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UNU-IAS Pocket Guide

Access to Genetic Resources, Benefit Sharing and Bioprospecting

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Foreword

There has been much debate on what is needed to achieve the third objective of the Convention on Biological Diversity (CBD) on access to genetic resources and benefit sharing (ABS). The issue of access to genetic resources and benefit sharing and associated issues such as traditional knowledge and intellectual property are being debated both within the CBD's processes and other forums such as the World Intellectual Property Organization Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC). The CBD processes continue to be the dominant fora however, and a major achievement of the debates was the adoption of the Bonn Guidelines which sets out a range of voluntary measures for both "provider countries" and "user countries" to achieve the CBD's ABS objective.

The World Summit on Sustainable Development (WSSD) mandated CBD to negotiate and

agree on an international regime on benefit sharing. Parties to the CBD began working on development of the regime since 2002. It was decided during CBD Eighth Conference of Parties in Curitiba that the negotiations for the regime should be completed by 2010. Despite progress in the negotiations of the international regime and the quickly approaching 2010 deadline, several stakeholders are unfamiliar with the international ABS debates. Sometimes the understanding of the principle that CBD calls for, facilitation of access, itself is misunderstood as regulation of access. Several country experiences indicate that a poor understanding of ABS principles results in inefficient policy development. The ABS debates can be difficult and given the social, environmental and ethical implications of any ABS regime it is important that all stakeholders, especially local communities in provider countries understand the basic issues and terminologies associated with the debates. This pocket guide thus

seeks to provide a simple and concise summary of the ABS and bioprospecting issues and a glossary of the terms being used. It is hoped that the guide will be used by local stakeholders and representatives to the Convention who are new to the debates as a quick introduction and reference to the issues.

The United Nations University Institute of Advanced Studies (UNU-IAS) was established in 1996 as a research and training centre of UNU to undertake research and post-graduate training on emerging issues of strategic importance to the United Nations and its Member States. Development of this pocket guide is part of the wider Bidiplomacy programme of the Institute. The programme has developed objective information documents for the international negotiation and also contributed to the work of the Ad-Hoc Open-ended Working Group. Several roundtable discussions on ABS and bioprospecting have also been convened

with various stakeholders and policy makers.

I hope this guide will contribute to an initial understanding of the issues being debated and help further negotiations of the regime at international level based on clear national understanding.

A. H. Zakri
Director, UNU-IAS

Introduction

For several thousands of years humankind was freely using as well as exchanging biological and genetic resources around the world for betterment of life. This situation has now changed due to emergence of issues like privatization of resources and knowledge through components like intellectual property rights (IPRs) and patents. The UN Convention on Biological Diversity (CBD) which came into force on 29 December 1993 outlines clear principles on access to biological and genetic resources and equitable sharing of benefits from using such resources. The Access and Benefit Sharing (ABS) provisions of CBD are based on the principles of prior informed consent (PIC) on access as well as use of resources with people who have such resources through a set of mutually agreed terms(MATs).

World-wide, countries are developing and implementing a range of access and benefit sharing actions. However, such actions need to be more participatory where different stakehold-

ers like local communities, local governments, research and development practitioners, private sector, legal professionals and policy makers make informed inputs. As ABS is a somewhat new as well as important issue with ethical, social, environmental and economic implications for the providers of the resources, a clear understanding of the issues is needed. For informed debates to ensue, stakeholders should understand how to: value-add to the available resources; negotiate ABS terms with users and providers of the resources; and ensure that benefits are gained by the local communities and translate into conservation actions.

Keeping this in mind, this ‘Pocket-Guide’ was designed to provide a simple and user friendly resource to stakeholders who are not very familiar with ABS policies and the global debates. The language is simple and attempts are made to provide an overview of ABS issues at different levels.

Definitions

(mostly based on CBD 1994)

Access

Access to genetic resources means to obtain samples of biological and/or genetic material from areas within national jurisdiction for purposes of research on conservation, commercial application or industrial use.

Benefit Sharing

Benefit sharing refers to equitable sharing of benefits, on agreed terms, arising from the use of biological and/or genetic material with the providers of the material.

Bioprospecting

Bioprospecting or prospecting refers to collection, research and use of biological and/or genetic material for purposes of applying the knowledge derived there from for scientific and/or commercial purposes. Bioprospecting entails the search for economically valuable genetic and biochemical resources from nature.

Biological Diversity

The variability among living organisms from all sources including terrestrial, marine and other aquatic ecosystems. The diversity includes variability within species (genetic diversity), between species (species diversity) and ecosystems (ecosystem diversity).

Biological Resources

Includes genetic resources, organisms or parts of it, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

Biotechnology

Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Biopiracy

The appropriation of biological resources with-

out prior informed consent of owners or local people or government.

Country of Origin

The country from where the genetic resources and/or biological material originated. A country of origin can be a primary or secondary centre of origin for the material.

