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UNU-IAS Report

Benefit Sharing in ABS:
Options and Elaborations

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Acknowledgements

The authors would like to thank David Leary, Claudio Chiarolla, Geoff Burton, Sam Johnston and Hiroji Isozaki for their comments on the draft paper. Thanks are also due to the participants at the national workshop on ABS for implementing the National Biodiversity Act in India for their inputs and suggestions to make the arguments based on real-life examples. Grateful thanks are due to Prof. A.H. Zakri, former Director of UNU-IAS for his support and encouragement to develop this report. Support from the Japan Society for the Promotion of Science for the postdoctoral research work of the first author is gratefully acknowledged.

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Foreword

The United Nations University Institute of Advanced Studies (UNU-IAS) and the Division of Environmental Law and Conventions (DELC) of the United Nations Environment Programme (UNEP) are happy to present this very important report on issues related to benefit sharing that arise from the use of genetic resources. It is especially relevant at a time when the international negotiations on developing an international regime on access to genetic resources and benefit sharing (ABS) are at a critical juncture to finalise the regime by the year 2010.

As those of you following the ABS discussions under the Convention on Biological Diversity (CBD) may know, there has been limited progress under the CBD on implementation of the ABS provisions, which is one of the three founding principles of the CBD. Though various reasons are cited for such slow progress, the key reason has been the lack of clarity and experience in understanding and applying ABS provisions at national and local levels. In spite of adopting the Bonn Guidelines on ABS, countries are still struggling to understand various dimensions of the ABS issues. In addition, much of the debate so far has been on issues of access to genetic resources, while there has been very limited focus on issues of benefit sharing.

UNU-IAS and UNEP have been working on issues of ABS for the past several years with a strong emphasis on capacity building and awareness raising through the development of knowledge, methodologies and action plans designed to aid in the implementation of ABS provisions at all levels. Its work is recognized as pioneering in areas such as certificates of origin, policy and legal aspects of ABS, and links to traditional knowledge.

This report attempts to provide inputs into the much needed discussions on how to deal with benefit sharing provisions within the ABS framework. It is based on research undertaken by UNEP and UNU-IAS together with several governments and agencies working on ABS issues, in particular with the Ministry of Environment and Forests of the Government of India, for which UNEP and UNU-IAS are together providing technical support to develop and implement national ABS guidelines.

We hope the work undertaken by the authors of this report will help to provide inputs for the ongoing negotiations on further defining the international regime on ABS until 2010 and beyond, and that this report will be helpful in addressing social and ethical dimensions of the CBD.

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Executive Summary

The third objective of the Convention on Biodiversity (CBD) to ensure *"the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources..."* has taken centre stage now with negotiations in full swing to develop an international regime on Access and Benefit Sharing (ABS) by the year 2010. While some progress has been achieved on negotiations related to access regulations, discussions on benefit sharing are still evolving. The provisions of the CBD and its Bonn Guidelines on ABS (Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization) provide direction to the measures that countries may implement to achieve fair and equitable sharing of benefits among the different stakeholders. Other international instruments, such as the Food and Agriculture Organization's (FAO) International Treaty on Plant Genetic Resources (ITPGR) and the World Intellectual Property Organization (WIPO) through its Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), also address issues related to the implementation of benefit sharing measures. Despite developments in deliberations on benefit sharing in such fora, countries are found to be cautious to implement measures related to benefit sharing.

Based on the experiences of implementing provisions of the international instruments and national measures, an attempt has been made to assess and analyse the issues related to benefit sharing, the entry points for discussions on the issues and the possible considerations that national implementing authorities should make before deciding on benefit sharing principles and policies. The principles are discussed under five topics in the order of a typical scheme in a bio-prospecting exercise: (i) Defining ownership over resources and related knowledge; (ii) By-products/Derivatives; (iii) Benefit sharing; (iv) Third Party Transfer of research results; and (v) Intellectual Property concerns. Issues that need to be considered under each context in addition to distinct and suitable examples have been quoted highlighting potential scenarios that national implementing agencies will be faced with. This therefore provides a framework for nations to assess their options of dealing with such issues.

It is also important to account for and reflect on the differences in benefits, costs and approaches to benefit sharing between various prominent sectors that use biological resources for their research and development ventures such as pharmaceuticals, botanicals/nutraceuticals, food and agriculture, natural personal care and cosmetic products as well as academia. As such, any particular scenario related to ABS is specific to sectors, locations, scales and policies, which highlights the need for an integrated approach by stakeholders at various levels to ensure effective implementation of ABS provisions. This requires the active participation of experts from multiple disciplines and different ministries at the national level to devise comprehensive policies and administrative procedures. It also necessitates appropriate and sufficient support from global mechanisms to implement the provisions of the Bonn Guidelines while strengthening efforts to adopt and implement an international regime on ABS.

1. Introduction

According to various estimates, the potential value of biological diversity and genetic resources ranges anywhere between US$ 800 billion to US$ 1 trillion (Costanza et.al., 1997; ten Kate and Laird 1999; Balmford *et al*, 2002). However, this potential is not currently available in a form for us to use directly but is based on the careful prospecting of genetic resources for products, derivatives and services. The use and non-use values of biodiversity provide humanity with a range of options to deal with livelihood and economic securities. Humans used this variability in biological systems to their advantage over time. New technologies such as biotechnology, nanotechnology, pharmaceuticals and others add value to biodiversity and genetic resources. With the advent of novel technologies, countries face new challenges to ensure equity amidst the different stakeholders using biological resources. This has resulted in the adoption of new rules in the game of who gains access to such resources, how such access is made available, what benefits will accrue to the providers and users of the resources, and how the benefits will be shared.

The Convention on Biological Diversity (CBD) is an almost universally accepted international agreement (with 191 countries Parties to the Convention as of October 2008) that provides countries with a set of principles, obligations and responsibilities on how access to genetic resources be provided and benefits arising from use of such resources be shared. The third objective of the CBD seeks to ensure "*the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.*"

In an era that facilitates privatization of knowledge and resources, governments have the sovereign right over exploitation of their natural resources and accordingly must decide how access is given to people to prospect and use genetic resources and how benefits are shared based on a set of agreed norms and principles derived from ethics and equity.[1]

The CBD attempts to facilitate such access and benefit sharing mechanisms and does not provide for restrictive scenarios. However, in the absence of clear principles of what constitutes a fair benefit sharing deal and how one can foresee the potential of genetic resources in realising benefits, countries are concerned about the entire provision of access and benefit sharing (ABS) within the CBD. Owing to the lack of clarity, many countries have found it challenging to implement relevant provisions of the CBD. Some countries, such as India, introduced strategic national instruments such as the National Biodiversity Act (2000) to provide policy guidance on issues of ABS. However, much needs to be done to operationalise the principles surrounding ABS.

The Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (Bonn Guidelines) that were adopted by the Parties to the CBD in 2002 to provide a voluntary set of guidelines and principles, including some clear mandates, are not being effectively implemented. Some reasons for poor implementation include the voluntary nature of the Guidelines, unclear legislation, asymmetries in market information and resultant uncertainty over the likelihood of receipt of benefits commensurate with the costs of regulation and the complexity of dealing with sub-national bodies such as states and local communities and private landowners.

The World Summit on Sustainable Development (WSSD) in 2000 called on nations to negotiate an international regime to promote and safeguard fair and equitable sharing of benefits arising out of utilization of genetic resources under the auspices of the CBD. The eighth Conference of Parties (COP) of the CBD through its decision (VIII/ 4) mandated Parties to complete the negotiations for an international regime in time for its tenth meeting of the Conference of Parties in 2010. As per this mandate, discussions are underway to develop such a regime by the year 2010.

In order to progress on ABS issues, it is important for countries to gain more experience on how to operationalise the principles of ABS at national levels without waiting for the 'perfect' system to be designed. These can be *sui-generis* systems but discussions under the international regime are to provide some operational principles. Innovative approaches such as the creation of best practice on ABS through the Swiss funded International Institute for Sustainable Development *ABS Management Tool- Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit-sharing Activities* provide a comprehensive approach to operationalising ABS measures.[2] Nevertheless, a comparison of the different benefit sharing measures within the ABS provisions of a sample of countries, based on their legislation (in Appendix), shows that while all the countries have fulfilled the minimum requirement for ensuring fair and equitable benefits, adequate laws providing minimum principles to be adhered to during negotiations are either absent or not fully coherent in several cases.[3]

Benefit Sharing: Need for specific guidelines

Provider countries are faced with the task of making decisions related to benefit sharing during any ABS activity. By focusing on issues related to benefit sharing, this paper provides a framework set of principles and options to facilitate fair and equitable benefit sharing. The paper also briefly highlights sectoral differences in product development, the resultant costs, benefits accrued and feasible shares between the stakeholders. It also seeks to address the gap between policy and practice through the

elaboration of major issues of concern in benefit sharing negotiations and what principles may be followed to address them. In this sense, it aims to facilitate discussions on the international regime (IR) on ABS.

