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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

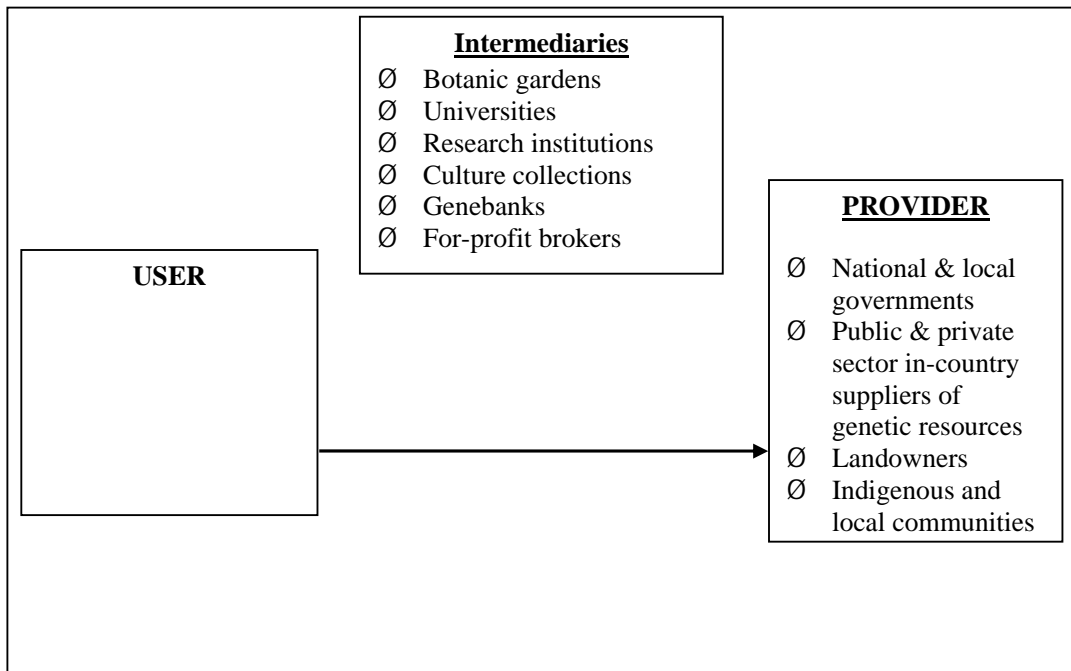
Source: FAO Food Balance Sheets (1984 – 86), cited in The Crucible Group, 1994

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

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-5(c)(the)dcgte swthc itit 1(ch(b)5(yr)-3(i)6(v)-1((t)67(Ilian)-)7(d



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 *in5TDTitie4ni.68ab(itiesa8 2Cf303 14d(in0(p)-8(resource*

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

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,

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):

- Ø Specify state's role in allowing access to genetic resources
- Ø Define scope of the resource and activities regulated
- Ø Describe application procedure
- Ø Establish an institution to administer and determine access applications
- Ø 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 PpTEMC ag6(untos41(0 -/d)7(o

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 precept of the Convention on Biological Diversity (CBD) (1992) and the Nagoya Protocol (2010), the law focuses on the conservation 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

provide competent national authorities with all information related to the genetic resource and

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*

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):

- Ø Per-sample fees
- Ø Advance payments
- Ø Efforts to screen samples
- Ø Results of research
- Ø Training for partner communities
- Ø Royalties
- Ø 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).

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

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:

- Ø The International Cancun Declaration of Indigenous Peoples, 2003.
- Ø The Johannesburg Declaration on Biopiracy, Biodiversity and Community Rights, 2002
- Ø 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
- Ø The Thammasat Resolution on Building and Strengthening of *Sui generis* Rights, 1997
- Ø Final statement from the UNDP Consultation on the Protection and Conservation of Indigenous Knowledge, Sabah, Malaysia, 1995
- Ø Final statement from the UNDP Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights, Suva, Fiji, 1995
- Ø Statement/basic points of agreement from the COICA/UNDP meeting, Intellectual Property Rights and Biodiversity, 1994
- Ø The Mataatua Declaration on Cultural and Intellectual Property Rights of

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):

- Ø 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)
- Ø Lack of awareness at the national level, including at the level of decision makers which has likely hindered implementation.
- Ø 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:

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

- Ø Engaging local and indigenous communities; and
- Ø 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):

- Ø the *option value* – the value of certain chemical properties present in plant and animal varieties that could prove beneficial for health and the environment
- Ø 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 is 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

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

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 (Afreeen, 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

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-

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

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 (Argumedo, 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

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):

Ø "*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.

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

Ø Promote and invest in research and development for both South South and North South joint ventures within and between provider and user countries; and

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