Country Providing Genetic Resources

The country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.

Commercial Use

Any use of biodiversity and/or genetic resources, their products or derivatives for monetary gains that includes selling in the market.

Domesticated or Cultivated Species

Species in which the evolutionary process has

been influenced by humans to meet their needs.

Ecosystem

A dynamic complex of plant, animal, fungal, and micro-organism communities and their associated non-living environment interacting as a functional unit; the organisms living in a given environment, such as a tropical forest, a coral reef or a lake, and the physical part of the environment that impinges on them.

Ex-situ Conservation

The conservation of components of biological diversity outside their natural habitats.

Genetic Material

Any material of plant, animal, microbial or other origin containing functional units of heredity.

Genetic Resources

The genetic material contained in the biological diversity of actual and/or potential value.

In-situ conditions

Conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

Material Transfer Agreement

A set of administrative procedures agreed by the provider and user of genetic resources on how the accessed material could be sourced, used as well as issues of compliance to benefit sharing principles.

Mutually Agreed Terms

A set of terms and conditions agreed between the provider and user of genetic resources for prospecting purposes.

Patents

The provision to an inventor of a temporary, limited monopoly during which period the inventor may exploit the invention from any

direct competition. Patents on their own do not grant anything. They only provide the legal means by which the inventor can prohibit another from using the invention. Usually these are country specific.

Prior Informed Consent

A set of administrative procedures for deciding on whether to grant access to genetic resources on defined terms.

Royalties

Sources of payment for an inventor who holds the patent for a particular product or process. Royalties accrue when someone uses the patented product or process.

Traditional Knowledge

The knowledge, innovations and practices of local and indigenous communities relevant to conservation and sustainable use of biological diversity.

Third Party Transfer

Transfer of material, knowledge and/or products arising from access to a party other than the user as identified in the PIC and MAT agreements.

Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (CBD) is one of the most comprehensive international agreements, signed by 190 countries, to conserve world's biological diversity, sustainably use the diversity and share the benefits of such use equitably. The CBD suggests ways in which countries could facilitate access to biological resources through Article 15 and recommends that countries make appropriate legal, administrative and other provisions to provide access to resources based on prior informed consent and mutually agreed terms. It also encourages the providers of resources to enter into a material transfer agreement with the users which defines conditions of further development and use of biological resources.

The principles on which the benefits accrue from use of the resources form the basis of a benefit sharing agreement. Decisions on who has the right to provide access, terms and conditions of access and benefit sharing are left for countries to define. The involved stakehold-

ers could range from the State to communities and their representatives.

The ABS provisions under CBD are still being hotly debated since access and use of genetic resources were never previously under the purview of an international regime. Experiences from countries are still unclear, making the ABS discussions at times very complex. However, some national ABS related actions and agreements were already in place before the CBD came into force.

Article 15 of the CBD addresses the terms and conditions for access to genetic resources and benefit sharing. Since 1993, countries who are Parties to the CBD began working on developing a set of internationally agreed principles on ABS which resulted in the adoption of the Bonn Guidelines on ABS in 2002 during the Sixth Conference of Parties to the CBD. The guidelines are expected to assist countries and other relevant stakeholders in develop-

ing and implementing ABS strategies.

Bonn Guidelines on Access and Benefit Sharing

The Bonn Guidelines are voluntary and seek to be practical, flexible and transparent, while responding to evolutions in the ABS international governance debates.

The Guidelines identify: steps in accessing genetic resources and benefit sharing; basic requirements for mutually agreed terms; and the roles and responsibilities of providers and users. The Guidelines also stress the importance of developing administrative, legal and regulatory mechanisms at the national level.

Several countries have developed national ABS provisions using the Bonn Guidelines. These voluntary guidelines are recognized as a useful first step in the implementation of the CBD's ABS provisions. They will be reassessed and refined as there are relevant developments on

related issues (such as traditional knowledge and technology transfer). Other approaches, complementary to the Bonn Guidelines, to assist with the implementation of the ABS provisions of the Convention are also being developed, not least being the negotiation of an international regime on access and benefit sharing.

Status of Access and Benefit Sharing Discussions

A recent study conducted by IUCN covering 42 countries in the Pacific region revealed that only 10 countries have developed a national ABS law or policy, 24 are in the process of developing ABS laws and policies and 8 are not engaged in any systematic process leading to the development of ABS frameworks. The study concluded that many countries were struggling to develop national ABS laws and policies. Common factors that prevented the development of effective policies include a lack of technical expertise and weak govern-

ment structures and political support. The study also noted that there is fragmentary knowledge of: the processes of science and discovery in bioprospecting and biotechnology; intellectual property; and contract terms. This is compounded by a shortage of information gathering, exchange, and dissemination.

Some countries like Philippines, South Africa, Costa Rica, Brazil, India and Peru, which are part of the Like-Minded Megadiverse Countries Group (LMMC), have devoted significant time and resources to developing ABS regimes.

