: if resources are subject to open access, payments can result in unsustainable harvesting and a decline in biodiversity.

1.6 Success Factors

1.6.1 Viability Criteria

This sub-section is intended as a tool for determining whether bioprospecting is a viable option. A "no" answer to any of the following questions indicates that bioprospecting is not feasible for the site at this time. Questions with "maybe" or "unknown" as a response require further analysis and possibly a willingness to take a risk on this mechanism. In the absence of any "no" responses, include this as a potential mechanism in the coarse screening tool. (See screening tools.)

Table BP 1: Coarse Screening Tools

QUESTION	YES	NO	MAYBE/ UNKNOWN
Does the area have a valuable and unique range of biodiversity?			
Are there ecosystems that can be set aside for research and collection?			
Are there corporations that are interested in bioprospecting partnerships?			
Does the source country have clearly-defined land and resource use rights?			
Is the government committed to controlling access to biological resources?			
Are there local/regional biotechnology industries and accompanying infrastructure?			
Will there be source country participation?			

Factors above are essential. Some "critical mass" of the following success factors should also be present; absence of more than a few greatly increases risk.

1.6.2 Success Criteria

In addition to the viability criteria above, the following criteria help to assess the conditions for success in pursuing bioprospecting:

- Wealth of genetic diversity, including high numbers of endemic plants (restricted to that region or country)
- Distribution mechanisms linking bioprospectors to biodiversity suppliers
- Accessibility to remote sites for specimen collection
- Equitable benefit-sharing mechanisms under existing laws
- Local communities knowledgeable about the importance of biodiversity and ethnobiology
- Collaboration among all parties, especially active participation from local communities and their communication with in-country researchers
- Clear agreements and an understanding of contractual terms
- Absence of major threats jeopardising the future supply of samples found to contain active ingredients
- Government support both legally and commercially for regulating and processing export of specimen. The support should be active and broad-based, from senior political leaders to regional and local bodies, extending beyond environmental ministries and departments to include ministries of finance and planning.
- A participative process which involves a broad set of stakeholders during the design process, and willingness of stakeholders to use these mechanisms.
- Availability of one or more mentors — a donor agency with good program support, a partnership with an international NGO, a professional yet fair broker — who can provide both moral and technical support during the start-up and program implementation phases.
- Conservation is closely tied to the ownership, control, use and value of the habitat being conserved. Bioprospecting will result in conservation only if the people or institutions who own or control these environmental resources benefit from prospecting to the extent that they are willing to conserve rather than deplete these resources for other purposes.
- Hence, for bio-prospecting to be successful as a conservation mechanism, it will need to compete with other land uses such as agriculture and cattle grazing.

1.7 Step-By-Step Methodology

Establishment of BP agreements generally moves through three phases of development:
- a feasibility study;
- a design phase;
- an implementation phase.

The following methodology walks through the general steps in a bioprospecting process. The subsequent chapters address the feasibility study, design and implementation in detail.

Step 1: Local research institution conducts an inventory of local bio-resources and compiles a database.
- Mobilizing and advising local institution, often based on motivation, training and help from development assistance projects, NGOs.
- Information about an area's biodiversity wealth will be useful for prospective partners and as leverage during negotiations of bioprospecting agreements.

Step 2: Source country government develops a national policy on bioprospecting.
- Review existing policies, strategies, and laws including contract law, intellectual property rights, wildlife laws, and enforcement procedures.
- Define the roles of the actors, e.g. regulatory role of the government
- Protection of indigenous communities and natural resources
- Guidelines for regulating access to genetic resources

Step 3: Source country seeks a partner, e.g. pharmaceutical/biotechnology company or a research institution.
- Approach research and development divisions of companies and research institutions with interests in the area.
- Approach scientists in the area with links to a company or research institute.
- Approach a "broker" that serves as an intermediary between companies and suppliers of genetic resources.

Step 4: Meetings between national government officials, corporate partner, and local research institutions.
- Organized by a coordinating ministry, such as the Ministry for Environment
- Include representatives from the Ministries of natural resources, health, trade, research and technology, etc.

Step 5: Government and local research institutions and industries identify the needs for scientific capacity building and technology transfer.
- Research partner's strengths and weaknesses to select benefits that might be provided for in the bioprospecting agreements.

IF A CORPORATE PARTNER OR BROKER EXISTS (Design phase):

Step 6: Partner and research institution obtain approval for bioprospecting proposal.
- Clarify, record, and detail the proposed activities and goals of the collecting institution.
- Approvals from the national government, provincial government, and local communities, the latter from visits to individual villages and community meetings.

Step 7: Partner prepares to negotiate bioprospecting agreements.
- Identify the real costs of participation and create a budget, ensuring that costs do not greatly exceed expectations.

Step 8: Source country prepares to negotiate bioprospecting agreements.

- Local community leaders survey stakeholders about their goals and constraints and incorporate into draft agreement.
- Set priorities on the kinds of benefits it would like to receive, e.g. royalties, up-front compensation, milestone payments, and retention of intellectual property rights.

Step 9: Design equitable bioprospecting agreements among the parties.

- Each party obtains legal advisers for contractual and equity issues.
- Hold open meeting in the source country to facilitate local participation.
- Content includes: criteria for collection, immediate compensation, payments per sample, advance payments, royalties, intellectual property rights, liabilities, etc.

Implementation phase:

Step 10: Parties approve and implement final agreements.

- Government and/or local communities issue permits that give the partner and/or research institution the right to access biological materials, with conditions.
- Local community can issue material transfer agreements, in conjunction with permits, that grant the right to transfer specimens to third parties, such as local researchers and laboratories, after collection.
- Government issues licenses, determining how collected samples can and cannot be used, to researchers and partners.

Step 11: Partner and research institution promote source country participation and capacity-building.

- Conduct workshops and training exercises for the local community to develop a sense of project ownership. Discuss the importance of biodiversity and ethnobiology, integrating it into sustainable village development.
- Locals learn to identify types of plants or animals that are becoming scarce or extinct and document ethnobiological knowledge that should be preserved.
- Partner and research institution implement a training program during the first year of project implementation to collect, identify, and screen samples.
- Access to and sharing of technology and research.

