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Bioprospecting: Promoting and Regulating Access to Genetic Resources and Benefit Sharing

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BIOPROSPECTING: PROMOTING AND REGULATING ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING

ABSTRACT

Advances in biotechnology and associated areas have increased the value of biodiversity and related knowledge of indigenous communities, and lent impetus to global bioprospecting activities. The Convention on Biological Diversity created a framework for regulation of such activities and replaced the existing regime of free access to bioresources with a framework where indigenous communities would be compensated for use of their knowledge, innovation, and practices.

Member nations have put in place or are in the process of establishing national and regional measures to operationalise the principles of the Convention, regulating bioprospecting so as to ensure that access to their genetic resources and subsequent benefit sharing are on mutually agreed terms based on prior informed consent of resource providers. This paper looks at bioprospecting in general, discusses how such activities can be encouraged and takes up various legislative, private legal and non-legislative measures that can be adopted to set up a regulatory regime.

1. INTRODUCTION

Biological diversity, besides forming the basis of man's very existence, also underpins a significant proportion of the world's economy. As significantly estimated by ten Kate et al (1999b), the combined annual global markets for some products derived from genetic resources lies in the range of US\$500 – 800 billion. Over the past few decades, the development of new capacities in the fields of biology, chemistry, genomics and information technology, has given impetus to the pace of change in industry, set new targets for

development of medicines and agricultural products and drastically affected the process of discovery and development.

This in turn has created greater demands for adequate supply of bioresources, further encouraging bioprospecting - the “exploration of biodiversity for commercially valuable biological and genetic resources” (Laird et al, 2002b; p 244). In today’s times this activity “involves the application of advanced technologies to develop new pharmaceuticals, agrochemicals, cosmetics, flavorings, fragrances, industrial enzymes, and other products from biodiversity” (Artuso, 2002; p 1355). Such advances in laboratory-based biotechnology have increased the value of genetic resources and the associated traditional knowledge (TK) of indigenous communities that provide important leads to commercially exploitable properties of the bioresources.

Till the early 1990s companies involved in bioprospecting were not required to compensate provider countries and indigenous communities for the bioresources collected. However, this regime of free access changed when the Convention on Biological Diversity (CBD) was adopted in 1992 to curb alarming rates of biodiversity loss and to “ensure that the discrepancy between resource provider and the technology developer became more balanced” (Heineke et al, 2004; p 26).

The Convention recognises that States have sovereign rights over their biological resources and establishes a framework for regulating access to such resources. It gives due importance to the role traditionally played by indigenous communities in conservation and sustainable use of biodiversity and through its Art. 8 (j)¹ recognises the “knowledge, innovations and practices of indigenous and local communities” and calls for “the equitable sharing of benefits arising from the utilisation of such knowledge, innovations and practices”. Significantly, it stipulates that access to biological resources be on mutually agreed terms and only after prior informed consent (PIC) of the resource provider was obtained.

Since the ratification of the CBD many national and regional efforts have been made to operationalize its principles and regulate access to genetic resources and benefit sharing (ABS). This paper looks at bioprospecting, explains how such activities can be encouraged

¹ Full text of the CBD available at <http://www.cbd.int/convention/convention.shtml>

and takes up various legislative, private legal and non-legislative measures that can be adopted for regulating ABS.

2. BIOPROSPECTING

It is a well known fact that no country is self sufficient in terms of biodiversity and even the most biologically independent nations have to reach out to other parts of the world for fulfilling their bioresource based needs (Kloppenburg, 1988, cited in The Crucible Group, 1994). In the last several centuries staple foods and high value cash crops have been moved from one part of the world to another, keeping pace with shifting markets and opportunities (The Crucible Group, 1994). Even a biodiversity rich country like Brazil has to draw two thirds of its plant based human calorie intake from species that are found in another continent (Table 1).

Table 1: Sources of Plant-derived Calories in Brazil

| Crop | Share of Plant-derived Calories (%) | Centre of Origin |
|--------------|--|-------------------------|
| Sugar | 20.38 | Indochina |
| Rice (paddy) | 17.64 | Asia |
| Wheat | 15.29 | West and Central Asia |
| Maize | 12.20 | Central America |
| Soybean | 8.84 | China – Japan |
| Cassava | 7.10 | Brazil – Paraguay |
| Beans | 6.40 | Andes |
| Bananas | 2.22 | Indochina |

Source: FAO Food Balance Sheets (1984 – 86), cited in The Crucible Group, 1994

Since distribution of the world’s biodiversity is in inverse proportion to scientific and technological wealth (Macilwain, 1998, cited in Laird et al, 2002b), research institutions and companies based in the developed nations look beyond their borders for diverse and novel genetic resources for their study and use. Bioprospecting is rooted in the sovereign rights of nation states over their biological resources. Governments of states being “*de jure* gatekeepers of biological resources” (Dutfield, 1999) are in a strong position to negotiate terms for favourable benefit sharing with interested stakeholders.

Bioprospecting covers a wide range of commercial activities in different industrial sectors including pharmaceuticals, food and beverages, biotechnology, seed, crop protection, horticulture, botanical medicines and cosmetics and personal care. It provides valuable leads for new product development and many companies look for new applications of biological species that have not been studied earlier. As such, they enter into collaborative programmes with collectors in different countries to procure their needed supply of bioresources. This brings into play a number of different stakeholders participating in a bioprospecting agreement as discussed in the following section.

2.1 The Stakeholders

The CBD does not specify who the actors in an ABS arrangement would be. As such it does not bind any stakeholder to any legal obligations, except the national governments, which are parties to the Convention. In turn, these governments have been authorised to place legal obligations on all stakeholders entering into an ABS agreement and chart out their roles and responsibilities. Seiler et al (2001) divide stakeholders into two broad categories: users and their representatives and providers and their representatives. According to the authors, the first category includes the private sector, universities, scientific research organisations and ex situ collections such as botanic gardens and culture collections. Providers include the national and local governments, public and private sector in-country suppliers of bioresources, landowners and the indigenous and local communities. However, the authors point out that the two groups are not mutually exclusive.

Glowka (1998, cited in Aguilar, 2001) is of the opinion that the two main actors in the ABS agreement are the States that own the bioresource and the States that are technology-rich and can put these resources to commercial use. Still others feel that in addition to these two actors, the third principal stakeholders are the local and indigenous communities that hold the crucial TK related to the genetic resource (Aguilar, 2001). Taking into consideration all these varied viewpoints, the following main actors can be identified:

2.1.1 The Private Sector

Private industry holds a dominant place in a ABS arrangement, having the requisite capability to discover, develop and market products derived from genetic resources. With rapid advancements in molecular biology, genomics, biotechnology, informatics, robotics and related areas of study, there has a major shift in the private sector's approach to research and

development (R&D) in the fields of medicine, agriculture and environment, making it a major user of biological resources (ten Kate et al, 1999a). Thus the views of the private sector about the CBD and the nature of commercial partnerships entered into by it will determine what and how benefits will be shared, whether bioresources are used sustainably or not and whether incentives are created for its conservation. Since laws and procedures related to access are not clear in most countries, ten Kate et al (1999a) emphasise that voluntary compliance by the private sector could go a long way in upholding the principles of PIC of the provider groups and fair and equitable benefit sharing.

2.1.2 The Public Sector

Government agencies can be involved in many different aspects of an ABS arrangement (ten Kate et al, 1999b). Many governments are responsible for funding and maintaining large botanical gardens, which the private sector often turns to for accessing genetic resources for its R&D. Moreover, although a lot of R&D around the world is increasingly being carried out by private research institutes, the public sector even today is responsible for a majority of the R&D activities and distribution and sale of the bioresource based product. Some examples of such organisations that collect genetic material for drug discovery are the US National Institute of Health, Central Drug Research Institute, Lucknow, India and Tropical Botanic and Garden Research Institute, Kerala, India. The government sector also plays the crucial role of putting in place appropriate legal and policy framework that will regulate how individuals and organisations access and commercialise biological diversity.

2.1.3 Intermediaries

Many intermediaries such as botanic gardens, culture collections, gene banks and brokers working for profit provide a large share of bioresources to companies seeking access to the same. Some intermediaries also provide access and benefit – sharing relationships with source countries either acting as representatives of interested companies or independently. Besides providing collection and scientific services, intermediaries may also be part of the ABS exercise between the initial collection phase and final commercialisation (ten Kate et al, 1999b).