Their experiences provide important insights on the necessary measures for developing an effective ABS regime. Although they have developed different ABS strategies for generating value and ensuring equity, they all have a strong commitment to capacity building. Countries that do not provide an environment that nurtures the development of the nec-

essary skills will be unable to negotiate fair bioprospecting deals even though there is an international regime. Furthermore, without prioritizing capacity building, it will be difficult to drive national development of new uses for their biodiversity and thus derive great benefits from the biotech revolution. Moreover, such capacities will be essential for distinguishing real from “imagined” barriers in ABS discussions.

Value addition to Biodiversity - Bioprospecting

Today, approximately 80% of the world's population relies on traditional plant-based medicines for primary health care. The remaining 20% also depends on plant products for health care.

It is estimated that about 25% of prescription drugs dispensed in the United States contain plant extracts or active ingredients derived from plants. Out of a total of 520 new drugs ap-

proved for commercial use between 1983 and 1994, 30 were new natural products and 127 were chemically modified natural products.

Some prominent plant-based medicines widely used today include:

- Quinine – the anti-malarial drug from the bark of *Chincona* species;
- Morphine – the analgesic from the opium poppy;
- Digoxin – for heart disorders from *Digitalis purpurea*;
- Reserpine – the anti-hypertensive agent from *Rauwolfia serpentine* which is traditionally used for snakebites and other ailments;
- Ephedrine – an anti-asthma agent from *Ephedra sinica*; and
- Tubocurarine Chloride – the muscle relaxant from curuare, an extract of *Chondrodendron tomentosum*, a plant from the Amazon used a source of arrow poison (GB&IITA, 2000).

Microorganisms have also been extremely important in drug applications, ushering in the ‘golden age of antibiotics’.

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

Several key anti-cancer agents have been produced from natural sources with more than 60% of cancer drugs on the market being based, at least in part, on natural products. These include:

- Vinblastine and vincristine – isolated from the Madagascar periwinkle, *Catharanthus roseus*;

- Etoposide and teniposide – semi-synthetic derivatives of the natural product epidophyl-loxin;
- Taxol – initially isolated from the bark of *Taxus brevifolia* in the North Western United States.

Natural products will continue to be an important part of drug development well into the future. Despite the great successes already achieved in natural products chemistry and drug development, we have barely begun to tap the potential of our molecular diversity. Only an estimated 5 - 15% of the 250,000 species of higher terrestrial plants in existence have been chemically and pharmacologically investigated in a systematic manner. The percentage of insects, marine organisms, and microbes investigated is still low. In the case of microbes, it is estimated that 95 - 99% of existing species are currently not even known, never mind analyzed (GBI&IITA, 2000).

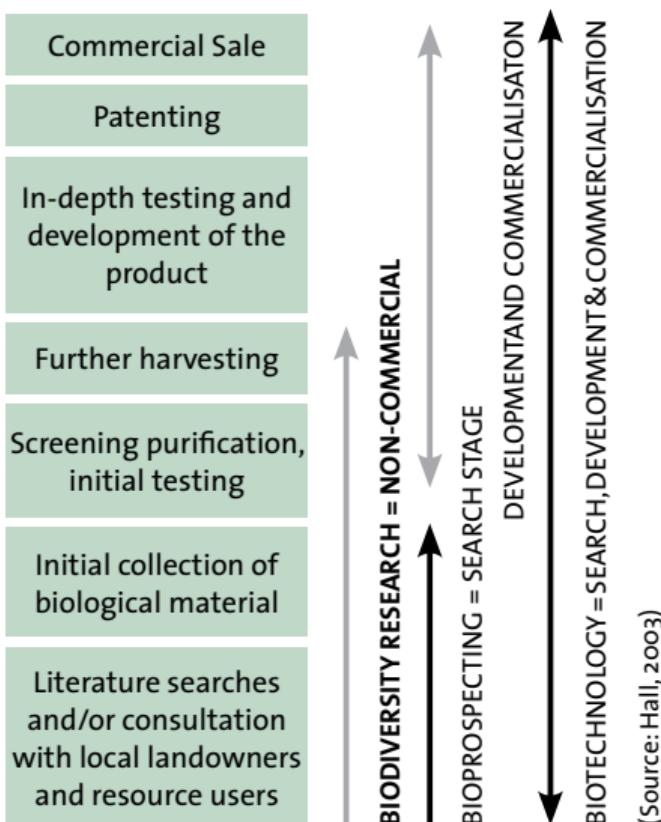
Currently, there is great interest in exploring extreme habitats for useful enzymes from microbes, including acidophiles (from acidic sulfurous hot springs), alkalophiles (from alkaline lakes), halophiles (from salt lakes), thermophiles (from deep sea vents), and psychrophiles (from extremely cold waters).