Step 12: Local researchers and institutions increase their capacity to process samples for value-added products.

- Use technology and research transfer benefits from bioprospecting agreements.
- Develop new value-added industries in the source country, such as pharmaceutical research and agricultural biotechnology.
- Train local researchers to run initial sample assays.

Step 13: Implement and monitor bioprospecting projects.

- Include trained locals.
- Government and partner reinvest in conservation efforts.
- Renew collection permits and licenses, if necessary.
- Partner and research institution submit records of all materials collected, to where they were transported, intended uses, and test results for governmental review.

2 FEASIBILITY ASSESSMENT PHASE

2.1 Overview of feasibility assessment

Typically, an NGO or bilateral donor government agency will assist a host country to commission a biodiversity expert to conduct an in-depth feasibility study of BP opportunities. More rapid and less expensive feasibility assessments can be conducted using the tools provided below, the resources listed above, and limited technical assistance as needed. Below is a generic terms of reference for a BP feasibility study, along with worksheet tools for summarizing and analyzing data collected during the feasibility study.

2.2 Generic terms of reference (TOR) for feasibility assessment

2.2.1 Overview of TOR

[COUNTRY] lies in the biodiversity-rich [region] and has [high number] of endemic species. [*If available name examples of already discovered and profitably used ones*]. [SUMMARY OF FINANCIAL/ CONSERVATION CONDITIONS LEADING TO STUDY]. To explore these opportunities [NAME OF CONTRACTING ENTITY] is commissioning a feasibility study. The consultant will work with [FILL IN RELEVANT PARTIES] to conduct a feasibility study of BD prospecting opportunities in general, and in particular their potential for financing conservation, including protected areas management, in [NAME OF COUNTRY].

The study will evaluate key issues and conditions influencing the feasibility of BP in [NAME OF COUNTRY]. In-country work will include an analysis of [NAME OF COUNTRY] legal and institutional environment for setting up BP agreements, accessibility, willingness and capacity of local communities, potential partners in pharmaceutical companies, brokers and overseas research institutes, an estimate of the transaction costs for establishment and operation of BP, and an estimate of the human resources and/or technical skills necessary.

The study should also identify the individuals or institutions within the [NAME OF COUNTRY] government who would be willing to promote the idea of BP agreements. Additional analysis will identify sources of bilateral, multilateral and potential national sources.

2.2.2 Terms of reference

Objectives:

The overall objective of the consultancy is to explore the feasibility of biodiversity prospecting in […].

Since it is hoped that the feasibility report will be the first phase in establishing an BP agreement, another objective of the consultancy is to recommend a step-by-step *follow-up strategy* for implementation, including recommendations regarding design options (e.g., involved communities and institutions, procedures and entities that could share benefits, conservation strategies for programming of proceeds, etc.).

Tasks:

1. Review of existing diagnostic and pre-feasibility studies in the country and other relevant examples.
   - Pay particular attention to soundness of information and diagnostic conclusions
   - Consistency between proposals from a strategic medium to long-term perspective,
   - especially regarding sustainability at the project (micro) level and at the fund (macro) level
2. Assessment of the legal framework regarding bioprospecting issues in [country] including constitutional, international and local laws.
3. Analysis of deficiencies in the present legal framework to support effective and equitable sharing of benefits from bioprospecting and draft legal amendments as necessary.
4. Recommendations for appropriate institutional arrangements for oversight and regulation of bioprospecting partnerships based on experience in other countries, as well as recommendations for the role of local communities and rules pertaining to prior informed consent.

5. Report on critical issues to be reflected in an equitable bioprospecting agreement/contract, and recommendations for design of agreements based on experience in other countries (for example, involvement of local communities and scientific institutions in gathering and processing of samples to develop skills in-country).
6. Recommendations for mechanisms whereby profits on the sale of samples and royalties on the commercialization of products are channelled to the conservation and sustainable use of [specify] resources, e.g. ....
7. Scoping with stakeholder groups
   - Participate in meetings and group discussions with different segments of civil society, private sector, government agencies and international donors/NGOs and advocacy groups in order to obtain their comments, opinions and suggestions regarding the potential design of a BP agreement
   - Assess current and probable levels of commitment by the various stakeholders to participate actively and transparently in the development process, incl. provision of time, expertise, potential projects, etc.
8. Host government policy
   - Provide a preliminary indication of the government's interest in BP agreements and capacity;
   - Identify government officials who would be key players in advocating BP agreements
   - Summarize government concerns and conditions
   - Research will be conducted through interviews with relevant government officials (Ministry of Environment, National Protected Area Agencies, Protected Area Managers, National Science and Research Institutions, community leaders, etc.)
9. Macroeconomic and political context
   - Analyze macroeconomic and political context and identify potential risks and constraints
   - Research will be conducted through a review of published sources of information about current economic and political conditions in [COUNTRY] and interviews with analysts and economists focusing on [COUNTRY] (private sector, government, UN and bilateral BD institutions, experiences in other cases in country or region).
10. Prepare negotiation strategy and design
    - As almost all elements of a BP deal are negotiable, the consultant will thoroghly prepare all arguments, supporting factors, potential competitors and broker partners, form alliances with projects in equal-minded neighbour-countries, etc.
    - Recommendations and Terms of Reference on preliminary design of BD agreements and a step-wise follow-up strategy for implementing them
    - The consultancy will prepare detailed ToR and budget for developing and implementing a mid- to long-term strategy for mobilizing environmental investments, and for the design and implementation of an environmental fund. These will include activities, sequencing, performance benchmarks, types and qualifications of specialists needed, required time frames, and estimated budget.

Deliverables:

1. Feasibility report and ToR. A preliminary report capturing all of the task points outlined above will be submitted to a "Review Team" for comments and discussion prior to the finalization of the report for submission to the contractor. A final report will be submitted in written and electronic form.
2. Contact list. A list of key contacts (name, title, address, email, phone number) will be attached to the final report.
3. Briefings. Concluding briefings will be provided in [LIST CITIES] to summarize preliminary results for contractor and other interested stakeholders.