Costa Rica's National Biodiversity Institute (INBio), New York Botanical Garden, the Missouri Botanical Garden and the University of Chicago are non-profit organisations that provide samples of bioresources to private pharmaceutical companies and public research

organisations. Private for-profit intermediaries like Biotics Ltd. based in United Kingdom, also exist in both developed and developing countries. Public organisations also serve as intermediaries, an example being Mexico's National Biodiversity Commission (Reid et al, 1993).

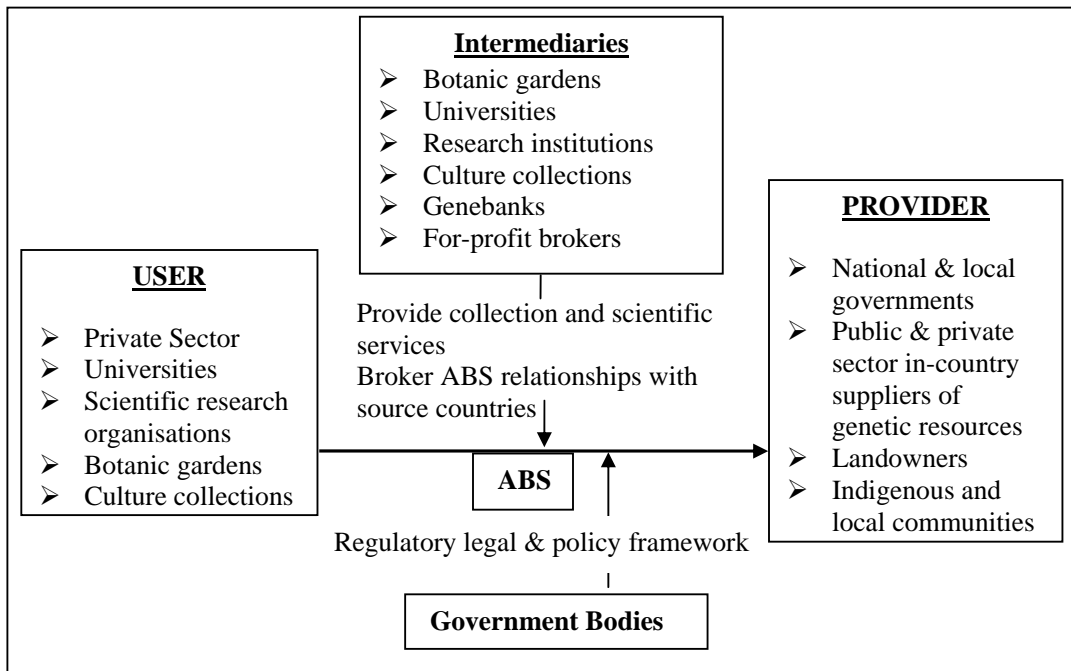
2.1.4 Communities

Local and indigenous communities, having lived in close proximity to biodiversity and having developed associated TK and management systems, have been involved in the conservation of biological diversity and trade in genetic resources. The bioresources and TK, of which these communities have long been custodians, are sought by academicians and commercial researchers for various purposes, such as developing new products and build better systems of species and ecosystem management (ten Kate et al, 1999b). In order to prevent exploitation of such communities, many countries like Philippines and members of the Andean Community have formulated access legislation that makes it mandatory for researchers to obtain their PIC for use of their knowledge and resources.

As the process of use and commercialisation of genetic resources moves from the initial stage of biodiversity conservation for providing the genetic raw material, through the subsequent stages of access to resource and related information, R&D, finding a market for the product and setting up of a regulatory environment to facilitate the complex relations between the various actors, all of the above stakeholders are involved and affected. For these actors to work in tandem for everyone's benefit, effective dialogue between the different groups is essential. The relationship between the above actors can be depicted as in Figure 1.

The various parties in a bioprospecting relationship often have competing agendas and conflicting interests. Valuable to this relationship is the ethnobotanical knowledge of the indigenous peoples who live in or near tropical forests and possess information related to use of plants for medicinal and other purposes. Such communities screen, select and maintain diverse plant populations through hundreds of generations and their knowledge reflects the "distilled experience of thousands of individual sections" (Brush, 1993; p.660).

Figure 1: Relationship between Various Actors Involved in an ABS Agreement



These knowledge systems are used directly by sample collectors from industrialised countries while collecting biological resources for new product development programmes. Moreover, industrial countries depend on the knowledge of indigenous communities for conservation of biological resources. This is significant because *in situ* conservation involving active participation of local people cannot be substituted by bioresources held in botanical gardens and seed banks as these can only capture a small portion of the total biological diversity found in a tropical forest.

To help biodiversity-rich developing countries benefit from the commercial use of their resources while creating incentives for conservation, some conservationists, economists and policy makers have in recent years been promoting bioprospecting programmes throughout the world, especially in the Tropics. If negotiated and implemented properly, bioprospecting can contribute significantly to environment friendly development and bring benefits to the custodians of biodiversity – the national public at large, conservation units, indigenous farmers and local communities and the forest dwellers. However, if carried out in the format of previous resource exploitation ventures, bioprospecting can have harmful effects on biodiversity conservation and hinder sustainable development. This calls for promoting bioprospecting partnerships even while regulating access to genetic resources and subsequent sharing of benefits arising from the commercial use of such resources.

3. ENCOURAGING ACCESS AND BENEFIT SHARING

Perceptions of industry and researchers about ABS and the CBD have not been very positive in the last decade (Laird et al, 2005). The three groups of concerns harboured by companies, as identified by ten Kate et al (1999a; p.297) include the lack of clarity concerning access rules, the bureaucracy and transaction costs involved in following them and the lack of understanding of the role of business on the part of the regulators and institutions providing access to genetic resources. According to Laird et al (2005), these concerns are very much visible even today; what is worrying is that they “are also increasingly accompanied by an underlying unease with what are characterized as “dangerous” and “political” minefields of fickle regulatory processes, and an absence of goodwill” (p.30). Expressing concern, the CBD (1999) emphasises that a restrictive policy of granting access to genetic resources could be a deterrent to industry and research institutions and have negative effects on transfer of technology and the attractiveness of natural substances, especially for the chemical and pharmaceutical industry. Thus measures have to be taken by provider countries to present incentives that would encourage such contractual arrangements. These include the following:

- i. *Certainty of ownership* – clearly defined rights of ownership and control over genetic resources are crucial for smooth negotiation and functioning of the arrangement, preventing disputes between the stakeholders. This would depend on the nature of the existing land-tenure system in the country and the way land laws are administered. Secure tenure and involvement of private land owners and their entitlement to a share of benefits would lead to stable and easily enforceable ABS arrangements.
- ii. *Stable political environment* – which enables a country to foster longstanding ties with foreign bioprospectors and nourish a long-term commitment to conservation and sustainable development (Artuso, 2002).
- iii. *Clear and short time-frame for determining PIC and granting access* – bioprospectors wish to avoid any regulatory bottlenecks that could delay access and sample collection. As such, an incentive for them is the efficient and quick handling of PIC application, review and decision-making. This is evident from the experience of South Africa where bioprospectors seem to intentionally avoid community-owned areas where taking consent involves lengthy and complicated negotiations with community members and are

increasingly choosing to collect from state-owned land and privately held farms where acquiring PIC is much simpler (Lewis-Lettington, 2006).

A lack of political will within governments which impedes coherent implementation of ABS regulations and delays the process of PIC is being seen as a major problem by many researchers and industry. According to a study undertaken by Holm-Muller et al (2005; cited in Laird et al, 2005) the absence of a clearly identifiable authority for negotiation and PIC was quoted by German companies as one of the most common problems related to bioprospecting.

Laird et al (2005) highlight this concern by quoting a researcher at a French personal care and cosmetics company: “Companies need security and for things to be clear. We want to know what we can do, where we go to ask for authorization, what partners are allowed to work with us, who can collect and send plants to the company. We are happy to apply for authorization and share benefits, but it can be very difficult to know how to do this” (p.35). As such, significantly for countries that do not have effective PIC procedures in place or have not identified authorities, “industries will have to choose their countries of CBD collaboration not only based upon where the most interesting biodiversity is located but also where PIC procedure and the CBD legislation are in place” (Lange, 2004; p.3). This is relevant in the existing scenario where many countries delegate PIC issues and requirements to individual communities. As such if resource had to be collected from multiple regions of a country, the collector would have to visit as many sites and meet the different demands and fulfil terms and conditions of as many communities to get the necessary number of PIC certificates (Medaglia et al, 2007). This can be problematic if it is difficult to identify which community has the authority to grant consent.