Synthetic methods can complement natural products in the search for new drugs. For example, with combinatorial biosynthesis, there is the potential to generate novel molecules that enhance known bioactivity from natural products and generate entirely new bioactivity through manipulation of biosynthetic pathways.

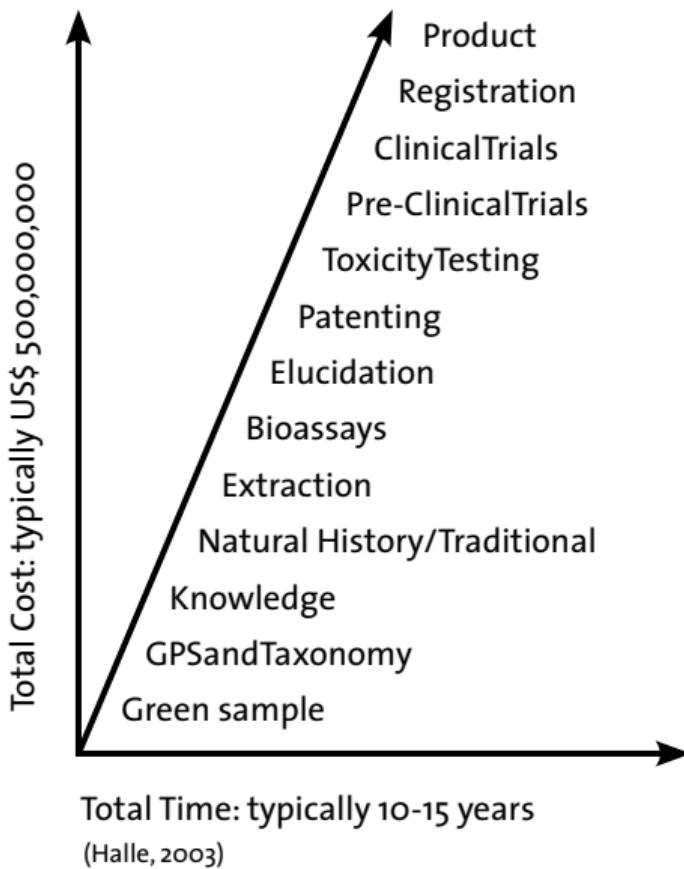
Synthesis of natural products, focusing on the synthesis and modification of drugs from natural sources that are difficult to isolate in sufficient quantities, can sometimes improve the essential active features of natural products.

Steps in prospecting

The following figure explains the steps involved in bioprospecting.



Steps and Costs in Bioprospecting



Biodiversity, Bioprospecting and ABS

The access and benefit sharing provisions within the CBD seek to facilitate the sustainable use of biological and genetic resources as well as find new uses for existing resources. Research and development activities for value addition to biodiversity are thus necessary. Bioprospecting is the key link between having the resources, using the resources and generating benefits for communities and stakeholders.

Benefits of defining an ABS regime

Defining an ABS regime can have several benefits. These can range from enhancing conservation efforts through targeted access and sustainable uses, to recognition of ownership and income generation to support such efforts.

A national ABS regime can help countries to better deal with obligations under the CBD and other instruments such as the rules of the World Trade Organization (WTO). It can facilitate collaborations between people who

have the genetic resources and those who can provide further value addition. The national regime can also support the development of better partnerships between: the private and public sector; communities and researchers; and policy makers and non-governmental organizations (NGOs). A national regime can also enhance the awareness of the resource uses and occurrence and facilitate capacity building. An ABS regime, with the potential to generate cash or in-kind benefits, can support rural development and poverty reduction programmes.

(Mis)conceptions about Bioprospecting and ABS

There are several (mis)conceptions about ABS. Common misconceptions include:

All biodiversity and genetic resources accessed can be converted into huge monetary gains

If this was true, then poverty would have been eradicated from areas with high biodiversity.

The values of biodiversity and genetic resources can be both direct use values as well as indirect use values such as provision of services (better watersheds, secured soil health, usefulness of pollinators etc.). Thus all values of biodiversity are not monetary. Nevertheless, several components of biodiversity provide us with opportunities to turn resources into products. This often requires enormous investments of resources – time, money and energy. It is therefore still impossible to tap all the potential benefits of biodiversity and genetic resources.

Therefore it is inaccurate to say that all biodiversity has a monetary value. Nevertheless, several components of biodiversity provide us with opportunities to turn resources into products. The chance to turn the value of resources into products needs enormous investments of time, resources, energy and money. This is why it is still not possible to entirely tap the potential benefits of biodiversity and genetic resources.

Provision of access guarantees the generation of money and profits

There are several intermediary steps and actions between accessing the resource, developing a product, placing it into the market and generating profits. Providing access does not guarantee immediate product development and accrual of benefits. Only an estimated 5-15% of the 250,000 species of known higher terrestrial plants have been chemically and systematically pharmacologically investigated.