The following section discusses the global policy framework and the guiding principles for implementation of ABS provisions with an emphasis on the CBD, Food and Agriculture (FAO) and World Intellectual Property Organization (WIPO) processes. Section 3 discusses various principles on benefit sharing that need to be taken into account and different scenarios that national policies should anticipate to chart guidelines for implementation of ABS provisions. Section 4 examines the rationale for fixing benefit sharing norms in ABS discussions, including modes and amounts of payment, arguing for a sectoral estimation of potential value of benefits. Care is taken to identify elements of the sections that are in tune with the ongoing discussions under the international regime.

2. Global Policy Framework for ABS Implementation

Intergovernmental, global processes determine the policy direction that individual countries shall take to deal with implementation at local levels. In the case of access to biodiversity, use of the resources and sharing the benefits of such use, three major processes influence country level implementation. These are the Convention on Biological Diversity (CBD), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Office (WIPO) that deals with ownership and intellectual property rights issues related to genetic resources and traditional knowledge.

2.1 Benefit Sharing within the Convention on Biological Diversity

The Convention on Biological Diversity (CBD) addresses Benefit Sharing through Articles 8(j), 15(4), 15(5), 15(7), 16 (3), and 19(1), 19(2) of the CBD text. Article 15 provides guidance when benefits arise from different kinds of utilization of genetic resources and on essential principles of obtaining informed consent on mutually agreed terms (Tvedt and Young, 2007). The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization that were adopted by the COP of the CBD in 2002 were developed to serve as guidelines for, among other measures, 'contracts and other arrangements under mutually agreed terms for access and benefit-sharing.'

With ABS debates based on issues of Prior Informed Consent (PIC), Mutually Agreed Terms (MATs) and Material Transfer Agreement (MTA), it is worthwhile to revisit how these issues are being addressed within the Bonn Guidelines. The Bonn Guidelines indicate that 'mutually agreed terms should be set out in a written agreement' with 'guiding parameters in contractual agreements' and provide 'an indicative list of typical mutually agreed terms' which may be applicable in contracts regarding access to genetic resources. They provide basic requirements in the development of MATs for ABS, including legal certainty, awareness, institutional mechanisms, and an indicative list of elements that could be included as MATs. These elements range from resources that can be accessed to issues of ownership over the final product, terms to use and transfer the material and benefit sharing. A separate section on benefit sharing highlights what could be covered under the terms including type (monetary types and non-monetary types of benefits), timing (short-term, medium or long-term benefits) and distribution mechanisms among the different stakeholders (including government, indigenous and local communities, industry, etc.) to ensure that the sharing process is fair and equitable.[4] The ABS Management Tool provides practical guidance for users of genetic resources to be compliant with the Bonn Guidelines, including best practices that may be followed in the implementation of the different provisions such as PIC, MAT, benefit sharing, traditional knowledge, conservation and sustainable use. Specifically, the Management Tool clearly highlights that fair and equitable benefit sharing is required to ensure compliance with the third objective of the CBD; it is provided based on the stages of value addition and should involve different stakeholders who may have contributed to the "resource management, scientific and commercial processes."

Given the role of the sovereign right to exploit genetic resources as enshrined in Article 3 of the CBD, it is important that every country assesses the way it wants to apply the principle in terms of its constitutional provisions. The complexity comes from the variety of ways countries are constitutionally organized to deal with ownership. There are sub-national bodies such as states or provinces, indigenous and local communities and private property land owners. It is therefore important that the ownership and/or other property rights of the resources be clearly defined in the PIC and MAT applications. One of the critical challenges for countries is to define community ownership of genetic resources, where applicable. In the absence of clear guidance on the ownership of resources, there is always scope for confusion in sharing the benefits.

When defining the details of distribution, it is important to have clear guidelines on when and how the benefits are distributed. In instances where local devolution of power is envisaged and local communities provide PIC and negotiate MAT, the type and kind of benefits can be decided in consultation with such communities.

Ideally, mechanisms for ensuring benefit sharing should be flexible, variable to suit stakeholder interests, include research co-operation, joint ventures, and preferential terms (Bonn Guidelines, 2002). One needs to be innovative in defining the mechanism in order to maximize benefits. Experiences have shown that wider stakeholder consultations will be needed to define various mechanisms. Each of the potential options above provides an opportunity to maximize the benefits, given market capitalization and cost constraints.

An additional example of a benefit sharing mechanism currently being tested is the mechanism within the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). It is discussed below in detail to provide some ideas for defining benefit sharing regimes both for the international regime on ABS as well as for national benefit sharing system development. It should be clearly noted that the discussions under the Treaty relate to the crops that are listed in Annex 1 of the ITPGRFA. However, the principles underlying each of the options under the Treaty are different from

the ABS principles under the CBD. Additionally, discussions within ITPGRFA on "certificate of origin" might provide some ideas for ABS discussions under the CBD whereby countries can, as a starting point, begin to address the possibility of defining sets of genetic resources. However, we cautiously note the details that need to be worked out to put forward this idea formally within the discussions under the international regime while recognizing this as a possible option.

2.2 Benefit Sharing within the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, 2001)[5]

The FAO Treaty provides an internationally agreed framework for the conservation and sustainable use of crop diversity, and the equitable sharing of benefits, consistent with the Convention on Biological Diversity.[6] In the exercise of their sovereign rights, the Contracting Parties of the FAO Treaty have decided to facilitate access to the 64 most important crops and forages to ensure worldwide food security. Such resources are listed in Annex I of the FAO Treaty. Part IV of the FAO Treaty establishes a Multilateral System (MLS) of Access and Benefit Sharing. Under the MLS, a recipient of material from the MLS is obliged to share benefits only if s/he restricts access to the material in the form received. It therefore aims to ensure free access of materials. Some of the options under the Treaty for benefit sharing include: scope for sharing non-monetary benefits in addition to monetary benefits arising from the use of Plant Genetic Resources for Food and Agriculture (PGRFA) (Article 6.9 of the Standard Material Transfer Agreement (SMTA), and encourages recipients to make voluntary payments into the trust fund administered by the FAO for such purpose (Article 6.8 of the SMTA).

2.2.1 Access Restriction Requirement

Under Article 6.7 of the SMTA, payments are due only when a "*Product*" is not freely available for further research and breeding.[7] In essence, this scheme entails the existence of a patented product (legal restrictions) or restrictions deriving from Genetic Use Restriction Technologies (GURTs) (technological restrictions) or certain licensing practices (contractual restrictions). However, technological and contractual forms of protection are normally used in addition to and not as a substitute for patent protection or plant breeder's rights. Countries need to consider provisions under International Union for Protection of New Varieties of Plants (UPOV) when using this system. For countries with *sui generis* provisions, it is important to link the provisions under the national plant variety protection and related rights (including farmers' rights).

2.2.2 Compulsory Benefit Sharing

The Treaty provides for a compulsory benefit sharing scheme with a provision for an alternative payment scheme under Article 6.11. Article 6.7 of the SMTA states that compulsory benefit sharing payments of 1.1% of sales income are subject to the requirement that the commercialised "*Product*" incorporates "*the Material*" received from the Multilateral System. A "*Product*" must 1) incorporate the material received from the Multilateral System or any of its genetic parts or components; and 2) be ready for commercialization implying that PGRFA under development are excluded. The *incorporation* includes progeny and unmodified derivatives (including genetic parts and components of the material). What the Multilateral System captures is the added value that has been created from the development and use of a new or modified crop. This also provides some direction to the discussions on by-products and derivatives within the CBD-ABS.

2.2.3 Alternative Payment Scheme

In the alternative payment scheme, recipients may choose as their option to make voluntary payments as provided for in Article 6.11 of the SMTA. Under this voluntary option, recipients share the benefits arising from the commercialisation of any products that are PGRFA regardless of 1) whether or not such products can be freely used for further research and breeding;[8] and 2) whether or not such products incorporate the material received from the Multilateral System.[9] Article 6.11 provides that benefit sharing payments must be calculated at the discounted rate of zero point five percent of the overall sales of any products pertaining to the same crop species received by the recipient. For example, if the recipient is a rice breeder that receives rice accessions under this option, the breeder's payments must be calculated on the basis of their overall sales of rice.

Users may want to take advantage of this alternative payments scheme for two reasons: 1) the discounted rate for such benefit sharing payments is considerably lower than the one provided under Article 6.7 of the SMTA; and 2) the Recipient will only have to comply with a single benefit sharing obligation, no matter how many SMTA s/he has entered into, expressly excluding cumulative payments.[10],[11] It is key to distinguish this system from the underlying assumption of the CBD's ABS provisions. The FAO Treaty obtains a share in benefits from the sale of the improved bulk commodity and the benefits so obtained do not directly go back to the in-situ provider country or local owner; whereas under the CBD, the focus is on capturing a share in the value of the discovery made from genetic resources, which is directly given to the in-situ providers, and distributed based on national guidelines.