It is a cause of concern to bioprospectors that government officials in many countries are unwilling to grant access even if regulatory frameworks are in place to support the same. Developing collaborations within complex and evolving regulatory frameworks calls for investment of significant time and costs. This is increasingly prompting companies to collect samples in countries that have simple and straightforward procedures (Laird et al, 2005). According to the aforementioned authors many companies normally avoid bioprospecting in biodiversity rich countries like Brazil and India because of the long time associated with permits, the hostility towards research involving bioresources and

the harassment of having to pass through what Thorstrom (2005) terms “national regulatory labyrinths” (quoted in Laird et al, 2005; p.37).

Bioprospectors have faced similar problems in Philippines where very complicated and comprehensive biodiversity legislation requires many government agencies to review and approve bioprospecting projects (Mathur et al, 2004). Interestingly, it took the University of Utah three years of negotiations with the Philippines government before its first commercial agreement could be signed and another year and a half for the first renewal (Chris Ireland, pers comm., 2005; cited in Laird et al, 2005). Such delays in reaching agreements can put an end to research after promising compounds or their derivatives have been synthesized (Cragg and Newman, pers. comm., 2005; cited in Laird et al, 2005).

It is also possible that many government agencies like the customs and public health officials responsible for overseeing and processing forms and documents related to ABS could be seeing them for the first time and hence lack the experience needed to handle such paperwork (Mathur et al, 2004). In such cases political will needs to be directed towards orienting and training concerned officials in matters related to bioprospecting activities.

- iv. *Easy availability of reliable information* – since the negotiation and administration of ABS agreements are information-intensive, provider countries wishing to enter into beneficial contracts need to generate reliable and updated information on status and distribution of genetic resources, national legislation and procedures and institutional arrangements and make it easily available to interested parties.
- v. *Fiscal incentives* – creating special tax-relief measures for companies involved in bioprospecting could be an attractive incentive for users. This could include tax exemptions on the import of equipment and other technological components by a company wishing to undertake research on biomaterial in partnership with local institutions within the provider country.

4. REGULATING ACCESS AND BENEFIT SHARING

CBD’s Art 15 (1) vests authority to control access to genetic resources in the national governments with access being “subject to national legislation”. In keeping with this many

countries have either formulated or are in the process of formulating legislation to regulate access to their biodiversity wealth. Such laws generally address the following issues (ten Kate, 1999):

- Specify state’s role in allowing access to genetic resources
- Define scope of the resource and activities regulated
- Describe application procedure
- Establish an institution to administer and determine access applications
- Define minimum terms for granting access to genetic resources

Governments have used their discretion to come up with different ways of regulating access to genetic resources, with some doing it through specific laws while others include ABS as a component of broader regulatory frameworks that are aimed at nature conservation and/or sustainable development (Seiler et al, 2001). Glowka (1998, cited in ten Kate, 1999) has categorised existing and draft legislation into five different groups (Table 2).

Table 2: Legislative Options for Access to Genetic Resources and Benefit-Sharing

| ABS Legislative Options | Selected Countries Pursuing These Options |
|--|--|
| <i>Environmental Framework Laws</i> – enabling in nature; entrust competent national authority with responsibility of providing more specific ABS legislation | Gambia, Kenya, Malawi, Republic of Korea, Uganda |
| <i>Sustainable development, nature conservation or biodiversity laws</i> – implement a number of CBD provisions, take up conservation and sustainable use of biodiversity, establish principles of PIC and MAT | Costa Rica, Eritrea, Fiji, India Mexico, Peru |
| <i>Dedicated or stand-alone national laws and decrees on access to genetic resources</i> – specifically design frameworks for regulating access | Philippines, draft laws in Brazil |
| <i>Modification of existing laws and regulations</i> – such as those governing wildlife, national parks, forestry, land and fisheries—to include ABS provisions | Nigeria at national level; State of Sarawak, Malaysia and Western Australia at sub-national level |
| <i>Regional Measures</i> – multilateral agreements establishing common principles and procedures for regulating access | The countries of the Andean Pact (Bolivia, Colombia, Ecuador, Peru and Venezuela). Regional initiatives under discussion by South East Asian countries and proposed by members of OAU. |

Source: Glowka, (1998); cited in ten Kate (1999)

Seiler et al (2001) present three general approaches to regulation ABS:

4.1. Legislative Measures

Most countries have developed their own laws, policy measures and legislative frameworks to suit their particular situations. Regional and supranational approaches have also been adopted in many cases.

4.1.1 National and Supranational Approaches

Many countries have developed their own national level laws on access to genetic resources, some examples being Philippines, Costa Rica and India.

i. Philippines Executive Order 247

This came into effect in May 1995 and prescribes guidelines and establishes a regulatory framework for “prospecting of biological and genetic resources, their by-products and derivatives, for scientific and commercial purposes, and for other purposes”. The State is empowered to regulate access to genetic resources so as to ensure their protection and conservation and their sustainable use for the benefit of the nation. The decree also mandates that access be allowed only with PIC “obtained in accordance with the customary laws of the concerned communities” (Section 2.1).

ii. Costa Rica

The Ley de Biodiversidad or Biodiversity Law aims at conservation and sustainable use of biological resources and fair and equitable distribution of benefits and derived costs (Art 1). Built on the precepts that all life forms and cultural diversity must be respected, elements of biodiversity are valuable and inter and intra-generational equity should be ensured, the law comprehensively covers all the issues taken up by the CBD. These include conservation and sustainable use of biodiversity, environmental safety, PIC, access to genetic resources and biochemical elements of biodiversity and associated technology transfer.

iii. India

The Indian Biological Diversity Act aims at regulating access to plant and animal genetic resources and fair sharing of benefits, curbing biopiracy, and protecting biodiversity and the interests of local growers by setting up a three-tier structure of national and state boards and local committees.

Policy makers and legislators must exercise caution that ABS legislation does not become so stringent and narrow as to hinder domestic research and partnerships with foreign organizations, thus blocking the very capacity building that such laws seek to promote. Such a situation was faced by Philippines where out of 11 research applications for access only 2 were approved from 1995, when the Philippines Executive Order 247 came into force, to 2001 (ten Kate et al, 2001).

Besides national legislations, many countries sidestep the option of developing separate and individual rules to come together and establish regional and supranational rules and regulations (Seiler et al, 2001). Many countries that share some kinds of biological resources with others find it difficult to negotiate with users from a point of strength as users can approach neighbouring countries if they do not get suitable terms of access. In such a case, the authors opine, a supranational ABS approach improves the bargaining power of the member countries. For countries lacking the scientific and technological infrastructure needed for value addition to their bioresources, such cooperation between member countries also facilitates capacity building. However, negotiation of supranational frameworks can pose problems as national constitutions may have different definitions of sovereignty over natural resources. Two such efforts are the ones made by the member states of the Andean Community and the Organisation of African Unity (OAU).

i. Andean Community Common System on Access to Genetic Resources

The Andean Decision 391 establishes the sovereignty of member countries over their genetic resources and aims at conservation and sustainable use of biodiversity and at setting up conditions for “just and equitable” sharing of benefits. It recognises the historic contribution made by the indigenous communities to “biological diversity, its conservation and development and the sustained use of its components, as well as to the benefits generated by that contribution”. The Decision introduces the term “intangible component” to include all really or potentially valuable “know-how, innovation or individual or collective practice” related to the genetic resource. It does not explicitly refer to PIC but requires applicants to

provide competent national authorities with all information related to the genetic resource and its derivative that they are aware of or are in a position to know at the time of application.

ii. OAU African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources

Its aims at conservation, evaluation and sustainable use of biological resources, including agricultural genetic resources, and knowledge and technologies so as to maintain and improve their diversity as a means of sustaining the life support systems. It puts forth 11 specific obligations covering recognition of the rights of local communities and breeders, regulation of access to biological resources and community knowledge and technologies, promotion of benefit sharing mechanisms, and various others relating to participation, community rights, capacity-building, conservation and sustainable use of plant genetic resources, agricultural sustainability, and food security.