Staffing and timetable:

The project will be implemented during the period [FILL IN]. A preliminary report will be due on [FILL IN] and a final report will be due on [FILL IN].

The level of effort will require a total of [FILL IN] consultant days. [IF A TEAM OF CONSULTANT:] The consulting team will consist of: [FILL IN NAMES, BREAKDOWN OF DAYS AND ROLES]

2.3 Worksheet tools for carrying out feasibility assessment

Worksheets have been developed to assist the feasibility stage. Instructions for how to use these tools are provided below. These worksheets are intended as generic tools to help summarize and analyze relevant information gathered during the feasibility stage. They will need to be customized to some degree for every site.

The first mini-worksheet includes criteria that should be considered when deciding to enter into a bioprospecting agreement. By completing the first worksheet, "Key Conditions," you can determine if a country's present situation can support bioprospecting projects.

Measure the political and legal conditions of a country to determine the government's commitment to conservation, which should be the primary motivation for bioprospecting. A developed and transparent legal framework in the source country is important since contracts play a major role in determining the success of bioprospecting agreements. An area's biodiversity wealth is the source of attraction. Sufficient biodiversity balances the need for "capital" for commercial products with the need for ecosystem maintenance. Recognizing the integral role of the source country, the capacities of the local infrastructure and local communities reveal the source-country's ability to support projects as well as areas that could benefit from a bioprospecting agreement's capacity-building initiatives. A site's remoteness may work in its favor, since most of its biodiversity probably has been conserved, but the critical factor is the link between collector/supplier and the purchasing company. Most often, such a link is provided by the local biotechnology industry.

Instructions for Table BP 2: Summary analysis of key conditions for successful BP Agreements

It is designed to help analyze the key conditions needed for a successful BP agreement and long-term program.

- Review the general structure of the worksheet, including data input categories (columns and rows) provided as defaults; modify as needed.
- Column 1 lists a variety of conditions under the general headings: political, economic, legal and other. For each condition, assign a relative ranking score (1 - 5 scale, with 5 being the highest) in the appropriate column to the right.

In analyzing these conditions for success, the following key analysis questions should be answered:

- Are there some conditions which are particularly important in this local setting? What are their scores? How could these conditions be improved if necessary?
- Are there a sufficient number of medium (3) or higher scores, suggesting a good likelihood of success?

BP 2: SUMMARY ANALYSIS OF KEY CONDITIONS FOR SUCCESSFUL BIOPROSPECTING AGREEMENTS

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CONDITIONS (Establishment)	CONDITIONS RANKINGS (1 - 5 scale) VERY LOW [1]	LOW [2]	MEDIUM [3]	HIGH [4]	VERY HIGH [5]
Political Conditions					
Active, broad-based and financially significant government support to scientific institutions, national and external companaies, local communities, export/import regimes, etc.					
Support within Finance Ministry					
Support within Sectoral Ministry (specify -Trade, Research ...)					
Support within Sectoral Ministry (specify)					
Government prioritization of environment					
Political stability (minimal political risk)					
Previous experience with use of financial and technical aid					
Mentors — donors, international NGO, experienced yet fair broker — for moral and technical support					
Other					
Biodiversity Wealth					
Uniqueness (are many species endemic?)					
Abundance (how many species & how abundant for re-sampling until they can be chemically synthesised or otherwise produced?)					
Variability					
Distribution					
Other					
Legal Conditions					
Defined property and land rights					
Intellectual property protection framework					
Enforceability of contracts					
Legal and financial practices and reliably functioning supporting institutions (including banking, auditing, and contracting)					
Government support both legally and commercially for regulating and processing export of specimen					
Other					
Local Infrastructure					
Site accesibility for collection					
Deliverability from supplier to purchaser					
Scientific/institutional capacity					
Biotechnology industries					
Traditional medicine/pharmaceutical industries					
Local communities					
Basic needs being met					
Commitment of conservation					
Ethnobiological knowledge					
Willingness to cooperate					
Available legal assistance/counsel					
Other conditions					
Support of other key domestic stakeholder groups					
Critical Mass of people with common vision from all sectors					
A participative process which involves a broad set of stakeholders during the design process					
Willingness of stakeholders to use these mechanisms					
Other					

To fill or otherwise edit the sheet in Excel, click **here** and go to sheet 2

The following financial planning worksheet is self-explanatory. To edit, click **here**

BP 3: WORKSHEET FOR FINANCIAL ANALYSES TO PLAN and SUPPORT IMPLEMENTATION OF BIOPROSPECTING

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	Contract 1 Description	% share of returns				Description	Contract 2 % share of returns
Location							
National partners							
International supporters: donor/mentor/adviser/NGO							
External partner(s') type (broker /pharmaceutical company) and name							
Degree of host country involvement / services	**Description**	**Financial return for host country** Starting which year	how many years	annual amount (beginning/ peak/average)		**Description**	... ...
a) Random sampling or b) interviews and guided sampling with local healers	..	..	..	._./ ._. / ._.			
Only sample collection assistance to external teams	..	..	..	._./ ._. / ._.			
Independent/local sampling, raw delivery to external partner	..	..	..	._./ ._. / ._.			
Sampling and processing (mark: identification, sample database management, extraction of active components, genetic analysis)	..	..	..	._./ ._. / ._.			
Patenting & holding property rights, receiving royalties	..	..	..	._./ ._. / ._.			