2.3 Benefit Sharing within the World Intellectual Property Organization (WIPO IGC)

The World Intellectual Property Organization (WIPO) has done considerable work on the protection of traditional knowledge (TK) and intellectual property issues related to benefit sharing through the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The IGC works closely with the CBD in identifying feasible options for the protection of genetic resources and associated traditional knowledge (TK) in the context of access and benefit sharing. It examines the feasibility of using various forms of intellectual property rights as effective tools for benefit sharing. Towards this, the IGC has published reports on contract based intellectual property protection and benefit sharing, defensive and positive protection options for genetic resources and TK.[12] One of the issues that the IGC deals in detail is the use of TK as *prior art* and how it can be effectively included in patent databases. The IGC's recommendations related to intellectual property protection and benefit sharing are quoted, wherever appropriate, in the following sections.

3. Benefit Sharing Principles

Based on the experiences of implementing the Bonn Guidelines and the terms for benefit sharing set out under the FAO Treaty, in this section we attempt to expand on, assess and analyse the issues related to benefit sharing, the entry points for discussions on issues, and the possible considerations that national implementing authorities should make before deciding on the benefit sharing principles and policies. We suggest that the discussions here be used to address benefit sharing issues under the international regime on ABS that is being elaborated and negotiated currently.

The Bonn Guidelines provide a blueprint to enter into negotiations on MATs on various aspects of ABS. However, national and international discussions on operationalising the provisions, especially related to benefit sharing, indicate the need for pragmatic measures in terms of policy development and the design of implementation guidelines. The following seeks to identify the issues that need to be addressed in the development of benefit sharing guidelines, an important sub-component within ABS. Each topic represents some of the difficult issues that need to be resolved to ensure transparent and comfortable transactions between the providers and users of genetic resources. We are hopeful that this will provide a useful checklist of principles or issues that should be addressed prior to the implementation of benefit sharing provisions of national legislations. Attempts have been made to provide relevant case studies to highlight possible scenarios that may be encountered during implementation of laws related to benefit sharing.

3.1 Access to and Ownership of Genetic Resources

Issues that need consideration:

1. *Defining ownership*

The transfer of Genetic Resources (GRs), which occurs in accordance with the concerned legislation of the country, does not necessarily entail "the conveyance of title or rights in the transferred material" (Chiarolla, 2007). In most of the cases, MTAs transfer only the possession and not the ownership of the material. Hence, sovereign rights over GRs may rest with the National Government. It is also important to clarify the differences in ownership claims over 'genetic resources which are examples of a species' and 'of the Species itself' (which is a rare occurrence) to avoid unrealistic ownership claims.

2. *Defining concepts of collective and co-ownership of resources and knowledge*

In cases where a resource and related knowledge may be shared between communities, it is pertinent to reach an agreement on the collective or co-ownership between the stakeholders. Collective ownership is called for in instances where the community members collectively own resources and knowledge related to resources; co-ownership is called for when ownership rights overlap between communities and other stakeholders such as the State, Research institutes and even other communities. Although this might be considered a time-consuming and difficult task, it is important that the guidelines provide for such eventualities.

The creation of intellectual property rights is the usual method for crystallizing the economic value of scientific research and development. Reaching agreement on how to share benefits from exploitation of these intellectual property (IP) rights will be vital in ensuring an equitable and effective outcome of a benefit sharing negotiation. This can entail agreeing on the value and level of contribution of each party to the access and benefit sharing arrangement. There is a wide range of potential factors to be discussed and weighed when assessing the relative contribution of various parties. Some key questions that need consideration include: is access being provided to the genetic resource and/or associated traditional knowledge? Could associated TK contribute directly and significantly to an invention based on the resource so that the TK provider is actually a co-inventor? Does the implementing authority provide for options to deal with PIC, MATs and MTA that is based on genetic resources and associated knowledge.

3. *Defining possible solutions for genetic resources that occur across countries (transboundary similarities) and thereby involve ownership issues in resources and/ or knowledge*

This issue is critical to effective implementation of ABS regulations/legislations especially with issues related to ABS discussions across countries and across provinces within countries. In many cases, countries exercise their sovereign rights over genetic resources as rights of ownership or in a manner indistinguishable from such rights. Unless a country owns all living examples of a given species it cannot legitimately claim to 'own' the genetic resources of that species. Therefore, ownership of material vested with communities that are residing in more than one country/state or province, and the negotiation on benefit sharing arrangements by the respective authorities need careful consideration to ensure no confusion exists with respect to benefit sharing arrangements. It is therefore pertinent to make provisions in benefit sharing measures anticipating circumstances where resources and related knowledge are common to different communities living in different countries. An example is shown in the Draft Bangladesh Law that allows for co-operation and co-ownership between communities in such instances, resulting in benefits accruing to the different stakeholders involved.[13]

3.2 By-Products (Derivatives)

Issues that need consideration:

1. *Definition of by-products and derivatives and the scope of a product qualifying to be a derivative/by-product*

Discussions on this issue need to be informed of differences and/or similarities between by-products and derivatives. Countries could consider inclusion of 'derivatives' within the definition of 'by-product' or attempt to define them separately. This should be clarified before agreeing on a MTA and benefit sharing agreement.

Definition of by-product and derivative

For example, a *by-product* can be defined as any part taken from biological and genetic resources such as hides, antlers, feathers, fur, internal organs, roots, trunks, branches, leaves, stems, flowers and the like, including compounds indirectly produced in a biochemical process or cycle. A *derivative* can be defined as something extracted from a biological or genetic resource such as blood, oils, resins, genes, seeds, spores, pollen and the like taken or modified to form a distinguishable product.

2. *Terms for unmodified by-products (from original material and/or from leads from traditional knowledge)*

The status of by-products that are unmodified from their original 'biochemical' form or when a resource is used for the same purposes as in original traditional knowledge will have to be clarified. Countries could choose to deal with such examples of biotrade through laws dealing with the conservation and sustainable use of biodiversity and the protection of traditional knowledge.

Using by-products

Consider the following examples from India that highlight the scenario and attempts at benefit sharing in the context of biotrade uses of traditional knowledge, albeit at a local level. The first example is a case study of how a herbal medicine was developed from a resource used in TK, with the product being put to similar use as in TK. The second example pertains to products being developed using modern technologies and markets but based exclusively on TK related to resources and processes of product development.

1. Members of Kani community in Kerala state of India have a rich herbal medicine tradition. They use the berries of *Trichopus zeylanicus* ssp.*travencorius* (Arogyapacha) for its anti-fatigue properties. This was observed by scientists of TBGRI (Tropical Botanic Garden and Research Institute, a government research institute), during a botanical exploration together with members of the community. The identity of the plant was not initially revealed by the Kanis as the plant is sacred to their community. But the scientists obtained the information based on their goodwill and an oral commitment to share any returns accrued from use of the plant. They found that the leaves of the plant also had similar properties and used them in the development of a poly-herb drug, Jeevani, which is marketed as an anti-fatigue drug (same use as in TK). The drug was licensed for commercial production to an established private Ayurvedic company. TBGRI shared 50% of its receipts with the Kani community through a Trust Fund established in the name of the community (Pushpangadan,P *et al*, 1988).

2. The Gram Mooligai Company Limited (GMCL) is a public company registered in India. Its shareholders are made up of small groups of members of a community of medicinal plant gatherers. GMCL procures plants and plant products (sold as unmodified by-products) directly from these groups, at remunerative rates but specifies the quality parameters. The company also promotes sustainable harvesting practices among the communities. The company sells the herbs and shares 70% of the returns with the communities. In addition to this, the company is also involved in the production of simple medicinal formulations based on traditional knowledge (unmodified TK use). These formulations are now available in the mainstream markets. This is also an example that indicates how a domestic company can involve local communities in the development of products and markets, with an emphasis on sustainable use of genetic resources and equity in transactions. It is also an instance of how knowledge related to genetic resource use can be effectively utilized to widen the economic opportunities of the communities (Personal Communication, 2004).

3. *Terms for modified by-products (from original material and/or from traditional knowledge leads)*

Modified by-products refers to changes in information encoded in the resource, either as synthetic or analogue, or in its use which is different from its purpose in TK. The MTA and benefit sharing discussion should deal with such modified by-products clearly.

Unintended use

The following example from Madagascar shows how a plant is shortlisted as a candidate for drug development due to its use in traditional communities, but later gives rise to successful products that are different in form and use from TK. The products therefore are modified from the original resource and related knowledge.

The indigenous communities of Madagascar use the plant *Catharanthes roseus* as an antidiabetic. 'Vincristine' and 'Vinblastine' are anti-cancerous alkaloids (different use from TK) developed from the plant. These products were isolated and identified for their potential by Eli Lilly Pharmaceutical Company based on an indirect lead obtained from the indigenous communities (Reid, 1994). There was no benefit sharing involved with the communities or the country. This is an instance of a

foreign researcher/ commercial body interacting with traditional communities, and developing a product different from original use. The contribution of TK in this case lies in providing a lead candidate for drug development, and thereby increasing the probability of success.

3.3 Benefit Sharing

Issues that need consideration:

Discussion under benefit sharing should address the following key questions.

1. *Under what circumstances is benefit sharing warranted?*

This forms the underlying basis for any benefit sharing arrangement. It would be futile to claim benefits for access to genetic resources that are normally traded commodities (that are traded regularly in various markets). By the same logic, it is unfair if access to new resources and/or related knowledge is not compensated.