The investment needed from the time a plant or genetic material is sourced, to the time useful products or derivatives find a market is estimated to be about 500 million USD over as long as 10-15 years.

Benefits are about the amounts of money that can be secured

Benefits can be both monetary and non-monetary. The discussions on what benefits are to be gained should always be done with the community providing access to the resource and should be based on an assessment of local needs. Successful bioprospecting and benefit sharing experiences reveal that often the benefits gained include some amount of money and locally relevant development activities. Careful agreement on the kind, volume and timing of benefit sharing increases the likelihood of the providers of the resources gaining the best out of the provision of access.

ABS regimes should restrict access to genetic resources

Unfortunately, this is a frequent assumption. However the ABS provisions of the CBD are clearly for facilitating access to genetic resources. Therefore ABS regimes should be facilitative rather than restrictive. Benefits are derived from the regime when the resources are accessed and used. However overly restrictive access discourages the very access that may support conservation efforts.

ABS regimes can stop misappropriation or unauthorized use of genetic resources

This is true to a certain extent. Access and benefit sharing regimes, if implemented effectively can avoid misappropriation or unauthorized use of genetic resources. However, the mere establishment of an ABS framework does not guarantee a halt to existing misappropriation or unauthorized access and use.

The ABS regime should enhance an understanding of the issues surrounding the use and ownership of the resources, build capacities of local communities and mainstream legal and regulatory instruments on genetic resources into national decision making. If these are done, then the ABS regime will support achievement of conservation targets through sustainable use and benefit sharing.

Having an ABS regime brings thousands and millions of dollars

As in the case of bioprospecting, it is erroneous to believe that having a national ABS regime would ensure making of money by the community and country providing the resources. The ABS regime will only facilitate bioprospecting or use of biodiversity and support an equitable way of sharing the benefits of use if it is supported by suitable policies and regulations, research and development (R&D) investments and a proper assessment of potential markets and supply.

Having an ABS regime strengthens the country's ownership of its resources

This has been the understanding of countries and some stakeholders that having an ABS regime ensures the establishment of sovereignty over its biodiversity. This is partly true since the regulatory aspect of ABS provides the framework within which people can use the country's biodiversity. Non-national agencies and individuals need to agree on the national principles and regulations on access and benefit sharing in order to access and use the genetic resources.

Providing prior informed consent (PIC) and agreeing on mutually agreed terms (MAT) ensures the flow of money into communities

As noted earlier, provision of access does not guarantee any monetary gain or return. Even after a patent has been established for a product or process based on the access, the

resource user might not find a market or appropriate conditions that facilitate the sale or commercial activities. Monetary benefit sharing will most likely only occur when the product or process makes a commercial gain.

Having an ABS regime enhances community rights and ensures their participation in conservation

Not necessarily so. This will only happen if the ABS regime is developed with community participation and empowerment, focusing on the benefits that the community can gain. National regulations relating to rights over biodiversity, traditional knowledge and genetic resources should also be supportive of the ABS regime. Effective participation and benefits of access cannot be realized unless communities are empowered and their awareness and capacity to participate are raised.

Bioprospecting and ABS discussions limit the freedom of researchers and scientists to conduct research activities as before

Again this has been a general complaint against the ABS regimes of several countries. To a certain extent this could be true, as actions at national and local level that were never regulated/facilitated will now be undertaken within a regulatory and policy framework, making research and collaboration more responsible and responsive to national interests.

If stakeholders understand the facilitative nature of ABS regimes, local research and development need not be compromised. An effective national ABS regime will enhance collaboration and cooperation within and between countries.

Intellectual Property, ABS and Bioprospecting

Some of the successes in bioprospecting can be attributed indigenous peoples and communities' prior knowledge of uses of plants and animals. Such knowledge increases the likelihood of developing a purified drug or compound and minimizes the time and resources needed to screen, identify and isolate compounds and apply them to different uses.

Discussions on intellectual property rights are now focusing on ways to protect the communities' traditional knowledge of the usefulness of plants and animals.

Debates are ongoing under the CBD and the Trade Related Intellectual Property Rights (TRIPS) regime to ensure that any application, which seeks an intellectual property protection such as a patent, should also disclose the source of origin of the material and associated knowledge in order to obtain the patent. Although there is some agreement on this issue under the CBD, it is still unresolved

under the TRIPS debates on ensuring the disclosure of origin of the material and associated knowledge.

There are also some pre-conceived ideas on the ways in which one can obtain intellectual property protection of genetic resources. Often the understanding has been that one needs to take a patent to protect such a right. This is not the only possibility. People who are prospecting can opt for other forms of protection of intellectual property, such as requesting for a license, geographical indication, trade secret, trademark, or plant variety protection.

Sovereign Rights over genetic resources

The country's constitution and other legal provisions define the ownership of its genetic resources and biodiversity. Ownership can lie with the state, private parties, with communities or a combination of these. Therefore, it is important to define who owns the biological

resources before ABS negotiations and even during the development of the ABS regime.