Payments/Income expected in yearly timeline

	Total	*Sampling*	*Sample management*	*Lab processing*			
Year 1							
Year 2							
Year 3							
Year 4							
Year 5							
Year 6							
Year 7							
Year 8							
Year 9							
Year 10							
Year 11							
Year 12							
Year 13							
Year 14							
Year 15							
Year 16							
Year 17							
Year 18							
Year 19							
Year 20							
Total	-	-	-	-		#BEZUG!	*#BEZUG!*

3 DESIGN PHASE

3.1 Legal Framework

Of primary importance is local communities' right to self-determination and the establishment of land and resource rights. Following on this, traditional knowledge must be recognized as an intellectual creation of communities and not the 'heritage of mankind'. In addition, communities must be given control over the process by which their knowledge is recorded and used (including the choice of whether or not to participate), and the nature of benefits that will be returned to them. There are a number of international and national laws which might be used to do this, including human rights law, environmental law, intellectual property law, transnational business regulation, and national or local tort and property law, although in each case a fundamental choice must be made between public or private law, national or international law, and state responsibility or corporate/individual liability. In many cases, western systems of law may not be appropriate to a particular community, and may not best protect communal systems of knowledge. A number of communities, such as the Kuna in Panama, and the Awa in Ecuador, have designed research agreements and codes of conduct for visiting researchers, or have entered into commercial agreements, which require respect of cultural norms, prior informed consent, and transfer of technology and expertise.

3.2 General recommendations

A recent training workshop in West Africa (GBDI/ITTA 2000) stressed some important general principles about bioprospecting and the art of negotiating a successful agreement:

It is extremely important to identify the costs of participating in the bioprospecting agreement as early and accurately as possible, for the protection of both parties. Understanding the real costs is the only way to negotiate a fair and reasonable up-front fee, and if the costs greatly exceed expectations, the entire project can collapse. The **budget** can extend for several years and include such varied components as materials collection, transportation, taxonomy, information systems, extraction equipment, bioassays, communications, administration, subcontracting, and so forth.

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

It is recommended to find out as much as possible in advance about the company before negotiating, and to understand the company's particular strengths and weaknesses in order to know what benefits to request.

Box: Consent to Use, and Sharing of Benefits: e.g. Shaman Pharmaceuticals Inc.

At the time of its incorporation as a for-profit corporation in 1989, Shaman Pharmaceuticals, Inc., also founded and continues to financially support the Healing Forest Conservancy (http://www.shaman.com/Healing_Forest.html), a nonprofit foundation established specifically to develop and implement a process to return benefits to Shaman's 30 collaborating countries and some 60 culture groups after a product is commercialized. Benefits from commercial products will be shared equally among all countries and culture groups that participate in Shaman's drug discovery process, no matter where the plant or knowledge originated. The Healing Forest Conservancy developed a constitution, a legal instrument available on the worldwide web, under which indigenous groups legally organize to receive monetary benefits. The company uses Agreements of Principles, legally enforceable contracts, to establish the terms under which Shaman conducts research. Culture groups' rights to prior informed consent, confidentiality, privacy, and fair compensation form the philosophical underpinnings of the company and its principles for research. Several publications supply detailed descriptions of Shaman's operations globally, including its lengthy prior informed consent process.
Recent economic conditions of the company limit implementation of the previously planned activities.

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

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

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

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

Proponents argue: If one takes absolutely no action at all, there will be absolutely nothing in return; this is the only complete certainty.

3.3 Worksheet for BD design

The worksheet, "Partners," examines the merits prospective bioprospecting companies or brokers and can be used as criteria for comparison among companies or brokers.

Instructions for Table 4: Prospective Partners for Bioprospecting Agreements

Use this worksheet to evaluate the potential of prospective bioprospecting companies. Since the main goal of the company is financial profit, meeting conservation objectives may require some creativity, such as designating bioprospecting payments for conservation. Since the immediate rewards from bioprospecting to a source country are limited, it is important to examine the non-monetary benefits included in bioprospecting agreements. From a meeting with local professional societies, researchers, and community leaders, identify needs that may be satisfied by foreign companies. Bargain for and include any other benefits specified in a contract proposal.

EF 4: Biodiversity Prospecting:

Partnership Agreements

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Partner's Name:

CONDITIONS RANKINGS (1 - 5 scale)

CONDITIONS	VERY LOW [1]	LOW [2]	MEDIUM [3]	HIGH [4]	VERY HIGH [5]	Comments
Philosophy						
Commitment to conservation	☐	☐	☐	☐	☐	
Good conduct of bioprospectors	☐	☐	☐	☐	☐	
Interaction with indigenous communities	☐	☐	☐	☐	☐	
Financial Terms						
Immediate payment per sample	☐	☐	☐	☐	☐	
Recollection fees	☐	☐	☐	☐	☐	
Future royalties	☐	☐	☐	☐	☐	
Contributions to local funds	☐	☐	☐	☐	☐	
Non-monetary Benefits						
Technology	☐	☐	☐	☐	☐	
Training (manuals, tools)	☐	☐	☐	☐	☐	
Equipment	☐	☐	☐	☐	☐	
Employment for locals	☐	☐	☐	☐	☐	
Patronage of local industries	☐	☐	☐	☐	☐	

To open this excel sheet for use and modification, click here and go to sheet 4

3.4 Contract agreement on intellectual property and sample contracts

Instructions for Table BP 5: Designing / Implementing BP Agreements

This Worksheet helps to define basic roles and responsibilities for delivery of services and assurance of property rights. This definition not only has to be completed vis-à-vis the main partner (e.g. the pharma company and/or broker), but it must also gain consensus among the partners in the host country. From ministry, research institute, to local community. The ranking might help to set priorities and reach agreement. In the course of implementation, the same criteria should be monitored for success/satisfaction.

Obviously, such a worksheet is also useful for all other contract issues. The user is invited to create, enter and discuss such tables for any kind of supplementary conditions, such as:

- work organisation and sharing of benefits among villagers,
- establishment of a local management team and even a trust fund for long-term sustainable financing of biodiversity sensitive measures,
- roles, functions and responsibilities of such a trust fund, etc.