2. *For whom is benefit sharing warranted?*

a. *For foreigners*: For instance, the Indian Biodiversity Act and Rules are oriented towards regulating the prospecting norms for foreigners, while the Brazilian Act is oriented towards all Users, foreign or domestic.

b. *For domestic researchers and companies*: For instance, in India, domestic researchers and companies are only required to inform the respective State or Provincial Biodiversity Boards of their research intentions, although they are expected to comply with benefit sharing principles in the event of accessing community resources or knowledge. Hence, benefit sharing norms for different actors need to be appropriately specified.

It has to be noted that in discussions during the 6th Working Group on ABS held in January 2008, interventions were made to reassess the discriminatory nature of provision of access. Such discussion will have implications for linking to World Trade Organization (WTO) based debates as well. Countries such as Australia have applied national treatment (as per WTO obligations) requiring that foreign or domestic applications be treated the same and are subject to the same rights and obligations. Thus, under Australia's national ABS law (the Environment Protection Biodiversity Conservation Regulations 2000) all applicants are treated equally. This approach has the advantage of encouraging investment and scientific collaboration with foreign-based companies and international research organisations. For example, AstraZeneca and the USA's National Institutes of Health have independent long-term research and development collaborations with Australian domestic partners (Personal Communication, Geoff Burton, 2008).

3. *Identification of various ABS scenarios*

In the development of benefit sharing guidelines, it is relevant to anticipate possible scenarios that the national authority may be faced with. These could include scenarios where the bioprospector wishes to gain access to resources only for documentation purposes, to scenarios where the user develops analogues for commercialization from resources using traditional knowledge. Some of the possible scenarios are highlighted below. Although the scenarios are individually indicated, guidelines may be developed for several of them *in toto*.

a. Terms when original genetic resource is only used for research purposes

Access to genetic resources may be sought purely for the purposes of research, training, education, etc., with no commercial intent. However, there is a possibility for commercial applications at a later date, by users of the research information. Therefore, ABS negotiators and implementers need to consider such un-intended product and process development (different from the original intent), while providing access and in dealing with MATs, and MTAs. Examples on terms to be adhered to by users for non-commercial research purposes and if the research product is intended to be commercialized or transferred can be found in the legislation and regulations of countries such as Australia.

Negotiating Access for Research

Development of biodiversity registers and related inventories, herbaria, and bioactivity studies are examples of how information on resources and associated traditional knowledge can be used for research purposes where the genetic resources accessed are used only for research purpose and do not enter into the commercial stream in the short-term. However, it is necessary to negotiate terms in the event of potential commercialization of the scientific or research information in the future.

WIPO addresses such concerns by suggesting the following benefit sharing mechanism:
"An initial agreement may concentrate on issues that do non-IP related benefit-sharing, such as research cooperation, evaluation of resources, training and education and technology transfer, and the parties may agree to negotiate a separate commercialization package (including agreement on ownership of IP, right to license the IP, benefit-sharing arising out of any licensing agreement etc.) at a later date, should the need arise, once initial research leads to commercial possibilities.." (WIPO/GRTKF/IC/7/9).

b. Terms when original genetic resource is commercialized

This refers to the commercial use of the genetic resource in its original form.

Negotiating Access for Commercialization

Such scenarios could especially arise with respect to micro-organisms and genetic resources whose utility can be commercially exploited in the form discovered. The following is an example of a related scenario:
Bayer company filed a patent on a novel process to manufacture acarbose, a drug for Type II diabetes. The process involved the use of a A*ctinoplanes sp*. bacteria strain called SE50 from Kenya's Lake Ruiru. The strain of bacteria possesses unique genes enabling the biosynthesis of acarbose in fermentors. No benefit sharing arrangement is apparent in this case (McGown, Jay, 2006).

c. Terms when information on original genetic resource is commercialized

Use of information for commercialization

There are examples of how databases can be used for commercial gain, which indicates the need for negotiations on the compilation of information, who gains access to it, what parts of the database is open for access to all and other related aspects. For instance, from their interviews with pharmacies using ethno-botanical knowledge, ten Kate and Laird (1999) report that 80% of these companies rely on secondary sources for their data requirements, such as databases and published literature, rather than field data collections. This often absolves them of any obligation to compensate the originators or custodians of knowledge.

d. Terms when a natural by-product of genetic resource is developed and commercialized

Commercialization of natural by-product

For instance, powders or aqueous extracts of a plant identified for medicinal properties may be commercialized in foreign markets. Terms for such simple and linear value addition will have to be discussed. It is worthwhile to reiterate that value addition can range from simple processes directly using the resource to more sophisticated processes including the development of synthetic molecules or analogues, whose action may or may not be directly related to the original material and related knowledge.

e. Terms when a synthetic by-product of genetic resource is developed and commercialized

Commercialization of synthetic by-product

Consider the hypothetical example given below:
An active ingredient of a medicinal plant may be identified and later isolated. This isolate may then be synthetically produced using various technological processes. It is then necessary to have terms of agreement on the extent to which benefits may be claimed on the commercial value realized.

f. Terms when a by-product analogous to the original molecule isolated is developed and commercialized

Commercialization of analogous compounds/material

Consider the hypothetical example given below:
A molecule that shows anti-cancerous activity is isolated from a genetic resource. Later, an analogue of it with higher activity is developed and commercialized. Clearly, the technology and costs involved in the development of the analogue are different, although the lead to its development was obtained from the original genetic resource. Negotiators and decision-makers may have to take into account the relative contribution of the genetic resource to the development of the final product in deciding norms for extent of benefits to be shared.

g. Terms when research product developed has same uses as TK information accessed (direct/ unmodified use)

Commercialization of product developed using traditional use

In the Kani case study referred to earlier, during the process of bio-exploration and related ethnopharmacological work, the TBGRI also developed several other research products, all of which were not commercialized. The uses of these products are in line with the traditional uses for the genetic resources by the Kani community (Pers. Comm. Dr.S.Rajashekaran, TBGRI, 2001). This is an instance where TK has directly enabled research. Terms for benefit sharing will have to account for degree of ownership over the product between the research institute and TK-holders, and the future commercial use of the product, apart from other research collaboration benefits.

h. Terms when research product developed with same uses as TK information accessed is commercialized

Commercialization of product developed by modifying traditional use

The following are examples of research products that were developed from TK and later commercialized. They also serve to highlight what kind of challenges are faced in the light of inadequate policy measures to ensure that benefits are shared with the TK-holders for their contributions.

1. The San tribe of South Africa uses the Hoodia plant as an appetite suppressant, which was used by the Council for Scientific and Industrial Research (CSIR) of the country to develop an anti-obesity drug. This drug was then licensed to a private international pharmaceutical company (Suneetha, 2004). Initially there was no benefit sharing with the San tribe, but later, with advocacy and pressure, CSIR negotiated a benefit sharing deal

with the tribe. This example also highlights the issue of co-ownership of resources between the State and communities and the need for reaching an agreement on such issues.

2. Extracts from a medicinal plant *Artemisia judaica* from Libya, Egypt and other North African countries for the treatment of diabetes was patented by a UK company, Phytopharm Plc. The company admits to knowing that the plant has been used in Libyan traditional medicine for the treatment of diabetes, although no benefit sharing deal is apparent (McGown, Jay, 2006). This example is also indicative of the collective ownership over resources/ related knowledge between communities of different countries and of the need to ensure that sufficient policy space is provided to address such issues, when they crop up.

i. Terms when research product developed has uses different from TK information accessed (indirect/ modified use)

   This refers to cases where research is carried out with contributions from TK, but the final non-commercialized research product developed has uses different to the original use in TK.

Commercialization of product based on modified TK usage

Consider the hypothetical example below:
For instance, an antihistaminic drug could be developed from a herb used by a TK community for treating injuries/ burns. The drug, however, is not yet commercialized. This in a sense makes the contribution of TK 'indirect' to the product development process. The terms for ownership rights over the product between TK-holders and researchers will not be considered as in a 'direct' contribution scenario, and terms for future commercial use would also vary.

j. Terms when research product developed with uses different from TK information accessed is commercialized

Commercialization of product with different use than originally accessed for

This scenario is best illustrated with the example of the development of 'Vincristine' and 'Vinblastine' from *Catharanthes roseus,* for use in hypertension. The plant was originally used by traditional communities as an antidiabetic, and was hence a candidate for further testing. While the case did not see any sharing of benefits, it is imperative for negotiators/ implementing agencies to anticipate and set guidelines under such circumstances.

One reason why these scenarios make reference to commercial and non-commercial activities is in order to capitalize on the market returns of the product during various stages of value addition. Hence, some of the scenarios may be part of a continuum, where a non-commercialized product is commercially exploited at a later time. It is therefore in the best interests of a provider country to negotiate on two terms: 1) on a commitment for renegotiation of an agreement in the event of commercialization; and 2) to enter into a benefit sharing arrangement that will provide a share of benefits at every stage of value addition and market capitalization.