The rights and obligations of each owner should be clearly defined when developing ABS terms and conditions. Generally, the ABS negotiators should appreciate that on the providers side there is a wider objective of community empowerment and conservation.

Key Stakeholders in ABS and Bioprospecting

Key stakeholders in the ABS and bioprospecting debates include local and indigenous communities and their representatives, local NGOs, scientists and research communities, provincial authorities, legal professionals and counsels, policy makers, private sector and multinational companies.

The roles, responsibilities and information needed by each stakeholder group differ. They are not equally involved in all stages of the bio-

prospecting activity or in implementation of the ABS terms. As their level of participation and entry differ, it is important that their roles are clearly defined and understood early in the process.

How to get Prior Informed Consent (PIC)

Prior Informed Consent (PIC) should be sought from the owners of the resources. Although procedures differ across countries, generally the PIC should be sought once the user of the resource makes an application for access. Consent discussions should be completed before access agreements and material transfer agreements are finalized. In some countries like Costa Rica, PIC procedures apply both at the national and sub-national or local levels. In giving their prior informed consent the owners of the genetic resources are agreeing to provide the resources or access to the resources under defined conditions and terms.

Meaning of Mutually Agreed Terms (MAT)

After consent for access has been granted, the next step is to agree on a set of terms and conditions on which access will be provided. The stages and actions involved in the prospecting and the kinds of benefits need to be defined through mutually agreed terms. As with the provision of PIC, the mutually agreed terms need to be negotiated with the owners of resources and the users using a set of non-negotiable terms and some negotiable ones. Generally, the details of such terms are defined in the material transfer agreement.

Developing a Material Transfer Agreement (MTA)

The CBD Bonn Guidelines define the elements of Material Transfer Agreements (MTAs) as the following:

Introductory provisions

- Preamble statement
- Legal status of provider and user of genetic resources
- Mandate of the provider and if appropriate the user

Access and Benefit Sharing provisions

Definitions

- Descriptions of resources covered by the MTA
- Permitted uses, including potential uses of genetic resources and their products or derivatives under the MTA (eg. research, breeding, commercialisation etc.)
- Statement for information and permission needs for change of use than the original

- one intended at the time of access
- Statement on IPR provisions and related conditions
 - Terms of benefit sharing arrangements, including commitments to share monetary and non-monetary benefits
 - Provisions for third party transfers and conditions related to these
 - Responsibilities related to environmental impacts

Legal provisions

- Obligations to comply with MTA
- Duration of agreement
- Notice to terminate the agreement
- Clauses that might serve after termination of the agreement
- Enforceability of clauses
- Description of events limiting liability of either party
- Dispute settlement arrangements
- Assignment of transfer of rights

- Assignment, transfer or exclusion of the right to claim IPRs and property rights over the genetic resources received through the MTA
- Choice of law
- Confidentiality clauses
- Warranty

Benefits and its kinds

According to the Bonn Guidelines, monetary and non-monetary benefits could include:

Monetary benefits

- Access fee/fee per sample collected or acquired
- Up-front payments
- Milestone payments
- Payments of royalties
- License fee in case of commercialization
- Special fee (trust funds etc.)
- Salaries and others mutually agreed
- Research funding
- Joint ventures
- Joint ownership of relevant IPRs

Non-monetary benefits could include

- Sharing of research and development
- Results collaboration and cooperation in research and development
- Participation in product development

- Collaboration and cooperation in education and training
- Admittance to *ex-situ* facilities of genetic resources and databases
- Transfer of knowledge and information in concessional terms
- Capacity building activities
- Specific and targeted training
- Access to scientific information in preferential terms
- Contributions to local development plans and economic activities
- Social recognition
- Joint ownership of IPRs

Possible elements in a national ABS regime

- Principles and Objective
- Provisions to integrate into national planning
- Terms and definitions
- Legal status of resources
- Scope of the regulatory regime
- Administrative provisions of the regime
- Procedures for establishment and implementation of the regime
- Financial information
- Prior informed consent
- Mutually agreed terms
- Material transfer agreement
- Compliance provisions
- Liability and compensation
- Enforcement

Linkages between ABS and Development

International Regime

During the World Summit on Sustainable Development (WSSD) that was held in 2002, countries agreed to develop a 'International Regime' on ABS under the CBD. Since then, countries are discussing the development of the Regime including its scope, status, elements and operational principles.

In general, there is an agreement that the Regime will be developed based on the experiences of countries on bioprospecting and benefit sharing and that the Bonn Guidelines will be used as a framework to further discuss the elements of the Regime. COP 8 meeting of the CBD in 2006 decided to finalise negotiations for developing the International Regime by the year 2010.