To open this excel sheet for use and modification, click **here** and go to sheet 5

BP5: Designing / Implementing PB Agreements: < Bioprospecting | < Guide-homepage

Deal Priority / Satisfaction Checklist for discussion with other partners before negotiation and for monitoring during implementation

Partner's Name (local community leaders, national research institute, etc.) :	**PRIORITY**					
	SATISFACTION	**RANKINGS (1 - 5 scale)**				**Comments**
	VERY LOW	**LOW**	**MEDIUM**	**HIGH**	**VERY HIGH**	
The contract should:	[1]	[2]	[3]	[4]	[5]	
establish confidentiality, which survives the term of the agreement						
prevent employee “siphoning” (recruiting employees of contractual partner or inducing them to provide confidential information)						
limit rights to and use of protected materials						
ensure access to testing site, data, and research results						
forbid reproduction of breed or testing procedures						
specify protection of original materials as well as subsequent byproducts, e.g., seeds, grain, plants and other materials produced from hybrids including DNA, RNA, pollen, etc.,						
ensure right to terminate agreement at any time						
insert a “grant back” clause for a free, non-exclusive license for inventions based on the agreement						
specify which state or nation’s laws will govern the agreement						
forbid the assignment of responsibility to third parties without first obtaining consent.						
... Enter your own criteria ...						

Sample contracts and agreements for biodiversity benefit sharing and intellectual property protection on genetic biodiversity resources are provided **here** .

4 IMPLEMENTATION

4.1 Assuring property rights

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

Patents cover machines, manufactures, compositions of matter, and processes; they prohibit making, using, selling, and importing without permission of the patent-holder, for a 20-year period (there is a narrow exemption for research). To be patentable, an innovation must be new, useful, and non-obvious. In addition, the inventor must make an "enabling disclosure," i.e., a disclosure of sufficient information about the invention that a person skilled in the relevant art can duplicate it. Patentability does not ensure commercial success: of a total of some six million patents granted in the United States, only a few thousand have resulted in products available in the market.
The benefits of patents include the affirmative protection against copying ("innocent" infringement not allowed, and extra penalties for willful infringement); the narrowness of the research exemption; the lack of a "saved seed" exemption, preventing competition from customers; the known term of protection; and the substantial jurisprudential experience in patent law. The disadvantages of patents, again from the seeker's point of view, are that the high standards make them difficult to obtain; enabling deposits create a potential "leak" of protected information; the term is finite (although known, and considerable at 20 years); and every standard of protection is a potential source of defense against infringement.

Plant Breeders' Rights (PBRs) were developed as an alternative, to deal more specifically with the special circumstances that plant breeders face. PBRs are similar to patents, having a 20-year term of protection (25 years for trees and vines), but have their own requirements and standards. The standards are that the breed in question must be new, distinct, uniform, and stable ("DUS standards"). "Distinct" is a kind of substitute for a patent's "non-obvious" requirement, and is a fairly low standard in that any new feature of the plant, even strictly visual features, can render it distinct; "uniform" means that all the plants in the breed are the same; and "stable" means that the plant is true-breeding generation after generation.

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

4.2 Compensating local communities

Most, even the successful bioprospecting agreements, have been concluded in a "legal vacuum." While this problem has been raised repeatedly, experts recommend there is no reason to wait for a complete and rational legal framework to evolve before beginning to explore the possibilities of bioprospecting. Indeed the experience gained in formulating bioprospecting agreements will help to inform the legislators as they seek sensible policies for the region.

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

the bioprospecting endeavor; therefore mechanisms for equitable compensation must be developed. The alternative is not only unfair exploitation of these communities, but the real possibility of actual hostilities.

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

The local communities' share of biodiversity prospecting proceeds are often best channelled into trust funds, which are managed subsequently for the long-term sustainablility of the local host community. These derive income across time from sample fees and up front payments, milestone payments, and royalties. Milestone payments are attached to various stages of drug discovery (e.g. screening, identification of active compounds) and development (e.g. pharmacology, safety studies, Phase I., II. and III clinical trials, or other steps linked to government regulatory requirements). As a promising sample moves through discovery and development, payments can automatically be made to a fund. Long-term fund revenues might come from licensing fees and royalties on net sales of a commercial product.

4.3 Criteria for Fund Disbursement and Compensation

Once the feasibility and design phases are settled, criteria for disbursement of income must be agreed upon. In some cases, such as Suriname, the returns are channelled to the communities via trust funds established at the beginning. In the case of biodiversity prospecting funds, the relative contribution of different stakeholders must be assessed, and difficult issues addressed such as: sharing of benefits with individuals vs. communities/institutions; distribution of benefits across communities and society, including to those not directly involved in research; and the most effective ways to promote conservation and sustainable development objectives.

Criteria such as the following can act as a starting point for the development of more detailed criteria used in the evaluation of grant proposals to the fund:

- Is the project in conformity with the underlying principles of the fund?
- Will it help to promote the conservation of biodiversity and sustainable development?
- Will it meet the priority needs of target communities/institutions/stakeholders, as defined by these groups?
- Does it recognize and reward the contributions of stakeholders?
- Will it promote the development of domestic and local capacity conserve biodiversity?

A clearly defined set of criteria, a reasonably simple application and transparent evaluation process, are all necessary in order to facilitate prompt response to potential grantees and the release of funds to approved beneficiaries or projects.

5 RESOURCES

5.1 Bibliographic references

To open a document via the internet, click on the URLs showing download locations. In addition some hyperlinked document names point to files available on this CD.

Aalbersberg, William G. et al. "The Role of a Fijian Community in a Bioprospecting Project." http://www.biodiv.org/doc/case-studies/cs-abs-fj.pdf

Columbia University SIPA-Environmental Policy Studies Workshop. 1999. Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements. Environmental Policy Studies Working Paper #4. Biodiversity Action Network (BIONET): Washington, DC. http://www.bionet-us.org/docs/agr-report.pdf or http://sipa.columbia.edu/func/eps/wkpaper-4.pdf

GBDI/IITA 2000. (The Global Biodiversity Institute/International Institute of Tropical Agriculture). **Training Course on Biodiversity, Biotechnology, and Law**. March 1-24, 2000. Ibadan, Nigeria. http://www.aaas.org/international/ssa/gbdi/

Guérin-McManus, Marianne et al. 1998. **"Bioprospecting in Practice: A Case Study of the Suriname ICBG Project and Benefits Sharing under the Convention on Biological Diversity."** Secretariat to the Convention on Biological Diversity, Fourth Meeting of the COP, Bratislava, Slovakia, May 1998. http://www.biodiv.org/doc/case-studies/cs-abs-sr.pdf

Kingston, David G.I. et al. 2000. "Biodiversity Conservation, Economic Development, and Drug Discovery in Suriname" in *Biologically Active Natural Products: Pharmaceuticals*. Ed. by Stephen J. Cutler and Horace G. Cutler. CRC Press: Boca Raton, London, New York, Washington, DC.