It is often difficult to fathom the likely value of benefits at the start of a research activity, resulting in benefit sharing deals that misrepresent the share of the resource or related knowledge. During various stages of the research and product development cycle, the value of the resource might increases due to increased information, and the negotiating power of the supplier is further strengthened. Hence, milestone payment streams based on appropriate economic valuation of the product at each stage could ensure a higher rate of return to the supplier. This should also be preferable to users over deterrent upfront payments on products, whose value, though promising, is still vague. This does not suggest doing away with upfront payments and other modes of benefit sharing, but draws attention to the merits of including higher negotiating bases during various milestones of a research process, when stronger likelihoods of success improves the product value.

4. Identify baseline typology of benefits (What), timing (When), and volume (How much)

A baseline indicates the modes and mechanisms by which benefits can be shared. If identified deliberately, it can provide crucial guidance to providers and users of genetic resources and associated knowledge. Some of the broad categories of benefits include:

a. Monetary benefits- upfront payments, milestone payments, funds, supply contracts/ linkages, IP benefits, etc.;
b. Institutional benefits- such as venture capital funds, enterprise development;
c. Capacity building- at various levels;
d. Access to and transfer of technologies;
e. Sharing and exchange of information.

It will be useful for countries to base decisions, especially with regard to monetary benefits, by devising a system to value potential benefits from the bioprospecting activity. This will also enable in identifying lacunae in capacities and institutions, which can be addressed in the benefit sharing scheme.

3.4 Third Party Transfers of Research Results

Issues that need consideration:

1. Define third party transfer

A comprehensive definition of who constitute a third party and what is entailed by third party transfer is required.

2. What is transferred

Each of the following and any related product will need to be defined in the light of transfer:

a. Original material;
b. Publications;
c. Research product;
d. Derivatives/ By-products;
e. Intellectual Property rights (IP).

Third Party Transfers

WIPO identifies the need for broad based negotiations in third party transfers. To quote WIPO on academic publishing and transfer:
"If the research activities are wholly academic in nature, and are not aimed at the development of new products or processes, it is nonetheless likely that the parties will wish to create and publish articles and associated data, giving rise to copyright in those publications and related transfer or licensing issues" (WIPO/GRTKF/IC/7/9).

3. Under what circumstances are terms for transfer set?

Clarity on the conditions for third party transfers is required. For instance, negotiators and implementing authorities will need to arrive at an understanding if the terms are set only in the event of commercial transfers, or any other transfer such as transfer of research results, etc.

4. What are baseline terms for transfer?

The terms on which third party transfer can occur, including the type of resources, products, in whose presence, authority to be intimated, type of benefits to be shared, obligation of receiver to honour benefit sharing agreements, and such related terms need to be negotiated. It is also important to negotiate terms for commercial transfers and research product transfers.

Research Product commercialized

The following example provides an illustration of a scenario where a research product was transferred for commercial application:
A micro-organism (that produced enzymes to fade colours) from a research inventory of a Kenyan researcher on extremophile microorganisms from a Kenyan lake was sold by her professor at a London university to a Dutch firm. The Dutch firm later sold the micro-organism to Genencor that took a patent on it, and cloned it to produce the enzyme which is used for fading jeans and as an ingredient in a detergent (Lacey, Marc, 2006). This resulted in a stand-off between Kenyan authorities and the company.
The example indicates the need for a provider country to include in transfer agreements clauses for renegotiation and arbitration in the event of commercial transfers, and for users to be explicit and transparent in their resource sourcing trails.

3.5 Intellectual Property

Issues that need consideration:

1. Joint Ownership of IP

a. Define joint ownership: this should include what is intended by the term and how it will be enforced.
b. Under what circumstances is joint ownership prescribed? This should include specifically what circumstances call for joint ownership such as in the event of unmodified product development or modified products but of the same use as in accessed TK. Joint ownership is a sensitive issue with product developers and hence needs to be carefully negotiated.

Ownership and Intellectual Property

An instance where joint ownership was practised between the different stakeholders is narrated below:
Joint ownership was claimed and assigned on plant anti-malarial know-how in the USA between Washington University (WU) in St. Louis, USA, Universidad Peruana Cayetano Heredia (UPCH) and Universidad Nacional Mayor de San Marcos, Museo de Historia Natural (USM), and Confederación de Nacionalidades Amazónicas del Perú (CONAP, that represented four groups of the indigenous Aguaruna community in Peru). The four institutions were partners in one of the International Co-operative Biodiversity Groups' (ICBG) projects which involved research partnerships leading to commercial products between a US University, a commercial company dealing with bio-products, and universities/ organizations in biodiversity supplying countries such as in Latin America. (Lewis, Walter H and Veena Ramani, 2003). This particular case indicates the possibility of joint ownership of a product between scientists and local communities.

Joint Ownership

WIPO has dealt at length on the implications of Joint ownership in its document WIPO/GRTKF/IC/7/9 (quoted below):
"Joint ownership of IP rights is one legal option, and may be preferred as one way of ensuring that the provider retains a distinct stake in the outcomes resulting from the access.
On the other hand, joint ownership can lead to unexpected practical problems and limitations, and may not always be an appropriate benefit-sharing

outcome or mechanism. For example, joint ownership does not necessarily create an entitlement to receive benefits from the other owner's exploitation of the common IP rights. In some jurisdictions, joint ownership of patent rights does not require one owner to share economic benefits with the other owner. In cases of joint ownership, the provider and user of the resources should consider how the responsibilities flowing from co-ownership of IP rights will be apportioned, as ownership generally brings with it the costs and responsibilities of securing and maintaining rights, as well as enforcing them;

Ownership can provide reassurance to the resource providers that they will retain a say over how the resources are developed and used, and how any new technology derived from the genetic resources are developed, used and disseminated. On the other hand, ownership of patents derived from access to genetic resources is unlikely in itself to generate tangible or sufficient benefits for the resource provider, in the absence of a strategy for managing actively a patent portfolio. One practical consideration is that maintaining and exercising a patent portfolio, potentially in several countries, can be complex and entail significant investment. Joint ownership of patents is one possibility, but the implications of various ways of structuring ownership should be considered in advance. In some jurisdictions, if there is more than one owner of IP, then the consent of the other owner(s) must be obtained for an assignment or license; i.e. the agreement of all owners is required for effective development and exploitation of the patent. In other cases, unless the joint owners have agreed differently, each one is free to use the patented invention without being accountable to the others. It may be difficult to arrange three-way partnerships between potential licensees and third parties. For this reason, it can be more practical for one co-owner to license or sell his or her interest in the patent to the other co-owner, subject to continuing access to the technology, payment or other conditions. In some cases, it may be more advantageous to concede ownership of any resulting patent in return for other benefits, such as a free license to use the patented product, process or technical solution, or broader benefits such as guarantees of access to technology for certain third parties, such as public authorities, developing country enterprises or non-commercial researchers.

Normally, a patent owner bears the financial and administrative obligations to maintain and to enforce that patent, although contractual agreements can provide for other arrangements. In cases of joint ownership, the parties will need to consider how certain responsibilities are shared, such as making and maintaining a patent application, enforcing the patent in the event of infringement, and negotiating and agreeing the terms of any subsequent licensing arrangement - the organization that carries out research on genetic material may not be competent to develop a commercial product arising out of any successful research, so third parties may need to be involved. How these detailed arrangements are settled should be determined with reference to the overall arrangements set for access and benefit-sharing. For instance, some agreements require that any licensing of patents derived from the access to genetic resources should refer back to the original access and benefit-sharing agreement."

2. Certificates of Origin/ Source/ Legal Provenance

There seems to be a growing consensus among countries that in order to ensure compliance to the various provisions on ABS, implementation of a system of certification that proves the origin of genetic resources, or source of the material or associated knowledge, or geographical origin (legal provenance) of the genetic resource may be worth pursuing (Tobin, 2008). These certificates, when used in conjunction with check-points such as applications for patents or product approval could prove effective in ensuring compliance with ABS measures. This is particularly so when the use of such certificates is matched by the availability to electronically verify the existence and terms of such certifications (Personal Communication, Geoff Burton, 2008).

3.6 Compliance

One of the key challenges in implementing an effective benefit sharing scheme is providing an appropriate and adequate mechanism that will ensure compliance by all parties with an agreement. While certificates of origin is one example of a measure to ensure compliance, other options that will 'facilitate access to justice and support mutual recognition and enforcement of judgments across jurisdictions' are essential (CBD, 2009). It is important, as pointed out in the Report of the Technical and Legal Experts on Compliance in the context of the International Regime on ABS, to examine the options considering issues related to political and economic feasibility (CBD, 2009*)*.

Some of the options currently being examined include a call for co-operation among the Parties to the CBD to address cross-jurisdiction issues; perhaps obligate domestic laws to ensure that users comply with ABS laws of the provider country; provide for legal aid to affected stakeholders who cannot afford the costs of litigation; public listing of defaulters of ABS contracts, etc. Respecting customary law in ABS agreements and the recognition of rights of indigenous people are some concerns that need to be addressed to ensure that international measures are sensitive to indigenous cultures. Countries are also examining scenarios to ensure compliance where no ABS contract or agreement exists.