Sustainable Development

One of the over-arching principles that resulted in the establishment of Multilateral

Environmental Agreements (MEAs) has been the need to link conservation with development. The CBD's access and benefit sharing principles reflect the need for sustainable use of genetic resources and the sharing of benefits from such use. As the Convention and its ABS provisions are based on principles of ethics and equity, its implementation is seen as a contributor to sustainable development.

Millennium Development Goals (MDGs)

The Millennium Development Goals (MDGs) are a set of eight goals adopted by countries around the world to achieve sustainable development by the year 2015. The MDGs are developed to include a set of targets and indicators for countries to assess their progress towards achieving the goals, having 1999 as the base year. MDG 7 and 8 are particularly relevant to the CBD's implementation as they deal with environmental sustainability and development partnerships respectively. It is therefore

important that stakeholders recognize the link between national actions on ABS and MDG achievement.

Case studies on bioprospecting using ABS principles (Balakrishna 2005)

The Inbio-Merck Agreement

This is perhaps the most cited bioprospecting and ABS agreement. The initiative started even before the CBD was designed and adopted. In this agreement, the Ministry of Environment and Energy of Costa Rica agreed with the National Institute of Biodiversity (InBio) to work on ABS and bioprospecting issues getting in return 10% of all bioprospecting budgets and 50% of royalty income InBio gets.

InBio provides access to the biodiversity of the country through mutually agreed terms to prospectors, receiving in return a revenue of about 264,000 USD per year on an average since 1991.

InBio also entered on an agreement with Merck & Co., providing access to the biodiversity of Costa Rica, getting a flat fee for providing access and a certain amount of royalty from the company for the products developed. The

benefits were discussed between the company, InBio and the Ministry and it was agreed that these would be both monetary and in-kind training for taxonomists.

The Arogyapacha Story

This initiative also pre-dates the CBD's ABS development. In a unique partnership, scientists of Tropical Botanical Gardens Research Institute (TBGRI) granted a local company the license to manufacture and sell a product derived from the plant *Trichopus zeylanicus*, which has energy boosting properties.

Although this agreement was between the institute and the company, the institute recognized the traditional knowledge of the local community (Kani Tribe) as critical for the prospecting to happen and agreed to share the license fee and royalty payments with the tribe. Although the initiative ran into some bureaucratic problems, now they are solved and

the renewal of license after the initial period of seven years resulted in better revenues for the institute and the community.

The Aguarunas Case

In Peru, the Aguarunas people negotiated a know-how license with Searle where the community would pass on the medicinal plants and the associated knowledge of use to the company in exchange to receive a know-how license fee. This fee that would be paid irrespective of the use of the plant or knowledge is called the milestone payment. This license to Searle is non-exclusive in that the Aguarunas hold the right to use, share, sell or transfer the plants as they wish. Therefore the legal ownership of the material is not a pre-condition for the communities to benefit.

Case studies on bioprospecting not based on ABS principles

The Enola Bean Case

In early 1990, a researcher of Prod-Ners INC. in USA collected samples of yellow beans from Mexico to USA and planted the samples in his field. After self-pollination and selection of the beans for several generations, Prod-Ners Inc. filed a patent for development of a new variety of yellow beans. Later, a plant variety protection was also taken on this variety with an exclusive monopoly patent on growing or importing the yellow bean into the United States.

The International Centre for Tropical Agriculture (CIAT) along with Mexican government and several NGOs filed a case against the patent in USA requesting revocation of the patent on the bean in the year 2000. This has been a classic case of access and use of material without acquiring PIC and violating the sovereign rights of a country while collecting genetic resources.

Case of Hoodia cactus

The San people in South Africa and Zimbabwe were using Hoodia Cactus, a plant that grows in the semi-deserts of South Africa, Bostwana, Namibia and Angola. This plant has a natural appetite suppressant. Scientists from the South African Council for Scientific and Industrial Research (CSIR) conducted some tests on Hoodia cactus and isolated an appetite suppressant molecule and patented the same. In 1997 CSIR sold the patent to a pharmaceutical firm called Phytopharm who in turn sold the rights on the molecule to Pfizer for 21 million dollars in 1998.

Realising these transactions after Pfizer acquired the rights on the molecule the San people along with a lawyer and an NGO threatened action against CSIR for not keeping them informed on the outcomes of research and threatened to file a law suit against CSIR. Meanwhile Phytopharm claimed that CSIR made them believe that the San people were

extinct and thus there was no discussion to secure PIC on the traditional knowledge from the San people during the transactions.

CSIR then came to an agreement with San people to offer them with 6% of profits from CSIR along with a range of offers including employment opportunities. However, in 2003 Pfizer stopped research on the molecule and has been unable to find a new partner to make a marketable product. This is a case where the State failed to recognize the need to seek PIC and establish a MAT contract with local holders of the associated traditional knowledge.