Laird, Sarah A. 1995. Fair Deals in the Search for New Natural Products. in: People and Plants Initiative by WWF, UNESCO, Royal Botanic Gardens, Kew, UK. Originally published May 1995 by WWF-World Wide Fund For Nature: Gland, Switzerland. http://www.rbgkew.org.uk/peopleplants/dp/dp1.htm

Laird, Sarah. 1998. **The Tools of the Trade in Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice**. A People and Plants Conservation Manual. Chapman and Hall Publishers: London.

Reid, Walter V. et al. 1993. **Biodiversity Prospecting: Using Genetic Resources for Sustainable Development**. WRI: Washington, DC. http://www.wri.org/wri/biodiv/bp-home.html

Simpson, R. David. 1997. Biodiversity Prospecting: Shopping the Wilds Is Not the Key to Conservation. Resources Feature, Winter 1997, Issue 126. Resources for the Future: Washington, DC. http://www.rff.org/resources_articles/files/biodprospect.htm

Simpson, R. David. 2001 forthcoming. **Bioprospecting as a Conservation and Development Policy: Overview and Insights from Three Cases**. OECD: Paris. Forthcoming (draft version not to be cited or quoted).

Supriatna, Jatna and Marianne Guerin-McManus. 1997. **Biodiversity Prospecting in Indonesia**. Conservation International: Washington, DC.

ten Kate, Kerry; Adrian Wells. 2001. Preparing a national strategy on access to genetic resources and benefit-sharing. A pilot study. Royal Botanic Gardens, Kew, UK/UNDP. http://www.undp.org/bpsp/thematic_links/docs/ABS_Manual_RBGK.pdf

World Intellectual Property Organization. 2000. **Case Studies on Intellectual Property, Biological Resources and Associated Traditional Knowledge**. WIPO: Geneva. http://www.wipo.int/globalissues/biotech/documents/pdf/cs_oct_2000.pdf

Intellectual Property and Genetic Resources - An Overview
http://www.wipo.int/globalissues/biotech/documents/word/ipgr002.doc

[This is a deliberately short list of key resources, but suggestions are welcome.]

5.2 Web sites

Bionet 2000 directory of web sites on biodiversity policy and law http://www.bionet-us.org/website.html

Convention on Biological Diversity maintains a highly informative website.
For Access to Genetic Resources and **Benefit-sharing** see
http://www.biodiv.org/socio-eco/benefit/
For **Traditional Knowledge**, Innovations and Practices, Instruments, Guidelines, Codes and Statements see http://www.biodiv.org/programmes/socio-eco/traditional/instruments.asp
National Biodiversity Strategy and Action Plan http://www.biodiv.org/world/reports.asp?t=ap

Indigenous Knowledge and Development Network (IK Network at CIRAN Centre for International Research and Advisory Networks) has nearly 4000 members and some 35 IK Resource Centres around the world. http://www.nuffic.nl/ik-pages/index.html

INBio Costa Rica's National Institute for Biodiversity Research http://www.inbio.ac.cr/en/default.html
A private non-profit organization participated in the best known example of bioprospecting with the US-based pharmaceutical firm Merck & Co. Ltd.

International Cooperative Biodiversity Groups http://www.nih.gov/fic/programs/icbg.html
Joint program of NIH, NSF, and the Foreign Agriculture Service of USDA. Integrating drug development, biological diversity, and economic growth.

Royal Botanic Gardens, Kew http://www.rbgkew.org.uk/index.html
Conservation programmes, horticultural databases, and the uses of plants

Rural Advancement Foundation International (RAFI): Bioprospecting/Biopiracy and Indigenous Peoples Advocacy. http://www.rafi.org/ or http://www.latinsynergy.org/bioprospecting.htm

From Plants in the South to Medicines in the North http://www.sum.uio.no/bioprospecting/BATeng.htm
A project by the Centre for Development and the Environment, University of Oslo. Bioprospecting for medicinal purposes

World Intellectual Property Organization (WIPO): Intellectual Property and Genetic Resources, Traditional Knowledge http://www.wipo.int/globalissues/tk/

World Trade Organisation: Fact sheet on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and pharmaceutical patents http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm

5.3 Contacts

Technical assistance

Randy Curtis, Director of Conservation Finance and Policy- Latin America and Caribbean Region, The Nature Conservancy

Marianne Guérin-McManus, Director of Conservation Finance, Conservation International Tel: 202-912 1289, Fax: 1-202-8875188,Email: m.guerin-mcmanus@conservation.org

Royal Botanical Gardens, Kew, see above

Sarah Laird SarahLaird@aol.com (not confirmed)

David Simpson, Resources for the Future, 1616 P Street NW , Washington, DC 20036-1400. Tel: 202-328 5078, Fax 202-939 3460. Email: simpson@rff.org

Dr. John Kilama, President, Global BioDiversity Institute, Inc. 19, S. Stuyvesant Drive, Wilmington, DE 19809-3433 U.S.A. Tel: 302-656 6439, Fax: 302-764-2809, E-mail: JKilama@Gbdi.org URL: http://www.Gbdi.org

Bilateral government donor officials (Please fill in and send to email below)

Canada:

European Union:

Finland:

France:

Germany: Andreas Gettkant, GTZ-Project Implementing the Biodiversity Convention, Dag-Hammarskjöld-Weg 1-5, P.O. Box 5180, 65726 Eschborn, Germany Tel: +49-6196-79-1280 Fax: +49-6196-79-7144. Andreas.Gettkant@gtz.de, http://www.gtz.de/biodiv