4. Sectoral Approaches to Benefit Sharing: Some Reflections

4.1 Economic value of biodiversity

In natural resource economics or environmental economics literature, the economic value of biodiversity broadly comprises of its *use value* (value ascribed due to direct or indirect use, be it in trade and commerce, or for cultural and spiritual purposes) and *non-use value* (value ascribed due to its inherent nature and to maintain populations and ecological balance).

Currently, policies related to benefit sharing arrangements generally identify a fixed percentage of gross sales of commercial product as a minimum requirement. This, however, does not fully reflect the economic potential of the resource. For instance, a prospecting firm may identify several potential candidate resources for the development of a drug for a particular disease condition. Not all of the candidates will prove successful. The probability of success could improve with information from local users of the resources and with additional tests or experiments. That is, with additional information or knowledge added, the probability of success rises, and that increases the value (worth) of the accessed resource. This increase in value with additional information is termed *quasi-option value* of the resource (Mitchell and Carson, 1989), and it will be to the advantage of users and providers of the resource to assess and utilize this value to arrive at a benefit sharing stream. Resorting to periodical valuation of the economic value will help in determining and realizing realistic estimates of benefits derivable from the accessed resources and thereby benefits accruable to the country and communities of origin of the resource or knowledge. This argument further strengthens the previous argument that the economic scope offered by milestone payments is fairly wide and should be effectively capitalized by both the users and providers and genetic resources.

4.2 Actors in Benefit Sharing

Drawing an analogy of bio-product development to an industrial value chain, it can be argued that every actor who has contributed to the development of a final product is a factor of production, be it in terms of labour or capital. By this argument, the 'income' derived from commercial use of biodiversity should be distributed as 'returns' to the various 'factors of production', proportional to the extent of contribution. The actors will therefore include 'direct factors' such as local communities that share knowledge and resources, researchers and institutions and 'supportive factors' such as the government, equipment and infrastructure. The extent of contribution can be determined by the extent to which the probability of product development was enhanced due to the role played by the respective 'factors of production'.

4.3 Benefit Sharing—examples by industry

Globally, the demand for 'bio-products' is on the rise (Christie and Mitchell, 2004). These are products that essentially are developed from genetic resources but have undergone various degrees of value addition. The economic value of bio-products varies with sectors using the resources that range from medicines, nutraceuticals, cosmetics, agricultural biotechnology, academic or research products. A brief outlook of each of these sectors on how the benefit sharing principles could work is highlighted in the following paragraphs.

It is noteworthy that not all sectors that use genetic resources or traditional knowledge for development of products enjoy similar economic revenues. Pharmaceutical products are medicines and the demand for medicines is inelastic, allowing the sector to realize sales on set prices, in the absence of substitute medicines. However, in the case of products from other sectors, the demand is elastic, implying that the consumers shift allegiance to a product for attractive substitutes. Conversely, the cost factors also vary commensurately, with pharmaceutical products being more expensive to produce and involving longer timelines in production. The implications of these cost and returns factors should be reflected appropriately in any benefit sharing arrangement. This therefore calls for a systematic and evaluative approach to define a benefit sharing stream, towards which adequate baseline guidelines should be provided in anticipation of potential commercial or non-commercial product development scenarios. Towards this end, it is useful to consider some modes of benefit sharing currently in vogue by the various sectors.

4.3.1 Biopharmaceuticals

Characteristics

Pharmaceuticals can be considered the largest users of biodiversity resources. It has been estimated that over 70% of the drugs developed so far are based on or derived from natural products (Newman and Cragg, 2007). The development of a single drug requires the screening and analysis of at least 10,000 resources. The various stages involved in the development of a drug include lead discovery, the pre-clinical phase, the clinical and post-marketing phase (PhRMA, 2007).

Predictably, the costs involved and the time taken for the development of a drug are high. The Pharmaceutical Manufacturers Association in the USA reports that the cost of the development of a drug is US$ 1.2 billion over a period of 10-15 years (PhRMA, *ibid*). Around 50% of this amount is spent for the screening and optimization phase and the remainder for the pre-clinical and clinical test phases. Typically,

the probability of successful drug development ranges from .0001 to 0.2 during the drug licensing stage (PhRMA, *ibid*).

Given the uncertainties involved at each stage, pharmaceutical companies are inclined to avoid or defer further commitments such as sharing benefits with local communities. The contribution of traditional knowledge largely involves the expansion of the probability of drug development at the lead discovery stage (sometimes as high as 0.5 or a 50% chance of success, (Reyes (1996)), and thereby reducing attendant costs and time taken for the initiation of the drug development process. Successful pharma products have the potential to earn significant revenue (estimated to be around US$ 100 million per annum per drug), which is usually played out in benefit-sharing negotiations. The pharmaceuticals are required to pay upfront lump sums of money and other benefits even before any conclusive results are obtained. This is believed to be discouraging pharmaceuticals in undertaking natural product development related research (Finston, 2005).

The value of the global Biopharmaceutical market is estimated to be around US$ 430 billion (Datamonitor, 2005). Traditionally, pharmaceutical companies obtained genetic resources from biodiversity rich countries for their natural products development work. However, with advances in combinatorial chemistry and relevant technologies, coupled with stringent terms for accessing genetic resources, they seem to have cut down on such research work (Finston,2005). Still, experts argue that natural products research is vital to identify novel products to alleviate human health problems (Cooper, 2004; Newman and Cragg, 2007). It is therefore unlikely to fade away and encourages bioprospecting for useful compounds in various ecosystems- *inter alia* forest, soil, desert and marine ecosystems (Cooper, 2004). Increasingly, pharmaceutical companies are targeting rare ailments or niche remedies for specific populations with specific ailments (Economist, 28 July 2007) i.e., "personalized medicines". These specialty drugs or targeted therapies have accounted for two-thirds of the total revenue growth in 2006 (Economist, *ibid).* This is in line with traditional medical philosophies and is indicative of potential fruitful collaborations between the various medical streams.

Studies highlight the need for biotechnology (broadly encompassing all bio-products research) firms to address their benefit sharing obligations towards various stakeholders in the value addition chain, including direct stakeholders such as employees, suppliers, local communities, to indirect stakeholders such as governments for their supportive functions.[14] The obligations could be ethical, economic and/or political and it necessitates decision making on which of the stakeholders should be a party to the benefit sharing process and to what extent.

Types of Benefits shared

Industry representative organizations such as International Chamber of Commerce (ICC, 2005) support the principles of the CBD, while at the same time calling for implementation of adequate IP protection for their products. The concern voiced by industrial sources relates to legal uncertainties in ABS negotiations. The pharmaceutical industry has by far more instances of benefit sharing examples among the various sectors that utilize biological resources for commercial gain (ten Kate and Laird, 1999, Finston, 2005). Monetary benefits include a host of options such as sample fees; research grants that covers salaries of researchers, funds for laboratory equipment and their maintenance, expenditure related to field surveys and related costs, access to scientific literature; equity stakes, profit sharing, joint ventures, royalties, and employment opportunities (ten Kate and Laird, 1999). Non-monetary benefits that pharmaceuticals have agreed to share include technology transfers, sharing of research results, training, capacity building, and support for conservation projects. Benefits in kind are also shared and include establishment or provision of services such as medical facilities, facilitating infrastructure such as roads and warehouses. Ownership of the intellectual property rights of the products rests usually with the companies, and in rare cases is shared with local communities (e.g. Aguaruna communities case in Lewis and Ramani, 2003).

4.3.2 Botanicals / Nutraceuticals

Characteristics

Botanicals are herbal medicines representing raw herbs, tinctures, extracts, and phytomedicines (ten Kate and Laird, 1999). Hence, while these products can claim medicinal properties, they are considered health supplements, and therefore do not require extensive trials and testing as in the case of pharmaceuticals. The cost of development of a botanical is therefore not as high as a pharmaceutical and is estimated to be less than US$ 10 million (ten Kate and Laird, 1999). Companies that sought to bring out products as pharmaceuticals have reclassified them as botanicals to tide over the cost factor, a classic example being the re-categorization and marketing of Sangre de Drago by Shaman pharmaceuticals (ten Kate and Laird, 1999). The global market for this sector is in the vicinity of US$ 62 billion (Patwardhan et al, 2005).

Traditional knowledge is extensively used in the development of these products, as stated by major industry players in a survey undertaken in the late 1990s (ten Kate and Laird, 1999). These products could also include traditional medicine products and products derived or modified from them. Usually, these products are developed from previously known properties of genetic resources and take between two years to seven years to develop (ten Kate and

Laird, 1999, Suneetha, 2004). Hence the probability of developing a successful product is fairly high. A closely related class of products include nutritional foods, termed nutraceuticals, functional foods or designer foods, which include food and dietary products fortified with nutrients not normally found in that food. These are consumed for their prophylactic and therapeutic properties, and constitute a US$ 11.7 billion global industry, that includes among others cereals, soups, beverages, probiotics, soy additives, juices and extracts (Freedonia, 2006).