Biodiversity-rich countries could also take up the option of adopting harmonised access legislation, which provides the incentive of allowing preferential access to genetic resources to those countries that have implemented complimentary legislative measure (Tobin, 2001). Such legislative measure would make it necessary that PIC be taken from the relevant owners of the resource. The biotechnology industry could be further induced to relocate to countries, which receive preferential fast-track access to genetic resources by prohibiting onward transfer of resources to countries that have not adopted appropriate complimentary legislative measures.

4.1.2 Local/Indigenous People's Access Regulations

Some local and indigenous communities with relatively secure land rights have taken the initiative to articulate culturally appropriate ways in which access to genetic resources and TK may be sought and scientific research conducted within their territories (Seiler et al, 2001; Laird et al, 2002c). Examples of some such communities are the Awa of Ecuador, Inuit of Nunavik, Canada and Kuna of Panama.

i. Awa terms for research relationship

The Awa foundation is a legal body that manages 101,000 hectares of land held under communal title. Because of its botanical and ethnobotanical wealth and its land, the

community is being approached by many research institutions for collaboration. In 1993 the *Convenio – Reglamentos para la Realizacion de Estudios Cientificos en el Territorio de la Federacion Awa* was developed, charting out terms for research relations. This includes issues related to permission for research, responsibilities of researchers with regard to respect for the local culture and environment, collection of samples, behaviour of researchers in the community, fees and acknowledgement of contributions made by the Awa. It specifies that permission has to be sought from the Awa as well as from the government (Laird et al, 2002a).

ii. Kuna –Yala agreement for research

The Kuna – Yala framework for researcher – community relationship has caused many other communities to establish written agreements with researchers. The Communities *Programa de Investigacion Monitoreo y Cooperacion Cientifica* outlines the Kuna objectives related to forest management, conserving biological and cultural diversity, scientific collaboration and research priorities and lays down guidelines for researchers, including the kind of benefits that the Kuna should receive (PEMANSKY, 1988; Chapin, 1991; cited in Laird et al, 2002a).

iii. Inuit Tapirisat’s principles for research relationships in the North

The Inuit Tapirisat of Canada brought forth a background paper “Negotiating research relationships in the North” which contained a list of principles on which research should be based. These dealt with issues like PIC, anonymity and confidentiality, communication of research objectives, methods and findings, use of local and TK in all stages of the research, training of aboriginal researchers, social responsibility of the research, respect for dignity, cultures and rights of the community and community’s access to research data (Laird et al, 2002a).

4.2 *Private Legal Arrangements*

4.2.1 *Contracts and Material Transfer Agreements*

Contracts are the most frequently used mechanism for establishing formal and legal partnership between provider and user of biological resources (Tobin, 2002). Consisting of “an exchange of negotiated promises or actions” (Posey et al, 1996; p 67), contracts are agreements that basically identify the parties, define the resource in question and how it is to

be used, provide for suitable compensation, regulate intellectual property if product is being developed and marketed, define period of agreement and conditions for termination and breach of contract and also the jurisdiction and law of the contract (Tobin, 2002).

In case of bioprospecting, communities generally undertake to collect, identify, process, resupply and sometimes conduct further research on samples that are subsequently sent to companies to be screened. Companies on their part may agree to provide communities with some or all of the following (Posey et al, 1996):

- Per-sample fees
- Advance payments
- Efforts to screen samples
- Results of research
- Training for partner communities
- Royalties
- Joint ownership of patent

Material Transfer Agreements (MTAs) guide transactions involving transfer of biological material from a provider to a user, with restrictions being imposed on how the recipient uses the material (Gollin, 2002). MTAs establish standards for transfer of bioresources for the purpose of research and possible commercial use in exchange for benefits to the supplier. They usually allow the recipient to apply for patents or other IPR protection if the material can be commercialised (Posey et al, 1996).

An example of an MTA is the one used by The Consultative Group on International Agricultural Research (CGIAR) centres for materials covered under the Food and Agriculture Organisation (FAO) Trust Agreement. The CGIAR, through a Germplasm Acquisition Agreement, acquires germplasm under the condition that it will use the material for research and for placing it in trust for the benefit of mankind. The Centre transfers germplasm through MTAs that restrict the recipient from getting intellectual property protection on the material (Gollin, 2002). An MTA has also been drawn up between Costa Rica's INBio and the pharmaceutical company Merck wherein the latter pays INBio an upfront fee as well as royalty of about 3% of sales if a product is developed from any of the 10,000 or so plants or other biological extracts sent to it by the Institute (Posey et al, 1996).

4.2.2 *Licensing Agreements*

Sometimes a community, institution or corporation holding an intellectual property right (IPR), instead of commercialising the protected product or process, may license the right to use the IPR to another organisation that has better capabilities to commercialise the inventions. In exchange, the holder of the IPR receives a fee or a share of future sales. Thus licensing offers the advantage of maximising benefit sharing without full transfer of property rights over the licensed invention (Tobin, 2002).

A know-how license agreement was signed between the Aguaruna people of Peru and Searle, the pharmaceutical division of Monsanto when the community felt that in the case of bioprospecting for resources with traditional use for medicinal purposes, it was the use rather than the resource itself that was valuable. Accordingly, the Aguarunas instead of receiving fixed payment for collection of samples, demanded compensation for collection of resource as well as for the use of their knowledge. In addition to a collection fee per sample, an annual know-how fee was determined, to be paid during the process of research, development and marketing of the product (Tobin, 1997). The advantage of this agreement is that it implicitly accepts the IPRs of the Aguarunas over their knowledge about biological resources even though they may not own these resources legally and enables them to receive benefits by allowing commercial use of the same (Seiler et al, 2001).

4.2.3 *Letter of Intent and Memorandum of Understanding*

A Letter of Intent (LOI) outlines a preliminary understanding between parties that they might be willing to negotiate towards entering into a contract, fulfilling more of a business or political purpose rather than a legal obligation (Downs et al, 1993; Laird, 1993). It could also go further to specify some obligations and put down a range for negotiation (Gollin, 2002).

An example of a LOI is the one designed by the National Cancer Institute (NCI) for negotiating and entering into agreement with a source country providing samples. It contained relatively little provision for collaboration between the two parties and no commitments were made for involving the source country or any organisation therein, in the process of product discovery and development. The main benefits offered to the source country were royalty, training of scientists at NCI's facilities in the US and dissemination of results of the research. The LOI also contained terms for commercialisation of the products derived from the samples.

A memorandum of understanding (MOU) is also not a binding contract – it just states intentions and could be the beginning point for further negotiations (Posey et al, 1996). It is less binding than the LOI, though the two terms are often interchangeably used (Gollin, 2002). An MOU was prepared by NCI which requires that the Institute make it an obligation for third party recipients to take the approval of source country before commercialising the product developed from the research (ten Kate et al, 1999a). An MOU was also signed by the South African Council for Scientific and Industrial Research (CSIR) and the San people of the Kalahari region which recognised the latter as the customary custodians of the *Hoodia* plant and also acknowledged CSIR's rights to protect its work on isolation of the plant's active ingredient (Bodekar, 2003).

The two agreements usually take up issues related to confidentiality, sharing of research results and benefit sharing but cannot protect the rights of the indigenous communities (Posey et al, 1996).

4.2.4 *Model Agreements*

A number of model contracts and MTAs have been developed to help suppliers of genetic resources lacking experience in drawing up ABS agreements. These provide useful information for negotiating fair agreements that would be in the interest of the suppliers (Seiler et al, 2001). Using pro forma contracts to regulate access to genetic resources would be effective even in those cases where a well-developed system of IPR protection does not exist. It would require governments to use adopt a pre-approved set of model MTAs, decide minimum terms of equity in research agreements and set up a way of determining whether PIC has been taken or not (Putterman, 1996). Examples of such agreements are the Third World Network's "Draft Model Contract between the Collector and the Government", the "Model Material Transfer Agreements for Equitable Biodiversity Prospecting" and the "Biodiversity Prospecting Contract".

The Biodiversity Prospecting Contract is a useful aid for negotiation of contracts for collection of biological samples, which could be used as a starting point for discussions with modifications made to suit different cases. The draft agreement is neither a complete business agreement nor does it provide an authoritative model. It just provide useful information regarding obligations of the collector with respect to sample supply and its other responsibilities, obligations of the pharmaceutical company with respect to compensation,

screening of samples and future compensation. Issues related to patent rights, confidentiality, exclusivity, resolution of disputes, choice of law and terms of agreement and termination are also taken up (Downes et al, 1993).