Japan:

Netherlands:

Switzerland:

United States:

United Kingdom:

5.4 Case Study references

The CBD Website hosts a range of case studies (the best ones are listed below) at http://www.biodiv.org/programmes/socio-eco/benefit/case-studies.asp and calls for more case studies for which excellent ToRs are provided at http://www.biodiv.org/programmes/socio-eco/benefit/call-action.asp

Suriname ICBG Project (See case study) http://www.biodiv.org/doc/case-studies/cs-abs-sr.pdf

Fiji (See Aalbersberg in references) http://www.biodiv.org/doc/case-studies/cs-abs-fj.pdf

Africa – ICBG: International Cooperative Biodiversity Group: Drug development and biodiversity conservation in Africa: Case study of a benefit-sharing plan. 1998 by Iwu, M. and Laird, Sarah A.for CBD. http://www.biodiv.org/doc/case-studies/cs-abs-icbg-africa.pdf

Nigeria and The Healing Forest Conservancy http://www.biodiv.org/doc/case-studies/cs-abs-ng-a.pdf

Brazil - PROBEM-Amazonia (the Brazilian Program of Molecular Ecology for the Sustainable Use of Biodiversity in Amazonia) encourages the development of regional biotechnology industries by establishing a $60 million Biotechnology Industrial Center in the Manaus Free Trade Zone. The objective is to attract investment (both national and foreign) in pharmaceutical products, cosmetic materials, food products, environmentally-friendly pesticides, enzymes of biotechnological interest, essential oils, anti-oxidants, natural dyes and fragrances (see Bayon et al. 2000: 27).

Brazil, Argentina, others - *Shaman Pharmaceuticals* in the U.S. raised US$100 million in capital to bio-prospect in co-operation with indigenous peoples. Patents on 2 drugs have been established thus far. *Andes Pharmaceuticals* seeks to build host countries' own capacity to screen biological materials through technology transfer agreements with universities or NGOs.

Ecuador - Pfizer tried to negotiate a similar arrangement as Merck with Costa Rica, but was unsuccessful.

Andean Community, Organisation of African Unity, U.S. International Cooperative Biodiversity Group Programme - Various policy and legal frameworks have been established at national and regional levels to regulate future bio-prospecting contracts, and to avoid further problems

with 'bio-piracy', the unauthorised exploitation of a country's biodiversity resources by foreign companies or researchers. A focus of such frameworks has been to ensure any benefits are shared with local communities, often repositories of the knowledge that enabled successful bio-prospecting in the first place (Moura Costa et al. 1999).

Indonesia Governance and Biodiversity: Weaving Resilience into the Web of Life - KEMALA project as an example of effective, strategic linkages between the biodiversity and governance sectors http://www.bsponline.org/publications//asia/kemala/newkemala.pdf

5.5 Case study summaries

While these case studies illustrate the considerable economic interest by pharma companies and general positive potential. even be it only for awareness generation regarding biodiversity values, they were particularly selected to illustrate to the readers also the critical, difficult aspects. It is no so much meant as a discouragement, rather it should motivate a better, professional analysis and preparation.

5.5.1 Costa Rica, InBio

(Quoted with kind permission from Norris/Curtis 2000, see above, TNC)

Perhaps the best known example of biodiversity prospecting as a source of income for conservation is the 1991 agreement between Costa Rica's National Biodiversity Institute (INBio) - a private, nonprofit organization - and the US-based pharmaceutical firm Merck & Co. Ltd. INBio agreed to provide Merck with chemical extracts from wild plants, insects, and micro-organisms from Costa Rica's protected areas. Merck would screen these extracts for their pharmaceutical potential. Merck paid 90 percent of the $1.1 million required to set up the sampling program, which trained and employed Costa Rican "parataxonomists," and agreed to provide technical assistance and training to help establish drug research capacity in Costa Rica. INBio would get royalties on any marketable products identified through the system, 50 percent of which would go to the government's National Park Fund. This agreement was a watershed in the history of biodiversity prospecting - the exploration of biodiversity for commercially valuable genetic and biochemical resources. INBio's agreement with Merck has now expired after several two-year renewals. Arrangements with other companies such as Bristol Myers-Squibb continue.

Simpson (2001, see above) acknowledges the eye-opening effect of these deals, but provides a more critical analysis of the financial side. No royalties have been paid to date. Though all contracts are estimated to have contributed approximately US$1.2 million to the Ministry of Environment and Energy and national conservation areas, and over $700,000 to universities, as well as $700,000 to other programs at INBio, less than 10% of the original million went directly to conservation activities.

For a position from the Instituto Nacional de Biodiversidad (INBio) itself on Biodiversity Prospecting see http://www.inbio.ac.cr/en/pdb/Prosp.html and other reports on their homepage.

5.5.2 Yellowstone, USA: A critical analysis

(summarised with kind permission from Simson 2001)

An enzyme from the hotsprings microorganism *Thermus Aquaticus* (*Taq*) is used in the biotechnology industry. The polymerase chain reaction (PCR) is a process by which DNA is copied and amplified. This technique is used in, for example, medical diagnosis and "DNA fingerprinting." *Taq* was first isolated in Yellowstone National Park. In 1997 Diversa, a San Diego based biotechnology company, entered into an agreement with the U. S. National Park Service (NPS) under which Diversa would pay the NPS $100,000, plus another $75,000 in kind, for the right to conduct research on microorganisms drawn from the Yellowstone hot springs. Royalties in an undisclosed amount were also specified in the event that a new product were developed. It was reported in 1998 that the NPS was considering over a dozen other such arrangements. NPSwas subsequently sued by the Edmonds Institute, a Seattle-based NGO, the International Center for Technology Assessment, and the Alliance for the Wild Rockies. This case illustrates a couple of troubling aspects.