Types of Benefits shared

Examples of benefit sharing in Botanical medicine / Nutraceuticals sectors are not common. However, there are instances where commercial benefits have been shared with local communities (e.g. Shaman pharmaceuticals shares a percentage of its benefits with communities it works with globally through The Healing Conservancy Funds; the TBGRI with the Kani tribes in the Kerala state of India). Monetary benefits shared by this sector include apart from prices paid for the resource, royalties on sales of products, share of license fees, advance payments, employment opportunities through commercial partnerships. Non-monetary benefits include training and capacity building for communities and host country institutions, support for the establishment of small scale enterprises based on medicinal plants and related resources. IP ownership of the product is retained primarily by the companies.

4.3.3 Food and Agriculture Biotechnology

Characteristics

The market for products of agricultural biotechnology is estimated to be around US$ 6.2 billion (Financial Times, 2006). The Biotech seed market alone is worth US$ 5.3 billion (Crop Life International, 2005). The cost and timelines involved in the development of a new, transformed varieties is between US$ 100 to 200 million (Jay, 2001) over a period of 8 to 15 years (ten Kate and Laird, 1999). The starting varieties are usually obtained from public sources, CGIAR deposits and from landraces. Biotechnology products also include a class of products termed Novel foods (chiefly in the EU for foods not commonly consumed within the EU before 15 May, 1995) or genetically modified foods. There is an increasing overlap between medicine and food, with the development of 'biopharmaceutical crops" (e.g. new advances in including vaccines in rice grain by Japanese researchers (Economist, 2007)). The tools of biotechnology are being used by public health researchers to enable fast and effective health delivery systems. However, such foods are still the subject of consumer censure and stringent government regulations such as in the European Union (Biotrade, 2009). [15]

Another active sub-sector of agricultural biotechnology is biotechnology for ornamental horticulture purposes, as for flowers and fragrances. This sector also uses genetic resources for unique characteristics such as colour, flower shape, form and related.

Types of Benefits Shared

Monetary measures of benefit sharing undertaken by agricultural biotechnology firms for the germplasm they receive is in the form of germplasm fees, license fees, research grants, and research contracts. Typically, the fees are paid to collaborating institutions or breeders. Reciprocal access to germplasm is apparently the most common form of non-monetary benefit shared within this sector (ten Kate and Laird, 1999). Other benefits include access to information on research results and training, joint research, and access to technology. Ownership over the varieties is chiefly held by the companies. However, arrangements such as free access (through Humanitarian Use Licenses as in the case of Golden Rice), conditional property rights (in the event of IP claims over varieties derived from varieties in public repositories as described by the ITPGR,and exemptions (such as exemption for breeders to conduct research or farmers for consumption or non-commercial use) are also observed in this sector.

4.3.4 Natural Personal Care and Cosmetics Products

Characteristics

Natural care products and cosmetics include a broad range of products such as cosmetics, toiletteries, fragrances and the like. Manufacturers resort to various means to obtain samples for product development, including field surveys to sub-contracting. Prime sources of information are databases and literature on chemicals and leads from traditional uses (ten Kate and Laird, 1999). This sector is apparently growing at the rate of approximately 9% per annum with the US market alone worth US$ 3.8 billion in 2003, and expected to be around US$ 6 billion by 2008 (Decision News Media, 2005). Research costs are less than US$ 10 million and take between 2 to 5 years to develop (ten Kate and Laird, 1999).

Types of Benefits Shared

Benefit sharing is not common within this industry and includes sample prices or fees, advance payments and humanitarian and environmental donations through Foundations (ten Kate and Laird, 1999). Non-monetary benefits include assured markets, development of local enterprises and support to community projects.

4.3.5 Research and Academia

Access to genetic resources and knowledge is also sought by research institutions across their territorial borders for the development of products for non-commercial purposes to advance the purpose of science and knowledge.

Academic societies such as International Society for Ethnobiology (ISE) encourage the use of equitable and ethical standards while pursuing research on genetic resources or using traditional knowledge (ISE Code of Ethics, 2006).[16] This includes a set of guiding principles that recognize rights of indigenous peoples over their resources and decision making, their rights to be active participants in all stages of the project, and hence their right to full information as regards the project. It also recognizes that the communities could prohibit publication of information they do not wish to be made public. Another useful resource is the Swiss Academy of Science's Access and Benefit Sharing: Good practice for academic research on genetic resources that provides a step-by-step guide for academic researchers to adhere to ABS measures (Biber-Klemm and Martinez, 2006).[17]

Types of Benefits Shared

Some of the common benefits shared with provider countries include collaborative research with a host country university or research institution, transfer of relevant technologies, joint publications and/or co-ownership of research outputs.

4.4 Recent Developments in Corporate Policies towards Benefit Sharing

Companies indulge in corporate social responsibility (CSR) practices, and for now appear to consider benefit sharing a part of CSR activities. Some companies have published Sustainability Reports and Corporate Social Responsibility Reports that highlight their social and financial commitments to local communities (e.g. Novo Nordisk's Annual Report (2006), Novozyme's Social Responsibility Report (2005), Syngenta's Corporate Social Responsibility Report (2006). Efforts on social responsibility by companies include host country university partnerships, enabling the development of services such as water and land quality, the provision of fellowships through funds established for charitable purposes, the non-pursuance of patents in least developing countries, transfer of technologies, the creation of foundations that enable enterprise development, and the pursuit of public policy (such as in health policy) related initiatives of the host or provider countries.

5. Conclusions

Having considered the national and international scenarios in terms of access to genetic resources and benefit sharing, it is clear that there are many examples and models available for countries to use. However, each of these is sector specific, location specific, scale specific or policy specific. There is no single model of access provision and benefit sharing that can provide the answer to questions being raised on how to implement ABS provisions.

Considering the difficult as well as crucial timing of negotiations under the development of the international regime on ABS, it is important for countries to undertake actions on the following fronts:

1. Implement provisions under Bonn Guidelines on ABS: Many countries are hesitating to implement the Bonn Guidelines due to potential changes in the ABS regime. Though voluntary in nature, the Guidelines provide distinct opportunities for countries to implement ABS provisions. Countries should recognize that this will be the case even with the adoption of an international regime on ABS and make effective use of existing provisions on ABS.

2. Development of ABS guidelines and regulations requires multi-disciplinary teams: One of the key challenges countries face is the establishment of teams to develop ABS principles and guidelines. It must be understood, from the examples provided above, that ABS issues are not just the prerogative of Ministries of Environment and conservation experts, but require the involvement of experts from legal, social, policy and financing fields. In the absence of collective thinking on how to deal with ABS issues, countries will be left with more questions than answers to implement ABS provisions, even in the event of an international regime being put into place. Therefore countries should consider preparing such teams of experts to begin discussions on ABS issues.

3. ABS is an issue that also links to markets and market economies: From the examples above, it may be clear that if countries are seriously interested in making use of the genetic resources they are endowed with, they have to provide for access on clear and defined terms. Without provision of access there is no debate on benefit sharing. Markets and market economics play an important role in ABS debates. Holders and providers of genetic resources should understand that in the absence of demand or a market for resources and products, debates on ABS are futile. However, one should not over-emphasise the issue of efficiency in markets in subversion of issues related to equity.

4. Complexity should not be an excuse for inaction: Several countries are postponing national actions on ABS issues, either waiting for the completion of negotiations for an international regime or for want of experience. Realising ABS is a contentious and complex issue; however actions should be implemented – however imperfect they may be – to build experience and progress. Local and national actions allow countries to build experience that enhances their ability to participate in discussions on further developing and negotiating the international regime on ABS.

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Annex 1 Country Legislation Related to Benefit Sharing