4.3 *Non legally-binding instruments*

4.3.1 *Scientific/Academic Codes of Practice*

Based on consensus among concerned scientists, professional societies have started drafting codes of practice aimed at providing guidelines for researchers, instructing about ethical behaviour of fieldworkers/bioprospectors and listing obligations that should be fulfilled. Even though they are not legally binding, involved parties are expected to comply with the guidelines (Seiler et al, 2001).

Examples of some codes and ethical guidelines are:

- The Code of Ethics of the International Society of Ethnobiology, 1998
- The Pew Conservation Fellows' Proposed Guidelines for Researchers and Local Communities Interested in Accessing, Exploring and Studying Biodiversity, 1996
- Guidelines for Equitable Partnerships in New Natural Products Development of the People and Plants Initiative of WWF, UNESCO, and Royal Botanic Gardens, 1993
- The FAO International Code of Conduct for Plant Germplasm Collecting and Transfer, 1993
- Professional Ethics in Economic Botany: A Preliminary Draft of Guidelines of the Society of Economic Botany, 1991
- Code of Ethics for Foreign Collectors of Biological Samples developed at the Botany 2000 Herbarium Curation Workshop, 1990

4.3.2 *Industry Codes of Practice*

Much like the Japan Bioindustry Association, many business concerns and individual organisations have taken the initiative to come up with statements affirming their commitment to the CBD and offering suggestions on how to implement objectives of the Convention (Seiler et al, 2001). An attempt to do this has been made by Novo Nordisk Health Care Discovery through its "Guiding Principles for Novo Nordisk's Implementation of the Convention" which applies to both its health care as well as enzyme divisions (Laird et al, 2002b).

4.3.3 *Statements and Declarations of Indigenous Peoples*

Indigenous communities, the major stakeholders in the ABS arrangements, are becoming increasingly aware of their rights with respect to their bioresources and TK. As such they are becoming more and more involved in the ABS process and proposing measures to implement such agreements and related provisions of the CBD. Indigenous peoples are coming together to hold conferences and issue declarations and statements which deal with ABS and the CBD, some examples being the following:

- The International Cancun Declaration of Indigenous Peoples, 2003.
- The Johannesburg Declaration on Biopiracy, Biodiversity and Community Rights, 2002
- Final statement from the conference on Protecting Knowledge: Traditional Resource Rights in the New Millennium hosted by the Union of British Columbia Indian Chiefs, 2000
- The Thammasat Resolution on Building and Strengthening of *Sui generis* Rights, 1997
- Final statement from the UNDP Consultation on the Protection and Conservation of Indigenous Knowledge, Sabah, Malaysia, 1995
- Final statement from the UNDP Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights, Suva, Fiji, 1995
- Statement/basic points of agreement from the COICA/UNDP meeting, Intellectual Property Rights and Biodiversity, 1994
- The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples from the First International Conference on the Cultural and Intellectual Property Rights of Indigenous Peoples, 1993
- Statements from the Julayinabul Conference on Intellectual and Cultural Property, 1993

4.3.4 *Voluntary Guidelines*

Voluntary guidelines on how to implement and regulate ABS agreements are useful where ABS regulations have not been established. Such guidelines are effective if developed in

consultation with as many of the stakeholders as possible (Seiler et al, 2001). An example is the Swiss draft Guidelines on Access and Benefit Sharing Regarding the Utilization of Genetic Resources which serve as a point of reference for all stakeholders involved in access to and utilisation of genetic resources and in fair and equitable sharing of resultant benefits.

5. OBSTACLES TO REGULATING ACCESS TO GENETIC RESOURCES

Even though the 2010 deadline for negotiation of the International Regime on access to genetic resources and benefit-sharing has drawn uncomfortably close, out of the 190 parties to the CBD, only about 60 have either adopted or are still in the process of adopting ABS measures (Normand, 2008). The failure on the part of so many countries to put in place an ABS regulatory framework even after more than one and half decades since ratification of the CBD, is due to a combination of several factors, namely (Normand, 2008):

- The complexity of the issue which involves different types of genetic resources (plant, animal, micro-organisms) used by different actors (scientists, private companies) for different purposes (research, commercialization) in different sectors (e.g. agriculture, pharmaceutical, cosmetics, horticulture)
- Lack of awareness at the national level, including at the level of decision makers which has likely hindered implementation.
- Lack of human and institutional capacity and absence of adequate infrastructure.

The difficulties faced by many countries in their efforts at ABS policy development are similar to those faced by the four African countries Botswana, Ghana, Uganda and Zambia. In a study analysing the national policy climate relating to ABS (UNU, 2008), these countries reported that they were presented with the following challenges:

- Raising awareness of ABS principles;
- Maintaining institutional capacity;
- Linking ABS and poverty alleviation;
- Building national technological capacities;
- Addressing the lack of ABS policy and increasing capacity to implement existing policies;

- Engaging local and indigenous communities; and
- Monitoring and enforcement of ABS agreements in user and provider countries.

There are five major obstacles that policy makers have to overcome while regulating access to genetic resources and ensuring equitable sharing of benefits. These include (Porzecanski et al, 1999):

i. The special character of genetic resources

The very nature of biological resources makes valuation difficult, which is a necessary step in establishing a CBD compliant market for genetic resources. According to the CBD² genetic resources are “any material of plant, animal, microbial or other origin containing functional units of heredity” and having “actual or potential value”. Of interest to ABS is the dynamic value of genetic resources which derives from (Porzecanski et al, 1999):

- the *option value* – the value of certain chemical properties present in plant and animal varieties that could prove beneficial for health and the environment
- the *exploration value* associated with the probability that a useful natural compound will be discovered.

Biotechnology has been successful in adding significant value to genetic resources and increased remarkably the potential returns from genetic product development. This has prompted governments to develop benefit sharing agreements in a bid to receive part of the profits associated with the dynamic value of biodiversity (Glowka, 1998; cited in Porzecanski et al, 1999). Such expectations to benefit from the commercialisation of biodiversity are however, not in line with the fact that characterising and measuring the value of genetic resources is difficult (CBD, 1995) and that such resources are not entirely the product of biotechnology.

Another feature of genetic resources that makes access regulation difficult if that species distribution is not limited by political boundaries and “few species have convenient geographical niches to fit the [ABS] agreements” (Bell, 1997). Rather, genetic resources are distributed in patterns that represent evolutionary and not political history. The problem of regulating use of such resources is illustrated by the example of Sangre de Drago, a plant that

² Full text of the Convention available at <http://www.cbd.int/doc/legal/cbd-un-en.pdf>

has been widely used by Shaman Pharmaceuticals for its drug development programme. This plant is found all over the Amazonian region and although its therapeutic value is well known in that area, Shaman has been dealing with individual Amazonian groups. This raises the issue of who should benefit from the arrangement and also allows bioprospectors to approach different groups for a profitable deal (Bell, 1997).

Similar issues underlie the case of Eli Lilly gaining huge profits from drugs derived from Madagascar's rosy periwinkle which is considered to be "One of the more notorious recent examples from a 350 year history of uncompensated takings" (McManis, 1998). A major misconception related to the plant is that its origin has been linked to Madagascar even though it is found throughout the tropics. In fact according to Mortan (1977, p237; cited in Dutfield, 2004), the Caribbean people have grown it for so long that it can be considered native to the region. Moreover, in contrast to its earlier supplies which came from Madagascar, Eli Lilly now procures the species from plantations in Texas. Significantly, ethnobotanical information that led to discovery of anti-cancer properties of the plant came not from Madagascar but from Philippines and Jamaica where rural communities traditionally used it to treat diabetes. As such it becomes pertinent to question "who, if anyone, should Eli Lilly share the benefits with in accordance with the principles of fairness and equity, and in what proportions?" (Dutfield, 2004; p47)

Those opposing the unsuccessful project undertaken by the Maya International Co-operative Biodiversity Group in Chiapas, Mexico, which was a collaboration between the University of Georgia, El Colegio de la Frontera Sur and a small natural products discovery company in Wales, also used the shared knowledge/shared resources argument against the project. An advisor to a local healers' group, the Council of Traditional Doctors and Midwives of Chiapas, stated (XERA Radio, 2000; quoted in Berlin et al, 2004):

Medicinal plants are not the sole property of Chiapas, they belong to all of Mexico. Furthermore, there are plants in Chiapas that exist in Guatemala. If we [Mexicans] come to an agreement that plants found here can be carried away, patented and sold, this could be the cause of an international controversy with Guatemala because plants that are found in Chiapas are also found in Guatemala.