First, there appears to have been considerable disagreement among environmental advocates as to the deal's merits. While Vice-President Al Gore had announced the deal himself on the occasion of the 125th anniversary of Yellowstone National Park as one in which industry could "do well by doing good," a court initially required an Environmental Impact Assessment be undertaken before Diversa could conduct its collection activity. Though samples taken were described as being of "teaspoon" size, the subsequent attracting of biotechnology researchers from around the world might have a larger impact. In 1994, dozens of microbiological research projects were underway, and virtually every week of the year some researcher is exploring Yellowstone's hidden resources.

Second, the plaintiffs were concerned that the public was not being adequately compensated. Mike Bader, Executive Director of the Alliance for the Wild Rockies claimed " . . . the National Park Service and the Department of the Interior . . . did a deal without the knowledge and consent of the American people . . . " The matter was ultimately resolved in favor of Diversa and NPS. Still, the conservation incentives afforded by the deal were negligible. Yellowstone has been designated as a National Park for over a hundred years. While the judge ruled, among other findings, that the Diversa agreement would "afford . . . monetary support for Park programs," the NPS has traditionally been precluded by law from appropriating funds received (for admissions and concessions for example), for its own budget. Thus the Diversa agreement would not have directly benefited Yellowstone, or the National Park System more generally.

Third, *Taq* enzymes from Yellowstone were the known source of compounds patented by Hoffman-Laroche and earning annual revenues in excess of $100 million. There are hot springs around the world. In this case, bioprospecting funds may have been attracted to the area in which they were needed least. Diversa is, positively viewed, active in other parts of the world, and has contracts with INBio in Costa Rica as well (see above). However, the money should urgently benefit conservation, as researchers come to Yellowstone because the other hotsprings of the world (in Japan, New Zealand, and Iceland, for example) have been degraded by geothermal use, bathers, and other stressors.

Fourth, even though the use of bioprospecting as a conservation policy is more germane in developing countries, it is striking that a deal could not be consummated without political controversy and judicial review even in a country where one might expect the conditions for successful transactions to be most favorable. While the court case was ultimately resolved in favor of Diversa and the NPS, this occurred only after a two-year delay and, one presumes, the accrual of significant litigation expenses. A cost that is more difficult to evaluate but probably at least as important is the negative publicity the parties received while the case was pending.

For another perspective on Yellowstone and the Diversa Corporation see the case study
http://www.biodiv.org/doc/case-studies/cs-abs-yellowstone.pdf

5.5.3 Mexico - Indigenous People Protest in Chiapas

Critical case study by Rural Advancement Forum International distributed freely in many fora, here quoted in part from http://www.projectcensored.org/c2001stories/18.html*)*

"Genetic resources are seldom "raw materials" in the traditional sense, because they have been selected, nurtured, and improved upon by farmers and indigenous peoples over thousands of years. While scientists and researchers searching for valuable genetic material and traditional knowledge about them use the term "bioprospecting," critics call it "biopiracy." They use the term for the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions who seek exclusive monopoly control (patents or intellectual property) of these resources and knowledge.

In this sense, the efforts of indigenous peoples in Chiapas, Mexico, to stop a U.S. government—funded bioprospecting project illustrates the larger struggles of communities and nations to control their sovereign genetic resources and knowledge in a world where biological products and processes are being privatized and patented.

In December 1999 Rural Advancement Foundation International first wrote about eleven indigenous people's organizations under the umbrella of the Council of Indigenous Doctors and Midwives from Chiapas who were demanding the suspension of the International Collaborative Biodiversity Group–Maya (ICBG-Maya). The ICBG-Maya is a U.S. government–funded $2.5 million, 5-year project aimed at

the bioprospecting of medicinal plants and traditional knowledge of the Mayan people. The project is led by the University of Georgia, in cooperation with a Mexican university research center, El Colegio de la Frontera Sur (ECOSUR), and Molecular Nature Ltd., a biotechnology company based in Wales, U.K. The ICBG's self-stated goal is to promote drug discovery from natural sources, biodiversity conservation, and sustainable economic growth in developing countries.

The council believes that the bioprospecting project and the pharmaceuticals they seek to discover will not ultimately benefit the communities that have managed and nurtured these resources for thousands of years. According to Sebastian Luna, a spokesperson for the council, "the project explicitly proposes to patent and privatize resources and knowledge that have always been collectively owned. …Besides being totally contradictory to our culture and traditions, the project creates conflict within our communities as some individuals, pressured by the grave economic situation, collaborate with the researchers for a few pesos or tools."

After one year of fruitless talks with the ICBG-Maya and Mexican government authorities, the council held a press conference on September 12, 2000, to again demand termination of the Chiapas project and all bioprospecting projects in Mexico. Shortly thereafter, the Mexican government denied the ICBG-Maya permission to conduct bio-assays (that is, analysis of bioactive compounds) on plants collected in Chiapas. While the ICBG project is not officially terminated, its activities have been temporarily suspended.

RAFI believes that biopiracy is the inevitable consequence of international agreements such as the Biodiversity Convention that have no real capacity to regulate bioprospecting or to ensure equitable benefit-sharing with local communities. Without agreed rules and monitoring mechanisms, all bioprospecting becomes biopiracy. RAFI's web site (www.rafi.org) provides regular updates on biopiracy worldwide. Together with partner civil society organizations, RAFI has produced the Captain Hook Awards: 2000—a poster highlighting the most egregious cases of biopiracy as well as the most exemplary actions by civil society and governments to halt these practices.

The circle of knowledge about life patenting needs to widen. It is not necessary to be a geneticist or a lawyer to understand the basics of patent law, or to see the natural world becoming commodified via the patent system. Rather than insisting that other countries change their patent laws to accommodate U.S. life patents, citizens can insist that the US change its laws to harmonize with the rest of the world. There are a handful of organizations that offer educational materials and activist resources for those interested in learning more.

Council for Responsible Genetics (CRG):	www.gene-watch.org
Rural Advancement Foundation International (RAFI):	www.rafi.org
Greenpeace International and Greenpeace Germany:	www.greenpeace.org
Institute for Agriculture and Trade Policy (IATP):	www.iatp.org