Country	Legislation/ Rules (Relevant sections)	Implementing Agency	Applicable to whom	Monetary elements of Benefit sharing
Australia	Environment Protection and Biodiversity Conservation Act (EPBC Act),1999, (Section 301) and EPBC Regulations, 2000 (Part 8 A)	Department of the Environment, Water, Heritage and the Arts	To any users who wish to conduct research and development on native species of genetic resources or their biochemical compounds from Commonwealth areas	1. Up-front payments 2. Milestone payments 3. Royalties 4. Research funding 5. License fees in case of commercialization 6. Special fees paid to trust funds supporting 7. Conservation and sustainable use of biodiversity 8. Salaries and preferential terms 9. Joint ventures
Brazil	Provisional Act No 2,186-16, 2001 (Title 7 -Articles 24 to 29)	The Genetic Heritage Governing Council, under the Ministry of Environment (aka The Management Council)	Brazilian or Foreign entity who make economic use of product/ process from resource/ associated TK	1. Sharing of profits 2. Payment of royalties
Bangladesh	Biodiversity and Community Knowledge Protection Act of Bangladesh, 1998	National Biodiversity Authority	To all those who seek access for commercial purposes	1. Not less than 50 % of net monetary gain 2. Compensation for ecological or environmental costs incurred
Malawi	National Environmental Policy of the Environmental Management Act (1996)	The Genetic Resources and Biotechnology Committee (GRBC) of the National Research Council of Malawi (NRCM)	Foreign applicants	Only access regulations defined-
Kenya	The Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing- Regulations, 2006 of the Environmental Management and Co-ordination Act (1999) (Part IV- 19, 20)	National Environment Management Authority	Any person who intends to access genetic resources in Kenya (except by local communities for own consumption and approved research activities for Kenyan educational purposes)	1. Access fee 2. Up-front payments 3. Milestone payments 4. Royalties 5. License fees 6. Fees to trust funds to support conservation activities 7. Research funding 8. Joint ventures
Costa Rica	Biodiversity Law (No. 7788)- Articles 63(3), 76, 82	National Commission for the Management of Biodiversity	All who seek access to genetic resources and related knowledge	1. 10% of research budget to National System of Conservation Areas 2. 50% of bonus to NSCA 3. Administrative costs
Guyana	Environmental Protection (Bioprospecting) Regulations, 2001 (Part III, section 17, 18)	Environmental Protection Agency (Agency)	All except local and indigenous peoples engaged in traditional activities	1. Royalties 2. Any other financial benefits 3. Share to Government on commercial profits
Ethiopia	Access to Genetic Resources and Community Knowledge and Community Rights Proclamation (No.482/ 2006)- Articles 9, 18, 19	Institute of Biodiversity Conservation	All those who seek to explore GR/ TK	1. 50% of benefits (to be shared with state) in form of money 2. License fee 3. Upfront payment 4. Milestone payment 5. Royalty 6. Research funding
Bolivia	Supreme Decree NO.24676, Regulation of Decision 391 on the Common Regime for Access to Genetic Resources (1997)- (Chapter 6, Articles 40-43)	National Secretary if Natural Resources and the Environment	Natural persons and legal foreigners	1. Royalties 2. Any other
Philippines	Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources (Department Administrative Order No.96-20), 1996- Articles 8.1(8, 9, 13), 8.2(2, 3, 4)	Inter-Agency Committee on Biological and Genetic Resources (under Dept of Environment and Natural Resources)	Both domestic and foreign bioprospectors, except traditional use	1. Equity 2. Remittances 3. Submit performance, compensation, ecological rehabilitation bond on MAT
India	Biological Diversity Act, 2002 and Biological Diversity Rules, 2004 (Art 14, 20)	National Biodiversity Authority	Primarily for Foreigners	1. Access fee, 2. Monetary benefits- upfront, milestones, royalty, etc. 3. Joint ventures 4. Product development 5. 5% of assessed benefits to be given to NBA 6. Venture capital funding

Non-monetary elements of Benefit sharing	Ownership rights (IPRs/ sui generis)	Punitive action
1. Sharing in research and development results 2. Collaboration, cooperation and contribution in scientific R&D programmes, particularly 3. Biotechnological research activities, where possible 4. Participation in product development collaboration, cooperation and contribution in education and training 5. Admittance to ex-situ facilities of genetic resources and to databases transfer to the provider of the genetic resources of knowledge and technology 6. Facilitate abilities of Indigenous and local communities to conserve and sustainably use their genetic resources 7. Institutional capacity building 8. Training related to genetic resources with the full participation of providing Parties 9. Information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies 10. Contributions to the local economy 11. Institutional and professional relationships that can arise from an access and benefit sharing agreement and subsequent collaborative activities 12. Social recognition	Joint ownership of relevant intellectual property rights	50 penalty units, discussions on between Commonwealth Government and States for higher penalties to deter non-compliance
1. Access and transfer of technologies 2. licensing without cost, of products and processes 3. Capacity building of human resources	To be specified in Contract for Use of Genetic Heritage and Benefit sharing	Offender to pay compensation @ 20% of gross income of receipts from product/ royalties irrespective of IP rights
1. Technology transfers 2. Knowledge transfer 3. Royalty free access to technology for domestic institutions in case of endemic species access	1. Recognizes collective/ community IP rights 2. Co-ownership rights over biological resources, knowledge and innovation defined between communities, with State and with communities from other countries	Varies from written warnings, fines, revocation of permits, and confiscation to perpetual ban, with widespread publicity given in international foras.
1. Sharing R&D results 2. Collaborative research projects in S&T 3. Participation in product development 4. Access to ex situ facilities of genetic resources and databases 5. Transfer of knowledge and technology under fair and most favourable terms 6. Capacity development for technology transfer 7. Institutional capacity development	Joint ownership where relevant	Liable to imprisonment and/ or fine
1. Technology transfer	1. Recognizes community intellectual property rights 2. Recognizes mere existence of cultural practice or knowledge related to GR and biochemicals and does not require any formal system of registration (Art 82)	Offenders to pay fines between one and twelve salaries; can be charged by the Penal Code and special laws
1. Inclusion of local counterparts and institutions or individuals in research activities 2. Co-authorship 3. Periodical reports and final reports on activity		Offenders to pay a fine between 300,000 to 750,000 dollars and face imprisonment for one year
1. Joint ownership of IP 2. Employment opportunity 3. Research participation of Ethiopian nations 4. Priority to supply raw materials for production processes 5. Training to enhance local skills in GR conservation etc 6. Equipment, technology support 7. Any other	Recognition of community rights in customary practices and norms	Suspension or termination of Access agreement and prohibit access to GR and associated knowledge
1. Transfer of technologies 2. S&T capacity development of national universities 3. Drugs at cost (tax exempted) 4. Involving domestic personnel in research, including indigenous representative as appropriate	Recognition of collective rights of community over existing natural resources and associated intangible components	Written reprimands, progressive fines, suspension of activities, revocation of authorization are various measures to tackle various degrees of offenses / infractions.
1. Regular reports 2. All discoveries of commercial product/s derived from Philippine GR to be made available to government and local communities 3. Collaborative research with domestic institutions 4. Royalty free access to technology 5. Donate equipments		Varying from criminal prosecution (without required Agreements or PIC), cancellation or revocation of agreement (non-compliance measures) and duly reported to international forums.
1. Transfer of technology 2. Collaborative research with domestic institutions, (research and local) 3. Education and awareness raising	Joint ownership wherever relevant	Varying from criminal prosecution to imposition of fines

Endnotes

[1] See Article 3 of the Convention on Biological Diversity.
[2] For more details, see http://www.iisd.org/pdf/2007/abs_mt_standard.pdf, last visited on 20 October 2008.
[3] The list of countries who have passed legislation related to ABS in the Appendix is not exhaustive. The information in the Appendix intends to provide a broad overview of the different approaches taken by countries to implement CBD provisions through national laws. It is also worth noting the differences among countries in addressing various dimensions of the issues related to benefit sharing.
[4] http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf (specifically section D.41-44 on MAT) last visited on 8 September 2008.
[5] This section draws heavily from Chiarolla, Claudio, 2007.
[6] The Treaty was adopted by the FAO Conference on 3 November 2001. It entered into force on 29th June 2004.
[7] Under "***Available without restriction***", Article 2 of the SMTA states: "***A Product is considered to be available without restriction to others for further research and breeding when it is available for research and breeding without any legal or contractual obligations, or technological restrictions, that would preclude using it in the manner specified in the Treaty***."
[8] Article 6.11.d states: "***The payments to be made are independent of whether or not the Product is available without restriction***" — ***i.e.*** such payments are due regardless of whether access to such products is limited by any legal, contractual or technological restrictions as provided for in Article 6.7.
[9] Hence, payments must be made not only when a "***Product***"—under the definition of Article 2—is commercialised. They will be calculated based upon "***the Sales of any other products that are Plant Genetic Resources for Food and Agriculture belonging to the same crop*** [...] ***to which the Material*** [received] ***belongs***." See Article 6.11(c). This is a type of provision that is fairly common in the commercial practice: the rights that it provides are called "reach-though rights". Normally, recipients must pay "fees or royalties on products discovered through the use of the material even though the material is not part of the product or necessary to manufacture the product."
[10] Article 6.11(f) provides that: "***The Recipient shall be relieved of any obligation to make payments under Article 6.7 of this Agreement or any previous or subsequent Standard Material Transfer Agreements entered into in respect of the same crop***."
[11] Appendix 3, paragraph 5, of the SMTA states: "***Where the Recipient has entered or enters in the future into other Standard Material Transfer Agreements in relation to Material belonging to the same crop[s], the Recipient shall only pay into the referred mechanism the percentage of sales as determined in accordance with this Article or the same Article of any other Standard Material Transfer Agreement. No cumulative payments will be required***."
[12] Latest updates on WIPO's recommendations can be obtained from http://www.wipo.int/meetings/en/details.jsp?meeting_id=12522 last visited on 28 February 2008.
[13] Biodiversity and Community Knowledge Protection Act of Bangladesh, 1998 (See Table in Appendix for more details.)
[14] MacDonald, Chris, from www.biotechethics.ca/papers/stakeholder.html last visited 10 September 2008.
[15] See for example Physicians for Social Responsibility, Oregon at http://www.oregonpsr.org/csf/BiopharmRecommendationsFinal.doc
[16] http://ise.arts.ubc.ca/global coalition/ethics.php last visited 15 January 2009.
[17] http://abs.scnat.ch./downloads/ABS_Brochure.pdf last visited 20 August 2008.

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