In this context the same authors however point out that one of the primary aims of the CBD was to grant nations sovereign rights over their own natural resources. Thus countries cannot be prevented from commercializing their natural endowments as “No international agreement requires one country to seek permission for access to a species within its own borders because that species is also distributed within the boundaries of the second country” (Berlin et al, 2004; p.480).

ABS issues, as discussed, become complicated when many countries share genetic resources with their neighbours. When such countries fail to co-ordinate with each other and share information especially about access applicants and their proposed projects, they not only risk lowering the value of benefits in their competition to facilitate access, they also leave themselves open to the problem of enforcement when bioprospectors collect resources in one country and claim to have collected from another (Nnadozie et al, 2003).

To overcome such problems countries that share a common genetic resource like India, Sri Lanka, Bangladesh, Malaysia and Pakistan, all of which are home to Basmati rice, could establish regional associations (like the Andean Pact countries Venezuela, Colombia, Ecuador, Peru and Bolivia signing the Decision 391 and the ASEAN member nations ratifying the ASEAN Framework Agreement on Access to Biological and Genetic Resources) that would work towards common goals for genetic resource use and formulate common ABS regulations.

A trust fund could be set up into which benefits would be deposited and shared between involved countries. In Southern Africa such a step was taken by the Councils of the indigenous San people of Namibia, Botswana and South Africa all of which are home to the *Hoodia* plant used by the South African Council for Scientific and Industrial Research for developing and patenting an appetite suppressant. The San Hoodia Benefit Sharing Trust was registered to receive and share among the source countries any monetary benefits generated from commercialisation of the product (Wynberg, 2004).

A body set up especially for the purpose and having representation from each nation could make decisions regarding ABS and the proportion of benefits accruing to each country. There however, remains the difficulty of establishing solidarity among such countries and common ABS decisions would finally be subject to each of their national legislations. It is important to note here that if regulations are tough in one country, firms could resort to collecting

resources from some other country where regulations are comparatively more lenient, leading to overexploitation and unsustainable use. This emphasises the need for establishing minimum international standards for access to genetic resources and related benefit sharing (Afreen, 2007).

Neighbouring countries sharing a common resource could establish an adapted version of Vogel's (1997a; cited in Dutfield, 2004) suggested cartel of *all* nations housing a common/identical resource, to set up regional cartels (as in the case of Basmati rice) that would be more feasible, easier to administer and build consensus. Involved countries could share the income from a fixed royalty rate of 15% of sales (which could be reduced later) of the product developed from the common resource. The country actually supplying the resource could be given an additional small percentage (2% suggested by Vogel). However, if there were too many partners in the cartel, monetary benefits accruing to each country would be too small to encourage membership.

Dutfield (2004) recommends that countries receive benefits in proportion to their efforts to conserve and sustainably use biodiversity. The problem associated with this is that it would be difficult to assess and quantify such efforts and much discussion and consultation would be needed among the members of the cartel to resolve the issue.

Crook (2001) suggests that TK holders of a particular region form a cartel and set up an organising body to facilitate access and ensure equitable benefit sharing. However, such cartels could suffer from the problem of building consensus among large numbers of people from many different ethnic groups.

ii. Existence of ex situ collections

In addition to the millions of species thriving in in-situ conditions, many hundreds of thousands are deposited in herbaria, arboreta, museums and national and international gene banks that regardless of the cultural, geographic or national origin of the bioresources allow open access to credited institutions and academic scholars. The major taxonomic collections are held by developed countries with the single largest collection belonging to the United States. This collection, maintained by the National Plant Germplasm System (NPGS) of the United States Department of Agriculture contains about 481,558 different accessions from about 12,459 species (Thro et al, 2008). As part of the NPGS, the Western Regional Plant Introduction Station in Washington alone maintains a collection of approximately 80,000

accessions filling approximately 1,500 seed orders each year and sending about 20,000 seed packets annually to researchers all over the world (Johnson, 2008). The CGIAR which has numerous gene banks holds 532,508 accessions through agreements with the FAO (CGIAR, undated).

A professional plant breeder acquiring genetic material from ex-situ collections benefits in three ways: first, the collections are extensive and freely accessible; second, basic information on accessions is usually available; and third, in many cases, some of the material has already been selected by CGIAR breeding programmes for its desirable characteristics (Rajotte, 2008). The presence of such ex-situ collections makes bioprospecting easier and does away with the complications involved in getting collection permits from government authorities and indigenous communities. This is reflected in the fact that bioprospectors are increasingly accessing material held in ex-situ collections (ten Kate et al, 1999). It has been proposed (Bass et al, 1999) that highly developed ex-situ collections in Canada coupled with the federal policy which provides unrestricted access to such resources for bona fide researchers and plant breeders could be the reason why very little in-situ bioprospecting is undertaken in the country.

The earlier informal exchange system which has been responsible for collection and exchange of a large amount of food crop germplasm throughout the world has been criticised for its “lack of clarity concerning the rights and obligations associated with participation in the system and its conformity with the objectives of the Convention on Biological Diversity (CBD) relative to benefit-sharing” (IPGRI, 1996; p.i). The International Treaty on Plant Genetic Resources for Food and Agriculture, which was adopted by the 31st session of the FAO Conference and entered into force in 2004, took a step towards conforming with the CBD and established a Multilateral System of Access and Benefit-Sharing which included the “plant genetic resources for food and agriculture listed in Annex I and held in the ex situ collections of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR)...” (Art.11.5)³. However, only material collected or obtained after the enforcement of the CBD (29th December, 1993) are covered by the treaty and can be accessed as per the terms of a standard MTA which was adopted in June, 2006.

³ Full text of the Treaty available at http://pgrc3.agr.gc.ca/itpgrfa/treaty-traite_e.html

Disturbingly, pre-CBD ex-situ collections (like those held by the CGIAR) are exempt of the CBD mandate and are exchanged under specific MTAs, many of which include specific clauses to take care of commercialisation and IPR issues (Pisupati, 2008). In this regard, IPGRI (1996) points out the problem of copies of the same gene being possibly stored in both pre and post-CBD accessions. In such a case it would be impossible to ensure whether the gene was obtained from post-CBD material (hence necessitating benefit sharing) or from pre-CBD collection (thus being exempt from the benefit sharing clause). Further difficulties could also arise as the latter category of collections “very often do not have passport data that is complete nor were collected using the CBD-ABS principles of prior informed consent or mutually agreed terms” (Pisupati, 2008).

All these problems associated with ex-situ collections can be appreciated when we take the case of the dispute between the governments of Ethiopia and Brazil over compensation for a decaffeinated variety of coffee that was developed in Brazil through selective breeding using plants collected from Ethiopia before the CBD came into force. The researcher responsible for the discovery claimed that his find had been based on plants collected by a United Nations scientific mission in 1964-65, reproductions of which had gone to Ethiopia, India, Portugal, Tanzania and Costa Rica. Brazil had obtained the seeds from Costa Rica’s collection in 1973 (Reuters, 2004). This case not only highlights difficulties in determining ownership of genetic resources but also “demonstrates special complications in terms of recovering compensation for ex-situ collections pre-dating the CBD” (UNDP, 2005; p.11).

Many countries like Malaysia, Philippines, Colombia, Costa Rica and Bhutan among others, have taken steps to ensure that their access regulations apply to genetic resources present under ex-situ conditions. In Philippines the EO247, which established a detailed ABS legal framework, and its Implementing Regulations failed to clearly specify if the government’s consent was required for accessing the collections of the International Rice Research Institute (IRRI), an International Agricultural Research Centre based in the country. Access to IRRI collection was through a standard MTA that prohibited ownership claims on the material or IPRs over the germplasm or related information. It was however, unclear whether such a clause applied to all materials held by IRRI or only to those originating in Philippines. Through its 2004 Draft Guidelines for Bioprospecting Activities in the Philippines, the country addressed this lack of clarity and brought ex-situ collections like those held by the IRRI under the jurisdiction of ABS regulations when they were used for commercial

purposes. This amendment required IRRI to shift from its normal practice of granting access to its collections without acquiring permission from the authorities to involving the government to a greater extent in all material transfers (Smagadi, 2005).