The Maca case

The Maca is a traditional Andean food and medicinal crop cultivated by the Quechua people for thousands of years. This plant is known to enhance fertility and energy. In 2001 the US company - Pure World Botanicals, was awarded a patent for its method of using an alcoholic

solvent to isolate Maca's active compounds. As of 2003, market value for Maca's related products was estimated at 20 million USD.

In 2002, a coalition of local communities in the Andes requested Pure World Botanicals to abandon the patent. They cited that the original material was collected from the Andean region in contradiction to the provisions of both CBD as well as the Decision 391 concerning a common regime on access to genetic resources, which is legislation in place in the region to protect genetic resources and traditional knowledge. Besides the local communities claimed that there is no novelty criteria in the patent application as claimed since the local communities have been using Maca for thousands of years for similar purposes mentioned in the patent application. This case has been cited as one of misappropriation or unauthorized use of genetic resources where there was no recognition of the associated traditional knowledge and one where there is contradiction with regional legislation and CBD principles.

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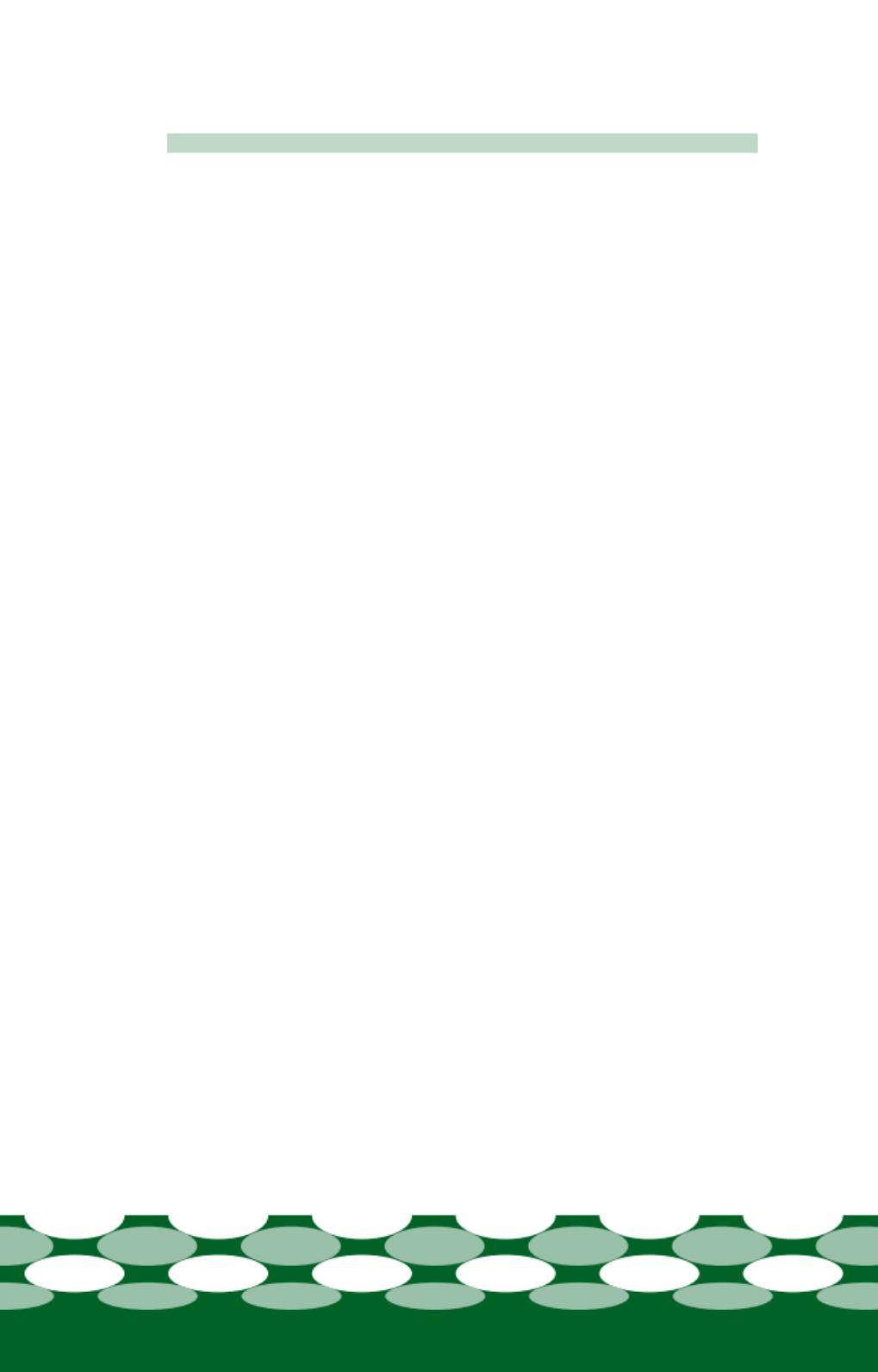
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Notes



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