As part of the Andean Community, Colombia's adoption of the Decision 391 requires bioprospectors desiring to access the country's conservation centres and other entities that undertake activities relating to ABS or their derivative products and/or their intangible components like knowledge to sign access contracts. This extends the scope of access regulation to all botanical collections, seed banks, zoos, breeding centres, botanical gardens, aquariums, tissue banks, collections in natural history museums, herbaria, *in vitro* collections, and any other institutions having genetic resources or derivatives products that could be used for ABS purposes. This brings the International Center for Tropical Agriculture, a research institution of the CGIAR located in Colombia under the purview of the Decision 391 (Ferreira-Miani, 2004).

Malaysia has also taken a step towards regulating access to ex-situ collections through its Sabah Biodiversity Enactment 2000. This piece of legislation establishes the Sabah Biodiversity Council which will review access applications and grant access licenses to bioprospectors seeking access to bioresources including those in any ex-situ collections maintained by the State (Omar et al, 2002).

With respect to control over ex-situ genetic resources, it has been suggested (RIS et al, 1999) that all such existing germplasm in private or public sector holdings be repatriated, where relevant, to communities/persons of origin. However, objections had been raised earlier to such an option by a Mexican delegation in the 2nd session of the ICCBD (1994) on the ground that repatriation to provider countries did not necessarily mean that the genetic resource would return to the original suppliers/communities that had developed and managed it over the ages. Repatriation would also be a futile exercise if such actual owner groups no longer existed in a recognisable nucleus even in their own country (Porzecanski et al, 1999).

The repatriation option has been wise employed by some local communities in Peru through the Agreement on the Repatriation, Restoration and Monitoring of Agrobiodiversity of Native Potatoes and Associated Community Knowledge Systems, an agreement between the International Potato Centre (a CGIAR centre) and the Association of Potato Park Communities for repatriation of traditional potato varieties (IIED et al, 2005). A sui generis

legal mechanism based on customary laws, the agreement recognises the collective rights of the indigenous communities, regulates the equitable sharing of benefits with them and ensures that genetic resources and associated knowledge remain in their custody and do not become subject to any form of IPRs (Argumeda, 2008).

iii. Difficulty in defining genetic resource ownership and tenure

Difficulties in determining rights of ownership and tenure of natural resources arise due to lack of knowledge about living organisms, widespread distribution of some species and processes and different levels of geographic jurisdiction over areas where species are endemically found. While the CBD recognises sovereign rights of individual nations, tenure and ownership systems are neither uniform nor clearly defined in all countries. Based on the legislative heritage of a country and its typical cultural traditions, a mixture of ownership regimes may be prevalent, ranging from traditional common tenure to state enforced private rights over land and natural resources (Porzecanski et al, 1999). For instance, in Mexico and signatories of the Andean Pact, communities enjoy tenure over biological resources while exclusive property rights are in the hands of the state. In fact, Garforth et al (2005) point out that the process of establishment and enforcement of an efficient ABS regime in Mexico has been largely unsuccessful due to conflicts of land tenure and resource use in rural areas.

Matters are complicated in Cameroon also where community claims to rights of ownership of lands and resources are based on customary laws while the State's property claims draw on statutory laws and supersede custom (Nnadozie et al, 2003). In Costa Rica confusion and debates arise with respect to definitions, ownership and intention of resource use as the law divides property rights of biodiversity into genetic and biochemical properties and the bioresource per se. While the former belong to the State and as such are under the administration of the Ministry of Environment and Energy, the biological resource itself is the property of the land owner (Sittenfeld et al, 2003).

In South Africa land ownership patterns are of several kinds falling in two major categories: western (freehold) and customary ownership. While statutory laws are applicable to both, in communal areas various forms of customary tenure systems exists which form the central component regulating natural resource use. While genetic and natural resources are not differentiated against, different levels of protection are provided to certain resources. In El Salvador controlling mechanisms are through necessary PIC for access to genetic resources

granted by the people who are empowered to allow access to bioresources located on their lands. This is in addition to authorisation granted by the state. This is in contrast to the situation in Ghana where rights over genetic resources come with ownership of land and no permits are required for access, exchange or export of the same. Customary laws are recognised by the constitution. However since such laws vary in different localities and customary land tenure also differ from one community to the other, complicating ownership issues further (Lewis-Lettington et al, 2006).

The other extreme are countries like India where centralised legal and policy systems have displaced customary practices and laws and created a situation where offences are no longer punishable by the latter, tribal leaders who could dispense justice at the community level lack the legitimacy and power required to do so and resources previously under community controls are increasingly moving into the government's hands (Kothari, 1998).

Thus the regional, national and international levels of political authority may assess ownership in radically different ways, which may also be divergent from some traditional community-based tenure systems. Since it is difficult to distinguish between naturally occurring genetic traits and those that have been improved and conserved by humans, assigning property rights to the rightful party and sharing benefits in a fair manner becomes a complicated matter.

As the CBD only mentions State's sovereignty over genetic and biochemical resources, property rights over them needs to be defined. A clear distinction must be made between concepts of property, sovereignty and national heritage so as to set up a mechanism for ensuring legal certainty (Medaglia, 2004). According to a report presented in the III meeting of the ABS Working Group (IUCN, 2005), "a party would have 'legal certainty' regarding an instrument if he was fully aware of all relevant laws, and certain that they were consistently and predictably in force and enforceable"(p.5). The report puts forth a narrower definition of 'legal certainty for users' which focuses on three elements (pp. 5 – 6):

- *“Process certainty*: This kind of legal certainty encompasses
 - Establishment and empowerment of competent national authorities, specifying rights and duties of others (landowners, communities, etc.) who may be involved;
 - Clarity regarding the procedures for applying for ABS rights;
 - Clarity regarding various deadlines for processing applications; and

- Clarity regarding appeal of the decision by the applicant or by others.
- *Scope and Nature of the Grant*: This factor enhances legal certainty by clearly defining the rights granted, as well as enunciating mandatory provisions and conditions that must be included within the 'mutually agreed terms'.
- *Legitimate Expectations and Vested Rights*: This kind of legal certainty can be supported in several ways, including
 - Clear and specific statutory requirements and limitations regarding subsequent challenges to the user's activities after receiving ABS rights, and
 - A clear delimitation of the nature of government's power to alter, cancel, repudiate, amend or suspend an ABS right, once it has been received."

The absence or uncertainty regarding ownership of genetic resources impedes the process of acquiring PIC and makes it difficult to fulfil company requirements of providing appropriate guarantees regarding legality of procedures so that public and legal problems do not arise. In fact, various bioprospecting agreements from around the world have been facing complaints, claims and lawsuits mainly due to the lack of legal certainty which in turn affects smooth functioning of projects and the ability to attract joint ventures (Sain et al, 1999; cited in Medaglia, 2004).

The importance of this factor is reflected in the recommendations of the Ad Hoc Working Group on Access and Benefit-Sharing at its fourth meeting (CBD, 2006) and the IUCN's (2008) recommendations on the Working Group's sixth meeting, both of which believe that an International ABS Regime must provide legal certainty for users and providers of genetic resources. The relevance of this factor is being realised by many countries as is evident from the position of Australia whose government ensures that the presence of legal certainty under its ABS legislation is an incentive for investing in bioprospecting in the country. This is provided by the legal regime of the country that includes clear and transparent regulations for granting permits, based on a well established system of commercial and intellectual property law (Australian Government Department of Environmental Heritage, 2005; cited in Medaglia et al, 2007).

Medaglia et al (2007) highlight the need to determine, legally recognise and differentiate through national law between owners of the land from which specimen was collected, the owner of the specimen and the owner of the genetic resources. Keeping in mind the existence

of diverse resource rights regimes, there is however, no single framework which can be effective in ABS regulation. However there are certain models which can be effective in granting community-held resource and knowledge rights. Traditional Resource Rights⁴ as suggested by Posey et al (1996) and Community Intellectual Property Rights that vest ownership of an innovation in the involved community and allow for its commercial use subject to acknowledgement, consent and compensation of such community (Nijar, 1998) could help protect, conserve and compensate for knowledge and resources of local and indigenous communities.

iv. Inadequacy of legal, institutional and scientific capacity

Historically, the absence of relevant legislation and national policy addressing issues of ownership and compensation has proved a handicap in regulating access to genetic resources. This is evident from the case of the rosy periwinkle (*Catharantus roseus*) of Madagascar which was used by Eli Lilly to produce two anti-cancer drugs, Vincristine and Vinblastine. In the absence of regulatory mechanism, although the company earned millions from sale of the drugs, 88% of which was profit (Farnsworth, 1988), it did not share royalties from sale of the medicines with the Malagasy people (Roht-Arriaza, Naomi, 1996; cited in Ragavan, 2001).

Even though the CBD calls for each Contracting Party to “Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes...” (Art.6(a)) factors like lack of technical expertise, budgetary constraints, weak government structures and political support, local social conflicts, and conflicts over ownership of genetic resources (GRCP, 2003) have prevented many of the member nations from developing national ABS measures. While many governments are caught between competing priorities which makes developing ABS laws

⁴ Traditional Resource Rights is a system of integrated rights that acknowledges that cultural and biological diversity are integrally inseparable and is guided by human rights principles of indigenous and local communities including the right to self-determination, collective right, land and territorial rights, religious freedom, the right to development, the right to privacy and PIC, environmental integrity, IPRs, neighbouring rights, the right to enter into legal agreements, rights to protection of cultural property, folklore and cultural heritage, the recognition of cultural landscapes, recognition of customary law and practice and farmers' rights (Posey, 1996).

and institutions a less attractive area for funds allocation, others are still in the process of identifying the objectives that ABS measures should target (Laird et al, 2005).

There are several factors which have discouraged governments from designing and putting in place a comprehensive consent process related to genetic resources and TK (Perrault, 2006). Not only are governments unsure about how to set up institutional structures and specify processes, they also lack information necessary for achieving the often complicated goal of establishing the “dual (and potentially competing)” framework of access that would also ensure benefit sharing (p.6). Many governments are also at a loss regarding the significance of local community rights in the PIC process and do not know how to resolve issues like whether local communities have the absolute right to refuse consent in every case or not and whether and under what conditions this right can be denied in the larger public interest. Some governments are also concerned if the cost associated with granting access to genetic resources would be offset by the benefits received, especially in cases where there are chances of patents being granted.

Overlapping jurisdiction of various natural resource government agencies also poses a problem. This has been seen in the case of El Salvador where different laws like those governing the environment, wildlife conservation, forestry, vegetable and animal health, seeds, fisheries and aquaculture, cultural heritage, science and technology and protected areas define jurisdictions that overlap and are duplicated, thus complicating access authorisation procedures (Lewis-Lettington et al, 2006). This has been a common complaint of bioprospectors who in many cases have to apply for different permits as required by multiple institutions that lack a co-ordinating mechanism among themselves. This could be the result of new legislation being adopted that regulates a different component of bioresources traditionally under the purview of other laws (Medaglia et al, 2007).

The task of access to genetic resources is also made complicated by the disparate agendas of national and regional governments. Additional conflicts may arise when universities, bioprospecting agencies and scientific research organisations develop research agreement guidelines and codes of behaviour that provide for benefit sharing with local partners (ten Kate et al, 1998). With many countries developing and implementing their individual access protocols, the complementarity of these bilateral agreements with new regulations needs to be assessed. It is also important to consider whether government agencies will honour agreements that have been signed before state policy implementation.

Tropical countries that house a majority of the world's biodiversity, lack sufficient infrastructure, researchers and budget for conducting basic biological research. Yet, reliable access decisions can be taken only after such research has yielded information about the scope, length and sustainability of use of genetic resources. In the absence of crucial information like taxonomic or habitat identification, enforcement of regulated access regimes becomes a difficult task.

Even in many countries which have already put in place well-developed ABS measures implementation has been slow due to PIC conflicts, lengthy and overly complex application procedures, ambiguities in the scope of ABS frameworks, inadequate biodiversity conservation incentives and variation in relevant expertise among individuals responsible for developing ABS policies (GRCP, 2003). For instance, Costa Rica's efforts at implementing a legal regime on access to genetic resources have been limited by the country's low policy of bioresources and the lack of technical expertise. There is laxity on the part of the government in implementing recommendations from technical and comprehensive assessments undertaken. Although legal measures are emphasised, necessary changes in the institutional framework and capacity building continue to be neglected (Garforth et al, 2005).

A study (Nnadozie et al, 2003) involving twelve African countries identified three factors which impeded the country's initiatives towards ABS: weak or nonexistent legal frameworks and institutions, lack of capacity and lack of awareness and participation especially from rural communities that are the custodians of much of the nation's biodiversity. With governments commonly modifying existing structures and legal frameworks in related sectors like protected areas, forestry and science and technology to accommodate ABS issues, the regimes governing the latter "are largely sectoral, multi-polar, and patchy" in these countries (Nnadozie et al, 2003; p.75).

In many cases local research institutions and the companies involved may not be aware of the new regulatory frameworks. This could again lead to problems in implementation as seen in the case of the Galapagos Islands where, in spite of Ecuador being a member of the Andean Pact and an active participant in ABS policy dialogues for more than 15 years, negotiation of an agreement in accordance with established ABS framework was disorganized and flawed. Moreover, "...the CBD's guidelines on ABS, coupled with the 391/96 provisions did not work very well in practice" (Thorstrom, 2005; p.3; quoted in Laird et al, 2005). Such problems are not specific to Ecuador only; all the members countries have been interpreting

the Decision 391 in different ways, making uniform implementation and regulation difficult (Garforth et al, 2005).

v. *Conflicting interests of stakeholders*

Armed with sovereign rights over natural resources granted by CBD, nation states play the most crucial role in regulating access to genetic resources and benefit sharing. However, these nation states are caught between the internal interests of traditional communities, regional governments and development objectives and the external interests of transnational enterprises and other parties pushing the enforcement of many multilateral agreements. The right to grant access and apportioning of benefits may be a subject of political debate in many cases. While one group may suggest working within the IPR system, another may demand that genetic resources and TK be kept out of its ambit. In such a scenario where different interest groups call for conflicting actions, governments may be hesitant to take a definite stand and resolve policy disputes.

NGOs have also contributed to the ongoing access to genetic resource debate and represented the communities in denouncing violations of the CBD provisions. Acting as facilitators and mediators among various stakeholders, NGOs could play different roles ranging from leading bioprospecting initiatives (for examples Conservational International), highlighting the inconsistency between various international agreements (for example GAIA Foundation and GRAIN) to condemning the violation of indigenous rights. Like these NGOs, scientists and researchers also have contrasting interests (Porzecanski et al, 1999). Thus the implementation and enforcement of access regulations in a harmonious manner that satisfies all the varied and often contradictory objectives presents a major problem to relevant authorities.

To sum up, countries seeking to overcome the above discussed obstacles and effectively implement CBD's third objective (fair and equitable sharing of the benefits arising out of the utilization of genetic resources) will find direction in the following points of action suggested by four African countries (Botswana, Ghana, Uganda and Zambia) (UNU, 2008):

- Promote a broader understanding and appreciation of ABS principles;
- Establish and strengthen national institutional frameworks;
- Identify and strengthen cooperation with and dialogue between ABS stakeholders;
- Provide capacity-building for human resources development;

- Promote and invest in research and development for both South-South and North-South joint ventures within and between provider and user countries; and
- Effectively participate in the CBD's process on the negotiation of an international ABS regime.

6. CONCLUSION

By and large, in a bioprospecting partnership multinational corporations are in a stronger bargaining position and stand to gain more than the provider countries and their indigenous communities. In such an equation, it is important to design ABS regulatory frameworks in such a way that they accommodate the interests of all involved parties that have a legitimate stake in the partnership. Top-down frameworks that cater only to the interests of the economically dominant groups and hence lack the support and participation of local and indigenous communities would not succeed.

Importantly, there is no one mechanism that can ensure responsible access to genetic resources and enhance benefits to provider groups. A well-designed regulatory framework would have to be a combination of various different instruments that would be dictated by individual bioprospecting agreements. Flexibility is also a key issue as the framework should be able to accommodate different stakeholders, their varying objectives and the different types of bioresource being accessed.

ABS regulations need to be simple and easy to comprehend and not discourage bioprospectors by being too stringent and time-consuming. Although it is believed that whether or not a company acknowledges or compensates the affected indigenous community will depend entirely on its corporate goodwill (RAFI, 1994b), well-designed ABS systems strengthened by national, regional and international supportive measures can bring significant returns to biodiversity rich countries.

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